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The terminology and phraseology of medico-legal documents in assisted reproduction treatments: Analysis of a comparable corpus of five informed consents from the USA and five informed consents from Spain

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Abstract

The need for Assisted Reproductive Technology has increased notoriously in the past twenty years. However, the limitations introduced by Law 14/2006 in Spain force many patients to pursue In Vitro Fertilization overseas, mostly in the United States of America. In these cases, translator help may be necessary in order to, among other tasks, have the different existing medico-legal documents translated into Spanish, including one or several informed consents. One of the main difficulties to be faced by the translator concerns the subject-specific terminology and phraseology of this type of documents. For this reason, in this project we have created a comparable corpus with five informed consents from US clinics and five consents from Spanish clinics. Our starting hypothesis is that the texts in English are more detailed than the Spanish ones. Moreover, we think that in both languages there is more medical terminology and phraseology than legal, as well as a higher amount of phraseology than terminology. To test these hypotheses, we have conducted a mixed methods analysis: on the one hand, qualitatively, resulting in an alignment of terminology and phraseology that has allowed us to devise a bilingual glossary; on the other hand, quantitatively, to calculate the different percentages and rates of occurrence. The results of our analysis prove our three hypotheses, which allows us to conclude that a bigger part of translator training should focus on becoming familiar with this specialized language so they can overcome such potential terminological and phraseological barriers more successfully, thereby adapting to the latest demands of the labor market.

Keywords: *alignment, comparable corpus, ESP, in vitro fertilization, informed consents, medico-legal documents, phraseology, specialized language, T/P units, terminology*

Resumen

La necesidad de recurrir a tratamientos de Reproducción Asistida ha aumentado notablemente en los últimos veinte años. Sin embargo, las limitaciones introducidas por la Ley 14/2006 en España hacen que muchos pacientes decidan realizar el tratamiento de Fecundación in Vitro en países como Estados Unidos. En estos casos, se hace necesario contar con un traductor para que, entre otras labores, traduzca los diferentes documentos de índole médico-jurídica al español, inclusive uno o varios consentimientos informados. Una de las principales dificultades a las que se enfrentará el traductor es la terminología y la fraseología específica de este tipo de documentos. Dado que la traducción médico-jurídica no es un campo demasiado explotado en los estudios de traducción, en este trabajo hemos recabado cinco consentimientos informados de clínicas estadounidenses y otros cinco de centros españoles para formar un corpus comparable. Nuestra hipótesis inicial es que los textos en inglés están mejor detallados que los españoles. Además, creemos que en ambos idiomas hay más terminología y fraseología médica que jurídica, además de una mayor cantidad de fraseología que terminología. Para probar estas hipótesis, dicho corpus ha sido analizado de forma mixta: por un lado, cualitativamente, lo que ha dado como resultado una alineación de la terminología y la fraseología que nos ha permitido confeccionar un glosario bilingüe; por otro lado, cuantitativamente, para calcular distintos porcentajes y frecuencias de uso. Los resultados de nuestro análisis demuestran estas tres hipótesis, lo que nos permite concluir que una mayor parte del proceso formativo de los traductores debería centrarse en conocer este lenguaje especializado para así poder superar posibles barreras terminológicas y fraseológicas con más éxito en el futuro. De este modo, les resultaría más sencillo adaptarse a las demandas del mercado laboral actual.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

ABBREVIATION	FULL FORM
ART	Assisted Reproductive Technology
ASRM	American Society for Reproductive Medicine
CBRC	Cross-Border Reproductive Care
CDC	Centers for Disease Control and Prevention
CL	Corpus Linguistics
CTT	Communicative Theory of Terminology
ELF	English as a Lingua Franca
ESP	English for Specific Purposes
GTT	General Theory of Terminology
ICSI	Intracytoplasmic Sperm Injection
IUI	Intrauterine Insemination
IVF	In Vitro Fertilization
L1	First Language
L2	Second Language
LSP	Language for Specific Purposes
LU	Lexical Unit
PGS	Preimplantation Genetic Screening
PoS	Part of Speech
SART	Society for Assisted Reproductive Technology
SEF	Sociedad Española de Fertilidad[1]
SL	Source Language
T/P unit	Terminological or Phraseological Unit
TL	Target Language
TOT	Translation-Oriented Terminography
TU	Terminological Unit
USA	United States of America

[1] *Spanish Fertility Society*, as translated in Cabello *et al.* (2010). The official website of the SEF (www.sefertilidad.net) is not available in Spanish; therefore, to date there is no official translation into English.

1. Introduction

The present project aims to investigate the terminology and phraseology present in informed consents as text genres. Given the number of medical procedures in which informed consents are used, this project focuses on the area of Assisted Reproductive Technology (ART) due to its high demand in today's society. We will build a comparable corpus with five informed consents from American fertility clinics and five informed consents from Spanish clinics, and it will be examined qualitatively in order to find terminological and phraseological units that are equivalent and then quantitatively in order to quantify different aspects such as the percentage of legal versus medical terminology or the rate of occurrence of terms and phrases. Our final goals are two: to create a bilingual terminological and phraseological glossary that is useful for prospective translators who are in charge of translating this type of document for ART patients, and to demonstrate our three starting hypotheses, connected to the nature of the terminology and phraseology of informed consents in ART treatments.

1. 1. Context

Assisted Reproductive Technology (ART), also known as *Assisted Reproduction*, is used to treat infertility. Amongst the main causes that lead couples to turn to ART we can find delayed childbearing, a phenomenon that is becoming increasingly common worldwide, especially throughout developed countries, mainly due to an increase in the number of women deciding to have children later in life, which can lead to greater chances of developing age-related infertility (Balasch & Gratacós, 2012). As we will see below, the most common treatment used is In Vitro Fertilization (IVF), a technique that Spanish couples often pursue abroad, mostly in the United States, due to reasons associated with legal restrictions. This has contributed to the creation of a sub-branch of medical tourism known as *fertility tourism*, which opens the door for the need of translators in this field, especially when it comes to translating the different medico-legal documents involved in the process.

In the era of globalization, fertility tourism "occurs when infertile individuals or couples travel abroad for the purposes of obtaining medical treatment for their infertility" (Storrow, 2005: 7). It is also known as *cross-border reproductive care* (CBRC) or *reproductive tourism*. According to Jacobson (2020: 2), "the majority of these out-of-country patients/clients seek standard IVF". It should be noted that this treatment will appear on uncountable occasions throughout this Master's dissertation, as it is the most common ART sought by Spanish patients who decide to start their

treatment in the United States of America (USA), especially when gamete (i.e. oocytes and/or sperm) donation is needed. As Álvarez Sarabia (2015: 33) puts it:

> *La fecundación in vitro, junto con la inseminación artificial y la donación de ovocitos, constituyen las principales fórmulas de reproducción asistida.*
>
> *In vitro fertilization, along with intrauterine insemination and egg donation, are the main formula in assisted reproduction*. [OWN TRANSLATION]

The main reason why intended parents from Spain may seek IVF is their impossibility to have a child naturally, which in many cases requires the need for a third-party sperm and/or oocyte donor. In fact, one of the main reasons why many Spanish intended parents seek IVF abroad is related to the identity of the donors (Jacobson, 2020). In the words of Martin (2014: 49-52), "when services are regulated to such an extent that they impinge on intended parents' and/or third parties' privacy or anonymity, fertility patients/clients may seek arrangements elsewhere".

Given this situation, it is only obvious that the work of a translator/interpreter will be needed for the intended parents, especially when it comes to being informed about the treatments that they will undergo and the medication that they may need to take. This is the reason why signing one or various informed consents will be necessary throughout the process, and it is essential that the patient(s) understand the process, the risks involved, the potential side effects, etc. These medico-legal texts are mainly divided, as we will see in Section 2.6 in more detail, into two sections: the Fact Sheet for Patients or Patient Information Sheet—which includes all the medical information—and the Informed Consent Form—which includes legal considerations and requires the signature of the patient(s) involved. For documents with these characteristics to be translated properly, translators must be familiar with both medical and legal translation. They should have specific knowledge about Medicine, Biomedicine and Law, particularly their terminology and phraseology. Thus, the task of the translator is highly important for the intended parents to comprehend every aspect of what they are about to sign.

The situation of ART in the USA and Spain is quite different if we analyze them from a legal and administrative point of view. Broadly speaking, if we look at the regulations governing assisted reproduction in the USA, we find that they are almost nonexistent, whereas in Spain we find well-developed policies as we will see in the following subsections.

1. 1. 1. Situation in the United States

Starting from the situation in the USA, we have had a look at the U.S. Code[2] to see what it says about ART at federal level. If we look for its definition (42 U.S. Code § 263a–7), we find the following:

> *The term "assisted reproductive technology" means all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency).*

Nonetheless, aside from defining *ART* and mentioning the main techniques, the truth is that there is no comprehensible federal law regulating the application and performance of infertility treatments. In the absence of this regulation at a national level, states have tried to adapt existing legal theories to the emerging scenarios presented by advances in ART. The federal government does regulate everything related with the use of medications and medical devices strictly, though (Casolo *et al.* 2019: 2).

There is, however, one federal law that regulates ART, but only the part that has to do with the success rates of treatments: the Fertility Clinic Success Rate and Certification Act of 1992, also known as *The Wyden Law* due to its primary sponsor in the US Congress, Senator Ron Wyden (Sauerbrun-Cutler *et al*., 2021; H.R.4773 - 102nd Congress, 1991-1992). This Act forces fertility clinics to systematically report their pregnancy success rates, which are calculated by live birth rates, to the Centers for Disease Control and Prevention (CDC). Such information is then made available to the general public by accessing the CDC's website[3]. The most recent report available corresponds to year 2019 and can be analyzed by state, as we shall see in the screenshot below:

[2] The United States Code (U.S. Code) arranges the statutes of the country by subject matter into 54 titles and five appendices (Congressional Research Service, 2018: 1).

[3] Available from: https://bit.ly/3MZNcFK (Accessed on 10 May 2022)

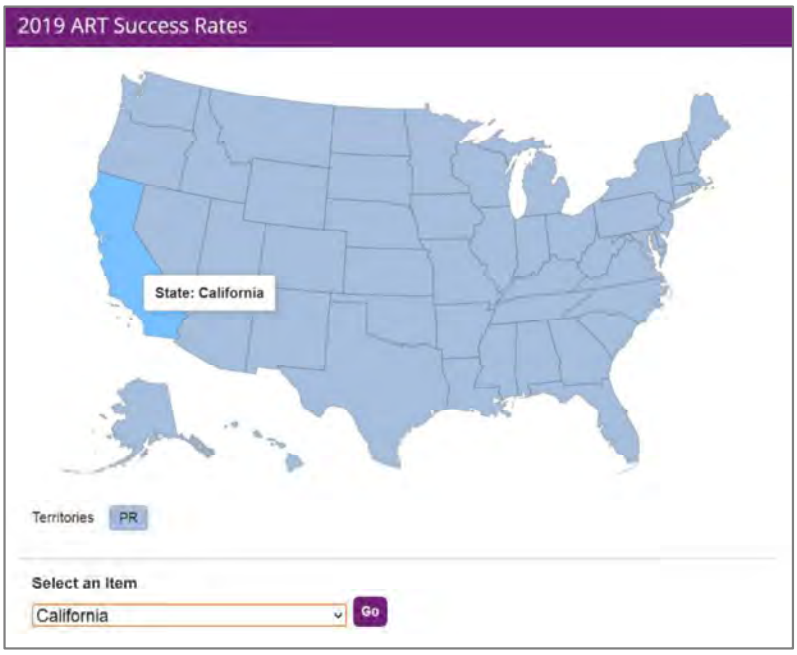

Figure 1. Map of fertility clinics provided on the CDC's website

Once we have located the state where we want to find a clinic, all we have to do is click on it. A new tab will open with a list of the clinics that are members of the Society for Assisted Reproductive Technology (SART) and provide their success rates through it. In our example, the state we selected was California, and the clinic was one we have selected an informed consent from: California Center for Reproductive Medicine. The following screenshot shows how its success rates would look like on the CDC's website:

Data Verified By: Lori L. Arnold, MD

Cumulative Success Rates for ART Intended Retrievals Among Patients Using Their Own Eggs: All Patients (with or without prior ART cycles)[a,b,c]

All patients (with or without prior ART cycles)	<35	35-37	38-40	>40
Number of intended retrievals	14	15	8	9
Average number of intended retrievals per live-birth delivery	2.3	2.1	8.0	
Percentage of intended retrievals resulting in live-birth deliveries	6 / 14	7 / 15	*/8	0 / 9
Percentage of intended retrievals resulting in singleton live-birth deliveries	6 / 14	6 / 15	*/8	0 / 9
Number of retrievals	14	14	7	8
Percentage of retrievals resulting in live-birth deliveries	6 / 14	7 / 14	*/7	0 / 8
Percentage of retrievals resulting in singleton live-birth deliveries	6 / 14	6 / 14	*/7	0 / 8
Number of transfers	11	13	5	*
Percentage of transfers resulting in live-birth deliveries	6 / 11	7 / 13	*/5	0/*
Percentage of transfers resulting in singleton live-birth deliveries	6 / 11	6 / 13	*/5	0/*
New patients (with no prior ART cycles)	**<35**	**35-37**	**38-40**	**>40**
Percentage of new patients having live-birth deliveries after 1 intended retrieval	5 / 12	6 / 11	*/*	0 / 8
Percentage of new patients having live-birth deliveries after 1 or 2 intended retrievals	5 / 12	6 / 11	*/*	0 / 8
Percentage of new patients having live-birth deliveries after all intended retrievals	5 / 12	6 / 11	*/*	0 / 8
Average number of intended retrievals per new patient	1.0	1.2	1.0	1.0
Average number of transfers per intended retrieval	0.6	0.8	0.8	0.1

Figure 2. Success rates provided to the CDC by California Center for Reproductive Medicine

The lack of a federal regulation of ART has created uncertainty across states about how courts will rule in ART-specific cases. In the words of Casolo *et al.* (2019: 5-6), "a patient's decision to engage in the use of ART is surrounded by murky legal doctrine". In fact, the absence of a national consensus has led to the creation of different initiatives by national organizations with the goal of unifying state legislation so that it becomes a federal regulation ultimately. An example of this process is The Uniform Parentage Act of 1973 (abbreviated *UPA*), which was enacted to address issues of paternity, embryo ownership and genetic testing (Casolo *et al.*, 2019: 6).

Indeed, as Frith & Blyth point out (2014: 2), there exists "considerable inter-state variation": while some states have limited or nonexistent regulation, others have more comprehensive policies. For these reasons, most clinics base their behavior on professional guidelines and good practice protocols in order to have their ART practice overseen. Examples of this support are the American Society for Reproductive Medicine (ASRM) and its affiliate, the SART. These organizations offer professional advice through the publication of guidelines and codes of conduct for fertility clinics and their personnel. As Reame (1999: 3) argues, "the major focus of these organizations is educational, and they have no regulatory or enforcement power". However, the ASRM has asserted that, owing to the existence of their Ethics and Practice Committees reports, guidelines and codes of conducts, ARTs are sufficiently well regulated and there is little need for further intervention (Frith & Blyth, 2014: 2).

This is perhaps the reason why the USA is a popular destination for foreign infertile couples who wish to pursue treatment abroad. Not only because of its flexible regulations, but also because it opens the door for the building of new family types, such as same-sex couples who may face many restrictions in their home country. According to Casolo *et al.* (2019: 30), "ART opens up the prospect of family-building for not only those who meet the clinical definition of infertility, but also for non-heterosexual couples".

This scenario, as we will see below, contrasts with the situation in Spain, where the National Health System covers infertility treatments in general and IVF in particular. Amongst the vast number of clinics that perform infertility treatments in the USA, not all of them are members of the SART. This is the reason why, for the purposes of our analysis, we have selected informed consents from clinics that are indeed members of the SART, as we shall see in Subsection 4.2 of the Methodology Section.

1. 1. 2. Situation in Spain

The legal context in Spain is quite different from that in the USA. Assisted reproduction is strictly regulated by Law 14/2006, of 26 May, on Human Assisted Reproduction Techniques. According to Article 1 of the mentioned law (p. 6), it is meant to:

> *a) Regular la aplicación de las técnicas de reproducción humana asistida acreditadas científicamente y clínicamente indicadas;*
> *b) regular la aplicación de las técnicas de reproducción humana asistida en la prevención y tratamiento de enfermedades de origen genético, siempre que existan las garantías diagnósticas y terapéuticas suficientes y sean debidamente autorizadas en los términos previstos en esta ley;*
> *c) la regulación de los supuestos y requisitos de utilización de gametos y preembriones humanos crioconservados.*
>
> *a) Regulate the application of the human assisted reproduction techniques scientifically accredited and clinically indicated;*
> *b) regulate the application of human assisted reproduction techniques in the prevention and treatment of genetic diseases, as long as there exist sufficient diagnostic and therapeutic guarantees and they are duly authorized under the terms provided in the law;*
> *c) the regulation of the cases and requirements for the use of human cryopreserved gametes and pre-embryos.* [OWN TRANSLATION]

And, if we go to the Appendix that can be found at the end of the document (p. 21), the techniques that are expressly regulated by the law are the following: 1) intrauterine insemination (IUI), 2) IVF with intracytoplasmic sperm injection (ICSI) using own or donor gametes and embryo transfer, and 3) gamete intrafallopian transfer.

On the other hand, Law 14/2006 implies a remarkable step forward in the field of ART in Spain, as it includes Preimplantation Genetic Diagnosis (PGD) in the pool of technologies available. This technique opens the door for the prevention of genetic diseases for which there is no cure or treatment nowadays. With PGD, embryos can be pre-selected before being transferred to the female patient. In order for this technique to be possible, IVF/ICSI is the treatment of choice for the infertile couple (Berrocal Lanzarot, 2007: 6). Moreover, according to Berrocal Lanzarot (2007: 6), "la aplicación de las técnicas de diagnóstico preimplatacional en estos casos deberá comunicarse a la autoridad sanitaria correspondiente, que informará de ella a la Comisión Nacional de

Reproducción Humana Asistida[4]". As we can see, aside from a well-developed Law, Spain has the assistance of the National Commission for Human Assisted Reproduction, which defines itself on its web portal as follows:

> *La Comisión Nacional de Reproducción Humana Asistida es el órgano colegiado del Ministerio de Sanidad, de carácter permanente y consultivo, dirigido a asesorar y orientar sobre la utilización de las técnicas de reproducción humana asistida, a contribuir a la actualización y difusión de los conocimientos científicos y técnicos en esta materia, así como a la elaboración de criterios funcionales y estructurales de los centros y servicios donde aquéllas se realizan.*
>
> *The National Commission for Human Assisted Reproduction is the collegiate body of the Health Ministry, of permanent and consultative nature, that aims to provide counsel and guidance about the use of assisted human reproduction techniques, to contribute to the update and dissemination of scientific and technical knowledge about this area, as well as to elaborate functional and structural criteria for the centers and services where they are performed.* [OWN TRANSLATION]

In addition to Law 14/2006, which affects the application of ARTs directly, Spain has Law 41/2002, of 14 November, which regulates patients' autonomy and the rights and obligations in relation to clinical information and documentation, hence that it is known as the *Patient's Law*. According to Article 8 of the Patient's Law, and in the words of De Las Heras Vives (2018: 9), "toda actuación en el ámbito de la salud necesita el consentimiento libre y voluntario del afectado, una vez este haya recibido toda la información disponible sobre la actuación concreta en su ámbito de salud, información que, en todo caso, deberá ser verdadera y comunicada de manera comprensible, adecuada a sus necesidades y garantizándosele la ayuda necesaria para tomar sus decisiones de acuerdo con su propia y libre voluntad[5]". This makes direct reference to the text genre we are dealing with in this research project: informed consents.

On the other hand, the SEF (Sociedad Española de Fertilidad) is, as defined on its website[6], "a scientific society that promotes research into the field of fertility and encourages their use to face

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[4] *The application of pre-implantation genetic diagnosis techniques in these cases must be notified to the corresponding medical authority, who will inform the National Committee for Human Assisted Reproduction about it.* [Own translation]

[5] *Any action in the health scope needs the subject's free and voluntary consent, once he or she has received all the information available about the particular action in his or her health scope, information which, in any case, must be true and communicated in a comprehensible manner, adapted to his or her needs and guaranteeing the necessary assistance in order to make any decisions based on his or her own, free will.* [Own translation]

[6] Available from: https://bit.ly/3JiEUGH (Accessed on 10 May 2022)

the social problems that are related to it". It also acts as a counselor for the Spanish Government and other entities that require it, giving advice on questions about reproductive health, as well as spreading any knowledge that has to do with it. One of the tasks carried out by the SEF is the writing of informed consent templates to be used by clinics. The template corresponding to IVF will be part of the comparable corpus that we are going to build and analyze in this project, as we can see in Sections 4.2 and 12.5. The SEF is categorical when it comes to referring to the use of informed consents–for them, these documents are key to complying with the principle of autonomy[7] from a legal perspective (Sociedad Española de Fertilidad, 2002: 11).

From this, we can conclude that the regulations governing ART in Spain are significantly different from those in the USA, hence the difficulties that any given translator may encounter when facing this sort of medico-legal texts. It is essential, though, to be aware of the legal and administrative contexts surrounding the application of these techniques in each country, as it can be highly useful to manage the terminology and the phraseology used in the source text and to transform them in a way that the original message is kept, but adapted to the language and knowledge of the receiver.

1. 2. Justification

Given these scenarios amongst patients from Spain who decide to pursue a fertility treatment in the USA, it is only obvious that there is a growing need for the presence of translators who are specialists in the terminology and the phraseology used in the different documents that the patients will have to deal with, including informed consents. However, as several authors that we will present in the following paragraphs confirm, to date the syllabuses of specialized translation courses do not put much emphasis on the field of medico-legal translation, let alone on ART.

Starting with my own personal trajectory during my years as a student of the Bachelor's Degree in Translation and Interpretation, the general perception was that the majority of the subjects were devoted to general translation studies and little or no time was devoted to the translation of specialized languages. However, when the time to enter the actual labor market arrived, the reality was that the biggest demand for translators was in areas that require them to know one or various specialized languages, such as legal, medical, technical, audiovisual or economic translation. An

[7] According to Motloba (2018: 418), "at root level, autonomy means having the capacity to self-govern, which is the ability to act independently, responsibly and with conviction. This concept of autonomy relies on the agency of a moral being to exercise his/her own decisions about his/her being. Legally, the agency of an individual or capacity for self-rule is concerned with mental competence and cognitive capability to make a decision at a particular time".

example is ART, a branch of Biomedicine that has consolidated in the past decades as an individual, ample area which nowadays can be studied in isolation, separated from other degrees such as Medicine or Biology. Today, we can find specific Master's Degrees that focus on this field, such as the Master's Degree in Biotechnology of Assisted Human Reproduction offered by the University of Valencia (UV) or the Master's Degree in Biology and Technology Applied to Human Assisted Reproduction offered by the European University (UE), among others.

If we examine chronologically the arguments given by different scholars in order to justify my motivation to pursue this Master's dissertation, we can see that the absence of training in specialized languages was already noticeable for García Izquierdo in 2009, who focused particularly on the information for patients' genre, which is covered in the fact sheets that are given to patients along with the informed consent form. Indeed, her work is especially interesting for us, as it focuses precisely on the area which we are analyzing here. As she explains, much more research in the field of biomedical translation needs to be conducted, for it is not as systematized as in other areas such as the literary field, which is by far the most researched one to date (García Izquierdo, 2009: 7). We agree with her in the motives for having chosen informed consents as the genre of our work. In her own words (García Izquierdo, 2009: 13):

> *El motivo de la selección de este género es* [...] *la escasa atención que ha recibido hasta el momento en el contexto de la investigación en España, como demuestra la práctica inexistencia de trabajos que aborden su caracterización específica [...] y el interés creciente que un género de divulgación de estas características puede adquirir no solo por la globalización y la democratización del conocimiento, en general, sino particularmente por la democratización del acceso a la información en Internet* [...].
>
> *The rationale for choosing this genre is* [...] *the scarce attention that has been paid to date in the context of research in Spain, as the almost inexistence of works that cover its specific characterization shows* [...] *and the increasing interest that a dissemination genre of such characteristics may gain not only due to the globalization and democratization of knowledge, in general, but due to the democratization of access to information through the Internet in particular* [...]. [OWN TRANSLATION]

Martínez López's work (2009: 14) also contributes to justifying the need for an update in the syllabuses of translation courses. He says that medico-legal documents are indeed studied in subjects such as Medical and/or Legal Translation, but the prototypical texts seen are health, birth

or death certificates; informed consents are rather unusual. He concludes his work by making reference to the urgent need for a higher degree of visibility of informed consents in Translation and Interpreting courses.

Pajares Nievas (2015: 2) is another author that supports this view by claiming that the quantity of studies available about the translation of medico-legal documents is scarce and, from an academic and professional point of view, this genre has not received the attention that it deserves. Moreover, Ruiz Escrivá (2021: 2) makes reference to the field of Translation and Interpreting by introducing an interesting point below:

> [...] *los consentimientos informados son un derecho y, por lo tanto, una obligación, por lo que los traductores e intérpretes serán imprescindibles. Se abre entonces el debate sobre qué tipo de traductor debe encargarse de la traducción de un tipo de texto como es el consentimiento informado, que combina tanto conocimientos médicos como jurídicos.*
>
> [...] *informed consents are a right and, as such, they are an obligation. Thus, translators and interpreters will be essential. This starts the discussion of which type of translator profile should be responsible of translating a type of text like an informed consent, which combines both medical and legal knowledge.* [OWN TRANSLATION]

It follows that from these positions we can conclude that there is a strong need for having well-trained, qualified translators available to cope with the terminology and phraseology of this kind of texts. And the basis for this starts as early as in the classrooms of the Degree of Translation and Interpreting. Indeed, in my opinion, there is a growing need in the educational side of Translation Studies to include new areas of study and up-to-date resources in order for prospective specialized translators to improve the quality of their work. In the era of globalization, the fields of Science, Technology, Medicine and Biomedicine are constantly evolving, and so does the language used in their discourse. Consequently, new and updated resources such as glossaries, dictionaries, software, guidelines and bibliography are needed. Within this context, the originality of the present study lies in that it aims to contribute to this update in the syllabuses of translation courses, incorporating an area of Biomedicine that has become so necessary for the general population in the 21st century.

For this to be possible, further research in the area is needed as well. What is clear is that, as the authors reviewed here claim, there is still a long way to walk in the field that we are analyzing throughout this Master's dissertation and we really hope that we will do our bit towards that end in the sections that follow.

1. 3. Objectives and hypotheses

The starting hypotheses of this project are related to the potential difficulties that we think translators may encounter when dealing with the terminology and phraseology of informed consents in assisted reproduction treatments. Thus, the following are our hypotheses:

1. Our first hypothesis (H1) is that, given the number of sections included in the documents that we have gathered from US clinics compared to those of the Spanish clinics, we expect informed consents from US fertility clinics to be more thorough and provide further details about the process than consents from Spanish clinics.
2. Our second hypothesis (H2) is that informed consents in both languages contain a greater percentage of medical contents than legal contents. This hypothesis is based on the literature read to develop the STATE OF THE ART section, mostly the work of Gallardo San Salvador (2012), who observes that, in medico-legal documents in general, the message has a medical basis but the format belongs to the legal-administrative field (see Section 2.5). Thus, considering that we are analyzing informed consents from an ART treatment, we can only expect that these characteristics are also present in our documents.
3. Our third hypothesis (H3) is that informed consents of ART treatments contain a greater amount of phraseology than single-word terminology. This supposition is based on two facts: firstly, our review of literature, where most of the examples listed by different authors constitute phraseological units (see Section 2.7); secondly, the names of the fertility treatments included in the title of the informed consents selected (e.g. *In Vitro Fertilization, Intracytoplasmic Sperm Injection, Assisted Hatching, Embryo Freezing*...).

In order to test these three hypotheses, we will build a comparable corpus and then analyze it qualitatively, obtaining a bilingual glossary as a result, and quantitatively, to measure different percentages and frequency rates.

As regards the objectives of this project, we mainly wish to promote research into the area of specialized translation so that translation students, professional translators, researchers and teachers can adapt to today's demands of the labor market. This will lead to the design of updated specialized translation syllabuses and further knowledge in the area of medico-legal translation.

In summary, my objectives with this project are four:

1. To demonstrate the usefulness of a corpus-based contrastive methodology for identifying the terminology and phraseology of informed consents in ART treatments when translating from English into Spanish.
2. To expand the area of Specialized Translation by incorporating the newest areas of Medicine and Law into the current set of resources available for specialized translators.
3. To enhance the linguistic resources available for health and legal professionals who are fluent in English and Spanish, possess language skills and are therefore able to translate medico-legal documents professionally[8].
4. To provide a bilingual glossary of terminology and phraseology as a solution to bridge the cross-linguistic disparities and/or gaps between different cultural backgrounds present in medico-legal documents when it comes to translating them.

With all this in mind, the ultimate goal is to aid future translators with a helpful tool when they access the labor market after finishing their Translation and Interpretation studies. Moreover, we think that our project would be useful as well for professionals in the areas of medicine and law who translate this kind of texts. Thus, the main areas that can benefit from this type of research are medicine and law, translation practice, translator training and foreign language teaching (FLT), among others.

1. 4. Structure

The project begins with SECTION 1, INTRODUCTION, where we introduce the context surrounding the informed consents selected in both the USA and Spain, explain our justification for having chosen this topic, and list our three starting hypotheses along with our objectives. In SECTION 2, STATE OF THE ART, we review the published literature that helps to understand the notions of terminology and phraseology. This will allow us to comprehend the concept of specialized language in text linguistics, which will take us directly to the area of English for Specific Purposes (ESP), where we specify its main features and present the differences with English for General Purposes (EGP). As a method for dealing with subject-specific vocabulary in ESP, we will introduce the reader to the field of Corpus Linguistics, making a detailed distinction between parallel and comparable corpora, though the latter is where we put our focus on given its relevance in this project. We also provide

[8] Muñoz-Miquel (2018: 2) distinguishes between translators with a scientific or medical background (TSBs) and translators with a linguistic background (TLBs) who both meet the medical translation and communication needs to translate.

the definition of *medico-legal texts* and present the different existing types, paying special attention to informed consents as text genres, since they constitute the type of texts that we are dealing with in this project. Once the different fields around the nature of our project have been covered, we introduce the main characteristics of medical and legal terminology, which will constitute the criteria to identify them when we later analyze our comparable corpus qualitatively.

Having examined the literature that is directly associated with the nature of our project, we move on to SECTION 3, where we present the THEORETICAL FRAMEWORK our work will be based on. In this vein, we:

a) Followed Cabré's Communicative Terminology Theory (CTT) when treating all the instances of the terminology and phraseology found;
b) Examined the nature of our work following Nuopponen's terminology framework in terms of target group, purpose, compiler profile, product and method followed to conduct our qualitative analysis and the resulting bilingual terminological and phraseological glossary;
c) And finally explained the TTC terminology extraction approach, which constituted the basis for carrying out the alignment process of the English and Spanish corpora and subsequent terminology and phraseology extraction workflow.

Then, in SECTION 4, METHODOLOGY, we present our research and reasoning methods–which are mixed-methods research with inductive reasoning–, the sampling procedure and the criteria followed to identify the terminology and phraseology in English and then in Spanish, once the texts were under examination. We also explained briefly how the AntConc toolkit works and how we used it for the purposes of our qualitative contrastive analysis. Finally, we explain how we reached the results of both the qualitative (QUAL) and the quantitative (QUAN) analyses conducted.

In SECTION 5, entitled QUALITATIVE ANALYSIS OF THE COMPARABLE CORPUS AND RESULTS, the reader will find our thorough analysis with references to dictionaries, glossaries and other resources that helped us understand and comment on the most notorious cases encountered. The different alignments made after reaching the most suitable option in each case are presented throughout the analysis, enumerating each terminological or phraseological unit (T/P unit) to make the commenting task more visual for the reader. This section is divided into SUBSECTIONS 5.1 and 5.2, where we present the different medical T/P units found (SUBSECTION 5.1) and then the legal T/P units encountered (SUBSECTION 5.2). It should be noted that the findings included in each subsection are classified according to the typology of the term or phrase based on the criteria

explained in SUBSECTION 2.7. The result of this qualitative analysis is presented in SUBSECTION 5.4 in the form of a bilingual terminological and phraseological glossary ordered alphabetically. In SECTION 6, QUANTITATIVE ANALYSIS AND RESULTS, bearing in mind the results of the qualitative analysis, we analyze the entries included in the glossary quantitatively with the purpose of conducting a brief statistical analysis of the results. Our numerical findings are presented in percentages and rates of occurrence.

Once both the QUAL and QUAN analyses have been conducted, in the SECTION 7, DISCUSSION, we examine the results obtained, suggesting what they may imply and commenting whether they are in line with the assertions of some authors mentioned in both the STATE OF THE ART and THEORETICAL FRAMEWORK (SECTIONS 2 and 3, respectively). We conclude our work in SECTION 8, enumerating the different conclusions that our research employing mixed methods has allowed us to reach considering the results obtained in both analyses. Then, in SECTION 9, we leave the door open for further research on this almost unexploited area of ESP, terminography and specialized translation studies, among others. Finally, in SECTION 10, the reader can find a list with all the REFERENCES used throughout the project and the link to each in case it was an online resource. In ANNEXES 1 and 2, the informed consents that we used to construct our comparable corpus are presented, firstly the ones from US clinics (SECTION 11, ANNEX 1) and secondly from Spanish centers (SECTION 12, ANNEX 2).

2. State of the art

2. 1. Definition of *terminology* and *phraseology*

In order to understand what is meant by *terminology*, we shall start with the definition provided by the Cambridge Dictionary[9]:

> *Special words or expressions used in relation to a particular subject or activity.*

Indeed, as Cabré (2000: 37) notes, Terminology as a field emerged from the need of professionals to unify ideas and terms of their specialized areas with the purpose of improving communication; hence the definition provided by Pavel & Nolet (2001: 17), who describe it as "the set of special words belonging to a science, an art, an author, or a social entity". According to Faber & Montero-Martínez (2019: 1), terminology work involves:

[9] Cambridge Advanced Learner's Dictionary & Thesaurus. (n.d.). *terminology*. In Cambridge Dictionary. Accessed on 10 May 2022: https://bit.ly/3xb6Av0)

- Describing how domain-specific knowledge structures are transmitted in different communicative situations;
- Organizing and recording the meaning and use of terms in terminological resources (e.g. terminological databases, dictionaries, glossaries...).

The need for structuring specialized conceptual systems and compiling terms has flourished in the past few years as the result of today's communicative needs. This has led to the emergence of a new discipline: Terminography (Montero Martínez, 2003: section 1.3.2[10]). According to De Bessé (1997: 66; cited in Montero Martínez, 2003, section 1.3), whilst Terminology as a standardizing discipline regulates the conceptual structuring of specialized domains, either by means of terms or specialized phraseological units (SPUs), Terminography as a discipline is responsible for describing such conceptual structuring.

The notion of SPUs leads us to the field of Phraseology, which is the discipline that studies phrases. As Pawley (2001: 122) puts it, by *phrases* we understand "any multi-word expression up to sentence level". Montero Martínez (2003: section 3.5.2) refers to them as *compound terms* and she makes reference to Sager (1997: 34; cited in Montero Martínez, 2003: section 3.5.2), for whom compounds in terminography are the result of combining two or more lexical elements that form a new syntagmatic unit and thus represent a concept.

As exemplified by Thomas (1993: 57), many names have been used in the literature to describe and define phraseology, including *terminological phrase, phraseological unit, phraseological term, specialized phraseological units* and *language-for-specific-purposes phrase*, among others. Another term to refer to phraseology is the one used by Faber & Montero-Martínez (2019: 23), who call it *terminological phrasemes*. What is clear is that they entail certain particularities that differentiate them from terminology *per se*. Thus, according to Corpas (1998: 167), phraseological units are characterized by the following criteria:

- polylexicality (i.e. they are composed by two or more words);
- high frequency;
- familiarity (i.e. the speakers of a language recognize them as familiar and treat them as a unit);

[10] This book is an electronic resource that lacks page numbers. For this reason, according to APA Citation Guide, 7th Edition, we will be including the section number each time we cite Montero Martínez (2003) in order to help the reader find the passage being cited.

- fixedness (e.g. in English, we say ‘black and white’ but not ‘white and black’);
- idiomaticity (i.e. their sense cannot be deduced from their parts separately);
- potential variation (e.g. the noun *conclusion* may collocate with different verbs: *to arrive at a conclusion, to come to a conclusion, to draw a conclusion, to reach a conclusion*).

On the other hand, according to Bevilacqua (1999: 10), who uses the term *specialized phraseological units* (in Spanish, *Unidades Fraseológicas Especializadas* or *UFE*), phraseology has the following properties:

- It includes, at least, a simple or syntagmatic terminological unit;
- It has certain degree of internal fixation;
- It has a relevant frequency in specialized texts;
- It includes an element that organizes the whole unit.

When terminology work is done for translation purposes, it is known *as Translation-Oriented Terminography (TOT)* as set out in ISO 12616-1:2021, entitled *Terminology work in support of multilingual communication — Part 1: Fundamentals of translation-oriented terminography*. This International Standard “specifies requirements and recommendations related to fundamentals of translation-oriented terminography for producing sound bilingual or multilingual terminology collections” (ISO, 2021). As mentioned by Cabré *et al.* (2002: 168-169), the main problems that translators encounter when performing TOT activities include a lack of familiarity with the terminological units of the source text and with the possible equivalence(s) in the target language (TL). Furthermore, the absence of reliable terminological databases obliges translators to create their own resources or apply their information management skills in order to resolve translation problems related to terminology and terminological phrasemes (Faber & Montero-Martínez, 2019: 2).

Indeed, as stated by Pavel & Nolet (2001: 17), “specialized translation requires mastery of specialized bilingual or multilingual terminologies”. When specialized knowledge is to be transferred between different language communities, it may occur that there is no equivalence of a concept from the source language (SL) in the TL. This is the reason why performing a comparative terminology work is necessary in many cases in order to identify the potential terms that will cause difficulty. Thus, we strongly agree with Pavel & Nolet (2001: 14) in their view that terminology work requires an excellent knowledge of the specialized languages under study, including the rules for lexical term formation, grammar, stylistic devices used in different levels of language, etc. In

short, being familiar with the specialized language of the documents to be translated helps translators to carry out their work by respecting quality-assurance criteria.

2. 2. Text linguistics and the notion of *specialized language*

The basic notion of 'text' has been extensively discussed in the field of text linguistics, although it is generally understood as a communicative unit that results from the linguistic activity used to transfer meaning. Given its pragmatic nature, the issuer of a text will pay attention to the communicative purpose belonging to a particular context of production (Bernárdez, 1982: 82; Castellà, 1992: 49-53; Van Dijk, 1980: 9-17; 1989: 13-30; 1993: 29-46; Eggins & Martin, 2000: 335-370; cited in Guantiva, Cabré & Castellà, 2008: 19).

In the approach to Text linguistics given by Beaugrande & Dressler (1981), a text, whether written or oral, is a communicative occurrence that meets seven standards of textuality: cohesion, coherence, intentionality, acceptability, informativity, situationality and intertextuality. Should any of these standards not be satisfied, the text will be considered not to be communicative, as it would have failed to fulfill its function. Considering that these standards are met, Ciapuscio (2003: 23) states that texts should be treated as the basic resources for the construction of knowledge and therefore their characteristics may become more specialized as the society or community where such knowledge is built becomes more specific.

When a text is used in a particular community, it is referred to as *specialized text* and this leads to the distinction between general language and specialized language (Guantiva, Cabré & Castellà, 2008: 19-20). The latter, specialized language, can be defined as the language used in a specific field with a particular set of linguistic resources (i.e. the topic, the type of interlocutors, the communicative situation, the speaker's intention...). It differs from general language in that it uses specialized expressions as well as terminology and phraseology that are characteristic of that field (Popova, 2015: 69). In this sense, we can say that it is a synonym of *jargon*, which is defined by the Cambridge Advanced Learner's Dictionary & Thesaurus as follows:

> *Special words and phrases that are used by particular groups of people, especially in their work.*[11]

In the same vein, Sinclair (2004: 151-152) uses the term *sublanguage* in order to refer to specialized discourse. This notion is subject to the principle of restriction, according to which "users of a

[11] Cambridge Advanced Learner's Dictionary & Thesaurus. (n.d.). *jargon*. In Cambridge Dictionary. Accessed on 10 May 2022: https://bit.ly/3NQaAqu)

language accept on certain occasions a set of voluntary restrictions on their expression" (Sinclair, 2004: 151). He makes a point that is very interesting for us, as he claims that sublanguage normally occurs in relation to specialized language, including scientific and technical topics, and in connection to the written discourse, typically at a formal register. These are precisely the characteristics of the type of texts that we are dealing with in the analysis that we have conducted for the present project.

Cabré (1993: 135) defines *specialized language* by differentiating it from general language, its functions and uses. She conceives it as specialized sets of discourse that differ from general knowledge due to reasons related to the topic, experience, field of use and users. Furthermore, for her these sets of discourse have interrelated characteristics and their communicative function stands out from the remaining complementary functions. As a matter of fact, the main difference between specialized languages and the general language is that the former are used to transmit a particular type of knowledge based on a determined topic (Sager, 1993: 40). In other words, they are specialized with regard to the contents of their discourse.

There are three types of lexis that allow us to conduct a thorough analysis of specialized texts considering their linguistic, functional and pragmatic aspects: 1) lexis that is common to general and specialized texts, 2) lexis that is on the border between the general and specialized language, and 3) lexis that is specific to the specialized text (Cabré, 1993: 152-156). To this distinction, Montero Martínez (2003: sec. 1.2.2) adds other characteristics that enable us to qualify the language of our text as specialized, including the presence of synapsis or syntagmatic structures, acronyms and specialized symbols, verbal nominalizations, short sentences, and scarce use of subordinate clauses.

In the context of Applied Linguistics, specialized language has been named *language for special/specific purposes* (LSP) and it is used to refer to the notion of "communication among specialists" (Fuertes Olivera, 2005: 41). The concept of LSP, due to its specification, requires special training in the field or discipline where it is used. In this sense, three types of users have been identified: the specialist *per se*, the would-be specialist (i.e. students or trainees) and the general audience (Fuertes Olivera, 2005: 1; Montero Martínez, 2003: sec. 1.2.2). Be it as it may, we very much agree with Fuertes Olivera (2005: 42) when he states that LSP is not a static phenomenon but it progresses at the same rate as our society and that "special languages are the result of the historical division of labor which has led to a growing diversification of scientific

disciplines". This has contributed to new ways of analyzing specialized texts based on several fields of applied linguistics. As Fuertes Olivera (2005: 42) puts it, some examples of these new approaches are included within the areas of terminology, contrastive linguistics, translation theory, and foreign language teaching, among others.

In summary, the progress made so far in the area of specialized languages, sublanguage or LSP highlights the role of linguists and philologists when it comes to dealing with specialized discourse. For this reason, as Fuertes Olivera (2005: 42) argues, these advances in the area of special communication could be incorporated into the traditional fields of research in English linguistics, the area of LSP–and more specifically English for Specific Purposes (ESP)–being an example of this need for updating as we will explain in the following section.

2. 3. English for Specific Purposes (ESP)

Nowadays, English language is not learnt by non-native speakers in order to use it to communicate with native speakers anymore (Jenkins, 2000: 1). In the era of globalization and technological explosion, the current scenario is that it has become a lingua franca that is employed as the international means of communication of many countries in order to establish social and economic links (Zaki, 2007: 1). However, in more general terms, this phenomenon does not only occur in professional situations or between entities, but between ordinary citizens. Indeed, the notion of *universal language* has been defined by Kachru (1981: 21) as that language used by a large number of people in communicative situations where each speaker comes from a different cultural and linguistic background.

The use of English as a Lingua Franca (EFL) has led to a shift in the learning contexts as well. In the past, the tendency was to learn English mainly due to an interest in the culture of its native speakers, such as its literary works (Zaki, 2007: 1). By way of an example, we can mention the work of Norris (2006: 577), who sixteen years ago stated that the main goals of foreign language (FL) courses in the USA were three: promoting the acquisition of the language for general communication, showing the Anglo-Saxon culture to the learners, and promoting the appreciation of cultural differences. These motives contrast with today's needs of learners, considering that they are not related to a mere interest anymore but to a necessity in most of the cases. In short, English has become a tool that is required in educational, professional and personal domains (Zaki, 2007:

1). This is what led to the emergence of the notion of English for Specific Purposes (ESP)[12] in the 1960s, which soon became increasingly popular because it met the employees' and learners' new needs, especially in the technical fields (Bracaj, 2014: 40).

One of the earliest definitions of ESP is the one provided by Strevens (1988: 1-2), who stated that it is "designed to meet specified needs of the learner; related in content (i.e. in its themes and topics) to particular disciplines, occupations, and activities; centered on the language appropriate to those activities, in syntax, lexis, discourse, semantics, etc.". In addition to Strevens' definition, many authors have attempted to describe the notion of ESP. For Robinson (1991: 1; cited in Agustina, 2014: 38), ESP was an enterprise comprising education, training and practice, and involving the areas of pedagogy, linguistics and the students' specialized area of interest. On the other hand, Richards and Rodge (2001: 107; cited in Agustina, 2014: 38) viewed ESP as a movement whose purpose is to serve the needs of the learners by providing them with real-world content and skills instead of acquiring the language without a specific goal. What is clear after examining these definitions is that ESP consists in equipping the learners with the specialized language that they will need to use in specific academic, professional and/or workplace environments. In other words, the decision of learning English is not made on the basis of mere curiosity or personal interest anymore, but to gain linguistic efficiency in certain situations (Basturkmen, 2006: 18).

For Trace, Hudson & Brown (2015: 2-3) LSP is, simply put, the opposite of Language for General Purposes (LGP). In fact, according to Lamri (2016), the increasing demand of ESP has led education administrators and authorities to request a replacement of English for General Purposes (EGP) with ESP. The following figure, adapted from Reinoso-Espinosa *et al.* (2020: 399), shows the main differences and common features between them:

[12] Note that, given that much of the research on LSP has been done solely in the context of ESP instruction, their definitions overlap and, in most of the cases, they are used interchangeably. According to Trace, Hudson & Brown (2015: 2-3): "[...] the similarities between ESP and LSP are numerous enough that it is difficult to talk about one without mentioning the other, and definitions of ESP tend to resemble (or in fact inform) definitions of LSP. ESP certainly seems to be more widely explored than LSP, perhaps because of the dominant role that English plays globally and the relatively large number of second language users of English around the world compared to other languages".

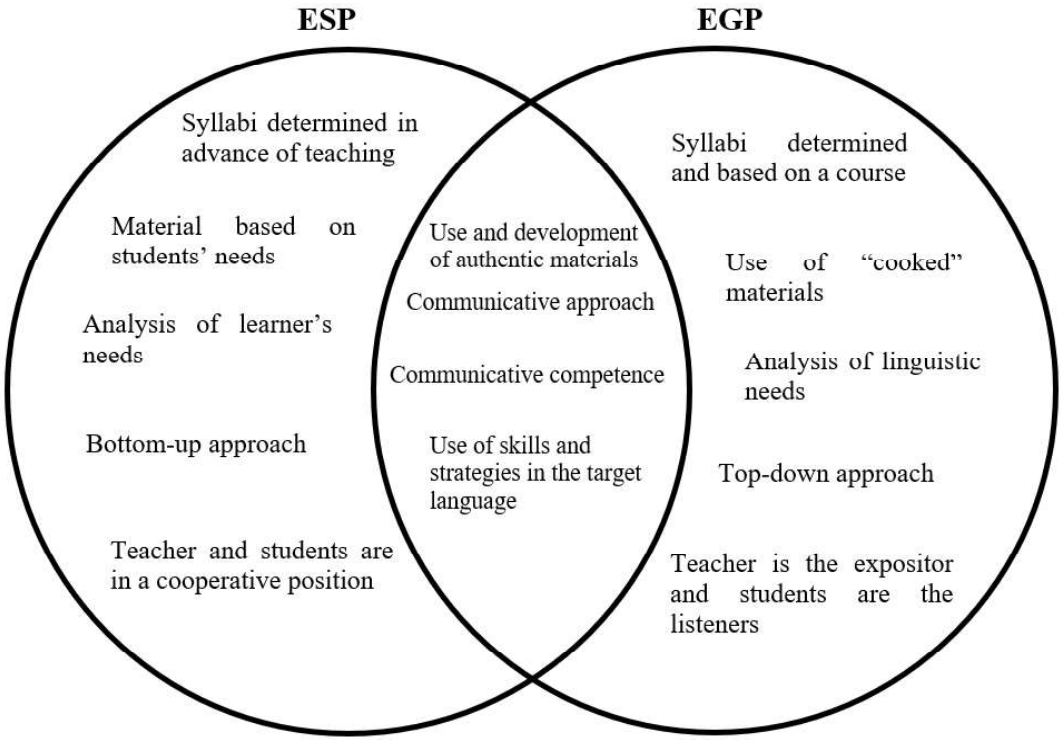

Figure 3. Characteristics of ESP and EGP (Source: Reinoso-Espinosa *et al*., 2020: 399)

Hewings (2002: 2), as cited by Fuertes Olivera (2005: 47), points out that, from a global perspective, ESP has experienced a steady increase in the past two decades, which might be due to two explanations. On the one hand, the fact that works on ESP have grown internationally; on the other hand, the acceptance of ESP as a discipline in the field of Applied Linguistics and the Departments of English. Moreover, ESP is expected to grow particularly in China, Hong Kong and the Mediterranean countries, "particularly in Spain, where ESP is becoming a focus of special interest in universities" (Hewings, 2002: 3; cited in Fuertes Olivera, 2005: 48). In accordance with Musikhin (2016), who is in line with Fuertes Olivera (2005)[13], the rapid advances in specialized fields such as science and technology are the reason leading to the failure of traditional models of language education. In fact, Ramírez (2015; cited in Reinoso-Espinosa *et al*., 2020: 400) asserts that current language learning approaches need to be based on the learners' particular specialized activity. As Fuertes Olivera (2005: 49) concludes, "ESP tends to become more international, more specialized, and more dependent on the tenets of Genre Analysis, Corpus Linguistics, Second Language Acquisition, and Discourse Analysis".

[13] According to Fuertes Olivera (2005: 42), "[...] special communication by means of LSP is a social necessity which has evolved accordingly. Special languages are the result of the historical division of labor which has led to a growing diversification of scientific disciplines and to a specialization of the branches of material production".

In order to help ESP students to cope with the particularities of specialized languages, Fuertes Olivera (2005: 51), based on Bowker and Pearson (2002), proposes the use of corpus linguistics as a methodology. In fact, according to Boulton (2016: 1), "[corpora] have become so ubiquitous that it is hard to imagine work without them–including in English for Specific or Academic Purposes (ESP/EAP[14])". Indeed, corpora are widely used in the context of ESP in order to create frequency lists of words and phrases (Boulton, 2016: 1). Moreover, if we focus on the field of Translation Studies, Peraldi (2019: 266) states that "corpus-based tools and methodologies are nowadays also being increasingly incorporated into translators' training programmes as an effective means of developing several key competencies among future translators".

2. 4. Parallel and comparable corpora

The use of corpora as tools for the linguist or applied linguist began in the 1980s and 1990s, although Corpus Linguistics (CL) has actually revolutionised the whole area of Linguistics over the last few decades, mainly due to the improved accessibility of computers (Hunston, 2002: 1; McCarthy & O'Keeffe, 2010: 34). Before it became a linguistic term *per se*, the word *corpus* was simply used to refer to a collection of written works of a similar nature. The Oxford English Dictionary's (OED) first citation of the word *corpus* dates back to 1956, where it was defined as "the body of written or spoken material upon which a linguistic analysis is based" (OED: second edition, 2009; cited in McCarthy & O'Keeffe, 2010: 34). In order to delve deeper into the current definition of the term *corpus*, we have analyzed the definitions provided by different dictionaries:

DICTIONARY	ENTRY #	DEFINITION
MERRIAM-WEBSTER[15]	3a	all the writings or works of a particular kind or on a particular subject. *especially*: the complete works of an author.
	3b	a collection or body of knowledge or evidence. *especially*: a collection of recorded utterances used as a basis for the descriptive analysis of a language
COLLINS[16]	1	a corpus is a large collection of written or spoken texts that is used for language research. [*technical*]

[14] *EAP* stands for *English for Academic Purposes*.

[15] Merriam-Webster. (n.d.). *corpus*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/39a6kCs

[16] Collins. (n.d.). *corpus*. In Collins Dictionary. Accessed on 10 May 2022: https://bit.ly/3ui5Baw

OXFORD LEARNER'S[17]	1	(*specialist*) a collection of written or spoken texts.
CAMBRIDGE[18]	1	an electronic collection of many millions of words that can be studied to show how language works
	2	a collection of written texts such as the complete works of a particular author or all the works of a particular type.
	3	a collection of written and/or spoken texts stored on computer and used for linguistic research.

Table 1. Definitions of *corpus*

As we can see, all the dictionaries listed above agree that a corpus is a collection of written or spoken texts, though some provide more details than others. We find the three definitions provided by the Cambridge Dictionary especially appropriate, in particular the first entry, which includes the adjective *electronic* in its definition. In our view, this definition is the one that best adapts to the current use of corpora, given the importance of technological advancements in the field of corpus linguistics. As McCarthy & O'Keeffe (2010: 35) put it:

> *Technology has been the major enabling factor in the growth of corpus linguistics but has both shaped and been shaped by it. The ability to store masses of data on relatively small computer drives and servers meant that corpora could be as big as one wanted.*

The expansion that technology has permitted in the field of CL allows its usage in different areas, including language teaching and learning, discourse analysis, literary stylistics, forensic linguistics, pragmatics, speech technology, sociolinguistics and health communication, among others (McCarthy & O'Keeffe, 2010: 36). Indeed, in consonance with Hunston (2002: 17), corpora nowadays have a wide range of uses, including:

a) The area of language teaching, where corpora can provide examples of phraseology that may not be accessible to native speaker intuition. Also, the frequency of certain characteristics can be estimated;

[17] Oxford University Press. (n.d.). *corpus*. In Oxford Learner's Dictionary. Accessed on 10 May 2022: https://bit.ly/3v05j79

[18] Cambridge University Press. (n.d.). *corpus*. In Cambridge Advanced Learner's Dictionary & Thesaurus. Accessed on 10 May 2022: https://bit.ly/3DKYDhg

b) Similarly, students can explore corpora by themselves in order to observe the particularities of the target language (TL) or make comparisons between their first language (L1) and the second language (L2);

c) In the areas of stylistics and clinical and forensic linguistics, general corpora can help to establish norms of frequency and usage;

d) Corpora can also be used to investigate the expression of cultural identity through language as well as a resource for critical discourse analysis;

e) Translators can use comparable corpora to compare the use of presumable translation equivalents in two languages or parallel corpora to see how certain words and phrases were translated in the past.

Indeed, as regards the last point, McEnery & Xiao (2007: 4) argue that "corpora provide a workbench for training translators and a basis for developing applications like machine translation (MT) and computer-assisted translation (CAT) systems". But what is meant by *comparable* and *parallel corpora*? In order to understand the definition of each, and the main differences between them, we have specified the characteristics of the eight types of existing corpora in the following table, adapted from Hunston's (2002: 14-16) classification:

TYPE OF CORPUS	DEFINITION
SPECIALIZED	It includes texts of a particular type (e.g. Geography textbooks) in order to be representative of that text type and, subsequently, to investigate that kind of specialized language.
GENERAL	It includes texts of many types, which can be written, spoken or both. It does not aim to be representative of any particular genre but to include as many examples as possible. Since they are often used to produce reference materials for language teaching or translation studies, they are also known as *reference corpora*.
COMPARABLE	It consists of two (or more) corpora in different languages (e.g. English and Spanish). It is often used by translators and learners to identify differences and equivalences between the SL and the TL.
PARALLEL	It consists of two (or more) corpora, one containing the original texts in the source language and the other its translations in the TL. It is often used by translators and learners to find equivalences and differences between the two languages.
LEARNER	It is a collection of texts produced by L2 learners. This type of corpus aims to identify in what aspects learners differ from each other and from native speakers. In the latter case, a comparable corpus of native-speaker texts would be necessary, too.

PEDAGOGIC	It contains the language a learner has been exposed to (e.g. all the course books the teacher has used). It might be used to collect together all the examples of a word or phrase the learner has come across during the course.
HISTORICAL OR DIACHRONIC	It contains texts from different periods of time in order to trace the evolution of certain aspects of a language over time.
MONITOR	Its purpose is to track the current changes that occur in a language. New contents are added annually, monthly or even daily, so its size is continually increasing.

Table 2. Types of corpora (Source: Hunston, 2002: 14-16)

For the purposes of this Master's dissertation, it is the definition of *comparable corpus* and its difference with *parallel corpus* that is of interest to us, since one of our objectives with this project is to build a comparable corpus. According to McEnery (2003: 450; cited in McEnery & Xiao, 2007: 3), comparable corpora contain texts that are collected using the same sampling frame as well as similar balance and representativeness. As McEnery & Xiao (2007: 3) put it, "the subcorpora of a comparable corpus are not translations of each other. Rather, their comparability lies in their same sampling frame and similar balance". Nonetheless, it should be borne in mind that both parallel and comparable corpora can be specialized or general simultaneously, depending on the specific research topic. In conformity with McEnery & Xiao (2007: 3), it is common to use a specialized parallel or comparable corpus when it comes to extracting terminology from a set of texts.

Zanettin (1998; cited in McEnery & Xiao, 2007: 7) explains that even small comparable corpora are useful in order to devise a kind of 'translator training workshop' in translation courses' lessons. In this vein, as McEnery & Xiao (2007: 7) assert, "specialized comparable corpora are particularly helpful for highly domain-specific translation tasks". Furthermore, when compared with parallel corpora, which contain the original texts and their translation equivalents, comparable corpora are advantageous in the sense that they usually contain more idiomatic expressions because the TL is not under the influence of the SL. This influence of the SL in the target text is known as *translationese*, a term coined for the first time by Gellerstam (1986: 88), who described it as the "systematic influence on target language (TL) from source language (SL), or at least generalizations of some kind based on such influence".

Thus, it follows from the above that the scenario in which comparable corpora are more useful is one that meets the following requirements (Delpech *et al.*, 2012: 3): 1) the goal is to extract domain-specific lexis and 2) the target and source texts are highly comparable. The study that we are conducting in this project meets these criteria and this is the reason why, to our view, building a

comparable corpus was the best option in order to identify the equivalences between the target and the source languages more efficiently. In other words, the use of comparable corpora will contribute to what Brown *et al.* (1993; cited in Delpech *et al.*, 2012: 3) called *fertile* translations. These authors defined the notion of *fertility* as the number of target words to which a source word *e* is connected in a randomly selected alignment. As Delpech *et al.* (2012: 3) explain:

> *The identification of fertile translations is useful because (i) they frequently correspond to non-canonical translations, e.g. paraphrastic*[19] *variants and (ii) they tend to correspond to vulgarized forms of technical terms (e.g. "cytotoxic" vs. "toxic to the cells").*

Turning specifically to the case of medico-legal documents, they are one of the most difficult texts to transform into 'fertile' translations in the context of medical and legal translation because most of the concepts existing in the source language lack an equivalent in the TL given the notorious differences between the legal and health systems in the source and target countries (Gallardo San Salvador, 2012: 229). Given this situation, Gallardo San Salvador (2012: 229) asserts the following:

> *Para resolver los problemas de estilo, del discurso jurídico específico, de la terminología, y de la configuración del texto, la única fuente documental son los documentos equivalentes o textos paralelos.*
>
> *In order to solve problems related to the stylistics of the text, the specific legal discourse, the terminology and the text's configuration, the only source document available are equivalent documents or parallel texts.* [OWN TRANSLATION]

The conclusion that we can draw in reference to the use of corpora in the translation process of medico-legal texts is that the resulting translations will be of a higher quality because the translator will have a better understanding of the field, and therefore the term choice will be more accurate than translations carried out using conventional resources (McEnery & Xiao, 2007: 7).

2. 5. Medico-legal texts

Medico-legal texts are defined by several authors (García Izquierdo, 2009; Martínez López, 2009; Gallardo San Salvador, 2012; Gallego Borghini, 2015b) as hybrid documents that mix part of medical texts and part of legal texts. However, when paying attention to the elements of the

[19] *adj*. of, having the nature of, or forming a paraphrase (Collins. (n.d.). *paraphrastic*. In Collins Dictionary. Accessed on 10 May 2022: https://bit.ly/3xa9i3x)

communication process[20], Gallardo San Salvador (2012: 5) observes two characteristics of medico-legal texts:

- The message has a medical nature;
- The code, channel and receiver are all related to the legal-administrative field.

Considering the nature of the message, it could be argued that the majority of the contents of medico-legal texts are, indeed, medical. In this sense, Gallardo San Salvador (2012: 6) wonders whether we should rename this kind of texts, and claims the following:

> *Todas las fuentes consultadas, provenientes de autores pertenecientes al campo de la medicina, utilizan el término "documentos médico-legales". Sin embargo, en el ámbito de la traducción hablamos de "documentos jurídicos (no legales) en el ámbito de la medicina", o de "traducción jurada de textos médicos", y de "medicina legal" (no jurídica) y "forense". No hay unanimidad en el uso de una u otra terminología.*
>
> *All sources consulted, coming from authors belonging to the field of medicine, use the term "medico-legal documents". However, in the field of translation we speak about "juridical documents (not legal) in the field of medicine" or "juridical translation of medical texts", and about "legal medicine" (not juridical) and "forensic". There is no unanimity in the use of one terminology or another.* [OWN TRANSLATION]

Carvajal Oviedo *et al.* (2020: 1) define *medico-legal texts* as all those written documents that doctors use in their professional relationship with the authorities, organisms, institutions, patients and others. The following documents are all considered by Carvajal Oviedo *et al.* (2020: 3-4) to have a medico-legal nature:

TYPES OF MEDICO-LEGAL DOCUMENTS	
a) Medical records	i) Expert reports
b) Informed consents	j) Anesthetic consent forms and information sheets
c) Records of auxiliary procedures for diagnosis and treatment	k) Interconsultations
d) Medical certificates	l) Descriptions of surgical procedures
e) Birth certificates of a stillborn child	m) Epicrisis[21]

[20] According to Jakobson's model of communication (1995), there are six necessary elements for communication to occur: 1) context, 2) addresser/sender, 3) addressee/receiver, 4) channel/mode of contact, 5) code and 6) message.

[21] *noun*. a critical or analytical summing up especially of a medical case history. (Merriam-Webster. (n.d.). *epicrisis*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3Kk7OaG)

f) Certificates of live birth	n) Transfers
g) Death certificates	o) Medico-legal reports
h) Autopsy protocols	p) Prescriptions

Table 3. Medico-legal documents (Source: Carvajal Oviedo *et al.,* 2020: 3-4)

As we shall see, the informed consent, which is the main focus of this Master's dissertation, is indeed a type of medico-legal document. It has, however, its own internal structure and differentiating elements that make it unique. For this reason, some authors like García Izquierdo (2009) and Ramírez Almansa (2019) consider it to be a particular text genre that should be analyzed separately and, following their approach, this is what the reader shall find in the following section.

2. 6. Informed consents as text genres

A *genre* is defined as the category assigned to a text on the basis of external criteria such as the intended audience, the purpose and the activity type (Lee, 2001: 38). Moreover, according to Lee (2001: 38-39), "genres also have the property of being recognized as having a certain legitimacy as groupings of texts within a speech community (or by sub-groups within a speech community, in the case of specialized genres)". In this sense, informed consents constitute an independent text genre, given that they are intended for a particular audience, have a determined purpose and are used under certain circumstances.

Firstly, we will start by defining them. Martínez López (2009: 14) defines *informed consents* as the type of medico-legal document with the highest level of hybridization. This author conceives it as a contract between two contracting parties: the patients (clients), who provide their consent to a particular health action to the specialist or institution that performs it (contractor) (Martínez López, 2009: 14). For Ruiz Escrivá (2021: 2), informed consents are hybrid documents because they combine two different types of information:

- Medical information about the description of the medical procedure that will be performed;
- Legal information to ensure that the patients have understood everything and they consent to the performance of such procedure.

Martínez-López (2009: 14) determines that the legal part is the one shaping the whole document with the common structural patterns of legal-administrative documents, whilst the medical information is provided through annexes or sections where the patients are informed about the conditions and the risks associated with the health procedure that they are about to authorize.

The Spanish Fertility Society (SEF) (2002: 11) is clear when it describes the utility of informed consents and states that, from the legal point of view, they are the fundamental exponent of the principle of autonomy. Moreover, the SEF establishes the contents that should be present in any document of this kind (2002: 15-16):

- Nature of the intervention: What is it about? What is to be done?
- Objectives of the intervention: What is it done for?
- Benefits of the intervention: What is the improvement expected?
- Risks, nuances and potential side effects, including the ones derived from not undergoing the intervention;
- Potential alternatives to the proposed intervention;
- Possibility of withdrawing consent freely if the patient wishes to.

Similarly, Spanish Royal Decree 223/2004, of 6 February, which regulates clinical trials with drugs, describes how the structure of informed consents should be in the following passage:

> *El consentimiento se documentará mediante una hoja de información para el sujeto y el documento de consentimiento. La hoja de información contendrá únicamente información relevante, expresada en términos claros y comprensibles para los sujetos, y estará redactada en la lengua propia del sujeto.*
>
> *The consent will be documented through the information sheet for the subject and the consent document. The information sheet will contain only relevant information, expressed through clear and comprehensible terms for the subjects, and will be written in the own language of the subject*. [OWN TRANSLATION]

In relation to this notion of using clear language, the SEF (2002: 17) establishes that the contents of informed consents must be written in a language that is comprehensible for the patient, with the minimum possible number of technicalities. This has to do with the concept of *plain reader* introduced by Gallego Borghini (2015a: 1), according to whom the readers of informed consents are not specialists in the field, that is to say, the receivers of the document are not health professionals or lawyers, for example−the persons who are going to read this document are ordinary people.

García Izquierdo (2009: 36) makes one further point in relation to the contents of informed consents, remarking that they constitute a far more institutionalized genre in English-speaking

countries than in Spanish-speaking ones. As Blanco & Gutiérrez (2002: 322) point out, it might be related to what they call *functional literacy*[22]. According to this notion, even though the degree of functional literacy is an inadequate one in both English-speaking and Spanish-speaking countries, it is considerable higher in the former, where it is directly linked to health education and information programs (Blanco & Gutiérrez, 2002: 322). Indeed, as Da Cunha & Escobar (2021: 132) assert, the Spanish population, with a few exceptions and particular groups, is not trained for this type of specialized language. For these reasons it is always of the utmost importance that informed consents are written using a neutral register and a language that is comprehensible and clear (Gallego Borghini, 2015b: 1).

According to Wright (1999: 85; cited in García Izquierdo, 2009: 37-38), informed consents are a type of 'functional texts', given that their communicative goal is to help the reader make a decision or follow a particular procedure. Moreover, these texts are not only conceived for the receiver(s) to find and understand the information given, but also to help in the decision-making process. Similarly, Mayor Serrano (2005: 2) defines their function using the following words:

> *La función comunicativa de la clase de texto objeto de estudio consiste, pues, en transmitir a los destinatarios informaciones de carácter médico, dar recomendaciones para la prevención de enfermedades y para la actuación ante estados de convalecencia e intentar, en cierto modo, influir en la conducta del receptor por medio del mensaje que se le envía.*
>
> *The communicative function of the text type under study consists, therefore, in transmitting to the receivers information of medical nature, giving them recommendations on how to prevent diseases and how to act before convalescence, and trying, in some way, to influence the behavior of the receiver through the message that is being sent*. [OWN TRANSLATION]

According to Montalt & González Davies (2007: 62), one should not forget that the function of informed consents is to serve as a complement of the verbal communication between the healthcare provider and the patient(s), and this should never be replaced by the former. In this sense, the consent is conceived as a written authorization given by the patient to the doctor so that the latter is allowed to interfere in the patient's physical and moral integrity (Gesinska, 2020: 71).

[22] In health, the concept of *literacy* is defined as the ability to understand and communicate information about health. A report published by The Institute of Medicine (IOM) of the United States, defines *health literacy* as the "degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions". (Ramos, 2012: 3; Ratzan & Parker, 2000)

For Gallego Borghini (2015b: 23), the predominant communicative functions of informed consents are the descriptive (representative) and the prescriptive (conative). In connection to the prescriptive or conative function, informed consents are characterized by the use of the imperative mode, which is softened in English by the use of the formula *please* at the beginning of the sentence. Conversely, in Spanish the use of the imperative is softened by the use of the polite second person singular pronoun *usted (*e.g. *Usted debe conocer bien los posibles efectos beneficiosos)* or the verb *rogar (*e.g. *Le rogamos que lea atentamente el documento).*

As regards the register of informed consents, we shall define it on the basis of Halliday's model of register (2009) in Systemic Functional Linguistics[23]. According to it, there are three key elements in the context of any particular situation that affect the linguistic choices made by the speaker. These elements are called *mode, tenor* and *field*, and their combination is what creates the register of a situation (Derewianka & Jones, 2016: 6). We have summarized all three elements in the following table, based on the classification made by Derewianka & Jones (2016: 5):

ELEMENT	DESCRIPTION
MODE	It refers to the channel of communication that is used. It includes the mode and the medium. Basically, we can distinguish between the spoken mode and the written mode. However, with the growth of new forms of media, we can also distinguish between visual and multimodal texts.
TENOR	It refers to the roles that speakers take up (e.g. student, customer, patient...) and their relationships with others in a particular situation. The tenor is affected by different factors, including the age, ethnic background, gender, status, level of expertise, etc. of the participants. Other factors such as how people know each other, how frequently they meet and how they feel about each other, among others, will also influence language choices.
FIELD	It refers to the content or subject matter. Thus, for instance, the language choices made in a scientific context will be different from those made in a school context.

Table 4. Elements of the register (Source: Derewianka & Jones, 2016: 5)

[23] Also known as *Systemic Functional Grammar (SFG)*, it is a form of grammatical description developed by Michael Halliday in the 1960s. It is part of a broad semiotic approach to Linguistics called *Systemic Linguistics*. It is called *systemic* because it refers to an interrelated system with many options available for making meaning, and *functional* because it is concerned with meaning in context (Halliday, 2009).

In the case of informed consents, the mode is written, considering that they are typically handed over to the patient in the medical consultation. However, as García Izquierdo (2009: 39-40) points out, nowadays many clinics require patients to fill them out online and sign them digitally. We can see, then, that the internet is gradually becoming an alternative written communication medium. Posteguillo Gómez & Piqué-Angordanas (2007: 171) have coined this phenomenon under the term *cyber-genre*, which is an evolution of an already established genre that has found a new space for developing on the internet.

In connection to the socio-professional field and the participants in the communicative act, the sender/source of informed consents–particularly of the information for patients' sheet–is normally a healthcare provider (García Izquierdo, 2009: 39-40). In this sense, the purpose that all medical professionals should seek when writing an informed consent is, according to Reame (1999: 3), "not to simply obtain a signature on a form. Rather, it is to assist the patient to come to a well-considered judgment about the nature and consequences of the risks and benefits and to understand the merit of proceeding with treatment, even when alternative options are available and might be less risky".

Finally, with respect to the tenor, we could argue that the level of formality of these texts is medium to high. However, we find the presence of explicative paraphrases in an attempt to bring them closer to the general public (e.g. *Cryopreservation (freezing) of eggs or embryos*[24]). In any case, though, in the words of García Izquierdo (2009: 42):

> *[...] el grado de accesibilidad al público [...] es limitado y solo accederán a la información en condiciones aceptables aquellos que posean determinado nivel formativo.*
>
> *[...] the degree of accessibility to the audience [...] is limited and only those who possess a determined formative level will have access to the information under acceptable conditions.* [OWN TRANSLATION]

This recalls the concept of *functional literacy* introduced by Blanco & Gutiérrez (2002: 322), which we explained above (see Section 2.6). Nevertheless, García Izquierdo (2009: 44) asserts that, sometimes, the level of formality is still higher than expected. On the other hand, Gallego Borghini (2015b: 21-22) states that utilizing a neutral, formal tone does not exclude the use of a plain, comprehensible language. Indeed, there have been certain initiatives in the English language to

[24] Example retrieved from Stanford Reproductive Medicine's informed consent (p. 2).

simplify the tone used in exchanges between the Administration and citizens, such as the Plain English Campaign. According to Felsenfeld (1981: 2):

> *The plain English movement is the name given to the first effective effort [...] to write legal documents, particularly those used by consumers, in a manner that can be understood, not just by the legal technicians who draft them, but by the consumers who are bound by their terms.*

In Spain, initiatives of this kind have been more modest than in English-speaking countries. Some examples include the *Manual de estilo del lenguaje administrativo* (Ministerio para las Administraciones Públicas, 1990), a stylistic guide to administrative language whose purpose was to update the language used by the public services when communicating with ordinary citizens; the *Manual de Documentos Administrativos*, (Ministerio de Administraciones Públicas, 1994) with a strongly practical nature; and, more recently, the *Convenio marco de colaboración para promover la claridad del lenguaje jurídico* (2011), the *Guía breve del prontuario de estilo para el Tribunal Supremo* (2016) and the *Libro de estilo de la Justicia* (2017), among others mentioned by Da Cunha & Escobar (2021: 132).

2. 7. Identifying the terminology and phraseology of informed consents

Given that one of the purposes of informed consents is that the reader understands their contents easily, a huge percentage of the terminology and phraseology belongs to the general language, although they also include a vast amount of specialized terminology from the medical and legal fields (Ruiz Escrivá, 2021: 280). It is this specialized terminology and phraseology that is of interest to us and this is the rationale of the following subsections.

Firstly, the reader shall find a classification of the main types of medical terminological and phraseological units. Secondly, we will present another classification with the common characteristics of legal terminology and phraseology. For these purposes, we have gathered together and adapted the classifications made by Van Hoof (1999), Díaz Rojo (2005), Alcaraz Varó & Hughes (2014) and Vázquez y del Árbol (2020) in connection to the types of terms and phraseological units that one usually finds in legal-scientific hybrid communication.

2. 7. 1. Medical terminology and phraseology

Medical terminology and phraseology are diverse mainly due to differences between registers or communication channels (Montalt, Zethsen & Karwacka, 2018: 29). Moreover, medical

terminology is a reflection of the beliefs and ideas that are part of certain cultures and their mindsets as well as the particular communities within those cultural environments (Díaz Rojo, 2005: 31).

As we shall see below, some of the most common characteristics of medical terminology include the presence of Latin and Greek influences (e.g. *granuloma*), acronyms and abbreviations (e.g. *RBC → red blood count*), eponyms (e.g. *Fallopian tubes*), and the doublet phenomenon (i.e. each erudite term has an equivalent from the general language, as in the pair *coagulation → clotting)* and terminological metaphors (e.g. *to fight against a disease*) (Montalt, Zethsen & Karwacka, 2018: 29-30; Van Hoof, 1999: 147).

2. 7. 1. 1. Technical vocabulary

Technical vocabulary is a major concern in ESP classrooms but, surprisingly, little is known about it, mainly because to date there are no well-established approaches that allow us to discern the words that are specialized from those that are not (Mihwa Chung & Nation, 2003: 251). Indeed, 'technicalness' is considered to be a functional feature of words; therefore, the particular use of that word or set of words by a speech community is what will allow us to decide whether it is technical or not. In fact, the idea that technical vocabulary goes hand in hand with the field of specialization where it is used is essential to identifying it–the more related a word is to a particular subject area, the more technical it is (Baker, 1988; Farrell, 1990; Sutarsyah *et al*., 1994; cited in Mihwa Chung & Nation, 2003: 251).

One method for deciding whether a word or set of words can be considered a technical term or phrase is to use a specialized dictionary (Mihwa Chung & Nation, 2003: 253). In our case, since we are dealing with Assisted Reproductive Technology (ART), we have selected two glossaries:

- First, the *International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization's (WHO) revised glossary of ART terminology*[25] (2009), which "is the result of discussion and consensus reached among 72 clinicians, basic scientists, epidemiologists, and social scientists" (Zegers-Hochschild *et al*., 2009a: 1521). Such glossary has its own version in Spanish[26], translated and published by the Red Latinoamericana de Reproducción Asistida in 2010.

[25] See Zegers-Hochschild *et al.* (2009a)

[26] See Zegers-Hochschild *et al.* (2009b)

- Second, the *International Committee for Monitoring Assisted Reproductive Technologies (ICMART)'s International Glossary on Infertility and Fertility Care* (2017), available online from the ICMART's website[27].

Moreover, we have also selected the *Glossary of Lay Terms for Use in Informed Consent Forms*[28] created by the Institutional Review Board (IRB) of the University of Florida due to its suitability for the purposes of our research, since we are precisely analyzing informed consents. As one shall see when examining the said glossary, we can see that it includes medical terminology.

According to Van Hoof (1999: 147), medical language is fundamentally based on erudite terms with a Greco-Latin base. Nonetheless, the English language has, along with the erudite term, a popular[29] term that belongs to everyday language and is, therefore, more usual. This has been named *doublet phenomenon* by Montalt, Zethsen & Karwacka (2018: 29-30). The table below contains some examples of erudite terms with their equivalent from everyday language (adapted from Van Hoof, 1999: 147):

ERUDITE TERM		POPULAR TERM
coagulation [from Latin *coagulationem*]	→	*clotting*
cicatrization [from Latin *cicatrix]*	→	*scarring*
myopia [from Late Greek *myōpia*]	→	*shortsightedness*
glycemia [*glyco-* (from Greek *glyky*) + *-emia* (from Latinized form of Greek *haima*)]	→	*blood sugar*

Table 5. Doublet phenomenon in medical discourse (Source: Van Hoof, 1999: 147)

2. 7. 1. 2. Eponyms

Eponyms are regarded as terms whose origin is a name, usually the name of a person. In some cases, people give their own name to their discovery, invention, place, etc., whilst sometimes others do it in their honor. The majority of eponyms come from the names of real people, but others are based on fictional characters or legendary heroes (Trahair, 1994: 17). In the field of medicine, there exist two types of medical eponyms, depending on whether the original name results in a noun (e.g.

[27] Available from: https://bit.ly/3DV40KU (Accessed on 10 May 2022)

[28] Available from: https://bit.ly/36Yu4so (Accessed on 10 May 2022)

[29] Note that we are using the term *popular* in the sense of *frequently encountered or widely accepted* (Merriam-Webster. (n.d.). *popular*. In Merriam-Webster Dictionary (entry #3). Accessed on 10 May 2022: https://bit.ly/3ucugNw)

addisonism) or remains with the original name, in such cases designating a particular disease, symptom or technique (e.g. *Banti's disease*) (Van Hoof, 1999: 212).

The translation of medical eponyms represents a particular challenge for the translator, since their adaptation to the TL does not always follow a particular set of rules. Moreover, there may be more than one eponym to refer to a single phenomenon (Van Hoof, 1999: 212). Below we are presenting a table with a classification, based on Van Hoof's work (1999: 212), of the different types of eponyms–with their definition and examples in English and Spanish–that a terminological translator may encounter:

TYPE OF EPONYM	DESCRIPTION	EXAMPLES		
		ENGLISH		SPANISH
TRIVIALIZED EPONYMS[30]	They are so widely used in everyday language that they have switched from proper noun to common noun, verb or adjective.	*Bartholinitis*	→	*Bartolinitis*
		Fallopian tube	→	*Trompa de Falopio*
SIMPLE EPONYMS, IDENTICAL IN BOTH LANGUAGES	They are numerous and built in using the Latin or Saxon genitive.	With Saxon genitive: *Cushing's syndrome*	→	*Síndrome de Cushing*
		With Latin genitive: *ducts of Cuvier*	→	*conductos de Cuvier, seno de Cuvier*
COMPOUND EPONYMS, IDENTICAL IN BOTH LANGUAGES	Their name is the result of unifying two or more proper names. In English, they can be found with or without a Saxon genitive.	With Saxon genitive: *Brown-Séquard's syndrome*	→	*Síndrome de Brown-Séquard*
		Without Saxon genitive: *Aschheim-Zondek test*	→	*prueba de Aschheim-Zondek*
IDENTICAL, DOUBLE EPONYMS WITH NAME SWITCHING IN THE TL	They are composed by the name or surname of two different people.	*Philippe-Gombault's tract*	→	*Triángulo de Gombault-Philippe*
COMPLEMENTARY EPONYMS IN THE SL AND THE TL	They have multiple synonyms that, apparently, have nothing to do by just observing their names.	*ventricle of Arantius, Duncan's ventricle, Sylvius's ventricle, Vieussens' ventricle*	→	*acueducto de Silvio, ventrículo de Quinto, de Silvio, de Duncan, de Vieusseus*

Table 6. Classification of eponyms (Source: Van Hoof, 1999: 212)

[30] Adapted from Van Hoof's (1999) original term in French *éponyme banalisé*.

2. 7. 1. 3. Greek-Latin hybrid nomenclature

The majority of medical terms stem from Latin and Greek origins due to the founding of modern medicine by the Greeks and the subsequent influence of Latin during its years as the universal language of the Western civilization (Canfield Willis, 2006: 9). Nonetheless, as Banay (1948: 1) and Canfield Willis (2006: 9) note, medical language has also been influenced by other languages, including German (e.g. *Mittelschmerz* to refer to ovulation pain) and French (e.g. *ambulance, assurance*). According to Canfield Willis (2006: 9), "most terms related to diagnosis and surgery have Greek origin, and most anatomical terms can be traced to Latin".

The key to identifying what Vázquez y del Árbol (2020: 2) has called *Greek + Latin hybrid nomenclature* is to analyze its term components separately, as most of them have three components: prefix, root and suffix (Canfield Willis, 2006: 9). Below is one example of a medical term containing all three components (adapted from Canfield Willis, 2006: 10). We can observe that it contains the prefix *hyper-*, from Greek origin[31], and the suffix *–emia*, which is a Latinized form of Greek *haima*[32]:

	hyper / ***lip*** / ***emia***
TYPE OF COMPONENT	PREFIX ROOT SUFFIX
MEANING	excessive fat blood condition

Table 7. Etymological analysis of *hyperlipemia* (Source: Canfield Willis, 2006: 10)

As we shall see, even words of Latin origin derive from a Greek form, as in the case of *–emia* seen above. Indeed, around three-fourths of the medical terminology is of Greek origin and this is due to the fact that Greeks founded the notion of rational medicine in the golden era of Greek civilization, around the 5th century BC (Banay, 1948: 1-2). Thus, in order to refine our search for the most common Greek prefixes, suffixes, nouns, adjectives and adverbs when analyzing our corpora, we are using the classification made by Jóskowska & Grabarczyk (2013)[33].

[31] Online Etymology Dictionary. (n.d.). *hyper-*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/3JbeAy9

[32] Online Etymology Dictionary. (n.d.). *-emia*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/3v3bB5S

[33] Available from: https://bit.ly/3r78BV3 (Accessed on 10 May 2022)

However, nowadays English has become the lingua franca in medical communication, which means that today we have many terms that come directly from the English language, including *clearance, screening, scanning, bypass operation*, etc. As a matter of fact, some of these words are imported directly to other languages (Wulff, 2004: 188), as in the case of the term *bypass*, which is also used in, for instance, German as a loanword and in Spanish with the adapted form *baipás*.

2. 7. 1. 4. Acronyms and abbreviations

Marchand (1969) uses the term *initialisms* to refer to abbreviations and acronyms as a whole and *word-manufacturing* to call the process of forming them. According to him (1969: 452), they are basically used to create names of organizations and scientific discoveries. As Ljung (2003: 158) puts it, the main difference between abbreviations and acronyms is that the later "have to be pronounceable" and "can only contain letter sequences permitted in ordinary English words". Thus, following this definition, the term *NATO (North Atlantic Treaty Organization)* would be an example of acronym, whilst *DNA (deoxyribonucleic acid)* an example of abbreviation.

Kuzmina *et al.* (2015: 551) have summarized the types of abbreviations and acronyms that we can find in medical language into five types according to their structure:

1) **Letter**, as *in BCG (bacillus Calmette-Guerin), AF (atrial fibrillation), BBB (bundle branch block), BM (bowel movement), MCA (middle cerebral artery), MH (malignant hyperthermia)* or *MI (myocardial infarction*);
2) **Syllabic**, as in *URAC (uric acid), magtape (magnetic tape)* or *NAPA (N-acetyl-paraaminophenol)*;
3) **Shortened words**, as in *mets (metastases), Neuro (neurology), QALY (Quality adjusted life year), readm (readmission), elect (electrolyte), inj (Injection)* or *postop (postoperative*);
4) **Letter or syllabic + word**, as in *MUGA scan (MUltiGAted radionuclide scan)*;
5) **Alphanumeric**, as in *A1 (A one)*, *VP-16 (epipodophyllotoxin)*, *T4 (thyroxine)* or *17-OHCS (17- hydroxycorticosteroid)*.

Once we have learnt how to identify initialisms, the table below, adapted from Van Hoof (1999: 227), summarizes the four possible scenarios that a translator may encounter when attempting to translate them into Spanish:

TYPES OF INITIALISMS	EXAMPLE(S)		
	ENGLISH		SPANISH
INITIALISMS THAT ARE IDENTICAL IN BOTH LANGUAGES	*ADP (adenosi disphosphate)*	→	*ADP (adenosindifosfato)*
INITIALISMS THAT ARE DIFFERENT BETWEEN ONE LANGUAGE AND THE OTHER	*DNA (deoxyribonucleic acid)*	→	*ADN (ácido desoxirribonucleico)*
	IVCD (intrauterine contraceptive device)	→	*DIU (dispositivo intrauterino)*
ABSENCE OF INITIALISM IN SPANISH	*ACD (absolute cardiac dullness)*	→	*zona de matidez cardíaca*
	RBC (red blood count)	→	*recuento eritocitario*
ABSENCE OF INITIALISM IN ENGLISH	*acute lung edema*	→	*EAP (edema agudo de pulmón)*
	intravenous urography	→	*UIV (urografía intravenosa)*

Table 8. The translation of initialisms (EN>ES) (Source: Van Hoof, 1999: 227)

2. 7. 1. 5. Compound and hyphenated terms

One particularity of the English language is its flexibility to exchange grammatical categories, which provides the language with the freedom to form compound words through the following processes (Van Hoof, 1999: 37-39):

- Adjectivization of verbs (e.g. *child-bearing a*ge);
- Adjectivization of nouns (e.g. *hospital nurse* or *glucose tolerance test*);
- Verbalization of nouns (e.g. *to sample/to sample out*).

As can be seen, in some cases the compound word appears with a hyphen, which is called *hyphenated compound* and is defined as the result of combining two or more words that have become one in terms of form and meaning, and therefore have their own lexical meaning and function as a single term (El-Wifati, 2016: 7). The following is a classification of the different types of hyphenated medical terms (adapted from El-Wifati, 2016: 8):

- Hyphenated prefix joined to an abbreviation (e.g. *anti-RNA, non-AIDS-related infection*);
- Hyphenated term modifying a phrase (e.g. *non-small-cell lung cancer, non-insulin, dependent diabetes mellitus*);
- Hyphenated adjective plus number indicating the temporality (e.g. *4-inch scar, 5-day growth, 8-month pregnancy*);

- Hyphenated terms and abbreviations indicating ratios (e.g. *A-G ratio*[34]*, BUN-Creatanine ratio*[35]);
- Hyphenated adjectives with participles (e.g. *FDA-approved system*[36])

2. 7. 1. 6. Terminological metaphors

Metaphors are one of the most employed linguistic resources to conceptualize the world and explain reality. Contrary to common belief, they are not only used in literature, but they are everywhere in political, journalistic, scientific and everyday language (Díaz Rojo, 2005: 8). In medicine, according to Díaz Rojo (2005: 8), terminological metaphors are a reflection of the culture where they are used and, when utilized as a verbal resource, they constitute a big part of the language of medicine. Thus, the following is a classification of the most common types of conceptual metaphors used in medical language (adapted from Díaz Rojo, 2005: 39-44)

- **Political metaphors**, based on the cognitive model[37] +THE BODY IS A HIERARCHICAL SOCIETY+, as in *therapeutic control, to regulate a function, to release insulin, cell population, cancer as the lack of cell control*;
- **War metaphors**, based on the cognitive model +THERAPY IS WAR+, as in *side effects, adverse reactions, to fight against a disease, antagonist drugs*, the use of the prefix *anti-* in several drugs (*antidepressant, antibiotic*...);
- **Economic metaphors,** based on the cognitive model +WELL-BEING IS WEALTH+, as in *to regain consciousness, rich/poor in vitamins, blood bank, energy consumption*;
- **Geographical metaphors,** based on the cognitive model +THE BODY IS A GEOGRAPHICAL TERRITORY+, as in *insulin, human genome mapping, region* (in anatomy), *area, carpal tunnel, ciliary valley;*
- **Hydraulic metaphors**, based on the cognitive model +THE BODY IS A HYDRAULIC SYSTEM+, as in *blood circulation* or *blood flow;*

[34] i.e. Albumin to Globulin ratio

[35] i.e. Blood urea nitrogen to creatanine ratio

[36] i.e. a system approved by the Food & Drug Administration

[37] According to Peña & Samaniego (2007: 32), "a metaphor is understood as a mapping or set of correspondences across conceptual domains. There is a source domain and a target domain. The conceptual structure of the source is used to understand and talk about the target". Thus, for example, in the metaphor +THE BODY IS A HIERARCHICAL SOCIETY+, *the body* is the target, whilst *the hierarchical society* is the source.

- **Containment metaphors**, based on the model +BODY PARTS ARE CONTAINERS+, as in *buccal cavity* or *ejaculatory duct*;
- **Architectural metaphors**, based on the cognitive model +THE BODY IS A BUILDING+, as in *vaginal walls, face reconstruction, cranial vault, nasal septum, kyphosis* (from Greek *kyfós* 'vault'), *cell wall*;
- **Mechanical metaphors**, based on the cognitive model +THE BODY IS A MACHINE+, as in *pumping blood, genetic engineering, physiological mechanism, pathogenic mechanism, drainage, apparatus*;
- **Domestic metaphors**, based on the cognitive model +THE BODY IS A HOUSE+, as in *bacteria* (from Greek *bacterion* 'stick'), *pelvis* (from Latin *pelvis* 'cauldron'), *thalamus* (from Greek *thalamós* 'bridal bed').

2. 7. 2. Legal terminology and phraseology

Legal terminology or legal lexis can be defined as the lexical units used in the specialized language of the legal field or legalese to achieve its communicative goal, irrespective of whether communication occurs intra-professionally (i.e. between legal professionals such as lawyers, judges...) or inter-professionally (i.e. between legal professionals and lay people) (Isani, 2011: 16; cited in Richard, 2018: 2).

According to Scotto di Carlo (2015: 7), legal English contains a high number of domestic words, which is to say, words from the general language, but also terminology from other languages, mostly Latin, in which case they are referred to as *borrowings*. Thus, in legal documents some words of the general language become terms with further semantic and legal characteristics, as in the case of *child*, which in ordinary language means "a young person especially between infancy and puberty" (Merriam-Webster Dictionary, entry #1a[38]), but in legal contexts it refers to "a person not yet of the age of majority" (Merriam-Webster Dictionary, entry #1b).

As we did above with medical terminology, what the reader shall find in the following subsections are different criteria that characterize legal terminology, thereby allowing us to detect it in our analysis more accurately. Thus, based on the classification offered by Vázquez y del Árbol (2020: 3), we will present here some of the most frequent aspects usually found in legal texts, including the

[38] Merriam-Webster. (n.d.). *child*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3r79nRX

presence of Latinisms (e.g. *affidavit*), archaisms and euphemisms (e.g. *notwithstanding*), pronominal adverbs (e.g. *hereby*) and performative verbs (e.g. *agree, admit*).

2. 7. 2. 1. Technical vocabulary

As explained above for the case of medical terminology (see Section 2.7.1.1), one of the best methods for deciding whether a term is legal or not is to use a specialized dictionary or glossary (Mihwa Chung & Nation, 2003: 253). For the needs of the present Master's dissertation, we opted for the following resources:

1) *Glossary of Legal Terms* of the United States Courts[39];
2) *Black's Law Dictionary, 4th Edition*, which contains definitions of the terms and phrases of American and English jurisprudence, ancient and modern;
3) *Handbook of Legal Terminology*[40] of the Mississippi Judicial College;
4) *Glossary of Legal Terminology - English to Spanish*[41] created by John Lombardi for the State of Connecticut Judicial Branch (Superior Court Operations Division).

In the case of the fourth resource, it should be noted that we will be using it by way of guidance only. One should not forget that we are dealing with two different legal systems, the Spanish and the American system, and therefore we cannot expect total equivalence between the terms provided in the selected glossary. As Sandrini (1999: 102-103) states, "legal dictionaries have to be regarded as a tool supporting the intellectual decision-making process of the translator".

Alcaraz Varó & Hughes (2014: 16-18) have made a classification of legal vocabulary based on three levels or strata: 1) purely technical terms, 2) semi-technical or mixed terms and 3) everyday vocabulary frequently found in legal texts. The table below is a summary of this classification:

[39] Available from: https://bit.ly/3JaEp1q (Accessed on 10 May 2022)
[40] Available from: https://bit.ly/3juBVkh (Accessed on 10 May 2022)
[41] Available from: https://bit.ly/3uhXPxj (Accessed on 10 May 2022)

TYPOLOGY	DEFINITION	EXAMPLE(S)
PURELY TECHNICAL TERMS/PHRASES	They are found exclusively in the legal field and have no utility outside it. They are distinguished from the others because they are monosemic (i.e. they have a single meaning) and are semantically stable in the sense that their legal function is clear.	*counsel, estoppel, mortgage, breach of official duty, bring an action, usufruct, defendant, co-defendant, respondent, plaintiff, applicant, pursuer*
SEMI-TECHNICAL OR MIXED TERMS/PHRASES	They are words and phrases from the general language that have acquired additional meanings in the legal context. Unlike purely technical terms, they are polysemic (i.e. they have multiple meanings). They are much more numerous than those in the first group.	Examples of polysemy with the term *issue*: a) *The parties could not agree on the issue*, i.e. 'disputed point' b) *Parties must wait for process to issue from the court*, i.e. 'be served'
EVERYDAY VOCABULARY	They are words of general use that are often found in legal texts but, unlike semi-technical terms, they have neither lost their general meaning nor acquired a new meaning by contact with legal language.	*subject-matter, paragraph, section, subsection, act, summarize, system*

Table 9. Types of legal terms and phrases (Source: Alcaraz Varó & Hughes, 2014: 16-18)

2. 7. 2. 2. Latinisms

The importance of Latin in the American legal language of earlier centuries is undeniable. However, what is interesting in the 21st century is that Latin continues to exist in legal discourse (Macleod, 1998: 235). In fact, it is so frequent in legal language that *Black's Law Dictionary* has an introductory section devoted to providing the reader with some guidelines on Latin pronunciation (Campbell Black, 1968: 7-12).

As Mattila (2006: 136; cited in Drăcşineanu, 2020: 1) points out, the terminology that comes from legal Latin is largely kept in its original form (i.e. *foreignism*) in both Roman languages and in English. Nonetheless, some words of Latin origin have also been adapted and transformed into loanwords in modern English, as in the following examples: *legislator*[42], *constitution*[43], *clause*[44],

[42] From Latin *legis lator* (Online Etymology Dictionary. (n.d.). *legislator*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/37o3gll)

[43] From Latin *constitutionem* (Online Etymology Dictionary. (n.d.). *constitution*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/3JhBwM8)

cession[45], *regime*[46], *act*[47]... When kept in its original form, Latin is mainly used with an aesthetic function in order to either get the readers' attention or to show the high status of the legal class (Vydysheva, 2020; cited in Drăcşineanu, 2020: 1).

The following table shows a classification of the different types of Latin expressions that we may encounter in legal language (adapted from Scotto di Carlo, 2015: 13-14):

TYPOLOGY	EXAMPLE(S)
LATIN ONE-WORD EXPRESSIONS	*ante* → before *anterior* → earlier *intra* → inside *per* → through, by means of *prior* → before *quasi* → as if it were; almost *sic* → so, thus *verbatim* → word for word, literally
MISCELLANEOUS LATIN LEGAL TERMS	*arbitrator, delinquent, homicide, injunction, mandamus, plenipotentiary, regicide, subpoena*
TWO-WORD LATIN PHRASES	*a fortiori* → with even stronger reason *ab inito* → from the beginning *ad acta* → to the archives (denoting the irrelevance of a thing) *ad hoc* → literally 'for this' (created or done for a particular purpose as necessary) *ad idem* → in agreement; at a meeting of the minds

Table 10. Latin expressions in legal discourse (Source: Scotto di Carlo, 2015: 13-14)

2. 7. 2. 3. Archaisms and euphemisms

In connection to the use of archaisms, in general they are used to add formality to the document. For example, as Drăcşineanu notes (2020: 3), many contemporary authors still prefer to use old forms like *forthwith* instead of *right away*, *to inquire* instead of *to ask* or the *-eth* ending for the third person singular in the present simple rather than the modern ending *-es* (e.g. *witnesseth* for *witnesses*). In the words of Drăcşineanu (2020: 3):

[44] From Medieval Latin *clausa* (Online Etymology Dictionary. (n.d.). *clause*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/3uqMFq9)

[45] From Latin *cessionem* (Online Etymology Dictionary. (n.d.). *cession*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/3r7agty)

[46] From Latin *regimen* (Online Etymology Dictionary. (n.d.). *regime*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/3jw9sdT)

[47] From Latin *actus* (Online Etymology Dictionary. (n.d.). *act*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/3ugcKb4)

With repeated use, some of these terms have acquired in time an authoritative interpretation and therefore altering them may come with a risk.

Further examples of archaisms include the use of prepositional phrases such as *pursuant to* or *subject to* or the adverb *notwithstanding* (i.e. *however, nevertheless*), which are often used in contracts; constructions like *sounding in* (e.g. *an action sounding in damages*), and some other lexical choices that mark the desired level of formality of legalese, including *deemed*, *imbibe* (i.e. 'to drink'), *peruse* (i.e. 'read'), *impugn* (i.e. 'challenge'), *devise and bequeath, chattel* (i.e. movable goods), *said and such* (as adjectives), *oath, ordeal, prior to, brethren*[48] (i.e. male judges referring to judges of the same rank), etc. (Drăcșineanu, 2020: 3; Alcaraz Varó & Hughes, 2014: 8).

Additionally, another feature that adds formality to legal discourse is the use of euphemisms, especially in areas of law concerned with more unpleasant aspects of criminal activities (Alcaraz Varó & Hughes, 2014: 12). In documents like informed consents, it is common to find euphemisms in the form of expressions that, according to Alcaraz Varó & Hughes (2014: 13), "invoke royal or divine intervention to describe what are essentially mundane though no doubt unfortunate situations", as in the expression *act of God*, which is used to refer to a natural disaster or to a calamity attributable to the forces of nature that cannot be foreseen or is unavoidable.

2. 7. 2. 4. Pronominal adverbs

Pronominal or compound adverbs are also an example of archaic language usage in legal English (Alcaraz Varó & Hughes, 2014: 9). They are based on the simple deictic markers *here, there, where*, etc. making reference to the document where they are inserted or to another document under discussion. According to Kaplan (2011: 291), as a general rule, when they are attached to *here* they refer to the document being read, whereas they refer to another document or event when they are attached to *there*. The following table summarizes the most common pronominal adverbs found in legal language (adapted from Kaplan, 2011: 291 and Alcaraz Varó & Hughes, 2014: 9):

[48] According to the Merriam-Webster Dictionary, *brethren* is the plural of *brother*, and it is "used chiefly in formal or solemn address or in referring to the members of a profession, society, or religious denomination". (Merriam-Webster. (n.d.). *brethren*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3xf3qGm)

PRONOMINAL ADVERB	MEANING
hereafter / thereafter	in the future, at a subsequent time
hereby / thereby	resulting from the document
herein / therein	appearing in the document
hereinafter / thereinafter	referred to later in the document
hereof / thereof	relating to the document or part of it
hereto / thereto	usually refers to an attachment to the document
heretofore / theretofore	previous to the production of the document
hereunder / thereunder	mentioned in the document
herewith / therewith	accompanying the document
hereunto / thereunto	in the document or place referred to
whereby	because of which

Table 11. Pronominal adverbs (Sources: Kaplan, 2011: 291; Alcaraz Varó & Hughes, 2014: 9)

2. 7. 2. 5. Performative verbs

According to Austin (1962: 133; cited in Alcaraz Varó & Hughes, 2014: 10), in Speech Act Theory[49] performative utterances are those speech acts in which the person uttering is performing some kind of action at the moment of uttering. In order to perform an act, certain conditions must occur: some words must be uttered, the circumstances must be adequate, and the speaker or some other person(s) must perform an additional action along with the utterance of the specific words leading to the performance of the speech act (Austin, 1962; cited in Alcaraz Varó & Hughes, 2014: 10). For example, when dealing with a contract, an uttered decision comes into effect through the very act of signing the document.

Performative verbs have a binding nature of legal relationships and judicial decisions, and for this reason they are used very frequently in legal texts (Alcaraz Varó & Hughes, 2014: 11). Some examples of this kind of verbs include *agree, admit* (i.e. 'recognize', 'allow'), *pronounce* (i.e. 'declare'), *uphold* (i.e. 'maintain', 'affirm'), *promise, undertake* (i.e. 'contract' or 'commit oneself'), *swear* (i.e. 'promise'), *affirm, certify, overrule* (i.e. 'disallow'), *confer, amend, enact* and so on.

[49] According to Austin's Speech Act Theory, utterances are actions that have effects on the outside world and are used in order for the speaker to achieve certain goals (Austin, 1962).

3. Theoretical framework

3. 1. Cabré's Communicative Theory of Terminology (CTT)

The field of terminology was born in Vienna with Eugene Wüster, who developed the General Theory of Terminology (GTT). According to this theory, terminology is a work tool used for disambiguating scientific and technical communication, thereby removing aspects such as variation and diversity (Cabré, 1999). The reductionist and idealist nature of this theory led María Teresa Cabré to analyze it with the goal of finding a solution towards a renewed multidimensional and variationist theory of terminology. Her goal was to develop a new linguistic theory, demonstrating that, contrary to Wüster's theory, terminology has a complex communicative nature in specialized discourse. This is how the Communicative Theory of Terminology (CTT) was born (Cabré, 1999).

Thus, our approach to terminology in the analysis that we are carrying out in this Master's dissertation is based on Cabré's CTT, which is summarized in the following points (adapted from Montero Martínez, 2003: sec. 1.3.2.2.1):

a) Terminology is an interdisciplinary subject that integrates part of:
    i. The theory of knowledge: it relates to the ways in which reality is conceptualized and the relationships between the concepts;
    ii. The theory of communication: it relates to how the characteristics, possibilities and limits of the different expression systems of a concept and its units are explained;
    iii. The theory of language: it gives account of the position of terminological units (TUs) in natural language whilst denoting their terminological nature.
b) The focus is on the TUs *per se*, which are considered part of natural language. In other words, terms are not independent units that form different specialized lexical units (LUs), but special modules with particular features associated to the LUs. LUs are described as groups of denominative-conceptual units that can have different roles when integrated in discourse. These units can belong to different fields and they become terms when inserted in a particular context;
c) Terms are units of form and content, where the latter occurs simultaneously with the former. Content may be expressed more or less rigorously using more than a single denomination, thereby creating new linguistic units of specialized content. It may also be expressed through other symbolic systems, thereby creating non-linguistic units of specialized content;

d) Concepts belonging to the same specialized field have different relationships between each other. This set of conceptual relationships constitutes the conceptual structure of the subject. Thus, the value of a particular term is established based on its location within this conceptual structure;
e) The theory of terminology aims to describe the units that are potential terms from a formal, semantic and functional perspective, explaining how this phenomenon may occur and how they interrelate with other types of signs from the same and/or different system. Considering that TUs are the privileged form of representing specialized knowledge, each TU corresponds to a cognitive node from a specialized domain. TUs not only represent a specialized reality, but they also help in the transmission of such knowledge. Thus, TUs have three dimensions: cognitive, social and communicative/linguistic. Within this three-dimensional reality, each TU must be seen as a linguistic sign that varies depending on its particular context and has its own cultural connotations.

In summary, according to the postulates of Cabré's CTT (1999), reality can be conceptualized in two ways: diffusely (through general knowledge) or accurately (through specialized knowledge). Such conceptualization will result in knowledge domains that are neither uniform nor static; they vary based on the context where they are used. Moreover, they will be reconceptualized as research in the field evolves, thereby creating new cognitive associations (Cabré, 1998: 180; cited in Montero Martínez, 2003: sec. 1.3.2.2.1).

3. 2. Nuopponen's terminology work framework

Nuopponen's (2018) framework for analyzing terminology management is divided into five factors that, according to her, shape the process and answer to the questions listed below:

1. Target group → To whom?
2. Purpose → Why?
3. Compiler → By whom?
4. Product → Which product?
5. Method → How?

Starting with the target group, she notes that terminology work has various target groups with different needs. One group is composed of domain experts who conduct normative terminology and terminological standardization work in order to meet their terminology needs. Another group is formed by translators, whose needs differ from those of domain experts, for they conduct

translation-oriented terminology work. A third group are users in organizations or companies. Finally, a fourth group is composed of machine translation tools (Nuopponen, 2018: 10). In the case of this Master's dissertation, the target group is the second one mentioned by Nuopponen: translators. Making the translation process through our translation-oriented terminological analysis is precisely one of the main objectives of our project.

Secondly, as to why conduct terminology work, she mentions two basic motives: immediacy and the purpose of the work. As regards the first motive, immediacy, "it can be either proactive or just-in-time terminology work, or something in between" (Nuopponen, 2018: 10). Proactive terminology management involves those activities required by terminology planning (e.g. anticipating future needs ahead). *Ad-hoc* or just-in-time terminology work is done at the moment of the need, i.e. when terminological needs must be solved shortly. In connection to the second motive, the purpose of the work, it can be descriptive or normative/prescriptive (Nuopponen, 2018: 12):

- **Descriptive**. It results in terminological products such as vocabularies, glossaries or term bases that include all terminological and conceptual variations available of a single term, leaving the final choice of the most suitable term to the user. This is the kind of work that we are doing in this project, since we are going to create a glossary of terminological and phraseological units that is available for those translators who need it in the future. Our work is, then, a descriptive one. Moreover, following Cabré's CTT approach, we are including all variations available of a single term so the final translator(s) select the most suitable based on context;
- **Normative/prescriptive**. It selects one preferred term and avoids the remaining ones. It is usually the purpose of terminology work for a product or service of a company, legal system, etc.

Thirdly, Nuopponen (2018: 12-14) establishes three compiler profiles: 1) creators, 2) compilers and mediators, and 3) users. In the first group we find domain experts who use the field's terminology for publication in handbooks, articles, textbooks... In the second group, Nuopponen (2018: 13) includes terminologists and others involved in collecting and analyzing terminology. In the third group, she includes those who need to consult terminology databases for work purposes, such as translators, teachers, students and so on. For the purposes of this Master's dissertation, we can say that we belong in the second compiler profile group.

Fourthly, the product can consist in extracting a single term in the context of processing, for example, terminology queries or adding entries to a term bank, or in creating an extensive terminological database in the form of a term bank. Moreover, the product can be mono-, bi- or multilingual depending on the language(s) of work Nuopponen (2018: 15). In our case, we are building a comparable bilingual corpus, for the languages selected are English and Spanish.

Finally, the representative materials of a terminology project should contain original sources of the field under research, which will make up a corpus in order for it to be used to extract terminological data. There are various types of electronic resources available nowadays to extract equivalent candidates in two or more languages, especially on the internet, including aligned or comparable corpora, parallel corpora, bi-texts and translation memories (Nuopponen, 2018: 15). In this project, as noted earlier, we are building a comparable corpus. The approach that we will follow for extracting terminological data is based on the TTC project, which is explained in the following section.

3. 3. The TTC terminology extraction approach

The TTC (Terminology Extraction, Translation Tools and Comparable Corpora) project was developed by the Institute for Natural Language Processing of the University of Stuttgart and its starting ideas are, on the one hand, that parallel corpora are a scarce resource and, on the other hand, that comparable corpora are useful in the terminology extraction task (Gornostay *et al.*, 2013: 1). The main objectives of this approach are as follows:

- To compile and use comparable corpora composed of texts found on the web;
- To define and combine several strategies for monolingual term alignment;
- To show the operational benefits of terminology extraction from comparable corpora, especially on computer assisted translation (CAT) tools and machine translation (MT systems).

In short, the TTC project "researches the way in which comparable corpora can be exploited in the terminology extraction task" (Gornostay *et al.*, 2013: 2).

Firstly, once the set of documents that will be used for building our corpora is gathered, the texts and the selected single-word (i.e. terminology) and multi-word terms (i.e. phraseology) go through three main pre-processing steps, which are summarized in the following table (adapted from Gornostay *et al.*, 2013: 3 and Michelbacher, 2013):

PRE-PROCESSING STEPS IN THE TTC TERMINOLOGY EXTRACTION WORKFLOW		
1) TOKENIZATION	**2) TAGGING**	**3) LEMMATIZATION**
It is the process of separating a text into smaller units called *tokens*, which can be words, characters or subwords[50]. This is a key step in natural language processing (NLP). The most common is to tokenize the text into single words (i.e. the text is split into words using space characters as word boundaries).	It is the process of annotating the part of speech (PoS) tags or labels of words. In case of ambiguity, context usually solves the problem. In many cases, the label for the current word is disambiguated if we look into the previous word (e.g. *bank* is a noun in *the bank* and a verb in *to bank*).	It is the process whereby each word is annotated with its lemma or canonical form, which represents all derivatives of the same lexeme (e.g. *does*, *did* and *done* are lemmatized *to do*).

Table 12. Pre-processing tasks (Sources: Gornostay *et al*., 2013: 3; Michelbacher, 2013)

Secondly, once these three pre-processing tasks have been finished, the terminology extraction process following the TTC approach continues with the following steps:

1. Extraction of single-word terms (SWT) and multi-word terms (MWT) from the domain-specific corpora;
2. Selection of domain-relevant term candidates;
3. Identification of term variants that may be synonyms or related words.

These processing steps are illustrated in the following figure (retrieved from Gornostay *et al.*, 2013: 2):

[50] The smallest grammatical subword is called *morpheme*, which can be free or bound. Free morphemes stand by themselves as words (i.e. they are root words), while bound morphemes need to adhere to a root in order to be functional (e.g. the prefix *anti*-) (Katamba, 2015).

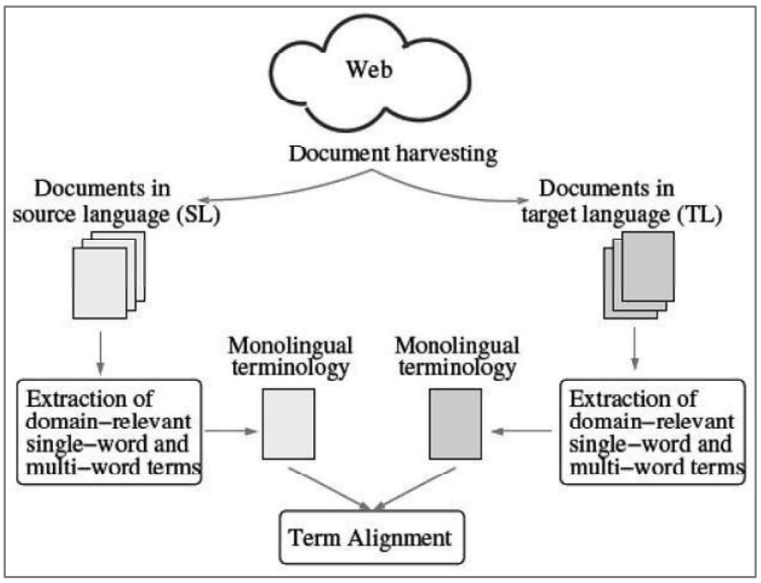

Figure 4. Monolingual terminology extraction process (Source: Gornostay *et al*., 2013: 2)

Thirdly, the final processing step is to align the SL and the TL monolingual terminologies extracted from the comparable corpora to each other, which results in bilingual domain-specific terminology. This process is summarized in the following figure:

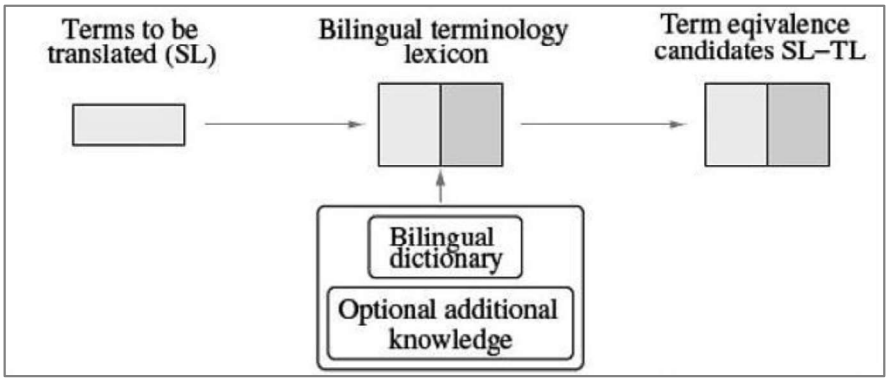

Figure 5. Bilingual terminology alignment process (Source: Gornostay *et al*., 2013: 2)

4. Methodology

4. 1. Research method

In order to analyze our comparable corpus, the data collection methodology that we used is mixed methods research, that is, a combination of quantitative and qualitative research. For our research purposes, this was the most adequate methodology because we wanted, on the one hand, to analyze words qualitatively in order to define different categories (medical or legal typology, and parts of speech), obtaining a bilingual glossary of terminology and phraseology as a result. The goal of our qualitative sampling process was to provide rich and varied insight into the phenomenon under

research with the purpose of maximizing the knowledge in this specific area. On the other hand, certain aspects of the data gathered qualitatively were quantified, such as the percentage of medical versus legal terminology, the quantity of instances that share the same part of speech and their frequency of occurrence, and the percentage of terminology compared to the amount of phraseology found.

Moreover, our analysis and conclusions were based on inductive reasoning, which resulted in a more contextualized understanding of the treatment of the terminology and phraseology of medico-legal documents, namely in the field of Assisted Reproductive Technology. Following Dörnyei's explanation (2007: 245), the qualitative categories (i.e. parts of speech and typology) assigned to the different terminological and phraseological units found in our corpus are derived inductively from the data analyzed. Simply put, the nature of our data analysis is largely iterative and inductive. According to Dörnyei (2007: 269), "qualitative analysis draws heavily on the theoretical and contextual knowledge and interpretive ability of the researcher". We believe that this is the best definition of the work we did in this project.

4. 2. Sampling procedure

This project began with the process of collecting samples of informed consents from US clinics. The criterion followed was that they were members of the American Society for Assisted Reproductive Technology (SART) as it is the primary organism dedicated to the practice of ART in the United States, setting the guidelines for the best practices in the field of ART (see Section 1.1.1). In total, we selected five informed consents with similar characteristics, such as being divided in two parts–the Information for Patients Sheet and the Consent Form–and having different sections. The fertility treatment of choice was IVF, which in most cases comes hand in hand with ICSI[51] as well as other treatments, as the reader shall see through our analysis (see Section 5.1.1). All the informed consents that we gathered in both English and Spanish have been included in the Annex sections that can be found at the end of this project. The following table shows the title of each consent form along with the source and its corresponding Annex section:

[51] ICSI is used in cases of male factor infertility or previous failure with IVF. (ASRM & SART, 2020: 1).

TITLE	SOURCE	ANNEX SECTION
Consent Form For In Vitro Fertilization	Boston IVF	11.1
In Vitro Fertilization/PGT[52]	Columbia University Fertility Center	11.2
In Vitro Fertilization: Process, Risk, and Consent	MGH Fertility Center	11.3
Informed Consent for Assisted Reproduction: In Vitro Fertilization, Intracytoplasmic Sperm Injection, Assisted Hatching[53]*, Embryo Freezing*[54]	Overlake Reproductive Health	11.4
In Vitro Fertilization Consent Booklet	Stanford Reproductive Medicine	11.5

Table 13. US informed consents gathered

Afterwards, we started the process of compiling samples in Spanish. In Spain, contrary to the USA, fertility clinics use the template designed by the SEF (Spanish Fertility Society) as the basis to design the informed consent that they give to their patients. For this reason, we based our corpus on SEF's model as well as on documents retrieved from public institutions that we will mention in the table below:

TITLE	SOURCE	ANNEX SECTION
Fecundación in Vitro o Microinyección Espermática (FIV/ICSI) con transferencia embrionaria y congelación de embriones	Centro Extremeño de Reproducción Humana Asistida (CERHA)	12.1
Itinerarios y condiciones asociadas con el uso de técnicas de Reproducción asistida en nuestro centro	Hospital Clínico Universitario de Valencia - Unidad de Reproducción Humana Asistida (GVA)	12.2
Fecundación in Vitro o Microinyección Espermática (FIV/ICSI) con transferencia embrionaria y congelación de embriones	Hospital Universitario Central de Asturias (HUCA)	12.3
Formulario de información y consentimiento informado escrito. Documento de información para Fecundación in Vitro-transferencia embrionaria (FIV-TE)	Consejería de Salud de la Junta de Andalucía	12.4

[52] The abbreviation *PGT* stands for *Preimplantation Genetic Testing*, which is sometimes integrated in the IVF process (see Section 5.1.1).

[53] According to the ASRM (2014: 1), "Assisted hatching (AH) involves the artificial thinning or breaching of the ZP [Zona Pellucida] and has been proposed as one technique to improve implantation and pregnancy rates following in vitro fertilization (IVF)".

[54] According to Bankowski *et al.* (2005: 1), "cryostorage and subsequent use of human embryos has become standard practice in assisted reproductive technology (ART) and is now involved in a significant proportion of all infertility treatments".

Fecundación in Vitro o Microinyección Espermática (FIV/ICSI) con transferencia embrionaria y congelación de embriones	Sociedad Española de Fertilidad (SEF)	12.5

Table 14. Spanish informed consents gathered

4. 3. Identifying the terminological and phraseological units

For the data management in our qualitative analysis, we did a highly labor-intensive manual task that consisted in reading each one of the English informed consents firstly, and then the Spanish ones. Following the TTC approach, we highlighted the different words that fitted into the criteria established in Section 2.7 for both medical and legal terminology and phraseology according to the literature review included therein. Then, we tagged all the words selected in different parts of speech, differentiating between noun and noun phrases, verbs and verbal phrases, etc. so that the difference between what is a terminological unit and what is a phraseological unit is clear. Once we had selected the terminology and phraseology of the English corpus, we started the same process with the Spanish corpus. Analyzing the terminology and phraseology was highly useful as proof that, as the authors reviewed in Sections 2.5 and 2.6 asserted, informed consents are indeed hybrid texts where terms from both areas of knowledge are combined.

The next step was to make a comparison between both corpora. For this to be achieved, we followed the TTC terminology extraction approach that can be seen in Figure 4 above. This process was, firstly, done manually and then we converted all the informed consents into plain text format (.txt) so that they could be compiled by AntConc, which is "a freeware corpus analysis toolkit for concordancing and text analysis[55]". This highly useful tool helped us find not only the different equivalences between each corpus but also the contexts where they were used, thus allowing us to see whether the meaning conveyed is, indeed, the same in both languages. Following Cabré's Communicative Terminology Theory (CTT), we included in our final bilingual glossary all the different synonyms found for one single terminological or phraseological unit in the alignment process. The detailed process that we followed with AntConc is explained in the following section.

4. 4. Contrastive analysis with AntConc

As mentioned earlier, once we gathered all the source documents and then the comparable texts, we conducted a comparative analysis of them using the AntConc toolkit. Once we had selected

[55] Laurence Anthony's Website (n.d.). *AntConc*. Available from: https://bit.ly/38yYe60 (Accessed on 10 May 2022)

manually in the English texts the different units that qualified for our qualitative analysis, we entered them into AntConc's Keyword-in-Context (KWIC) or Concordance tool to find all the instances where they appear. In order to locate a potential equivalent in Spanish, we relied quite often on:

1. The resources mentioned in Section 2.7.1.1 for medical terminology and phraseology, such as the ICMART and the WHO's revised glossary of ART terminology (2009) or the ICMART's International Glossary on Infertility and Fertility Care (2017);
2. The resources listed in Section 2.7.2.1 for legal terminology and phraseology, such as the Glossary of Legal Terms of the US Courts, the Black's Law Dictionary, the Handbook of Legal Terminology of the Mississippi Judicial College and the Glossary of Legal Terminology - English to Spanish;
3. Different dictionaries such as the Merriam-Webster Dictionary, WordReference, Collins English Dictionary, Cambridge Dictionary and Oxford Learner's Dictionary;
4. The root of many words in the English texts in order to find an equivalent in Spanish that contained the same Greek and/or Latin root, which is usually the same (see Section 2.7.1.3);
5. Our knowledge of the English language and the context where each terminological or phraseological unit appeared.

Once we had a potential equivalent located in the alignment process, we used AntConc's KWIC tool to conduct our qualitative analysis more accurately. Out of the different tools that AntConc puts at the user's disposal, KWIC was the most useful for the purposes of this project, for it allowed us to observe how words and phrases are most frequently used in the corpus introduced.

4. 5. Results analysis

During the analysis of our comparable corpus, we turned frequently to monolingual dictionaries of English and Spanish in order to grasp the exact meaning of the different potential equivalents before selecting them as the definitive equivalents. When the final selections were made from our comparable corpus, the result was a bilingual terminological and phraseological glossary that is presented in the form of a table ordered alphabetically. As we shall see, the part of speech and the typology (medical or legal) of each unit are duly indicated. The first column shows us the terminological or phraseological unit (T/P unit) in English, aligned with the equivalent or equivalents that we found in Spanish. Note that the parts of speech do not always coincide in both languages.

Our qualitative analysis and its resulting glossary allowed us to quantify the data obtained statistically. Firstly, we compared the total amount of tokens found in English versus the total amount of tokens in Spanish, and we presented them in the form of bar graphs that allow us to visualize the differences between both corpora. Secondly, we quantified the most frequent terminological and phraseological units in each language and presented them in the form of a table with the top twenty-five most frequent terms and phrases in both corpora. Thirdly, we compared the number of instances included in each part of speech for each group of informed consents. Fourthly, we built two pie charts, one for English and the other for Spanish, with the percentages of medical and legal T/P units found in each corpus.

5. Qualitative analysis of the comparable corpus and results

5. 1. Medical terminology and phraseology

This section is divided into four major subsections based on the results obtained after aligning the English texts with the Spanish ones:

5. 1. 1. Technical vocabulary;
5. 1. 2. Instances of the doublet phenomenon[56] (i.e. presence of an erudite term with its popular equivalent);
5. 1. 3. Terms with a Greco-Latin base;
5. 1. 4. Hyphenated phrases.

As the reader shall see below, the first group is the largest one, for the highest percentage of medical terminology and phraseology is composed of technical vocabulary from the field of medicine in general as well as ART in particular. Thus, in order to present our analysis of the different technical terminological and phraseological units found, we will go through the vocabulary associated with the different phases of the IVF procedure in chronological order:

1. Assisted Reproductive Technologies (ARTs) available: IVF (and its derivatives), ICSI, PGD/PGS, assisted hatching and so on;
2. Infertility and the adjective *infertile;*
3. Terminological and phraseological units from the areas of human reproduction and the human reproductive system (e.g. *embryo, pregnancy, ovary, sperm*);

[56] Term coined by Montalt, Zethsen & Karwacka (2018: 29-30) and mentioned by Van Hoof (1999: 147).

4. Phraseological units derived from embryo (e.g. *embryo transfer, embryo attachment, best-developed embryos*);
5. References to the recipient of the treatment (i.e. the woman) and the tests and treatments that she has to undergo (e.g. ovulation induction, follicular aspiration, oocyte retrieval);
6. Expected outcomes of the mentioned tests and treatments (e.g. ovarian response, egg maturation);
7. Potential side effects and adverse outcomes of IVF (e.g. Ovarian Hyperstimulation Syndrome, multiple pregnancy, ectopic pregnancy, ovarian torsion);
8. Measurement of the treatment outcomes in terms of success rates and/or pregnancy rates;
9. Disposition of the potential unused embryos after IVF (e.g. cryopreservation, embryo donation).

The original terminological or phraseological unit in English and its alignment (abbreviated below as *T/P Unit*) with the Spanish equivalent found are presented in the form of a table along with the corresponding part of speech (PoS). The following is the key to each one of the abbreviations used to indicate the PoS of each instance:

POS		MEANING		DEFINITION
adj	→	adjective	→	Modifier that denotes a quality of the noun.
n	→	noun	→	Word used to refer to a person or thing.
n ph	→	noun phrase	→	Group of words that is headed by a noun and includes modifiers. It functions like a noun.
n (pl)	→	noun (frequently used in plural)	→	Word that is often used in plural to refer to a person or thing.
n ph (pl)		noun phrase (frequently used in plural)	→	Group of words that are often used in plural to refer to a person or thing.
v	→	verb	→	Word used to say what someone or something does.

Table 15. Key of PoS abbreviations in medical T/P units

5. 1. 1. Technical vocabulary

Firstly, in connection to the different ARTs available, we started our analysis with the comparison of the phrase *In Vitro Fertilization*, which is the treatment on which our informed consents are based. In Spanish, the equivalent term is *Fecundación in Vitro*. However, it should be noted that, in some cases, Spanish texts add the adjective *convencional* (in English, literally *conventional* or *standard*) afterwards in order to distinguish it from *Intracytoplasmic Sperm Injection (ICSI)*, a

technique that will be discussed further on. Thus, the following is the equivalence that we encountered when analyzing this unit:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
1	In Vitro Fertilization (IVF)	n ph	Fecundación in Vitro (FIV) convencional	n ph

Several phraseological units are created using the abbreviation *IVF* plus a noun such as *process, cycle* or *treatment*, which results in phrasemes such as *IVF process, IVF cycle* and *IVF treatment* used interchangeably. This is possible thanks to the versatility of the English language to create compound words. In this particular case, the resulting phraseological units are compound adjectives created by means of noun adjectivization (see Section 2.7.1.5), where *IVF* has acquired the function of adjective in all these cases. In the Spanish text, we found that the most frequently used equivalent is *ciclo de FIV*, as the following snapshot from AntConc's Concordance Tool shows:

	File	Left Context	Hit	Righ
1	Centro Extremeño de Reproducción Asistida - Hoja informativa y de ...	sobrantes de un	ciclo	de Fecundación in Vitro
2	Hospital Universitario Central de Asturias - Hoja informativa y ...	sobrantes de un	ciclo	de Fecundación in Vitro
3	SEF - Hoja informativa y consentimiento FIV o ICSI con transferencia ...	sobrantes de un	ciclo	de Fecundación in Vitro
4	Centro Extremeño de Reproducción Asistida - Hoja informativa y de ...	sobrantes de un	ciclo	de fecundación in Vitro
5	Hospital Universitario Central de Asturias - Hoja informativa y ...	sobrantes de un	ciclo	de fecundación in Vitro
6	SEF - Hoja informativa y consentimiento FIV o ICSI con transferencia ...	sobrantes de un	ciclo	de fecundación in Vitro
7	GVA (Hospital Clínico Valencia) - Hoja informativa y consentimiento FIV-...	múltiple. En un	ciclo	de FIV lo que buscamos
8	GVA (Hospital Clínico Valencia) - Hoja informativa y consentimiento FIV-...	va a realizar un	ciclo	de FIV, la lista de espera

Figure 6. Concordances with *ciclo* (Source: AntConc).

We also found the equivalent *tratamiento de fecundación in vitro* or *tratamiento de FIV*, although it is not as frequent as *ciclo de fecundación in vitro*. As the following analysis with AntConc shows, *tratamiento* is used to refer to assisted reproduction treatments in general:

File	Left Context	Hit	Right Context
Centro Extremeño de Reproducción Asistida - Hoja informativa y de ...	decuado un	tratamiento	de reproducción asistida a tra
GVA (Hospital Clínico Valencia) - Hoja informativa y consentimiento FIV-...	ormativo de	tratamiento	de reproducción asistida dura
SEF - Hoja informativa y consentimiento FIV o ICSI con transferencia ...	decuado un	tratamiento	de reproducción asistida a tra
GVA (Hospital Clínico Valencia) - Hoja informativa y consentimiento FIV-...	lidad de los	tratamiento	de reproducción asistida (inse
Hospital Universitario Central de Asturias - Hoja informativa y ...	decuado un	tratamiento	de reproducción asistida, a tra
Centro Extremeño de Reproducción Asistida - Hoja informativa y de ...	revención y	tratamiento	de enfermedades de origen g
Hospital Universitario Central de Asturias - Hoja informativa y ...	revención y	tratamiento	de enfermedades de origen g
SEF - Hoja informativa y consentimiento FIV o ICSI con transferencia ...	revención y	tratamiento	de enfermedades de origen g
Hospital Universitario Central de Asturias - Hoja informativa y ...	arios para el	tratamiento	de Fecundación in Vitro (FIV)/
SEF - Hoja informativa y consentimiento FIV o ICSI con transferencia ...	arios para el	tratamiento	de Fecundación in Vitro (FIV) ,
Centro Extremeño de Reproducción Asistida - Hoja informativa y de ...	arios para el	tratamiento	de FIV/ICSI, transferencia de p

Figure 7. Concordances with *tratamiento* (Source: AntConc)

Therefore, our proposals for the translation of these English compounds are two:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
2	IVF cycle	n ph	ciclo de fecundación in vitro, ciclo de FIV	n ph
3	IVF process			
4	IVF treatment			

The informed consents of our corpora mention other ART procedures that may be performed prior or in addition to in vitro fertilization, including Preimplantation Genetic Screening (PGS)/Preimplantation Genetic Diagnosis (PGD), assisted hatching, and Intracytoplasmic Sperm Injection (ICSI). Special attention should be paid to the case of PGS, PGD and PGT (T/P units #7-9), as they are both part of a group of treatments called *Preimplantation Genetic Testing*. We had a look at the WHO's glossary (Zegers-Hochschild *et al.*, 2009a: 1523) and found the following distinction between both phrases:

> *Preimplantation genetic diagnosis (PGD): analysis of polar bodies, blastomeres, or trophectoderm from oocytes, zygotes, or embryos for the detection of* ***specific genetic, structural, and/or chromosomal alterations****.*
>
> *Preimplantation genetic screening (PGS): analysis of polar bodies, blastomeres, or trophectoderm from oocytes, zygotes, or embryos for the detection of* ***aneuploidy, mutation, and/or DNA rearrangement****.*

As we can see, the definition of both phraseological units is the same except for the parts that we have marked in bold, which refer to the kind of anomalies that each technique is able to detect.

After having checked the English version of the WHO's glossary, we turned to the corresponding version in Spanish. There, we encountered only one equivalent (Zegers-Hochschild *et al.*, 2009b: 5) as shown below:

> *Diagnóstico genético preimplantacional (DGP): análisis de cuerpos polares, blastómeras o trofoectodermo de ovocitos, zigotos o embriones para la* ***detección de alteraciones específicas, genéticas, estructurales, y/o cromosómicas***[57]*.*

Moreover, we checked the website of the Spanish Society of Gynecology and Obstetrics (SEGO, for its name in Spanish) to further investigate on the definition of *DGP*, and we found the following result[58]:

> *El Diagnóstico Genético Preimplantacional (DGP) es el estudio de alteraciones cromosómicas y genéticas en el embrión antes de su transferencia a la madre. El DGP permite conocer aquellos embriones libres de anomalías cromosómicas (PGS) y mutaciones genéticas (DGP de enfermedades monogénicas).*
>
> *Preimplantation Genetic Diagnosis (PGD) is the study of chromosomal and genetic abnormalities in the embryo before being transferred to the mother. PGD allows us to detect which embryos are free from chromosomal anomalies (PGS) and genetic mutations (PGD for monogenic diseases).* [OWN TRANSLATION]

As we can see, SEGO's definition includes the whole set of anomalies that was included in the separate definitions of PGD and PGS provided in WHO's glossary. In fact, we can see that it mentions *PGS* in parentheses when it refers to chromosomal anomalies, which suggests that PGS is part of the main treatment, i.e. Preimplantation Genetic Diagnosis. Moreover, in our Spanish corpus we found that this treatment is referred to as *Diagnóstico Genético Preimplantacional* in all cases. Thus, our conclusion is that both PGD and PGS can be translated as *DGP* in Spanish, for it incorporates the analysis that is conducted in PGS as well.

On the other hand, the case of Intracytoplasmic Sperm Injection (ICSI) (T/P unit #6) should be highlighted, too. If we take a look at the Spanish equivalent in WHO's glossary, we find that it is

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[57] *Preimplantation genetic diagnosis (PGD): analysis of polar bodies, blastomeres, or trophectoderm from oocytes, zygotes, or embryos for the detection of specific genetic, structural, and/or chromosomal alterations* (translation retrieved from Zegers-Hochschild *et al.*, 2009a: 1523).

[58] Sociedad Española de Ginecología y Obstetricia (SEGO) (n.d.). *Diagnóstico Genético Preimplantacional (DGP)*. Available from: https://bit.ly/3v2cf3v (Accessed on 10 May 2022)

translated as *inyección intracitoplasmática de espermatozoide* (Zegers-Hochschild *et al.*, 2009b: 7). However, the truth is, we did not find this term in any of the texts that make up our Spanish corpus. Instead, in all cases, the equivalent found is *microinyección espermática*, although, interesting enough, the English acronym *ICSI* is maintained, making it a case of an initialism that is identical in both languages (see Table 8, Section 2.7.1.4). This is illustrated in the following screenshot from AntConc:

GVA (Hospital Clínico Valencia) - Hoja informativa ...	‹O O	MICROINYECCIÓN ESPERMÁTICA (	FIV/ICSI) PARA LA TRAI
SEF - Hoja informativa y consentimiento FIV o ICSI ...	‹O O	MICROINYECCIÓN ESPERMÁTICA (	FIV/ICSI) CON TRANSFE
Centro Extremeño de Reproducción Asistida - Hoja...	aliza	Microinyección Espermática (	ICSI), se inyectará un es
Hospital Universitario Central de Asturias - Hoja ...	aliza	Microinyección Espermática (	ICSI), se inyectará un es
SEF - Hoja informativa y consentimiento FIV o ICSI ...	aliza	Microinyección Espermática (	ICSI), se inyectará un es
Hospital Universitario Central de Asturias - Hoja ...	FIV)/	Microinyección Espermática (	ICSI), transferencia de e
SEF - Hoja informativa y consentimiento FIV o ICSI ...	IV) /	Microinyección Espermática (	ICSI), transferencia de e
GVA (Hospital Clínico Valencia) - Hoja informativa ...	; y la	Microinyección Espermática (	ICSI), en la que la fecun

Figure 8. Concordances with *Microinyección Espermática* (Source: AntConc)

Bearing this in mind, *microinyección espermática* is the noun phrase that we decided to include in our translation proposal. As we mentioned above when we spoke about T/P unit #1, the Spanish consent forms add the adjective *convencional* after *fecundación in vitro* in order to distinguish it from ICSI because it is quite common to perform them altogether. Although both techniques look for the union of egg and sperm, the procedure is different, as described in SEF's informed consent itself:

> *Si se realiza Fecundación in Vitro (FIV), los óvulos y espermatozoides se cultivarán en el laboratorio conjuntamente en condiciones favorables para su unión espontánea (fecundación).*
>
> *Si se realiza Microinyección Espermática (ICSI), se inyectará un espermatozoide dentro de cada uno de los óvulos maduros que se hayan recuperado.*
>
> *If In Vitro Fertilization (IVF) is performed, the eggs and sperm will be cultured in the laboratory altogether under conditions that promote their spontaneous union (fertilization).*
>
> *If Intracytoplasmic Sperm Injection (ICSI) is performed, a single sperm will be injected into each one of the mature eggs that have been retrieved.* [OWN TRANSLATION]

The resulting terminological equivalents of all the complementary treatments found after aligning our corpora are the following:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
5	assisted hatching	n ph	eclosión asistida	n ph
6	Intracytoplasmic Sperm Injection (ICSI)	n ph	microinyección espermática (ICSI)	n ph
7	Preimplantation Genetic Diagnosis (PGD)	n ph	Diagnóstico Genético Preimplantacional (DGP)	n ph
8	Preimplantation Genetic Screening (PGS)			
9	Preimplantation Genetic Testing (PGT)			

Up to this point, the reader may have noticed that each technique comes with its corresponding initialism in parentheses, whether it is an acronym (e.g. *ICSI*) or an abbreviation (e.g. *IVF, PGD/PGS/PGT*). In this regard, it is worth mentioning that all the documents that form our comparable corpus, both in the case of the US and the Spanish informed consents, use the initialism corresponding to each particular technique throughout the text after having mentioned the full name the first time it appears. The following screenshots show the use of the English and Spanish initialisms *IVF* and *FIV*, respectively:

MGH Fertility Center - IVF.txt	and Consent In Vitro Fertilization (	IVF)	is a treatment that
Boston IVF - IVF.txt	s after its initiation. The success of	IVF	is dependent on the
Boston IVF - IVF.txt	ishment of a pregnancy following	IVF	is dependent on ma
Columbia University Fertility ...	rts believe having a child through	IVF	is now just as safe a
MGH Fertility Center - IVF.txt	rts believe having a child through	IVF	is now just as safe a
Overlake Reproductive Health ...	rms of infertility. The main goal of	IVF	is to allow a patien
Stanford Medicine - IVF.txt	rms of infertility. The main goal of	IVF	is to allow a patien

Figure 9. Concordances with *IVF* (Source: AntConc)

F - Hoja informativa y ...	tamiento de Fecundación in Vitro (	FIV) /	Microinyección Esper
VA (Hospital Clínico Valencia) - ...	espermatozoide en cada óvulo. La	FIV	y la ICSI comienzan c
ospital Universitario Central de ...	dimientos La Fecundación in Vitro (	FIV)	y la Microinyección E
VA (Hospital Clínico Valencia) - ...	recuperan los ovocitos en un ciclo	FIV?	Durante el proceso d
ospital Universitario Central de ...	avés de al técnica de denominada (	FIV/	ICSI) y dentro de las
VA (Hospital Clínico Valencia) - ...	ada respuesta, se pasará a realizar	FIV/	ICSI. ¿Cómo se admir
VA (Hospital Clínico Valencia) - ...	a público financia hasta 3 ciclos de	FIV/	ICSI. Estamos hablan
VA (Hospital Clínico Valencia) - ...	ansfieren los embriones en un ciclo	FIV?	Los embriones crecer

Figure 10. Concordances with *FIV* (Source: AntConc)

Turning to the particular case of the IVF treatment, it is defined in our set of informed consents as a procedure to treat many forms of *infertility* (T/P unit #11) and it is aimed at *infertile* (T/P unit #10) couples. The first option that crossed our mind when performing this analysis was to look for the noun *infertilidad* in the Spanish consents. However, we turned to the Spanish language dictionary by the Real Academia Española (RAE) (hereinafter *DRAE*) in the first place, and this is the result that we found:

> **infertilidad**[59]
> *Del lat. tardío infertilĭtas, -ātis.*
> 1. f. esterilidad.

As we can see, the dictionary defines *infertilidad* as a synonym of *esterilidad*, and this is precisely the equivalent that we encountered in our Spanish corpus. In fact, we did not find the noun *infertilidad* in any of the tokens that make up our texts. And the same occurs with the corresponding adjectives: the equivalent of *infertile* is *estéril*. Simultaneously, we also found that Spanish consent forms refer to *infertility* with the phrase *trastorno de la fertilidad* in an attempt to reduce the semantic load of the term *esterilidad*. Therefore, the following are the translations that we propose based on the results found in our comparable corpus:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
10	infertile	adj	estéril	adj
11	infertility	n	esterilidad	n
			trastorno de la fertilidad	n ph

In connection to the basic terms from the field of Assisted Reproductive Technology (ART) that we found, we can mention *embryo*, *culture, sperm, pregnancy* (and its derivative *natural pregnancy*), *ovary*, *offspring, Fallopian tubes* and *hormone*, most of them related to the areas of human reproduction and the human reproductive system. The case of *pregnancy* (T/P unit #19) should be emphasized, as we have found both the terms *gestación* and *embarazo* in Spanish, though the latter is by far the most frequent. Thus, these are the equivalences for these terms:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
12	embryo	n	embrión	n
13	culture	n	cultivo	n

[59] Real Academia Española (RAE). (n.d.). *infertilidad*. In Diccionario de la lengua española. Accessed on 10 May 2022: https://bit.ly/3v3ILm3

14	Fallopian tubes	n ph (pl)	trompas (de Falopio)	n ph (pl)
15	hormone	n	hormona	n
16	natural pregnancy	n ph	embarazo espontáneo	n ph
17	offspring	n	descendencia	n
18	ovary	n	ovario	n
19	pregnancy	n	embarazo, gestación	n
20	sperm[60]	n	espermatozoide	n
21	to have a child naturally	v ph	quedarse embarazada de forma natural, conseguir un embarazo de forma espontánea	v ph
22	uterine cavity	n	cavidad uterina	n
23	uterus	n	útero	n

Uterine cavity (T/P unit #22), which is a synonym of *uterus*, represents an example of a containment metaphor (see Section 2.7.1.6) that follows the cognitive model +BODY PARTS ARE CONTAINERS+. Indeed, we looked the definition of *cavity* up in the Merriam Webster's dictionary and obtained the following result:

> **cavity (noun)[61]**
> 1. an unfilled space within a mass

The reason why the uterus is also called *uterine cavity* can be better understood with the following illustration, where the reader can appreciate its shape and exact location within the female reproductive system in more detail:

[60] Note that *sperm* can be used in both singular and plural.

[61] Merriam-Webster. (n.d.). *cavity*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3ui8ub8

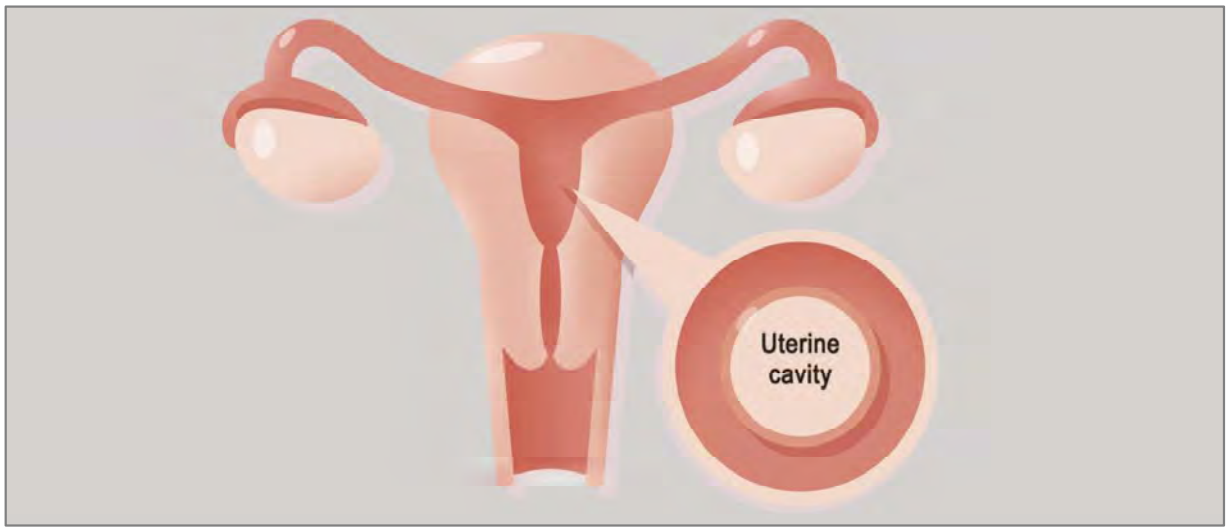


Figure 11. Location of the uterine cavity (Source: Shutterstock©)

As can be appreciated in the image above, the uterus is, indeed, a cavity, as it is an unfilled space of the body or, following the metaphor of containment, an empty container.

Furthermore, the phraseological unit *Fallopian tubes* (T/P unit #14) is an example of eponymy where the adjective *Fallopian* derives from the name of Gabriello Fallopio (1523-1562), the Italian anatomist who first described the pair of tubes that carry the oocyte from the ovary to the uterine cavity. As we can see, the equivalent that we found in our corpus is just *trompas* (in English, literally *tubes*). However, the full name, *trompas de Falopio*, is also an eponym, as can be seen when consulting the DRAE:

> **Falopio**[62]
> De *G. Falloppio*, 1523?-1562, célebre cirujano italiano[63].
> *trompa de Falopio*

This is the reason why, even though our Spanish corpora only mention *trompas*, we decided to include *de Falopio* in parentheses in our final glossary, so that it is the prospective translator who decides which will be the final option based on the context where this unit is inserted.

By the same token, the case of the term *embryo* is a special one in that many compound terms are created using it, which, in the majority of the cases, become cases of noun adjectivization. Some examples include *embryo transfer, embryo attachment, frozen embryos, unused embryos, remaining*

[62] Real Academia Española (RAE). (n.d.). *Falopio*. In Diccionario de la lengua española. Accessed on 10 May 2022: https://bit.ly/3rabcgO

[63] *Renowned Italian surgeon* [Own translation]

embryos, surplus embryos and *extra embryos*. The last four examples all mean the same, and refer to the embryos that were created using IVF but were not transferred to the maternal uterus, thereby remaining unused. These are the equivalences that we found for these and the rest of the phraseological units derived from *embryo*:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
24	embryo development	n ph	desarrollo embrionario	n ph
25	embryo transfer	n ph	transferencia de embriones, transferencia embrionaria	n ph
26	fresh embryo transfer	n ph	transferencia de embriones en fresco	n ph
27	fresh embryos	n ph (pl)	embriones frescos	n ph (pl)
28	frozen embryo transfer	n ph	transferencia de embriones congelados	n ph
29	frozen embryos	n ph (pl)	embriones congelados, embriones criopreservados	n ph (pl)
30	normal embryos	n ph (pl)	embriones normales, embriones viables, embriones aptos, embriones con características biológicas de viabilidad	n ph (pl)
31	thawing of embryos	n ph	descongelación de embriones	n ph
32	unused embryos	n ph (pl)	embriones (viables) no transferidos, embriones sobrantes	n ph (pl)
33	remaining embryos			
34	surplus embryos			
35	extra embryos			
36	excess embryos			
37	viable embryos	n ph (pl)	embriones normales, embriones viables, embriones aptos, embriones con características biológicas de viabilidad	n ph (pl)

We would like to emphasize the case of *embryo transfer* (T/P unit #25), which is aligned with two potential equivalents that differ in their structure rather than in their meaning. The difference is that the first option is constructed using a noun plus a prepositional complement (*transferencia de embriones*) and the other is made up of a noun plus the adjectivized form of the term *embrión* (*transferencia embrionaria*), which consists of adding the suffix *–aria* to the noun *embrión*. This is precisely the example that appears in the definition of *–ario/a* provided in DRAE:

-ario, ria[64]

Del lat. -ārius

1. suf. Forma adjetivos que indican relación con la base derivativa[65]. *Bancario, embrionario*.

We would also like to highlight the cases of *fresh embryo transfer* and *frozen embryo transfer* (T/P units #26 and #28, respectively). If we look at the phraseological units *fresh embryos* and *frozen embryos* (T/P units #27 and #29, respectively), we can see that their equivalents are *embriones frescos* and *embriones congelados*, respectively. However, when these units are embedded within the term *transfer*, thereby creating new specialized phraseology, we find that *frozen embryo transfer* equals *transferencia de embriones congelados*, whilst *fresh embryo transfer* is aligned with *transferencia de embriones en fresco* and not *transferencia de embriones frescos*, as we could expect. In order to understand the reasons behind the meaning and use of *en fresco*, the first step we took was to look it up in the Corpus del Español del Siglo XXI (CORPES XXI)[66], created by the RAE, and got the following results:

ciertas empresas que se dedican al congelado o a su consumo	en	fresco". Los trabajadores
as radica en que la primera protege exclusivamente el producto	en	fresco y la segunda se e
as radica en que la primera protege exclusivamente el producto	en	fresco y la segunda se e
rir una vía de comercialización alternativa a la venta tradicional	en	fresco. No obstante, ya
a de Cambados no renuncia a la posibilidad de vender la vieira	en	fresco sin el hepatopánc
donde debían romper el hielo para pescar. El consumo se hacía	en	fresco y el excedente se
de noche, desde donde tiró el vaso, para tratar de capturar así,	en	fresco, algunas de las ir
vez cosechados los hongos se pueden consumir, comercializar	en	fresco o almacenar. Si e
izar en fresco o almacenar. Si el objetivo es la comercialización	en	fresco, ésta debe realiza
uiera de los casos, estos huevos no son aptos para el consumo	en	fresco y deben ser apar
to y transporte es de 7,2ºC. Incluso, para el huevo de consumo	en	fresco se está llevando a
erentemente cuando está en floración (excepto las raíces) tanto	en	fresco como seca.
era excepto raíces, entre junio y agosto y puede utilizarse tanto	en	fresco como en seco.

Figure 12. Collocations with *en fresco* (Source: CORPES XXI)

We can observe that this expression is normally used in the food, fishing and agriculture sectors to refer to products that are consumed or commercialized right after being harvested or caught, without undergoing any previous product handling process. This is, precisely, what occurs in the

[64] Real Academia Española (RAE). (n.d.). *-ario*. In Diccionario de la lengua española. Accessed on 10 May 2022: https://bit.ly/3NOllK5

[65] *It forms adjectives that indicate a relationship with their derivative base.* [Own translation]

[66] Real Academia Española (version 0.94, 2021). Corpus del Español del Siglo XXI (CORPES XXI). Available from: https://bit.ly/3ug0JCA (accessed on 10 May 2022)

case of a fresh embryo transfer, as can be proven after reading the definition of this procedure, especially the part marked in bold below (Conceptum Fertilitat, 2020):

> *Cuando hablamos de 'transferencia embrionaria en fresco' nos referimos a aquella transferencia en la que los embriones generados tras la punción folicular y posterior fecundación en laboratorio,* ***son transferidos a la mujer en el mismo ciclo en el que se ha producido la estimulación y la punción, es decir, sin vitrificar (congelar).***
>
> *When we speak about 'fresh embryo transfer' we refer to that transfer where the embryos generated right after the egg retrieval procedure and subsequent fertilization in the lab* ***are transferred to the woman during the same cycle in which the stimulation and the retrieval have been performed, that is, without vitrifying (freezing) them.*** [OWN TRANSLATION]

Simply put, the meaning conveyed with the addition of the phrase *en fresco* is the same as in the contexts that we found in the CORPES XXI, hence the use of this expression instead of the adjective *frescos* in the Spanish equivalent of *fresh embryo transfer*.

At this point, mention should be made to the role of the woman in the IVF process. Indeed, she is the one who undergoes the greatest part of the medical treatment, for she is the patient taking the fertility drugs and then undergoing the oocyte retrieval procedure, which will be discussed below. In the English informed consents, she is referred to with the term *recipient* or, more specifically, *recipient partner* (T/P units #38 and 39, respectively). After looking its definition up in the Merriam Webster's Dictionary, we got the following result:

> **recipient (noun)**
> one that receives: RECEIVER

Indeed, the woman is the one that receives the medications and then has the embryo(s) transferred into her uterus. In short, she is the one that receives the treatment, hence the use of this denomination. It should be noted, however, that we found no instance of *receiver*, which is reflected in the dictionary as a synonym of *recipient*. The table below shows the Spanish equivalent that we found–a phraseological unit that shows a higher level of specificity than its English counterpart:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
38	recipient	n	(mujer) receptora de las técnicas, usuaria de las técnicas	n ph
39	recipient partner	n ph		

Now that we are aware that the woman plays the role of the recipient in this medical procedure, the next area of special interest is the one related to the specific procedures that she will have to undergo prior to the embryo transfer, which is the final step in the IVF process, as well as during pregnancy. As mentioned above, this includes the use of fertility drugs or medications, ovulation induction, blood tests and transvaginal ultrasounds. Moreover, the goal of these pre-treatment tests is to retrieve mature eggs from her ovaries using two techniques called *egg/oocyte retrieval* (T/P units #42 and #46) and *follicular aspiration* (T/P unit #44), which in addition require anesthesia (T/P unit #40).

In the case of the medications used during this process, we find two alternatives in both the English and the Spanish corpora. The English language turns to the adjectivization of the noun *fertility* placed before the general word *drug*, thereby creating the subject-specific term *fertility drug* (T/P unit #43). However, we did not find any equivalent as specific as *fertility drug* in Spanish. Instead, what we found are general terms that have acquired a new specialized meaning due to the semantic extension mechanism (Van Hoof, 1999: 153)[67]. Given these results, our suggestion for the translation of these terms is that they can be used interchangeably. In fact, if we search the word *fármaco* in the DRAE, we find that it takes us to *medicamento,* which supports our idea:

> **fármaco**[68]
>
> Del lat. *pharmăcum*, y este del gr. *φάρμακον* 'phármakon'
>
> 1. m. medicamento.

Consequently, following Cabré's Communicative Theory of Terminology (CTT) in that content may be expressed more or less rigorously using more than a single denomination[69], our final proposal is to agglutinate them as synonyms of the same terminological unit. This case and the other treatments underwent by the woman are listed below, aligned with the corresponding equivalent found in our Spanish corpus:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
40	anesthesia	n	anestesia	n
41	blood test	n ph	análisis en sangre	n ph

[67] See Section 2.7.1.1.

[68] Real Academia Española (RAE). (n.d.). *fármaco*. In Diccionario de la lengua española. Accessed on 10 May 2022: https://bit.ly/3KgkVtr

[69] See Section 3.1.

42	egg retrieval	n ph	punción de los ovarios, punción ovárica[70]	n ph
43	fertility drug	n ph	medicación, fármaco	n ph
44	follicular aspiration	n ph	aspiración de los folículos	n ph
45	medication	n	medicación, fármaco	n
46	oocyte retrieval	n ph	punción de los ovarios, punción ovárica	n ph
47	ovulation induction	n ph	estimulación de los ovarios, estimulación ovárica	n ph
48	transvaginal ultrasound	n ph	ecografía vaginal, visión ecográfica por vía vaginal	n ph
49	chorionic villus sampling (CVS)	n ph	biopsia de corión, biopsia corial	n ph

The use of medications to induce ovulation has certain consequences on the patient, which takes us to the next thematic area dealt with in our set of informed consents. Firstly, they are taken in order to get an ovarian response (T/P unit #51), hence the use of ultrasound monitoring to check whether multiple eggs are developing or not. In this regard, we found that the Spanish equivalent is very similar: *respuesta ovárica* or, more accurately, *respuesta a la estimulación ovárica*. This is shown in the following screenshot from AntConc:

	File	Left Context	Hit	Righ
1	Centro Extremeño de Reproducción Asistida - Hoja ...	a: En ocasiones, la	respuesta	ovárica al tratamiento es e
2	GVA (Hospital Clínico Valencia) - Hoja informativa y ...	a: En ocasiones, la	respuesta	ovárica al tratamiento es e
3	Hospital Universitario Central de Asturias - Hoja informati...	a: En ocasiones, la	respuesta	ovárica al tratamiento es e
4	Junta de Andalucía - Hoja informativa y consentimiento ...	a: En ocasiones, la	respuesta	ovárica al tratamiento es e
5	SEF - Hoja informativa y consentimiento FIV o ICSI con ...	a: En ocasiones, la	respuesta	ovárica al tratamiento es e
6	Centro Extremeño de Reproducción Asistida - Hoja ...	e, en función de la	respuesta	a la estimulación ovárica c
7	SEF - Hoja informativa y consentimiento FIV o ICSI con ...	e, en función de la	respuesta	a la estimulación ovárica c

Figure 13. Concordances with *respuesta* (Source: AntConc)

Additionally, some of the medications are used in order to prevent premature ovulation (T/P unit #52), an unwanted situation in which the woman ovulates earlier than expected whilst on treatment. The equivalent of this phraseme was not easy to find in our comparable corpus. However, when reading the section that deals with the purpose of using medications in one of the consents that make up our English corpus, we found the following statement about a particular type of medication:

[70] This is a case of noun adjectivization in Spanish using the suffix *-ico, a*. It is used to form adjectives and indicates a relationship with the derivative base (Real Academia Española, n.d.: 1596). In this case, the derivative base is the noun *ovario* (*ovary* in English).

GnRH-antagonists (ganirelix acetate or cetrorelix acetate): These drugs are used to prevent ***premature ovulation****.* (Source: Columbia University Fertility Center's informed consent)

In order to understand how the mentioned medication works to prevent premature ovulation, we looked for the definition of *GnRH-antagonists* and found the following result (Olivennes *et al.*, 2002):

GnRH antagonists induce a rapid decrease in LH[71] *and FSH*[72]*.*

We can see, then, that GnRH antagonists modify the levels of certain hormones, which is to say, this medication interacts with hormones in order to prevent premature ovulation. Considering this information, we took the following extract from the SEF's informed consent into consideration:

Con el fin de evitar la ***ovulación espontánea*** *se asocian otros medicamentos con acción hormonal*[73]*.*

As we can see, although it does not mention *GnRH antagonists* explicitly, it refers to certain drugs that have an effect on hormones in order to prevent *la ovulación espontánea*. It is apparent from this that the equivalent of the phrase *premature ovulation* is *ovulación espontánea*.

According to the contents of the different information sheets of our corpora, the final goal of taking fertility drugs is to achieve egg maturation so the eggs can be retrieved successfully from the woman. In the case of the phrase *egg maturation* (T/P unit #50), the results of our alignment process showed that Spanish informed consents are more precise when referring to this stage, as the equivalent is *maduración final de los óvulos/ovocitos*.

In summary, the phraseological units referring to the potential consequences of taking fertility drugs could be translated as follows, based on the equivalences found in our corpus:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
50	egg maturation	n ph	maduración final de los óvulos/ovocitos	n ph (pl)
51	ovarian response	n ph	respuesta ovárica, respuesta a la estimulación ovárica	n ph
52	premature ovulation	n ph	ovulación espontánea	n ph

[71] i.e. luteinizing hormone

[72] i.e. follicle-stimulating hormone

[73] *With the purpose of preventing premature ovulation, other hormone-based medications are used.* [Own translation]

An additional area that deserves consideration is the one including all the vocabulary about the side effects of the IVF treatment, including the potential adverse reactions caused by fertility drugs, the oocyte retrieval procedure, the embryo transfer and so on. Both the informed consents from US fertility clinics and those from Spanish clinics include a section devoted to the risks of the procedure, which made the word alignment process easier than in previous cases. Thus, the following is a list with the different specific risks of the IVF procedure in English along with their Spanish equivalents:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
53	adnexal torsion	n ph	torsión ovárica	n ph
54	ectopic pregnancy	n ph	embarazo ectópico	n ph
55	increased ovarian size	n ph	aumento del tamaño ovárico	n ph
56	miscarriage	n	aborto espontáneo	n
57	multiple pregnancy	n	embarazo múltiple, gestación múltiple	n
58	Ovarian Hyperstimulation Syndrome (OHSS)	n	síndrome de hiperestimulación ovárica	n
59	ovarian torsion	n ph	torsión ovárica	n ph
60	ovarian twisting			

Special attention should be paid to the cases of *ectopic pregnancy* and *miscarriage* (T/P units #54 and #56, respectively). As for the first unit, we would like to provide its definition as provided by the Merriam Webster's dictionary:

> **ectopic pregnancy**[74]
>
> n. development of a fertilized egg elsewhere than in the uterus (as in a fallopian tube or the peritoneal cavity)

In this vein, we found that in all examples found in the English texts, an informative parenthetical remark that explains the different locations where the fertilized egg may develop outside the uterus is inserted, as we shall see in the following screenshot retrieved from AntConc:

[74] Merriam-Webster. (n.d.). *ectopic pregnancy*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3r7f02G

	File	Left Context	Hit	Right Context
1	Boston IVF - IVF.txt	directly into the uterus with IVF,	ectopic	(tubal, cervical and abdominal) pregnancies a
2	Columbia University Fertility Center - IVF.txt	directly into the uterus with IVF,	ectopic	(tubal, cervical and abdominal) pregnancies a
3	Overlake Reproductive Health - IVF-ICSI, ...	directly into the uterus with IVF,	ectopic	(tubal, cervical and abdominal) pregnancies a
4	Stanford Medicine - IVF.txt	directly into the uterus with IVF,	ectopic	(tubal, cervical and abdominal) pregnancies h
5	MGH Fertility Center - IVF.txt	al or grow in the correct place –	ectopic	(outside the uterus) pregnancies can occur. Th
6	MGH Fertility Center - IVF.txt	tside the uterus. The majority of	ectopic	pregnancies are present in the fallopian tube.

Figure 14. Concordances with *ectopic* (Source: AntConc)

Thus, we can see that the term *ectopic pregnancy* in isolation does not appear in any of our documents, but it is accompanied by a brief explanation in order to make it easier for the 'plain reader'[75] to understand the information provided.

Secondly, the case of *miscarriage* (T/P unit #56) was a tricky one when attempting to find an accurate equivalent. At first glance, we found *aborto* as a viable equivalent. However, the word *aborto* may have two different meanings in Spanish, as the second entry provided in the DRAE shows:

> **aborto**
> Del lat. *abortus*.
> 2. m. Interrupción del embarazo por causas naturales o provocadas[76].

The translation into English of this definition is "termination of pregnancy due to natural or intentional causes". As we can see, it may occur for two different causes. This dichotomy is perfectly solved in English, for it has one exclusive word depending on the cause: *miscarriage*, when it is due to natural causes, and *abortion*, when it is induced. Let's see the definition of each in the Cambridge Dictionary:

> **miscarriage**[77]
> n. an early, unintentional end to a pregnancy when the foetus is born too early and dies because it has not developed enough.

> **abortion**[78]
> n. the intentional ending of a pregnancy.

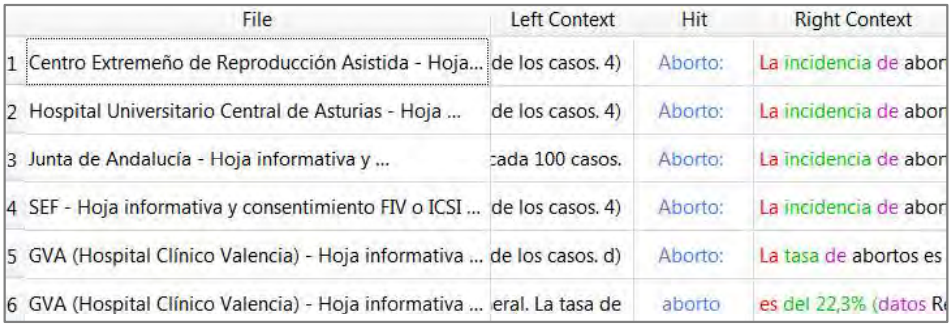
[75] Term coined by Gallego Borghini (2015a: 1)

[76] *Interruption of pregnancy due to natural or induced causes*. [Own translation]

[77] Cambridge Advanced Learner's Dictionary & Thesaurus. (n.d.). *miscarriage*. In Cambridge Dictionary. Accessed on 10 May 2022: https://bit.ly/3KlpfIb

[78] Cambridge Advanced Learner's Dictionary & Thesaurus. (n.d.). *abortion*. In Cambridge Dictionary. Accessed on 10 May 2022: https://bit.ly/3uhPLN2

In Spanish, however, the word *aborto* is used to refer to both situations, and it is the context which usually eliminates the potential ambiguity of the term. In fact, this is the equivalent that we found in our Spanish corpus, as can be seen in the following screenshot:



	File	Left Context	Hit	Right Context
1	Centro Extremeño de Reproducción Asistida - Hoja...	de los casos. 4)	Aborto:	La incidencia de abor
2	Hospital Universitario Central de Asturias - Hoja ...	de los casos. 4)	Aborto:	La incidencia de abor
3	Junta de Andalucía - Hoja informativa y ...	cada 100 casos.	Aborto:	La incidencia de abor
4	SEF - Hoja informativa y consentimiento FIV o ICSI ...	de los casos. 4)	Aborto:	La incidencia de abor
5	GVA (Hospital Clínico Valencia) - Hoja informativa ...	de los casos. d)	Aborto:	La tasa de abortos es
6	GVA (Hospital Clínico Valencia) - Hoja informativa ...	eral. La tasa de	aborto	es del 22,3% (datos R

Figure 15. Concordances with *aborto* (Source: AntConc)

In order for the potential ambiguity to be removed from our translation proposal, we finally opted for *aborto espontáneo*, which is the option provided in the Spanish version of the WHO's glossary (Zegers-Hochschild *et al.*, 2009b: 4). It can be found below, aligned with its original definition in English (Zegers-Hochschild *et al.*, 2009a: 1523):

ENGLISH	SPANISH
***Spontaneous abortion/miscarriage**: the spontaneous loss of a clinical pregnancy before 20 completed weeks of gestational age (18 weeks after fertilization) or, if gestational age is unknown, the loss of an embryo/fetus of less than 400 g.*	***Aborto espontáneo:** pérdida espontánea de un embarazo clínico antes de completadas las 20 semanas de edad gestacional (18 semanas después de la fecundación) o si la edad gestacional es desconocida, la pérdida de un embrión/feto de menos de 400 g.*

Table 16. Definitions of *miscarriage* and *aborto espontáneo* (Source: WHO's glossary)

One more area where we encountered specialized phraseological units is the one related to the outcomes of the treatment, that is to say, whether it is successful and results in pregnancy or, conversely, it fails and the woman does not get pregnant in the end. Whilst the English consent forms refer to it as *success rates* or *pregnancy rates,* its equivalents in Spanish are more specific as we can see in the following alignment:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
61	pregnancy rate	n ph	tasa de embarazo por transferencia de embriones	n ph
62	success rates	n ph (pl)	tasas de éxito, probabilidades de éxito, posibilidades de éxito	n ph (pl)

It is necessary to point out that the Spanish consents also use the phrase *éxito reproductivo* (*reproductive success*) when referring to the chances of success, as we can see in the following screenshot from AntConc:

Centro Extremeño de Reproducción Asistida - Hoja ...	arantice posibilidades razonables de	éxito	reproductivo de cada caso. U
Hospital Universitario Central de Asturias - Hoja ...	os, garantice en límites razonables el	éxito	reproductivo de cada pareja.

Figure 16. Concordances with *éxito* (Source: AntConc)

On the other hand, one of the final stages of the IVF process is for the couple to decide what to do with the potential surplus or extra embryos that have not been transferred to the recipient's uterine cavity. In other words, they have to choose the embryo's 'fate'. In the English consent forms, this step is referred to as *disposition of the embryos* (T/P unit #63). In this sense, the word *disposition* is defined in the second entry of the Merriam Webster's dictionary as follows:

> **disposition (noun)**[79]
> 2: the act or the power of disposing or the state of being disposed: such as
> a: ADMINISTRATION, CONTROL
> b: final arrangement: SETTLEMENT

As we can see, definition 2b is the most appropriate in our case. As for the Spanish equivalent found, it literally uses the word *fate* (in Spanish, *destino*) to refer to this final arrangement, which suggests a greater degree of fidelity with the overall meaning that is intended to convey with this phrase. *Disposition*, on the other hand, is typically used in formal situations (i.e. formal register), as the Collins dictionary indicates:

> **disposition (singular noun)** [formal][80]
> If you refer to the disposition of a number of objects, you mean the pattern in which they are arranged or their positions in relation to each other. Synonyms: *arrangement, grouping, ordering, organization*.

We also found a verbal phrase that is more similar to the term *disposition* used in English, for it uses the verb *disponer* (in English, *to dispose, to arrange*). The following is the resulting alignment:

[79] Merriam-Webster. (n.d.). *disposition*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3uhHCrV

[80] Collins. (n.d.). *disposition*. In Collins Dictionary. Accessed on 10 May 2022: https://bit.ly/36UG4LD

T/P UNIT #	ENGLISH	POS	SPANISH	POS
63	disposition of the embryos	n ph	destino de los embriones	n ph
			disponer de embriones	v ph

In order for the couple to dispose of their extra embryos after IVF, they have different options at their disposal. In the words of Gurmankin, Sisti & Caplan (2004: 5):

> *Numerous options exist for the management of spare, extra, or unwanted embryos. Embryos can be* ***maintained in a frozen state*** *indefinitely. They can be* ***made available for medical research****. They* ***can be given to those in need of donor sperm and egg*** *to reproduce with assisted reproductive technologies (ART).*

Thus, couples have three different options available: 1) to maintain them frozen, 2) to donate them for medical research, and 3) to donate them to another couple. The phrases that we found for these three possible scenarios along with their Spanish equivalents are given in the following table:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
64	donation for research	n ph	donación con fines de investigación	n ph
65	donation to another couple	n ph	donación con fines reproductivos, donación para otras parejas	n ph
66	embryo donation	n ph	donación de embriones	n ph
67	storing of any unused embryos	n ph	mantenimiento de la congelación embrionaria	n ph

5. 1. 2. Doublet phenomenon

Due to its high frequency in our corpora, special attention should be paid in the first place to the case of the term *egg*, which was not found in either ICMART or WHO's glossaries of ART terminology. In both glossaries, the term that we found was *oocyte*, which is the erudite version of *egg*. Indeed, this is an example of the doublet phenomenon described by Montalt, Zethsen & Karwacka (2018)[81], whereby an erudite term is replaced by an equivalent retrieved from everyday language. In our texts, we observed that they follow a common pattern whereby, instead of replacing it, the erudite term is followed by its popular equivalent in parentheses, as we can see below:

[81] See Section 2.7.1.1.

File	Left Context	Hit	Ri
Boston IVF - IVF.txt	ted material includes follicular fluid,	oocytes (	eggs) and granulosa (
Stanford Medicine - IVF.txt	ted material includes follicular fluid,	oocytes (	eggs) and granulosa (
Overlake Reproductive Health - IVF...	ted material includes follicular fluid,	oocytes (	eggs) and granulosa (
Overlake Reproductive Health - IVF...	the simultaneous growth of several	oocytes (	eggs) over the span c
Stanford Medicine - IVF.txt	the simultaneous growth of several	oocytes (	eggs) over the span c
Stanford Medicine - IVF.txt	e Transfer A cycle to transfer frozen	oocytes (	eggs) may use some

Figure 17. Doublet phenomenon with *ooocytes* <> *eggs* (Source: AntConc)

Likewise, this phenomenon occurs in Spanish as well with the term *óvulo*, whose erudite version is *ovocito*. In this case, the popular term is used firstly and the erudite version follows in parentheses as we can see in the following examples:

	File	Left Context	Hit	
1	Centro Extremeño de Reproducción Asistida - Hoja informativa y de ...	gina 1 de 6 Los	óvulos (	ovocitos) (
2	Hospital Universitario Central de Asturias - Hoja informativa y ...	do variable. Los	óvulos (	ovocitos) (
3	SEF - Hoja informativa y consentimiento FIV o ICSI con transferencia ...	nteresados: Los	óvulos (	ovocitos) (
4	Centro Extremeño de Reproducción Asistida - Hoja informativa y de ...	itar la unión de	óvulos (	ovocitos) y
5	Hospital Universitario Central de Asturias - Hoja informativa y ...	itar la unión de	óvulos (	ovocitos) y
6	SEF - Hoja informativa y consentimiento FIV o ICSI con transferencia ...	itar la unión de	óvulos (	ovocitos) y

Figure 18. Doublet phenomenon with *óvulos* <> *ovocitos* (Source: AntConc)

Considering these equivalences, we consider that a distinction should be made between the erudite term and the popular term when aligning the equivalences between English and Spanish, and therefore the result would be as follows:

T/P UNIT #	T/P UNIT TYPOLOGY	ENGLISH	POS	SPANISH	POS
68	POPULAR	egg	n	óvulo	n
69	ERUDITE	oocyte	n	ovocito	n

Indeed, the doublet phenomenon is extremely frequent in both corpora, and especially in the case of the English consent forms, where in almost all cases the erudite term is aligned with its popular version throughout the document. It is likely that this is a strategy used by fertility clinics to make it easier for the patients to understand what they are about to read. One should not forget that the addressees of these documents are not specialists in medicine but, in the words of Gallego Borghini

(2015a: 1), *plain readers*[82]. The following are all examples of erudite terms and their equivalents of popular nature ordered by frequency of occurrence. It should be noted, however, that the doublet phenomenon does not occur in all Spanish equivalents, for the Spanish texts use a single term, as in the case of T/P units #72 and #73:

T/P UNIT #	T/P UNIT TYPOLOGY		ENGLISH	POS	SPANISH	POS
70	POPULAR	→	uterine lining	n ph	capa interna del útero	n ph
71	ERUDITE	→	endometrium	n	endometrio	n
72	POPULAR	→	embryo attachment	n ph	implantación embrionaria, implantación del embrión	n ph
73	ERUDITE	→	implantation	n		
74	POPULAR	→	freezing	n	congelación	n
75	ERUDITE	→	cryopreservation	n	criopreservación	n
76	POPULAR	→	eggs and sperm	n ph (pl)	espermatozoides y óvulos	n ph (pl)
77	ERUDITE	→	gametes	n (pl)	gametos	n (pl)

5. 1. 3. Terms with a Greco-Latin base

The case of the term *embryo* is a special one, as it is the most frequent term in our English corpus, with a total of 239 concordance hits in singular (*embryo*) and 377 in plural (*embryos*) according to AntConc. If we look this word up in the Online Etymological Dictionary, we find the following origin:

> **embryo (n.)**[83]
>
> mid-14c., from Medieval Latin *embryo*, properly *embryon*, from Greek *embryon*.

Moreover, we did the same with its Spanish equivalent, *embrión*, and looked it up in the DRAE, getting the following result:

> **embrión**[84]
>
> Del griego *ἔμβρυον* 'émbryon'

As shown above, the origin of the words *embryo* and *embrión* can be found in the Greek language, thereby making it a case of Greek terminology.

[82] See Section 2.6.

[83] Online Etymology Dictionary. (n.d.). *embryo*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/3x6Pbn7

[84] Real Academia Española (RAE). (n.d.). *embrión*. In Diccionario de la lengua española. Accessed on 10 May 2022: https://bit.ly/3Kd4WMV

Another example of a word with a Greco-Latin base is *cryopreservation*. If we look into the word's components, the resulting analysis is the following:

	cryo /	**preserv** /	**ation**
TYPE OF COMPONENT	PREFIX	ROOT	SUFFIX
MEANING	icy cold	guard beforehand	action or process
ORIGIN	Greek *kryos*[85]	Latin *preservationem*[86]	Latin *-atio*[87]

Table 17. Etymological analysis of *cryopreservation*

Oocyte, the erudite version of *egg*, is also an example of Greek-Latin terminology. It is formed by putting together the word-forming elements *oo-* and *-cyte*. Let's see what the resulting analysis looks like:

	oo /	**cyte**
TYPE OF COMPONENT	PREFIX	ROOT
MEANING	ovum, egg	cell
ORIGIN	Greek *ōon*	Latinized form *-cyta*, from Greek *kytos*

Table 18. Etymological analysis of *oocyte*

The Spanish version of oocyte is *ovocito*, whose components are *ovo-* and *-cito*. If we look both word-forming elements up in the DRAE, we find that the provided etymological references are the same as in English:

[85] Online Etymology Dictionary. (n.d.). *cryo-*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/3DO8VNo

[86] Online Etymology Dictionary. (n.d.). *preservation*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/3LHn6qg

[87] Merriam-Webster. (n.d.). *-ation*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3KeyQ3k

ovo[88]	**cito-, -cito**[89]
Del lat. *ovum* 'huevo'.	Del lat. cient. *cyto-*, tomado de *cytoblastus* 'núcleo celular', término acuñado por Schleiden en 1838, y este del gr. *κύτος kýtos* 'vaso', 'receptáculo'.

Table 19. Etymology of *ovo* and *cito-, -cito* in Spanish (Source: DRAE)

The term *ectopic* is another example of a word formed by two components, in this case both deriving from Greek: on the one hand, *ek-* 'out' and, on the other hand, *topos* 'place'. The resulting analysis would be as follows:

TYPE OF COMPONENT	**ec**	**/**	**topic**
	PREFIX		ROOT
MEANING	out from		place
ORIGIN	Greek *ektopos (ek-* 'out' + *topos* 'place')[90]		

Table 20. Etymological analysis of *ectopic*

Finally, we found that our corpus contains other words whose origin can be found in the Latin language, such as the cases of *ovary, stimulation* and *uterus*. In the case of *ovary*, it derives from classical Latin *ovarius,* which literally meant 'egg-keeper'. In the case of the Spanish equivalent, *ovario*, the DRAE provides the following definition as regards its etymology:

> **ovario**[91]
>
> Del lat. cient. *ovarium*, der. del lat. *ovum* 'huevo'.

As regards the case of *stimulation*, it derives from Latin *stimulationem* (nominative *stimulatio*), which literally meant 'an incitement'. In Spanish, the equivalent *estimulación* has its origin in the Latin language too, as the DRAE indicates:

> **estimulación**[92]

[88] Real Academia Española (RAE). (n.d.). *ovo*. In Diccionario de la lengua española. Accessed on 10 May 2022: https://bit.ly/3rvyIW3

[89] Real Academia Española (RAE). (n.d.). *cito-*. In Diccionario de la lengua española. Accessed on 10 May 2022: https://bit.ly/38sm9nr

[90] Online Etymology Dictionary. (n.d.). *ectopic*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/3KeySrY

[91] Real Academia Española (RAE). (n.d.). *ovario*. In Diccionario de la lengua española. Accessed on 10 May 2022: https://bit.ly/3DMeImK

Del lat. *stimulatio*, *-ōnis*.

Finally, the origin of *uterus* and its Spanish equivalent, *útero*, can be found in the Latin word *uterus*, which means 'womb, belly' (plural *uteri*). Moreover, the derivative adjective *uterine* used in words such as *uterine lining* is created using the root *uterus* plus the suffix *-ine*, from Latin *-īnus* and the same applies to its Spanish equivalent, *uterino*. The following are the definitions of *-ine* and *-ino* provided in Merriam Webster's Dictionary and the DRAE, respectively:

-ine (adjective suffix)[93]

1. [French *-in, -ine*, from Latin *-īnus*]: of or relating to.

-ino, na[94]

Del latín *-īnus* o *-ĭnus*, latín vulgar *-īnus*.

1. suf. En adjetivos, indica pertenencia o relación[95].

As we can conclude from these results, those terms whose origin is found in the Greek and/or Latin languages used in the English texts are aligned with an equivalent that also has its origin in one or both of these languages. This endorses Montalt, Zethsen & Karwacka's (2018: 29) assertion that Latin and Greek influences constitute a feature of medical terminology observable across languages.

5. 1. 4. Hyphenated phrases

As regards the presence of hyphenated phraseology, one representative example of this phenomenon is the phrase *egg-containing follicles*, where the first item is a compound adjective resulting from the process of verb adjectivization. The verb *to contain* has been transformed into an adjective and embedded within the word *egg* in order to form an adjective, as we can see in the following schema:

PART OF SPEECH		PART OF SPEECH		RESULTING ADJECTIVE
Noun (*egg*)	+	Present participle (*containing*)	=	*egg-containing*

[92] Real Academia Española (RAE). (n.d.). *estimulación*. In Diccionario de la lengua española. Accessed on 10 May 2022: https://bit.ly/37lth4C

[93] Merriam-Webster. (n.d.). *-ine*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3NTNPSn

[94] Real Academia Española (RAE). (n.d.). *-ino, na*. In Diccionario de la lengua española. Accessed on 10 May 2022: https://bit.ly/3jcorth

[95] *In adjectives, it indicates belonging or relationship*. [Own translation]

Although we found the potential equivalent *folículos en desarrollo* in the Spanish corpus, we also encountered the following explicative sentence in the SEF's informed consent:

> *La finalidad de este tratamiento es obtener el desarrollo de varios* ***folículos en cuyo interior se encuentran los óvulos***[96].

We find that, when attempting to translate the term *egg-containing follicles*, the translator may need to turn to the translation technique called *transposition*, whereby a term is translated into a syntactic category–e.g. into a prepositional phrase (PP), noun phrase (NP), verb phrase (VP) or relative clause–other than the original in the ST (Labrador de la Cruz & Ramón García, 2010: 254). Using the sentence exemplified above would be a case of transposition into a PP and we find that this would be the most accurate option as an equivalent in Spanish. As a result, below we present the equivalences found:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
78	egg-containing follicles	n ph (pl)	folículos en desarrollo, folículos en cuyo interior se encuentran los óvulos	n ph (pl)

Another instance of hyphenation by verb-to-adjective transformation is found in *best-developed embryos* and *best-appearing embryos*. In the former, the verb *to develop* in its past participle form (*developed*) is joined to the adjective *good* in its superlative form (*best*). In the latter, the verb *to appear* in its present participle form (*appearing*) is embedded in *best* as well. The following schema summarizes the structure of both in more detail:

PART OF SPEECH		PART OF SPEECH		RESULTING ADJECTIVE
Adjective (*best*)	+	Verb in past participle (*developed*)	=	*best-developed*
Adjective (*best*)	+	Verb in present participle (*appearing*)	=	*best-appearing*

The equivalent in Spanish that we found is *embriones de buena calidad,* although we would like to emphasize the case of *embriones FINALES de buena calidad* found in SEF's consent. In this example, the adjective *finales* (in English, literally *final*) is inserted to add more specificity to the phrase. It indicates that the embryos have reached an adequate stage of maturation and, at this point, they have a good quality. This meaning resembles the meaning conveyed with the English equivalent *best-developed embryos* to a large extent. One final option found in our English corpus is *good-quality embryos*, which is a case of noun adjectivization that has the below structure:

[96] *The purpose of this treatment is to obtain the development of several egg-containing follicles.* [Own translation]

PART OF SPEECH		PART OF SPEECH		RESULTING ADJECTIVE
Adjective (*good*)	+	Noun (*quality*)	=	*good-quality*

The following, then, is the result of aligning the English phraseological units found with their Spanish equivalent:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
79	best-developed embryos	n ph (pl)	embriones (finales) de buena calidad	n ph (pl)
80	best-appearing embryos			
81	good-quality embryos			

When referring to the children born after IVF, the versatility of the English language has allowed for the creation of the hyphenated phrase *IVF-conceived baby*. Again, this phraseological unit contains a compound adjective that is formed by means of the verb-to-adjective transformation mechanism, as illustrated below:

PART OF SPEECH		PART OF SPEECH		RESULTING ADJECTIVE
Noun (*IVF)*	+	Verb in past participle (*conceived*)	=	*IVF-conceived*

The equivalent in Spanish is *niño nacido de FIV/ICSI*, which, as a translation option, would be another case of transposition into a VP:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
82	IVF-conceived baby	n ph	niño nacido de FIV/ICSI	n ph

Finally, reference must be made to the case of gamete (eggs and/or sperm) donation. In the English consents selected for our corpus, we found several references to the donors by using the adjective *third-party*, which is formed out of the following parts of speech:

PART OF SPEECH		PART OF SPEECH		RESULTING ADJECTIVE
Adjective (*third)*	+	Noun (*party*)	=	*third-party*

Let's have a look at the definition of *third-party* as an adjective and *third party* as a noun[97] provided by the Merriam Webster's dictionary:

third-party (adjective) [Entry 1 of 2][98]
of, relating to, or involving a third party

third party (noun) [Entry 2 of 2]
a person other than the principals

[97] Note that, as an adjective, it is hyphenated (*third-party*), whereas, as a noun, no hyphen is inserted (*third party*).

[98] Merriam-Webster. (n.d.). *third party*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3LN4HIR

It makes sense, then, that the adjective *third-party* is inserted before the term *donor*, which transforms it into a more accurate phraseological unit that removes any doubt as regards the profile of donors. This level of detail, however, is not achieved in Spanish, as we can see in the alignment we made below:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
83	third-party donor	n ph	donante	n

5. 2. Legal terminology and phraseology

This section is divided into three major subsections based on the results obtained after aligning the English texts with the Spanish ones:

5. 2. 1. Legal vocabulary;
5. 2. 2. Pronominal adverbs;
5. 2. 3. Performative verbs.

As can be seen in each one of these subsections, the first group is the largest one, for the highest percentage of legal terminology and phraseology found in our set of ART informed consents is composed of technical vocabulary. Thus, in order to present our analysis of the different technical terminological and phraseological units found, we will analyze the different types of legal references made throughout the document:

1. References to the law and its application;
2. References to the couple and their marital status;
3. References to the couple/recipient's agreement to have treatment;
4. References to potential unforeseen events and the outcome of the treatment;
5. References to the physician's counsel;
6. References to the endorsement of the consent and its validity over time.

The original terminological or phraseological unit in English and its alignment with the Spanish equivalent (abbreviated below as *T/P Unit*) found are presented in the form of a table along with the corresponding part of speech (PoS) of each. The following is the key to each one of the abbreviations used to indicate the PoS of each instance:

POS		MEANING		DEFINITION
adj	→	adjective	→	Modifier that denotes a quality of the noun.

adv	→	adverb	→	Modifier of other parts of speech (verbs, adjectives, other adverbs, prepositions, phrases, clauses or sentences) that expresses some relation of manner, place, time, number, cause, opposition, etc.
col	→	collocation	→	Regular grouping or juxtaposition of words and/or sounds.
n	→	noun	→	Word used to refer to a person or thing.
n ph	→	noun phrase	→	Group of words that is headed by a noun and includes modifiers. It functions like a noun.
n (pl)	→	noun (frequently used in plural)	→	Word used to refer to a person or thing that is often used in plural.
n ph (pl)	→	noun phrase (frequently used in plural	→	Group of words that is often used in plural to refer to a person or thing.
prep ph	→	prepositional phrase	→	Preposition (word that usually combines with a noun phrase to show place, direction, time, etc.) followed by a noun phrase.
v	→	verb	→	Word used to say what someone or something does.
v ph	→	verbal phrase	→	Phrase that uses a verb followed by other parts of speech such as nouns, adverbs or adjectives.

Table 21. Key of PoS abbreviations in legal T/P units

5. 2. 1. Legal vocabulary

As explained above, the first group we are going to present in this section is the one comprising the different terms and phrases that make reference to the law and its application from a general perspective, as can be seen below:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
1	applicable law	n ph	marco jurídico regulador	n ph
2	in accordance with	prep ph	de acuerdo con	prep ph
3	legal considerations	n ph (pl)	información legal	n ph
			aspectos legales	n ph (pl)
4	legal requirements	n ph (pl)	mandato legal	n ph
5	under the provision of	prep ph	estar constituido por	v ph
			seguirse lo dispuesto en	v ph

The reason why T/P unit #4, *legal requirements*, has been aligned with *mandato legal* can be explained by showing an example of the context in which they appear in both the English and the Spanish corpora:

> *Stanford will use all reasonable efforts to protect the privacy of your medical information, in* ***accordance with legal requirements*** [...]. (Source: Stanford IVF's informed consent)

El número de preembriones transferidos al útero no puede ser superior a tres en un ciclo, ***por mandato legal***[99]. (Source: SEF's informed consent)

As these examples reveal, in both sentences the text is referring to the restrictions imposed by the current law governing ART.

In T/P unit #3, *legal considerations*, context was a clear clarifying element in order to find the most appropriate alignment. As a matter of fact, we found that the context of both the English and the Spanish phrases is the same–they appear as the title of a subsection that refers to the general legal information applicable to that particular document:

XI. Legal Considerations and Legal Counsel

The law regarding embryo cryopreservation, subsequent thaw and use, and parent-child status of any resulting child(ren) is, or may be, unsettled in the state in which either the patient, spouse, partner, or any donor currently or in the future lives, or the state in which the ART Program is located. (Source: Boston IVF's informed consent)

VIII. Aspectos legales relacionados con la reproducción asistida

1.- De carácter general

El marco jurídico regulador de la reproducción humana asistida está constituido básicamente por la Ley 14/2006 sobre Técnicas de Reproducción Humana Asistida[100]. (Source: SEF's informed consent)

The second group of legal terms and phrases that should be highlighted is the one referring to the marital status of the recipient and her partner, and the resulting parental relationship with the child born from IVF. In this sense, although the alignment was rather easy because the concepts utilized are similar in both languages, it should be mentioned that the notions of *divorce* and *separation* (T/P units #6 and #14, respectively) appear in the form of nouns as well as in the form of verbs in both English and Spanish. However, there is one concept that was found in the Spanish texts that has no equivalent in the US informed consents. By way of illustration, let's take the following instance:

[99] *The number of embryos to transfer to the uterus cannot be higher than three per cycle, in accordance with legal requirements*. [Own translation]

[100] *VIII. Legal aspects related to assisted reproduction. 1.- General. The applicable law regulating assisted reproductive technology is Law 14/2006 on Human Assisted Reproduction Techniques.* [Own translation]

Cuando la mujer esté casada, se requerirá además el consentimiento del marido, a menos que estuvieran ***separados legalmente o de hecho*** *y así conste fehacientemente.*[101] (Source: SEF's informed consent)

What we are handling in this case are three different legal concepts: 1) divorce, 2) legal separation, and 3) *de facto* separation. Indeed, although, at first, one may think that *legal separation* is a synonym of *divorce*, we found that they are not equivalents as the following definitions prove:

Separación de hecho[102]*: la separación de hecho supone el cese de la convivencia de los cónyuges, antes de poder tramitar una separación legal o un divorcio.*	***De facto separation****: de facto separation means the cessation of the cohabitation of the couple before they can process a legal separation or a divorce.*
Separación matrimonial[103]*:* [...] *a diferencia del divorcio y la nulidad del matrimonio, la separación no extingue el vínculo matrimonial.*	***Marital separation****:* […] *contrary to divorce and marriage annulment, a separation does not extinguish the marriage bond.*
Divorcio[104]*: el divorcio es una vía legal que se abre para disolver un matrimonio y permitir, consecuentemente, que los miembros de éste vuelvan a casarse con quien deseen.*	***Divorce****: a divorce is the legal way of dissolving a marriage and permit, subsequently, that its members can get married again when they wish to.* [OWN TRANSLATION]

Thus, considering these differences, we could not opt for aligning the English noun *divorce* with *separación legal*, as it is not exactly the same. For this reason, we will not use this phrase in our final translation proposal and the only equivalent provided in our glossary will be *divorcio*, thereby eliminating *separación legal* as a potential translation unit. Moreover, our proposal for the translation of *separation* is to add the dichotomy *legal o de hecho* after the noun in order to include both concepts as the Spanish texts do. The below are, then, the resulting equivalences for this second group of vocabulary:

---

[101] *When the woman is married, consent from the husband will also be required unless they are legally or de facto separated, and they are shown to be so in a satisfactory mann*er. [Own translation]

[102] Conceptos Jurídicos. (n.d.). *separación de hecho*. In ConceptosJuridicos.com. Accessed on 10 May 2022: https://bit.ly/3NRNEqN

[103] Conceptos Jurídicos. (n.d.). *separación matrimonial*. In ConceptosJuridicos.com. Accessed on 10 May 2022: https://bit.ly/38zmxRk

[104] Conceptos Jurídicos. (n.d.). *divorcio*. In ConceptosJuridicos.com. Accessed on 10 May 2022: https://bit.ly/3xb7kQs

T/P UNIT #	ENGLISH	POS	SPANISH	POS
6	divorce	n	divorcio	n
7	divorce	v	divorciarse	v
8	marital status	n ph	estado civil	n ph
9	marriage	n	matrimonio	n
10	parentage of the child	n ph	filiación del hijo, filiación matrimonial del hijo	n ph
11	parent-child status			
12	partnership	n	pareja de hecho	n ph
13	separate	v	separarse legalmente o de hecho	v
14	separation	n	separación legal o de hecho	n ph
15	spouse	n	cónyuge	n

Thirdly, we found different instances of terminology and phraseology related to the couple's and/or recipient's agreement to undergo treatment. In this group, we found many examples of idioms that are prototypical of each language. Thus, as we could expect, we had to look for potential equivalents based on the contexts where they appear. This is the result of our alignment:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
16	confirm	v	declarar	v
17	express written consent	n ph	consentimiento escrito específico previo	n ph
18	freely choose	v ph	prestar consentimiento formal, libre y expreso	v ph
19	have read and understood	col	haber leído, comprendido y suscrito	col
20	mutual and written agreement	col	consentimiento escrito de la pareja	col
21	pay	v	asumir + el coste económico	col
22	physician signature	n ph	firma del médico	n
			Fdo. El/La médico/a	col
23	signature	n	firma	n

Special attention should be paid to the equivalent for *physician signature* (T/P unit #22). Although we found an equivalent which could serve as the literal translation for the English phrase, we also found the abbreviation *Fdo. El/La médico/a*. Indeed, *Fdo.* is a common abbreviation used in the Spanish language, as can be found in the list of abbreviations provided in the Diccionario Panhispánico de Dudas (DPD)[105]:

ABBREVIATION	MEANING
Fdo.	firmado

[105] Real Academia Española (RAE). (2005). *abreviaturas*. In Diccionario Panhispánico de Dudas (DPD). Accessed on 10 May 2022: https://bit.ly/3xaaLqB

We can also appreciate that an initial capital letter is used deliberately. According to the DPD, although courtesy abbreviations are always written using an initial capital letter, in the rest of the cases the first letter may be capitalized based on the context or the status of the referent. In our example, since it refers to the signature of a physician, its first letter is capitalized accordingly. On the other hand, the reason why we aligned *Fdo. El/La médico/a* as an equivalent of *physician signature* is due to their location in the documents, which allows us to see that the context of use is the same. Let's have a look at the following screenshots retrieved from our texts:

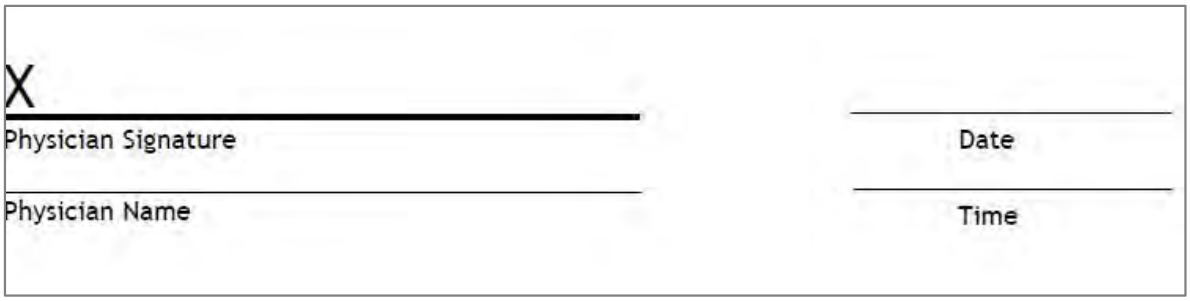


Figure 19. Signature section in English (Source: Stanford Medicine's informed consent)

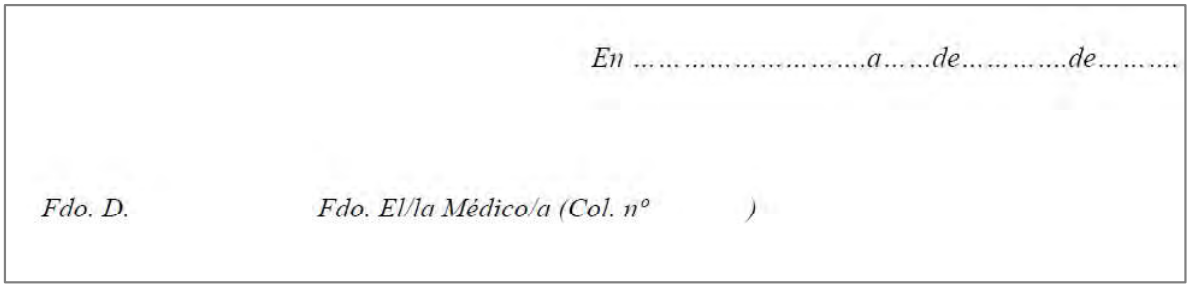


Figure 20. Signature section in Spanish (Source: HUCA's informed consent)

Note that, in the Spanish screenshot, we can see another abbreviation next to *Fdo. El/La médico/a*: *Col. nº,* which stands for *colegiado número*. It refers to the physician's identification number as a member of the Spanish College of Physicians. This is an example of cultural reference that would not make sense in an informed consent from an American fertility clinic, and this is the reason why we have removed it from our final proposal. Nevertheless, the USA has the National Provider Identifier Standard (NPI), which is defined in the Centers for Medicare & Medicaid Services' (CMS) website as follows[106]:

> *The National Provider Identifier (NPI) is a Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Standard. The NPI is a unique identification number for*

[106] Centers for Medicare & Medicaid Services (CMS), US government. (2021). *National Provider Identifier Standard (NPI*). Federal government website. Available from: https://go.cms.gov/3r8i0LQ (Accessed on 10 May 2022)

covered health care providers. Covered health care providers and all health plans and health care clearinghouses must use the NPIs in the administrative and financial transactions adopted under HIPAA. [...]As outlined in the Federal Regulation, The Health Insurance Portability and Accountability Act of 1996 (HIPAA), covered providers must also share their NPI with other providers, health plans, clearinghouses, and any entity that may need it for billing purposes.

The NPI, then, is not used for the same purposes as the college number in Spain, and this is the reason why it is not present in our collection of informed consents and we have removed this concept from our translation proposal.

Continuing with the references made to the physician, mention must be made to the relationship of the patient(s) with him/her or the medical team, for which we found the following equivalences:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
24	based on the best medical judgment of	col	según el equipo médico	col
25	discuss with the physician	v ph	ser informado por el equipo médico	v ph
26	explain + INFORMATION	col	recibir + INFORMACIÓN	col

There are two cultural differences that called our attention in connection to the verb phrase *to discuss with the physician* (T/P unit #25), for which we found the equivalent *ser informado por el equipo médico*. First, because in the USA, there is one physician who is in continuous contact with the patient(s) and s/he is the one who explains the different steps to be made throughout the IVF process. In Spain, on the contrary, this role is occupied by the medical team as a whole and not by a unique leading figure. Second, because American patient(s) are supposed to *discuss* the conditions of their treatment with the physician, which means that they "investigate by reasoning or argument" (Merriam Webster dictionary[107]). In Spain, conversely, they *are informed*, meaning that *a priori* they do not have the opportunity to discuss anything with the medical team.

Another section included in this type of informed consent is the one referring to potential unforeseen events and to the likely outcomes of the treatment. In a broad sense, we found the following equivalences:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
27	fail	v	fracasar	v

[107] Merriam-Webster. (n.d.). *discuss*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3uhR6mV

28	in the event of	prep ph	en caso de	prep ph

In a narrow sense, two major scenarios may occur: the woman or couple may decide to withdraw their consent to have treatment or, in the worst-case scenario, the partner may pass away before the treatment concludes. Both cases are taken into consideration in the Spanish consents, as can be appreciated in the following alignment:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
29	withdrawal of consent	col	revocación del presente consentimiento	col
30	death of partner	col	fallecimiento del varón, fallecimiento del marido	col

The final area we found equivalents for is the one related to the endorsement of the informed consent and its validity over time. Firstly, we will present phrases related to the generalities of the document, i.e. how to select an item out of a list of options or justifications of scientific assertions or recommendations:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
31	check only one box	col	marque según proceda	col
32	current data	n ph (pl)	estado actual del conocimiento	col
33	current recommendations	n ph (pl)		
34	current studies	n ph (pl)		

As regards the validity of the document over time, we found one reference related to the time period during which it will be considered valid. In both documents, such period is the same, though in English it is expressed in years and in months:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
35	pass one (1) calendar year	prep ph	en los 12 meses siguientes, en los doce meses siguientes	prep ph
36	twelve (12) month period	n ph	12 meses, doce meses	n ph (pl)
37	within one (1) year	v ph	en los 12 meses siguientes, en los doce meses siguientes	prep ph

5. 2. 2. Pronominal adverbs

As regards the use of pronominal adverbs, we found that they are not as common as in other types of legal documents such as contracts, for instance. Since they are considered archaisms that add

unnecessary complexity to the text, we could argue that their scarcity might be due to simplicity reasons based on the audience to whom our informed consents are aimed. Particularly, it has to do with the Plain English Movement, according to which legal documents should use a clear and coherent language that contains words with everyday meaning (Felsenfeld, 1981: 410).

These are pronominal adverbs along with their equivalents as a result of our alignment process:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
38	hereby	adv	en este acto	prep ph
39	thereafter	adv	posteriormente	adv
40	whereby	adv	mediante	prep

In the case of *hereby* (T/P unit #38), we appreciated that it is used in the paragraph that precedes the patient's signature, as can be seen below:

	File	Left Context	Hit	Right Context
1	Columbia University Fertility Center - IVF.txt	fail to result in a pregnancy, I/we	hereby	agree not to sue and agree to hc
2	MGH Fertility Center - IVF.txt	or fail to result in a pregnancy, I	hereby	agree not to sue and agree to hc
3	MGH Fertility Center - IVF.txt	or fail to result in a pregnancy, I	hereby	agree not to sue and agree to hc
4	Overlake Reproductive Health - IVF-ICSI, ...	ate your choice below: ____I/we	hereby	CONSENT to allow the clinic to u
5	Overlake Reproductive Health - IVF-ICSI, ...	_____ __/__/____ ____I/we	hereby	DO NOT CONSENT to allow the
6	Overlake Reproductive Health - IVF-ICSI, ...	ccurred by the above date, I/we	hereby	waive any and all interest in said

Figure 21. Concordances with *hereby* (Source: AntConc)

And the same occurs in the texts that make up our Spanish corpus:

File	Left Context	Hit	Right Con
Centro Extremeño de Reproducción ...	mayor de edad, provisto de DNI nº_____	en este acto	presto mi consentimiento p
Centro Extremeño de Reproducción ...	mayor de edad, provisto de DNI nº_____	en este acto	presto mi consentimiento p
Hospital Universitario Central de Asturias ...	(Col. nº) Mayor de edad, provisto de DNI nº	en este acto	presto mi consentimiento a
SEF - Hoja informativa y consentimiento ...	e edad, provisto de DNI nº_____	en este acto	presto mi consentimiento a
Centro Extremeño de Reproducción ...	e/plaza _____ de _____,	en este acto	solicitamos la modificación
Hospital Universitario Central de Asturias ...	stado civil Con domicilio en la calle/plaza de	en este acto	solicitamos la modificación
SEF - Hoja informativa y consentimiento ...	_____ de _____,	en este acto	solicitamos la modificación
Hospital Universitario Central de Asturias ...	de DNI nº y domicilio en la calle/plaza de	En este acto	solicito la SUSPENSIÓN de
Centro Extremeño de Reproducción ...	_____ _____ de _____,	en este acto	solicito la SUSPENSIÓN de
SEF - Hoja informativa y consentimiento ...	de ,	en este acto	solicito la SUSPENSIÓN de

Figure 22. Concordances with *en este acto* (Source: AntConc)

5. 2. 3. Performative verbs

Concerning the performative verbs that we found throughout the selected informed consents, we noticed that they are used to convey three main meanings that we will illustrate below. The first is the case of the verb *to acknowledge* used in the sense conveyed in Merriam Webster dictionary's entry #3c:

> **acknowledge (verb)**[108]
> 3c: to make known the receipt of

This meaning can be perceived by seeing its use in context:

> *We **acknowledge** that we have read all pages of this consent form and all of our questions concerning the treatment have been fully answered to our satisfaction.* (Retrieved from Boston IVF's informed consent)

This is precisely the reason why we chose two possible translation options out of the different verbs that are used in the Spanish documents, which results in the following result:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
41	acknowledge	v	afirmar, declarar	v

Let's have a look at the contexts where both Spanish verbs appear:

CONTEXT WHERE *AFIRMAR* IS USED	CONTEXT WHERE *DECLARAR* IS USED
*De igual forma en la consulta médica **he/hemos afirmado**:* *No padecer enfermedades congénitas, hereditarias o infecciosas transmisibles con riesgo grave para la posible descendencia.*	***DECLARO/DECLARAMOS**:* [...] *3) Haber recibido, anteriormente a este acto, información verbal y escrita* [...]

Table 22. Uses of *afirmar* and *declarar* (Source: CERHA's informed consent)

Moreover, the second is the case of *to consent* and *to agree*, which are used interchangeably throughout the document. In fact, the Merriam Webster dictionary, in its definition of *consent* as an intransitive verb, refers the reader to the verb *agree*:

[108] Merriam-Webster. (n.d.). *acknowledge*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3NXlZVp

consent (intransitive verb)[109]

to give assent or approval: AGREE. (e.g. *consent to being tested*)

agree (intransitive verb)[110]

1b: to consent to as a course of action. (e.g. *She agreed to sell him the house*)

Bearing this in mind, the two performative verbs encountered in Spanish that convey the same meaning are *consentir* and *autorizar*, the first being taken as a literal equivalent of the original. The resulting alignment would read as follows:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
42	agree	v	consentir, autorizar	v
43	consent			

Finally, the woman or couple have to make certain decisions throughout the document, such as that concerning the disposition of their unused embryos. This decision must be made in both the US and Spanish consents, and in the former case it is expressed through several performative verbs that we have included in the alignment shown below, where only one equivalent was found in Spanish:

T/P UNIT #	ENGLISH	POS	SPANISH	POS
44	choose	v	desear	v
45	desire	v		
46	make the decision of	v ph		
47	wish	v		

The reason why we aligned all these English options with a single terminological unit in Spanish is due, once again, to context. The following table shows our options as they appear in some of the consent forms selected from US fertility clinics:

VERB/VERB PHRASE	CONTEXT	SOURCE
choose	*Regarding the number of eggs to expose to sperm, we (I)* ***choose****:* [...]	Stanford Medicine
desire	*I/we do not wish to freeze excess embryos. I/we* ***desire*** *the following disposition of any excess embryos:* [...]	

[109] Merriam-Webster. (n.d.). *consent*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3v12geT

[110] Merriam-Webster. (n.d.). *agree*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/38Azryr

make the decision of	*Excess Embryos: I/we* ***make*** *the following* ***decision*** *with respect to excess embryos remaining following my/our treatment:* [...]	
wish	*I/we DO NOT* ***wish*** *to donate to another person/couple.*	Columbia University Fertility Center

Table 23. Performative verbs examples in English

As we can see by reading these examples, these verbs are always used when making reference to the disposition of excess embryos. Thus, we did the same with our Spanish informed consents–we looked for the same context and got the following results:

VERB	CONTEXT	SOURCE
desear	***Deseo/deseamos*** *que se generen TODOS los embriones posibles como consecuencia de la inseminación o microinyección de todos los ovocitos obtenidos.*	SEF
	No ***deseo/deseamos*** *la generación de embriones sobrantes, por lo que autorizamos la inseminación de un máximo de X ovocitos.*	HUCA
	Que el destino que ***deseo/deseamos*** *dar a los posibles ovocitos y/o preembriones congelados sobrantes sería (marcar lo que proceda):* [...]	SEF

Table 24. Performative verb example in Spanish

5. 3. English terminology and phraseology with no Spanish equivalent

The examination of our comparable corpus provided us with highly interesting results as we saw in Sections 5.2 and 5.3. However, the alignment process also showed many instances of English medical and legal terminology and/or phraseology for which no Spanish equivalent was found, and consequently they could not be included in our bilingual glossary. In the vast majority of the cases, it is due to the simple fact that the section containing such units does not exist in the Spanish informed consents. We classified the instances gathered from our English corpus into different thematic groups that are listed below:

1. Medications and their effects;
2. Stages of embryo development;
3. Potential birth defects associated with IVF/ICSI;
4. Risks associated with IVF pregnancies;
5. Laws and authorities regulating ART in the USA.

In connection to the first group, medications and their effects, we noticed that all US informed consents include an introductory section where the different medications that the woman will take for IVF treatment are listed and thoroughly explained, enumerating the specific hormones involved.

As a result, we found a considerable number of units that could not be included in our glossary as they are not specified in the Spanish consents. The following list contains the main medications included in the English informed consents:

T/P UNIT #	ENGLISH	POS
1	estradiol	n
2	GnRH-agonists (GnRH-a)	n ph (pl)
3	GnRH-antagonists	n ph (pl)
4	gonadotropins	n (pl)
5	oral contraceptive pills	n ph (pl)
6	progesterone	n

We can appreciate cases of hyphenation, as in *GnRH-agonists* and *GnRH-antagonists* (T/P units #2 and #3, respectively), which simultaneously contain *GnRH*, which is the abbreviation of *gonadotropin-releasing hormone*[111]. We encountered further cases of hyphenation and the use of initialisms when mentioning certain hormones used to stimulate the ovaries, as can be appreciated in the following list:

T/P UNIT #	ENGLISH	POS
7	anti-Müllerian hormone (AMH)	n ph
8	follicle-stimulating hormone (FSH)	n ph
9	human chorionic gonadotropin (hCG)	n ph
10	luteinizing hormone (LH)	n ph

The case of *anti-Müllerian hormone (AMH)* represents an example of eponymy. *Müllerian* is used in honor of Johannes Peter Müller, the physiologist who described the Müllerian ducts for the first time in 1830.

T/P units #7-10 are subject-specific phraseological units that are used in their abbreviated form throughout the document after having mentioned the full form the first time they are used. By way of an example, we found that they are used to create hyphenated compounds such as *LH-like activity* or *low-dose hCG*.

In the second thematic group, we included the terminology and phraseology related to the field of embryology. Indeed, when they inform the patient about the embryo culture process, certain stages

[111] Merriam-Webster. (n.d.). *GnRH*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3LNYCM6

of embryonic development are mentioned. The terminological and phraseological units found are listed below:

T/P UNIT #	ENGLISH	POS
11	zygote	n
12	2PN embryo	n ph
13	blastocyst	n
14	inner cell mass	n ph
15	trophectoderm	n

The term *2PN embryo* is a very good example of what Kuzmina *et al.* (2015: 551) defined as *alphanumeric abbreviation*[112], a type of initialism that is very frequent in medicine. Its meaning can be inferred from the information provided in one of the documents:

> *At this stage, normal development is evident by the still single cell* ***having 2 nuclei****; this stage is called a 'zygote' or a '2PN embryo'.* (Source: Stanford IVF's informed consent)

Special mention should be made to the cases of *zygote* and *blastocyst*, as they both are terms with a Greek-Latin base. The noun *zygote* comes from Greek *zygotos* (literally, *yoked*). *Blastocyst*, on the other hand, is the result of joining *blasto-* and *-cyst* as can be seen in the following structural analysis[113]:

TYPE OF COMPONENT	**blasto**	/	**cyst**
	↓		↓
	PREFIX		ROOT
MEANING	↓		↓
	germ, bud		sac
ORIGIN	↓		↓
	Greek *blasto-*		Latin *cystis*

Table 25. Etymological analysis of *blastocyst*

The third thematic group containing terms without an equivalent is the one related to the potential birth defects associated with IVF offspring, a section that is not included in neither of the Spanish consent forms. In the English documents, we found the following potential birth defects:

T/P UNIT #	ENGLISH	POS
16	Beckwith-Weidermann Syndrome	n ph

[112] See Section 2.7.1.4.

[113] Online Etymology Dictionary. (n.d.). *blastocyst*. In Etymonline.com. Accessed on 10 May 2022: https://bit.ly/3DOTyo6

17	chromosomal microdeletion	n ph
18	deletion	n
19	gene mutation	n ph
20	imprinting disorder	n ph
21	prematurity	n
22	sex chromosome abnormality	n ph
23	translocation	n

We can see another example of eponymy with the unit *Beckwith-Weidemann Syndrome*, which is named after the American pediatric pathologist John Bruce Beckwith and the German pediatrician Hans-Rudolf Wiedemann[114].

Fourthly, the US consent forms devote a subsection to enumerate the potential risks in singleton IVF-conceived pregnancies, where they list several pregnancy complications, including:

T/P UNIT #	ENGLISH	POS
24	cesarean delivery	n ph
25	gestational diabetes	n ph
26	placenta previa	n ph
27	placental abruption	n ph
28	pre-eclampsia	n ph

Finally, in connection to the legal terminology and phraseology found, there are several cases which were not included in our glossary because no alignment was possible. In this case, the differences are due to the cultural differences between the USA and Spain as well as to the different laws regulating the field of ART. Taking this into consideration, it is only obvious that no equivalence was observed.

An example can be found in the case of *Patient Initials*, which is included in different sections where the patients have to choose from a list of potential options. Instead of asking them to sign every time they check an item, they are required to initial the document. As a verb, *initial* has the following meaning:

[114] Borjas Mendoza, P.A., & Mendez, M.D. (2022). *Beckwith Wiedemann Syndrome*. In StatPearls. StatPearls Publishing. Available from: https://bit.ly/38o2pRU (Accessed on 10 May 2022)

initial (verb)[115]

2. to authenticate or give preliminary approval to by affixing the initials of an authorizing representative

Although adding the initials to the pages of legal documents such as contracts is also a common practice in Spain, our informed consents do not ask the patients to do so—only their signatures are required.

Furthermore, we found an instance of the expression *act of God* that we explained in Section 2.7.2.3 in reference to the use of euphemisms in legal language. According to Alcaraz Varó & Hughes (2014: 13), this expression invokes divine intervention to describe unfortunate situations such as natural disasters. Let's see our particular example in context:

> *Stanford takes great care of all eggs, embryos and sperm in the lab. In spite of reasonable precautions, there are many reasons why pregnancy may not happen:*
> [...]
> *Earthquakes, hurricanes, floods or other **"acts of God"**, including bombings or other terrorist acts, could destroy the laboratory or its contents, including any sperm, eggs or embryos.* (Source: Stanford IVF's informed consent)

Finally, multiple references to US entities or federal laws are present in our set of informed consents, such as the ones included in the following list:

T/P UNIT #	ENGLISH	POS
29	1992 Fertility Clinic Success Rate and Certification Act	n ph
30	American Society for Reproductive Medicine	n ph
31	Federal Center for Disease Control and Prevention (CDC)	n ph
32	Public Health Act	n ph

In these cases, it is only obvious that no equivalent was to be found in the Spanish consent forms, considering that each contains references to the laws, acts and organisms governing ART in their corresponding country.

[115] Merriam-Webster. (n.d.). *initial*. In Merriam-Webster Dictionary. Accessed on 10 May 2022: https://bit.ly/3uqPhUZ

5. 4. Results: Bilingual terminological and phraseological glossary

T/P UNIT #	TYPOLOGY	ENGLISH	POS	SPANISH	POS
			A		
1	LEGAL	acknowledge	v	afirmar, declarar	v
2	MEDICAL	adnexal torsion	n ph	torsión ovárica	n ph
3	LEGAL	agree	v	consentir, autorizar	v
4	MEDICAL	anesthesia	n	anestesia	n
5	LEGAL	applicable law	n ph	marco jurídico regulador	n ph
6	MEDICAL	assisted hatching	n ph	eclosión asistida	n ph
			B		
7	LEGAL	based on the best medical judgment of	col	según el equipo médico	col
8	MEDICAL	best-appearing embryos	n ph (pl)	embriones (finales) de buena calidad	n (pl)
9	MEDICAL	best-developed embryos	n ph (pl)		
10	MEDICAL	blood test	n ph	análisis de sangre	n ph
			C		
11	LEGAL	check only one box	col	marque según proceda	col

12	LEGAL	choose	v	desear	v
13	MEDICAL	chorionic villus sampling (CVS)	n ph	biopsia de corión, biopsia corial	n ph
14	LEGAL	confirm	v	declarar	n
15	LEGAL	consent	v	consentir, autorizar	v
16	MEDICAL	cryopreservation	n	criopreservación	n
17	MEDICAL	culture	n	cultivo	n
18	LEGAL	current data	n ph (pl)	estado actual del conocimiento	col
19	LEGAL	current recommendations	n ph (pl)		
20	LEGAL	current studies	n ph (pl)		
			D		
21	LEGAL	death of partner	col	fallecimiento del varón, fallecimiento del marido	col
22	LEGAL	desire	v	desear	v
23	LEGAL	discuss with the physician	v ph	ser informado por el equipo médico	v ph
24	MEDICAL	disposition of the embryos	n ph	destino de los embriones	n
				disponer de embriones	v ph
25	LEGAL	divorce	n	divorcio	n
26	LEGAL	divorce	v	divorciarse	v
27	MEDICAL	donation for research	n ph	donación con fines de investigación	n ph

28	MEDICAL	donation to another couple	n ph	donación con fines reproductivos, donación para otras parejas	n ph
			E		
29	MEDICAL	ectopic pregnancy	n ph	embarazo ectópico	n ph
30	MEDICAL	egg	n	óvulo	n
31	MEDICAL	egg maturation	n ph	maduración final de los óvulos/ovocitos	n ph
32	MEDICAL	egg retrieval	n ph	punción de los ovarios, punción ovárica	n ph
33	MEDICAL	egg-containing follicles	n ph (pl)	folículos en desarrollo, folículos en cuyo interior se encuentran los óvulos	n ph (pl)
34	MEDICAL	embryo	n	embrión	n
35	MEDICAL	embryo attachment	n ph	implantación embrionaria, implantación del embrión	n ph
36	MEDICAL	embryo development	n ph	desarrollo embrionario	n ph
37	MEDICAL	embryo donation	n ph	donación de embriones	n ph
38	MEDICAL	embryo transfer	n ph	transferencia de embriones, transferencia embrionaria	n ph
39	MEDICAL	endometrium	n	endometrio	n
40	MEDICAL	excess embryos	n ph (pl)	embriones (viables) no transferidos, embriones sobrantes	n ph (pl)
41	LEGAL	explain + INFORMATION	col	recibir + INFORMACIÓN	col
42	LEGAL	express written consent	n ph	consentimiento escrito específico previo	n ph
43	MEDICAL	extra embryos	n ph (pl)	embriones (viables) no transferidos, embriones sobrantes	n ph

			F		
44	LEGAL	fail	v	fracasar	v
45	MEDICAL	Fallopian tubes	n ph (pl)	trompas (de Falopio)	n ph (pl)
46	MEDICAL	fertility drug	n ph	medicación, fármaco	n
47	MEDICAL	follicular aspiration	n ph	aspiración de los folículos	n ph
48	LEGAL	freely choose	v ph	prestar consentimiento formal, libre y expreso	v ph
49	MEDICAL	freezing	n	congelación	n
50	MEDICAL	fresh embryo transfer	n ph	transferencia de embriones en fresco	n ph
51	MEDICAL	fresh embryos	n ph (pl)	embriones frescos	n ph (pl)
52	MEDICAL	frozen embryo transfer	n ph	transferencia de embriones congealados	n ph
53	MEDICAL	frozen embryos	n ph (pl)	embriones congelados, embriones criopreservados	n ph (pl)
			G		
54	MEDICAL	gametes	n (pl)	gametos	n (pl)
55	MEDICAL	good-quality embryos	n ph (pl)	embriones (finales) de buena calidad	n ph (pl)
			H		
56	MEDICAL	have a child naturally	v ph	quedarse embarazada de forma natural, conseguir un embarazo de forma espontánea	v ph

57	LEGAL	have read and understood	col	haber leído, comprendido y suscrito	col
58	LEGAL	hereby	adv	en este acto	prep ph
59	MEDICAL	hormone	n	hormona	n
			I		
60	MEDICAL	implantation	n	implantación embrionaria, implantación del embrión	n ph
61	LEGAL	in accordance with	prep ph	de acuerdo con	prep ph
62	LEGAL	in the event of	prep ph	en caso de	prep ph
63	MEDICAL	In Vitro Fertilization (IVF)	n ph	Fecundación in Vitro (FIV) convencional	n ph
64	MEDICAL	increased ovarian size	n ph	aumento del tamaño ovárico	n ph
65	MEDICAL	infertile	adj	estéril	adj
66	MEDICAL	infertility	n	esterilidad	n
67	MEDICAL	Introcytoplasmic Sperm Injection (ICSI)	n ph	microinyección espermática (ICSI)	n ph
68	MEDICAL	IVF cycle	n ph	ciclo de fecundación in vitro, ciclo de FIV	n ph
69	MEDICAL	IVF process	n ph		
70	MEDICAL	IVF treatment	n ph		
71	MEDICAL	IVF-conceived baby	n ph	niño nacido de FIV/ICSI	n ph
			L		

72	LEGAL	legal considerations	n ph (pl)	información legal	n ph
				aspectos legales	n ph (pl)
73	LEGAL	legal requirements	n ph (pl)	mandato legal	n ph
			M		
74	LEGAL	make the decision of	v ph	desear	v
75	LEGAL	marital status	n ph	estado civil	n ph
76	LEGAL	marriage	n	matrimonio	n
77	MEDICAL	medication	n	medicación, fármaco	n
78	MEDICAL	miscarriage	n	aborto espontáneo	n ph
79	MEDICAL	multiple pregnancy	n ph	embarazo múltiple, gestación múltiple	n ph
80	LEGAL	mutual and written agreement	col	consentimiento escrito de la pareja	col
			N		
81	MEDICAL	natural pregnancy	n ph	embarazo natural	n ph
82	MEDICAL	normal embryos	n ph (pl)	embriones normales, embriones viables, embriones aptos, embriones con características biológicas de viabilidad	n ph (pl)
			O		
83	MEDICAL	offspring	n	descendencia	n
84	MEDICAL	oocyte	n	ovocito	n

85	MEDICAL	oocyte retrieval	n ph	punción de los ovarios, punción ovárica	n ph
86	MEDICAL	Ovarian Hyperstimulation Syndrome (OHSS)	n ph	síndrome de hiperestimulación ovárica	n ph
87	MEDICAL	ovarian response	n ph	respuesta ovárica, respuesta a la estimulación ovárica	n ph
88	MEDICAL	ovarian torsion	n ph	torsión ovárica	n ph
89	MEDICAL	ovarian twisting	n ph	torsión ovárica	n ph
90	MEDICAL	ovary	n	ovario	n
91	MEDICAL	ovulation induction	n ph	estimulación de los ovarios, estimulación ovárica	n ph
			P		
92	LEGAL	parentage of the child	n ph	filiación del hijo, filiación matrimonial del hijo	n ph
93	LEGAL	partnership	n	pareja de hecho	n ph
94	LEGAL	pass one (1) calendar year	v ph	en los 12 meses siguientes, en los doce meses siguientes	prep ph
95	LEGAL	pay	v	asumir + EL COSTE ECONÓMICO	col
96	LEGAL	physician signature	n ph	firma del médico	n ph
				Fdo. El/La médico/a	col
97	MEDICAL	pregnancy	n	embarazo, gestación	n
98	MEDICAL	pregnancy rate	n ph	tasa de embarazo por transferencia de embriones	n ph
99	MEDICAL	Preimplantation Genetic Diagnosis (PGD)	n ph	Diagnóstico Genético Preimplantacional (DGP)	n ph
100	MEDICAL	Preimplantation Genetic Screening (PGS)	n ph		

101	MEDICAL	Preimplantation Genetic Testing (PGT)	n ph		
102	MEDICAL	premature ovulation	n ph	ovulación espontánea	n ph
			R		
103	MEDICAL	recipient	n	(mujer) receptora de las técnicas, usuaria de las técnicas	n ph
104	MEDICAL	recipient partner	n ph		
105	MEDICAL	remaining embryos	n ph (pl)	embriones (viables) no transferidos, embriones sobrantes	n ph (pl)
			S		
106	LEGAL	separate	v	separarse legalmente o de hecho	v ph
107	LEGAL	separation	n	separación legal o de hecho	n ph
108	LEGAL	signature	n	firma	n
109	MEDICAL	sperm	n	espermatozoide	n
110	LEGAL	spouse	n	cónyuge	n
111	MEDICAL	storing of any unused embryos	n ph	mantenimiento de la congelación embrionaria	n ph
112	MEDICAL	success rates	n ph (pl)	tasas de éxito, probabilidades de éxito, posibilidades de éxito	n ph (pl)
113	MEDICAL	surplus embryos	n ph (pl)	embriones (viables) no transferidos, embriones sobrantes	n ph
			T		
114	MEDICAL	thawing of embryos	n ph	descongelación de embriones	n ph

115	LEGAL	thereafter	adv	posteriormente	adv
116	MEDICAL	third-party donor	n ph	donante	n ph
117	MEDICAL	transvaginal ultrasound	n ph	ecografía vaginal, visión ecográfica por vía vaginal	n ph
118	LEGAL	twelve (12) month period	n ph	12 meses, doce meses	n ph (pl)
			U		
119	LEGAL	under the provision of	prep ph	estar constituido por	v ph
				seguirse lo dispuesto en	v ph
120	MEDICAL	unused embryos	n ph (pl)	embriones (viables) no transferidos, embriones sobrantes	n ph
121	MEDICAL	uterine cavity	n ph	cavidad uterina	n ph
122	MEDICAL	uterine lining	n ph	capa interna del útero	n ph
			V		
123	MEDICAL	viable embryos	n ph (pl)	embriones normales, embriones viables, embriones aptos, embriones con características biológicas de viabilidad	n ph (pl)
			W		
124	LEGAL	whereby	adv	mediante	adv
125	LEGAL	wish	v	desear	v
126	LEGAL	withdrawal of consent	col	revocación del presente consentimiento	col
127	LEGAL	within one (1) year	prep ph	en los 12 meses siguientes, en los doce meses siguientes	prep ph

6. Quantitative analysis and results

The qualitative analysis developed in the previous section and the resulting bilingual glossary of terminological and phraseological units allowed us to conduct a quantitative analysis of the data obtained. The first and most obvious data that we compared were the total number of tokens present in the informed consents from US fertility clinics versus those of the informed consents from Spanish centers. To this end, we used AntConc's counter, and the results of each corpus were the following:

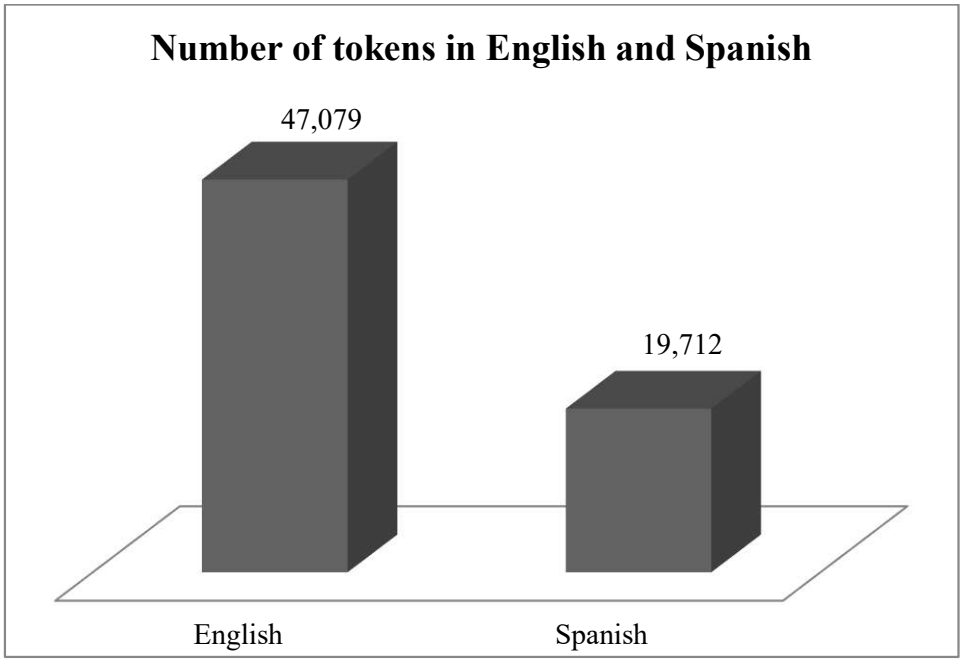


Figure 23. Bar graphs with the no. of tokens in the corpora

As it is evident from these illustrative bar graphs and the figures obtained via AntConc, the number of words of our English corpus is more than twice the number of the Spanish one, which adds evidence to our initial hypothesis that the US consents are richer and more detailed than the Spanish documents. Actually, this was already demonstrated in section 5.3 when we enumerated the English terminological and phraseological units with no Spanish equivalent, for the reason was simply that the section where they appeared was nonexistent in Spain's informed consents.

Continuing with our statistical analysis of the terminological and phraseological units identified in our comparable corpus, we used AntConc's Word List tool in order to make a frequency list containing all the tokens in each corpus ordered from the most frequent to the least. When this tool is used, the resulting list is headed by 'stopwords', that is to say, articles, determiners, pronouns, prepositions, etc., which are irrelevant for the purposes of our analysis. Thus, we removed them

from the resulting list and selected the top twenty-five most frequent terms in both languages, and as a result we obtained the following frequency lists:

	ENGLISH		SPANISH	
RANK	TERM	FREQUENCY	TERM	FREQUENCY
1	embryos	462	embriones	132
2	eggs	332	consentimiento	102
3	risk	288	fecundación	87
4	pregnancy	278	mujer	85
5	sperm	207	transferencia	82
6	treatment	183	tratamiento	77
7	transfer	171	reproducción	68
8	patient	164	fiv	63
9	icsi	144	número	60
10	multiple	113	embarazo	56
11	children	111	icsi	55
12	birth	108	riesgos	54
13	retrieval	108	centro	52
14	consent	105	pareja	51
15	fertilization	104	ovocitos	50
16	number	102	información	49
17	fertility	101	óvulos	48
18	frozen	99	útero	46
19	freezing	89	técnica	45
20	studies	87	ciclo	44
21	procedure	86	edad	44
22	partner	85	médico	42
23	injection	82	firma	41
24	infertility	77	punción	41
25	cycle	76	paciente	40

Table 26. Top 25 most frequent terminological units

In the tables above, we can observe that *embryos* and its equivalent *embriones* are on top of both lists. Note that, as it is only obvious, the frequency of the Spanish terminology is lower due to the different number of tokens in each corpus.

Moreover, we continued our analysis in order to spot the most frequent phraseology in both languages. To this end, we used AntConc's N-gram tool and deleted combinations included in the list that had no meaning for the purposes of our research, mostly compound conjunctions. Then, we followed the same procedure that in the analysis of the most frequent terminology, and obtained the following list:

	ENGLISH		SPANISH	
RANK	PHRASE	FREQUENCY	PHRASE	FREQUENCY
1	in vitro fertilization	47	fecundación in vitro	51
2	egg retrieval	32	reproducción asistida	41
3	birth defects	27	microinyección espermática	31
4	intracytoplasmic sperm injection	25	donación con fines	24
5	embryo transfer	21	en el laboratorio	22
6	in accordance with	19	técnicas de reproducción	20
7	in the event of	18	mayor de edad	19
8	in the lab	18	fecundación in vitro o microinyección	18
9	number of embryos	17	consentimiento informado	18
10	icsi procedure	16	en el útero	17
11	multiple pregnancy	15	icsi con transferencia	16
12	disposition of embryos	15	reproducción humana asistida	16
13	eggs and sperm	15	número de embriones	14
14	ivf pregnancies	15	transferidos al útero	14
15	ovarian hyperstimulation syndrome	15	equipo médico	13
16	side effects	15	en este acto	13
17	injection site	15	capacidad de obrar	12
18	number of fetuses	14	fines de investigación	12
19	assisted reproductive technology	13	transferencia embrionaria	12

20	date of birth	13		con fines reproductivos	11
21	fertility drugs	13		estimulación ovárica	11
22	general population	13		plazo máximo	11
23	frozen embryo transfer	12		congelación embrionaria	10
24	in the uterus	12		de buena calidad	9
25	into the uterus	12		fiv icsi	9

Table 27. Top 25 most frequent phraseological units

Again, as it happened with the list of the top twenty-five most common terms found in both corpora, the most frequent phrases coincide as well: *in vitro fertilization* and its equivalent *fecundación in vitro* are situated on the top of both lists. This was the expected result considering that the purpose of the selected informed consents is precisely to authorize such ART procedure.

On the other hand, we examined the parts of speech (PoS) of all the terms included in our bilingual glossary. Firstly, we counted the different PoS of the English terminological and phraseological units (T/P units) and then we did the same with the Spanish T/P units. The resulting breakdown of each T/P unit's PoS was gathered in the following bar graphs:

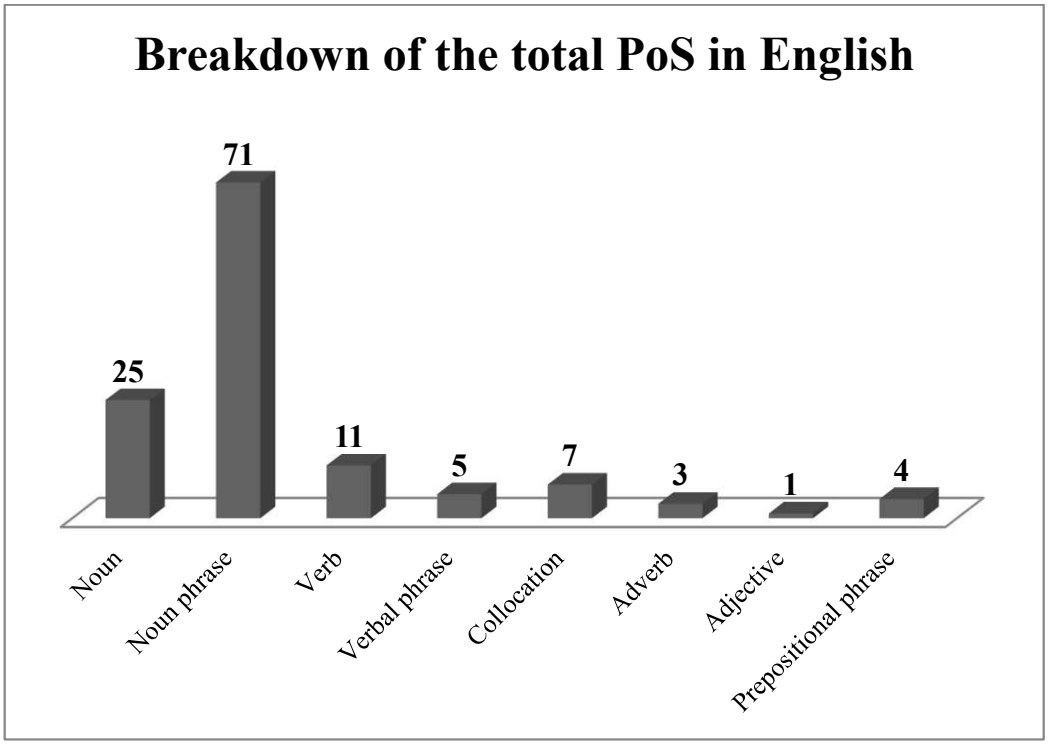


Figure 24. Bar graphs with the breakdown of the total PoS in English

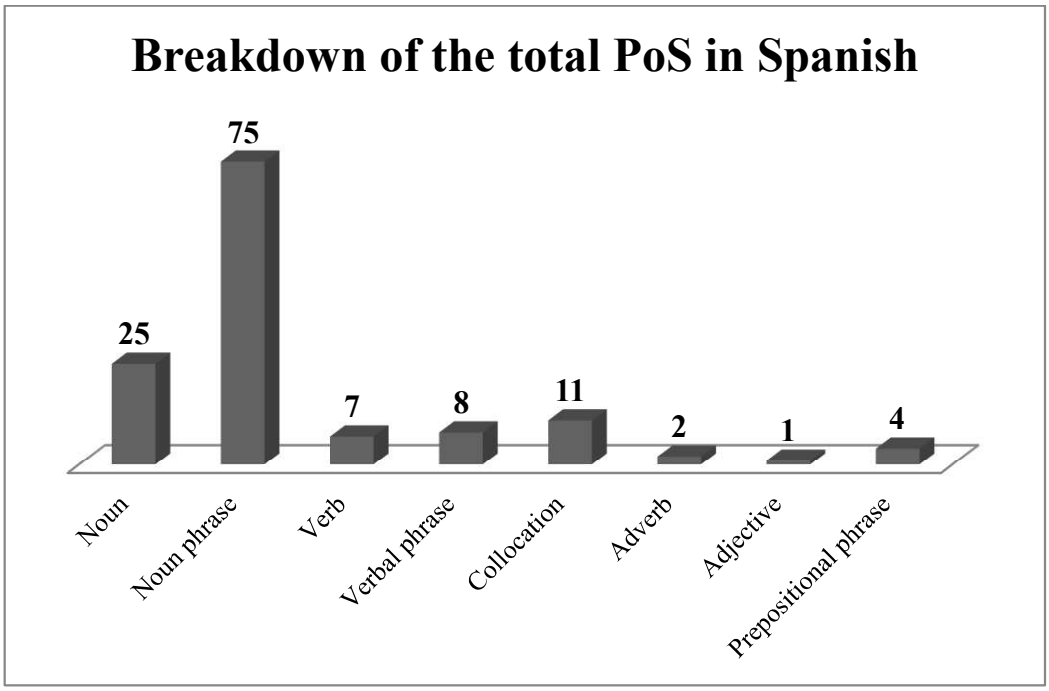


Figure 25. Bar graphs with the breakdown of the total PoS in Spanish

The slight differences in the number of T/P units for each category are due to the presence of a higher or lower number of equivalences and synonyms, which is not always the same in both languages. For example, in the case of noun phrases, the total number found in our glossary is 71, whilst in Spanish the figure rises to 75, thereby suggesting that synonymy as a resource is more used in Spanish than in English. Indeed, the total number of T/P units in English for which we found an equivalent in Spanish is 127, whilst the total amount of equivalents in Spanish rises to 133. This indicates that we found a greater number of alternatives (i.e. synonyms) in Spanish for each English T/P unit.

Finally, we calculated the percentage of medical and legal T/P units in both languages and compared them. The results, as shown in the pie charts below, are quite similar:

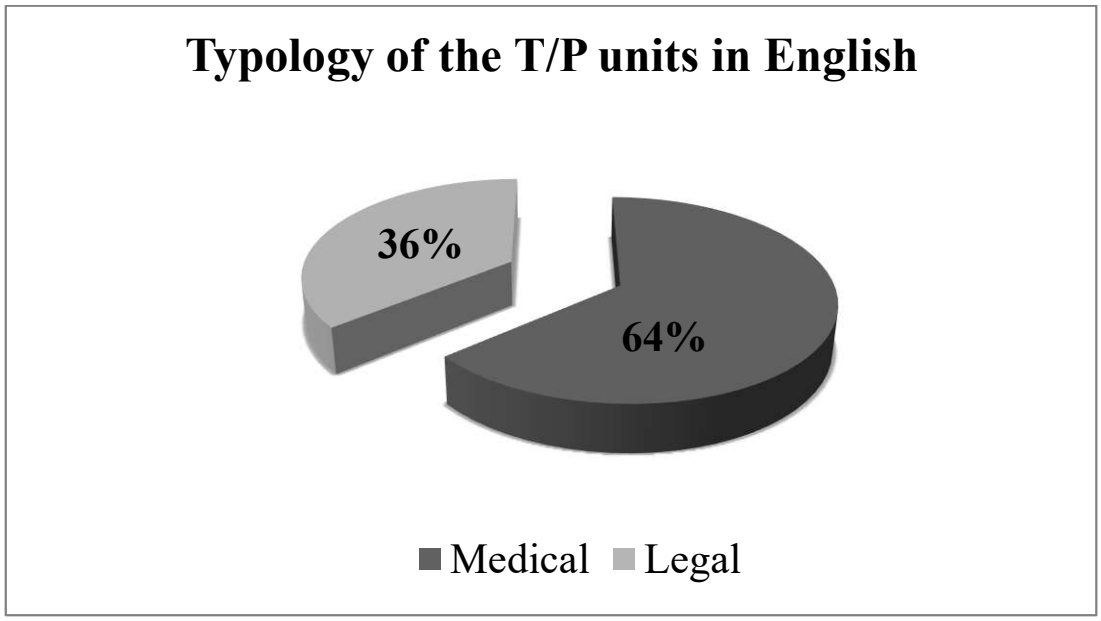


Figure 26. Pie chart with the percentage of medical and legal T/P units in English

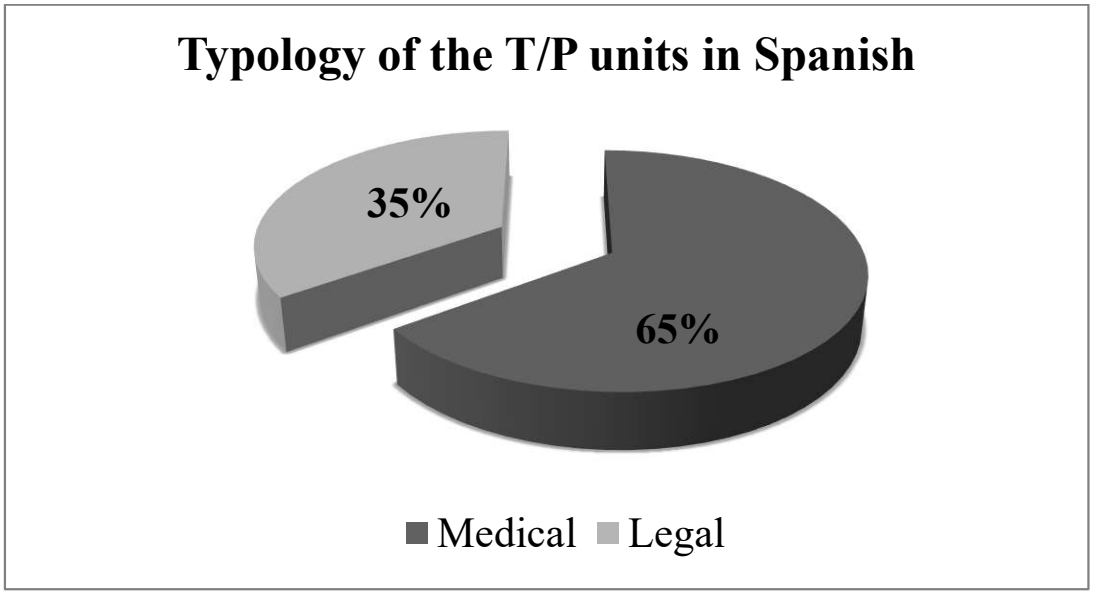


Figure 27. Pie chart with the percentage of medical and legal T/P units in Spanish

In both languages, we can see that the percentage of medical terminological and phraseological units is much larger than that of terminology and phraseology of legal nature. It should be noted that we did not find any case of terminology or phraseology that is 'mixed', i.e. which could be classified as either legal or medical.

7. Discussion

Firstly, the results obtained in our qualitative analysis suggest that working with a comparable corpus is useful, but only to some extent. Informed consents are highly subject to their cultural background, including the legal requirements of each country where ART treatments are carried out. In fact, not only did we find difficulties in connection to cultural and legal references, but also regarding the names of medications and their active ingredients. However, we could solve successfully the task of finding equivalences for the most important sections of the informed consents in both languages, thereby supporting McEnery & Xiao (2007: 7) assertion that specialized comparable corpora are especially helpful for particularly domain-specific terminological tasks.

Moreover, the qualitative analysis carried out in this research project demonstrates that working with comparable corpora is enormously useful when it comes to translating English compound or hyphenated words. As we already explained above, this mechanism is possible thanks to the versatility of the English language, which allows the speaker to put in one word the meaning of complex lexical units. The Spanish language does not allow for such level of versatility and it is only obvious that more extensive terminological or phraseological units will be needed as an equivalent. It is the case of the example we showed above with *egg-containing follicles*, for which we found *folículos en cuyo interior se encuentran los óvulos* in the Spanish texts. The use of a comparable corpus allowed us to find an equivalent that sounds perfectly natural in Spanish. Our qualitative analysis, then, supports Gornostay *et al*. (2013: 1)'s theory that comparable corpora are useful in the terminology extraction task.

On the other hand, due to the lack of data in Spanish in relation to the medications taken by the woman and their effects, the stages of embryo development, the potential birth defects associated with IVF/ICSI and the risks associated with IVF pregnancies, we could not propose an adequate equivalent for initialisms such as *2PN embryo* or terms with a Greco-Latin base such as *zygote or blastocyst* (see Section 5.3). Thus, we could not confirm whether certain eponyms found in the US consents are identical or different in the TL or whether the root of these Greco-Latin T/P units remains the same in the TL.

The analysis also provides a new insight into the relationship between ART patients and the medical team in each country. While in the United States phraseological units like *discuss with the physician* are used, we can see that the Spanish documents employ structures such as *ser informado por el equipo médico*. This suggests that the formal relationship patient-doctor is different in each

cultural scenario. This could be related to the concept of 'functional literacy' introduced by Blanco & Gutiérrez (2002: 322), according to which the ability to understand and communicate information about health is more developed in English-speaking countries due to better health education and information programs.

We now turn to the implication of our quantitative analysis. The first and most evident aspect is concerned with the differences in the number of total tokens of each corpus as we could see in Figure 24 (see Section 6), thereby proving our initial hypothesis (H1) that English consents are more detailed than Spanish ones. In our view, this could be directly linked to the explanation given by Montalt & González Davies (2007: 62), in which they indicate that the function of informed consents is to complement the oral communication between the doctor and the patients. Considering this, it could be argued that the tendency in Spain is to verbalize the procedures to be conducted, the medications and any potential doubt and/or query during medical visits, and then the informed consent is conceived as a mere written authorization, as pointed out by Gesinska (2020: 71). In fact, this could be the reason why the Spanish informed consents use the verb *autorizar*, whilst in English it is more common to find *agree* or *consent*.

In spite of the differences in the tokenization process and the cultural scenarios, the results of our quantitative analysis using AntConc's N-gram tool (see Tables 26 and 27, Section 6) indicate a great degree of similarity between the most frequent terminological and phraseological units in US and the Spain's informed consents, which suggests that the overall contents are the same in general terms. In fact, even the top one most frequent terms (*embryos* and *embriones*) and phrases (*in vitro fertilization* and *fecundación in vitro*) coincide in both languages. This demonstrates that the purpose of fertility clinics in both countries is the same: to provide information about the IVF process step by step, paying special attention to the risks involved and the procedures that the patients will undergo in order to obtain their written consent.

Similarly, the quantitative data contributes to proving our second hypothesis (H2), according to which there is a stronger presence of medical terminology and phraseology than legal in ART informed consents (see Figures 26 and 27, Section 6). Although the level of formality of the texts is that of legal discourse and the format resembles that of a contract, the main purpose of this type of documents is to inform the patients about the different procedures and medications that they are going to go through during the IVF journey. For this reason, it is only logical that the majority of the linguistic contents included in it have a medical nature. However, it is beyond the scope of this

study to determine whether greater focus should be introduced at the possibility of inserting further legal sections to authorize or agree to certain procedures and/or fertility drugs, or to make the signatories more aware that they are signing a medico-legal document and not just a medical information leaflet. These results build on existing evidence provided by Gallardo San Salvador (2012: 5), who observes the following characteristics of medico-legal texts: 1) the message has a medical nature and 2) the code, channel and receiver are all related to the legal field (see Section 2.5).

Finally, we can see in Figures 24 and 25 (see Section 6) that the parts of speech in each language are almost the same, with the exception of a few cases. This observation might suggest that medical and legal discourse in both English from the USA and Spanish from Spain is similar in connection to the communicative function and usage of the terminology and phraseology. It should be reminded that, as explained by Gallego Borghini (2015b: 23), one of the predominant communicative functions of informed consents is the descriptive (representative) one. Moreover, the bar graph shows that the most frequent PoS in both languages are noun phrases. This suggests that informed consents of assisted reproduction treatments contain a stronger presence of phraseology than single-word terminology, for almost all units found are formed by two or more words as can be seen in the bilingual glossary that we set out above. Thus, our third hypothesis (H3) is confirmed as well.

8. Conclusions

This research aimed to determine whether informed consents offered to patients by US fertility clinics are more detailed than the consents of Spanish clinics. Based on the qualitative analysis of the comparable corpus and the subsequent quantitative analysis of the data collected, it can be concluded that the document that American clinics offer to the patient(s) is more exhaustive than that of Spanish clinics, thereby proving our first hypothesis (H1). This is especially noticeable in the data we presented in Section 5.3, ENGLISH TERMINOLOGY AND PHRASEOLOGY WITH NO SPANISH EQUIVALENT. There, we listed a total of thirty-two terminological and phraseological units for which no equivalent could be found in the alignment process mainly because the Spanish texts lack the section where these T/P units are located. References to medications and their effects, stages of embryo development, potential birth defects associated with IVF/ICSI, and risks associated with IVF pregnancies are absent or mentioned very briefly in Spanish consents, hence the impossibility of finding an equivalent.

Furthermore, some of the T/P units that were found in Section 5.3 had no Spanish equivalent due to evident cultural differences between the United States and Spain, namely the names of laws and organisms regulating the ART field (e.g. *1992 Fertility Clinic Success Rate and Certification Act, American Society for Reproductive Medicine, Federal Center for Disease Control and Prevention*...). These results indicate that comparable corpora are useful when it comes to finding a translation equivalent for medical and legal terminology and phraseology as long as it refers to the names of body parts, diseases, side effects of the medications, marital status of the patient(s), etc. but not when it comes to finding equivalences to T/P units that exist only as a part of a particular cultural background. Our conclusion, then, is that parallel corpora are more adequate when cultural and social elements are part of the source text.

Comparable corpora are also highly useful when it comes to avoiding translationese, that is to say, the influence of the source language in the target language (Gellerstam, 1986: 88), which was explained in Section 2.4. herein. In this sense, we strongly agree with McEnery & Xiao (2007) when they assert that comparable corpora help to prevent the influence of the source text in the target text. We found very illustrative examples of this usefulness in the cases of *infertility* and its equivalent *esterilidad* instead of *infertilidad*, as we may suspect at first glance, and the same applies to *infertile* and *estéril* instead of *infértil*. Another example is the case of *fresh embryo transfer*, which a priori would be translated as *transferencia de embriones frescos*, considering that the equivalent that we found for *fresh embryos* is *embriones frescos*. However, in this case, the equivalent is *transferencia de embriones en fresco* as our comparable corpus revealed. Furthermore, the case of *egg-containing follicles*, for which we found *folículos en cuyo interior se encuentran los óvulos,* is a perfect example of how illustrative a comparable corpus can turn out to be.

By analyzing the most frequent terminology and phraseology found in both the English and the Spanish corpora, this Master's dissertation has shown that the terms for which we have found an alignment are common to both languages, with slight differences in some instances. This can be seen if we examine Tables 26 and 27 (see Section 6), where we listed the top 25 most frequent terminological and phraseological units found in our English and Spanish corpora. There we can see that, although not in the same order of frequency, most of the terms ranked coincide in both languages, as the following examples of terminological units retrieved from Table 26 demonstrate:

	ENGLISH		SPANISH	
EXAMPLE #	TERM	RANK	TERM	RANK
1	embryos	1	embriones	1
2	eggs	2	ovocitos	15
3	risk	3	riesgos	12
4	pregnancy	4	embarazo	10
5	treatment	6	tratamiento	6
6	transfer	7	transferencia	5

Table 28. Terminological equivalences ordered by frequency

Furthermore, this fact is also illustrated by the following examples of phraseological units retrieved from Table 27:

	ENGLISH		SPANISH	
EXAMPLE #	PHRASE	RANK	PHRASE	RANK
1	in vitro fertilization	1	fecundación in vitro	1
2	intracytoplasmic sperm injection	4	microinyección espermática	3
3	in the lab	8	en el laboratorio	5
4	number of embryos	9	número de embriones	13
5	assisted reproductive technology	19	reproducción asistida	2
6	in the uterus	24	en el útero	10

Table 29. Phraseological equivalences ordered by frequency

We can conclude, then, that the contents of informed consents in assisted reproduction treatments have a common purpose no matter the country where they are utilized–to provide the patient(s) with information as regards the different steps and procedures involved in the IVF process and to obtain her/their agreement to getting involved in the process. Thus, in spite of the American consents being more detailed than the Spanish ones, their communicative function and overall purpose is the same.

It should be noted, however, that these examples correspond to medical terminology and phraseology. In the case of T/P units of legal nature, we did not find any example of legal terminological units among the list of the top 25 most frequent ones (Table 26), which contributes to corroborating our second hypothesis (H2), in which we suspected that the presence of medical

terminology is greater than the legal terminology in this type of informed consents. Nevertheless, in the case of phraseological units, we found several examples in both English and Spanish, although no equivalents were found among the ranked elements. The following table includes the legal phraseology found among the top 25 most frequent phraseological units in English retrieved from Table 27:

	ENGLISH	
EXAMPLE #	PHRASE	RANK
1	in accordance with	6
2	in the event of	7
3	date of birth	20
4	general population	22

Table 30. Most frequent legal phraseology in English

And the table below shows the legal phraseology found among the top 25 most frequent phraseological units in Spanish, also from Table 27:

	SPANISH	
EXAMPLE #	PHRASE	RANK
1	mayor de edad	7
2	consentimiento informado	9
3	en este acto	13
4	capacidad de obrar	17

Table 31. Most frequent legal phraseology in Spanish

From these examples we can conclude that, even though in our qualitative analysis we were able to align many of the instances of legal phraseology found in our English corpus with a suitable equivalent in Spanish, each language makes its particular use of legal language or legalese. Indeed, as we can see in these examples, the most frequent phraseological units found in each language have nothing to do between each other. Thus, again, we consider that a parallel corpus would be more illustrative when it comes to adapting into the target language the different legal aspects that the source text focuses on.

In order to make our conclusions on the use of comparable corpora for translating the terminology and phraseology of ART informed consents more visual, we have summarized in the following table the advantages and disadvantages that we found:

ADVANTAGES	DISADVANTAGES
Helpful to find an equivalent for T/P units that refer to body parts, diseases, side effects of the medications, marital status of the patient(s), etc.	Unhelpful to find an equivalent for T/P units that exist only as a part of a particular cultural background, especially in the case of legal language.
They help us to prevent the influence of the source text in the target text (i.e. translationese).	
Useful to determine whether the communicative function and overall purpose of the documents in the SL and the TL is the same.	
We can determine whether the degree of hybridization of medico-legal documents is equitable or if, conversely, one specialized language prevails over the other.	

Table 32. Advantages and disadvantages of comparable corpora

As we shall see, the number of advantages outweighs that of disadvantages. However, the drawback identified is a big reason leading us to recommend the use of parallel corpora along with comparable corpora in order to make the most out of our research, thereby obtaining fruitful findings that, from our point of view, will increase the quality of any translation project of these characteristics.

On the other hand, this research clearly illustrates that the most used part of speech out of all the instances included in our bilingual glossary are noun phrases, with a total of 71 instances in English and 75 in Spanish, only followed by the category of nouns, with 25 cases in both English and Spanish (see Figures 24 and 25, Section 6). This implies that phraseology is more noticeable in this type of document than mere single-word terms, at least when dealing with informed consents from the field of Assisted Reproductive Technology. The presence of compound adjectives (e.g. *egg-containing, best-developed, good-quality*), hyphenated phrases (e.g. *best-developed embryos, IVF-conceived baby, third-party donor*) and collocations (e.g. *based on the best medical judgment of, check only one box, death of partner*) is high in our final glossary, thereby suggesting that a future translation of the whole document should take into consideration the words surrounding each potential term that the translator detects, as in the case of Figures 19 and 20 (see Section 5.2.1), where context allowed us to find *Fdo. El/La médico/a* as a suitable equivalent for the English phrase *Physician Signature*.

Finally, the resulting bilingual glossary as well as our quantitative analysis using pie charts shows that the percentage of medical terminology and phraseology is almost twice that of legal T/P units (64% medical and 36% legal in English, and 65% medical and 35% legal in Spanish). These data raise the question of what should be the area of specialization of the prospective translator: medicine, law, or both, or if it would be better that a physician with linguistic and legal knowledge translates the document. In the case of translators, what these results clearly show is that a profound knowledge about medicine and, more particularly, on biomedicine is required in order to tackle the task of translating medico-legal documents in assisted reproduction treatments.

9. Further research

Based on these conclusions, further studies should consider building a much more extensive comparable corpus than the one we have created here, which is limited due to time constraints and the nature of this project itself. With a greater corpus, perhaps more instances could be added to the bilingual glossary that we devised above, thereby facilitating the subsequent translator task. Moreover, practitioners should consider analyzing the terminology and phraseology of this text genre applied to the field of ART using parallel corpora as well in order to find how other translators solved translation problems such as adapting legal references or the name of certain medications.

Aside from examining the terminology and phraseology of this type of documents, other aspects of them could be examined, which will surely lead to highly interesting findings. Some examples of areas that could be examined would be the structure of the documents and the arrangement of its elements, the grammatical choices made in each language or the layout, just to name a few examples. This would help future researchers build a more extensive theory of the characteristics of informed contexts as texts genres.

Finally, further research is needed in order to determine how specialized translation syllabuses should be updated with practice on documents such as the one we have examined in this project. To better understand the implications of these results, further studies in the area of English for Specific Purposes (ESP) could address this area of knowledge and incorporate it to the contents taught in ESP courses. Moreover, deeper research could help build up-to-date glossaries, dictionaries and other resources that are adapted to the requirements of the translation profession in today's society.

10. References

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11. Annex 1: Informed consents from the USA

11. 1. Boston IVF

BOSTON IVF

CONSENT FORM FOR
IN VITRO FERTILIZATION

INSTRUCTIONS:

This consent form provides a description of the treatment that you are undertaking.

- Read the consent completely. If you have any questions please speak with your doctor.
- Do not make any additions or deletions to the consent.
- Treatment **cannot** be started until all consents are signed.
- Consents must be signed in front of your nurse or physician.

INTRODUCTION

In Vitro Fertilization (IVF) is a treatment that helps an infertile woman achieve a pregnancy. The technique involves four main steps: 1) the development of eggs in the woman's ovaries; 2) the removal of eggs from her ovaries; 3) the placement of the eggs and sperm together in the laboratory to allow fertilization to occur; and; 4) the transfer of fertilized eggs (embryos) into the woman's uterus for the establishment of pregnancy. This consent explains the IVF procedure and describes the major risks. In addition, the responsibilities of those who participate in this treatment are discussed.

This consent is valid for a period of one calendar year after it has been signed. Please make a copy for your records. It is recommended that you review the consent prior to each treatment cycle. If you have any questions about your treatment then it is your responsibility to speak with your physician.

Pre-treatment Recommendations

During treatment a woman should avoid any activity, behavior and medications that could reduce her chance of conceiving and having a healthy baby. In addition, the recommendations listed below should be followed.

1. A prenatal vitamin should be taken on a daily basis before the treatment is begun, optimally for at least one month prior to conception. This will reduce the chance that a baby will be born with a neural tube defect (e.g. spina bifida), which is a birth defect that affects the development of the spine.
2. Smoking must be avoided before and during treatment. It is also contraindicated during pregnancy.
3. Recreational drugs are absolutely contraindicated.
4. Ingestion of aspirin or aspirin-like products (e.g. Motrin®, Advil®, Anaprox®, Naprosyn®, Aleve®, etc.) should be avoided during treatment. However, in certain circumstances your doctor may prescribe low dose aspirin (baby aspirin, 81 mg). Tylenol® is safe to take before and during pregnancy.
5. The use of alcohol should be avoided during treatment and after pregnancy is established.
6. The use of all prescription and over-the-counter medications (including herbal remedies) should be discussed with a physician before starting a treatment cycle. We do not recommend the use of any herbal remedies and/or medications that are not FDA-regulated.
7. HIV (human immunodeficiency virus) screening is strongly recommended for all couples undergoing infertility treatment. HIV is the virus that causes acquired immunodeficiency syndrome (AIDS). A woman infected with HIV can pass the virus to her unborn child. Please talk to your physician about having this test performed.

8. Ingestion of some fish, which contain higher amounts of mercury, can affect the development of the nervous system of a fetus. During the treatment and after pregnancy is established you should avoid eating these fish shark, swordfish, king mackerel, tilefish and tuna. You should limit the intake of all other fish to 12 oz per week.

DESCRIPTION OF IVF TREATMENT

Treatment with IVF involves several steps as outlined below. Patients are not guaranteed success at any or all of these steps. If optimal results are not achieved at any step, it may be recommended that the treatment be stopped and the cycle cancelled.

I. Ovulation Induction

The eggs are present in the ovaries within fluid-filled cysts called follicles. During a woman's menstrual cycle, usually one mature follicle develops, which results in the ovulation of a single egg. Several hormones including follicle stimulating hormone (FSH) and luteinizing hormone (LH) influence the growth of the ovarian follicle. These hormones are produced by the pituitary gland, which is located at the base of the brain. FSH is the main hormone that stimulates the growth of the follicle, which produces an estrogen hormone called *estradiol*. When the follicle is mature, a large amount of LH is released by the pituitary gland. This surge of LH helps to mature the egg and leads to ovulation 36-40 hours after its initiation.

The success of IVF is dependent on the number of eggs that are removed from the ovaries. Medications are administered to increase the number of follicles that develop, which will increase the number of eggs that are obtained at the egg retrieval, which will increase the number of embryos that will be available for transfer. By increasing the number of embryos that can be transferred, the chance of pregnancy increases. There are several medications that can be used for this phase of treatment.

1. *Gonadotropins* - these are injectable medications commonly prescribed to stimulate the ovaries of women undergoing IVF treatment. Two types of gonadotropins can be prescribed and are discussed below:
   - FSH (Gonal-F®, Follistim®, Bravelle®) - These medications contain only FSH and are administered on a daily basis by injection.
   - LH (Luveris®) – This medication contains only LH and is administered by injection. It is used in combination with FSH containing medications.
   - Human Menopausal Gonadotropins (Menopur®, Repronex®) - These medications contain equal amounts of FSH and LH, and are administered on a daily basis by injection.
2. *GnRH Agonist (Lupron®)* – This medication is taken by injection. There are two forms of the medication: a short acting medication requiring daily injections and a long-acting preparation lasting for 1-3 months. The primary role of this medication is to prevent a premature LH surge, which could result in the release of eggs before they are ready to be retrieved. Since GnRH-agonists initially cause a release of FSH and LH from the pituitary, they can also be used to start the growth of the follicles or initiate the final stages of egg maturation. Though leuprolide acetate is an FDA (Federal Drug Administration) approved medication, it has not been approved for use in IVF, although it has routinely been used in this way for more than 20 years. Potential side effects usually experienced with long-term use include but are not limited to hot flashes, vaginal dryness, bone loss, nausea, vomiting, skin reactions at the injection site, fluid retention, muscle aches, headaches, and depression. No long term or serious side effects are known. Since GnRH-a are often times administered after ovulation, it is possible that they will be taken early in pregnancy. The safest course of action is to use a barrier method of contraception (condoms) the month you will be starting the GnRH-a. GnRH-a have not been associated with any fetal malformations however you should discontinue use of the GnRH-a as soon as pregnancy is confirmed.

3. *GnRH Antagonist (Cetrotide®, Ganirelix®)* - GnRH antagonists are medications that reversibly bind to GnRH receptors in the pituitary gland and prevent release of FSH and LH. GnRH antagonists are administered in combination with gonadotropins. The major benefit of a GnRH antagonist is that it suppresses a LH surge thereby preventing ovulation.

4. *Clomiphene Citrate (Clomid®, Serophene®)* and letrozole *(Famara®)* - These medications are synthetic hormones that are taken orally for a period of five days and cause the release of FSH and LH, which stimulate the development of follicles. These medications are used in combination with injectable medications.

5. *Human Chorionic Gonadotropin [hCG] (Ovidrel®, Profasi® Pregnyl®, Novarel®)* - This medication contains the pregnancy hormone, hCG, which functions similarly to LH. It is administered 36 hours before the egg retrieval by injection and matures the eggs, which will allow them to become fertilized.

6. *Oral contraceptive pills*- Many treatment protocols include oral contraceptive pills to be taken for 2 to 4 weeks before gonadotropin injections are started in order to suppress hormone production or to schedule a cycle. Side effects include unscheduled bleeding, headache, breast tenderness, nausea, swelling and the risk of blood clots or stroke.

Note: Many of the medications that are used are administered by an injection. The patient or another person can be instructed to give these injections.

Side Effects

As with all injectable medications, bruising, redness, swelling, or discomfort can occur at the injection site. Rarely, there can be an allergic reaction to these drugs. The use of the above listed medications can cause side effects such as nausea, vomiting, hot flashes, headaches, mood swings, visual symptoms, memory difficulties, joint problems, weight gain and weight loss, all of which are temporary. The intent of giving these medications is to mature multiple follicles, and many women experience some bloating and minor discomfort as the follicles grow and the ovaries become temporarily enlarged. Other possible side effects include the following:

- *Ovarian Hyperstimulation* - After the egg retrieval is performed, the ovarian follicles, which have been aspirated, can fill up with fluid and form cysts. The formation of cysts will result in ovarian enlargement and can lead to lower abdominal discomfort, bloating and distention. These symptoms generally occur within two weeks after the egg retrieval. The symptoms usually resolve within 1-2 weeks without intervention. If ovarian hyperstimulation occurs your physician may recommend a period of reduced activity and bed rest. Pregnancy can worsen the symptoms of ovarian hyperstimulation. Severe ovarian hyperstimulation is characterized by the development of large ovarian cysts and fluid in the abdominal and, sometimes, chest cavities. Symptoms of severe ovarian hyperstimulation include abdominal distention and bloating along with weight gain, shortness of breath, nausea, vomiting and decreased urine output. Approximately 2% of women will develop severe ovarian hyperstimulation and may need to be admitted to the hospital for observation and treatment. To help alleviate the symptoms of severe ovarian hyperstimulation an ultrasound-guided paracentesis can be performed which results in the removal of fluid from of the abdominal cavity. Rare, but serious consequences of severe ovarian hyperstimulation include formation of blood clots that can lead to a stroke, kidney damage and possibly death. Every woman who takes these medications can develop ovarian hyperstimulation. In some cases when there is concern that a woman is at significant risk for ovarian hyperstimulation, the cycle may be cancelled or the eggs will be retrieved and any embryos that result may be frozen.

- *Ovarian Torsion (Twisting)* - In less than 1% of cases, a fluid filled cyst(s) in the ovary can cause the ovary to twist on itself. This can decrease the blood supply to the ovary and result in significant lower abdominal pain. Surgery may be required to untwist or possibly remove the ovary.

- *Ovarian Cancer*- Some research suggested that the risk of ovarian tumors may increase in women who take any fertility drugs over a long period of time. These studies had significant flaws which limited the strength of the conclusions. More recent studies have not confirmed this risk. A major risk factor for ovarian cancer is infertility per se, suggesting that early reports may have falsely attributed the risk resulting from infertility to the use of medications to overcome it. In these studies, conception lowered the risk of ovarian tumors to that of fertile women.

- *Breast and Uterine Cancer*: More research is required to examine what the long-term impact of fertility drugs may be on breast and ovarian cancer prevalence rates. For uterine cancer, the numbers are too small to achieve statistical significance, but it is at least possible that use of fertility drugs may indeed cause some increased risk of uterine cancer.

Monitoring

During the ovulation induction phase of treatment, monitoring of follicular development is performed with periodic blood hormone tests and/or vaginal ultrasound exams. Monitoring helps the physician to determine the appropriate dose of the medications and the timing of the egg retrieval. Vaginal ultrasound examinations are usually painless and generally considered to be safe. However, the possibility of harm cannot be excluded. Blood drawing may be associated with mild discomfort and, possibly, bruising, bleeding, infection or scar at the needle sites. The need for repeated ultrasound examinations and/or blood drawing on a frequent basis requires the woman's presence in the vicinity of a Boston IVF monitoring site.

II. Egg Retrieval

Oocyte retrieval is the removal of eggs from the ovary. A transvaginal ultrasound probe is used to visualize the ovaries and the egg-containing follicles within the ovaries. A long needle, which can be seen on ultrasound, can be guided into each follicle and the contents aspirated. The aspirated material includes follicular fluid, oocytes (eggs) and granulosa (egg-supporting) cells. Specimens normally discarded from this procedure may be used for future research purposes. If this is done all specimens will be anonymized and your name or medical information will not used. Rarely the ovaries are not accessible by the transvaginal route and laparoscopy or transabdominal retrieval is necessary. These procedures and risks will be discussed with you by your doctor if applicable. Anesthesia is generally used to reduce if not eliminate discomfort. Risks of egg retrieval include:

Infection Bacteria normally present in the vagina may be inadvertently transferred into the abdominal cavity by the needle. These bacteria may cause an infection of the uterus, fallopian tubes, ovaries or other intra-abdominal organs. The estimated incidence of infection after egg retrieval is less than 0.5%. Treatment of infections could require the use of oral or intravenous antibiotics. Severe infections occasionally require surgery to remove infected tissue. Infections can have a negative impact on future fertility. Prophylactic antibiotics are sometimes used before the egg retrieval procedure to reduce the risk of pelvic or abdominal infection in patients at higher risk of this complication. Despite the use of antibiotics, there is no way to eliminate this risk completely.

Bleeding The needle passes through the vaginal wall and into the ovary to obtain the eggs. Both of these structures contain blood vessels. In addition, there are other blood vessels nearby. Small amounts of blood loss are common during egg retrievals. The incidence of major bleeding problems has been estimated to be less than 0.1%. Major bleeding will frequently require surgical repair and possibly loss of the ovary. The need for blood transfusion is rare. (Although very rare, review of the world experience with IVF indicates that unrecognized bleeding has lead to death.)

Trauma: Despite the use of ultrasound guidance, it is possible to damage other intra-abdominal organs during the egg retrieval. Previous reports in the medical literature have noted damage to the bowel, appendix, bladder, ureters, and ovary. Damage to internal organs may result in the need for additional treatment such as surgery for repair or removal of the damaged organ. However, the risk of such trauma is low.

Failure: It is possible that the aspiration will fail to obtain any eggs or the eggs may be abnormal or of poor quality and otherwise fail to produce a viable pregnancy.

Anesthesia - For the egg retrieval, medications usually are administered by an anesthesiologist. The patient will have a consultation with the anesthesiologist before the procedure to review the risks and benefits of the anesthesia. In some cases the use of anesthesia on a specific patient may be associated with an increased risk. In such cases the physician may offer local anesthesia without the assistance of an anesthesiologist. It is mandatory that there is no oral intake after midnight prior to the egg retrieval. After the procedure is completed, the patient will be discharged home usually within one hour. Because of the anesthetic medications that are used a patient must be accompanied home by a responsible adult. Each patient is responsible for bringing a responsible adult with them on the day of the egg retrieval. Following the egg retrieval, vaginal spotting and lower abdominal cramping are normal. During the remainder of the day following the surgery, activities should be limited. If significant bleeding, vomiting, abdominal pain or any other symptoms develop, you should contact her physician. If you should have any difficulty in contacting your physician the patient or her caretaker should proceed to the emergency department of the nearest hospital.

III. Insemination of the Eggs

On the day of the egg retrieval, a sperm sample is obtained. Under some circumstances, sperm can be frozen prior to the day of egg retrieval for use on the day of egg retrieval. Reasons to consider sperm freezing would be if the male partner may not be available on the day of the egg retrieval or there has been difficulty in the past with the production of a semen sample. You are responsible for making arrangements to freeze sperm prior to the start of treatment if this applies to you. The source of the sperm can be from the male partner or in some situations the couple (patient) may choose to use donor sperm. The biologist processes the sperm sample and then the eggs are inseminated. There are two approaches to the insemination of the eggs that are discussed below:

1. ***Standard Insemination***- If the sperm sample is adequate then a standard insemination of the eggs can be performed. After the sperm sample has been processed, a mixture of the sperm and eggs is placed in a plastic dish containing a nutrient culture media and then placed in an incubator in the laboratory to allow fertilization to occur. The nutrient culture media contains a serum additive, which is a blood product, and there is a rare chance of transmission of a viral infection. The morning after the egg retrieval, the eggs are examined to see if fertilization has occurred.

2. ***Intracytoplasmic sperm injection (ICSI)*** - ICSI is a laboratory procedure performed to increase the chances of fertilization.

   The ICSI procedure is a process, whereby, with the aid of a microscope and fine instruments, a single sperm is injected directly into the egg. Indications for ICSI include- a previous IVF cycle with poor fertilization, a previous semen analysis demonstrating significant abnormalities and in situations where surgical aspiration of sperm from the vas deferens or testicle is required. In most cases it is known at the start of the IVF cycle that ICSI will be performed. However, in other cases the sperm sample on the day of the egg retrieval may be unexpectedly inadequate for standard insemination and the ICSI procedure may be performed.

   Reports on the risk of birth defects associated with ICSI (compared to those associated with conventional fertilization in IVF cycles) have yielded conflicting results. The most comprehensive study conducted thus far, based on data from five-year-old children, has suggested that ICSI is associated with an increased risk of certain major congenital anomalies. However, whether the association is due to the ICSI procedure itself, or to inherent sperm defects, could not be determined because the study did not distinguish between male factor conditions and other causes of infertility. Note that even if there is an increased risk of congenital malformations in children conceived with ICSI, the risk is relatively low (4.2% versus ~3% of those conceived naturally). The impact of ICSI on the intellectual and motor development of children conceived via ICSI also has been controversial. An early report suggested that development in such children lagged significantly behind that of children resulting from conventional IVF or those conceived naturally. However, more recent studies from larger groups, using standardized criteria for evaluation, have not detected any differences in the development or the abilities of children born after ICSI, conventional IVF, or natural conception.

The prevalence of sex chromosome (X and Y) abnormalities in children conceived via ICSI is higher than observed in the general IVF population, but the absolute difference between the two groups is small (0.8% to 1.0% in ICSI offspring vs. 0.2% in the general IVF population). The reason for the increased prevalence of chromosomal anomalies observed in ICSI offspring is not clear. Whereas it may result from the ICSI procedure itself, it might also reflect a direct paternal effect. Men with sperm problems (low count, poor motility, and/or abnormal shape) are more likely themselves to have genetic abnormalities and often produce sperm with abnormal chromosomes; the sex chromosomes (X and Y) in the sperm of men with abnormal semen parameters appear especially prone to abnormalities. If sperm with abnormal chromosomes produce pregnancies, these pregnancies will likely carry these same defects. The prevalence of translocations (a re-arrangement of chromosomes that increases the risk of abnormal chromosomes in egg or sperm and can cause miscarriage) of paternal origin is increased with ICSI. The prevalence of de novo (not inherited) balanced translocations in offspring derived from ICSI is increased. The prevalence of these combined (0.36%) appears higher than in the general population (0.07%).

Some men are infertile because the tubes connecting the testes to the penis did not form correctly. This condition, called congenital bilateral absence of the vas deferens (CBAVD), can be bypassed by aspirating sperm directly from the testicles or epididymis, and using them in IVF with ICSI to achieve fertilization. However, men with CBAVD are affected with a mild form of cystic fibrosis (CF), and this gene will be passed on to their offspring. All men with CVABD, as well as their partners, should be tested for CF gene mutations prior to treatment, so that the risk of their offspring having CF can be estimated and appropriate testing performed. It is important to understand that there may be CF gene mutations that are not detectable by current testing and parents who test negative for CF mutations can still have children affected with CF.

Some men have no sperm in their ejaculate because their testes do not produce adequate quantities (non-obstructive azoospermia). This can be due to a number of reasons such as prior radiation, chemotherapy or undescended testicles. In some men, small deletions (mutations) on their Y chromosomes lead to extremely low or absent sperm counts. Testicular biopsy and successful retrieval of viable sperm can be used to fertilize eggs with ICSI. However, any sperm containing a Y chromosomal microdeletion will be transmitted to the offspring. Thus the risk that male offspring might later manifest disorders including infertility is very real. However, men without a detectable deletion by blood testing can also generate offspring having a Y chromosome microdeletion, because the chromosomes in the sperm may not be the same as those seen when tested by a blood test. If you would like additional information about the genetic issues surrounding IVF and the ICSI procedure talk to your physician about a referral to a genetics counselor.

The following additional risks are associated with the performance of the ICSI procedure:

1. The eggs may fail to become fertilized or may be damaged precluding their ability to be fertilized.
2. ICSI may yield presently unknown risks to the baby and/or mother.
3. Studies have shown that some cases of male infertility may be genetic. Therefore there is the possibility that infertility may be passed on to the offspring as stated above. Some studies show an increased risk of chromosomal and other abnormalities in babies born as a result of the ICSI procedure. If pregnancy is achieved testing can be performed to determine the chromosomal makeup of the fetus. If you would like additional information concerning genetics and inheritance, you should ask your physician to refer you to a genetic counselor prior to the start of your treatment cycle.
4. ICSI may compromise the protective effect of the membrane that surrounds the embryo, which may result in bacterial contamination and infection in the embryo that would render it non-viable.

On average, 60-70% of eggs will fertilize following the standard insemination or the ICSI procedure but in some cases none of the eggs fertilize. If fertilization is confirmed, plans are then made for the embryo transfer. In some cases of documented fertilization the embryos stop their development and the embryo transfer is cancelled.

IV. Embryo Transfer

After fertilization has been confirmed, the development of the embryos is monitored in the laboratory. If the embryos continue their development then plans are made for the embryo transfer. The embryo transfer is performed 3 to 6 days following the egg retrieval. Embryos transferred 3 days after the egg retrieval are generally at the 4 to 8 cell stage. Embryos transferred on day 5 or 6 are at a more advanced stage and may have developed into a blastocyst, which is made up of over 50 cells. Your physician will discuss with you the optimal time of the transfer. In the event that the embryos stop their development the embryo transfer is not performed.

At the time of the embryo transfer, a physician will review the fertilization results and the development of the embryos. A decision will be made regarding the number of embryos that will be transferred. Increasing the number of embryos transferred will increase the chances of pregnancy, but will also increase the risk of a multiple pregnancy (e.g., twins, triplets, etc). Remaining embryos that are not transferred will be examined and, if they are of suitable quality, may be frozen, stored and transferred at a later date. Alternatively, these "extra" embryos can be discarded.

Embryos which result from abnormal fertilization (i.e., polyspermy -when more than one sperm fertilizes an egg) will be discarded because they have no chance of developing normally. In addition, embryos that fail to develop properly (e.g., fail to divide, demonstrate other significant abnormalities of development) will also be discarded. Eggs and/or embryos, which have failed to develop (not viable), will not be transferred and will be discarded.

In order to perform the embryo transfer the woman is placed in the same position for a pelvic exam. A speculum is placed into the vagina and the cervix is visualized. The vagina and cervix are rinsed with a solution. In some cases an abdominal ultrasound is performed to help visualize the passage of the catheter. The biologist loads the embryos into a catheter, which the physician inserts through the cervical canal and into the uterine cavity. After placement of the catheter the embryos are injected into the uterine cavity. The catheter is examined by the biologist to confirm that the embryos have been discharged. Following the procedure the woman will be sent home. Activity should be limited on the day of the embryo transfer. Thereafter, normal activity should be resumed.

Very rarely, a uterine infection may occur after embryo transfer. The most common symptoms associated with infection are pain and fever. If fever, vomiting, abdominal pain or any other symptoms develop following embryo transfer, you should contact your physician.

Assisted Embryo Hatching

Your physician may recommend that assisted hatching be performed on the embryos just prior to the transfer. The zona pellucida is the outer protective membrane that surrounds the egg. After the sperm has penetrated the egg and fertilization has occurred, the embryo develops within the confines of the zona pellucida for a period of 5-7 days. Thereafter, an area of the zona pellucida thins out and the embryo "hatches" or is expelled out of the confines of the zona pellucida. It is only then that the embryo has the opportunity to implant into the uterine wall for the establishment of a pregnancy. It is possible that some embryos do not undergo this "hatching" process normally. A laboratory technique has been developed to facilitate the embryo with this "hatching" process and is referred to as *assisted hatching*. There is controversy as to whether the performance of assisted hatching increases the chance of a successful pregnancy following IVF treatment.

The assisted embryo hatching procedure- With the aid of a microscope and fine instruments, the zona pellucida (the outer membrane surrounding the embryo) is thinned by either the application of a dilute acidic solution or a laser. The embryos are then transferred back into the incubator until the embryo transfer is performed. Your physician may prescribe an antibiotic and a corticosteroid (methylprednisolone), which will be started on the day of the egg retrieval and continued for a period of four days.

The following risks are associated with the assisted hatching procedure.

1. The embryos may be destroyed or injured precluding their ability to implant.
2. There is an increased chance that an embryo splits and leads to a set of identical twins. This type of a multiple pregnancy is referred to as monozygotic twinning (MZT). The risks associated with MZT are described later in the consent. .
3. The procedure may yield presently unknown risks to the baby and/or mother.
4. Assisted hatching may not improve your chances of establishing a pregnancy.
5. There are risks associate with medications that may be prescribed
    a. Methylprednisolone- This medication has an anti-inflammatory action and modifies the immune response. The following side effects may occur but are more common when this drug is administered for a longer duration or at higher doses: mood swings, insomnia, depression, psychotic manifestations, muscle weakness, permanent hip replacement, impaired wound healing, increase sweating, headaches, vertigo, allergic reaction, loss of muscle mass, osteoporosis and abdominal distention. Other side effects include an increase in blood pressure, salt and water retention, increase excretion of potassium and calcium may occur. The use of methylprednisolone may mask the signs of an infection, make one susceptible to a new infection, and make it difficult to localize the source of an infection.
    b. The use of antibiotics may result in the following side effects which are dose-related: nausea, vomiting, diarrhea, loss of appetite, rashes, sensitivity to the sun, rare hypersensitivity reaction which may cause shock, blood diseases including reduced platelets or fractured blood cells which could result in anemia and/or bleeding.

V. Freezing (Cryopreservation) of Embryos

Extra embryos that remain after the embryo transfer will be examined to assess their quality, which helps determine their suitability for freezing. Embryos that are not of sufficient quality will not be frozen and will be discarded. At a later date frozen embryos can be thawed for transfer without the need for ovulation induction medications or an egg retrieval. If the couple decides later that they no longer want to continue treatment then the frozen embryos can be thawed and discarded. The decision regarding the disposition of extra embryos will be elaborated in the **"Consent Form for the Disposition of Embryos, Eggs & Sperm".** This consent must be signed and presented to Boston IVF before the treatment cycle is begun.

Overall pregnancy rates at the national level with frozen embryos are lower than with fresh embryos. This, at least in part, results from the routine selection of the better quality embryos for fresh transfer, reserving the 'second-best' for freezing. There is some evidence that pregnancy rates are similar when there is no such selection.

Risks of embryo cryopreservation: There are several techniques for embryo cryopreservation, and research is ongoing. Traditional methods include "slow," graduated freezing in a computerized setting, and "rapid" freezing methods, called "vitrification." Current techniques deliver a high percentage of viable embryos thawed after cryopreservation, but there can be no certainty that embryos will thaw normally, nor be viable enough to divide and eventually implant in the uterus. Cryopreservation techniques could theoretically be injurious to the embryo. Extensive animal data (through several generations), and limited human data, do not indicate any likelihood that children born of embryos that have been cryopreserved and thawed will experience greater risk of abnormalities than those born of fresh embryos. However, until very large numbers of children have been born following freezing and thawing of embryos, it is not possible to be certain that the rate of abnormalities is no different from the normal rate.

VI. Luteal Phase Support following Embryo Transfer

Progesterone, a hormone produced by the ovary, prepares the lining of the uterus for implantation. Studies have shown that some women who have taken ovulation induction drugs may need supplemental progesterone. For this reason, progesterone is administered following the egg retrieval. Natural progesterone is available and can be administered vaginally (Endometrin®, Crinone®, Prochieve®, Prometrium®, or pharmacist-compounded suppositories) or by intramuscular injection. If pregnancy occurs, the progesterone may be continued for a period of time. Studies have

confirmed that there is no increased risk of birth defects or health risks to women who take natural progesterone supplements during pregnancy. Some women may receive alternate forms of luteal phase support in lieu or in addition to progesterone. These include oral estradiol and human chorionic gonadotropin injections. Side effects of progesterone include depression, sleepiness, allergic reaction and if given by intra-muscular injection includes the additional risk of infection or pain at the application site. Estradiol, if given, can be by oral, trans-dermal, intramuscular, or vaginal administration. Side effects of estradiol include nausea, irritation at the injection site if given by the trans-dermal route and the risk of blood clots or stroke.

Eleven days after embryo transfer, a blood pregnancy test will be done. If this test is found to be positive, a repeat pregnancy test may be done 2-3 days later. If the pregnancy test results are within expected values then a vaginal ultrasound will be done approximately five weeks after the embryo transfer to determine the status of the pregnancy. Because of the potential for complications following the embryo transfer, access to medical care is important up to the time of the pregnancy test and beyond if pregnancy is established. If travel is absolutely necessary, it should be discussed with a physician.

The chance of success (the delivery of a live born infant) following a cycle of IVF is highly individual. The establishment of a pregnancy following IVF is dependent on many factors, some of which include: the age of the woman, the infertility diagnosis, the number of previous cycles of treatment, the number and quality of the eggs, the quality of the semen sample and the number and quality of the embryos that are transferred. Despite repeated attempts of IVF treatment, there is the possibility that pregnancy will not occur.

VII. Risks to the Woman

1. Ovarian Hyperstimulation Syndrome
To increase the number of eggs that develop, a series of hormone shots are given. The hormones used in this regimen are known to have, or suspected of having a variety of side effects, some minor and some potentially major. The most serious side effect of ovarian stimulation is ovarian hyperstimulation syndrome (OHSS). Its symptoms can include increased ovarian size, nausea and vomiting, accumulation of fluid in the abdomen, breathing difficulties, an increased concentration of red blood cells, kidney and liver problems, and in the most severe cases, blood clots, kidney failure, or death. The severe cases affect only a very small percentage of women who undergo in vitro fertilization—0.2 percent or less of all treatment cycles—and the very severe are an even smaller percentage. Only about 1.4 in 100,000 cycles has lead to kidney failure, for example. OHSS occurs at two stages: early, 1 to 5 days after egg retrieval (as a result of the hCG trigger); and late, 10 to 15 days after retrieval (as a result of the hCG *hormone* if pregnancy occurs). The risk of severe complications is about 4 to 12 times higher if pregnancy occurs which is why sometimes no embryo transfer is performed to reduce the possibility of this occurring.

2. Cancer
Many have worried that the use of fertility drugs could lead to an increased risk of cancer—in particular, breast, ovarian, and uterine (including endometrial) cancers. One must be careful in interpreting epidemiological studies of women taking fertility drugs, because all of these cancers are more common in women with infertility, so merely comparing women taking fertility drugs with women in the general population inevitably shows an increased incidence of cancer. When the analysis takes into account the increased cancer risk due to infertility per se, the evidence does not support a relationship between fertility drugs and an increased prevalence of breast or ovarian cancer. More research is required to examine what the long-term impact of fertility drugs may be on breast and ovarian cancer prevalence rates. For uterine cancer, the numbers are too small to achieve statistical significance, but it is at least possible that use of fertility drugs may indeed cause some increased risk of uterine cancer.

3. Risks of Pregnancy
Pregnancies that occur with IVF are associated with increased risks of certain conditions including pre-eclampsia, placenta previa, plancental abruption, gestational diabetes and cesarean section. Some of these risks stem from the higher average age of women pregnant by IVF and the fact that the underlying cause of infertility may be the cause of the increased risk of pregnancy complications. There may be additional risks related to the IVF procedure per se, but it is difficult to assign the relative contributions.

Currently more than 30% of IVF pregnancies are twins or higher-order multiple gestations (triplets or greater). Identical twinning occurs in 1.5% to 4.5% of IVF pregnancies. IVF twins deliver on average three weeks earlier and weigh 1,000 gm (2.2 pounds) less than IVF singletons. Of note, IVF twins do as well as spontaneously conceived twins. Triplet (and greater) pregnancies deliver before 32 weeks (7 months) in almost half of cases.

Additionally, while embryos are transferred directly into the uterus with IVF, ectopic (tubal, cervical and abdominal) pregnancies as well as abnormal intra-uterine pregnancies have occurred either alone or concurrently with a normal intra-uterine pregnancy . These abnormal pregnancies often times require medical treatments with methotrexate (a weak chemotherapy drug) or surgery to treat the abnormal pregnancy. Side effects of methotrexate include nausea or vomiting, diarrhea, cramping, mouth ulcers, headache, skin rash, sensitivity to the sun and temporary abnormalities in liver function tests. Risks of surgery include the risks of anesthesia, scar tissue formation inside the uterus, infection, bleeding and injury to any internal organs.

A miscarriage is a failed intrauterine pregnancy. The risk of miscarriage in the general population is 15-20%. The risk of miscarriage increases with advancing maternal age. For women over 40 years of age, the risk may exceed 40%. Studies have shown that there is either no increase or a slight increase in the risk of miscarriage in women who conceive with IVF. Most miscarriages are associated with lower abdominal cramping and bleeding, but do not necessarily require surgical treatment. In some cases, removal of the pregnancy tissue must be accomplished by a surgical procedure called a dilatation and curettage (D&C).

VIII. Risks to Offspring

1. **Overall risks**:
Since the first birth of an IVF baby in 1978, more than 3 million children have been born worldwide following IVF treatments. Numerous studies have been conducted to assess the overall health of IVF children and the majority of studies on the safety of IVF have been reassuring. As more time has passed and the dataset has enlarged, some studies have raised doubts about the equivalence of risks for IVF babies as compared to naturally conceived babies. A major problem in interpreting the data arises from the fact that comparing a group of infertile couples to a group of normally fertile couples is not the proper comparison to make if one wants to assess the risk that IVF technology engenders. Infertile couples, by definition, do not have normal reproductive function and might be expected to have babies with more abnormalities than a group of normally fertile couples. This said, even if the studies suggesting an increased risk to babies born after IVF prove to be true, the absolute risk of any abnormal outcome appears to be small. Singletons conceived with IVF tend to be born slightly earlier than naturally conceived babies (39.1 weeks as compared to 39.5 weeks). IVF twins are not born earlier or later than naturally conceived twins. The risk of a singleton IVF conceived baby being born with a birth weight under 5 pounds nine ounces (2500 grams) is 12.5% vs. 7% in naturally conceived singletons.

2. Birth Defect:
The risk of birth defects in the normal population is 2-3 %. In IVF babies the birth defect rate may be 2.6-3.9%. Studies to date have not been large enough to prove a link between IVF treatment and specific types of birth defects.

3. **Imprinting Disorders:**
These are rare disorders having to do with whether a maternal or paternal gene is inappropriately expressed. Since the incidence of this syndrome in the general population is 1/15,000, even if there is a 2 to 5-fold increase to 2-5/15,000, this absolute risk is very low.

4. **Childhood cancers**: Most studies have not reported an increased risk with the exception of retinoblastoma:

5. **Infant Development**: In general, studies of long-term developmental outcomes have been reassuring so far; most children are doing well.

6. **Risks of a Multiple Pregnancy**: The most important maternal complications associated with multiple gestation are preterm labor and delivery, pre-eclampsia and gestational diabetes (see prior section on Risks to Woman). Others include gall bladder problems, skin problems, excess weight gain, anemia, excessive nausea and vomiting, and exacerbation of pregnancy-associated gastrointestinal symptoms including reflux and constipation. Chronic back pain, intermittent heartburn, postpartum laxity of the abdominal wall, and umbilical hernias also can occur. Triplets and above increase the risk to the mother of more significant complications including post-partum hemorrhage and transfusion.
Prematurity accounts for most of the excess perinatal morbidity and mortality associated with multiple gestations. Moreover, IVF pregnancies are associated with an increased risk of prematurity, independent of maternal age and fetal numbers. Fetal growth problems and discordant growth among the fetuses also result in perinatal morbidity and mortality. Multifetal pregnancy reduction (where one or more fetuses are selectively terminated) reduces, but does not eliminate, the risk of these complications.

Fetal death rates for singleton, twin, and triplet pregnancies are 4.3 per 1,000, 15.5 per 1,000, and 21 per 1,000, respectively. The death of one or more fetuses in a multiple gestation (vanishing twin) is more common in the first trimester and may be observed in up to 25% of pregnancies after IVF. Loss of a fetus in the first trimester is unlikely to adversely affect the surviving fetus or mother. No excess perinatal (mature fetus or newborn) or maternal morbidity has been described resulting from a "vanishing" embryo.

Demise of a single fetus in a twin pregnancy after the first trimester is more common when they share a placenta, ranging in incidence from 0.5% to 6.8%, and may cause harm to the remaining fetus.

Monozygotic twinning (MZT) is a multiple pregnancy that results from the splitting of a single embryo, which will lead to a set of identical twins. The incidence of MZT is increased in pregnancies conceived following IVF and may occur between 1.5-5% of IVF pregnancies. In addition to the above stated complications associated with a multiple pregnancy with MZT there is a greater chance of twin-to-twin transfusion, which can affect the growth of the fetuses and increase the chance of other complications. Twins sharing the same placenta have a higher frequency of birth defects compared to pregnancies having two placentas. MZT occurs more frequently after blastocyst transfer.

Placenta previa and vasa previa are more common complications in multiple gestations. Abruptio placenta also is more common and postpartum hemorrhage may complicate 12% of multifetal deliveries. Consequences of multiple gestations include the major sequelae of prematurity (cerebral palsy, retinopathy of prematurity, and chronic lung disease) as well as those of fetal growth restriction (polycythemia, hypoglycemia, necrotizing enterocolitis). It is unclear to what extent multiple gestations themselves affect neuro-behavioral development in the absence of these complications. Rearing of twins and high-order multiples may generate physical, emotional, and financial stresses, and the incidence of maternal depression and anxiety is increased in women raising multiples. At mid-childhood, prematurely born offspring from multiple gestations have lower IQ scores, and multiple birth children have an increase in behavioral problems compared with singletons. It is not clear to what extent these risks are affected by IVF per se.

A multiple pregnancy may pose increased emotional and financial hardship for a couple. The risk of a multiple pregnancy can be reduced by decreasing the number of embryos that are transferred but this also reduces the overall chance of success. You are encouraged to have a discussion with your physician about the optimal number of embryos to transfer.

The Option of Selective Reduction: Pregnancies that have more than 2 fetuses are considered an adverse outcome of infertility treatment. The greater the number of fetuses within the uterus, the greater is the risk for adverse perinatal and maternal outcomes. Patients with more than twins are faced with the options of continuing the pregnancy with all the risks previously described, terminating the entire pregnancy, or reducing the number of fetuses in an effort to decrease the risk of maternal and perinatal morbidity and mortality. Multifetal pregnancy reduction (MFPR) decreases risks associated with preterm delivery, but often creates profound ethical dilemmas. Pregnancy loss is the main risk of MFPR. However, current data suggest that such complications have decreased as experience with the procedure has grown. The risk of loss of the entire pregnancy after MFPR is approximately 1%.

In general, the risk of loss after MFPR increases if the number of fetuses at the beginning of the procedure is more than three. While there is little difference between the loss rates observed when the final number of viable fetuses is two or one, the loss rate is higher in pregnancies reduced to triplets. Pregnancies that are reduced to twins appear to do as well as spontaneously conceived twin gestations, although an increased risk of having a small for gestational age fetus is increased when the starting number is over four. The benefit of MFPR can be documented in triplet and higher-order gestations because reduction prolongs the length of gestation of the surviving fetuses. (This has been demonstrated for triplets; triplets have a 30-35% risk of birth under 32 weeks compared to twins which is 7 to 10%.)

IX. Ethical and Religious Considerations in Infertility Treatment
Infertility treatment can raise concerns and questions of an ethical or religious nature for some patients. The technique of in vitro fertilization (IVF) involves the creation of human embryos outside the body, and can involve the production of excess embryos and/or 'high-order' multiple pregnancy (triplets or more). We encourage patients and their spouses or partners who so desire to consult with trusted members of their religious or ethics community for guidance on their infertility treatment.

X. Psychosocial Effects of Infertility Treatment

IVF can be psychologically stressful. Anxiety and disappointment may occur at any of the phases described above. Significant commitment of time and finances may be required. Couples are encouraged to consider meeting with a counselor. If you are interested in meeting with a social worker or psychologist please speak to your physician.

XI. Legal Considerations and Legal Counsel

The law regarding embryo cryopreservation, subsequent thaw and use, and parent-child status of any resulting child(ren) is, or may be, unsettled in the state in which either the patient, spouse, partner, or any donor currently or in the future lives, or the state in which the ART Program is located. We acknowledge that the ART Program has not given us legal advice, that we are not relying on the ART Program to give us any legal advice, and that we have been informed that we may wish to consult a lawyer who is experienced in the areas of reproductive law and embryo cryopreservation and disposition if we have any questions or concerns about the present or future status of our embryos, our individual or joint access to them, our individual or joint parental status as to any resulting child, or about any other aspect of this consent and agreement.

XII. Alternatives to IVF
There are alternatives to IVF treatment including gamete Intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT) or tubal embryo transfer (TET) where eggs and sperm, fertilized eggs or developing embryos, respectively, are placed into the fallopian tube(s). Using donor sperm, donor eggs, adoption or not pursuing treatment are also options. Gametes (sperm and/or eggs), instead of embryos may be frozen for future attempts at pregnancy in an effort to avoid potential future legal issues relating to disposition of any cryopreserved embryos. Sperm freezing, but not egg freezing, has been an established procedure for many decades.

XIII. Reporting Outcomes
The 1992 Fertility Clinic Success Rate and Certification Act requires the Centers for Disease Control and Prevention (CDC) to collect cycle-specific data as well as pregnancy outcome on all assisted reproductive technology cycles performed in the United States each year and requires them to report success rates using these data. Consequently, data from my/our IVF procedure will be provided to the CDC, and to the Society of Assisted Reproductive Technologies (SART) of the American Society of Reproductive Medicine (ASRM) (if my/our clinic is a member of this organization). The CDC may request additional information from the treatment center or contact me/us directly for additional follow-up. Additionally, my/our information may be used and disclosed in accordance with HIPAA guidelines in order to perform research or quality control. All information used for research will be de-identified prior to publication. De-identification is a process intended to prevent the data associated with my/our treatment being used to identify me/us as individuals.

There are many complex and sometimes unknown factors, which may prevent the establishment of pregnancy. Known factors, which may prevent the establishment of pregnancy, include, but are not limited to, the following:

1. The ovaries may not respond adequately to the medications.
2. Technical problems including inadequate visualization or the position of the ovaries may prevent the retrieval of the eggs.
3. There may be failure to recover an egg because ovulation has occurred prior to the time of the egg retrieval.
4. Eggs may not be recovered.
5. The eggs may not be normal.
6. The male partner may be unable to produce a semen sample or the semen sample may be of insufficient quantity or quality.
7. Fertilization of the eggs and sperm to form embryos may not occur.
8. Cell division of the embryos may not occur.
9. The embryos may not develop normally.
10. Embryo transfer into the uterus may be technically difficult or impossible.
11. If the transfer is performed, implantation may not result.
12. If implantation occurs, the embryo(s) may not grow or develop normally
13. Equipment failure, infection, technical problems, human error and/or unforeseen factors may result in loss or damage to the eggs, semen sample and/or embryos.

The foregoing general information is based upon the experience and knowledge of the Boston IVF physicians. It is based, in part, upon a review of the literature pertaining to Reproductive Medicine. This information is generally accurate and comprehensive, however, medicine is a dynamic discipline and reproductive medicine in particular is constantly evolving. Estimates of risks factors and the relative benefits of alternative treatment that have been discussed with you represent the best professional judgment of the physicians and caregivers of Boston IVF taking into account your specific needs and circumstances.

PRIVACY

Data from your ART procedure will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on you, CDC applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308(d). This means that any information that CDC has that identifies you will not be disclosed to anyone else without your consent.

ACKNOWLEDGEMENT OF INFORMED CONSENT AND AUTHORIZATION

We acknowledge that we, the undersigned, are voluntarily seeking treatment with **In Vitro Fertilization (IVF)** in order to conceive a child. We will acknowledge our natural parentage of any child or children born through this treatment.

We have discussed this treatment in detail with a Boston IVF physician and caregivers in language that we understand. We understand the purpose, risks and benefit of the treatment. **We acknowledge that we have read all pages of this consent form and all of our questions concerning the treatment have been fully answered to our satisfaction.**

We are aware that there are other centers in the area that offer this treatment and we have freely chosen to have the treatment at Boston IVF.

By consenting to treatment at Boston IVF we accept the responsibilities, conditions and risks involved as set out in this document and as explained by the staff of Boston IVF. In addition, we consent to the techniques and procedures used to accomplish this treatment described in this document and as explained by the physicians and staff of Boston IVF.

We understand and acknowledge that medicine is not an exact science and that in cases of doubt Boston IVF physicians and caregivers will exercise their best professional judgment.

We acknowledge and agree that acceptance into treatment and our continued participation is within the sole discretion of Boston IVF. We understand that should this cycle be unsuccessful, it may be determined that further treatment may not be indicated.

We acknowledge that it is our responsibility to notify Boston IVF in writing if we become aware of any information that Boston IVF should have in order to discharge its obligations under this agreement.

We agree to notify BIVF immediately in writing of any change in our marital status including separation or divorce.

We understand that we are financially responsible for any medical expenses that are not covered by our insurance policy.

In order to obtain required cycle outcome data we give Boston IVF consent to contact any physicians who provided care during and after a pregnancy.

By signing this document we acknowledge that we have had a thorough discussion with our Boston IVF physician and caregivers. This discussion included information on the risks, benefits, side effects and complications of the treatment. Furthermore, we acknowledge that the discussion with our Boston IVF physician provided sufficient information to allow us to make an informed decision whether or not to proceed with treatment. The discussion with our Boston IVF physician included alternatives including the option of having no treatment.

By signing this document we acknowledge that our Boston IVF physician and caregivers have obtained from us informed consent to proceed with In Vitro Fertilization (IVF).

It is required that you have this document witnessed at Boston IVF, if unable because of distance the default is to have this document officially notarized.

_____	_____	_____
Signature of Patient	Signature of Partner	Signature of Physician
_____	_____	
Printed name	Printed name	
_____	_____	
Date of Birth	Date of Birth	
_____	_____	
Date	Date	
_____	_____	
Signature of BIVF Witness or Notary	Signature of BIVF Witness or Notary	
_____	_____	
Printed Name of Witness or Notary	Printed Name of Witness or Notary	
_____	_____	
ID Type	ID Type	
_____	_____	
ID Number and Exp Date	ID Number and Exp Date	

_____(State)

On this ____day of _____, 201___, before me, the undersigned notary public, personally appeared _____, proved to me through satisfactory evidence of identification, which were_____, to be the person whose name is signed on the proceeding or attached document in my presence.

_____
Notary Public

_____(State)

On this ____day of _____, 201___, before me, the undersigned notary public, personally appeared _____, proved to me through satisfactory evidence of identification, which were_____, to be the person whose name is signed on the proceeding or attached document in my presence.

_____
Notary Public

11. 2. Columbia University Fertility Center

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New York, NY 10019 | O: 646.756.8282 | Fax: 646.756.8281

DOB:

In Vitro Fertilization/ PGT

In Vitro Fertilization Consent

This "In Vitro Fertilization" (IVF) consent is intended to inform you about the IVF process at the Columbia University Fertility Center (the Fertility Center) in detail, including the risks to both patients and potential children. If you do not understand the information provided, please speak with your nurse or physician. Consent may be withdrawn at any time before embryos are created and requires a Columbia University Fertility Center witnessed directive. While this consent is comprehensive, there are circumstances that cannot be foreseen that may have a negative effect on your cycle or stored material.

In Vitro Fertilization Process & Risks

In Vitro Fertilization (IVF) is a treatment that aspirates eggs from a female ovary or ovaries to be fertilized with pre-selected sperm; resulting embryos may be transferred, cryopreserved or biopsied and cryopreserved in an attempt to achieve a pregnancy either with this treatment cycle or at a later time. The majority of transfers at the CUFC are from cryopreserved embryos. A patient can use sperm provided by her partner or from a pre-selected sperm donor.

We will be testing all patients for COVID-19. The protocol is changing rapidly as information on this virus is changing rapidly. Speak to your care coordinator team concerning the latest protocol. Please be aware if you test positive at any time during the course of treatment the cycle may be delayed by a few weeks or cancelled.

An IVF cycle typically includes the following steps or procedures:

- Taking medication to grow several eggs at once
- Under anesthesia, surgically removing the eggs from the ovary or ovaries
- Mixing eggs and sperm together in the embryology lab so the eggs may be fertilized
- Injecting individual sperm into each egg, called intracytoplasmic sperm injection (ICSI)
- Growing any resulting fertilized eggs (embryos) in the embryology lab
- The choice of biopsy/ genetic screening and cryopreserving embryos for a future transfer
- Assisted hatching embryos for biopsy or embryo transfer
- Cryopreservation (freezing) of eggs or embryos for a future transfer
- Placement ("transfer") of typically one embryo into the uterus, typically during a frozen embryo transfer
- Taking hormone medications to help you have a successful pregnancy during and after your frozen embryo transfer cycle.

Medications for IVF Treatment:

- The success of IVF largely depends on growing several eggs at once
- Injections of the natural hormones FSH and/or LH (gonadotropins) are used
- Other medications are used to keep ovulation from happening too soon
- Sometimes the ovaries respond too strongly—and sometimes not enough

Medications Commonly Used in IVF Cycles

Sometimes, especially when testing prior to the IVF cycle has shown that the woman has a lower number of eggs available, the medications may not help multiple eggs to grow. There may be very few or even no eggs harvested at the egg retrieval procedure, or the cycle may be canceled before egg retrieval can be attempted.

Gonadotropins, or injectable "fertility drugs": (Follistim®, Gonal-F®, Menopur®, low dose hCG or human chorionic gonadotropin): These are all natural hormones that help the ovary to grow several eggs (oocytes) at once over 8 or more days. All injectable fertility drugs have FSH (follicle stimulating hormone), a hormone that will stimulate the growth of your ovarian follicles (which contain the eggs). Some of them also contain LH (lutenizing hormone) or LH like activity. LH is a hormone that may work with FSH to increase the production of estrogen and growth of the follicles. These injections

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may be given either just under the skin or directly into muscle. Taking any medicine in an injection can cause bruising, redness, swelling, or pain at the injection site. In rare cases, there may be an allergic reaction. Some patients have bloating or minor discomfort as the ovaries briefly become enlarged. Other side effects can include headaches, weight gain, feeling tired, mood swings or nausea. About 1% of patients will develop a potentially dangerous syndrome called Ovarian Hyperstimulation Syndrome (OHSS). This condition is rare due to advances in IVF medications and cycle management, but is more likely in patients with very high AMH (ovarian reserve). While bloating and dehydration are common in most patients going through IVF, OHSS can include severe bloating, laboratory changes (involving electrolytes, liver function and/or kidney function), and/or increased risk of clots in blood vessels. [See full discussion of OHSS in the Risks to the Patient section which follows.]

GnRH-agonists (leuprolide acetate) (Lupron®): This medication is an injection. There are two forms of the drug. One is a short-acting form that needs to be injected daily, and the other is a long-acting form that lasts for 1-3 months. Leuprolide is often given to help prevent the release of eggs (by ovulation) before they can be retrieved. Leuprolide can also be used to start the growth of eggs, or trigger the final stages of their growth. Leuprolide is approved by the FDA (U.S. Food and Drug Administration), but not approved for use in IVF. Still, because it has been studied in IVF patients, the medicine has been used in IVF for more than 20 years. Leuprolide can cause a number of side effects. These include hot flashes, vaginal dryness, nausea, headaches, and muscle aches. Some patients may retain fluid or feel depressed, and long-term use can result in bone loss. Since Leuprolide is taken as an injection, skin reactions can also occur where the injection is given. No long term or serious side effects are known. If Leuprolide is given in a cycle after ovulation has occurred, you should use condoms for birth control in that month. Leuprolide has not been linked with any birth defects, but it should be stopped if you become pregnant while taking it.

GnRH-antagonists (ganirelix acetate or cetrorelix acetate): (Ganirelix®, Cetrotide®): These drugs are used to prevent premature ovulation. Side effects may include stomach pain, headaches, skin reactions where the shot is given, and nausea.

Human chorionic gonadotropin (hCG) (Profasi®, Novarel®, Pregnyl®, Ovidrel®): hCG is a natural hormone used in IVF to help the eggs become mature and ready to be aspirated and attempt to be fertilized. This drug must be taken at just the right time in to retrieve mature eggs. Side effects can include breast tenderness, bloating, and pelvic pain.

Progesterone, and in some cases, estradiol: These two hormones are normally produced by the ovaries after ovulation. In some patients, after egg retrieval, the ovaries will not produce enough of these hormones to support a pregnancy. Adding them helps improve your chances of getting pregnant and staying pregnant. Progesterone can be taken as a daily intramuscular injection (injection into muscle, most commonly in the hip). It can also be taken by placing a suppository (Endometrin®, Crinone®, Prochieve®, Prometrium®, or pharmacist-compounded suppositories) directly into the vagina as frequently as three times per day after egg retrieval. Progesterone is often continued for some weeks after you become pregnant. Progesterone has not been shown to cause birth defects. Side effects of progesterone can include depression, sleepiness, or an allergic reaction. The intra-muscular injection can cause infection or pain at the injection site. Estradiol can be taken by pill, in a patch, as an intramuscular shot, or as a vaginal suppository. Side effects of estradiol include nausea, irritation at the site of the injection or patch, and the risk of blood clots or stroke.

Oral contraceptive pills (birth control pills): Your doctor may ask you to take birth control pills for 2 to 4 weeks before starting hormone stimulation injections. This is done to slow down hormone production or to schedule a treatment cycle. Side effects include bleeding, headache, breast tenderness, nausea, and swelling. There is also a risk of blood clots or, very rarely, stroke.

Clomid or Letrozole: These medicines are used in some treatments to increase the number of growing eggs or reduce the estrogen level in the bloodstream. Short-term side effects in some patients include headache, hot flashes, or increased moodiness. They are taken by mouth in pill form.

Other medications: Antibiotics may be given for a short time during the treatment cycle. This may reduce the risk of infection from egg retrieval or embryo transfer. Antibiotic use may cause a number of side effects, including vaginal yeast

infection, nausea, vomiting, diarrhea, rashes, sensitivity to the sun, or allergic reactions. Your doctor may suggest using anti-anxiety medications or a muscle relaxant before the embryo transfer. The most common side effect of these medicines is drowsiness. Other medicines such as steroids, heparin, low molecular weight heparin, or aspirin may also be recommended.

Egg Retrieval and Risks

Oocyte retrieval is the removal of eggs from the ovary. Before removing the eggs, the doctor will look at your ovaries using an ultrasound probe placed into the vagina. A long needle, which can be seen on ultrasound, is attached to the ultrasound probe. Guiding the needle into the ovaries, the physician will draw out fluid, eggs, and egg-supporting cells. Anesthesia administered by an anesthesiologist will be used to reduce or eliminate pain; the anesthesia is considered conscious sedation or "twilight sleep" where you are breathing on your own and sleeping. After the retrieval you may feel mildly uncomfortable which is considered normal.

Infection: Bacteria from the vagina may be transferred into the pelvis or ovaries by the needle. This can cause an infection of nearby organs. The incidence of infection after egg retrieval is very small (less than 0.1%). If you do get an infection, you may be given antibiotics. Severe infections sometimes require surgery to remove infected tissue. Infections can reduce your chance of getting pregnant in the future. Antibiotics may be used before the egg retrieval to help reduce the chance of infection. Still, there is no way to remove the risk completely.

Bleeding: The needle passes through the vaginal wall and into the ovary to obtain the eggs. Both of these structures contain blood vessels. There are also other blood vessels nearby. This means that small amounts of blood may be lost while removing the eggs. The risk of major bleeding is small (< 0.1%). Major bleeding may require surgery to stop, and could very rarely result in the removal of an ovary. Only rarely is a blood transfusion needed. If bleeding occurs and is not noticed (also rare), it can lead to death.

Trauma: Even with ultrasound guidance, nearby organs can be damaged. This includes damage to the intestines, appendix, bladder, ureters, and ovary. In some cases, a damaged organ may need to be fixed or removed through surgery. Still, the risk of damage during egg retrieval is very low.

Anesthesia: The use of anesthesia while removing eggs can cause an allergic reaction or low blood pressure. It can also cause nausea or vomiting. In rare cases, use of anesthesia has resulted in death.

Failure: Sometimes no eggs are found during the retrieval process. In other cases, the eggs are not normal, or are of poor quality. These situations can prevent you from having a successful pregnancy.

In Vitro Fertilization and Embryo Culture

The physician will aspirate fluid, eggs, and egg-supporting cells from the ovary; the aspirates are immediately transferred to the embryology lab to be processed by an embryologist. The eggs are placed in small petri dishes containing "culture medium," which is specially developed media to support egg growth. The fluid is made to resemble the conditions in the Fallopian tubes and uterus. The eggs are then placed into incubators, which keep the temperature, humidity, gas, and light at appropriate levels to support embryo development. In some cases, individual sperm are injected into each mature egg in a technique called Intracytoplasmic Sperm Injection (ICSI) (see "ICSI" section). The eggs are then returned to the incubator, where they continue to develop and grow. They are assessed at various intervals over the next few days, to check their progress.

- Sperm and eggs are placed together (or ICSI is performed).
- The dish is kept under special conditions to promote fertilization.
- The fluid in the dish (culture medium) helps the sperm fertilize the egg and helps embryos to grow.
- Embryos remain in controlled culture conditions throughout their time in the embryology laboratory and are inspected at regular intervals.

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- The embryologist chooses the best embryos for transfer, for biopsy or cryopreservation by the way they look under a microscope (embryo assessment).

Embryo Development

Embryo development typically proceeds along the following cleavage (dividing) schedule:

- *Day 0*: This is retrieval day (or egg thaw day), the day the eggs and sperm will be placed together or ICSI performed.
- *Day 1*: This is the day that the eggs and sperm have already come together, and we will check for signs of fertilization. Not all eggs fertilize and some fertilize abnormally. At this stage, the normally fertilized egg is still a single cell with 2 nuclei, called a 2PN or zygote.
- *Day 2*: Typically, embryos will divide into 2 to 4 cells (the embryos are not checked on this day).
- *Day 3*: Normally developing embryos will continue to divide and usually contain 4 to 8 cells.
- *Day 4*: The cells of the embryo begin to merge to form a solid ball of cells called a morula (the embryos are not checked on this day).
- *Day 5/6/7*: Embryos now have 100 cells or more, and are called blastocysts. It has an inner fluid-filled cavity and a small cluster of cells on the inside called the inner cell mass. An embryo that makes it to the blastocyst stage does not automatically mean it is a chromosomally normal embryo. Approximately half of all fertilized embryos reach this stage but it can vary from none to all embryos in a given cycle.

It is important to understand that for any age group, many eggs and embryos are abnormal. This means that some eggs will not fertilize, some embryos will not divide at a normal rate or may simply stop dividing. Even if your embryos develop according to the normal cleavage schedule, they may not be genetically normal. It is possible to biopsy embryos ("preimplantation genetic screening"), to identify an embryo with a normal number of chromosomes, even genetically normal embryos may not be healthy and will not produce a pregnancy. Unless genetic testing is done, the embryos that look the best under the microscope are chosen for transfer.

There are many reasons why pregnancy may not happen with IVF:

- The eggs may fail to fertilize.
- One or more eggs may fertilize abnormally. This can lead to an abnormal number of chromosomes in the embryo. These abnormal embryos cannot be transferred or cryopreserved.
- The fertilized eggs may not divide, or the embryos may not develop normally.
- In spite of having backup systems in place, lab equipment may fail or power may be lost. Anticipated (hurricane, blizzard) or unforeseen disasters (floods, building shutdown, acts of terrorism, pandemic) may prevent clinical activities at the Fertility Center; both can lead to the destruction of eggs, sperm, and embryos.
- A lab accident or human error can happen and can lead to tissue lost.
- Other unforeseen events may prevent any step of the process from being performed or prevent a pregnancy from occurring.

Quality Control: The process of running tests to ensure that lab conditions are the best they can be to help eggs fertilize and embryos grow. Systems in the lab are frequently checked to make sure conditions are optimal. Sometimes immature or abnormal eggs, or embryos that have not developed normally (and can never result in a normal pregnancy), can be used for quality control checks before they are discarded. None of the material that would normally be discarded - blood, tissues, eggs, sperm or embryos - will be used to create a pregnancy or a cell line.

Intracytoplasmic Sperm Injection (ICSI)

Intracytoplasmic sperm injection or ICSI involves the direct injection of a single sperm into the interior of an egg using an extremely thin glass needle. This lets the sperm enter the egg without having to break through the shell around the egg (the *zona pellucida*); for ICSI to work, the sperm must be healthy, and the egg must be mature. ICSI is a good choice when the sperm count, movement, or quality is poor. Live birth rates are very close if not equal to those of IVF for men with normal sperm counts.

In some cases, fertilization will not happen when eggs and sperm are placed together in a petri dish. Injecting a single sperm into each egg (ICSI, or intracytoplasmic sperm injection) can help fertilization occur. ICSI does not guarantee normal fertilization.

- The egg may be damaged or destroyed during the ICSI process.
- There may be a slight increased risk of genetic problems in children born from ICSI.
- ICSI will not improve any defects in the eggs.

Reports on the risk of birth defects associated with ICSI (compared to those associated with conventional fertilization in IVF cycles) have yielded conflicting results. It is hard to know if the increased risk is due to the ICSI procedure itself or to defects in the sperm. The risk of birth defects after ICSI is relatively low (4.2% compared with 3% in children conceived naturally). Experts are still debating the impact of ICSI on the mental and physical development of children. Most recent studies have not detected any differences in the development of children born after ICSI, regular IVF, or natural conception. Children conceived by ICSI have slightly more problems with their sex chromosomes (the X and Y chromosomes) than children conceived by IVF alone, but only by a very small margin (0.8% to 1.0% for ICSI pregnancies compared to 0.2% for IVF pregnancies). The reason for the difference is not clear. It may be caused by the ICSI procedure itself, or by the sperm. Men with sperm problems such as very low count and low motility are more likely to have genetic abnormalities. They often produce sperm with abnormal chromosomes, especially with abnormal sex chromosomes (X and Y). If sperm with abnormal chromosomes produce pregnancies, the pregnancies will likely carry the same defects. Translocations (a re-arrangement of chromosomes that can cause miscarriage or birth defects) may be more common after ICSI.

Some men with extremely low sperm counts or no sperm have small deletions on their Y chromosomes. In some of these cases, sperm can be obtained to fertilize eggs with ICSI. Any sperm containing a Y chromosome microdeletion will pass on the deletion to any male child. These male children will also carry the microdeletion and may be infertile. A Y chromosome microdeletion can often, but not always, be detected by a blood test. This is because the chromosomes in the sperm may not always be the same as those seen when tested in the blood.

Some men are infertile because the tubes connecting the testes to the penis did not form correctly (congenital bilateral absence of the vas deferens, CBAVD). These men can still father children, but sperm must be taken directly from the testicles or the tubes next to them. This sperm is then used in ICSI. These men have a mild form of cystic fibrosis (CF), and may pass on this gene to their children. Men with CBAVD and their partners should be tested for CF gene mutations before treatment. However, some CF mutations may not be detected by current tests, so that some parents who test negative for CF mutations can still have children affected by CF.

Embryo Transfer

Embryos can be transferred during a fresh cycle at day 1 to day 5 of development. Typically, at the CUFC the embryos are frozen for transfer at a future date. Usually one embryo is placed in the uterus using a thin tube called a transfer catheter. Ultrasound is used to help guide the catheter and to help confirm placement through the cervix and into the uterus. Although this is a simple process, and does normally not require anesthesia, there are some very rare risks. These risks include infection, loss of the embryos, or damage to the embryos. Not all embryos become pregnancies, and not all pregnancies are normal or grow in the correct place – tubal pregnancies can occur. Very rarely the physician cannot perform the transfer and the embryos may be transferred under anesthesia.

- Embryos can be transferred on any day of embryo development, but at the CUFC morphologically normal appearing embryos are routinely cryopreserved for transfer at a future date; embryos that are/ or are not biopsied are routinely cryopreserved at the blastocyst stage development day 5 to day 7.
- You will discuss with your physician the number of embryos to thaw and transfer before the transfer event. Typically, one blastocyst stage embryo is transferred.
- If preimplantation genetic screening has been performed, one euploid (normal) embryo will be transferred during a thawing cycle.
- If you transfer more than one embryo you proceed with the knowledge that you are at risk for becoming pregnant multiple implantation (twins or greater attaching to the lining of the uterus).

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DOB:

Hormonal Support of the Uterine Lining

The most important hormones to support implantation are progesterone and estrogen. Normally, the ovaries make these hormones to support pregnancy. However, in IVF cycles, retrieving the eggs causes reduced production of progesterone and estrogen by the ovaries. Therefore, in most cases, progesterone and sometimes estrogen are routinely taken. Progesterone is most commonly taken as an injection or as a vaginal suppository. Estrogen can be given as pills, an injection, vaginal suppositories, or a skin patch. Progesterone and/or estrogen are usually continued for several weeks to help support the pregnancy.

Assisted Hatching

The cells that make up the early embryo are coated with a membrane (outer shell) called the zona pellucida. Normally, as the embryo grows, this shell becomes very thin so the embryo can "hatch" from its shell. Only after hatching can the embryo implant in the uterus. Assisted hatching makes it easier for the embryo to escape the shell. This is done in the lab, by making a small hole in the shell with a laser. The procedure is usually done on the day of the frozen embryo transfer, before putting the embryos into the transfer catheter. During a biopsy cycle, all normally fertilized developing embryos will be assisted hatched for potential biopsy. Assisted hatching does have some risks. Very rarely, the embryo can be damaged, lose cells, or even be destroyed. There is also a higher chance of having identical twins if the embryo is hatched. There may also be other risks not yet known.

- Assisted hatching involves making a small hole in the outer shell (zona pellucida) that surrounds the embryo.
- Assisted hatching will be used for all developing embryos in an embryo biopsy cycle.
- Hatching may make it easier for embryos to be released from the shell and implant in the uterus.
- Assisted hatching is performed on all oocytes/embryos after they are thawed before transfer.

Cryopreservation

- At the CUFC most cycles are cryopreservation cycles without a fresh transfer.
- Embryos can be cryopreserved on any cycle day, but typically embryos that reach the blastocyst stage on day 5, 6, or 7 and are normal appearing may be biopsied and cryopreserved or cryopreserved without embryo biopsy for a future frozen embryo transfer cycle. After embryo biopsy, embryos are cryopreserved to await genetic testing results and may be transferred during a frozen embryo transfer cycle.
- Fertility preservation can be achieved when eggs or embryos are frozen and banked (stored) for short or long periods of time; the eggs or embryos can be thawed when the person or couple are ready to attempt a pregnancy.
- Frozen eggs and embryos do not always survive the process of freezing and thawing.
- Studies on children born from frozen embryo cycles do not have any greater chance of birth defects than children born after fresh embryo transfers. However, until very large numbers of children have been born from frozen embryos, it is not possible to be absolutely certain that there are no increased risks.
- Legal questions can arise when couples terminate their relationship (e.g. divorce) or one both contributor(s) to the embryo passes away. It is vital to agree on what will be done with cryopreserved embryos remaining in storage beforehand by signing an embryo disposition consent before embryos are cryopreserved. It is suggested you also have a written plan for your cryopreserved embryos.
- A person or couple with frozen eggs or embryos MUST stay in touch with the Fertility Center. If it is greater than 3 years with no patient communication, despite the Fertility Center attempting to contact the person or couple, it will be assumed the cryopreserved material has been abandoned and may be discarded without additional consenting.
- Cryopreserved material should not be stored indefinably at the Fertility Center, it is recommended if your infertility treatment is complete that the oocytes or embryos are transported to a commercial storage facility or you sign a disposition form to donate or discard the cryopreserved material.
- As cryopreserved storage at the Fertility Center is limited, the stored eggs or embryos in storage may be transported to a long-term storage facility on your behalf. You will be contacted concerning details of this transport.
- There are annual fees to store cryopreserved gametes (eggs and sperm) and embryos.

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DOB:

If you choose to freeze embryos, you MUST complete this section on embryo donation. It is vital to agree on embryo donation before the IVF procedure to satisfy regulatory requirements. Please choose one disposition choice below. **By signing to donate, this does not mean you are required to donate, but your embryos will be eligible to donate.**

_______**I/we are considering** donating my/our cryopreserved embryo(s) to another person/couple. I/we understand to satisfy regulatory requirements for embryo donation, the contributors to the embryo (unless donor) will need additional blood testing and complete a simple questionnaire either the week before or the week after the egg retrieval. The third-party reproduction team will guide you through this process to make it as simple as possible. **Embryo(s) cannot be donated to a person/couple without this additional testing and a completed questionnaire.**

_______I/we **DO NOT** wish to donate to another person/couple. **I/we understand without the additional regulatory testing** before embryos are created we will not be able to donate to another person/couple.

By signing below, I/We acknowledge the above selection:

Patient ____________ Partner (if applicable) ____________ Date ____________

Risks of Freezing

In accordance with its protocols, the Fertility Center makes reasonable efforts to manage and properly maintain its patient's cryopreserved material (eggs, sperm and embryos), including, but not limited to storage tank maintenance and monitoring, continual monitoring of the storage tanks via an alarm system with remote capability, and 24 hour embryology surveillance. There is a slight risk that the cryopreservation process (freezing/ storage and thawing) can damage an embryo (the CUFC experience is that ~97% of frozen blastocysts survive thawing/warming). There is no proof that children born from frozen and thawed embryos or frozen and thawed eggs have any more health problems than those born from fresh embryos.

There are circumstances out of the Fertility Center's control that could have harmful effects on your cryopreserved materials:

- Natural and man-made disasters.
- Loss of power to 5 Columbus Circle or New York City.
- Equipment failure (including but not limited to loss of nitrogen or other tank failures).
- Transportation or shipping accidents.

In the event my cryopreserved donor eggs or embryos are damaged, lost or destroyed, are otherwise unavailable for further treatment or implantation, or fail to result in a pregnancy, I/we hereby agree not to sue and agree to hold harmless, the Fertility Center, Columbia University and any of its physicians, employees, or agents.

Risks to the Patient

Ovarian Hyperstimulation Syndrome (OHSS): This is the most severe side effect of stimulating the ovaries. Signs of OHSS include increased ovarian size, nausea, vomiting, and a buildup of fluid in the stomach. You may also have trouble breathing. In some cases, OHSS increases the level of red blood cells, and causes kidney and liver problems. In the most severe cases, it can cause blood clots, kidney failure, or death. All of these complications occur very rarely (in only 0.2% of all treatment cycles). Your physician may suggest freezing embryos for a future transfer.

OHSS occurs at two stages:

- Early, 1 to 5 days after egg retrieval (as a result of the hCG trigger), and
- Late, 10 to 15 days after retrieval (because of the hCG if pregnancy occurs).

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DOB:

The risk of severe problems from OHSS is much higher if you become pregnant. For this reason, your doctor may suggest that your embryos ***be frozen*** for later use instead of transferring them in the fresh cycle. A frozen transfer can be done later, when there is no risk of OHSS.

Cancer: Many have worried that the use of fertility drugs could lead to an increased risk of cancer—in particular, breast, ovarian, and uterine (including endometrial) cancers. One must be careful in interpreting epidemiological studies of women taking fertility drugs, because all of these cancers are more common in women with infertility, so merely comparing women taking fertility drugs with women in the general population inevitably shows an increased incidence of cancer. When the analysis takes into account the increased cancer risk due to infertility per se, the evidence does not support a relationship between fertility drugs and an increased prevalence of breast or ovarian cancer. More research is required to examine what the long-term impact fertility drugs may be on breast and ovarian cancer prevalence rates. For uterine cancer, the numbers are too small to achieve statistical significance, but it is at least possible that use of fertility drugs may indeed cause some increased risk of uterine cancer.

Risks of Pregnancy: Getting pregnant through IVF comes with certain risks. This is partly because women using IVF are often older than those who might get pregnant on their own. In addition, the cause of the infertility itself may be to blame. There may be other risks linked to IVF that are not known at this time. Please see the table below for certain known risks.

Maternal Risks	Absolute Risk (%) in IVF-conceived Pregnancies	Relative Risk (vs. non IVF-conceived Pregnancies)
Pre-eclampsia	10.3%	1.6 (1.2–2.0)
Placenta previa	2.4%	2.9 (1.5–5.4)
Placental abruption	2.2%	2.4 (1.1–5.2)
Gestational diabetes	6.8%	2.0 (1.4–3.0)
Cesarean delivery	26.7%	2.1 (1.7–2.6)

In this table, the Absolute Risk is the percent of IVF Pregnancies in which the risk occurred. The Relative Risk is the risk in IVF versus the risk in non-IVF pregnancies; for example, a Relative Risk of 2.0 indicates that twice as many IVF pregnancies experience this risk as compared to non-IVF pregnancies. The numbers in parentheses (called the "Confidence Interval") indicate the range in which the actual Relative Risk lies.

While embryos are transferred directly into the uterus with IVF, ectopic (tubal, cervical and abdominal) pregnancies as well as abnormal intra-uterine pregnancies have occurred either alone or concurrently with a normal intra-uterine pregnancy. These abnormal pregnancies oftentimes require medical treatments with methotrexate (a weak chemotherapy drug) or surgery to treat the abnormal pregnancy. Side effects of methotrexate include nausea or vomiting, diarrhea, cramping, mouth ulcers, headache, skin rash, sensitivity to the sun and temporary abnormalities in liver function tests. Risks of surgery include the risks of anesthesia, scar tissue formation inside the uterus, infection, bleeding and injury to any internal organs.

Risks of Multiple Gestation

Historically more than 25% of IVF pregnancies were multiple gestation (multiple pregnancies), at the Columbia University Fertility Center we have successfully lowered our multiple gestation rate by performing single embryo transfers; in 2019 less than 4% of IVF pregnancies were multiples. Identical twins occur in less than 5% of all IVF pregnancies, identical twins may happen more often after blastocyst (Day 5/6/7) transfers.

Multiple gestation in general has an increased risk of pregnancy problems. The most important maternal complications associated with multiple gestation are premature delivery ("early delivery" accounts for most of the excess perinatal morbidity and mortality associated with multiple gestations), pre-eclampsia (high blood pressure and protein in the urine), diabetes of pregnancy (gestational diabetes), excessive bleeding at delivery and placental disorders are more common. Other problems more common with multiple pregnancy include gallbladder problems, skin problems, excess weight gain, anemia, excessive nausea and vomiting, and exacerbation of pregnancy-associated gastrointestinal symptoms including reflux and constipation. Chronic back pain, intermittent heartburn, postpartum laxity of the abdominal wall, and umbilical hernias also can occur. Triplets and above increase the risk to the mother of more significant complications including post-partum hemorrhage and transfusion.

Placenta previa and vasa previa are more common complications in multiple gestations. Abruptio placenta also is more common and postpartum hemorrhage may complicate 12% of multifetal deliveries. Consequences of multiple gestations include the major sequelae of prematurity (cerebral palsy, retinopathy of prematurity and chronic lung disease) as well as those of fetal growth restriction (polycythemia, hypoglycemia, necrotizing enterocolitis). It is unclear to what extent multiple gestations themselves affect neuro-behavioral development in the absence of these complications. Rearing of twins and high-order multiples may generate physical, emotional, and financial stresses, and the incidence of maternal depression and anxiety is increased in women raising multiples. At mid-childhood, prematurely born offspring from multiple gestations have lower IQ scores, and multiple birth children have an increase in behavioral problems compared with singletons.

Fetal death rates for singleton, twin, and triplet pregnancies are 4.3 per 1,000, 15.5 per 1,000, and 21 per 1,000, respectively. Fetal growth problems and discordant growth among the fetuses also result in perinatal morbidity and mortality. The death of one or more fetuses in a multiple gestation (vanishing twin) is more common in the first trimester and may be observed in up to 25% of pregnancies after IVF. Loss of a fetus in the first trimester is unlikely to adversely affect the surviving fetus or mother. No excess perinatal or maternal morbidity has been described resulting from a "vanishing" embryo. Demise of a single fetus in a twin pregnancy after the first trimester is more common when they share a placenta, ranging in incidence from 0.5% to 6.8%, and may cause harm to the remaining fetus. Multifetal pregnancy reduction (where one or more fetuses are selectively terminated) reduces, but does not eliminate, the risk of these complications.

Multiple fetuses (including twins) that share the same placenta have additional risks. Twin-twin transfusion syndrome in which there is an imbalance of circulation between the fetuses may occur in up to 20% of twins sharing a placenta. Excess or insufficient amniotic fluid may result from twin-to-twin transfusion syndrome. Twins sharing the same placenta have a higher frequency of birth defects compared to pregnancies having two placentas. Twins sharing the same placenta appear to occur more frequently after blastocyst transfer.

Risks to Your Baby

IVF babies may be at a slightly higher risk for birth defects and genetic defects; IVF has a slightly increased risk of multiple pregnancy, even when only one embryo is transferred.

Overall Risks: The first IVF baby was born in 1978. Since then, more than 5 million children around the world have been born through IVF. Studies have shown that these children are quite healthy. In fact, some experts believe having a child through IVF is now just as safe as having a child naturally. IVF single babies are often born about 2 days earlier than naturally conceived babies. They are about 5% more likely to weigh less than 5 pounds, 8 ounces (2,500 grams) than a naturally conceived single baby.

Birth Defects: The risk of birth defects through normal birth is about 4.4 %, and it is about 3% for severe birth defects; no higher risks are seen in frozen embryo or donor egg cycles.

Imprinting Disorders: These are rare disorders caused by whether the genes from the mother or the genes from the father are working. Studies do not agree on whether these disorders are associated with IVF. Even if they are, these disorders are extremely rare (1 out of 15,000 people).

Childhood Cancers: Most studies do not suggest any extra risk, except for retinoblastoma (a cancer behind the eye). One study did report an increased risk after IVF treatment, but further studies did not find an increased risk.
Infant Development: Most studies of long-term developmental outcomes have been reassuring so far. Most children are doing well. However, these studies are hard to do, and they have some limitations. A more recent study using better methods shows an extra risk of cerebral palsy and developmental delay. However, this arose mostly from prematurity and low birth weight that was a result of multiple pregnancy.

The Option of Multifetal Pregnancy Reduction (Selective Reduction)

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The more fetuses there are in the uterus, the greater the chance of a problem. Patients with twins or more have 3 choices:

- Continue on with the pregnancy (with all the risks that have already been stated).
- End the pregnancy.
- Reduce the number of fetuses (terminate one or more of the fetuses) to lower the health risks to mother and child.

Reducing the number of fetuses lowers the risk of some complications. This can be a difficult decision to make. The main danger is losing the entire pregnancy. The odds of losing the entire pregnancy are about 1 in 100 (1%). The odds of losing the entire pregnancy are greater if there are more than 3 fetuses present before the procedure is done. Raising twins or higher multiples may cause physical, emotional, and financial stresses. The chance of having depression and anxiety is higher in women raising multiples. Patients may consider working with mental health professionals who are specially trained in the area of infertility care, as well as with their health care team, to minimize the emotional impact of infertility.

Consent for Preimplantation Genetic Testing for Aneuploidy (PGT-A)

Preimplantation Genetic Testing (PGT) of embryos. This portion of the consent pertains to the specific procedures, risks, benefits and results of PGT.

Trophectoderm biopsy is the primary method of embryo biopsy. Since trophectoderm cells are extra-embryonic tissue, they do not become part of the fetus but do become part of supporting structures, such as the placenta and membranes. The advantage of this method is ~5 trophectoderm cells can be removed from the embryo for analysis. Trophectoderm biopsy takes place at the blastocyst stage on day 5, day 6 or day 7 of embryo development. For this procedure to be performed, all normally dividing embryos will undergo assisted hatching on day 3. There must be at least one fully expanded, morphologically normal blastocyst on day 5, day 6 or day 7 for trophectoderm biopsy to be performed. After the biopsy is performed, the blastocysts will be cryopreserved for possible future embryo transfer.

PGT-A Results

Euploid: Normal number of chromosomes per cell. This embryo is recommended for transfer.

Aneuploid: Abnormal number of chromosomes per cell. This embryo is not recommended for transfer.

Mosaic: This embryo is predicted to have some cells with an abnormal number of chromosomes and some with a normal number of chromosomes. These embryos are not recommended for transfer. However, apparently normal live births have been reported from the transfer of embryos with a mosaic result. There is still limited experience with transfer of mosaic embryos and no long-term data. This embryo may be considered for transfer if no euploid embryos are available and the risks have been thoroughly explained by your physician and/or genetic counselor.

No Result: No DNA, no result or degraded DNA – a reliable result could not be obtained from these embryos. These embryos can be transferred with an untested status or the embryo can be re-biopsied, re-frozen and sent for analysis. This would require a follow-up conversation with your physician.

Euploid (normal) embryos and mosaic embryos
Will remain in cryopreserved storage.

Disposition of abnormal embryos

Please select and initial A, or B, or C concerning disposition of abnormal embryos.

A. Continue to store all embryos in cryopreserved storage, no matter what the result even if classified as abnormal. Storage fees may apply.

B. Donate to research or discard (discard if cannot be used for research).

C. Discard only.

++

By initialing below, I/We acknowledge the above selection.

______________________ ______________________
Patient Initials Partner Initials (if applicable)

PGT Risks of the Procedure

Damage to the embryo during the biopsy procedure may result in a decrease in the embryo's ability to develop and/or implant. The risk of damage from biopsy is uncertain but one publication found no significant impact from trophectoderm biopsy (Scott RT, Upham KM, Forman EJ, et. al. Cleavage-stage biopsy significantly impairs human embryonic implantation potential while blastocyst biopsy does not: a randomized and paired clinical trial. *Fertil Steril* 2013;100:624-30)

- Embryos may not progress to the blastocyst stage of development by day 5, day 6 or day 7 and will not be biopsied.
- The DNA from the biopsy may be affected during transport to the outside laboratory.
- There is a 3-5% risk of a cryopreserved blastocyst not surviving cryopreservation or thawing.
- None of the embryos may be eligible for transfer and aneuploid embros will not be transferred.
- The genetic testing of the embryo may be inaccurate or inconclusive.

Additionally, given that testing is not perfect and only the trophectoderm layer is sampled, please understand that prenatal non-invasive and/or invasive genetic testing is strongly recommended. Invasive methods such as chorionic villous sampling or amniocentesis may be recommended and are associated with a risk of pregnancy loss (<1%).

The laboratory will only release the results of the screening tests to my/our doctor or to his/her agent unless otherwise authorized by you as required by law.

Reporting Outcomes

In 1992, the Fertility Clinic Success Rate and Certification Act was passed. This law requires the Centers for Disease Control and Prevention (CDC) to gather information about IVF cycles and pregnancy outcomes in the U.S. each year. This information is used to calculate success rates which are reported each year. We will report the required information from your IVF procedure to the CDC. Since our Clinic is a member of the Society of Assisted Reproductive Technologies (SART) of the American Society for Reproductive Medicine (ASRM), it will also be reported to SART. Information reported to SART about your cycle may be used for research or quality assessment according to HIPAA guidelines; your name will never be connected to your cycle information in any research that is published by ASRM or SART.

Since 2006, the Society for Assisted Reproductive Technology has participated in a series of studies looking at the health of women and children after IVF. Many of these studies are still being conducted. The studies compare women who have not had trouble conceiving and their children with women who used IVF and their children. The studies also compare women who had trouble conceiving but did not do IVF, and their children, to women and their IVF children. IVF children

who have siblings form another study group. They are compared with their siblings who were conceived with IVF, conceived with non-IVF fertility treatment, or conceived spontaneously. The items studied are problems related to pregnancy or birth, and the risk of birth defects. Children are also followed to find out if they have developmental delays, problems in school, or increased risk of childhood or adult cancer. You can see the results of many of these studies in the information given below. Results can also be found on the SART website (www.sart.org) under "Research".

Regulatory Inspections

The Fertility Center is licensed by the New York State Department of Health, accredited by the American Association for Accreditation of Ambulatory Surgery Facilities and is registered with the Food and Drug Administration (FDA). These agencies inspect the Fertility Center regularly to maintain licensure and accreditation. All program records must be made available to regulatory inspectors during the course of an inspection.

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DOB:

In Vitro Fertilization/ PGT

Informed Consent

Signing this consent indicates that the consent has been read in its entirety, all of your questions have been answered and the information is understood. If you have questions or concerns or require additional clarification, please contact your physician/ nurse team before signing. This consent is valid for one year from the date it is signed. This consent may be rescinded at any time by any of the signed parties. In the event that any of the signed parties withdraw from participation, then this consent is nullified and will require consultation with a Columbia University Fertility Center physician and the resigning of all pertinent consents.

Additional consents will be signed at the time of the retrieval and will include procedure and anesthesia consents.

Partner Name _____
(If applicable)

Signatures:

Patient _____ Date: _____

Partner _____ Date: _____
(If applicable)

11. 3. MGH Fertility Center

MGH Fertility Center
In Vitro Fertilization
Process, Risk, and Consent

Date: _____

Patient **Last Name:** _____ **First Name:** _____

ID#_____

If applicable:

Partner **Last Name:** _____ **First Name:** _____

ID #_____

In Vitro Fertilization (IVF) is a treatment that removes eggs from an ovary or ovaries to achieve a pregnancy either at that time or at a later time. A patient can use sperm provided by a partner or from a donor for the insemination of eggs, and have the resulting embryos transferred to the uterus or a gestational carrier.

In Vitro Fertilization Process & Risks

An IVF cycle can include the following steps or procedures:

- Taking medicine to grow several eggs at once
- Removing the eggs from the ovary or ovaries
- Combining eggs and sperm together so the eggs will be fertilized
- Growing any resulting fertilized eggs (embryos) in the lab
- Placement ("transfer") of one or more embryo(s) into a uterus
- Taking hormone medications to assist for a successful pregnancy

Other IVF steps may be included:

- Injecting individual sperm into each egg, called intracytoplasmic sperm injection
- Cryopreservation (freezing) of eggs or embryos that are not transferred to the uterus
- Genetic testing of the embryos for abnormal genes or number of chromosomes
- Utilization of a donor oocytes, donor sperm or a gestational carrier

Medications for IVF Treatment

- **The success of IVF largely depends on growing several eggs at once.**
- **Injections of the hormones FSH and/or LH (gonadotropins) are used for this purpose.**
- **Other medications are used to keep ovulation from happening too soon.**
- **Sometimes the ovaries respond too strongly—and sometimes not enough.**

Here are some medicines commonly used in an IVF cycle:

- ***Gonadotropins, or injectable "fertility drugs"*** (Follistim®, Gonal-F®, Menopur®, Bravelle®, low dose hCG or human chorionic gonadotropin): These are hormones that help the ovary to grow several eggs (oocytes) at once over approximately 8 or more days. These injections may be given either just under the skin or directly into muscle.

  Taking any medicine in an injection can cause bruising, redness, swelling, or pain at the injection site. In rare cases, there may be an allergic reaction. They can cause bloating or minor discomfort as the ovaries briefly become enlarged. About 1% of the time Ovarian Hyperstimulation Syndrome (OHSS) can occur [see "Risks of Medication and Pregnancy" section]. Other side effects can include headaches, weight gain, feeling tired, mood swings, nausea, or development of clots in blood vessels.

  Sometimes, especially when testing prior to the IVF cycle has shown a lower number of eggs available, the medications may not help multiple eggs to grow. There may be very few or even no eggs harvested at the egg retrieval procedure, or the cycle may be canceled before egg retrieval can be attempted.

- ***GnRH-agonists (leuprolide acetate) (Lupron®):*** This medication is an injection. There are two forms of the drug. One is a short-acting form that needs to be injected daily, and the other is a long-acting form that lasts for 1-3 months. Leuprolide is often given to help prevent the release of eggs (by ovulation) before they can be retrieved. Leuprolide can also be used to start the growth of eggs or as a trigger the final stages of their growth. Leuprolide is approved by the FDA (U.S. Food and Drug Administration), but not approved for use in IVF. However, because it has been extensively studied in IVF patients, the medicine has been safely used in IVF for more than 20 years.

  Leuprolide can cause a number of side effects. These include hot flashes, vaginal dryness, nausea, headaches, and muscle aches. Some patients may retain fluid or feel depressed, and long-term use can result in bone loss. Since Leuprolide is taken as an injection, skin reactions can also occur where the injection is given. No long term or serious side effects are known. If Leuprolide is given in a cycle after ovulation has occurred, you should use condoms for birth control in that month. Leuprolide has not been linked with any birth defects, but it should be stopped with pregnancy.

- ***GnRH-antagonists (ganirelix acetate or cetrorelix acetate)*** (Ganirelix®, Cetrotide®): These drugs are used to prevent premature ovulation. Side effects may include stomach pain, headaches, skin reactions where the shot is given, and nausea. If given in a cycle after ovulation has occurred, pregnancy should be avoided. It should be stopped with pregnancy.

- ***Human chorionic gonadotropin (hCG)*** (Profasi®, Novarel®, Pregnyl®, Ovidrel®): hCG is a natural hormone used in IVF to help the eggs become mature and ready to harvest and be fertilized. This drug must be taken at just the right time to retrieve mature eggs. Side effects can include breast tenderness, bloating, and pelvic pain.

- ***Progesterone, and in some cases, estradiol:*** These two hormones are normally produced by the ovaries after ovulation. After egg retrieval, the ovaries may not produce enough of these hormones to support pregnancy. If planning pregnancy, adding them helps improve chances of getting pregnant and staying pregnant. Progesterone can be taken as a daily intramuscular injection (injection into muscle, most commonly in the hip). It can also be taken by placing a suppository (Endometrin®, Crinone®, Prochieve®, Prometrium®, or pharmacist-compounded suppositories) directly into the vagina as frequently as three times per day after egg retrieval. Progesterone is often continued for several weeks after pregnancy is established. Progesterone has not been shown to cause birth defects. Side effects of progesterone can include depression, sleepiness, or an allergic reaction. The intra-muscular injection can cause infection or pain at the injection site. Estradiol can be taken by pill, in a patch, as an intramuscular shot, or as a vaginal suppository. Side effects of estradiol include nausea, irritation at the site of the injection or patch, and the risk of blood clots or stroke.

- ***Oral contraceptive pills (birth control pills):*** Your doctor may advise use of birth control pills for 2 to 6 weeks before starting hormone stimulation injections. This is done to slow down hormone production or to schedule a treatment cycle. Side effects include bleeding, headache, breast tenderness, nausea, and swelling. There is also a risk of blood clots or, very rarely, stroke.

- ***Clomid® or Letrozole®:*** These medicines are used in some treatments to increase the number of growing eggs or reduce the estrogen level in the bloodstream. They are taken by mouth in pill form. Short-term side effects include headache, hot flashes, or increased moodiness. In rare situations, visual changes may occur with Clomid. The doctor should be notified and Clomid should be discontinued if this occurs.

- ***Other medications:*** Antibiotics will be given at the time of an oocyte (egg) retrieval. This may reduce the risk of infection from egg retrieval or embryo transfer. Antibiotic use may cause a number of side effects, including vaginal yeast infection, nausea, vomiting, diarrhea, rashes, sensitivity to the sun, or allergic reactions. Your doctor may suggest anti-anxiety medications or a muscle relaxant before the embryo transfer. The most common side effect of these medicines is drowsiness. Other medicines such as steroids, heparin, low molecular weight heparin, or aspirin may also be recommended.

Transvaginal Oocyte (Egg) Retrieval

- **Eggs are removed from the ovary with a needle under ultrasound guidance.**
- **Amesthesia is given to make this more comfortable.**
- **Complications such as injury and infection are rare.**

Oocyte retrieval is the removal of eggs from the ovary. Before removing the eggs, the doctor will look at the ovaries using an ultrasound probe placed into the vagina. A long needle, which can be seen on ultrasound, can be attached to the ultrasound probe using a needle guide. Guiding the needle into the ovaries, the doctor will draw out fluid, eggs, and egg-supporting cells. Very rarely, the ovaries cannot be reached through the vagina. In that case, the eggs might be removed by guiding the needle through the belly to reach the eggs. Anesthesia is used to reduce or eliminate pain.

Risks of egg retrieval:

Infection: Bacteria from the vagina may be transferred into the pelvis or ovaries by the needle. This can cause an infection of nearby organs. The incidence of infection after egg retrieval is very small (less than 0.1%). If an infection occurs, antibiotics may be given. Severe infections sometimes require surgery to remove infected tissue. Infections can reduce your chance of getting pregnant in the future. Antibiotics will be used before the egg retrieval to help reduce the chance of infection. Still, there is no way to remove the risk completely.

Bleeding: The needle passes through the vaginal wall and into the ovary to obtain the eggs. Both of these structures contain blood vessels. There are also other blood vessels nearby. This means that small amounts of blood may be lost while removing the eggs. The risk of major bleeding is small (< 0.1%). Major bleeding may require surgery to stop and could result in the removal of an ovary. Only rarely is a blood transfusion needed. If bleeding occurs and is not noticed (also rare), it can lead to death.

Trauma: Even with ultrasound guidance, nearby organs can be damaged. This includes damage to the intestines, appendix, bladder, ureters, and ovary. In some cases, a damaged organ may need to be fixed or removed through surgery. Still, the risk of damage during egg retrieval is very low.

Anesthesia: The use of anesthesia while removing eggs can cause an allergic reaction or low blood pressure. It can also cause nausea or vomiting. In rare cases, use of anesthesia has resulted in death.

Failure: Sometimes no eggs are found during the retrieval process or there may be an issue where we cannot safely access an ovary or ovaries; thereby resulting in eggs that cannot be retrieved. In other cases, the eggs are not normal, or are of poor quality. These situations can prevent a successful pregnancy from occurring.

In vitro fertilization and embryo culture

- **Sperm and eggs are placed together in a petri dish.**
- **The dish is kept under special conditions to promote fertilization.**
- **The fluid in the dish (culture medium) helps the sperm fertilize the egg and helps embryos to grow. Each clinic may have its own blend of fluids in which to grow the embryos.**
- **In most cases, the embryologist chooses the best embryos for pregnancy by the way they look under a microscope.**

After eggs are retrieved, they are transferred to the embryology laboratory where they are kept in conditions that support their growth. The eggs are placed in small dishes or tubes containing "culture medium," which is special fluid to support development of the embryos. The fluid is made to resemble the conditions in the fallopian tubes and uterus. The eggs are then placed into incubators, which keep the temperature, humidity, gas, and light at just the right levels.

Three to four hours after the eggs are retrieved, sperm are placed in the culture medium with the eggs. In some cases, individual sperm are injected into each mature egg in a technique called Intracytoplasmic Sperm Injection (ICSI) (see "ICSI" section). The eggs are then returned to the incubator, where they remain to develop and grow. They are inspected at intervals over the next few days, to check their progress.

Embryo development usually proceeds along the following schedule:

- *Day 1*: This is the day that the eggs and sperm come together, and we can check for signs of fertilization. At this stage, the normally fertilized egg is still a single cell with 2 nuclei, called a 2PN or zygote.
- *Day 2*: Normal embryos will divide into 2 to 4 cells.
- *Day 3*: Normally developing embryos will continue to divide and contain 4 to 8 cells.
- *Day 4*: The cells of the embryo begin to merge to form a solid ball of cells called a morula (named because it looks like a mulberry).
- *Day 5*: Normal embryos now have 100 cells or more and are called blastocysts. It has an inner fluid-filled cavity and a small cluster of cells on the inside called the inner cell mass.

It is important to understand that many eggs and embryos are abnormal. This means that some eggs will not fertilize, and some embryos will not divide at a normal rate. Some embryos may stop growing. Even if embryo(s) develop normally in the lab, pregnancy may still not occur with the embryo(s). Some embryos end up being genetically abnormal. Testing for genetic abnormalities is possible ("preimplantation genetic testing, or "PGT"), but genetic testing is not routinely done. The best embryo(s) for transfer are usually selected by the way they look under the microscope.

We take great care of all eggs, embryos, and sperm in the lab. Still, there are many reasons why pregnancy may not happen with IVF:

- The eggs may fail to fertilize.
- One or more eggs may fertilize abnormally. This can lead to an abnormal number of chromosomes in the embryo. These abnormal embryos cannot be transferred.
- The fertilized eggs may fall apart before dividing into embryos, or the embryos may not develop normally.
- Rarely, the eggs or embryos may be harmed by contact with bacteria in the lab.
- In spite of having backup systems in place, lab equipment may fail or power may be lost. Both can lead to the destruction of eggs, sperm, and embryos.
- A lab accident or human error can happen and can lead to embryo loss.

- Other unplanned events may prevent any step of the process from being performed or prevent a pregnancy from occurring.
- Hurricanes, floods, or other "acts of God," including bombings or other terrorist acts, could destroy the laboratory or its contents, including any sperm, eggs, or embryos.

Quality control is the process of running tests to ensure that lab conditions are the best they can be to help embryos grow. Systems in the lab are continuously monitored to make sure conditions are optimal. Sometimes immature or abnormal eggs, or embryos that have not developed normally, can be used for quality control checks before they are discarded. None of the material that would normally be discarded--blood, tissues eggs, sperm or embryos--will be used to create a pregnancy or a cell line.

Embryo transfer

- **After a few days of development, the best-developed embryos are chosen for transfer.**
- **The number of embryos transferred affects the pregnancy rate and the risk of twins or other multiple pregnancies.**
- **The age of the person providing the egg, and the quality of the developing embryo(s) have the greatest effect on pregnancy outcome.**
- **Embryos are placed in the uterus using a thin tube.**
- **Extra, normally developing embryos that are not transferred can be frozen for future use.**

After a few days of development, the embryo transfer takes place, or the embryos are frozen for transfer at a later date. One or more embryos are placed in the uterus using a thin tube called a catheter. Ultrasound is used to help guide the catheter. It can also confirm placement through the cervix and into the uterus. Although this is a simple process, there are some very rare risks. These risks include infection, loss of the embryo(s), or damage to the embryo(s). Not all embryos become pregnancies, and not all pregnancies are normal or grow in the correct place - ectopic (outside the uterus) pregnancies can occur.

The number of embryos to transfer is an important decision. The age of the eggage and the quality of the embryo affect both the chance for pregnancy as well as the chance for multiple embryos to implant. If multiple embryos implant, a multiple pregnancy (twins, triplets, or more) will result. In some cases, an embryo can split into two (identical twins) after transfer. Before the transfer, it is critical to discuss with your doctor how many embryos to transfer.

Guidelines for the maximum number of embryos to transfer are included on the attachment "Embryo Transfer Guidelines".

Hormonal support of the uterine lining

- **For pregnancy to occur, the embryo(s) must attach to the lining of the uterus. This process is called *implantation*.**
- **Implantation has a better chance of happening if you take extra progesterone hormone.**

The most important hormones to support implantation are progesterone and estrogen. Normally, the ovaries make these hormones to support pregnancy. However, in IVF cycles, retrieving the eggs causes reduced production of progesterone and estrogen by the ovaries. Therefore, in most cases, progesterone and sometimes estrogen are routinely taken. Progesterone is most commonly taken as an injection or as a vaginal suppository. Estrogen can be given as pills, an injection, vaginal suppositories, or a skin patch. Progesterone and/or estrogen are usually continued for several weeks to help support the pregnancy.

Additional Elements

Intracytoplasmic Sperm Injection (ICSI)

- **In some cases, fertilization will not happen when eggs and sperm are placed together in a lab dish. Injecting a sperm into each egg (ICSI, or intracytoplasmic sperm injection) can help fertilization occur.**
- **ICSI does not guarantee normal fertilization.**
- **There may be an increased risk of genetic problems in children born from ICSI (possibly related to underlying problems with abnormal sperm).**
- **ICSI will not improve any defects in the eggs.**

ICSI involves the direct injection of a single sperm into the interior of an egg using an extremely thin glass needle. This lets the sperm enter the egg without having to break through the shell around the egg (the *zona pellucida*). For it to work, the sperm must be healthy, and the egg must be mature.

ICSI is a good choice when the sperm count, movement, or quality is poor. Live birth rates are very close to those of IVF for patients with normal sperm counts. ICSI may also be recommended to reduce failure of fertilization. This may occur more frequently when infertility is unexplained.

ICSI may be associated with a slightly higher risk of birth defects. It is hard to know if the increased risk is due to the ICSI procedure itself or to defects in the sperm. The risk of birth defects after ICSI is still quite small (4.2% compared with 3% in children conceived naturally). Experts are still debating the impact of ICSI on the mental and physical development of children. Most recent studies have not detected any differences in the development of children born after ICSI, regular IVF, or natural conception.

Children conceived by ICSI have slightly more problems with their sex chromosomes (the X and Y chromosomes) than children conceived by IVF alone, but only by a very small margin (0.8% to 1.0% for ICSI pregnancies compared to 0.2% for IVF pregnancies). The reason for the difference is not clear. It may be caused by the ICSI procedure itself, or by the sperm. Patients with sperm problems such as very low count and low motility are more likely to have genetic abnormalities. They often produce sperm with abnormal chromosomes, especially with abnormal sex chromosomes (X and Y). If sperm with abnormal chromosomes produce pregnancies, the pregnancies will likely carry the same defects. Translocations (a re-arrangement of chromosomes that can cause miscarriage or birth defects) may be more common after ICSI.

Small deletions on a Y chromosome may be associated with extremely low sperm counts or no sperm. In some of these cases, sperm can be obtained to fertilize eggs with ICSI. Any sperm containing a Y chromosome microdeletion will pass on the deletion to any child with a Y chromosome. These children will also carry the microdeletion and may be infertile. A Y chromosome microdeletion can often, but not always, be detected by a blood test. This is because the chromosomes in the sperm may not always be the same as those seen when tested in the blood.

Some patients are infertile because the tubes connecting the testes to the penis did not form correctly (congenital bilateral absence of the vas deferens [CBAVD]). These patients can still have children, but sperm must be taken directly from the testicles or the tubes next to them. This sperm is then used in ICSI. This is a mild form of cystic fibrosis (CF), which can be passed on to their children. If CBAVD is detected, the person giving the egg and the sperm should both be tested for CF gene mutations. However, some CF mutations may not be detected by current tests, so that some patients who test negative for CF mutations can still have offspring affected by CF.

Preimplantation Genetic Testing (PGT)

- **Preimplantation genetic testing of embryos requires removal of one or more cells from the embryo (*embryo biopsy*).**
- **This test is most often done on Day 5 or Day 6 of embryo development, but it may be done sooner in some circumstances.**
- **The cells removed from the embryo will be sent to an off-site lab for the testing, while embryos remain in storage at the clinic.**
- **The tested embryos will need to be frozen (cryopreserved) while the test is being run.**
- **Test results can be incorrect.**

There are several reasons that some patients choose to do PGT. Current reasons include:

- determining whether the embryo has the incorrect number of chromosomes ("PGT-A").
- determining whether the embryo has a structural rearrangement of its chromosomal material ("PGT-SR").
- determining whether the embryo has a specific disease-causing mutation ("PGT-M")
- determining the biological sex of the embryo to reduce or eliminate risk of disease if determined by sex chromosomes.

PGT does not guarantee that a pregnancy will occur, even if embryo testing is normal. Factors other than the genes also influence pregnancy rates.

Screening the embryo's chromosomes, or testing for one specific genetic disease, does not guarantee that the embryo will be healthy and free of other disorders. For example, some common disorders that cannot be checked with PGT are autism and diabetes. Some birth defects can also occur even if chromosome screening is normal. An example of this would be a cleft lip or palate (failure of the lip and upper mouth to join properly).

It is always a possibility that PGT will show that there are NO normal embryos available to transfer.

Risks of embryo biopsy

- Damage. There is a small risk of damage to the embryo. This may result in no healthy embryos available to transfer.
- No result. The test may not give a result. Sometimes, there is not enough genetic material retrieved to run the test. It may be necessary to repeat the biopsy and try again to test the embryo.

- Misdiagnosis. The test may give the wrong result, and say that a normal embryo is actually abnormal, or that an abnormal embryo is actually normal. The accuracy of testing is determined by the off-site lab. Most testing is extremely accurate, so the chance of misdiagnosis is low. Furthermore, since not all embryos are made up of cells with identical genetics ("mosaicism"), it is possible that the test result does not reflect the genetics of the entire embryo. Consequently, the current recommendation is to confirm the result in early pregnancy.

Assisted Hatching

- **Assisted hatching involves making a hole in the outer shell (zona pellucida) that surrounds the embryo.**
- **Hatching may make it easier for embryos to be released from the shell and implant in the uterus.**

The cells that make up the early embryo are coated with a membrane (shell) called the zona pellucida. Normally, as the embryo grows, this shell melts away. This lets the embryo be released or "hatch" from the shell. Only after hatching can the embryo implant in the uterus for the pregnancy to continue.

Assisted hatching makes it easier for the embryo to escape the shell. This is done in the lab, by making a small hole in the shell with a needle, a laser, or with chemicals. The procedure is usually done on the day of transfer, before putting the embryos into the transfer catheter.

Some programs use assisted hatching because of the belief that it improves implantation and birth rates. There is no absolute evidence of this, however. Assisted hatching could be helpful in who are over 38 years old when their eggs are harvested, or if they have failed to get pregnant in a previous IVF cycle. It can also be done when the shell around the embryo is extra thick as well as with frozen embryos. For this reason, assisted hatching is performed in our clinic on all embryos that have been frozen and thawed for transfer.

Assisted hatching does have some risks. Very rarely, the embryo can be damaged, lose cells, or even be destroyed. There is also a higher chance of having identical twins if the embryos are hatched, which is a riskier pregnancy. There may also be other risks not yet known.

Cryopreservation

- **Freezing of eggs and embryos provides other chances for pregnancy in the future.**
- **Frozen eggs and embryos do not always survive the process of freezing and thawing.**
- **Freezing of eggs before fertilization does not work as well as freezing of embryos.**
- **Ethical and legal questions can arise when couples separate or divorce. It is vital to agree on what will be done with remaining eggs or embryos in those cases.**
- **A person or couple with frozen eggs or embryos MUST be in touch with the clinic once a year.**
- **There are usually yearly fees for keeping embryos or eggs frozen.**

Sometimes there are normally developing embryos left after embryo transfer. Additional normal-appearing embryos can be frozen for future use. In some cases, it may be planned for all embryos from an IVF cycle to be frozen (for example, when PGT is used). On the other hand, some patients may wish to freeze their eggs because they are not ready to conceive now, or because they are planning to have therapy that could damage their eggs.

Benefits of freezing:

- Prevention from going through ovarian stimulation again if you need eggs or embryos in the future.
- Transfer of fewer embryos in the fresh cycle, and ability to keep the others for a frozen cycle. This can reduce the risk of a multiple pregnancy (twins, triplets, or greater).
- Freezing all embryos in the fresh cycle can prevent over-stimulation of the ovaries.
- Allows for test results from PGT to return.
- Allows for fertility preservation if one is at risk because of surgery or other treatments such as cancer or gender affirming therapy.

There are different ways to freeze embryos. The most common are "slow" freezing and "rapid" freezing (called *vitrification*). You should know that embryos do not always survive the freezing and thawing process. There is always a risk that no embryos will survive. If this happens, the transfer will have to be cancelled. Studies of animals and humans indicate that children born from frozen embryo cycles do not have any greater chance of birth defects than children born after fresh embryo transfers. However, until very large numbers of children have been born from frozen eggs or embryos, it is not possible to be absolutely certain that there are no increased risks.

Risks of freezing:

The process of cryopreservation (freezing), storage, and thawing can damage cryopreserved eggs or embryos, and not all eggs and embryos will be successfully cryopreserved, or, if cryopreserved, successfully thaw, fertilize (if eggs), or be available for further treatment or implantation.

It is also possible that cryopreserved eggs and embryos may be damaged, destroyed, lost or fail to develop, and therefore be unavailable for further treatment or implantation, due to a number of potential factors, including, but not limited to: patient-specific differences in tolerance of gamete freezing; accidents; power outages; mechanical or equipment failure (including but not limited to loss of nitrogen or other tank failures); materials (including vials, straws and other containers used to freeze and store the samples and their labels); changes of any applicable law or regulations; human error; labelling errors; inventory record loss; natural and man-made disasters; sabotage; transportation or shipping accidents or other events which may be beyond the control of MGH Fertility Clinic or its laboratory. In accordance with its protocols, MGH Fertility Clinic makes reasonable efforts to handle and maintain its patients' eggs and embryos, including, but not limited to maintenance and monitoring of its equipment, materials and laboratory. Despite such efforts, I understand that as a result of one or more of these potential factors, my eggs and/or embryos may become unavailable for further treatment or implantation, or that the likelihood of a pregnancy resulting from any treatment or implantation may be reduced.

NOTE: In some cases, the clinic may not own or operate the laboratory responsible for cryopreservation or storage of your eggs or embryos and, therefore, cannot be responsible for laboratory processes beyond its knowledge and control. If this is true for your treatment, you may be asked to sign further documents with the laboratory. In the event eggs or embryos are damaged, lost or destroyed, are otherwise unavailable for further treatment or implantation, or fail to result in a pregnancy, I hereby agree not to sue and agree to hold harmless, the MGH Fertility Clinic, and any of MGH Fertility Clinic's physicians, employees, or agent except in the event of willful misconduct or gross negligence on the part of MGH Fertility Clinic, or any of MGH Fertility Clinic's physicians, employees, contractors or agents.

In some cases, eggs or embryos transported to another facility for storage. In the event the embryos are lost, damaged or destroyed during transport, are otherwise unavailable for further treatment or implantation, or fail to result in a pregnancy, I hereby agree not to sue and agree to hold harmless, MGH Fertility Clinic, and any of MGH Fertility Clinic's physicians, employees, or agent except in the

event of willful misconduct or gross negligence on the part of MGH Fertility Clinic, or any of MGH Fertility Clinic's physicians, employees, or agents.

If you choose to freeze eggs or embryos, you MUST complete the Disposition of Eggs or Disposition of Embryos statement before freezing. The statement explains the choices you have for disposing of the eggs or embryos in a variety of situations that may arise. The intended parent(s) can submit a new statement later if a change in choice occurs. For frozen embryos, any change requires that the intended parent(s) -- agree in writing to the change. Intended parent(s), please let us know if you change your address. Storage fees will be required as they come due.

Risks of Medication and Pregnancy

Ovarian Hyperstimulation Syndrome (OHSS)

This is the most severe side effect of stimulating the ovaries. Signs of OHSS include increased ovarian size, nausea, vomiting, and a buildup of fluid in theabdomen and pelvis. There may also be trouble breathing. In some cases, OHSS increases the level of red blood cells, and causes kidney and liver problems. In the most severe cases, it can cause blood clots, kidney failure, or death. These complications occur very rarely (in only 0.2% of all treatment cycles).

OHSS occurs at two stages:

- early, 1 to 5 days after egg retrieval (as a result of the hCG that may be used for trigger); and
- late, 10 to 15 days after retrieval (because of the hCG if pregnancy occurs).

The risk of severe problems from OHSS is much higher if pregnancy occurs as hCG remains in the bloodstream. For this reason, your doctor may suggest that your embryos be frozen for later use instead of transferring them in the fresh cycle. A frozen transfer can be done later, when there is no risk of OHSS.

Cyst Formation

There may be large cysts that form in the ovaries. In the majority of cases, ovarian cysts induced by fertility medications disappear spontaneously without requiring any intervention. In very rare instances (less than 1% of cycles) these cysts could result in significant abdominal discomfort that could result in the need for hospitalization for observation purposes. One of these cysts could rupture requiring emergency surgery to stop the bleeding and could result in a need for blood transfusions and possible loss of one or both ovaries (this occurs in less than 0.1% of cycles).

Adnexal Torsion (Ovarian Twisting)

In less than 1% of cases, a fluid filled cyst(s) in the ovary can cause the ovary to twist on itself. This can decrease the blood supply to the ovary and result in significant abdominal or pelvic pain. Surgery may be required to untwist or possibly remove the ovary.

Cancers

There is some concern that using fertility drugs can cause breast, ovarian, or uterine cancer. These cancers are more common in patients with infertility, so it is difficult to know whether the reason for the cancer is infertility or use of the drugs. In current studies that take into consideration the increased risk of cancer due to infertility, there does not seem to be an increased risk of cancer due to

the fertility drugs alone. More studies need be done to confirm whether there is an association of cancer with use of fertility drugs.

Risks of Pregnancy

If you are planning a pregnancy through IVF, there are certain risks. This is partly because some patients using IVF are older than those who get pregnant without IVF. In addition, the cause of the infertility itself may increase pregnancy risks. There may be other risks linked to IVF that are not known at this time. Please see the table below for certain known risks.

Risks of Pregnancy with IVF

	Singleton Pregnancies			Twin Pregnancies		
	Incidence in IVF Pregnancies (%)	Risk compared to other infertile patients	Risk compared to fertile patients	Incidence in IVF Pregnancies (%)	Risk compared to other infertile patients	Risk compared to fertile patients
Pregnancy diabetes	8.2%	No difference	41% higher	10.7%	No difference	23% higher
Pregnancy-induced hypertension	12.6%	No difference	No difference	25.5%	No difference	15% higher
Placental complications	5.2%	95% higher	281% higher	4.9%	No difference	83% higher
Primary cesarean delivery	32.2%	10% higher	20% higher	65.4%	8% higher	17% higher
Low birthweight (<5.5 pounds)	7.7%	21% higher	65% higher	50.4%	No difference	No difference
Preterm birth (<37 weeks of pregnancy)	10.3%	26% higher	70% higher	53.8%	No difference	7% higher

About 20% of IVF pregnancies are multiple pregnancies (twins, triplets, or greater), of which less than 1% are triplets or more. Identical twins occur in less than 5% of all IVF pregnancies. Identical twins may happen more often after blastocyst (Day 5 or 6) transfers or assisted hatching. Multiple pregnancies in general have an increased risk of pregnancy problems. In addition to early delivery, problems include pre-eclampsia (high blood pressure and protein in the urine), excess bleeding with delivery, and diabetes of pregnancy (gestational diabetes). Problems with the placenta (afterbirth) are also more common. Other problems more common with multiple pregnancy include gall bladder problems, skin problems, and the need for extra weight gain.

In IVF, embryos are transferred directly into the uterus of the person intended to carry the pregnancy. However, tubal, cervical, or abdominal pregnancies can sometimes occur. These abnormal pregnancies may need to be treated with medication or surgery. Abnormal pregnancies within the uterus can also occur.

Miscarriage: The risk of miscarriage in the general population is 15-20%. The risk of miscarriage increases with the age of the egg. In patients over 40 years of age, the risk may be as high as 40%. Studies have shown either no increase or a slight increase in the risk of miscarriage with pregnancy by IVF. Most miscarriages are associated with lower abdominal cramping and bleeding, but do not necessarily require treatment. If additional medical treatment is indicated, the medication Misoprostol may be used to assist in resolving an impending miscarriage. In some cases, however, complete removal of the pregnancy tissue must be accomplished by a surgical procedure called dilatation and curettage

(D&C). This procedure is usually performed under anesthesia in the operating room and involves placing a suction tube into the uterus to remove the pregnancy tissue.

Tubal (Ectopic) Pregnancy: Approximately 6-7% of pregnancies that result from IVF are located outside the uterus. The majority of ectopic pregnancies are present in the fallopian tube. The chance of tubal pregnancy is greater if there are damaged tubes. If there is a tubal pregnancy, surgical treatment may be required, which may involve the removal of the involved tube. Medical treatment with Methotrexate, an injectable medicine that may help resolve a tubal pregnancy and thus avoid surgery, may be an option in selected cases.

Risks to The Baby

- **Babies born after IVF may be at a slightly higher risk for birth defects and genetic defects.**
- **IVF has a greater chance of multiple pregnancy, even when only one embryo is transferred.**
- **A multiple pregnancy is the greatest risk to your baby when using IVF.**

Overall Risks

The first IVF baby was born in 1978. Since then, more than 5 million children around the world have been born through IVF. Studies have shown that these children are quite healthy. In fact, some experts believe having a child through IVF is now just as safe as having a child naturally. Still, one must be careful when making this claim. Infertile patients do not have normal reproductive function. This means that a baby they have through IVF may have more health problems than a baby conceived naturally.

Single babies born after using IVF are often born about 2 days earlier than naturally conceived babies. They are about 5% more likely to weigh less than 5 pounds, 8 ounces (2,500 grams) than a naturally conceived single baby.

IVF twins are not born earlier or later than naturally conceived twins.

The risks of freezing eggs or embryos have been examined in animal studies over several generations. Research also has been done in humans. There is no proof that children born from frozen and thawed embryos or frozen and thawed eggs have any more health problems than those born from fresh embryos, but this is being closely evaluated. Still, it is hard to know for sure if the rate of health problems is the same as the normal rate.

Birth Defects

The risk of birth defects is about 4.4%, and it is about 3% for severe birth defects. In IVF babies, the risk for any birth defect is about 5.3%, while the risk for a severe birth defect is about 3.7%. Most of the increased risk with IVF seems to be due to aging of the egg and to having infertility. No higher risk of birth defects is seen in IVF cycles using eggs or frozen embryos from young donors.

Imprinting Disorders. These are extremely rare disorders occurring in 1 out of 15,000 people. Studies do not agree on whether these disorders are associated with IVF. Even if they are, the absolute risk is likely to remain low.

Childhood cancers. Most studies do not suggest any extra risk. One study did report an increased risk for retinoblastoma (a cancer behind the eye) after IVF treatment, but further studies did not find an increased risk.

Infant development. Most studies of long-term developmental outcomes have been reassuring so far. Most children are doing well. However, these studies are hard to do, and they have some limitations. A more recent study using better methods shows an extra risk of cerebral palsy and developmental delay. However, this arose mostly from prematurity and low birth weight that was a result of multiple pregnancy.

Risks of Multiple Pregnancy

Approximately 20% of IVF pregnancies are multiple pregnancies (twins, triplets, or greater). Identical twins occur in less than 5% of all IVF pregnancies. Identical twins may happen more often after blastocyst (Day 5) transfers, and with assisted hatching of embryos.

Early delivery accounts for most of the extra problems associated with babies from multiple pregnancies. IVF twins deliver an average of three weeks earlier than IVF single babies, and they weigh about 2 pounds less than IVF single babies. Triplet (and greater) pregnancies deliver before 32 weeks (7 months) in almost half of cases. Fetal growth problems and unequal growth among the fetuses can also result in illness and death before or shortly after delivery.

Multiple fetuses that share the same placenta, such as most identical twins, have additional risks. Twin-to-twin transfusion syndrome, where the circulation is not equal between the fetuses, may occur in up to 20% of twins who share a placenta. Twins sharing the same placenta have a higher frequency of birth defects compared to twins with two placentas. Death of one fetus in a twin pregnancy after the first trimester is more common with a shared placenta; this may cause harm to the remaining fetus.

Other problems babies can face include cerebral palsy, retinopathy of prematurity (eye problems that result from early delivery), and chronic lung disease. No one knows how much multiple pregnancies affect neurological or behavioral development, even when none of the other problems occur.

Fetal death rates for single pregnancies are 4.3 per 1,000. For twins, that number is higher at 15.5 per 1,000; and for triplets, the fetal death rate is 21 per 1,000. The death of one or more fetuses in a multiple pregnancy ("vanishing twin") is more common in the first trimester and may be happen in up to 25% of IVF pregnancies. Loss of a fetus in the first trimester does not usually affect the surviving fetus.

The Option of Multifetal Pregnancy Reduction (Selective Reduction): The more fetuses there are in the uterus, the greater the chance of a problem. Patients with twins or more have 3 choices:

- Continue with the pregnancy (with all the risks that have already been stated).
- End the pregnancy.
- Reduce the number of fetuses (terminate one or more of the fetuses) to lower the health risks to mother and child.

Reducing the number of fetuses lowers the risk of early delivery. This can be a difficult decision to make. The main danger is losing the entire pregnancy. There also may be psychological distress. The odds of losing the entire pregnancy are about 1 in 100 (1%). The odds of losing the entire pregnancy are greater if there are more than 3 fetuses present before the procedure is done.

Ethical and Religious Considerations in Treatment

Infertility treatment can raise ethical or religious concerns for some patients. IVF involves the creation of embryos outside the human body. It can also involve the production of extra embryos and can lead to a high number of fetuses (triplets or more). Patients who have concerns should speak with their counselor or religious leader, or with someone else they trust. This can be a helpful step in treatment.

Psychosocial Effects of Treatment

Infertility and its treatment can affect emotions, health, finances, and social life. During treatment, one may feel anxious, helpless, depressed, or all alone. There may be highs and lows. Be sure to notice if these feelings get severe. In some cases, you may want to seek the help of a mental health expert. Here are some of the warning signs you should watch out for:

- Losing interest in the things you usually like to do.
- Feeling depressed most of the time.
- Strained feelings with a partner (if applicable), family, friends, or those with whom you work.
- Thinking about treatments all of the time.
- Feeling extremely anxious or nervous.
- Having trouble finishing tasks.
- Finding it hard to focus or concentrate.
- Having changes in your sleep patterns, such as having a hard time falling asleep or staying asleep, waking up early every morning, or sleeping more than normal.
- Having a change in appetite or weight (increase or decrease).
- Using illegal drugs or alcohol in excess.
- Thinking about death or suicide.
- Staying away from other people.
- Feeling negative, guilty, or worthless much of the time.
- Feeling bitter or angry much of the time.

For intended parent(s), raising twins or higher multiples may cause physical, emotional, and financial stresses. The chance of having depression and anxiety is higher if raising multiples.

Patients may consider working with mental health professionals who are specially trained in the area of fertility care, as well as with their health care team, to minimize the emotional impact of infertility treatments. National support groups are also available, such as RESOLVE, (www.resolve.org, or Path2Parenthood ((www.path2parenthood.org.org).

Reporting Outcomes

In 1992, the Fertility Clinic Success Rate and Certification Act was passed. This law requires the Centers for Disease Control and Prevention (CDC) to gather information about IVF cycles and pregnancy outcomes in the U.S. each year. This information is used to calculate success rates which are reported each year.

We (the Clinic) will report the required information from your IVF procedure to the CDC. Since our Clinic is a member of the Society of Assisted Reproductive Technologies (SART) of the American Society for Reproductive Medicine (ASRM), it will also be reported to SART. Information reported to SART about your treatment may be used for research or quality assessment according to HIPAA guidelines; your name will never be connected to your information in any research that is published by ASRM or SART.

Research Conducted by SART

Since 2006, the Society for Assisted Reproductive Technology has participated in a series of studies looking at the health of patients and children after IVF. Many of these studies are still being conducted. The studies compare children of patients who have not had trouble conceiving and children of patients who used IVF. The studies also compare children of patients who had trouble conceiving but did not use IVF to children of patients who used IVF. Children conceived with IVF are also compared with their siblings who were conceived with IVF, conceived with non-IVF fertility treatment, or conceived spontaneously. Problems related to pregnancy or birth, and the risk of birth defects are examined in these studies. Children are also followed to find out if they have developmental delays, problems in school, or increased risk of childhood or adult cancer. You can see the results of many of these studies in the information given below. Results can also be found on the SART website (www.sart.org) under "Research".

Additional Information

General IVF overviews available on the internet

www.reproductivefacts.org

www.sart.org/

www.cdc.gov/art/

www.resolve.org/site/PageServer

MGH Fertility Center

Informed Consent For In Vitro Fertilization (IVF) Treatment

ACKNOWLEDGEMENT OF INFORMED CONSENT AND AUTHORIZATION

I/We acknowledge that I/we, the undersigned, are voluntarily participating, individually or as a couple with the physicians in the Massachusetts General Hospital (MGH) Fertility Center and that I/we will acknowledge our parentage of any child born to me/us through this technique.

I/We acknowledge that I/we have read and fully understand this written material; that I/we have considered treatment alternatives, and that all of my/our questions concerning the treatment have been fully answered to my/our satisfaction.

I/We are aware that there are other centers in the area that offer IVF treatment and I/we have freely chosen to have my/our treatment at the MGH Fertility Center.

By participating in the program, I/we accept the responsibilities, conditions and risks involved as set out in this document and as explained to me/us by the MGH Fertility Center staff. In addition, I/we consent to the IVF techniques and procedures described in this document and explained by the MGH Fertility Center.

I/We acknowledge and agree that my/our acceptance into treatment and my/our continued participation is within the sole discretion of the MGH Fertility Center.

I/We understand that, should this IVF cycle be unsuccessful, it may be determined that further treatment with IVF may not be appropriate. I/We also understand that I/we are financially responsible for any medical expenses associated with IVF treatment that are not covered by my/our insurance policy.

I/We understand that the disposition of embryos not transferred but of suitable quality for transfer will be governed by wishes as indicated in the form entitled "Agreement and Informed Consent to Embryo Freezing and Frozen Embryo Disposition".

I/We understand that bodily tissues or fluids remaining from my/ourIVF treatment may be photographed and/or be preserved for diagnostic and teaching purposes.

In addition, the disposition of embryos that are not suitable for transfer or freezing (such as those that result from abnormal fertilization or that fail to develop properly), eggs that are not suitable for use (such as those that are immature or fail to fertilize), and unused sperm will be governed by my/our wishes as follows:

Choose

☐ Donate to research or activities related to improving assisted reproductive therapies (ART):

- The research and activities related to improving ART may include, for example, studies of ways to improve techniques or fertility success rates or studies that may improve our understanding of infertility and reproductive medicine.
- The research may include embryonic stem cell research. In this case, MGH would contact us to provide more information about a particular study and to ask whether or not we consent to donate embryos to the study. MGH would retain a link between my/our embryos and limited information about me/us in order to contact us about such research.

☐ Discard according to standard hospital and program procedures.

(Note: The above options may not apply in the exceptional case where Patient/Partner have signed another consent form to be in a separate research study.)

Initials of Patient and Partner (if applicable): _____ _____
(initial here)

I/We understand that medical information concerning my/our treatment may be analyzed and could be used in a publication without any identifying information, and I/we authorize such analysis and publication. I/We further understand that, in accordance with federal law, identifying information and information concerning my/our treatment will be submitted to a national data registry that publishes statistics on treatment outcomes and I/we may be contacted by a representative of this registry to verify the outcome of my treatment. Furthermore, the agencies charged with publishing these statistics may randomly audit the MGH Fertility Center and may have access to and review the identifiable information in my medical record in order to verify the data that the Program is required to report.

I/We the undersigned, consent to undergo IVF treatment. I/We have read the Consent for IVF Treatment and understand the purpose, risks and benefits of the IVF process, and I/we have been given the opportunity to ask questions, which have been answered to my/our satisfaction by the staff of the MGH Fertility Center.

X _____ _____
Patient Signature Date

_____ _____
Patient Name Date of Birth

X _____ _____
Partner Signature (if applicable) Date

_____ _____
Partner Name (if applicable) Date of Birth

X _____ _____
Legal Guardian Signature Date

_____ _____
Legal Guardian Name Date of Birth

==========

If Patient is a minor (less than 18 years of age):

Parent/Parents or Legal Guardian Signature is Required:

X _____ _____
Parent or Legal Guardian Signature Date

_____ _____
Legal Guardian Name Date of Birth

X _____ _____
Parent or Legal Guardian Signature Date

_____ _____
Legal Guardian Name Date of Birth

11. 4. Overlake Reproductive Health

Overlake Reproductive Health

Informed Consent for Assisted Reproduction

In Vitro Fertilization,
Intracytoplasmic Sperm Injection
Assisted Hatching
Embryo Freezing

/ signing below you are indicating which components of IVF treatment you agree to undertake in ur upcoming treatment cycle. Also, you should initial each page to indicate that you have read d understand the information provided, regardless of consenting to that particular procedure. If u do not understand the information provided, please speak with your treating physician, or clinic presentative. There are a few locations within the consent form where you are being asked to ake a decision. Please initial your choice and sign where requested.

tient Name: _____ & _____

own Elements of Treatment:

Patient Signature | Partner signature | Date

Vitro Fertilization
cluding egg retrieval & medication administration)

of donated oocytes from IDE

emination by partner sperm

emination by donor sperm IDE

ntracytoplasmic Sperm Injection (ICSI)

isted Hatching

bryo Transfer (# of embryos to be decided on transfer day)

bryo Cryopreservation

Signed and sworn before me on this _____ day of _____, 20__

Signature of Notary Public

Printed name of Notary Public

Expiration date of Notary Public appointment

nsent to the transfer of _____ embryos on day ____ of culture

ician/Witness

Patient initials: _____ Partner initials: _____

Page 1 of 16

Overlake Reproductive Health

OVERVIEW

In Vitro Fertilization (IVF) has become an established treatment for many forms of infertility. The main goal of IVF is to allo a patient the opportunity to become pregnant using her own eggs and sperm from her partner or from a donor. This is an elective procedure designed to result in the patient's pregnancy when other treatments have failed or are not appropriate.

This consent reviews the IVF process from start to finish, including the risks that this treatment might pose to you and your offspring. While best efforts have been made to disclose all known risks, there may be risks of IVF which are not yet clarifie or even suspected at the time of this writing.

An IVF cycle typically includes the following steps or procedures:

- Medications to grow multiple eggs
- Retrieval of eggs from the ovary or ovaries
- Insemination of eggs with sperm
- Culture of any resulting fertilized eggs (embryos)
- Placement ("transfer") of one or more embryo(s) into the uterus
- Support of the uterine lining with hormones to permit and sustain pregnancy

In certain cases, these additional procedures can be employed:

- Intracytoplasmic sperm injection (ICSI) to increase the chance for fertilization
- Assisted hatching of embryos to increase the chance of embryo attachment ("implantation")
- Embryo Cryopreservation (freezing)

Note: At various points in this document, rates are given which reflect what are believed to be U.S. national averages for those employing IVF treatments. These include items such as pregnancy rates, Cesarean delivery rates, and preterm delivery rates. These rates are not meant to indicate the rates of these outcomes within individual practices offering IVF, and are not to be understood as such. Individual practices may have higher or lower pregnancy and delivery rates than these national averages, and also higher or lower risks for certain complications. It is appropriate to ask the practice abou their specific rates.

Also note that while this information is believed to be up to date at the time of publication (2008), newer reports may not yet be incorporated into this document.

Outline of Consent for IVF

A. Technique of In Vitro Fertilization
   1. Core elements and their risk
      a. medications
      b. transvaginal oocyte retrieval
      c. in vitro fertilization and development
      d. embryo transfer
      e. luteal support
   2. Additional elements and their risk
      a. intracytoplasmic sperm injection
      b. assisted hatching
      c. embryo disposition
      d. cryopreserved embryo storage
      e. donated or research embryo fate

B. Risks to woman
   1. ovarian hyperstimulation
   2. oocyte retrieval
   3. pregnancy

C. Risks to offspring
   1. overall risks
   2. birth defects
   3. multiple pregnancy

D. Ethical / religious concerns

E. Psychosocial risks

F. Legal considerations and legal counseling

G. Alternatives to IVF

Patient initials: _____ Partner initials: _____

Page 2 of 16

. Technique of IVF

. Core elements and their risk

a. Medications for IVF Treatment

- **The success of IVF largely depends on growing multiple eggs at once**
- **Injections of the natural hormones FSH and/or LH (gonadotropins) are used for this purpose**
- **Additional medications are used to prevent premature ovulation**
- **An overly vigorous ovarian response can occur, or conversely an inadequate response**

edications may include the following (not a complete list):

- ***Gonadotropins or injectable "fertility drugs"*** (Follistim®, Gonal-F®, Bravelle®, Menopur®): These natural hormones stimulate the ovary in hopes of inducing the simultaneous growth of several oocytes (eggs) over the span of 8 or more days. All injectable fertility drugs have FSH (follicle stimulating hormone), a hormone that will stimulate the growth of your ovarian follicles (which contain the eggs). Some of them also contain LH (luteinizing hormone) or LH like activity. LH is a hormone that may work with FSH to increase the production of estrogen and growth of the follicles. Luveris®, recombinant LH, can also be given as a separate injection in addition to FSH or alternatively, low-dose hCG can be used. These medications are given by subcutaneous or intramuscular injection. Proper dosage of these drugs and the timing of egg recovery require monitoring of the ovarian response, usually by way of blood tests and ultrasound examinations during the ovarian stimulation.

  As with all injectable medications, bruising, redness, swelling, or discomfort can occur at the injection site. Rarely, there can be there an allergic reaction to these drugs. The intent of giving these medications is to mature multiple follicles, and many women experience some bloating and minor discomfort as the follicles grow and the ovaries become temporarily enlarged. Up to 2.0 % of women will develop Ovarian Hyperstimulation Syndrome (OHSS) [see full discussion of OHSS in the Risks to Women section which follows]. Other risks and side effects of gonadotropins include, but are not limited to, fatigue, headaches, weight gain, mood swings, nausea, and clots in blood vessels.

  Even with pre-treatment attempts to assess response, and even more so with abnormal pre-treatment evaluations of ovarian reserve, the stimulation may result in very few follicles developing, the end result may be few or no eggs obtained at egg retrieval or even cancellation of the treatment cycle prior to egg retrieval.

  Some research suggested that the risk of ovarian tumors may increase in women who take any fertility drugs over a long period of time. These studies had significant flaws which limited the strength of the conclusions. More recent studies have not confirmed this risk. A major risk factor for ovarian cancer is infertility per se, suggesting that early reports may have falsely attributed the risk resulting from infertility to the use of medications to overcome it. In these studies, conception lowered the risk of ovarian tumors to that of fertile women.

- ***GnRH-agonists (Leuprolide acetate)*** (Lupron®): This medication is taken by injection. There are two forms of the medication: A short acting medication requiring daily injections and a long-acting preparation lasting for 1-3 months. The primary role of this medication is to prevent a premature LH surge, which could result in the release of eggs before they are ready to be retrieved. Since GnRH-agonists initially cause a release of FSH and LH from the pituitary, they can also be used to start the growth of the follicles or initiate the final stages of egg maturation. Though leuprolide acetate is an FDA (Federal Drug Administration) approved medication, it has not been approved for use in IVF, although it has routinely been used in this way for more than 20 years. Potential side effects usually experienced with long-term use include but are not limited to hot flashes, vaginal dryness, bone loss, nausea, vomiting, skin reactions at the injection site, fluid retention, muscle aches, headaches, and depression. No long term or serious side effects are known. Since GnRH-a are oftentimes administered after ovulation, it is possible that they will be taken early in pregnancy. The safest course of action is to use a barrier method of contraception

(condoms) the month you will be starting the GnRH-a. GnRH-a have not been associated with any fetal malformatior however you should discontinue use of the GnRH-a as soon as pregnancy is confirmed.

- ***GnRH-antagonists (Ganirelix Acetate or Cetrorelix Acetate)*** (Antagon®, Cetrotide®): These are another class of medications used to prevent premature ovulation. They tend to be used for short periods of time in the late stages ovarian stimulation. The potential side effects include, but are not limited to, abdominal pain, headaches, skin reaction at the injection site, and nausea.

- ***Human chorionic gonadotropin (hCG)*** (Profasi®, Novarel®, Pregnyl®, Ovidrel®): hCG is a natural hormone used in IVF to induce the eggs to become mature and fertilizable. The timing of this medication is critical to retrieve matur eggs. Potential side effects include, but are not limited to breast tenderness, bloating, and pelvic discomfort.

- ***Progesterone, and in some cases, estradiol***: Progesterone and estradiol are hormones normally produced by the ovaries after ovulation. After egg retrieval in some women, the ovaries will not produce adequate amounts of these hormones for long enough to fully support a pregnancy. Accordingly, supplemental progesterone, and in some cases estradiol, are given to ensure adequate hormonal support of the uterine lining. Progesterone is usually given by injection or by the vaginal route (Endometrin®, Crinone®, Prochieve®, Prometrium®, or pharmacist-compounded suppositories) after egg retrieval. Progesterone is often continued for some weeks after a pregnancy has been confirmed. Progesterone has not been associated with an increase in fetal abnormalities. Side effects of progesterone include depression, sleepiness, allergic reaction and if given by intra-muscular injection includes the additional risk of infection or pain at the application site. Estradiol, if given, can be by oral, trans-dermal, intramuscular, or vaginal administration. Side effects of estradiol include nausea, irritation at the injection site if given by the trans-dermal route and the risk of blood clots or stroke.

- ***Oral contraceptive pills:*** Many treatment protocols include oral contraceptive pills to be taken for 2 to 4 weeks before gonadotropin injections are started in order to suppress hormone production or to schedule a cycle. Side effects include unscheduled bleeding, headache, breast tenderness, nausea, swelling and the risk of blood clots or stroke.

- ***Other medications:*** Antibiotics may be given for a short time during the treatment cycle to reduce the risk of infection associated with egg retrieval or embryo transfer. Antibiotic use may be associated with causing a yeast infection, nausea, vomiting, diarrhea, rashes, sensitivity to the sun, and allergic reactions. Anti-anxiety medication or muscle relaxants may be recommended prior to the embryo transfer; the most common side effect is drowsiness. Other medications such as steroids, heparin, low molecular weight heparin or aspirin may also be included in the treatment protocol.

b. Transvaginal Oocyte Retrieval

- **Eggs are removed from the ovary with a needle under ultrasound guidance**
- **Anesthesia is provided to make this comfortable**
- **Injury and infection are rare**

Oocyte retrieval is the removal of eggs from the ovary. A transvaginal ultrasound probe is used to visualize the ovaries and the egg-containing follicles within the ovaries. A long needle, which can be seen on ultrasound, can be guided into each follicle and the contents aspirated. The aspirated material includes follicular fluid, oocytes (eggs) and granulosa egg-supporting) cells. Rarely the ovaries are not accessible by the transvaginal route and laparoscopy or transabdominal retrieva is necessary. These procedures and risks will be discussed with you by your doctor if applicable. Anesthesia is generally use to reduce if not eliminate discomfort. Risks of egg retrieval include:

Infection: Bacteria normally present in the vagina may be inadvertently transferred into the abdominal cavity by the needle. These bacteria may cause an infection of the uterus, fallopian tubes, ovaries or other intra-abdominal organs. The estimated incidence of infection after egg retrieval is less than 0.5%. Treatment of infections could require the use of oral intravenous antibiotics. Severe infections occasionally require surgery to remove infected tissue. Infections can have a negative impact on future fertility. Prophylactic antibiotics are sometimes used before the egg retrieval procedure to reduc the risk of pelvic or abdominal infection in patients at higher risk of this complication. Despite the use of antibiotics, there i no way to eliminate this risk completely.

leeding: The needle passes through the vaginal wall and into the ovary to obtain the eggs. Both of these structures contain ood vessels. In addition, there are other blood vessels nearby. Small amounts of blood loss are common during egg trievals. The incidence of major bleeding problems has been estimated to be less than 0.1%. Major bleeding will equently require surgical repair and possibly loss of the ovary. The need for blood transfusion is rare. (Although very rare, view of the world experience with IVF indicates that unrecognized bleeding has lead to death.)

rauma: Despite the use of ultrasound guidance, it is possible to damage other intra-abdominal organs during the egg trieval. Previous reports in the medical literature have noted damage to the bowel, appendix, bladder, ureters, and vary. Damage to internal organs may result in the need for additional treatment such as surgery for repair or removal of the maged organ. However, the risk of such trauma is low.

nesthesia: The use of anesthesia during the egg retrieval can produce unintended complications such as an allergic action, low blood pressure, nausea or vomiting and in rare cases death.

ailure: It is possible that the aspiration will fail to obtain any eggs or the eggs may be abnormal or of poor quality and herwise fail to produce a viable pregnancy.

c. In vitro fertilization and embryo culture

- **Sperm and eggs are placed together in specialized conditions (culture media, controlled temperature, humidity and light) in hopes of fertilization**
- **Culture medium is designed to permit normal fertilization and early embryo development, but the content of the medium is not standardized.**
- **Embryo development in the lab helps distinguish embryos with more potential from those with less or none.**

fter eggs are retrieved, they are transferred to the embryology laboratory where they are kept in conditions that support eir needs and growth. The embryos are placed in small dishes or tubes containing "culture medium," which is special fluid eveloped to support development of the embryos made to resemble that found in the fallopian tube or uterus. The dishes ntaining the embryos are then placed into incubators, which control the temperature and atmospheric gasses the embryos perience.

few hours after eggs are retrieved, sperm are placed in the culture medium with the eggs, or individual sperm are injected to each mature egg in a technique called Intracytoplasmic Sperm Injection (ICSI) (see below). The eggs are then returned the incubator, where they remain to develop. Periodically over the next few days, the dishes are inspected so the evelopment of the embryos can be assessed.

he following day after eggs have been inseminated or injected with a single sperm (ICSI), they are examined for signs that e process of fertilization is underway. At this stage, normal development is evident by the still single cell having 2 nuclei; is stage is called a zygote. Two days after insemination or ICSI, normal embryos have divided into about 4 cells. Three ys after insemination or ICSI, normally developing embryos contain about 8 cells. Five days after insemination or ICSI, rmally embryos have developed to the blastocyst stage, which is typified by an embryo that now has 80 or more cells, an ner fluid-filled cavity, and a small cluster of cells called the inner cell mass.

is important to note that since many eggs and embryos are abnormal, it is expected that not all eggs will fertilize and not l embryos will divide at a normal rate. The chance that a developing embryo will produce a pregnancy is related to hether its development in the lab is normal, but this correlation is not perfect. This means that not all embryos developing the normal rate are in fact also genetically normal, and not all poorly developing embryos are genetically abnormal. onetheless, their visual appearance is the most common and useful guide in the selection of the best embryo(s) for transfer.

spite of reasonable precautions, any of the following may occur in the lab that would prevent the establishment of a egnancy:

- Fertilization of the egg(s) may fail to occur.
- One or more eggs may be fertilized abnormally resulting in an abnormal number of chromosomes in the embryo, these abnormal embryos will not be transferred.
- The fertilized eggs may degenerate before dividing into embryos, or adequate embryonic development may fail to occur.
- Bacterial contamination or a laboratory accident may result in loss or damage to some or all of the eggs or embryos.

- Laboratory equipment may fail, and/or extended power losses can occur which could lead to the destruction of eggs sperm and embryos.
- Other unforeseen circumstances may prevent any step of the procedure to be performed or prevent the establishment a pregnancy.
- Hurricanes, floods, or other 'acts of God' (including bombings or other terrorist acts) could destroy the laboratory or its contents, including any sperm, eggs, or embryos being stored there.

Quality control in the lab is extremely important. Sometimes immature or unfertilized eggs, sperm or abnormal embryos (abnormally fertilized eggs or embryos whose lack of development indicates they are not of sufficient quality to be transferred) that would normally be discarded can be used for quality control. You are being asked to allow the clinic to use this material for quality control purposes before being discarded in accordance with normal laboratory procedures and applicable laws. None of this material will be utilized to establish a pregnancy or a cell line unless you sign other consent forms to allow the clinic to use your eggs, sperm or embryos for research purposes. Please indicate your choice below:

_____I/we hereby CONSENT to allow the clinic to utilize my/our immature or unfertilized eggs, left-over sperm or abnormal embryos for quality control and training purposes before they are discarded.

Patient	Partner (if applicable)	Date
_____	_____	_/_/____

_____I/we hereby DO NOT CONSENT to allow the clinic to utilize my/our immature or unfertilized eggs, left-over sperm or abnormal embryos for quality control and training purposes. This material will be discarded in accordance with normal laboratory procedures and applicable laws.

Patient	Partner (if applicable)	Date
_____	_____	_/_/____

d. Embryo transfer

- **After a few days of development, the best appearing embryos are selected for transfer**
- **The number chosen influences the pregnancy rate and the multiple pregnancy rate**
- **A woman's age and the appearance of the developing embryo have the greatest influences on pregnancy outcome**
- **Embryos are placed in the uterine cavity with a thin tube**
- **Excess embryos of sufficient quality that are not transferred can be frozen**

After a few days of development, one or more embryos are selected for transfer to the uterine cavity. Embryos are placed in the uterine cavity with a thin tube. Ultrasound guidance may be used to help guide the catheter or confirm placement through the cervix and into the uterine cavity. Although the possibility of a complication from the embryo transfer is very rare, risks include infection and loss of, or damage to the embryos.

The number of embryos transferred influences the pregnancy rate and the multiple pregnancy rate. The age of the woman and the appearance of the developing embryo have the greatest influence on pregnancy outcome and the chance for multipl pregnancy. While it is possible, it is unusual to develop more fetuses than the number of embryos transferred. It is critical to discuss the number to be transferred before the transfer is done.

In an effort to help curtail the problem of multiple pregnancies (see multiple pregnancies), national guidelines published in 2006 recommend limits on the number of embryos to transfer (see Tables below). These limits differ depending on the developmental stage of the embryos and the quality of the embryos and take into account the patient's personal history.

Recommended limits on number of 2-3 day old embryos to transfer

Embryos	age <35	age 35-37	age 38-40	age >40
favorable	1 or 2	2	3	5
unfavorable	2	3	4	5

Recommended limits on number of 5-6 day old embryos to transfer

Embryos	age <35	age 35-37	age 38-40	age >40
favorable	1	2	2	3
unfavorable	2	2	3	3

n some cases, there will be additional embryos remaining in the lab after the transfer is completed. Depending on their levelopmental normalcy, it may be possible to freeze them for later use. (See section 2.c. for an in-depth discussion of mbryo cryopreservation).

e. Hormonal support of uterine lining

- **Successful attachment of embryo(s) to the uterine lining depends on adequate hormonal support**
- **Progesterone, given by the intramuscular or vaginal route, is routinely given for this purpose**

uccessful attachment of embryos to the uterine lining depends on adequate hormonal support of the lining. The critical ormones in this support are progesterone and estradiol. Normally, the ovary makes sufficient amounts of both hormones. lowever, in IVF cycles, this support is not always adequate. Therefore, progesterone is routinely given, and some clinics also rescribe estradiol. Progesterone is given by the intramuscular or vaginal route. Estradiol is given by the oral, vaginal, or ntramuscular route. The duration of this support is from 2 to 10 weeks.

2. Additional Elements and their risk

a. Intracytoplasmic Sperm Injection (ICSI)

- **ICSI is used to increase the chance of fertilization when fertilization rates are anticipated to be lower than normal**
- **Overall success rates with ICSI are slightly lower than for conventional insemination**
- **An increased risk of genetic defects in offspring is reported**
- **ICSI will not improve oocyte defects**

he use of ICSI provides an effective treatment for male factor infertility. The negative effects of abnormal semen haracteristics and sperm quality on fertilization can be overcome with ICSI if viable sperm are available because the echnique bypasses the shell around the egg (zona pellucida) and the egg membrane (oolemma) to deliver the sperm directly nto the egg. ICSI involves the direct injection of a single sperm into the interior of an egg using an extremely thin glass eedle. ICSI allows couples with male factor infertility to achieve fertilization and live birth rates close to those achieved vith in vitro fertilization (IVF) using conventional methods of fertilization in men with normal sperm counts. ICSI can be erformed even in men with no sperm in the ejaculate if sperm can be successfully collected from the epididymis or the estis.

eports on the risk of birth defects associated with ICSI (compared to those associated with conventional fertilization in IVF ycles) have yielded conflicting results. The most comprehensive study conducted thus far, based on data from five-year-old hildren, has suggested that ICSI is associated with an increased risk of certain major congenital anomalies. However, whether the association is due to the ICSI procedure itself, or to inherent sperm defects, could not be determined because he study did not distinguish between male factor conditions and other causes of infertility. Note that even if there is an ncreased risk of congenital malformations in children conceived with ICSI, the risk is relatively low (4.2% versus ~3% of those onceived naturally). The impact of ICSI on the intellectual and motor development of children conceived via ICSI also has

been controversial. An early report suggested that development in such children lagged significantly behind that of children resulting from conventional IVF or those conceived naturally. However, more recent studies from larger groups, using standardized criteria for evaluation, have not detected any differences in the development or the abilities of children born after ICSI, conventional IVF, or natural conception.

The prevalence of sex chromosome abnormalities in children conceived via ICSI is higher than observed in the general IVF population, but the absolute difference between the two groups is small (0.8% to 1.0% in ICSI offspring vs. 0.2% in the genera IVF population). The reason for the increased prevalence of chromosomal anomalies observed in ICSI offspring is not clear. Whereas it may result from the ICSI procedure itself, it might also reflect a direct paternal effect. Men with sperm problems (low count, poor motility, and/or abnormal shape) are more likely themselves to have genetic abnormalities and often produce sperm with abnormal chromosomes: the sex chromosomes (X and Y) in the sperm of men with abnormal semen parameters appear especially prone to abnormalities. If sperm with abnormal chromosomes produce pregnancies, these pregnancies will likely carry these same defects. The prevalence of translocations (a re-arrangement of chromosomes that increases the risk of abnormal chromosomes in egg or sperm and can cause miscarriage) of paternal origin and of de novo balanced translocations in ICSI offspring (0.36%) also appears higher than in the general population (0.07%).

Some men are infertile because the tubes connecting the testes to the penis did not form correctly. This condition, called congenital bilateral absence of the vas deferens (CBAVD), can be bypassed by aspirating sperm directly from the testicles or epididymis, and using them in IVF with ICSI to achieve fertilization. However, men with CBAVD are affected with a mild form of cystic fibrosis (CF), and this gene will be passed on to their offspring. All men with CVABD, as well as their partners, should be tested for CF gene mutations prior to treatment, so that the risk of their offspring having CF can be estimated and appropriate testing performed. It is important to understand that there may be CF gene mutations that are not detectable by current testing and parents who test negative for CF mutations can still have children affected with CF.

Some men have no sperm in their ejaculate because their testes do not produce adequate quantities (non-obstructive azoospermia). This can be due to a number of reasons such as prior radiation, chemotherapy or undescended testicles. In some men, small deletions on their Y chromosomes lead to extremely low or absent sperm counts. Testicular biopsy and successful retrieval of viable sperm can be used to fertilize eggs with ICSI. However, any sperm containing a Y chromosomal microdeletion will be transmitted to the offspring. Thus the risk that male offspring might later manifest disorders including infertility is very real. However, men without a detectable deletion by blood testing can generate offspring having a Y chromosome microdeletion, because the chromosomes in the sperm may not be the same as those seen when tested by a blood test.

If it is in the opinion of the Laboratory that Intracytoplasmic Sperm Injection (ICSI) is required to ensure fertilization, then it is understood that my consent is expressly given with my consent to undergo IVF – unless expressly noted by me in **writing** prior to the egg retrieval, and delivered in person to the Laboratory Director.

b. Assisted Hatching

- **Assisted Hatching involves making a hole in the outer shell (zona pellucida) that surrounds the embryo**
- **Hatching may make it easier for embryos to escape from the shell which surrounds them.**

The cells that make up the early embryo are enclosed within a flexible membrane (shell) called the zona pellucida. During normal development, a portion of this membrane dissolves, allowing the embryonic cells to escape or "hatch" out of the shell. Only upon hatching can the embryonic cells implant within the wall of the uterus to form a pregnancy.

Assisted hatching is the laboratory technique in which an embryologist makes an artificial opening in the shell of the embryo. The hatching is usually performed on the day of transfer, prior to loading the embryo into the transfer catheter. The opening can be made by mechanical means (slicing with a needle or burning the shell with a laser) or chemical means by dissolving a small hole in the shell with a dilute acid solution.

Some programs have incorporated artificial or "assisted hatching" into their treatment protocols because they believe it improves implantation rates, and ultimately, live birth rates although definitive evidence of this is lacking.

Risks that may be associated with assisted hatching include damage to the embryo resulting in loss of embryonic cells, or destruction or death of the embryo. Artificial manipulation of the zygote may increase the rates of monozygotic (identical) twinning which are significantly more complicated pregnancies. There may be other risks not yet known.

c. Embryo disposition

- **Freezing of viable embryos not transferred after egg retrieval provides additional chances for pregnancy.**
- **Frozen embryos do not always survive the process of freezing and thawing.**
- **Freezing of eggs before fertilization is currently much less successful than freezing of fertilized eggs (embryos).**
- **Ethical and legal dilemmas can arise when couples separate or divorce; disposition agreements are essential.**
- **It is the responsibility of each couple with frozen embryos to remain in contact with the clinic on an annual basis.**

ezing (or "cryopreservation") of embryos is a common procedure. Since multiple eggs (oocytes) are often produced during rian stimulation, on occasion there are more embryos available than are considered appropriate for transfer to uterus. These embryos, if viable, can be frozen for future use. This saves the expense and inconvenience of stimulation obtain additional eggs in the future. Furthermore, the availability of cryopreservation permits patients to transfer fewer bryos during a fresh cycle, reducing the risk of high-order multiple gestations (triplets or greater). Other possible reasons cryopreservation of embryos include freezing all embryos in the initial cycle to prevent severe ovarian hyperstimulation drome (OHSS), or if a couple were concerned that their future fertility potential might be reduced due to necessary dical treatment (e.g., cancer therapy or surgery). The pregnancy success rates for cryopreserved embryos transferred into human uterus can vary from practice to practice. Overall pregnancy rates at the national level with frozen embryos are er than with fresh embryos. This, at least in part, results from the routine selection of the best-looking embryos for fresh nsfer, reserving the 'second-best' for freezing. There is some evidence that pregnancy rates are similar when there is no h selection.

ications:

- To reduce the risks of multiple gestation
- To preserve fertility potential in the face of certain necessary medical procedures
- To increase the chance of having one or more pregnancies from a single cycle of ovarian stimulation
- To minimize the medical risk and cost to the patient by decreasing the number of stimulated cycles and egg retrievals
- To temporarily delay pregnancy and the risks of OHSS occurs by freezing all embryos, when this risk is high.

ks of embryo cryopreservation: There are several techniques for embryo cryopreservation, and research is ongoing. ditional methods include "slow," graduated freezing in a computerized setting, and "rapid" freezing methods, called trification." Current techniques deliver a high percentage of viable embryos thawed after cryopreservation, but there can no certainty that embryos will thaw normally, nor be viable enough to divide and eventually implant in the uterus. opreservation techniques could theoretically be injurious to the embryo. Extensive animal data (through several erations), and limited human data, do not indicate any likelihood that children born of embryos that have been opreserved and thawed will experience greater risk of abnormalities than those born of fresh embryos. However, until y large numbers of children have been born following freezing and thawing of embryos, it is not possible to be certain that rate of abnormalities is no different from the normal rate.

ause of the possibility of you and/or your partner's separation, death or incapacitation, it is important to decide on the osition of any embryo(s), fresh or cryopreserved that remain in the laboratory. Since this is a rapidly evolving field, both dically and legally, the clinic cannot guarantee what the available or acceptable avenues for disposition will be at any ure date.

bryos are understood to be your property, with rights of survivorship. No use can be made of these embryos without the sent of both partners (if applicable).

he event of divorce or dissolution of the marriage or partnership, the ownership and/or other rights to the embryo(s) will as follows:

a) All embryos are to be discarded
b) All embryos are to be donated to medical research
c) All embryos are to be transferred to _____ (Insert name of recipient partner)

In the event of the death or incapacitation of one partner, the embryo(s) will be as follows:

a) All embryos will discarded
b) All embryos will be donated to medical research
c) All embryos are to be transferred to the surviving partner

In the event of death or incapacitation of both partners the embryo(s) will be as follows:

a) All embryos are to be discarded
b) All embryos are to be donated to medical research
c) We have selected another disposition for our frozen embryos and have indicated as such in our will

Patient	Partner (if applicable)	Date
_____	_____	__/__/____

d. Cryopreserved embryo storage

The Clinic will only maintain cryopreserved embryos for a period of 5 years. After that time, any cryopreserved embryos must be:

1) Thawed and transferred
2) Donated to research
3) Discarded or
4) Transferred to another storage facility

Additionally, maintaining embryo(s) in a frozen state is labor intensive and expensive. There are fees associated with freez and maintaining cryopreserved embryo(s). Patients/couples who have frozen embryo(s) must remain in contact with the cli on an annual basis in order to inform the clinic of their wishes as well as to pay fees associated with the storage of their embryo(s). In situations where there is no contact with the clinic for a period of 2 years or fees associated with embryo storage have not been paid for a period of 2 years and the clinic is unable to contact the patient after reasonable efforts have been made, the embryo(s) will be considered to be abandoned and may be destroyed by the clinic in accordance with normal laboratory procedures and applicable law.

I/We understand that before I (the patient) reach 56 years of age (DATE __/__/__), the cryopreserved embryo(s) must be:

1) Thawed and transferred
2) Donated to research
3) Discarded or
4) Transferred to another storage facility

If no disposition has occurred by the above date, I/we hereby waive any and all interest in said cryopreserved embryo(s) ar the cryopreserved embryo(s) shall become the sole and exclusive property of the clinic. In this event I/we elect to: (please initial your choice)

	patient	partner
1) Discard the cryopreserved embryo(s)	_____	_____
2) Donate the cryopreserved embryo(s) for research	_____	_____

Donated or research embryo fate

certain situations, donating embryo(s) for research or to another couple may not be possible or may be restricted by law. hile efforts will be made to abide by your wishes, no guarantees can be given that embryo(s) will be used for research or nated to another couple. In these instances, if after 1 years no recipient or research project can be found, or your embryos e not eligible, your embryo(s) will be discarded by the lab in accordance with laboratory procedures and applicable laws.

. Risks to the Woman

1. Ovarian Hyperstimulation Syndrome

increase the number of eggs that develop, a series of hormone shots are given. The hormones used in this regimen are own to have, or suspected of having a variety of side effects, some minor and some potentially major.

e most serious side effect of ovarian stimulation is ovarian hyperstimulation syndrome (OHSS). Its symptoms can include creased ovarian size, nausea and vomiting, accumulation of fluid in the abdomen, breathing difficulties, an increased ncentration of red blood cells, kidney and liver problems, and in the most severe cases, blood clots, kidney failure, or ath. The severe cases affect only a very small percentage of women who undergo in vitro fertilization—0.2 percent or less all treatment cycles—and the very severe are an even smaller percentage. Only about 1.4 in 100,000 cycles has lead to dney failure, for example. OHSS occurs at two stages: early, 1 to 5 days after egg retrieval (as a result of the hCG trigger); d late, 10 to 15 days after retrieval (as a result of the hCG if pregnancy occurs). The risk of severe complications is about 4 12 times higher if pregnancy occurs which is why sometimes no embryo transfer is performed to reduce the possibility of is occurring.

2. Cancer

ny have worried that the use of fertility drugs could lead to an increased risk of cancer—in particular, breast, ovarian, and erine (including endometrial) cancers. One must be careful in interpreting epidemiological studies of women taking fertility ugs, because all of these cancers are more common in women with infertility, so merely comparing women taking fertility ugs with women in the general population inevitably shows an increased incidence of cancer. When the analysis takes into count the increased cancer risk due to infertility per se, the evidence does not support a relationship between fertility ugs and an increased prevalence of breast or ovarian cancer. More research is required to examine what the long-term pact fertility drugs may be on breast and ovarian cancer prevalence rates. For uterine cancer, the numbers are too small achieve statistical significance, but it is at least possible that use of fertility drugs may indeed cause some increased risk uterine cancer.

3. Risks of Pregnancy

egnancies that occur with IVF are associated with increased risks of certain conditions (see Table below from the Executive mmary of a National Institute of Child Health and Human Development Workshop held in September 2005, as reported in e journal Obstetrics & Gynecology, vol. 109, no. 4, pages 967-77, 2007). Some of these risks stem from the higher average e of women pregnant by IVF and the fact that the underlying cause of infertility may be the cause of the increased risk of egnancy complications. There may be additional risks related to the IVF procedure per se, but it is difficult to assign the lative contributions.

Potential Risks in Singleton IVF-conceived Pregnancies

	Absolute Risk (%) in IVF-conceived Pregnancies	Relative Risk (vs. non IVF-conceived Pregnancies)
e-eclampsia	10.3%	1.6 (1.2--2.0)
acenta previa	2.4%	2.9 (1.5--5.4)
acental abruption	2.2%	2.4 (1.1--5.2)
stational diabetes	6.8%	2.0 (1.4--3.0)
sarean delivery	26.7%	2.1 (1.7--2.6)

In this table, the Absolute risk is the percent of IVF Pregnancies in which the risk occurred. The Relative Risk is the risk in I versus the risk in non-IVF pregnancies; for example, a relative risk of 2.0 indicates that twice as many IVF pregnancies experience this risk as compared to non-IVF pregnancies. The numbers in parentheses (called the "Confidence Interval") indicate the range in which the actual Relative Risk lies.

Currently more than 30% of IVF pregnancies are twins or higher-order multiple gestations (triplets or greater), and about hal of all IVF babies are a result of multiple gestations. Identical twinning occurs in 1.5% to 4.5% of IVF pregnancies. IVF twins deliver on average three weeks earlier and weigh 1,000 gm less than IVF singletons. Of note, IVF twins do as well as spontaneously conceived twins. Triplet (and greater) pregnancies deliver before 32 weeks (7 months) in almost half of case

Additionally, while embryos are transferred directly into the uterus with IVF, ectopic (tubal, cervical and abdominal) pregnancies as well as abnormal intra-uterine pregnancies have occurred either alone or concurrently with a normal intra-uterine pregnancy. These abnormal pregnancies oftentimes require medical treatments with methotrexate (a weak chemotherapy drug) or surgery to treat the abnormal pregnancy. Side effects of methotrexate include nausea or vomiting, diarrhea, cramping, mouth ulcers, headache, skin rash, sensitivity to the sun and temporary abnormalities in liver function tests. Risks of surgery include the risks of anesthesia, scar tissue formation inside the uterus, infection, bleeding and injury any internal organs.

C. Risks to Offspring

- **IVF babies may be at a slight increased risk for birth defects**
- **The risk for a multiple pregnancy is significantly higher for patients undergoing IVF, even when only one embryo is transferred**
- **Multiple pregnancies are the greatest risk for babies following IVF**
- **Some risk may also stem from the underlying infertile state, or from the IVF techniques, or both**

1. Overall risks.

Since the first birth of an IVF baby in 1978, more than 3 million children have been born worldwide following IVF treatments Numerous studies have been conducted to assess the overall health of IVF children and the majority of studies on the safety of IVF have been reassuring. As more time has passed and the dataset has enlarged, some studies have raised doubts about the equivalence of risks for IVF babies as compared to naturally conceived babies.

A major problem in interpreting the data arises from the fact that comparing a group of infertile couples to a group of normally fertile couples is not the proper comparison to make if one wants to assess the risk that IVF technology engenders. Infertile couples, by definition, do not have normal reproductive function and might be expected to have babies with more abnormalities than a group of normally fertile couples. This said, even if the studies suggesting an increased risk to babies born after IVF prove to be true, the absolute risk of any abnormal outcome appears to be small.

Singletons conceived with IVF tend to be born slightly earlier than naturally conceived babies (39.1 weeks as compared to 39.5 weeks). IVF twins are not born earlier or later than naturally conceived twins. The risk of a singleton IVF conceived bab being born with a birth weight under 5 pounds nine ounces (2500 grams) is 12.5% vs. 7% in naturally conceived singletons.

2. Birth Defects.

The risk of birth defects in the normal population is 2-3 %. In IVF babies the birth defect rate may be 2.6-3.9%. The differen is seen predominately in singleton males. Studies to date have not been large enough to prove a link between IVF treatmen and specific types of birth defects.

Imprinting Disorders. These are rare disorders having to do with whether a maternal or paternal gene is inappropriately expressed. In two studies approximately 4% of children with the imprinting disorder called Beckwith-Weidemann Syndrome were born after IVF, which is more than expected. A large Danish study however found no increased risk of imprinting disorders in children conceived with the assistance of IVF. Since the incidence of this syndrome in the general population is 1/15,000, even if there is a 2 to 5-fold increase to 2-5/15,000, this absolute risk is very low.

ldhood cancers. Most studies have not reported an increased risk with the exception of retinoblastoma: In one study in Netherlands, five cases were reported after IVF treatment which is 5 to 7 times more than expected.

ant Development. In general, studies of long-term developmental outcomes have been reassuring so far; most children are ng well. However, these studies are difficult to do and suffer from limitations. A more recent study with better thodology reports an increased risk of cerebral palsy (3.7 fold) and developmental delay (4 fold), but most of this mmed from the prematurity and low birth weight that was a consequence of multiple pregnancy.

Potential Risks in Singleton IVF Pregnancies

	Absolute Risk (%) in IVF Pregnancies	Relative Risk (vs. non-IVF Pregnancies)
term birth	11.5%	2.0 (1.7--2.2)
birth weight (< 2500 g)	9.5%	1.8 (1.4--2.2)
low birth weight (< 1500 g)	2.5%	2.7 (2.3--3.1)
all for gestational age	14.6%	1.6 (1.3--2.0)
U admission	17.8%	1.6 (1.3--2.0)
birth	1.2%	2.6 (1.8--3.6)
natal mortality	0.6%	2.0 (1.2--3.4)
ebral palsy	0.4%	2.8 (1.3--5.8)
netic risks		
-imprinting disorder	0.03%	17.8 (1.8--432.9)
-major birth defect	4.3%	1.5% (1.3--1.8)
mosomal abnormalities (after ICSI):		
-of a sex chromosome	0.6%	3.0
-of another chromosome	0.4%	5.7

is table, the Absolute risk is the percent of IVF Pregnancies in which the risk occurred. The Relative Risk is the risk in IVF versus the risk in non-IVF nancies; for example, a relative risk of 2.0 indicates that twice as many IVF pregnancies experience this risk as compared to non-IVF pregnancies. The bers in parentheses (called the "Confidence Interval") indicate the range in which the actual Relative Risk lies.

3. *Risks of a Multiple Pregnancy*

e most important maternal complications associated with multiple gestation are preterm labor and delivery, pre-ampsia, and gestational diabetes (see prior section on Risks to Woman). Others include gall bladder problems, skin blems, excess weight gain, anemia, excessive nausea and vomiting, and exacerbation of pregnancy-associated trointestinal symptoms including reflux and constipation. Chronic back pain, intermittent heartburn, postpartum laxity of abdominal wall, and umbilical hernias also can occur. Triplets and above increase the risk to the mother of more nificant complications including post-partum hemorrhage and transfusion.

maturity accounts for most of the excess perinatal morbidity and mortality associated with multiple gestations. Moreover, pregnancies are associated with an increased risk of prematurity, independent of maternal age and fetal numbers. Fetal wth problems and discordant growth among the fetuses also result in perinatal morbidity and mortality. Multifetal gnancy reduction (where one or more fetuses are selectively terminated) reduces, but does not eliminate, the risk of se complications.

al death rates for singleton, twin, and triplet pregnancies are 4.3 per 1,000, 15.5 per 1,000, and 21 per 1,000, pectively. The death of one or more fetuses in a multiple gestation (vanishing twin) is more common in the first trimester l may be observed in up to 25% of pregnancies after IVF. Loss of a fetus in the first trimester is unlikely to adversely affect surviving fetus or mother. No excess perinatal or maternal morbidity has been described resulting from a "vanishing" oryo.

nise of a single fetus in a twin pregnancy after the first trimester is more common when they share a placenta, ranging in idence from 0.5% to 6.8%, and may cause harm to the remaining fetus.

tiple fetuses (including twins) that share the same placenta have additional risks. Twin-twin transfusion syndrome in ch there is an imbalance of circulation between the fetuses may occur in up to 20% of twins sharing a placenta. Excess or fficient amniotic fluid may result from twin-to-twin transfusion syndrome. Twins sharing the same placenta have a higher

frequency of birth defects compared to pregnancies having two placentas. Twins sharing the same placenta appear to occ more frequently after blastocyst transfer.

Placenta previa and vasa previa are more common complications in multiple gestations. Abruptio placenta also is more common and postpartum hemorrhage may complicate 12% of multifetal deliveries. Consequences of multiple gestations include the major sequelae of prematurity (cerebral palsy, retinopathy of prematurity and chronic lung disease) as well as those of fetal growth restriction (polycythemia, hypoglycemia, necrotizing enterocolitis). It is unclear to what extent multiple gestations themselves affect neuro-behavioral development in the absence of these complications. Rearing of twi and high-order multiples may generate physical, emotional, and financial stresses, and the incidence of maternal depressic and anxiety is increased in women raising multiples. At mid-childhood, prematurely born offspring from multiple gestations have lower IQ scores, and multiple birth children have an increase in behavioral problems compared with singletons. It is clear to what extent these risks are affected by IVF per se.

The Option of Selective Reduction: Pregnancies that have more than 2 fetuses are considered an adverse outcome of infertility treatment. The greater the number of fetuses within the uterus, the greater is the risk for adverse perinatal and maternal outcomes. Patients with more than twins are faced with the options of continuing the pregnancy with all risks previously described, terminating the entire pregnancy, or reducing the number of fetuses in an effort to decrease the risk maternal and perinatal morbidity and mortality. Multifetal pregnancy reduction (MFPR) decreases risks associated with preterm delivery, but often creates profound ethical dilemmas. Pregnancy loss is the main risk of MFPR. However, current data suggest that such complications have decreased as experience with the procedure has grown. The risk of loss of the entire pregnancy after MFPR is approximately 1%.

In general, the risk of loss after MFPR increases if the number of fetuses at the beginning of the procedure is more than three. While there is little difference between the loss rates observed when the final number of viable fetuses is two or on the loss rate is higher in pregnancies reduced to triplets. Pregnancies that are reduced to twins appear to do as well as spontaneously conceived twin gestations, although an increased risk of having a small for gestational age fetus is increased when the starting number is over four. The benefit of MFPR can be documented in triplet and higher-order gestations beca reduction prolongs the length of gestation of the surviving fetuses. (This has been demonstrated for triplets; triplets have a 30-35% risk of birth under 32 weeks compared to twins which is 7 to 10%)

D. Ethical and Religious Considerations in Infertility Treatment

Infertility treatment can raise concerns and questions of an ethical or religious nature for some patients. The technique of vitro fertilization (IVF) involves the creation of human embryos outside the body, and can involve the production of excess embryos and/or 'high-order' multiple pregnancy (triplets or more). We encourage patients and their spouses or partners wh so desire to consult with trusted members of their religious or ethics community for guidance on their infertility treatment

E. Psychosocial Effects of Infertility Treatment

A diagnosis of infertility can be a devastating and life-altering event that impacts on many aspects of a patient's life. Infertility and its treatment can affect a patient and her spouse or partner medically, financially, socially, emotionally and psychologically. Feelings of anxiousness, depression, isolation, and helplessness are not uncommon among patients undergoing infertility treatment. Strained and stressful relations with spouses, partners and other loved ones are not uncommon as treatment gets underway and progresses.

Our health care team is available to address the emotional, as well as physical, symptoms that can accompany infertility. I addition to working with our health care team to minimize the emotional impacts of infertility treatments, patients may al consider working with mental health professionals who are specially trained in the area of infertility care.

While it is normal to experience emotional ups and downs when pursuing infertility treatment, it is important to recognize when these feelings are of a severe nature. If you experience any of the following symptoms over a prolonged period of tin you may benefit from working with a mental health professional:

- loss of interest in usual activities

- depression that doesn't lift
- strained interpersonal relationships (with partner, family, friends and/or colleagues)
- difficulty thinking of anything other than your infertility
- high levels of anxiety.
- diminished ability to accomplish tasks
- difficulty with concentration
- change in your sleep patterns (difficulty falling asleep or staying asleep, early morning awakening, sleeping more than usual for you)
- change in your appetite or weight (increase or decrease)
- increased use of drugs or alcohol
- thoughts about death or suicide
- social isolation
- persistent feelings of pessimism, guilt, or worthlessness
- persistent feelings of bitterness or anger

ealth care team can assist you in locating a qualified mental health professional who is familiar with the emotional fence of infertility, or you can contact a national support group such as RESOLVE, (www.resolve.org, Tel. 1-888-623- or The American Fertility Association (AFA), (www.theafa.org, Tel: 1-888-917-3777).

egal Considerations and Legal Counsel

aw regarding embryo cryopreservation, subsequent thaw and use, and parent-child status of any resulting child(ren) is, y be, unsettled in the state in which either the patient, spouse, partner, or any donor currently or in the future lives, or tate in which the ART Program is located. We acknowledge that the ART Program has not given us legal advice, that we ot relying on the ART Program to give us any legal advice, and that we have been informed that we may wish to consult yer who is experienced in the areas of reproductive law and embryo cryopreservation and disposition if we have any ions or concerns about the present or future status of our embryos, our individual or joint access to them, our individual nt parental status as to any resulting child, or about any other aspect of this consent and agreement.

lternatives to IVF

are alternatives to IVF treatment including gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT) al embryo transfer (TET) where eggs and sperm, fertilized eggs or developing embryos, respectively, are placed into llopian tube(s). Using donor sperm, donor eggs, adoption or not pursuing treatment are also options. Gametes (sperm r eggs), instead of embryos may be frozen for future attempts at pregnancy in an effort to avoid potential future legal relating to disposition of any cryopreserved embryos. Sperm freezing, but not egg freezing, has been an established dure for many decades. Egg freezing is considered an experimental procedure at this time.

eporting Outcomes

992 Fertility Clinic Success Rate and Certification Act requires the Centers for Disease Control and Prevention) to collect cycle-specific data as well as pregnancy outcome on all assisted reproductive technology cycles rmed in the United States each year and requires them to report success rates using these data. Consequently, from my/our IVF procedure will be provided to the CDC, and to the Society of Assisted Reproductive Technologies T) of the American Society of Reproductive Medicine (ASRM). The CDC may request additional information from the nent center or contact me/us directly for additional follow-up. Additionally, my/our information may be used and osed in accordance with HIPAA guidelines in order to perform research or quality control. All information used for rch will be de-identified prior to publication. De-identification is a process intended to prevent the data associated my/our treatment being used to identify me/us as individuals.

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11. 5. Stanford Reproductive Medicine

Stanford MEDICINE
Fertility and Reproductive Health

IN VITRO FERTILIZATION CONSENT BOOKLET

TABLE OF CONTENTS:

I. In Vitro Fertilization

In Vitro Fertilization (IVF) has become an established treatment for many forms of infertility. The main goal of IVF is to allow a patient the opportunity to become pregnant using her own eggs or donor eggs and sperm from her partner or from a donor. This is an elective procedure designed to result in the patient's pregnancy when other treatments have failed or are not appropriate.

This consent reviews the IVF process employed by the Fertility and Reproductive Health team at Lucile Salter Packard Children's Hospital at Stanford (Stanford) from start to finish, including the risks that this treatment might pose to you and your offspring. Stanford is an academic medical center affiliated with the Stanford University School of Medicine. As part of the medical education and training programs, postgraduate fellows, residents, medical students, and other approved healthcare practitioners may observe care, and if appropriately trained, participate in aspects of the process. These practitioners will be under the supervision of a Fertility and Reproductive Health team attending physician.

The medical risks of IVF vary with respect to each specific step of the procedure. Your physician will discuss with you the following primary risks of IVF as they relate to you and your care plan specifically:

An IVF cycle typically includes the following steps or procedures:

- Medications to grow multiple eggs
- Retrieval of eggs from the ovary or ovaries
- Insemination of eggs with sperm
- Culture of any resulting fertilized eggs (embryos)
- Placement ("transfer") of one or more embryo(s) into the uterus
- Support of the uterine lining with hormones to permit and sustain pregnancy

In certain cases, these additional procedures can be employed:

- Intracytoplasmic sperm injection (ICSI) to increase the chance for fertilization
- Assisted hatching of embryos to potentially increase the chance of embryo attachment ("implantation")
- Preimplantation genetic screening (PGS) and preimplantation genetic diagnosis (PGD) to test for genetic abnormalities
- Cryopreservation (freezing) of eggs or embryos

II. IVF Procedures

Medications for IVF Treatment

- **The success of IVF largely depends on growing multiple eggs at once.**
- **Injections of the natural hormones FSH and/or LH (gonadotropins) are used for this purpose.**
- **Additional medications are used to prevent premature ovulation.**
- **An overly vigorous ovarian response can occur, or conversely an inadequate response.**

Medications may include the following (not a complete list):

- ***Gonadotropins, or injectable "fertility drugs"***: These natural hormones stimulate the ovary in hopes of inducing the simultaneous growth of several oocytes (eggs) over the span of 8 or more days. All injectable fertility drugs have FSH (follicle stimulating hormone), a hormone that will stimulate the growth of your ovarian follicles (which contain the eggs). Some of them also contain LH (luteinizing hormone) or LH-like activity. LH is a hormone that may work with FSH to increase the production of estrogen and growth of the follicles. Low-dose hCG (human chorionic gonadotropin) can be used in lieu of LH. These medications are given by subcutaneous or intramuscular injection. Proper dosage of these drugs and the timing of egg recovery require monitoring of the ovarian response, usually by way of blood tests and ultrasound examinations during the ovarian stimulation.

  As with all injectable medications, bruising, redness, swelling, or discomfort can occur at the injection site. Rarely, there can be an allergic reaction to these drugs. The intent of giving these medications is to mature multiple follicles, and many women experience some bloating and minor discomfort as the follicles grow and the ovaries become temporarily enlarged. Up to 2.0 % of women will develop Ovarian Hyperstimulation Syndrome (OHSS) [see full discussion of OHSS in the Risks to Women section that follows]. Other risks and side effects of gonadotropins include, but are not limited to, fatigue, headaches, weight gain, mood swings, nausea, and clots in blood vessels.

  Even with pre-treatment attempts to assess response, and even more so with abnormal pre-treatment evaluations of ovarian reserve, the stimulation may result in very few follicles developing. The end result may be few or no eggs obtained at egg retrieval or even cancellation of the treatment cycle prior to egg retrieval.

  Concerns have been raised that the risk of ovarian cancer may increase with the use of fertility drugs, but recent studies have not confirmed this. A major risk factor for ovarian cancer is infertility per se, and early reports may have falsely attributed the risk resulting from infertility to the use of medications to overcome it (see further discussion below).

- ***GnRH-agonists:*** This medication is taken by injection. There are two forms of the medication: A short acting medication requiring daily injections and a long-acting preparation lasting for 1-3 months. The primary role of this medication is to prevent a premature LH surge, which could result in the release of eggs before they are ready to be retrieved. Since GnRH-agonists initially cause a release of FSH and LH from the pituitary, they can also be used to start the growth of the follicles or initiate the final stages of egg maturation. Though leuprolide acetate is an FDA (U.S. Food and Drug Administration) approved medication, it has not been approved for use in IVF, although it has routinely been used in this way for more than 20 years. Potential side effects usually experienced with long-term use include, but are not limited to: hot flashes, vaginal dryness, bone loss, nausea, vomiting, skin reactions at the injection site, fluid retention, muscle aches, headaches, and depression. No long term or serious side effects are known. Since GnRH-a are oftentimes administered after ovulation, it is possible that they will be taken early in pregnancy. The safest course of action is to use a barrier method of contraception (condoms or oral contraceptives) the month you will be starting the GnRH-a. GnRH-a has not been associated with any fetal malformations, however you should discontinue use of the GnRH-a immediately if pregnancy is confirmed.

- ***GnRH-antagonists***: These are another class of medications used to prevent premature ovulation. They tend to be used for short periods of time in the late stages of ovarian stimulation. The potential side effects include, but are not limited to: abdominal pain, headaches, skin reaction at the injection site, and nausea.

- ***Human chorionic gonadotropin (hCG)***: hCG is a natural hormone used in IVF to induce the eggs to become mature and fertilizable. The timing of this medication is critical to retrieve mature eggs. Potential side effects include, but are not limited to: breast tenderness, bloating, and pelvic discomfort.

- ***Progesterone, and in some cases, estradiol:*** Progesterone and estradiol are hormones normally produced by the ovaries after ovulation. After egg retrieval in some women, the ovaries will not produce adequate amounts of these hormones for long enough to fully support a pregnancy. Accordingly, supplemental progesterone, and in some cases estradiol, are given to ensure adequate hormonal support of the uterine lining. Progesterone is usually given by injection or by the vaginal route after egg retrieval. Progesterone is often continued for some weeks after a pregnancy has been confirmed. Progesterone has not been associated with an increase in fetal abnormalities. Side effects of progesterone include depression, sleepiness, allergic reaction, and if given by intra-muscular injection, includes the additional risk of infection or pain at the injection site. Estradiol, if given, can be by oral, trans-dermal, intramuscular, or vaginal administration. Side effects of estradiol include nausea, irritation at the application site if given by the trans-dermal route and the risk of blood clots or stroke.

- ***Oral contraceptive pills:*** Some treatment protocols include oral contraceptive pills to be taken for 2 to 4 weeks before gonadotropin injections are started in order to suppress hormone production or to schedule a cycle. Side effects include unscheduled bleeding, headache, breast tenderness, nausea, swelling and the risk of blood clots or, very rarely, stroke.

- ***Other medications:*** Antibiotics may be given for a short time during the treatment cycle to reduce the risk of infection associated with egg retrieval or embryo transfer. Antibiotic use may be associated with vaginal yeast infection, nausea, vomiting, diarrhea, rashes, sensitivity to the sun, and allergic reactions. Anti-anxiety medications or muscle relaxants may be recommended prior to the embryo transfer. The most common side effect is drowsiness. Other medications such as steroids, heparin, low molecular weight heparin or aspirin may also be included in the treatment protocol.

Transvaginal Oocyte (Egg) Retrieval

- **Eggs are removed from the ovary with a needle under ultrasound guidance.**
- **Anesthesia is provided to make this comfortable.**
- **Complications are rare.**

Oocyte retrieval is the removal of eggs from the ovary. A transvaginal ultrasound probe is used to visualize the ovaries and the egg-containing follicles within the ovaries. A long needle, which can be seen on ultrasound, can be guided into each follicle and the contents aspirated. The aspirated material includes follicular fluid, oocytes (eggs) and granulosa (egg-supporting) cells. Rarely, the ovaries are not accessible by the transvaginal route and laparoscopy or trans-abdominal retrieval is necessary. These procedures and risks will be discussed with you by your doctor if applicable. Anesthesia is generally used to reduce, if not eliminate, discomfort. Risks of egg retrieval include:

abdominal cavity by the needle. These bacteria may cause an infection of the uterus, fallopian tubes, ovaries or other intra-abdominal organs. The estimated incidence of infection after egg retrieval is less than 0.1%. Treatment of infections could require the use of oral or intravenous antibiotics. Severe infections occasionally require surgery to remove infected tissue. Infections can have a negative impact on future fertility. Prophylactic antibiotics are sometimes used before the egg retrieval procedure to reduce the risk of pelvic or abdominal infection in patients at higher risk of this complication. Despite the use of antibiotics, there is no way to eliminate this risk completely.

Bleeding: The needle passes through the vaginal wall and into the ovary to obtain the eggs. Both of these structures contain blood vessels. In addition, there are other blood vessels nearby. Small amounts of blood loss are common during egg retrievals. The incidence of major bleeding problems has been estimated to be less than 0.1%. Major bleeding may require surgical repair and possibly loss of the ovary. The need for blood transfusion is rare. (Although very rare, review of the world experience with IVF indicates that unrecognized bleeding has lead to death.)

Trauma: Despite the use of ultrasound guidance, it is possible to damage other intra-abdominal organs during the egg retrieval. Previous reports in the medical literature have noted damage to the bowel, appendix, bladder, ureters, and ovary. Damage to internal organs may result in the need for additional treatment such as surgery for repair or removal of the damaged organ. However, the risk of such trauma is very low.

Anesthesia: The use of anesthesia during the egg retrieval can produce unintended complications such as an allergic reaction, low blood pressure, nausea or vomiting and in rare cases, death.

Failure: It is possible that the aspiration will fail to obtain any eggs or the eggs may be abnormal or of poor quality and otherwise fail to produce a viable pregnancy.

In vitro fertilization and embryo culture

- **Sperm and eggs are placed together in specialized conditions (culture media, controlled temperature, humidity and light) to achieve fertilization.**
- **Culture medium is designed to permit normal fertilization and early embryo development, but the content of the medium is not standardized.**
- **Embryo development in the lab helps distinguish embryos with more potential from those with less or none.**

After eggs are retrieved, they are transferred to the Stanford embryology laboratory where they are kept in conditions that support their needs and growth. The eggs are placed in small dishes or tubes containing "culture medium," which is special fluid developed to support development of the eggs and embryos made to resemble that found in the fallopian tube or uterus. The dishes containing the eggs are then placed into incubators, which control the temperature and atmospheric gasses the eggs and embryos experience.

A few hours after eggs are retrieved, sperm are placed in the culture medium with the eggs, or individual sperm are injected into each mature egg in a technique called Intracytoplasmic Sperm Injection (ICSI) (see below). The eggs are then returned to the incubator, where they remain to develop. Periodically over the next few days, the dishes are inspected so the development of the embryos can be assessed.

The following day after eggs have been inseminated or injected with a single sperm (ICSI), they are examined for signs that the process of fertilization is underway. At this stage, normal development is evident by the still single cell having 2 nuclei; this stage is called a zygote or a 2PN embryo. Two days after insemination or ICSI, normal embryos have divided into about 4 cells. Three days after insemination or ICSI, normally developing embryos have developed to the blastocyst stage, which is typified by an embryo that now has 80 or more cells, an inner fluid-filled cavity, a small cluster of cells called the inner cell mass, and an outer group of cells called the trophectoderm.

It is important to note that since many eggs and embryos are abnormal, it is expected that not all eggs will fertilize and not all embryos will divide at a normal rate. The chance that a developing embryo will produce a pregnancy is related to many factors including whether its development in the lab is normal, but this correlation is not perfect. This means that not all embryos developing at the normal rate are in fact also genetically normal, and not all poorly developing embryos are genetically abnormal. Nonetheless, their visual appearance is the most common and useful guide in the selection of the best embryo(s) for transfer.

Stanford takes great care of all eggs, embryos and sperm in the lab. In spite of reasonable precautions, there are many reasons why pregnancy may not happen:

- The eggs may fail to fertilize.
- An egg may be fertilized abnormally resulting in an abnormal number of chromosomes in the embryo; these abnormal embryos will not be transferred if testing is performed which detects the abnormality.
- The fertilized eggs may degenerate before dividing into embryos, or adequate embryonic development may fail to occur.
- Rarely, the eggs or embryos may be harmed by contact with bacteria in the lab.
- In spite of having backup systems in place, lab equipment may fail or power may be lost. Both can lead to the destruction of eggs, sperm, and embryos.
- A lab accident or human error can happen and can lead to sperm, egg or embryo loss.
- Other unplanned events may prevent any step of the process from being performed or prevent pregnancy from occurring.
- Earthquakes, hurricanes, floods or other "acts of God," including bombings or other terrorist acts, could destroy the laboratory or its contents, including any sperm, eggs or embryos.

During the first 3 days of embryo culture after fertilization, Stanford may use an embryo imaging system within our incubators that captures key events during early development. Information from these automated cell division measurements are used to enhance the ability to select the most viable embryo from the cohort and provide some information about the embryo's potential. Long-term effects on the embryos of this imaging are unknown but the amount of additional light exposure to the embryos is minimal and equivalent to approximately the same or less amount of light that an embryo is exposed to during traditional evaluations outside of the incubator.

Embryo transfer

- **After a few days of development, the best appearing embryos are selected for transfer.**
- **The number chosen influences the pregnancy rate and the multiple pregnancy rate.**
- **A woman's age and the appearance of the developing embryo have the greatest influences on pregnancy outcome.**
- **Embryos are placed in the uterine cavity with a thin tube called a catheter.**
- **Surplus embryos of sufficient quality that are not transferred can be frozen.**

After a few days of development, one or more embryos are selected for transfer to the uterine cavity. Embryos are placed in the uterine cavity with a thin tube (catheter). Ultrasound guidance may be used to help guide the catheter or confirm placement through the cervix and into the uterine cavity. Although the possibility of a complication from the embryo transfer is very rare, risks include infection and loss of, or damage to, the embryos.

The number of embryos transferred influences the pregnancy rate and the multiple pregnancy rate. The age of the woman and the appearance of the developing embryo have the greatest influence on pregnancy outcome and the chance for multiple pregnancy. While it is possible, it is unusual to develop more fetuses than the number of embryos transferred if one of the embryos splits into identical twins. It is critical to discuss with your doctor the number to be transferred before the transfer is done.

In some cases, there will be additional embryos remaining in the lab after the transfer is completed. Depending on their developmental normalcy, it may be possible to freeze them for later use. (See below for an in-depth discussion of embryo cryopreservation).

Hormonal support of the uterine lining

- **Successful attachment of embryo(s) to the uterine lining depends on adequate hormonal support.**
- **Progesterone, given by the intramuscular or vaginal route, is routinely given for this purpose.**

Successful attachment of embryos to the uterine lining (endometrium) depends on adequate hormonal support of the lining. The critical hormones in this support are progesterone and estradiol. Normally, the ovary makes sufficient amounts of both hormones. However, in IVF cycles, this support is not always adequate. Therefore, progesterone is routinely given, and in some cases, estradiol is also prescribed. Progesterone is given by the intramuscular or vaginal route. Estradiol is given by the oral, vaginal, trans-dermal or intramuscular route. The duration of this support is from 2 to 10 weeks.

III. Additional Elements

Intracytoplasmic Sperm Injection (ICSI)

- **ICSI is used to increase the chance of fertilization when fertilization rates are anticipated to be lower than normal.**
- **An increased risk of genetic defects in offspring is reported.**
- **ICSI will not improve oocyte defects.**

The use of ICSI provides an effective treatment for male factor infertility. The negative effects of abnormal semen characteristics and sperm quality on fertilization can be overcome with ICSI if viable sperm are available because the technique bypasses the shell around the egg (zona pellucida) and the egg membrane (oolemma) to deliver the sperm directly into the egg. ICSI involves the direct injection of a single sperm into the interior of an egg using an extremely thin glass needle. ICSI allows couples with male factor infertility to achieve fertilization and live birth rates similar to those achieved with in vitro fertilization (IVF) using conventional methods of fertilization in men with normal sperm counts. ICSI can be performed even in men with no sperm in the ejaculate if sperm can be successfully collected from the epididymis or the testis.

ICSI is associated with a slightly higher risk of birth defects. Whether this association is due to the ICSI procedure itself or to inherent sperm defects has not been determined. The impact of ICSI on the intellectual and motor development of children has also been controversial, but recent studies have not detected any differences in the development of children born after ICSI, conventional IVF, or natural conception.

Certain genetic abnormalities have been shown to increase in IVF offspring. The prevalence of sex chromosome (X and Y) abnormalities in children conceived via ICSI is higher than observed in the general IVF population, but the difference between the two groups is small (0.8% to 1.0% in ICSI offspring vs. 0.2% in the general IVF population). Translocations (a re-arrangement of chromosomes that can cause miscarriage) may be more common in ICSI offspring (0.36%) than in the general population (0.07%). Although these differences might result from the ICSI procedure itself, men with abnormal semen analyses are more likely themselves to have chromosome abnormalities and may produce sperm with abnormal chromosomes. These abnormalities could be passed to their offspring.

Some men with extremely low or absent sperm counts have small deletions on their Y chromosome. When viable sperm can be obtained to fertilize eggs with ICSI, sperm containing a Y chromosomal microdeletion may result in male offspring who also carry the microdeletion and may be infertile. A Y chromosome microdeletion can often, but not always, be detected by a blood test.

Men who are infertile because of congenital bilateral absence of the vas deferens (CBAVD) are affected with a mild form of cystic fibrosis (CF). When sperm aspiration and ICSI results in conception, the CF gene will be passed on to the offspring. Men with CBAVD and their partners should be tested for CF gene mutations prior to treatment. However, some CF mutations may not be detected by current testing, so that some parents who test negative for CF mutations could still have affected children.

Assisted Hatching

- **Assisted hatching involves making a hole in the outer shell (zona pellucida) that surrounds the embryo.**
- **Hatching may make it easier for embryos to escape from the shell that surrounds them.**

The cells that make up the early embryo are enclosed within a flexible membrane (shell) called the zona pellucida. During normal development, a portion of this membrane dissolves, allowing the embryonic cells to escape or "hatch" out of the shell. Only upon hatching can the embryonic cells implant within the wall of the uterus to form a pregnancy.

Assisted hatching is the laboratory technique in which an embryologist makes an artificial opening in the shell of the embryo. The hatching is usually performed on the day of transfer, prior to loading the embryo into the transfer catheter. The opening is made by mechanical means, thinning the shell with a laser.

Risks that may be associated with assisted hatching include damage to the embryo resulting in loss of embryonic cells, or destruction or death of the embryo but these risks are very low. Artificial manipulation of the zygote may increase the rates of monozygotic (identical) twinning which are significantly more complicated pregnancies. There may be other risks not yet known.

Pre-Implantation Genetic Testing (PGD or PGS)

If you decide to undergo PGD or PGS, the eggs will be fertilized by either standard IVF procedures or by sperm microinjection procedure, using intracytoplasmic sperm injection (ICSI). PGD involves the removal of several cells from a day 5 or 6 embryo (called a trophectoderm biopsy). Under rare circumstances, 1-2 cells from a day 3 embryo (called a blastomere biopsy) or 2 cells from an egg (called a polar body biopsy) may be offered as an alternative to day 5 biopsy. This testing occurs prior to embryo transfer.

The specific tests done for your embryos will depend on your history and test results. Preimplantation genetic testing is sometimes referred to as Preimplantation Genetic Screening (PGS) when the screening is done to count the number of chromosomes in the embryo rather than to test for a specific genetic disorder caused by one gene which is called Preimplantation Genetic Diagnosis (PGD). The genetic material from these cells is analyzed to determine whether the egg or embryo carries an abnormal number of whole chromosomes or large segments of chromosomes that may lead to a decreased chance for pregnancy or an increased chance for early miscarriage of a pregnancy. If relevant to your particular situation, the cells may be tested to see if any embryo has a specific genetic condition which may cause abnormalities in the resulting child. Your physicians at Stanford will be provided with the results of these tests to help inform your decision about which embryos to transfer.

The advantage of PGD and PGS are that they are performed earlier than standard prenatal diagnosis and, therefore, can potentially reduce the likelihood of having an affected child and/or the need for a termination of a pregnancy due to a genetic condition which may affect the health of the fetus.

Risks:

There is no risk of bodily injury to the recipient as a results of participation in the PGD or PGS procedure beyond the risks associated with the standard IVF procedures. There may be a risk to your eggs or embryos from the embryo biopsy procedures beyond the risks of standard IVF. The process of removing the cells may cause unexpected damage to the embryo. Unexpected damage may include destruction of the embryo, such that it would not be suitable for implantation. With a skilled embryologist, the risk of damaging the embryo is expected to be very low. Embryo biopsy has been performed for over 20 years with thousands of babies born. Studies indicate that the risk of congenital defects is similar to the general population rate which is about 3%. However, it is not definitively known whether or not there are any long-term risks of embryo biopsy.

No genetic testing is error proof. It is possible that the test will indicate that an embryo is abnormal when in fact the embryo is viable. Therefore, there is a risk of unintentionally withholding a normal embryo from transfer. In addition, errors may be due to technical or biological limitations of testing, including chromosomal mosaicism. The term "chromosomal mosaicism" refers to the presence of normal and abnormal chromosomes within the same sample. If reported, a mosaic result may indicate higher rates of adverse outcomes when compared to embryos with normal chromosomes. These outcomes may include implantation failure, pregnancy complications, or health complications in the resulting fetus. Genetic counseling regarding the implications of transferring a mosaic embryo is recommended. Mosaicism cannot be ruled out regardless of the result. The diagnostic procedures used in PGD and PGS are not designed to identify all possible genetic abnormalities and a tested egg or embryo could result in the birth of a child with genetic abnormalities. PGD and PGS do not provide information regarding multifactorial or adult onset conditions. It is possible the resulting pregnancy may have abnormalities of non-genetic etiology. At most, the chance of such an abnormality would be the same as if the embryo were transferred without the diagnostic procedure. We estimate the risk of misdiagnosis in PGD and PGS is less than 10%. Therefore, we recommend that you undergo standard prenatal testing of your developing baby as recommended by your obstetrician. Prenatal options may include ultrasound, chorionic villus sampling (CVS), amniocentesis, or blood tests to detect abnormalities in the pregnancy. There is a risk that PGD and PGS could have adverse consequences that are currently unknown.

Cryopreservation

- **Freezing of eggs and embryos can provide additional chances for pregnancy in the future.**
- **Frozen eggs and embryos do not always survive the process of freezing and thawing.**
- **Ethical and legal dilemmas can arise when couples separate or divorce, especially for embryos; disposition agreements are essential.**
- **It is the responsibility of each couple with frozen eggs and / or embryos to remain in contact with LPCH on an annual basis.**

Embryo Cryopreservation

Freezing (or "cryopreservation") of eggs or embryos is a common procedure. Since multiple eggs (oocytes) are often produced during ovarian stimulation, there may be more embryos available than are considered appropriate for transfer to the uterus. Such embryos can be frozen for future use. Alternatively, some eggs can be frozen before being exposed to sperm. Both strategies save the expense and inconvenience of stimulation to obtain additional eggs in the future. Furthermore, the availability of cryopreservation permits patients to transfer fewer embryos during a fresh cycle, reducing the risk of high-order multiple gestations (triplets or greater). Other possible reasons for cryopreservation of embryos include freezing all embryos in the initial cycle to prevent severe ovarian hyperstimulation syndrome (OHSS), if there is a greater chance of pregnancy expected in a frozen cycle, if genetic testing is being performed with no results available for a fresh transfer, if a couple were concerned that their future fertility potential might be reduced due to necessary medical treatment (e.g., cancer therapy or surgery), or for personal reasons.

Indications:

- To reduce the risks of multiple gestation
- To preserve fertility potential in the face of certain necessary medical procedures or for personal reasons
- To increase the chance of having one or more pregnancies from a single cycle of ovarian stimulation
- To minimize the medical risk and cost to the patient by decreasing the number of stimulated cycles and egg retrievals
- To temporarily delay pregnancy and decrease the risks of hyperstimulation (OHSS- see below) by freezing all embryos, when this risk is high
- To await results of genetic testing
- To increase pregnancy rate if there are concerns about uterine lining in a fresh cycle

Risks of cryopreservation: There are several techniques for embryo cryopreservation, and research is ongoing. Traditional methods include "slow," graduated freezing in a computerized setting, and "rapid" freezing methods, called "vitrification." Current techniques deliver a high percentage of viable eggs and embryos thawed after cryopreservation, but there can be no certainty that eggs and embryos will thaw normally, nor be viable enough to divide and eventually implant in the uterus. Cryopreservation techniques could theoretically be injurious to the embryo. Extensive animal data (through several generations), and limited human data, do not indicate any likelihood that children born of embryos that have been cryopreserved and thawed will experience greater risk of abnormalities than those born of fresh embryos. However, until very large numbers of children have been born following freezing and thawing of embryos, it is not possible to be certain that the rate of abnormalities is no different from the normal rate.

Egg Cryopreservation

While embryos and sperm have been frozen and thawed with good results for many years, eggs have proved much more difficult to manage. Newer egg freezing methods have been more successful, at least in younger women, the main population in which the techniques have been studied. Egg freezing takes place by one of two methods: a slow freeze protocol, or a different "flash freeze" method known as vitrification. Both methods remove the surrounding support cells, the cumulus, from the eggs prior to freezing. Once the cumulus cells are removed, eggs may not fertilize readily. In addition, the zona pellucida "shell" around the egg hardens with freezing. For these two reasons, injection of sperm directly into the egg (ICSI) is currently recommended after eggs have been frozen.

When eggs are vitrified, they may come in direct contact with liquid nitrogen. This could carry a risk of transmitting infection if the liquid nitrogen should be contaminated, although there has never been a case of infection reported by this means.

Achieving Pregnancy. As mentioned, most studies have looked at success rates using either donor eggs or women who produced larger numbers of eggs. The best studies randomly assign patients into two groups (fresh eggs versus frozen eggs) and compare the outcomes. There are four strong studies of this design currently published. In these studies, fertilization rates, implantation rates, and pregnancy rates using frozen eggs appear similar to rates using fresh eggs in these studies. One caution is that there are still only small numbers of studies available, and these results may not be the same at all centers or in older women.

Other information on egg freezing comes from Italy, where the law limits the number of eggs that may be fertilized in a cycle. Italian patients with extra eggs available have been offered egg freezing for many years now, and at many different centers. These types of studies show higher fertilization rates, implantation rates, and pregnancy rates when using fresh eggs instead of frozen eggs. The rates were also higher with the use of frozen embryos rather than frozen eggs. Other non-randomized studies in the US show fertilization, implantation, and pregnancy rates that are similar with frozen eggs and fresh eggs when the woman providing the eggs was under 35 years old.

What are the reasons a woman would elect to freeze her eggs?

- Chemotherapy for cancer or other medical conditions can be toxic to the ovaries. Women undergoing treatment may not have a male partner, or they may have ethical concerns about freezing embryos. Pregnancy and success rates from this group of women are limited, but egg freezing is recommended in this group after appropriate discussion of the procedure and its risks and limitations.

- Some genetic disorders like the BRCA mutations carry a high risk for ovarian cancer, and removal of the ovaries may be suggested in this group. Other genetic conditions can lead to premature menopause. Egg freezing could be considered in these groups, although data on success, safety of pregnancy, and risks of genetic problems in children born in these groups are not known.

- In some cases, there may not be enough sperm to fertilize the eggs on the day of egg retrieval in couples undergoing IVF. In this case, surplus eggs can be frozen and used in the future when more sperm are available.

- Some patients undergoing IVF do not want to freeze embryos for ethical or other reasons. In these cases, even though pregnancy rates using frozen eggs may be lower than pregnancy rates using frozen embryos, any eggs not inseminated may be frozen for future use.

- Some women may choose to freeze eggs in order to delay childbearing. Unfortunately, the success rates with egg freezing appear to decline significantly for older women (38 years or older). There are no data available that look at success rates for women choosing to freeze eggs in order to delay childbearing. Therefore, it is impossible to determine the success rates and cost-effectiveness of freezing eggs in this population of women. Freezing eggs is not a guarantee of the ability to conceive a biologically-related child in the future. Women wishing to freeze eggs for this purpose should carefully consider the success rates available at their clinics, and the available alternatives.

Risks to offspring. One concern with the use of egg freezing is that the cellular machinery that helps to separate the chromosomes of the eggs could be damaged, leading to chromosomal abnormalities

such as Down Syndrome. However, a large study looking at 900 live births after eggs freezing, most done via the slow freeze method, showed no increased risk of birth defects compared to the general US population. Another study of 200 live births from eggs that had been vitrified showed no difference in birth defects or birth weight in those children and the children who had been born after IVF cycles using fresh eggs. There is no information about children born after egg freezing in older women, or from follow-up years after birth.

The techniques for freezing eggs, both with the slow freeze method and with vitrification, have become successful enough that they are no longer considered experimental. Implantation and pregnancy rates may be lower with frozen eggs than with fresh eggs. Most reports have focused on young women who have responded well to the medications used for egg retrieval, so success rates in older women or poor responders may not be as good. Success rates can be expected to vary among clinics. Many good reasons exist for freezing eggs rather than embryos, such as ethical concerns or medical problems that can affect fertility in women without male partners. In women who wish to freeze their eggs solely to delay childbearing, extreme caution should be exercised due to limited data on success and safety.

Frozen Embryo Transfer

If there is a desire to attempt pregnancy with frozen embryos, one or more of the frozen embryos will be thawed. Only those embryos which are considered to be potentially viable in the reasonable medical judgement of the Stanford physicians and embryologists will be transferred. Transfer of the embryos requires a normal uterine lining and very close synchronization to the normal process of ovulation. Therefore, a cycle to transfer frozen embryos may use some of the same medications used in ovulation induction for a fresh cycle as well as blood tests and ultrasound monitoring. The protocol selected is based on individual patient characteristics and parameters. The embryo transfer procedure is similar to the process described above for a fresh embryo transfer.

There is a small possibility that an embryo will not survive the thaw. If an embryo does not survive the thawing process and there are additional suitable embryos available, an additional embryo can be thawed and transferred. It is recommended that all patients pregnant after ICSI/AH/PGD undergo routine prenatal care and testing.

Frozen Oocyte Transfer

A cycle to transfer frozen oocytes (eggs) may use some of the same medications used in ovulation induction for a fresh cycle as well as ultrasound monitoring. The protocol selected is based on individual patient characteristics and parameters. Fertilization, embryo culture and the embryo transfer procedure are similar to what is outlined above for a fresh cycle.

There is a possibility that not all oocytes will survive the freezing and thawing process. Therefore, multiple eggs may be thawed. In addition, not all oocytes will fertilize and reach the blastocyst stage. If more embryos are created than are desired for embryo transfer, good quality embryos can be frozen at the blastocyst stage. It is recommended that all patients pregnant after ICSI/AH/PGD undergo routine prenatal care and testing.

Disposition of Excess Embryos or Oocytes

Stanford desires to provide you with relevant and appropriate information so that you may make an informed and voluntary choice regarding the disposition of any embryos remaining following your treatment. Because of the possibility of you and/or your partner's separation, divorce, death or incapacitation after embryos have been produced, it is important to decide on the disposition of any embryos (fresh or cryopreserved) that remain in the laboratory in these situations. Since this is a

rapidly evolving field, both medically and legally, the clinic cannot guarantee what the available or acceptable avenues for disposition will be at any future date.

Your physician will discuss with you the following options and you will be require to complete Stanford's *Disposition of Embryos* consent form prior to commencing treatment:

1. Storing (cryopreservation) any unused embryo(s)
2. Discarding any unused embryo(s)
3. Donating any unused embryo(s) for approved research studies
4. Donating any unused embryos to another individual in order to attempt pregnancy.
5. Use by one partner with the contemporaneous permission of the other for that use

Disposition of Clinically Unsuitable or Non-Selected Materials

In most cycles, some eggs retrieved during the in vitro fertilization process are immature, fail to fertilize, or are abnormally fertilized and incapable of further development. Some embryos are determined to be nonviable because they stop developing in vitro. These eggs and embryos that are unsuitable for transfer, which would normally be discarded, could be of use to our clinical team in undertaking quality control or trying to improve IVF techniques or to researchers interested in the study of human reproduction or development or human embryonic stem cell research. The determination that an egg or embryo is unsuitable for clinical use will be made by staff embryologists who are not performing the research. In addition, in cycles in which PGD is performed, PGD embryos that you and your physician agree will not be used for your care (due to abnormality or other documented reason) may be donated to research or quality improvement techniques or discarded, in accordance with your choice.

In certain situations, donating materials to research may not be possible; in this instance, your materials will be discarded in accordance with current institutional and departmental policies.

Deciding that you do not want to donate to research or technique improvement will have no effect on your future care at Stanford. Even if you do decide now that you would like to donate, you may change your mind by notifying Stanford at any time up until the time of your discharge from our clinic after the oocyte retrieval procedure.

All patients are required to complete the Disposition of Eggs or Disposition of Embryos consent form, as applicable, prior to oocyte retrieval. That form outlines the choices you have with regard to the disposition of oocytes and embryos in a variety of situations that may arise. You are free to submit a statement at a later time indicating different choices, provided you both agree in writing. It is also incumbent upon you to remain in touch with Stanford regarding your contact information, and to pay for storage charges as they come due.

IV. Risks to the Woman

Ovarian Hyperstimulation Syndrome

The intent of giving gonadotropins is to mature multiple follicles, but some women have an excessive response to the medications and are at risk for ovarian hyperstimulation syndrome (OHSS). This is the most serious side effect of ovarian stimulation. Its symptoms can include increased ovarian size, nausea and vomiting, accumulation of fluid in the abdomen, breathing difficulties, an increased concentration of red blood cells, kidney and liver problems, and in the most severe cases, blood clots, kidney failure, or death. The severe cases affect only a very small percentage of women who undergo in vitro fertilization—0.2 percent or less of all treatment cycles—and the very severe are an even

smaller percentage. Only about 1.4 in 100,000 cycles has lead to kidney failure, for example. OHSS occurs at two stages: early, 1 to 5 days after egg retrieval (as a result of the hCG trigger); and late, 10 to 15 days after retrieval (as a result of the hCG if pregnancy occurs). The risk of severe complications is about 4 to 12 times higher if pregnancy occurs which is why sometimes no embryo transfer is performed to reduce the possibility of this occurring.

Cancer

Many have worried that the use of fertility drugs could lead to an increased risk of cancer—in particular, breast, ovarian, and uterine (including endometrial) cancers. One must be careful in interpreting epidemiological studies of women taking fertility drugs, because all of these cancers are more common in women with infertility, so merely comparing women taking fertility drugs with women in the general population inevitably shows an increased incidence of cancer. When the analysis takes into account the increased cancer risk due to infertility per se, the evidence does not support a relationship between fertility drugs and an increased prevalence of breast or ovarian cancer. A final answer may require decades of follow-up to resolve. Note that an increased chance for "borderline" ovarian tumors has been observed with IVF, even when compared to the subfertile population (see reference section for citation). More research is required to examine what the long-term impact fertility drugs may have on breast and ovarian cancer prevalence rates. For uterine cancer, the numbers are too small to achieve statistical significance, but it is at least possible that use of fertility drugs may cause some increased risk of uterine cancer.

Risks of Pregnancy

Pregnancies that occur with IVF are associated with increased risks of certain conditions (see Table below from the Executive Summary of a National Institute of Child Health and Human Development Workshop held in September 2005, as reported in the journal *Obstetrics & Gynecology*, vol. 109, no. 4, pages 967-77, 2007). Some of these risks stem from the higher average age of women pregnant by IVF and the fact that the underlying cause of infertility may be the cause of the increased risk of pregnancy complications. This was demonstrated in an Australian study that reviewed adverse obstetric and perinatal outcomes in sub-fertile women conceiving without ART. There may be additional risks related to the IVF procedure per se, but it is difficult to assign the relative contributions.

Potential Risks in Singleton IVF-conceived Pregnancies

	Absolute Risk (%) in IVF-conceived Pregnancies	Relative Risk (vs. non IVF-conceived Pregnancies in a control population)	Relative Risk of Non-IVF Infertile Patients (vs. control population)
Pre-eclampsia	10.3%	1.6 (1.2--2.0)	1.29 (1.02-1.61)
Placenta previa	2.4%	2.9 (1.5--5.4)	
Placental abruption	2.2%	2.4 (1.1--5.2)	
Gestational diabetes	6.8%	2.0 (1.4--3.0)	1.25 (0.96-1.63)
Cesarean delivery *	26.7%	2.1 (1.7--2.6)	1.56 (1.37-1.77)

In this table, the Absolute risk is the percent of IVF Pregnancies in which the risk occurred. The Relative Risk is the risk in IVF versus the risk in non-IVF, non-infertile pregnancies; for example, a relative risk of 2.0 indicates that twice as many IVF pregnancies experience this risk as compared to non-IVF pregnancies. However, the third column indicates the increased risk of adverse outcome in infertile women conceiving without ART suggesting that being infertile increases the risk of adverse outcomes unrelated to ART/IVF. The numbers in parentheses (called the "Confidence Interval") indicate the range in which the actual Relative Risk lies.

* Please note that most experts believe the rate of Cesarean delivery to be well above the 26.7% rate quoted here.

multiple gestations substantially increase the risk of pregnancy complications. The most important maternal complications associated with multiple gestations are preterm labor and delivery, pre-eclampsia, and gestational diabetes. Placenta previa (placenta extends over the cervical opening), vasa previa (one or more of the blood vessels extends over the cervical opening), and placental abruption (premature separation of the placenta) are also more common in multiple gestations. Postpartum hemorrhage may complicate 12% of multifetal deliveries. Having triplets or more increases the risk of more significant complications including post-partum hemorrhage and transfusion. Other complications of multiple gestations include gall bladder problems, skin problems, excess weight gain, anemia, excessive nausea and vomiting, and exacerbation of pregnancy-associated gastrointestinal symptoms.

Although embryos are transferred directly into the uterus with IVF, ectopic (tubal, cervical and abdominal) pregnancies have occurred either alone or concurrently with a normal intra-uterine pregnancy. These abnormal pregnancies oftentimes require medical treatments with methotrexate (a weak chemotherapy drug) or surgery to treat the abnormal pregnancy.

V. Risks to Offspring

- **IVF babies seem to be at a slight increased risk for birth defects.**
- **The risk for a multiple pregnancy is significantly higher for patients undergoing IVF, even when only one embryo is transferred.**
- **Multiple pregnancies are the greatest risk for babies following IVF.**
- **Some risk may also stem from the underlying infertile state, or from the IVF techniques, or both.**

Overall Risks

Since the first birth of an IVF baby in 1978, more than 5 million children have been born worldwide following IVF treatments. Numerous studies have been conducted to assess the overall health of IVF children and the majority of studies on the safety of IVF have been reassuring. A major problem in interpreting the data arises from the fact that comparing a group of infertile couples to a group of normally fertile couples is not the proper comparison to make if one wants to assess the risk that IVF technology engenders. Infertile couples, by definition, do not have normal reproductive function and might be expected to have babies with more abnormalities than a group of normally fertile couples. This said, even if the studies suggesting an increased risk to babies born after IVF prove to be true, the absolute risk of any abnormal outcome appears to be small.

Singletons conceived with IVF tend to be born slightly earlier than naturally conceived babies (39.1 weeks as compared to 39.5 weeks). IVF twins are not born earlier or later than naturally conceived twins. The risk of a singleton IVF conceived baby being born with a birth weight under 5 pounds nine ounces (2500 grams) is 12.5% vs. 7% in naturally conceived singletons.

Birth Defects

The risk of birth defects in the normal population is 2-3%, and is slightly higher among infertile patients. Most of this risk is due to delayed conception and the underlying infertility issues. In a recent large study performed in Australia, the risk of birth defects was not increased among women who had routine IVF treatment, but was higher among those who employed ICSI as part of the treatment. No higher risk was seen in frozen embryo transfer and donor egg cycles.

Imprinting Disorders. These are rare disorders having to do with whether a maternal or paternal gene is inappropriately expressed. In two studies of children with the imprinting disorder called Beckwith-Weidemann Syndrome, more were born after IVF than expected. A large Danish study, however, found

no increased risk of imprinting disorders in children conceived with the assistance of IVF. Since the incidence of this syndrome in the general population is 1/15,000, even if there is a 2 to 5-fold increase to 2-5/15,000, this absolute risk is very low.

Childhood cancers. Most studies have not reported an increased risk with the exception of retinoblastoma: In one study in the Netherlands, five cases were reported after IVF treatment which is 5 to 7 times more than expected. Further studies have not supported this finding. There are ongoing studies.

Infant development. In general, studies of long-term developmental outcomes have been reassuring so far; most children are doing well. However, these studies are difficult to do and suffer from limitations. A more recent study with better methodology reports an increased risk of cerebral palsy (3.7 fold) and developmental delay (4 fold), but most of this stemmed from the prematurity and low birth weight that was a consequence of multiple pregnancy.

Risks of a Multiple Pregnancy

Many IVF pregnancies are twins or higher-order multiple gestations (triplets or greater), generally as a result of more than one embryo being transferred. Some multiple pregnancies are due to identical twinning which occurs in 1.5% to 4.5% of IVF pregnancies, and may occur more frequently after blastocyst transfer.

Prematurity accounts for most of the excess perinatal morbidity and mortality associated with multiple gestations. IVF twins deliver on average three weeks earlier and weigh 1,000 gm less than IVF singletons. Triplet (and greater) pregnancies deliver before 32 weeks (7 months) in almost half of cases. Fetal growth problems and discordant growth among the fetuses also result in perinatal morbidity and mortality. Multifetal pregnancy reduction (where one or more fetuses are terminated) reduces, but does not eliminate, the risk of these complications and may not be acceptable to all couples.

Fetal death rates for singleton, twin, and triplet pregnancies are 4.3 per 1,000, 15.5 per 1,000, and 21 per 1,000, respectively. The death of one or more fetuses in a multiple gestation (vanishing twin) is more common in the first trimester and may be observed in up to 25% of pregnancies after IVF if more than one embryo is transferred. Loss of a fetus in the first trimester is unlikely to adversely affect the surviving fetus.

Multiple fetuses that share the same placenta, as in most identical twins, have additional risks. Twin-twin transfusion syndrome, in which excess or insufficient amniotic fluid results from an imbalance of circulation between the fetuses, may occur in up to 20% of twins sharing a placenta. Twins sharing the same placenta have a higher frequency of birth defects compared to twins with two placentas. After the first trimester, death of one fetus in a twin pregnancy is more common with a shared placenta and may cause harm to the remaining fetus.

Long-term consequences of multiple gestations include the major complications of prematurity (cerebral palsy, retinopathy of prematurity, and chronic lung disease), as well as those of fetal growth restriction (polycythemia, hypoglycemia, necrotizing enterocolitis). It is unclear to what extent multiple gestations themselves affect neuro-behavioral development in the absence of these complications. At mid-childhood, prematurely born offspring from multiple gestations have lower IQ scores, and multiple birth children have an increase in behavioral problems compared with singletons. It is not clear to what extent these risks are affected by IVF per se.

The Option of Multifetal Pregnancy Reduction: The greater the number of fetuses within the uterus, the greater is the risk for adverse perinatal and maternal outcomes. Patients with more than twins are

faced with the options of continuing the pregnancy with all risks previously described, terminating the entire pregnancy, or undergoing a procedure called multifetal pregnancy reduction. By reducing the number of fetuses, multifetal pregnancy reduction (MFPR) decreases risks associated with preterm delivery, but often creates important ethical dilemmas. Pregnancy loss is the main medical risk of MFPR. However, current data suggest that such medical complications have decreased as experience with the procedure has grown. The risk of loss of the entire pregnancy after MFPR is approximately 2-3%, although this risk increases when the number of fetuses prior to the procedure is greater than three.

VI. Ethical and Religious Considerations in Infertility Treatment

Infertility treatment can raise concerns and questions of an ethical or religious nature for some patients. The technique of in vitro fertilization (IVF) involves the creation of human embryos outside the body, and can involve the production of excess embryos and/or "high-order" multiple pregnancy (triplets or more). Patients and their spouses or partners who so desire are encouraged to consult with trusted members of their religious or ethics community for guidance on their infertility treatment.

VII. Psychosocial Effects of Infertility Treatment

A diagnosis of infertility can be a devastating and life-altering event that impacts on many aspects of a patient's life. Infertility and its treatment can affect a patient and her spouse or partner medically, financially, socially, emotionally and psychologically. Feelings of anxiety, depression, isolation, and helplessness are not uncommon among patients undergoing infertility treatment. Strained and stressful relations with spouses, partners and other loved ones are not uncommon as treatment gets underway and progresses.

Rearing of twins and high-order multiples may generate physical, emotional, and financial stresses; and the incidence of maternal depression and anxiety is increased in women raising multiples.

Patients may consider working with mental health professionals who are specially trained in the area of infertility care, as well as with their health care team, to minimize the emotional impact of infertility treatments. You may call the Stanford Fertility and Reproductive Health clinic at 650-498-7911 or a national support group, such as RESOLVE, (www.resolve.org, Tel. 1-888-623-0744) or The American Fertility Association (AFA), (www.theafa.org, Tel: 1-888-917-3777).

VIII. Alternatives to IVF

There are alternatives to IVF treatment including gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT) or tubal embryo transfer (TET) where eggs and sperm, fertilized eggs or developing embryos, respectively, are placed into the fallopian tube(s). Using donor sperm, donor eggs, adoption, or not pursuing treatment are also options. Gametes (sperm and/or eggs), instead of embryos may be frozen for future attempts at pregnancy in an effort to avoid potential future legal or ethical issues relating to disposition of any cryopreserved embryos.

IX. Reporting Obligations and Privacy

Stanford will use all reasonable efforts to protect the privacy of your medical information, in accordance with legal requirements and the Lucile Packard Children's Hospital at Stanford Notice of Privacy Practices (which you have received). Stanford sends data to the Society for Assisted Reproductive Technology, an affiliate of the American Society for Reproductive Medicine, who in turn sends the data to the Federal Center for Disease Control and Prevention ("CDC") national registry. The

1992 Fertility Clinic Success Rate and Certification Act requires that the CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. This information is identifiable, and it is possible that at some time in the future, information regarding the fertility treatment of a particular Recipient would be part of an audit. Such audit may include, but not be limited to, examination of medical and laboratory records and comparison of the data in the medical records with the data in the CDC's reporting database. Because sensitive information will be collected by the CDC, the CDC has obtained an "assurance of confidentiality" for this project under the provision of the Public Health Service Act, Section 308(d). Additionally, your information may be used and disclosed in accordance with HIPAA guidelines in order to perform research, data aggregation and/or quality control. All information used for research will be de-identified prior to publication. De-identification is a process intended to prevent the data associated with your treatment being used to identify you as an individual.

Stanford MEDICINE
Fertility and Reproductive Health

IVF Treatment Plan

Patient name: _____ **Date:**_____**Time:** _____

Partner name: _____ **Date:**_____**Time:** _____

Provider of Sperm

We (I) plan to use sperm from:
- ❑ **Patient**
- ❑ **Partner**
- ❑ **Donor (specify arrangement):** _____

Initials: _____/_____

Provider of Eggs

We (I) plan to use eggs from:
- ❑ **Patient**
- ❑ **Partner**
- ❑ **Donor (specify arrangement):** _____

Initials: _____/_____

Carrier of embryos

We (I) plan to transfer the embryos into:
- ❑ **Patient**
- ❑ **Partner**
- ❑ **A Gestational Carrier**
  —if known, her name: _____

Initials: _____/_____

Limit on Number Inseminated/Plan for Eggs Not Inseminated

Regarding the number of eggs to expose to sperm, we (I) choose:
- ❑ **Inseminate ALL Mature Eggs**
- ❑ **Inseminate SOME Mature Eggs:** number or fraction of eggs to be exposed to sperm: _____

Regarding the eggs **NOT** exposed to sperm for fertilization, we (I) choose:
- ❑ **Freeze for my later use**
- ❑ **Donate to:**
  - ❑ Research
  - ❑ Another person or couple
- ❑ **Discard**

Initials: _____/_____

INFORMED CONSENT FOR IN VITRO FERTILIZATION (IVF)

A. **IVF General**. By my/our signature(s) below, I/we confirm that:

1. I/we have read and understood the information presented in this In Vitro Fertilization Consent Booklet and the nature and purpose of the procedures have been explained to me/us. The risks and benefits of the procedures have been explained to me/us. In addition, the alternative treatments and the risks and benefits of these alternatives have been explained to me/us. I/we have had the opportunity to ask questions and have received all the information I/we desire about the procedures.

2. I/we understand that in an emergency, there may be different or further procedures required if the doctor believes they are necessary, and I/we consent to such procedures.

3. I/we understand that the administration of anesthesia and/or sedation and associated procedures may be necessary to assure safety and comfort during the procedure, and I/we consent to such procedures if indicated. I/we understand certain risks and complications may be associated with the use of anesthesia and/or sedation and that the appropriate practitioner will discuss these risks with me prior to the procedure.

4. I/we consent to the taking of ultrasound images and pictures, videotapes, or other electronic reproductions of the eggs/sperm/embryos and the use of the pictures, videotapes, or electronic reproductions for treatment or internal or external activities consistent with Stanford's mission of education and research, conducted in accordance with Stanford policies.

B. **Intracytoplasmic Sperm Injection (ICSI)**. I/we have discussed the possibility of the need for ICSI with my/our physician and understand, agree and consent that:

- ❑ ICSI will NOT be used.
- ❑ ICSI will be used on SOME mature eggs.
- ❑ ICSI will be used on ALL mature eggs.
- ❑ ICSI will NOT be used, UNLESS the semen at time of egg retrieval is sub-optimal based on the best medical judgment of Stanford staff. In these cases ICSI may be used. I/we understand that I/we will be notified if ICSI is performed.

Patient Initials _____ Partner Initials _____

C. **Assisted Hatching**. I/we have discussed the option of assisted hatching with my/our physician and understand, agree and consent that:

- ❑ Assisted hatching will NOT be performed.
- ❑ Assisted hatching of embryo(s) selected for transfer will be performed.
- ❑ Assisted hatching of embryo(s) selected for transfer will NOT be performed unless, at the time of transfer, assisted hatching is determined to be necessary in the best medical judgment of Stanford staff.
- ❑ Assisted hatching will performed as part of embryo biopsy procedure for pre-implantation in genetic testing.

Patient Initials _____ Partner Initials _____

D. **Preimplantation Genetic Diagnosis and Screening (PGD/PGS)**. I/we have discussed the use of preimplantation genetic testing with my/our physician and understand, agree and consent to:

- ❑ Chromosomal Screening will NOT be performed.
- ❑ Chromosomal Screening of all blastocysts, regardless of number
- ❑ Chromosomal Screening of all blastocysts if ≥_____ are available for testing (in consultation with embryology lab staff)

- ❑ Single Gene Testing will NOT be performed.
- ❑ Single Gene Testing for _____

Patient Initials _____ Partner Initials _____

E. **Excess Embryos:** I/we make the following decision with respect to excess embryos remaining following my/our treatment:

❑ I/we consent to have the excess embryos frozen. (*Must complete Informed Consent to Embryo Freezing and Frozen Embryo Disposition*)

Patient Initials _____ Partner Initials _____

❑ I/we do not wish to freeze excess embryos. I/we desire the following disposition of any excess embryos:

❑ **Donate to research.** Donated embryos and oocytes may be used by researchers interested in the study of human reproduction or development or human embryonic stem cell research. By initialing this choice, you may be contacted by a Stanford University research coordinator who will provide additional information and/or a separate research consent form.

Patient Initials _____ Partner Initials _____

AND/OR

❑ **Donate to quality improvement techniques.** Donated embryos and oocytes may be used in ongoing efforts to develop and improve IVF techniques, train staff and conduct quality control.

_____ Patient Initials _____ Partner Initials

❑ **Donate to another person or couple.**

_____ Patient Initials _____ Partner Initials

OR

❑ **Discard.** The excess embryos or oocytes will be discarded in accordance with current institutional and department policies. The excess embryos or oocytes will no longer be available for attempting pregnancy.

_____ Patient Initials _____ Partner Initials

F. **Clinically Unsuitable or Non-Selected Materials:** I/we agree to the following disposition of my/our oocytes and embryos that are unsuitable for clinical use or otherwise not selected or cryopreserved:

❑ **Donate to research:** Oocytes and embryos that are unsuitable for clinical use or otherwise not selected or cryopreserved may be donated to research. Donated materials may be used by researchers interested in the study of human reproduction or development or human embryonic stem cell research. By initialing this choice, you may be contacted by our research coordinator who will provide additional information and a separate research consent form.

AND

❑ **Donate to quality improvement techniques:** Donated materials may be used in ongoing efforts to develop and improve IVF techniques, train staff and conduct quality control.

OR

❑ **Discard:** Oocytes and embryos that are unsuitable for clinical use or otherwise not selected or cryopreserved will be discarded in accordance with current institutional and department policies.

G. I/we understand this Informed Consent for In Vitro Fertilization, including the procedures and disposition instructions set forth above, will remain in effect until one of the following events occurs: (i) one (1) calendar year has passed from the date of signature, (ii) death of patient or patient's partner, (iii) dissolution of the patient's marriage or partnership, (iv) patient's successful pregnancy which results in a live birth, or (v) written notice to Stanford of withdrawal of consent by the patient and/or the patient's partner, if applicable. I/we acknowledge and agree that in the event of the dissolution of the patient's marriage or partnership or a live birth, Stanford will require the patient and the patient's partner to execute a new consent form prior to the performance of any additional procedures.

H. I/we understand that this original consent form will be maintained in my medical record and a copy will be provided to me/us. I/we understand that this consent is an important document and should be retained with other vital records.

X _____ _____ _____
Patient Signature Date Time

_____ _____
Patient Name Date of Birth

X _____ _____ _____
Partner Signature Date Time

_____ _____
Partner Name Date of Birth

Informed Consent Attestation:

I have discussed the IVF procedures and the disposition instructions, including the risks, benefits, and alternatives with the patient and their partner. I have also explained that with any procedure there is always the possibility of an unexpected complication, and no guarantees or promises can be made concerning the results of any procedure or treatment. All questions were answered and the patient (and their partner, if applicable) consents to the IVF procedures.

X _____ _____
Physician Signature Date

_____ _____
Physician Name Time

X _____ _____
Translator Signature Language

_____ _____
Date of Translation Time

By my/our signature(s) below, I/we confirm that:

1. I/we have read and understood the information related to Frozen Embryo Transfer presented in this In Vitro Fertilization Consent Booklet and the nature and purpose of the procedure(s) have been explained to me/us. The risks and benefits of the procedure(s) have been explained to me/us. I/we understand that Lucile Salter Packard Children's Hospital at Stanford (Stanford) is not obligated to proceed with transfer of the thawed embryos if, in the reasonable professional judgment of Stanford physicians, the medical risks outweigh the potential benefits. I/we have had the opportunity to ask questions and have received all the information I/we desire about the procedure.

2. I/we direct Stanford to proceed with a frozen embryo thaw cycle and transfer.

3. I/we understand this consent will remain in effect until one of the following events occurs: (i) one (1) calendar year has passed from the date of signature, (ii) death of the patient/patient's partner, (iii) dissolution of the patient's marriage or partnership, (iv) patient's successful pregnancy which results in a live birth, or (v) written notice to Lucile Salter Packard Children's Hospital at Stanford of withdrawal of consent by the patient and/or the patient's partners, if applicable. I/we acknowledge and agree that in the event of the dissolution of the patient's marriage or partnership or a live birth, Stanford will require the patient and the patient's partner, if applicable, to execute a new consent form prior to the performance of any additional transfers.

4. I/we understand that this original consent form will be maintained in my medical record and a copy will be provided to me. I understand that this consent is an important document and should be retained with other vital records.

Lucile Salter Packard Children's Hospital

Stanford MEDICINE
Fertility and Reproductive Health

X _____ _____ _____
Patient Signature Date Time

_____ _____
Patient Name Date of Birth

X _____ _____ _____
Spouse / Partner Signature Date Time

_____ _____
Spouse / Partner Name Date of Birth

Informed Consent Attestation:

I have discussed the procedures described in the Frozen Embryo Transfer portion of this In Vitro Fertilization Consent Booklet, including the risks, benefits, and alternatives with the patient and their partner. I have also explained that with any procedure there is always the possibility of an unexpected complication, and no guarantees or promises can be made concerning the results of any procedure or treatment. All questions were answered and the patient (and their partner, if applicable) consents to the procedures described above.

X _____ _____ _____
Physician Signature Date Time

_____
Physician Name

X _____ _____
Translator Signature Language

_____ _____
Date of Translation Time

A. **Introduction**. Lucile Salter Packard Children's Hospital at Stanford (Stanford) desires to provide you with relevant and appropriate information so that you may make an informed and voluntary choice regarding the disposition of any embryos remaining following your treatment. Frequently, the IVF process produces more embryos than the participants in that process with to have transferred as part of their IVF cycle. The freezing process, as outlined in the Embryo Cryopreservation section of this In Vitro Fertilization Consent Booklet, describes the freezing process. Because of the possibility of you and/or your partner's separation, divorce, death or incapacitation after embryos have been produced, it is important to decide on the disposition of any embryos that remain in the laboratory in these situations. Since this is a rapidly evolved field, both medically and legally, Stanford cannot guarantee what the available or acceptable avenues for disposition will be at any future date.

B. **Embryo Freezing.** By my/our signature(s) below, I/we confirm that I/we have read and understood the information related to Embryo Freezing presented in this In Vitro Fertilization Consent Booklet. Stanford maintains frozen embryos (i) for transfer into the patient until the patient reaches the age of 55 or (ii) for transfer into a gestational surrogate until the patient reaches the age of 59.

C. **Financial Terms.** I/we understand that I/we will be billed an annual storage fee for cryopreservation of embryos following the initial twelve (12) months of storage. If continued storage is desired, I/we are responsible for timely payment of the storage fee which shall be billed in advance of each subsequent twelve (12) month period. Payment is due within thirty (30) days of billing.

D. **Change of Address.** I/we understand that it is my/our responsibility to notify Stanford promptly in writing of any change of address or telephone number.

E. **Abandoned Embryos.** I/we understand that my/our embryos will be considered to be abandoned if I/we have not paid in accordance with the Financial Terms above and, despite diligent efforts including certified mail, Stanford is unable to contact me at my last known address. If I/we do not respond within one (1) year of the certified letter, Stanford reserves the right to discontinue storage and follow the disposition instructions and discard in accordance with normal laboratory procedures and applicable law.

F. **Important Notes Regarding Embryo Disposition**.

- Embryos cannot be used to produce pregnancy against the wishes of the partner. For example, in the event of a separation or divorce, embryos cannot be used to create a pregnancy without the express, written consent of both parties, even if donor gametes were used to create the embryos.
- Disposition of embryos that are created using donated sperm or eggs may be subject to prior enforceable agreements that you have entered into with a sperm, egg or embryo donor.
- Embryo donation to achieve a pregnancy is regulated by the FDA (U.S. Food and Drug Administration), as well as state laws, as donated tissue. Certain screening and testing of the persons providing the sperm and eggs are required before donation can occur.
- You are free to revise the choices you indicate here at any time by completing another form in person at Stanford or remotely, provided it is notarized.
- Your wills should also include your wishes on disposition of the embryos and be consistent with this consent form. Any discrepancies will need to be resolved by court order.

G. **Embryos Donated for Research**. If you are considering donating any unused embryos for research, you should know the following:

- Early human embryos may be used to derive human pluripotent stem cells for research. The cells may be used, at some future time, for human transplantation research.
- All identifiers associated with the embryos will be removed prior to the derivation of human pluripotent stem cells.
- You will not receive any information about subsequent testing on the embryo or the derived human pluripotent cells.
- Derived cells or cell lines, with all identifiers removed, may be kept for many years.
- The donated material may have commercial potential, and you will not receive financial or any other benefits from any future commercial development.
- Human pluripotent stem cell research is not intended to provide direct medical benefit to you.
- Early human embryos donated will not be transferred to a woman's uterus, will not survive the human pluripotent stem cell derivation process, and will be handled respectfully, as is appropriate for all human tissue used in research.
- If the donated embryos were formed with gametes (eggs or sperm) from someone other than the patient and her spouse or partner (those who sign this document), the gamete donor(s) may be required to provide a signed, written consent for use of the resulting embryos for research purposes.

H. **Legal Considerations**. The law regarding embryo cryopreservation, subsequent thaw and use, and parent-child status of any resulting child(ren) is, or may be, unsettled in California or the state in which either the patient, spouse, partner, or any donor currently or in the future lives. I/We acknowledge that Stanford has not given us legal advice, that we are not relying on Stanford to give us any legal advice, and that we have been informed that we may wish to consult a lawyer who is experienced in the areas of reproductive law and embryo cryopreservation and disposition if we have any questions or concerns about the present or future status of our embryos, our individual or joint access to them, our individual or joint parental status as to any resulting child, or about any other aspect of this consent and agreement.

DISPOSITION DIRECTIVES

A. Death of Patient or Partner

In the event the patient or her partner dies prior to use of all the embryos, the patient and partner desire the embryos to be (*check only one box*):

- ❑ Made available to the living patient or partner, providing complete control for any purpose, including reproductive use, donation for research or to another couple, or destruction. This may entail maintaining the embryos in storage, and the fees and other payments due the clinic for these cryopreservation services. _____ Patient Initials _____ Patient Initials
- ❑ Donation for quality improvement and /or research purposes. _____ Patient Initials _____ Patient Initials
- ❑ Discard _____ Patient Initials _____ Patient Initials
- ❑ Donation to another couple or individual for reproductive purposes. This may entail maintaining the embryos in storage, and the fees and other payments due to Stanford for these cryopreservation services. _____ Patient Initials _____ Patient Initials
- ❑ Other disposition (*Describe*) _____ _____ Patient Initials _____ Patient Initials

_____

_____

B. Death of Both Patient and Partner or Patient Without Partner

In the event of death of both the patient and her partner or the death of a patient without a partner, prior to use of all the embryos, the embryos should be disposed of in the following manner (*check one box only*):

- ❑ Donation for quality improvement and /or research purposes. _____ Patient Initials _____ Patient Initials
- ❑ Discard _____ Patient Initials _____ Patient Initials
- ❑ Donation to another couple or individual for reproductive purposes. This may entail maintaining the embryos in storage, and the fees and other payments due to Stanford for these cryopreservation services. _____ Patient Initials _____ Patient Initials
- ❑ Other disposition (*Describe*) _____ _____ Patient Initials _____ Patient Initials

_____

_____

C. Separation or Divorce of the Partners

In the event of separation, dissolution or divorce of the patient and her partner the embryos should be disposed of in the following manner (*check one box only*):

- ❑ Donation for quality improvement and /or research purposes. _____ Patient Initials _____ Patient Initials
- ❑ Discard _____ Patient Initials _____ Patient Initials
- ❑ Made available to the female partner.** _____ Patient Initials _____ Patient Initials
- ❑ Made available to the male partner.** _____ Patient Initials _____ Patient Initials
- ❑ Donation to another couple or individual for reproductive purposes. This may entail maintaining the embryos in storage, and the fees and other payments due to Stanford for these cryopreservation services. _____ Patient Initials _____ Patient Initials
- ❑ Other disposition (*Describe*) _____ _____ Patient Initials _____ Patient Initials

_____

_____

*** Note: Additional consent of both patient and partner will be required; legal consultation is recommended.*

D. Nonpayment of Cryopreservation Storage Fees

Maintaining embryo(s) in a frozen state is labor intensive and expensive. Patients/partners who have frozen embryo(s) are responsible for timely payment of annual storage fees. Payment is due within thirty (30) days of billing. In the event of non-payment, Stanford will try to contact patient and partner at the last known address(es) by certified mail. If the patient and partner do not respond within one (1) year of the certified letter, Stanford reserves the right to discontinue storage and follow the disposition instructions elected below without further communications to or from patient and partner (*check one box only*):

- ❑ Donation for quality improvement. _____ Patient Initials _____ Patient Initials
- ❑ Discard _____ Patient Initials _____ Patient Initials
- ❑ Donation to another couple or individual for reproductive purposes. This may entail maintaining the embryos in storage, and the fees and other payments due to Stanford for these cryopreservation services. _____ Patient Initials _____ Patient Initials
- ❑ Other disposition (*Describe*) _____ _____ Patient Initials _____ Patient Initials

_____

_____

*** Note: Additional consent of both patient and partner will be required; legal consultation is recommended.*

***Special note for embryos created with gamete donors:** If your embryos were formed using gametes (eggs or sperm) from a known third-party donor, your instruction to donate these embryos to another couple or individual must be consistent with and in accordance with any and all prior agreements made with the gamete donor(s). If anonymous donor gametes were used, written authorization from the gamete donor must have been obtained to use these gametes for anything other than reproduction or destruction of the embryos.

By our signatures below, I/we authorize and consent to the cryopreservation of embryos and certify the disposition selections I/we have made above. We understand that we can change our selections in the future, but need mutual and written agreement as outlined above. We also understand that in the event that none of our elected choices is available, Lucile Salter Packard Children's Hospital at Stanford is authorized, without further notice from us, to thaw and discard our frozen embryos.

X_____ Patient Signature

_____ Date

_____ Time

X_____ Patient Name

_____ Date of Birth

X_____ Partner Signature

_____ Date

_____ Time

X_____ Partner Name

_____ Date of Birth

Informed Consent Attestation:

I have discussed the procedures described in the Frozen Embryo Transfer portion of this In Vitro Fertilization Consent Booklet, including the risks, benefits, and alternatives with the patient and their partner. I have also explained that with any procedure there is always the possibility of an unexpected complication, and no guarantees or promises can be made concerning the results of any procedure or treatment. All questions were answered and the patient (and their partner, if applicable) consents to the procedures described above.

X_____ Physician Signature

_____ Date

X_____ Physician Name

_____ Time

X_____ Translator Signature

_____ Language

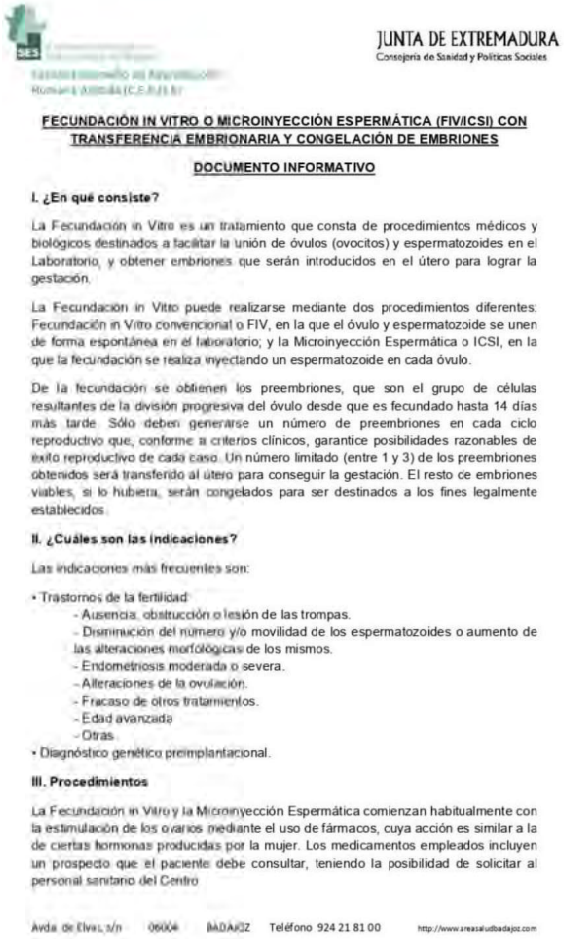
X_____ Translator Name

_____ Date

_____ Time

12. Annex 2: Informed consents from Spain

12. 1. Centro Extremeño de Reproducción Humana Asistida (CERHA)



JUNTA DE EXTREMADURA
Consejería de Sanidad y Políticas Sociales

FECUNDACIÓN IN VITRO O MICROINYECCIÓN ESPERMÁTICA (FIV/ICSI) CON TRANSFERENCIA EMBRIONARIA Y CONGELACIÓN DE EMBRIONES

DOCUMENTO INFORMATIVO

I. ¿En qué consiste?

La Fecundación in Vitro es un tratamiento que consta de procedimientos médicos y biológicos destinados a facilitar la unión de óvulos (ovocitos) y espermatozoides en el Laboratorio, y obtener embriones que serán introducidos en el útero para lograr la gestación.

La Fecundación in Vitro puede realizarse mediante dos procedimientos diferentes: Fecundación in Vitro convencional o FIV, en la que el óvulo y espermatozoide se unen de forma espontánea en el laboratorio; y la Microinyección Espermática o ICSI, en la que la fecundación se realiza inyectando un espermatozoide en cada óvulo.

De la fecundación se obtienen los preembriones, que son el grupo de células resultantes de la división progresiva del óvulo desde que es fecundado hasta 14 días más tarde. Sólo deben generarse un número de preembriones en cada ciclo reproductivo que, conforme a criterios clínicos, garantice posibilidades razonables de éxito reproductivo de cada caso. Un número limitado (entre 1 y 3) de los preembriones obtenidos será transferido al útero para conseguir la gestación. El resto de embriones viables, si lo hubiera, serán congelados para ser destinados a los fines legalmente establecidos.

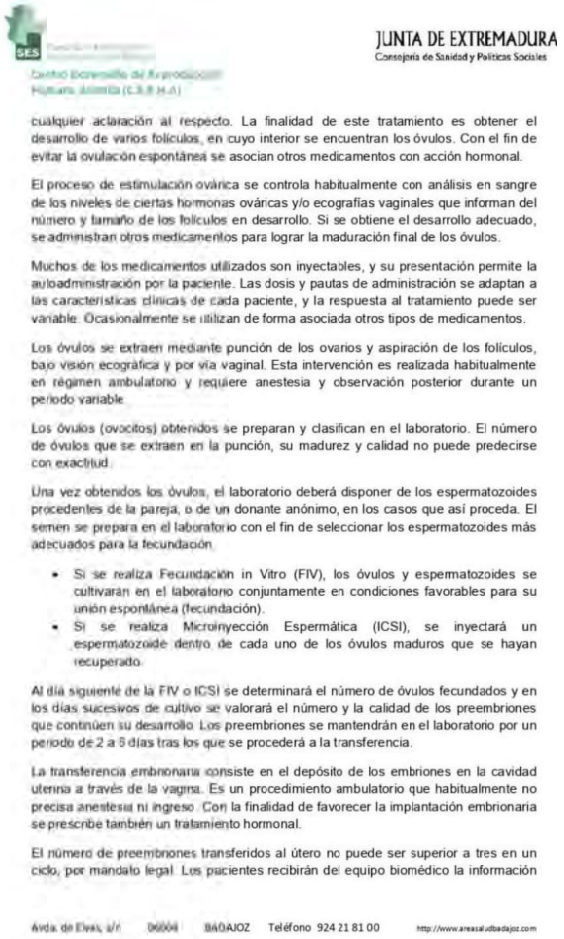
II. ¿Cuáles son las indicaciones?

Las indicaciones más frecuentes son:

- Trastornos de la fertilidad:
  - Ausencia, obstrucción o lesión de las trompas.
  - Disminución del número y/o movilidad de los espermatozoides o aumento de las alteraciones morfológicas de los mismos.
  - Endometriosis moderada o severa.
  - Alteraciones de la ovulación.
  - Fracaso de otros tratamientos.
  - Edad avanzada
  - Otras.
- Diagnóstico genético preimplantacional.

III. Procedimientos

La Fecundación in Vitro y la Microinyección Espermática comienzan habitualmente con la estimulación de los ovarios mediante el uso de fármacos, cuya acción es similar a la de ciertas hormonas producidas por la mujer. Los medicamentos empleados incluyen un prospecto que el paciente debe consultar, teniendo la posibilidad de solicitar al personal sanitario del Centro



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Consejería de Sanidad y Políticas Sociales

cualquier aclaración al respecto. La finalidad de este tratamiento es obtener el desarrollo de varios folículos, en cuyo interior se encuentran los óvulos. Con el fin de evitar la ovulación espontánea se asocian otros medicamentos con acción hormonal.

El proceso de estimulación ovárica se controla habitualmente con análisis en sangre de los niveles de ciertas hormonas ováricas y/o ecografías vaginales que informan del número y tamaño de los folículos en desarrollo. Si se obtiene el desarrollo adecuado, se administran otros medicamentos para lograr la maduración final de los óvulos.

Muchos de los medicamentos utilizados son inyectables, y su presentación permite la autoadministración por la paciente. Las dosis y pautas de administración se adaptan a las características clínicas de cada paciente, y la respuesta al tratamiento puede ser variable. Ocasionalmente se utilizan de forma asociada otros tipos de medicamentos.

Los óvulos se extraen mediante punción de los ovarios y aspiración de los folículos, bajo visión ecográfica y por vía vaginal. Esta intervención es realizada habitualmente en régimen ambulatorio y requiere anestesia y observación posterior durante un período variable.

Los óvulos (ovocitos) obtenidos se preparan y clasifican en el laboratorio. El número de óvulos que se extraen en la punción, su madurez y calidad no puede predecirse con exactitud.

Una vez obtenidos los óvulos, el laboratorio deberá disponer de los espermatozoides procedentes de la pareja, o de un donante anónimo, en los casos que así proceda. El semen se prepara en el laboratorio con el fin de seleccionar los espermatozoides más adecuados para la fecundación.

- Si se realiza Fecundación in Vitro (FIV), los óvulos y espermatozoides se cultivarán en el laboratorio conjuntamente en condiciones favorables para su unión espontánea (fecundación).
- Si se realiza Microinyección Espermática (ICSI), se inyectará un espermatozoide dentro de cada uno de los óvulos maduros que se hayan recuperado.

Al día siguiente de la FIV o ICSI se determinará el número de óvulos fecundados y en los días sucesivos de cultivo se valorará el número y la calidad de los preembriones que continúen su desarrollo. Los preembriones se mantendrán en el laboratorio por un periodo de 2 a 5 días tras los que se procederá a la transferencia.

La transferencia embrionaria consiste en el depósito de los embriones en la cavidad uterina a través de la vagina. Es un procedimiento ambulatorio que habitualmente no precisa anestesia ni ingreso. Con la finalidad de favorecer la implantación embrionaria se prescribe también un tratamiento hormonal.

El número de preembriones transferidos al útero no puede ser superior a tres en un ciclo, por mandato legal. Los pacientes recibirán del equipo biomédico la información

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necesaria para decidir el número de embriones que se deben transferir, con el fin de obtener el embarazo y evitar en lo posible la gestación múltiple.

Finalmente, en caso de existir preembriones viables sobrantes de un ciclo de Fecundación in Vitro se preservarán mediante congelación. Los posibles destinos de los preembriones criopreservados se detallan en el apartado de información legal de este documento informativo (apartado VIII). En algunos casos, las técnicas habituales de FIV e ICSI pueden complementarse con otros procedimientos sobre los gametos o embriones destinados a mejorar la capacidad de implantación embrionaria (eclosión asistida, extracción de fragmentos, etc.).

IV. Resultados

Los factores que condicionan la probabilidad de gestación son: la causa de la esterilidad, la edad de la paciente, el número de ovocitos obtenidos y de embriones finales de buena calidad.

Sin embargo, hay que tener presente que no todas las pacientes que inician el tratamiento logran el desarrollo folicular adecuado para ser sometidas a la punción, y ni todas las pacientes con punción ovárica tienen transferencia de embriones, ya que en algunos casos fracasa la obtención de óvulos, la fecundación o el desarrollo embrionario precoz. Por ello, el resultado del tratamiento se puede expresar como porcentaje de gestaciones sobre el total de ciclos iniciados, sobre ciclos con punción folicular y sobre ciclos con transferencia.

El Registro FIV/ICSI de la Sociedad Española de Fertilidad del año 2005 refería unas tasas de embarazo del 30.1% por ciclo iniciado, 33.9% por punción y 38.1% por transferencia.

El 80% de las gestaciones se obtienen en los tres primeros ciclos de FIV/ICSI con transferencia embrionaria satisfactoria, por lo que el fracaso hace necesario discutir con el equipo asistencial la conveniencia de emprender más tratamientos. Entre un 40% y 60% de las pacientes obtienen embriones aptos para preservar mediante congelación, teniendo en cuenta que solo serán congelados aquellos con características biológicas de viabilidad.

De estos embriones congelados, un 50-70% sobreviven tras la descongelación y son válidos para su transferencia a la cavidad uterina. La tasa de embarazo por transferencia de embriones congelados en el Registro FIV/ICSI de la Sociedad Española de Fertilidad del año 2005 es el 21.1 % por descongelación y 25.7% por transferencia.

V. Riesgos

Los principales riesgos de este procedimiento terapéutico son:

1) Embarazo múltiple: El riesgo de embarazo múltiple está relacionado con la edad de la mujer, el número de embriones transferidos al útero y la calidad de los mismos. En

JUNTA DE EXTREMADURA
Consejería de Sanidad y Políticas Sociales
Centro Extremeño de Reproducción Humana Asistida (C.E.R.H.A)

pacientes jóvenes y con embriones de buena calidad, la conducta más recomendable es transferir uno o dos embriones en los primeros intentos. La transferencia de tres embriones se suele indicar en pacientes de edad avanzada sin embriones de buena calidad, o ante fracaso de transferencias previas de menor número de embriones. En el Registro de la Sociedad Española de Fertilidad de 2005 la tasa de embarazos múltiples es del 26.1% con embriones frescos y 18.2% con congelados. La gestación de dos o más fetos supone un aumento de los riesgos médicos para la madre y los niños, tales como incremento de la patología del embarazo, prematuridad, bajo peso al nacimiento y complicaciones neonatales severas. La gravedad de esta complicación se incrementa de manera paralela al número de fetos. La gestación múltiple se acompaña igualmente de un aumento de las dificultades sociales, económicas y laborales de los padres.

2) Síndrome de hiperestimulación ovárica: En ocasiones, la respuesta ovárica al tratamiento es excesiva, se desarrolla un gran número de folículos, aumenta el tamaño ovárico y se eleva considerablemente la cantidad de estradiol en sangre. Además, el desarrollo de este síndrome tiene relación directa con la administración del fármaco necesario para la maduración final de los ovocitos (HCG) y la consecución de embarazo. Se clasifica en leve, moderada y severa, siendo esta última excepcional (menos de un 2 %) y se caracteriza por acumulación de líquido en el abdomen e incluso en el tórax, así como por alteraciones de la función renal y/o hepática. En casos críticos se puede asociar a insuficiencia respiratoria o alteraciones de la coagulación. Puede precisar hospitalización y tratamiento médico-quirúrgico y sólo excepcionalmente se hace aconsejable la interrupción del embarazo.

3) Embarazo ectópico. Consiste en la implantación del embrión fuera del útero, habitualmente en las trompas. Excepcionalmente puede coexistir con un embarazo situado en el útero. Se produce en un 3 % de los casos.

4) Aborto: La incidencia de abortos es discretamente superior a la observada en embarazos espontáneos (15.5% con embriones frescos y 30.1% con congelados en el Registro SEF de 2005).

5) Edad avanzada, el consumo de tabaco y las alteraciones importantes del peso corporal aumentan el riesgo de complicaciones durante el tratamiento, embarazo y para la descendencia, requieren adaptaciones en el tratamiento necesario para la estimulación ovárica y reducen las tasas de éxito.

6) Defectos congénitos y alteraciones cromosómicas de los hijos: los datos actuales sugieren que en los niños nacidos de FIV/ICSI puede incrementarse ligeramente el riesgo de anomalías congénitas y cromosómicas, sin que se haya podido establecer con exactitud la causa de este aumento. Por ello puede ser aconsejable realizar técnicas de diagnóstico prenatal como ecografías, amniocentesis o biopsia de corion.

7) Riesgos psicológicos. Pueden aparecer trastornos psicológicos como síntomas de ansiedad y síntomas depresivos, tanto en el hombre como en la mujer. En algunos casos, pueden surgir dificultades en la relación de pareja (sexual y emocional) y

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niveles elevados de ansiedad en el periodo de espera entre la aplicación de la técnica y la confirmación de la consecución o no del embarazo, así como ante los fallos repetidos de la técnica.

8) Riesgos de la anestesia que se detallan en el consentimiento informado específico.

9) Otros riesgos y complicaciones que excepcionalmente se pueden producir:

a) Reacciones adversa o intolerancia a la medicación.

b) Infección peritoneal.

c) Complicaciones de la punción folicular:

- Hemorragia grave por punción accidental de vasos sanguíneos o del propio ovario.
- Punción de un asa intestinal u otras estructuras.

d) Torsión ovárica.

e) Cancelación de la estimulación ovárica por ausencia o inadecuado desarrollo folicular o por excesiva respuesta a los tratamientos.

f) No obtención de óvulos en la punción.

g) No realización de la transferencia por:

- Óvulos no adecuados para fecundación.
- Ausencia de fecundación.
- No obtención de embriones normales o viables.
- Imposibilidad física de la transferencia por alteraciones anatómicas del útero

VI. Riesgos Personalizados

Las características médicas, sociales o laborales de cada paciente pueden suponer una modificación de los riesgos generales o aparición de riesgos específicos.

VII. Información económica (si procede)

Los precios que rigen en este centro se detallan en presupuesto adjunto, significándose la imposibilidad de concretar previamente de forma exacta el coste total, debido a que los tratamientos varían en cada paciente y, muy especialmente, en función de la respuesta a la estimulación ovárica de cada mujer.

El coste económico del mantenimiento de la congelación embrionaria deberá ser asumido por los pacientes, sea cual sea la decisión sobre el destino de los mismos.

VIII. Aspectos legales relacionados con la reproducción asistida

1.- De carácter general

El marco jurídico regulador de la reproducción humana asistida está constituido básicamente por la Ley 14/2006 sobre Técnicas de Reproducción Humana Asistida.

Las técnicas de reproducción asistida tienen como objetivo principal la solución de los problemas de esterilidad humana, para facilitar la procreación, cuando otras terapéuticas se hayan descartado por inadecuadas o ineficaces.

También pueden utilizarse en la prevención y tratamiento de enfermedades de origen genético o hereditario, cuando sea posible recurrir a ellas con suficientes garantías diagnósticas y terapéuticas y estén estrictamente indicadas.

Sólo pueden llevarse a cabo cuando haya posibilidades razonables de éxito y no supongan riesgo grave para la salud física o psíquica de la mujer o de la posible descendencia; y siempre en mujeres mayores de edad, con plena capacidad de obrar, con independencia de su estado civil y orientación sexual, que deben haber sido anterior y debidamente informadas de sus posibilidades de éxito, así como de sus riesgos y de las condiciones de dicha aplicación.

La mujer receptora de las técnicas podrá pedir que se suspendan en cualquier momento de su realización anterior a la transferencia embrionaria, debiendo atenderse su petición.

Cuando la mujer esté casada, se requerirá además el consentimiento del marido, a menos que estuvieran separados legalmente o de hecho y así conste fehacientemente. Si se trata de una pareja no casada, el consentimiento del varón será obligatorio si se usan sus espermatozoides en el tratamiento y voluntario si recurre al uso de semen de donante. En este último caso, si lo presta con anterioridad a la utilización de las técnicas, dicho consentimiento determinará la filiación paterna de la futura descendencia.

La mujer soltera, la viuda y la separada legalmente o de hecho, pueden ser receptoras o usuarias de las técnicas de reproducción asistida a título personal, valiéndose de semen procedente de donante, siempre que tengan más de 18 años, plena capacidad de obrar y hayan prestado su consentimiento escrito de manera libre, consciente y expresa.

2. Información para el caso de utilización de gametos o embriones procedentes de donante

La donación de gametos y preembriones es un contrato gratuito, formal y confidencial concertado entre el donante y el centro autorizado. Tanto el banco de gametos, como los registros de donantes y de actividad de los centros, tienen obligación de garantizar la confidencialidad de los datos de identidad de los donantes.

Sin perjuicio de ello, las receptoras y los hijos nacidos tienen derecho a obtener información general de los donantes, que no incluya su identidad. Asimismo, en circunstancias extraordinarias que comporten peligro cierto para la vida o la salud del

nacido, o cuando proceda de acuerdo con las leyes procesales penales, podrá revelarse la identidad de los donantes, con carácter restringido y sin que ello modifique nunca la filiación establecida previamente.

La elección de los donantes sólo puede realizarse por el equipo médico que aplica la técnica, y en ningún caso a petición de la receptora o la pareja. No obstante lo anterior, en todo caso el equipo médico deberá procurar la mayor similitud fenotípica e inmunológica posible con la mujer receptora.

Los donantes de los que procede el material genético han de tener más de 18 años, buen estado de salud psicofísica y plena capacidad de obrar. Su estado psicofísico debe cumplir las exigencias de un protocolo obligatorio de estudio de los donantes, que incluya sus características fenotípicas y psicológicas, así como las condiciones clínicas y determinaciones analíticas necesarias para demostrar que no padecen enfermedades genéticas, hereditarias o infecciosas transmisibles a la descendencia. A tal efecto se seguirá lo dispuesto en el R.D. 1301/2006.

Ni la mujer progenitora ni el marido, cuando hayan prestado su consentimiento formal, previo y expreso a determinada fecundación con contribución de donante o donantes, podrán impugnar la filiación matrimonial del hijo nacido como consecuencia de tal fecundación. De igual forma ocurrirá en estos casos con el varón no casado que hubiera firmado el consentimiento informado con anterioridad a la utilización de las técnicas.

3.- Sobre el destino de los embriones sobrantes criopreservados

Los preembriones viables sobrantes de un ciclo de fecundación in Vitro se criopreservarán en nitrógeno líquido, pues no todos los embriones no transferidos son aptos para la congelación. El destino posterior de los preembriones congelados puede ser:

a) La utilización por la propia mujer o, en su caso, su cónyuge femenino.
b) La donación con fines reproductivos.
c) La donación con fines de investigación.
d) El cese de su conservación sin otra utilización.

La utilización por la propia mujer o su cónyuge podrá efectuarse en cualquier momento mientras la mujer reúna los requisitos clínicamente adecuados para la realización de la técnica de reproducción asistida (lo que constituye el plazo máximo de conservación). En caso de pareja separada, si la mujer deseara utilizarlos para su reproducción personal habría de contar con el consentimiento del exmarido para la nueva transferencia que hubiera de realizarse, ya que los hijos serían de ambos.

En la donación con fines reproductivos los embriones son donados a parejas estériles que los necesitan. La donación es voluntaria, gratuita, anónima y altruista y precisa de un consentimiento escrito específico previo. Las receptoras y los hijos nacidos tienen

JUNTA DE EXTREMADURA
Consejería de Sanidad y Políticas Sociales
Centro Extremeño de Reproducción Humana Asistida (C.E.R.H.A)

derecho a obtener información general de los donantes, que no incluya su identidad. En circunstancias extraordinarias que comporten peligro cierto para la vida o la salud del nacido, o cuando proceda de acuerdo con las leyes procesales penales, podrá revelarse la identidad de los donantes, con carácter restringido y sin que ello modifique nunca la filiación establecida previamente.

En la donación con fines de investigación los embriones se ceden de forma altruista para proyectos de investigación biomédica en centros especialmente autorizados y con proyectos concretos también autorizados. El ejercicio efectivo de esta opción conllevará la suscripción de un consentimiento adicional y específico en el que se expliquen los fines que se persigan con la investigación y sus implicaciones.

El cese de su conservación sin otra utilización, que en el caso de los preembriones y los ovocitos crioconservados sólo será aplicable una vez finalizado el plazo máximo de conservación establecido en la Ley sin que se haya optado por alguno de los destinos mencionados en los apartados anteriores. La crioconservación de los ovocitos, del tejido ovárico y de los preembriones sobrantes se podrá prolongar hasta el momento en que se considere por los responsables médicos, con el dictamen favorable de especialistas independientes y ajenos al centro correspondiente, que la receptora no reúne los requisitos clínicamente adecuados para la práctica de la técnica de reproducción asistida.

4.- Obligación de renovación del consentimiento respecto de los embriones criopreservados

Cada dos años como mínimo se solicitará de la mujer o de la pareja progenitora la renovación o modificación del consentimiento. Si al vencimiento de dos periodos de conservación consecutivos fuera imposible obtener de la mujer o la pareja progenitora la renovación del consentimiento correspondiente, habiendo sido previamente requerida por el centro de forma fehaciente (burofax con acuse de recibo, carta certificada con acuse de recibo, telegrama con acuse de recibo, carta notarial, etc.), los preembriones quedarán a disposición de este centro, que podrá destinarlos a cualquiera de los fines citados en el apartado 3, manteniendo las exigencias de confidencialidad y anonimato establecidas, así como la gratuidad y ausencia de ánimo de lucro.

5.- En relación con la posibilidad de tener un hijo póstumo

En caso de fallecimiento del varón, sólo podrá determinarse legalmente la filiación si el material reproductor de éste se encontrase en el útero de la mujer en la fecha de la muerte, excepto si el marido o el varón no unido por matrimonio hubiesen prestado su consentimiento en el documento de consentimiento informado de las técnicas, en escritura pública, testamento o documento de instrucciones previas, para que su material reproductor pueda ser utilizado en los doce meses siguientes a su fallecimiento para fecundar a su mujer. Este consentimiento podrá ser revocado en cualquier momento con anterioridad a la realización de las técnicas.

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Asimismo, previene la ley de reproducción que se entenderá otorgado el consentimiento del varón fallecido a la fecundación post mortem de su mujer (tanto si es pareja casada o no), cuando ésta hubiera estado sometida a un proceso de reproducción asistida ya iniciado para la transferencia de preembriones constituidos con anterioridad a la fecha de fallecimiento del marido. Desde el punto de vista médico, se considera iniciado el tratamiento cuando la paciente recibe la primera dosis de la medicación necesaria para el procedimiento.

IX. Alternativas ante el fracaso de la técnica

Si después de haber realizado uno o varios intentos de fecundación in vitro o microinyección espermática no se ha conseguido el embarazo, puede ser aconsejable adoptar, tras la oportuna reflexión, alguna de las siguientes alternativas:

- Volver a iniciar el tratamiento.
- Profundizar en estudios complementarios.
- Aplicar modificaciones a la técnica utilizada.
- Realizar un diagnóstico genético preimplantacional (DGP).
- Realizar nuevos tratamientos con gametos donados (óvulos y/o espermatozoides).
- Utilizar embriones donados.
- Desistir de los tratamientos de reproducción asistida. El contenido del presente documento refleja el estado actual del conocimiento y, por tanto, es susceptible de modificación en caso de que así lo aconsejen nuevos hallazgos o avances científicos.

En _____ a _____ de _____ de _____

Fdo. El/La Médico/a (Col. nº _____) Fdo. Dª. Fdo. D

JUNTA DE EXTREMADURA
Consejería de Sanidad y Políticas Sociales
Centro Extremeño de Reproducción Humana Asistida (C.E.R.H.A)

FECUNDACIÓN IN VITRO O MICROINYECCIÓN ESPERMÁTICA (FIV/ICSI), CON TRANSFERENCIA Y CONGELACIÓN EMBRIONARIA

DOCUMENTO DE CONSENTIMIENTO

Dña. _____

mayor de edad, con DNI/Pasaporte nº _____, estado civil _____ y D/Dña. _____

mayor de edad, con DNI/Pasaporte nº _____, estado civil _____ y con domicilio en _____, calle _____ nº _____ C.P._____ País_____, concurriendo como (matrimonio/pareja de hecho/ mujer sin pareja) _____

DECLARO/DECLARAMOS:

1. Tener plena capacidad de obrar.

2. En este acto, de manera libre, consciente y expresa, presto/prestamos nuestro consentimiento escrito a la utilización de técnicas de reproducción asistida (marque con una X lo que proceda):

- o Con semen de la PAREJA.
- o Con semen de DONANTE.

3. Haber recibido, anteriormente a este acto, información verbal y escrita, esta última a través del "***Documento Informativo sobre Fecundación In Vitro o Microinyección Espermática (FIV/ICSI), con Transferencia Embrionaria y Congelación de Preembriones***", el cual ha sido leído, comprendido y firmado. En consecuencia, he/hemos recibido información sobre las siguientes cuestiones:

- Información y asesoramiento sobre las técnicas de reproducción asistida en sus aspectos biológicos, jurídicos y éticos.
- En caso de utilizar semen de donante, la relevancia jurídica que tiene la firma de este consentimiento informado por el matrimonio o pareja no casada en orden a la determinación de la filiación paterna respecto de la descendencia que se consiga, que será considerada legalmente como propia a todos los efectos.

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- La indicación, procedimiento, probabilidades de éxito, riesgos, contraindicaciones y complicaciones del tratamiento propuesto y de la medicación empleada.
- La disposición del personal sanitario para ampliar cualquier aspecto de la información que no haya quedado suficientemente aclarado.
- Los destinos de los posibles preembriones viables que quedarán criopreservados en el banco del centro por no haber sido transferidos al útero.
- Los posibles riesgos que se pueden derivar de la maternidad a una edad clínicamente inadecuada, tanto para la mujer durante el tratamiento y el embarazo, como para la descendencia.
- Los riesgos genéticos, ya que la utilización de gametos procedentes de donante no permite asegurar que no se produzcan mutaciones o alteraciones genéticas (surgidas de nuevo o hereditarias) que conlleven la transmisión de enfermedades a la descendencia.
- La obligación de renovar o modificar periódicamente (cada dos años) el consentimiento respecto de los embriones criopreservados, así como de comunicar al centro cualquier cambio de domicilio o circunstancia personal que pueda afectar a su destino (separación, fallecimiento o incapacidad sobrevenida de uno de los cónyuges, etc.)
- Información relativa a las condiciones económicas del tratamiento (sólo en caso de precisar semen de donante.

4. Que, según el equipo médico, para éste proyecto reproductivo, es adecuado un tratamiento de reproducción asistida a través de la técnica denominada: FIV/ICSI y dentro de las alternativas de tratamiento expuestas es la que aquí consentimos.

5. Conocer que, en cualquier momento anterior a la transferencia embrionaria, se podría pedir que se suspenda la aplicación de las técnicas de reproducción asistida, debiendo ser atendida.

6. El equipo médico, me/nos ha informado también de los siguientes riesgos relacionados con mi/nuestras circunstancias personales.

Además, he/hemos sido informado/s de la conveniencia de consultar el prospecto de los medicamentos prescritos, para conocer con más detalle los posibles riesgos asociados a su utilización, sin perjuicio de poder solicitar también las aclaraciones adicionales al equipo médico.

7. Se autoriza y consiente la transferencia de un máximo de _____ preembriones.

8. Respecto a la posibilidad de generar preembriones que no vayan a ser transferidos al útero (en fresco) y en base al proyecto reproductivo de futuro: (marque lo que proceda)

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Consejería de Sanidad y Políticas Sociales

- Deseo/deseamos **que se generen TODOS los preembriones posibles** como consecuencia de la inseminación o microinyección de todos los ovocitos obtenidos, asumiendo la obligación de congelar los preembriones viables no transferidos.
- Deseo/deseamos que se genere un NÚMERO LIMITADO de preembriones, consecuencia de la inseminación o microinyección de _____ (número) ovocitos, asumiendo la obligación de congelar los preembriones viables no transferidos. El resto de ovocitos serán:
  - ☐ Vitrificados
  - ☐ Desechados
- Deseo/deseamos que NO se genere NINGÚN PREEMBRIÓN que no vaya a ser transferido, por lo que se autoriza la inseminación o microinyección de un máximo de _____ (número) ovocitos. El resto de ovocitos serán:
  - ☐ Vitrificados
  - ☐ Desechados

9. Que el destino que se desea dar a los posibles ovocitos y/o preembriones congelados sobrantes sería (marcar lo que proceda):

- Uso propio, es decir, utilización por la propia pareja, mujer o, en su caso, su cónyuge femenino.
- Donación con fines reproductivos *(si la mujer tiene 35 años o menos)*.
- Donación con fines de investigación *(en base a un proyecto debidamente presentado y autorizado por las autoridades sanitarias competentes, previo informe favorable del órgano competente y consentimiento escrito de la pareja o de la mujer)*.
- Cese de su conservación sin otra utilización al finalizar el plazo máximo de conservación *(cuando la receptora no reúna los requisitos clínicamente adecuados para realizar la técnica de reproducción asistida)*.

Me comprometo/nos comprometemos a acudir a la clínica para formalizar la renovación o cambio de destino del material criopreservado (preembriones).

10. He/Hemos comprendido toda la información facilitada, por parte del Dr./Dra. _____.

11. De igual forma en la consulta médica he/hemos afirmado:

- No padecer enfermedades congénitas, hereditarias o infecciosas transmisibles con riesgo grave para la posible descendencia.
- No haber omitido o falseado ningún dato de tipo médico o legal que pudiera incidir en el tratamiento o sus consecuencias.
- Adquirir el compromiso de notificar al centro los cambios de circunstancias personales (defunción, separación, divorcio...).
- Adquirir el compromiso de notificar al centro los cambios de domicilio en caso de existir preembriones congelados.

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Y una vez debidamente informada/os,

AUTORIZO/AUTORIZAMOS:

A la aplicación de los procedimientos de tratamiento y control necesarios para el tratamiento de FIV/ICSI, transferencia de preembriones y congelación embrionaria si procede.

El contenido del presente documento refleja el estado actual del conocimiento, y por tanto, es susceptible de modificación en caso de que así lo aconsejen nuevos hallazgos o avances científicos.

Según lo establecido en la Ley Orgánica 15/1999, de protección de datos de carácter personal, sus datos de carácter personal y sanitario quedarán registrados en un fichero propiedad del centro _____, pudiendo ser utilizados y cedidos única y exclusivamente a los efectos de la actuación encargada, gozando de los derechos de acceso, rectificación, cancelación y oposición. Todos los datos que se derivan del proceso quedarán reflejados en la correspondiente historia clínica, que será custodiada en las instalaciones de la entidad para garantizar su correcta conservación y recuperación.

NOTA. La clínica hará todo lo posible para mantener el almacenaje de las células/tejidos en condiciones óptimas, pero no se hará responsable de la pérdida de viabilidad de los mismos debido a desastres naturales u otras emergencias que estén fuera del control de la clínica. Debe conocer que sus preembriones podrían ser trasladados a una localización alternativa en caso de una situación de emergencia (inundaciones, disturbios, fuego, situaciones violentas – armas-, amenazas/ataques terroristas, gas u otras explosiones, terremotos, cierre de la Clínica, etc.).

En _____ a _____ de _____ de 20_____

Fdo.....Fdo.....

D.N.I. ..... D.N.I.

Fdo. ..... D.N.I.

(El Director del CENTRO o delegado)

JUNTA DE EXTREMADURA
Consejería de Sanidad y Políticas Sociales
Centro Extremeño de Reproducción Humana Asistida (C.E.R.H.A)

ANEXO para el cónyuge/pareja o para el varón no casado:

D_____, mayor de edad, provisto de DNI nº_____ en este acto presto mi consentimiento para a que en el caso de que falleciera con anterioridad a que mi material reproductor se halle en el útero de Dña_____, pueda ésta, en los 12 meses siguientes a mi fallecimiento, proceder a fecundarse con el mismo, y que se determine la filiación del hijo como nacido conmigo.

En _____ a _____ de _____ de _____

Fdo. D
Firma del Médico

ANEXO para el cónyuge femenino:

Dña_____, mayor de edad, provisto de DNI nº_____ en este acto presto mi consentimiento para a que en el caso de que falleciera con anterioridad a que mi material reproductor se halle en el útero de Dña_____, pueda ésta, en los 12 meses siguientes a mi fallecimiento, proceder a fecundarse con el mismo, y que se determine la filiación del hijo como nacido conmigo.

En _____ a _____ de _____ de _____

Fdo. D/Da. Firma
del Médico

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ANEXO para la REVOCACIÓN del presente consentimiento

D/Dña_____, mayor de edad, provista de DNI/pasaporte nº_____ y domicilio en la calle/plaza _____ _____ de _____, en este acto solicito la SUSPENSIÓN de la aplicación de la técnica de reproducción asistida a la que me estoy sometiendo.

Fdo. D/Dña _____
Firma del Médico:

JUNTA DE EXTREMADURA
Consejería de Sanidad y Políticas Sociales
Centro Extremeño de Reproducción Humana Asistida (C.E.R.H.A)

ANEXO para la VARIACIÓN del destino de los ovocitos y/o preembriones criopreservados

Dña_____, mayor de edad, provista de DNI/pasaporte nº_____ y domicilio en la calle/plaza _____ de _____, D_____, mayor de edad, provisto de DNI/pasaporte nº_____ y domicilio en la calle/plaza _____ de _____, en este acto solicitamos la modificación del destino de nuestros preembriones sobrantes / criopreservados y consentimos en que el nuevo destino sea:

- Utilización por la propia mujer.
- Donación con fines reproductivos (*si la mujer tiene 35 años o menos*).
- Donación con fines de investigación (*en base a un proyecto debidamente presentado y autorizado por las autoridades sanitarias competentes, previo informe favorable del órgano competente y consentimiento escrito de la pareja o de la mujer*).

Me comprometo/nos comprometemos a acudir a la clínica para formalizar la renovación o cambio de destino del material criopreservado (preembriones).

En_____ a ____ de _____ de _____

Fdo. Dña _____ Fdo. D _____

Firma del Médico:
D _____

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12. 2. Hospital Clínico de Valencia (GVA)

HOSPITAL CLÍNICO UNIVERSITARIO DE VALENCIA
UNIDAD DE REPRODUCCIÓN HUMANA ASISTIDA
(nºRegistro de Centros: 9029)

Consellería de Sanidad Universal y Salud Pública

ITINERARIOS Y CONDICIONES ASOCIADAS CON EL USO DE TÉCNICAS DE REPRODUCCIÓN ASISTIDA EN NUESTRO CENTRO

Primera visita

En la primera visita, que se realizará de forma no presencial, se tomarán vuestros datos y se realizará la historia clínica preguntando antecedentes médicos y otras informaciones necesarias para el tratamiento.

Se os aclararán las dudas que os surjan, por lo que es importante haber leído previamente los consentimientos informados y los documentos disponibles en esta página web. Además, se os explicará en detalle el proceso que vamos a seguir.

Es posible que tras esta primera visita no presencial, sea necesario que acudáis al hospital, bien para realizar alguna exploración o bien para alguna gestión administrativa que quedara pendiente.

Es importante llegar a la visita habiéndose leído detenidamente los documentos que se os proporciona.

Estimulación ovárica

La estimulación ovárica es el procedimiento necesario para llevar a cabo casi la totalidad de los tratamiento de reproducción asistida (inseminación artificial, fecundación in vitro, preservación de ovocitos). Pero es importante saber que cada caso requiere unas dosis y unas medicaciones diferentes, pues se trata de tratamientos personalizados para cada mujer.

Ciclo ovárico normal

De forma natural, cada mes los ovarios generan varios folículos susceptibles de ser captados en las técnicas de reproducción. Los **folículos** son estructuras redondeadas llenas de líquido y en cada una de ellas puede madurar un **ovocito**.

En un ciclo ovulatorio normal, solo uno de los folículos es capaz de crecer y alcanzar el tamaño suficiente para permitir la maduración del ovocito y posterior ovulación. Por eso cada mes, de forma natural, tendremos a disposición solo un ovocito. Los demás folículos se pierden, así como los ovocitos que contenían.

¿Qué hacemos durante la estimulación?

Gracias a la medicación que os pautamos, conseguimos que algunos o la mayoría de los folículos que en un ciclo normal se perderían, puedan madurar. Haciendo eso, tendremos a disposición no solo un ovocito sino muchos más.

En el caso de las inseminaciones artificiales, pautamos una medicación que permitirá que sólo uno o dos folículos crezcan hasta fase ovulatoria. En el caso de que se constate que están creciendo más folículos se cancelará el ciclo por el riesgo de embarazo múltiple.

En un ciclo de FIV lo que buscamos es que crezcan todos los folículos que se encuentran disponibles en cada ovario para así extraer el máximo de ovocitos maduros, lo que aumentará las probabilidades de éxito de la técnica.

¿Qúe se hace tras la estimulación en un ciclo de inseminación artificial?

Cuando el folículo (máximo 2) tiene el tamaño esperado, pautamos una medicación para su maduración y posterior ovulación.

Tras 36h se cita a la mujer para trasferir la muestra de semen preparada en el laboratorio al interior del útero.

Este procedimiento se puede realizar tanto en consulta como en el quirófano, según la disponibilidad, pero NO precisa de ningún tipo de anestesia.

¿Cómo se recuperan los ovocitos en un ciclo FIV?

Durante el proceso de estimulación, se harán controles ecográficos para controlar el desarrollo de los folículos. Una vez alcanzan un tamaño adecuado desencadenamos la ovulación con otra medicación.

Tras 36 horas desde la administración de dicha medicación, se realiza una intervención bajo sedación (anestesia general poco profunda que no precisa de intubación ni ventilación) en quirófano. El acceso es por vía vaginal, lo que permite puncionar los folículos y aspirar el líquido folicular, que es donde encontraremos a los ovocitos. Para ello empleamos una sonda ecográfica para acceder a los folículos bajo visión directa.

Los ovocitos recuperados se estudiarán en el laboratorio por el personal especializado. Se seleccionarán de esta forma los ovocitos maduros.

Según la técnica a realizar, los ovocitos se "congelarán" (criopreservación) o se pondrán en medio de cultivo en presencia de espermatozoides para facilitar la fecundación y la génesis de un embrión (el primer estadio de lo que será un bebé en 9 meses aproximadamente). Para dicha fecundación se pueden realizar dos técnicas:

- FIV clásica donde son los espermatozoides los que fecundan el ovocito por ellos mismos. Esto requiere un buen recuento y una buena vitalidad de espermatozoides.
- ICSI o inyección intracitoplasmática, donde el espermatozcide se microinyecta en el interior del ovocito. Esta técnica se prefiere cuando el recuento de espermatozoides o su calidad son bajos.

La elección de una u otra técnica corre a cargo del personal del laboratorio de la unidad, una vez ha estudiado la muestra de semen.

¿Por qué me dicen que tengo muchos folículos y al final tengo pocos embriones?

Los folículos que se visualizan ecográficamente durante las visitas no se traducirán necesariamente en el número de embriones de los que voy a poder disponer.

Como ya se ha comentado, no todos los folículos que vemos van a tener ovocitos maduros en su interior.

Además no todos los ovocitos maduros van a poder fecundar.

Y por último, no todos los embriones van a sobrevivir.

Por eso es importante tener en cuenta que NO vamos a tener tantos embriones disponibles como folículos se visualizan en las ecografías de control de cada ciclo.

¿Cuándo y dónde se transfieren los embriones en un ciclo FIV?

Los embriones crecerán en laboratorio y los que consigan alcanzar los 3-5 días de vida, según cada caso, podrán:

- transferirse al útero en el mismo ciclo. En un número entre 1 y 2 (lo que se consensuará con el equipo médico) y tras 3-5 días según el caso.
- ser "congelados" para utilizarse más adelante.

Al día siguiente de la punción se informará del número de ovocitos que han fecundado. Por lo tanto se sabrá el número de embriones disponibles.

Durante el proceso de crecimiento de los embriones en laboratorio se seguirá informando vía telefónica, con una periodicidad variable dependiendo de cada caso, de la supervivencia de los mismos. De esa forma, los pacientes sabrán cuántos embriones vivos hay y su calidad. Será en este momento en el que se plantee cuántos embriones se van a transferir y el resto se congelarán.

En ciclos posteriores, si sigue habiendo necesidad y acuerdo por parte de los usuarios, y según el número de embriones disponibles, se podrán realizar ciclos con embriones congelados. Se descongelará en cada ciclo entre 1 y 2 embriones para transferirlos.

La transferencia embrionaria se lleva a cabo con control ecográfico y en el quirófano, porque los embriones precisan de unas condiciones especiales. Para esta técnica no se precisa de ningún tipo de anestesia. La paciente llega andando y se va tras la transferencia de los mismos.

¿Si no se transfiere el embrión en el útero en el mismo mes de la estimulación, qué ocurre?

Si decidimos congelar los embriones (bien por causa médica o porque se han conseguido muchos embriones en un ciclo) podremos transferirlos en ciclos posteriores.

Para ello no se precisará repetir la estimulación ovárica. Únicamente tendremos que preparar la capa interna del útero, el endometrio, con hormonas.

Los embriones, así como los ovocitos, pueden seguir congelados durante mucho tiempo sin sufrir alteraciones. Su descongelación sí puede implicar que algunos de ellos no sobrevivan, aunque esto ocurre en un número pequeño.

¿Qué pasa si me quedo embarazada y tengo embriones congelados?

El sistema público de salud solo cubre los procedimientos para obtener un recién nacido vivo por pareja. Por tanto, en el caso de que se dispongan de embriones congelados se enviará de forma periódica un recordatorio de la situación.

Tampoco se contempla la donación de los mismos para otras parejas o mujeres.

Si se deseara tener más embarazos, los interesados tendrían que ponerse en contacto con una clínica privada. El traslado de los embriones, el nuevo ciclo y la transferencia no están financiados por el sistema público.

¿Cuántos ciclos se pueden realizar? ¿qué cubre el sistema público de salud?

El sistema público financia hasta 3 ciclos de FIV/ICSI. Estamos hablando de 3 ciclos de estimulación ovárica, lo que conlleva tres punciones. Hay que tener en cuenta que en cada ciclo se pueden conseguir más embriones de los que se van a transferir, por lo que el número de transferencias dependerá del número de embriones disponibles. En este caso, habrá que hacer la correspondiente preparación endometrial para cada transferencia embrionaria.

Es importante tener presente que aunque el sistema público financia un máximo de 3 ciclos de FIV/ICSI, ese número que puede verse reducido en función del pronóstico, y en particular del resultado del primer tratamiento, según la respuesta y la situación de cada paciente.

Cuando las condiciones permiten intentar inseminaciones artificiales, se pueden realizar un número de 3-4 ciclos de inseminación. Si no se consigue embarazo, o si durante los primeros intentos se viera que no hay una adecuada respuesta, se pasará a realizar FIV/ICSI.

¿Cómo se administra la medicación para la estimulación ovárica?

La mayoría de los medicamentos que se utilizan en reproducción asistida se administran por medio de inyecciones subcutáneas. Se trata de un procedimiento sencillo, que se autoadministra por la usuaria. El lugar más común para ello es la zona abdominal.

Estos fármacos ya van preparados en jeringuillas precargadas o "bolis" (algunos son de un solo uso y se desechan, otros solo precisan ajustar la cantidad a administrar), y en otros casos necesitan de una pequeña preparación previa para su administración. Aunque cada caja lleva una explicación sencilla para que la autoadministración se realice sin problema, el personal de la unidad ayudará cuando ello sea necesario.

¿Si pertenezco a otro departamento puedo realizar algunas visitas en mi centro?

Si perteneces a otro departamento y se te ha derivado a nuestro centro:

- la primera visita será no presencial, por medios telemáticos, habitualmente por teléfono. Es posible, no obstante, que se pueda requerir una visita presencial.

- Las visitas de control se podrán realizar en tu centro.
- La visita antes de la punción, la propia punción, y la transferencia de embriones, se realizarán siempre en nuestro centro.

¿Es necesario que venga mi pareja a todas las visitas?

Aunque la primera visita se realizará de forma no presencial, es importante que se encuentre contigo, tanto para tener en cuenta sus datos e información médica de interés, como para que pueda reflejar sus dudas. Además, vais a recibir mucha información, por lo que es mejor que estéis los dos presentes.

Para los controles ecográficos no es necesario que acuda la pareja. De hecho, en las condiciones actuales de pandemia covid, no se admite al acompañante en nuestro centro. Sin embargo, es IMPRESCINDIBLE QUE ACUDA en el caso de que se vaya a utilizar su muestra de semen, bien el día de la punción en el caso de ciclo FIV/ICSI, o el día de la inseminación.

Hay que tener en cuenta que el día de la punción la interesada va a pasar gran parte de la mañana en el hospital. No va a poder estar acompañada durante el tiempo que dure la punción ni durante la duración de la recuperación, pero va a precisar de un acompañante para volver a casa, ya que se le ha realizado una intervención con sedación.

¿Tengo que guardar reposo en algún momento del cido?

En este sentido hay dos consideraciones muy diferentes.

En ciclos de inseminación, NO se va a precisar de reposo, ya que únicamente crecen uno o dos folículos durante el ciclo, al igual que se haría de forma natural. Tras la inseminación tampoco hace falta guardar reposo, al igual que no se guarda en el domicilio tras mantener relaciones sexuales.

En los ciclos de FIV:

- no se recomienda hacer deporte ni actividad física intensos durante el proceso de estimulación, pues va a crecer el tamaño de los ovarios, lo que puede acarrear un aumento de riesgo de torsión ovárica. Además es normal tener sensación de pesadez, lo que puede generar incomodidad.
- Es importante mantener reposo físico durante las primeras 48h tras la punción.
- Tras la transferencia embrionaria NO hay que realizar reposo, mas allá de evitar actividades físicas intensas.

¿Cúanta lista de espera hay? ¿ Cúanto voy a tener que esperar para empezar?

El día que se realiza la primera visita, la paciente queda dada de alta en nuestra base de datos. Como ya se ha comentado, es posible que se requiera alguna prueba más o alguna exploración. A partir de ahí:

En el caso de que se puedan realizar **inseminaciones**, no hay lista de espera. Únicamente habrá que esperar a la primera regla para iniciar la estimulación.

Si se va a realizar un ciclo de **FIV**, la lista de espera está en torno a un año. Si viene derivada de un hospital de otro departamento donde ya le han realizado inseminaciones, la lista de espera de un año empieza a contar desde el inicio del primer ciclo de inseminación.

Cuando se aproxime la fecha de inicio por lista de espera, le contactaremos para recordarles cómo proceder, si falta algún documento y/o prueba necesaria.

DOCUMENTOS IMPORTANTES:

Es imprescindible que los interesados hayan leído este documento al completo, al igual que el documento informativo y los consentimientos informados de ambas técnicas (FIV e inseminación artificial) disponibles en la página web (www.saludmujerclinico.es - área paciente) ANTES del inicio del tratamiento.

Específicamente:

- Por una parte encontraréis el documento informativo que habla sobre las consideraciones legales de las técnicas (ambas). Ese documento debe traerse a la consulta leído y firmado en todas las hojas, por delante y por detrás, por la interesada (en el caso de que se trate de mujer sola) o por las dos personas interesadas (en el caso de que se inicien estos procedimientos como una pareja). Este documento sólo se **firmará una vez** y se entregará al inicio del primer ciclo que se vaya a realizar.

- Consentimiento informado de la técnica a realizar. Es un documento informativo que habla de la técnica en concreto desde punto de vista médico, procedimiento, riesgos, etc. Hay que leerlo y traerlo firmado en todas las hojas, por delante y por detrás, también por la interesada (en el caso de que se trate de mujer sola) o por las dos personas interesadas (en el caso de que se inicien estos procedimientos como una pareja). Hay que fijarse porque hay que rellenar distintas partes en el documento (ver anexos, donde se explica qué hay que rellenar). Los consentimientos informados son válidos únicamente para cada ciclo, por lo que **se firmarán tantos como ciclos se realicen**. Se debe entregar firmado al inicio de cada ciclo.

- Documento informativo de tratamiento de reproducción asistida durante la pandemia por SARS-COV-2. Las condiciones especiales que ha impuesto la pandemia han obligado a establecer un consentimiento informado específico, que deberá firmarse también

¿Qué hago si me encuentro mal una vez iniciado un ciclo?

Si te encuentras mal debes, en primer lugar, llamar al teléfono de nuestra consulta de enfermería, de 8:00 a 15:00 h, lunes a viernes.

En el caso de que te encuentres fuera de este horario y no mejores tras tomar un analgésico habitual, lo mejor es que acudas a urgencias de tu hospital más cercano, siempre con los papeles donde se encuentra la medicación que te estás administrando y explicando el proceso que estás siguiendo. Tras ello, deberás ponerte en contacto con nosotros lo antes posible para contarnos lo sucedido.

¿Me puedo dar de baja en cualquier momento?

Es importante saber que DEBES ponerte en contacto con nosotros para darte de baja y salir de la lista de espera si:

- Te quedas embarazada de forma natural.
- Has iniciado los trámites con tu pareja y no estás con dicha persona.
- Han cambiado tus planes y no vas a querer someterte a estas técnicas.

¿Y si tengo dudas?

Ante las dudas que puedan surgir, estamos a tu entera disposición en cualquier momento.

Lo ideal, teniendo en cuenta la marcha de la consulta, es que nos llames entre las 8:15 y las 9:00 o entre la 13:00 y las 14:30 de lunes a viernes.

- **Teléfono de enfermería y laboratorio, 961973926**
  Para dudas generales del proceso o de la medicación. También puedes llamar para pedir cita no presencial si tus dudas requieren que uno de los ginecólogos hable contigo, o para pedir cita para inicio de los ciclos cuando te baje la regla (siempre que se te haya dado indicación en tal sentido).
  El laboratorio informará en cuanto a dudas sobre los ovocitos recuperados, estado de los embriones, ovocitos o embriones congelados, ciclos de DGP

GENERALITAT VALENCIANA
Conselleria de Sanitat Universal i Salut Pública

UNIDAD DE REPRODUCCIÓN HUMANA ASISTIDA

FECUNDACIÓN IN VITRO O MICROINYECCIÓN ESPERMÁTICA (FIV/ICSI)

PARA LA TRANSFERENCIA Y/O CRIOPRESERVACIÓN DE PREEMBRIONES

DOCUMENTO DE INFORMACIÓN Y CONSENTIMIENTO

1. **¿Qué es?:** La Fecundación in Vitro es un procedimiento médico y biológico destinado a facilitar la unión de ovocitos y espermatozoides en un laboratorio, obteniendo preembriones que podrán ser introducidos en el útero para lograr la gestación y/o criopreservados.

2. **¿Cómo se realiza?:** La Fecundación in Vitro puede realizarse mediante dos procedimientos diferentes: Fecundación in Vitro convencional (FIV), en la que el óvulo y espermatozoide se unen de forma espontánea; y la Microinyección Espermática (ICSI), en la que la fecundación se realiza inyectando un espermatozoide en cada óvulo. La FIV y la ICSI comienzan con la estimulación de los ovarios mediante fármacos y posteriormente se procederá de manera individualizada según su caso, a la transferencia y/o criopreservación de los preembriones.

3. **¿Cuáles son sus riesgos?:** Los principales riesgos de este procedimiento terapéutico son:

   a) **Embarazo múltiple:** El riesgo de embarazo múltiple está relacionado con la edad de la mujer, el número de preembriones transferidos al útero y la calidad de los mismos. La tasa de gestación, con 2 sacos gestacionales, es del 14,2% (datos Registro Nacional de Actividad de la Sociedad Española de Fertilidad 2018).

   b) **Síndrome de hiperestimulación ovárica:** En ocasiones, la respuesta ovárica al tratamiento es excesiva, se desarrolla un gran número de folículos, aumenta el tamaño ovárico. En casos críticos se puede asociar a insuficiencia respiratoria o alteraciones de la coagulación.

   c) **Embarazo ectópico:** Consiste en la implantación del embrión fuera del útero, habitualmente en las trompas. Se produce en un 1,7% de los casos.

   d) **Aborto:** La tasa de abortos es ligeramente superior a la que corresponde a la población general. La tasa de aborto es del 22,3% (datos Registro SEF 2018).

   e) **Defectos congénitos y alteraciones cromosómicas de los hijos:** El procedimiento FIV/ICSI puede incrementar, ligeramente, la aparición de anomalías congénitas y cromosómicas.

   f) **Riesgos genéticos:** No pueden descartarse, completamente, enfermedades genéticas en la descendencia.

   g) **Otros riesgos:** Reacciones adversas a la medicación, infección peritoneal, hemorragia ovárica por punción accidental, torsión ovárica, dolor o impotencia funcional.

4. **Consecuencias previsibles de su realización:** El Registro 2018 de la SEF refiere una tasa de embarazo del 19% por ciclo iniciado, 21% por punción y 35,6% por transferencia.

5. **Consecuencias previsibles de su no realización**: Imposibilidad de llevar a cabo con éxito en su caso esta técnica reproductiva.

6. **Alternativas:** Volver a iniciar el tratamiento; profundizar en estudios complementarios; modificar la técnica utilizada; realizar un diagnóstico genético preimplantacional (DGP); realizar otros tratamientos con gametos donados (ovocitos y/o espermatozoides); utilizar preembriones donados; desistir de los tratamientos de reproducción asistida.

7. **Riesgos en función de la situación de la paciente:** La edad avanzada, el consumo de tabaco y las alteraciones importantes del peso corporal, aumentan el riesgo de complicaciones durante el tratamiento, embarazo y para la descendencia.

   Otros riesgos o complicaciones que podrían aparecer, dada su situación clínica y sus circunstancias personales, son ……..

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PARA LA TRANSFERENCIA Y/O CRIOPRESERVACIÓN DE PREEMBRIONES

DECLARACION DE INFORMACION Y CONSENTIMIENTO

DATOS PACIENTE

APELLIDOS	NOMBRE	DNI	FECHA DE NACIMIENTO

Nº SIP	DOMICILIO (CALLE/PLAZA, NUMERO Y PUERTA)	CP

LOCALIDAD	PROVINCIA	TELEFONO	CORREO ELECTRÓNICO

DATOS REPRESENTANTE LEGAL

APELLIDOS	NOMBRE	DNI	FECHA NACIMIENTO	EN CALIDAD DE

DATOS PROFESIONAL

APELLIDOS	NOMBRE	CATEGORÍA PROFESIONAL	NUM. COLEGIACIÓN

DECLARO que:

- *Se me ha explicado que es conveniente/necesario la realización de este procedimiento*
- *He comprendido la información recibida*
- *He podido formular todas las preguntas que he creído oportunas*
- *Se me ha informado de que en cualquier momento puedo revocar mi consentimiento*

Por lo tanto:

☐ *Autorizo la realización de este procedimiento* ☐ *No autorizo la realización de este procedimiento*

_____, ____ de _____ de _____

Paciente / su representante. *Profesional sanitario/a*

Firma:_____ Firma: _____

REVOCACIÓN DE LA DECLARACIÓN DE INFORMACIÓN Y CONSENTIMIENTO

Revoco el consentimiento prestado en la fecha indicada

_____ ____ de _____ de _____

Paciente / su representante. *Profesional sanitario/a*

Firma:_____ Firma: _____

RENUNCIA AL DERECHO DE INFORMACIÓN

Manifiesto que por razones personales, renuncio al derecho a la información que me corresponde como paciente y expreso mi deseo de no recibir información, en el momento actual, sobre el proceso de mi enfermedad sin que ello implique que no pueda dar mi consentimiento para someterme a la realización de esta intervención, tal como he prestado y firmado en el apartado anterior.

_____, ____ de _____ de _____

Paciente / su representante. *Profesional sanitario/a*

Firma:_____ Firma: _____

UTILIZACIÓN DE IMÁGENES Y VÍDEOS CON FINES CIENTÍFICOS

He sido informado/a de que el procedimiento puede ser grabado y los datos utilizados con fines científicos y/o didácticos, asegurando siempre mi intimidad y mi anonimato. Por ello:

AUTORIZO: ☐ *NO AUTORIZO:* ☐

Paciente / su representante: *Profesional sanitario/a:*

Firma: *Firma:*

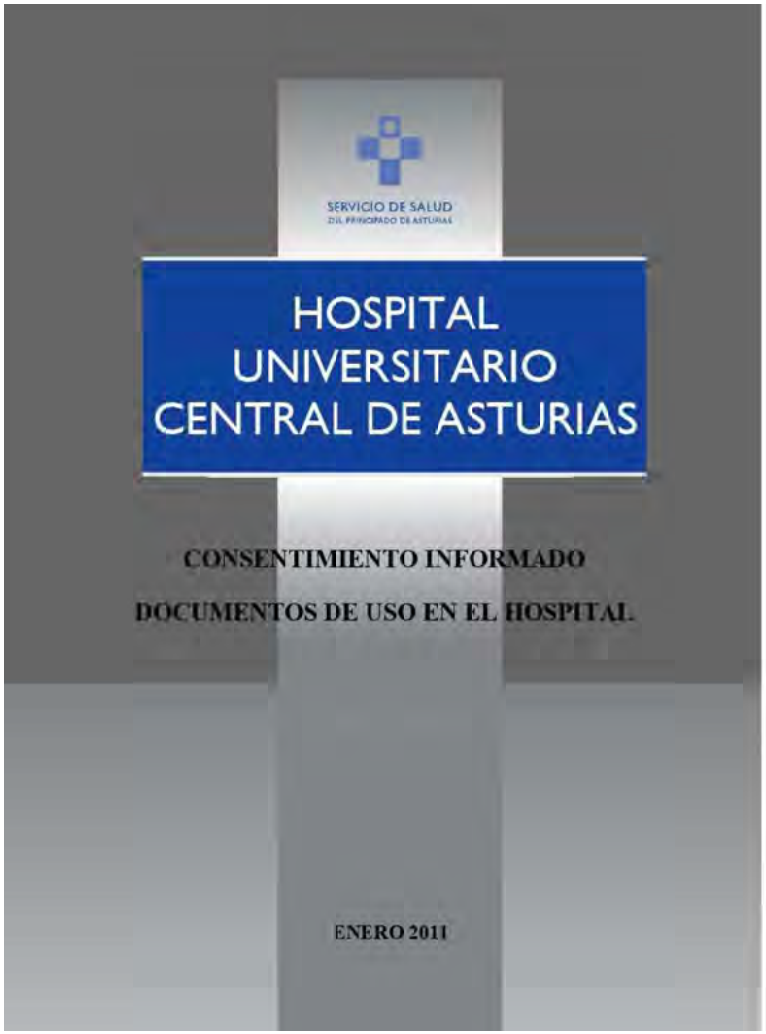
REVOCACIÓN DE LA UTILIZACIÓN DE IMÁGENES Y VÍDEOS CON FINES CIENTÍFICOS

Paciente / su representante: *Profesional Sanitario/a:*

Firma: *Firma:*

Los datos de carácter personal serán tratados atendiendo a la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales

12. 3. Hospital Universitario Central de Asturias (HUCA)



GINECOLOGÍA

UNIDAD DE REPRODUCCIÓN ASISTIDA

FECUNDACIÓN IN VITRO O MICROINYECCIÓN ESPERMÁTICA (FIV/ICSI), CON TRANSFERENCIA EMBRIONARIA Y CONGELACIÓN DE EMBRIONES

DOCUMENTO INFORMATIVO

I. ¿En qué consiste?

*La **Fecundación in Vitro** es un tratamiento que consta de procedimientos médicos y biológicos destinados a facilitar la unión de óvulos (ovocitos) y espermatozoides en el Laboratorio, y obtener embriones que serán introducidos en el útero para lograr la gestación.*

*La Fecundación in Vitro puede realizarse mediante dos procedimientos diferentes: **Fecundación in Vitro convencional o FIV**, en la que el óvulo y espermatozoide se unen de forma espontánea en el laboratorio; y la **Microinyección Espermática o ICSI**, en la que la fecundación se realiza inyectando un espermatozoide en cada óvulo.*

*De la fecundación se obtienen los **preembriones**, que son el grupo de células resultantes de la división progresiva del óvulo desde que es fecundado hasta 14 días más tarde. Sólo pueden generarse un número de preembriones en cada ciclo reproductivo que, conforme a criterios clínicos, garantice en límites razonables el éxito reproductivo de cada pareja.*

Un número limitado de los preembriones obtenidos serán transferidos al útero para conseguir la gestación. El resto de embriones viables serán congelados para ser destinados a los fines legalmente establecidos.

II. ¿Cuáles son las indicaciones?

Las indicaciones más frecuentes son:

- *Trastornos de la fertilidad:*
  - *Ausencia, obstrucción o lesión de las trompas.*
  - *Disminución del número y/o movilidad de los espermatozoides o aumento de las alteraciones morfológicas de los mismos.*
  - *Endometriosis moderada o severa que consiste en la aparición y crecimiento en lugares anormales de la mucosa que reviste el interior del útero.*
  - *Alteraciones de la ovulación.*
  - *Fracaso de otros tratamientos.*
  - *Edad avanzada*
  - *Otras.*
- *Diagnóstico genético preimplantacional.*

III. Procedimientos

*La **Fecundación in Vitro (FIV) y la Microinyección Espermática (ICSI)** comienzan habitualmente con la **estimulación de los ovarios** mediante el uso de fármacos*, cuya acción es similar a la de ciertas hormonas producidas por la mujer. La finalidad de este tratamiento es obtener el desarrollo de varios folículos, en cuyo interior se encuentran los óvulos. Con el fin de evitar la ovulación espontánea se asocian otros tratamientos con acción hormonal.*

*El proceso de estimulación ovárica se controla habitualmente con **análisis en sangre de los niveles de ciertas hormonas ováricas** y/o **ecografías vaginales** que informan del número y tamaño de los **folículos** en desarrollo. Obtenido el desarrollo adecuado se administran otros medicamentos para lograr la maduración final de los óvulos.*

Muchos de los medicamentos utilizados son inyectables, y su presentación permite la autoadministración por la paciente. Las dosis y pautas de administración se adaptan a las características clínicas de cada paciente, y la respuesta al tratamiento puede ser variable. Ocasionalmente se utilizan de forma asociada otros tipos de medicamentos.

554

*Los óvulos se extraen mediante **punción de los ovarios** y **aspiración** de los folículos, bajo visión ecográfica y por vía vaginal. Esta intervención es realizada habitualmente en régimen ambulatorio y requiere **anestesia y** observación posterior durante un periodo variable.*

*Los **óvulos** (ovocitos) obtenidos se preparan y clasifican en el laboratorio. El número de óvulos que se extraen en la punción, su madurez y calidad no puede predecirse con exactitud.*

*Una vez obtenidos los óvulos, el laboratorio deberá disponer de los **espermatozoides** procedentes de la pareja, o de un donante anónimo, en los casos que así proceda. El semen se prepara en el laboratorio con el fin de seleccionar los espermatozoides más adecuados para la fecundación.*

*Si se realiza **Fecundación in Vitro (FIV),** los óvulos y espermatozoides se cultivarán en el laboratorio conjuntamente en condiciones favorables para su unión espontánea (fecundación).*

*Si se realiza **Microinyección Espermática (ICSI)**, se inyectará un espermatozoide dentro de cada uno de los óvulos maduros que se hayan recuperado.*

*Al día siguiente de la FIV o ICSI se determinará el número de **óvulos fecundados o preembriones**. Los preembriones se mantendrán en el laboratorio por un periodo de 2 a 6 días tras los que se procederá a la **transferencia**.*

*La **transferencia embrionaria** consiste en el depósito de los embriones en la cavidad uterina a través de la vagina. Es un procedimiento ambulatorio que habitualmente no precisa anestesia ni ingreso. Con la finalidad de favorecer la implantación embrionaria se prescribe también un tratamiento hormonal.*

El número de preembriones transferidos al útero no puede ser superior a tres, en un ciclo. Los pacientes recibirán del equipo biomédico la información necesaria para decidir el número de embriones que se deben transferir, con el fin de obtener el embarazo y evitar en lo posible la gestación múltiple.

*Finalmente, los **preembriones viables sobrantes** de un ciclo de Fecundación in Vitro se preservarán mediante congelación. **Los posibles destinos de los preembriones criopreservados se detallan en el apartado de información legal de este documento informativo (apartado VIII).***

En algunos casos, las técnicas habituales de FIV e ICSI pueden complementarse con otros procedimientos sobre los gametos o embriones destinados a mejorar la capacidad de implantación embrionaria (eclosión asistida, extracción de fragmentos, etc).

** Los medicamentos empleados incluyen un prospecto que el paciente debe consultar, teniendo la posibilidad de solicitar al personal sanitario del Centro cualquier aclaración al respecto.*

IV. Resultados

Los factores que condicionan la probabilidad de gestación son: la causa de la esterilidad, la edad de la paciente, el numero de ovocitos obtenidos y de embriones finales de buena calidad.

Sin embargo, hay que tener presente que no todas las pacientes que inician el tratamiento logran el desarrollo folicular adecuado para ser sometidas a la punción, y no todas las que alcanzan esta fase pueden recibir transferencia de embriones, ya que en algunos casos fracasa la obtención de óvulos, la fecundación o el desarrollo embrionario precoz. Por ello, el rendimiento del tratamiento se puede expresar como porcentaje de gestaciones sobre el total de ciclos iniciados, sobre ciclos con punción folicular y sobre ciclos con transferencia.

El Registro FIV/ICSI de la Sociedad Española de Fertilidad del año 2004 refería unas tasas de embarazo del 28,6% por ciclo iniciado, 32,4% por punción y 36,7% por transferencia.

El 80 % de las gestaciones se obtienen en los tres primeros ciclos de FIV/ICSI con transferencia embrionaria satisfactoria, por lo que el fracaso hace necesario discutir con el equipo asistencial la conveniencia de emprender más tratamientos.

Entre un 40% y 60% de las pacientes obtienen embriones aptos para preservar mediante congelación, teniendo en cuenta que solo serán congelados aquellos con características biológicas de viabilidad.

De estos embriones congelados, un 50-70% sobreviven tras la descongelación y son válidos para su transferencia a la cavidad uterina. La tasa de embarazo por transferencia de embriones congelados en el

Registro FIV/ICSI de la Sociedad Española de Fertilidad del año 2004 es el 23,4 % por descongelación y 27,5 % por transferencia.

V. Riesgos

Los principales riesgos de este procedimiento terapéutico son:

1) ***Embarazo múltiple**: El riesgo de embarazo múltiple está relacionado con la edad de la mujer, el número de embriones transferidos al útero y la calidad de los mismos. En pacientes jóvenes y con embriones de buena calidad, la conducta más recomendable es transferir uno o dos embriones en los primeros intentos. La transferencia de tres embriones queda reservada para pacientes de edad avanzada sin embriones de buena calidad, o ante fracaso de transferencias previas de menor número de embriones. En el Registro de la Sociedad Española de Fertilidad de 2004 la tasa de embarazos múltiples es del 29,8 % con embriones frescos y 22% con congelados.*

   La gestación de dos o más fetos supone un aumento de los riesgos médicos para la madre y los niños, tales como incremento de la patología del embarazo, prematuridad, bajo peso al nacimiento y complicaciones neonatales severas. La gravedad de esta complicación se incrementa de manera paralela al número de fetos.

   La gestación múltiple se acompaña igualmente de un aumento de las dificultades sociales, económicas y laborales de los padres.

2) ***Síndrome de hiperestimulación ovárica:** En ocasiones, la respuesta ovárica al tratamiento es excesiva, se desarrolla un gran número de folículos, aumenta el tamaño ovárico y se eleva considerablemente la cantidad de estradiol en sangre. Además, el desarrollo de este síndrome tiene relación directa con la administración del fármaco necesario para la maduración final de los ovocitos (HCG) y la consecución de embarazo.*

   Se clasifica en leve, moderada y severa, siendo esta última excepcional (menos de un 2 %) y se caracteriza por acumulación de líquido en el abdomen e incluso en el tórax, así como por alteraciones de la función renal y/o hepática. En casos críticos se puede asociar a insuficiencia respiratoria o alteraciones de la coagulación.

   Puede precisar hospitalización y tratamiento médico-quirúrgico y sólo excepcionalmente se hace aconsejable la interrupción del embarazo.

3) ***Embarazo ectópico**. Consiste en la implantación del embrión fuera del útero, habitualmente en las trompas. Excepcionalmente puede coexistir con un embarazo situado en el útero. Se produce en un 3 % de los casos.*

4) ***Aborto**: La incidencia de abortos es discretamente superior a la observada en embarazos espontáneos (13,2 % con embriones frescos y 24,9% con congelados en el Registro de la Sociedad Española de Fertilidad de 2004).*

5) ***Edad avanzada, el consumo de tabaco y las alteraciones importantes del peso corporal** aumentan el riesgo de complicaciones durante el tratamiento, embarazo y para la descendencia, requieren adaptaciones en el tratamiento necesario para la estimulación ovárica y reducen las tasas de éxito.*

6) ***Defectos congénitos y alteraciones cromosómicas de los hijos**: los datos actuales sugieren que en los niños nacidos de FIV/ICSI puede incrementarse ligeramente el riesgo de anomalías congénitas y cromosómicas. Por ello puede ser aconsejable realizar técnicas de diagnóstico prenatal como ecografías, amniocentesis o biopsia de corion.*

7) ***Riesgos psicológicos**. Pueden aparecer trastornos psicológicos como síntomas de ansiedad y síntomas depresivos, tanto en el hombre como en la mujer. En algunos casos, pueden surgir dificultades en la relación de pareja (sexual y emocional) y niveles elevados de ansiedad en el periodo de espera entre la aplicación de la técnica y la confirmación de la consecución o no del embarazo, así como ante los fallos repetidos de la técnica.*

8) ***Riesgos de la anestesia** que se detallan en el consentimiento informado específico.*

9) **Otros riesgos y complicaciones** que excepcionalmente se pueden producir:

a) Intolerancia a la medicación.
b) Infección peritoneal.
c) Hemorragia por punción accidental de vasos sanguíneos.
d) Punción de un asa intestinal u otras estructuras.
e) Torsión ovárica.
f) Cancelación de la estimulación ovárica por ausencia o inadecuado desarrollo folicular o por excesiva respuesta a los tratamientos.
g) No obtención de óvulos en la punción.
h) No realización de la transferencia por:
   - Óvulos no adecuados para fecundación.
   - Ausencia de fecundación.
   - No obtención de embriones normales o viables.
   - Imposibilidad física de la transferencia por alteraciones anatómicas del útero.

VI. Riesgos Personalizados:

Las características médicas, sociales o laborales de cada paciente pueden suponer una modificación de los riesgos generales o aparición de riesgos específicos.

VII. Aspectos legales relacionados con la reproducción asistida

1.- De carácter general

El marco jurídico regulador de la reproducción humana asistida está constituido básicamente por la **Ley 14/2006 sobre Técnicas de Reproducción Humana Asistida**.

Las técnicas de reproducción asistida tienen como objetivo principal la solución de los problemas de esterilidad humana, para facilitar la procreación, cuando otras terapéuticas se hayan descartado por inadecuadas o ineficaces.

También pueden utilizarse en la prevención y tratamiento de enfermedades de origen genético o hereditario, cuando sea posible recurrir a ellas con suficientes garantías diagnósticas y terapéuticas y estén estrictamente indicadas.

Sólo pueden llevarse a cabo cuando haya posibilidades razonables de éxito y no supongan riesgo grave para la salud física o psíquica de la mujer o de la posible descendencia; y siempre en mujeres mayores de edad, con plena capacidad de obrar, con independencia de su estado civil y orientación sexual, que deben haber sido anterior y debidamente informadas de sus posibilidades de éxito, así como de sus riesgos y de las condiciones de dicha aplicación.

La mujer receptora de las técnicas podrá pedir que se suspendan en cualquier momento de su realización anterior a la transferencia embrionaria, debiendo atenderse su petición.

Cuando la mujer esté casada, se requerirá además el consentimiento del marido, a menos que estuvieran separados legalmente o de hecho y así conste fehacientemente. Si se trata de una pareja no casada, el consentimiento del varón será voluntario, pero si lo presta con anterioridad a la utilización de las técnicas, dicho consentimiento determinará la filiación paterna de la futura descendencia.

La mujer soltera, la viuda y la separada legalmente o de hecho, pueden ser receptoras o usuarias de las técnicas de reproducción asistida a título personal, valiéndose de semen procedente de donante, siempre que tengan más de 18 años, plena capacidad de obrar y hayan prestado su consentimiento escrito de manera libre, consciente y expresa.

2.- En relación con la posibilidad de tener un hijo póstumo

En caso de fallecimiento del varón, sólo podrá determinarse legalmente la filiación si el material reproductor de éste se encontrase en el útero de la mujer en la fecha de la muerte, excepto si el marido o el varón no unido por matrimonio hubiesen prestado su consentimiento en el documento de consentimiento informado de las

técnicas, en escritura pública, testamento o documento de instrucciones previas, para que su material reproductor pueda ser utilizado en los doce meses siguientes a su fallecimiento para fecundar a su mujer. Este consentimiento podrá ser revocado en cualquier momento con anterioridad a la realización de las técnicas.

Asimismo, previene la ley de reproducción que se entenderá otorgado el consentimiento del varón fallecido a la fecundación post mortem de su mujer (tanto si es pareja casada o no), cuando ésta hubiera estado sometida a un proceso de reproducción asistida ya iniciado para la transferencia de preembriones constituidos con anterioridad a la fecha de fallecimiento del marido. Desde el punto de vista médico, se considera iniciado el tratamiento cuando la paciente recibe la primera dosis de la medicación necesaria para el procedimiento.

3.- Sobre el destino de los embriones sobrantes criopreservados

Los **preembriones viables sobrantes** de un ciclo de fecundación in Vitro se criopreservarán en nitrógeno líquido, pues no todos los embriones no transferidos son aptos para la congelación. El destino posterior de los preembriones congelados puede ser:

a) La utilización por la propia mujer o, en su caso, su cónyuge femenino.
b) La donación con fines reproductivos.
c) La donación con fines de investigación.
d) El cese de su conservación sin otra utilización.

La **utilización por la propia mujer o su cónyuge** podrá efectuarse en cualquier momento mientras la mujer reúna los **requisitos clínicamente adecuados** para la realización de la técnica de reproducción asistida (lo que constituye el plazo máximo de conservación). En caso de pareja separada, si la mujer deseara utilizarlos para su reproducción personal habría de contar con el consentimiento del exmarido para la nueva transferencia que hubiera de realizarse, ya que los hijos serían de ambos.

En la **donación con fines reproductivos** los embriones son donados a parejas estériles que los necesitan. La donación es **voluntaria, gratuita, anónima y altruista** y precisa de un **consentimiento escrito específico previo**. Las receptoras y los hijos nacidos tienen derecho a obtener información general de los donantes, que no incluya su identidad. En circunstancias extraordinarias que comporten peligro cierto para la vida o la salud del nacido, o cuando proceda de acuerdo con las leyes procesales penales, podrá revelarse la identidad de los donantes, con carácter restringido y sin que ello modifique nunca la filiación establecida previamente.

En la **donación con fines de investigación** los embriones se ceden de forma altruista para proyectos de investigación biomédica en centros especialmente autorizados y con proyectos concretos también autorizados. El ejercicio efectivo de esta opción conllevará la suscripción de un consentimiento adicional y específico en el que se expliquen los fines que se persigan con la investigación y sus implicaciones.

El **cese de su conservación sin otra utilización,** que en el caso de los preembriones y los ovocitos crioconservados sólo será aplicable una vez finalizado el **plazo máximo de conservación** establecido en la Ley sin que se haya optado por alguno de los destinos mencionados en los apartados anteriores. La crioconservación de los ovocitos, del tejido ovárico y de los preembriones sobrantes se podrá prolongar hasta el momento en que se considere por los responsables médicos, con el dictamen favorable de especialistas independientes y ajenos al centro correspondiente, que la receptora no reúne los requisitos clínicamente adecuados para la práctica de la técnica de reproducción asistida.

4.- Obligación de renovación del consentimiento respecto de los embriones criopreservados

Cada **dos años** como mínimo se solicitará de la mujer o de la pareja progenitora la **renovación o modificación del consentimiento**. Si al vencimiento de dos períodos de conservación consecutivos fuera imposible obtener de la mujer o la pareja progenitora la renovación del consentimiento correspondiente, habiendo sido previamente requerida por el centro de forma fehaciente (burofax con acuse de recibo, carta certificada con acuse de recibo, telegrama con acuse de recibo, carta notarial, etc.), los preembriones **quedarán a disposición de este centro**, que podrá destinarlos a cualquiera de los fines citados en el apartado 3, manteniendo las exigencias de confidencialidad y anonimato establecidas, así como la gratuidad y ausencia de ánimo de lucro.

5. Información para el caso de utilización de gametos o embriones procedentes de donante

La donación de gametos y preembriones es un contrato gratuito, formal y confidencial concertado entre el donante y el centro autorizado. Tanto el banco de gametos, como los registros de donantes y de actividad de los centros, tienen obligación de garantizar la confidencialidad de los datos de identidad de los donantes.

Sin perjuicio de ello, las receptoras y los hijos nacidos tienen derecho a obtener información general de los donantes, que no incluya su identidad. Asimismo, en circunstancias extraordinarias que comporten peligro cierto para la vida o la salud del nacido, o cuando proceda de acuerdo con las leyes procesales penales, podrá revelarse la identidad de los donantes, con carácter restringido y sin que ello modifique nunca la filiación establecida previamente.

La elección de los donantes sólo puede realizarse por el equipo médico que aplica la técnica, y en ningún caso a petición de la receptora o la pareja. No obstante lo anterior, en todo caso el equipo médico deberá procurar la mayor similitud fenotípica e inmunológica posible con la mujer receptora.

Los donantes de los que procede el material genético han de tener más de 18 años, buen estado de salud psicofísica y plena capacidad de obrar. Su estado psicofísico debe cumplir las exigencias de un protocolo obligatorio de estudio de los donantes, que incluya sus características fenotípicas y psicológicas, así como las condiciones clínicas y determinaciones analíticas necesarias para demostrar que no padecen enfermedades genéticas, hereditarias o infecciosas transmisibles a la descendencia. A tal efecto se seguirá lo dispuesto en el R.D. 1301/2006.

Ni la mujer progenitora ni el marido, cuando hayan prestado su consentimiento formal, previo y expreso a determinada fecundación con contribución de donante o donantes, podrán impugnar la filiación matrimonial del hijo nacido como consecuencia de tal fecundación. De igual forma ocurrirá en estos casos con el varón no casado que hubiera firmado el consentimiento informado con anterioridad a la utilización de las técnicas.

IX. Alternativas ante el fracaso de la técnica

Si después de haber realizado uno o varios intentos de fecundación in vitro o microinyección espermática no se ha conseguido el embarazo, puede ser aconsejable adoptar, tras la oportuna reflexión, alguna de las siguientes alternativas:

- *Volver a iniciar el tratamiento.*
- *Profundizar en estudios complementarios.*
- *Aplicar modificaciones a la técnica utilizada.*
- *Realizar un diagnóstico genético preimplantacional (DGP).*
- *Realizar nuevos tratamientos con gametos donados (óvulos y/o espermatozoides).*
- *Utilizar embriones donados.*
- *Desistir de los tratamientos de reproducción asistida.*

El contenido del presente documento refleja el estado actual del conocimiento, y por tanto, es susceptible de modificación en caso de que así lo aconsejen nuevos hallazgos o avances científicos.

En _____ a _____ de _____ de _____

Fdo. El/La Médico/a (Col.nº) Firma Firma

GINECOLOGÍA
UNIDAD DE REPRODUCCION ASISTIDA

CONSENTIMIENTO INFORMADO PARA FECUNDACIÓN IN VITRO O MICROINYECCIÓN ESPERMÁTICA (FIV/ICSI), CON TRANSFERENCIA Y CONGELACIÓN EMBRIONARIA

Dª _____

Mayor de edad, con DNI/Pasaporte nº _____ *Estado civil* _____

y D/Dª _____

Mayor de edad, con DNI/Pasaporte nº _____ *Estado civil* _____

Con domicilio en la ciudad de _____

Calle, nº, CP _____

Concurriendo como (matrimonio/pareja de hecho/ mujer sin pareja) _____

DECLARO/ DECLARAMOS:

1. *Tener plena capacidad de obrar.*

2. *En este acto, de manera libre, consciente y expresa, presto/prestamos nuestro consentimiento escrito la utilización de técnicas de reproducción asistida (marcar lo que proceda):*

☐ *Con semen de la* ***PAREJA***
☐ *Con semen de* ***DONANTE***

3. *Haber recibido, anteriormente a este acto, información verbal y escrita, esta última a través del "Documento informativo sobre fecundación in Vitro o Microinyección Espermática (FIV/ICSI), con Transferencia Embrionaria y Congelación de Embriones", el cual ha sido leído, comprendido y suscrito. En consecuencia, he/hemos recibido información sobre las siguientes cuestiones:*

- *Información y asesoramiento sobre las técnicas de reproducción asistida en sus aspectos biológicos, jurídicos y éticos. En caso de utilizar semen de donante, también sobre su utilización y en especial, sobre la relevancia jurídica de la firma de este consentimiento informado por el marido o varón no casado en orden a la determinación con el mismo de la filiación paterna respecto de la descendencia que se consiga.*
- *La indicación, procedimiento, probabilidades de éxito, riesgos, contraindicaciones y complicaciones del tratamiento propuesto y de la medicación empleada.*
- *La disposición del personal sanitario a ampliar cualquier aspecto de la información que no haya quedado suficientemente aclarado.*
- *Los destinos de los posibles preembriones viables que quedarán criopreservados en el banco del centro por no haber sido transferidos al útero en el ciclo de tratamiento.*
- *Los posibles riesgos que se pueden derivar de la maternidad a una edad clínicamente inadecuada, tanto para la mujer durante el tratamiento y el embarazo, como para la descendencia.*
- *La obligación de renovar o modificar periódicamente nuestro consentimiento respecto a los preembriones criopreservados, así como de comunicar al centro cualquier cambio de domicilio o circunstancia personal que pueda afectar a su destino (separación, fallecimiento o incapacidad sobrevenida de uno de los cónyuges, etc).*

4. *Que, según el equipo médico, para mi/nuestro proyecto reproductivo, es adecuado un tratamiento de reproducción asistida, a través de al técnica de denominada* _____ *de las alternativas expuestas hemos comprendido que la técnica más adecuada es la que aquí consentimos.*

5. *Conocer que, en cualquier momento anterior a la transferencia embrionaria, puedo/podemos pedir que se suspenda la aplicación de las técnicas de reproducción asistida, y que dicha petición deberá atenderse.*

6. *El equipo médico me/nos ha informado también de los siguientes riesgos relacionados con nuestras circunstancias personales:* _____

7. Autorizo/ Autorizamos y consiento/consentimos la transferencia de un máximo de ___ (uno, dos o tres) preembriones.
8. Respecto a la posibilidad de generar embriones viables sobrantes que nos sean ☐ nsferidos al útero en el mismo ciclo: (marque lo que proceda)

Asumo/Asumimos la obligatoriedad de congelar los posibles preembriones viables sobrantes, y consentimos la misma.

No deseo/deseamos la generación de embriones sobrantes, por lo que autorizamos la inseminación de un máximo de ☐ ovocitos.

9. Que de **no utilizarlos** en el futuro para mi/nuestro proyecto reproductivo, el destino que deseo/ deseamos par los posibles preembriones congelados sobrantes es: (marque lo que proceda)

- ☐ donación con fines de reproductivos.
- ☐ Donación con fines de investigación.
- ☐ Cese de su conservación sin otra utilización al finalizar el plazo máximo de conservación.

10. He/Hemos comprendido toda la información que considero/consideramos adecuada y suficiente, por parte del Dr./Dra. _____

11. De igual forma en la consulta médica hemos afirmado:

- No padecer enfermedades congénitas, hereditarias o infecciosas transmisibles con riesgo grave para la posible descendencia.
- No haber omitido o falseado ningún dato de tipo médico o legal que pudiera incidir en el tratamiento o sus consecuencias.
- Comprometerme/Comprometernos a notificar al centro los cambios de circunstancias personales (defunción, separación, divorcio….)
- Obligarme/Obligarnos a comunicar los cambios de domicilio en caso de existir preembriones congelados.

Y una vez debidamente informados,

AUTORIZO/AUTORIZAMOS:

A la aplicación de los procedimientos de tratamiento y control necesarios para el tratamiento de Fecundación in Vitro (FIV)/ Microinyección Espermática (ICSI), transferencia de embriones y congelación embrionaria si procede.

El contenido del presente documento refleja el estado actual del conocimiento, y por tanto, es susceptible de modificación en caso de que así lo aconsejen nuevos hallazgos o avances científicos.
Según los establecido en la Ley Orgánica 1571999, de protección de datos de carácter personal, mis datos de carácter personal y sanitario quedarán registrados en un fichero propiedad del centro ……
pudiendo ser utilizados y cedidos única y exclusivamente a los efectos de la actuación encargada, gozando de los derechos de acceso rectificación y cancelación. Todos los datos que se derivan del proceso quedarán reflejados en la correspondiente historia clínica, que será custodiada en las instalaciones de la entidad para garantizar su correcta conservación y recuperación.
NOTA: El centro sanitario hará todo lo posible para mantener el almacenaje de las células/tejidos en condiciones óptimas, pero no se hará responsable de la pérdida de viabilidad de lo mismos debido a desastres naturales u otras emergencias que estén fuera del control de la clínica. Deber conocer que sus embriones podrían ser trasladados a una localización alternativa en caso de una situación de emergencia (inundaciones, disturbios, fuego, etc)

En ……a ……de …….. de……..

Fdo. Dª Fdo. D. Fdo. El/la Médico/a (Col. nº ……)

ANEXO para el esposo/pareja o para el varón no casado:

D. _____ Mayor de edad, provisto de DNI nº _____
en este acto presto mi consentimiento a que en el caso de que falleciera con anterioridad a que mi material reproductor se halle en el útero de Dª _____ pueda esta, en los 12 meses siguientes a mi fallecimiento, proceder a fecundarse con el mismo, y que se determine la filiación del hijo nacido conmigo.

Fdo. El/la Médico/a (Col. nº ……) Fdo. D.

ANEXO para la VARIACIÓN del destino de los preembriones criopreservados

Dª _____

Mayor de edad, con DNI/Pasaporte nº _____ Estado civil _____

Con domicilio en la calle/plaza _____
de _____

y D/Dª _____

Mayor de edad, con DNI/Pasaporte nº _____ Estado civil _____

Con domicilio en la calle/plaza _____
de _____

en este acto solicitamos la modificación del destino de nuestros preembriones sobrantes/ criopreservados y consentimos en que el nuevo destino sea (utilización por la propia mujer/ donación con fines reproductivos/ donación con fines de investigación cese de su conservación sin otra utilización una vez finalizado el plazo máximo de conservación):

_____

En ……a……de……de……

Fdo. Dª Fdo. D. Fdo. El/la Médico/a (Col. nº)

ANEXO para REVOCACIÓN del presente consentimiento

D/Dª. _____ *Mayor de edad, provisto de DNI nº*

_____ *y domicilio en la calle/plaza* _____

de _____

En este acto solicito la SUSPENSIÓN de la aplicación de la técnica de reproducción asistida a la que me estoy sometiendo

En ..... a .....de..... de.....

Fdo. Dª *Fdo. D.* *Fdo .El/la Médico/a (Col. nº.....)*

12. 4. Consejería de Salud de la Junta de Andalucía

JUNTA DE ANDALUCIA CONSEJERIA DE SALUD

FORMULARIO DE INFORMACIÓN Y CONSENTIMIENTO INFORMADO ESCRITO

Orden de 8 de julio de 2009 (BOJA nº 152 de fecha 6 de agosto) por la que se dictan instrucciones a los Centros del Sistema Sanitario Público de Andalucía, en relación al procedimiento de Consentimiento Informado.

CENTRO SANITARIO	SERVICIO DE

1. DOCUMENTO DE INFORMACIÓN PARA (*) FECUNDACIÓN IN VITRO-TRANSFERENCIA EMBRIONARIA (FIV-TE)

Este documento sirve para que usted, o quien lo represente, dé su consentimiento para esta intervención. Eso significa que nos autoriza a realizarla.
Puede usted retirar este consentimiento cuando lo desee. Firmarlo no le obliga a usted a hacerse la intervención. De su rechazo no se derivará ninguna consecuencia adversa respecto a la calidad del resto de la atención recibida. Antes de firmar, es importante que lea despacio la información siguiente.

Díganos si tiene alguna duda o necesita más información. Le atenderemos con mucho gusto.

(*) Indicar el nombre del procedimiento/intervención a realizar, si es posible, además del nombre técnico que siempre debe figurar, puede tratar de expresarlo con un nombre más sencillo.

1.1 LO QUE USTED DEBE SABER:

EN QUÉ CONSISTE. PARA QUÉ SIRVE:
La fecundación in vitro-transferencia embrionaria (FIV-TE) es un procedimiento que consiste en obtener gametos masculinos y femeninos (espermatozoides y óvulos) para ponerlos en contacto en el laboratorio. Sirve para realizar una fecundación fuera del organismo de la mujer (fecundación in vitro) y obtener embriones que serán depositados en el útero de la mujer (transferencia embrionaria) con el propósito de conseguir un embarazo.

CÓMO SE REALIZA:
La Fecundación in vitro se hace habitualmente en régimen ambulatorio y requiere anestesia y observación posterior durante un periodo variable.
Puede realizarse mediante dos procedimientos diferentes:

- Fecundación in Vitro convencional o FIV, en la que el óvulo y el espermatozoide se unen de forma espontánea en el laboratorio.
- Microinyección Espermática o ICSI, en la que la fecundación se realiza inyectando un espermatozoide en cada óvulo.

En su caso la técnica propuesta es

Antes de realizar unc de estos procedimientos (FIV o ICSI) hay que estimular los ovarios. Se usan fármacos de acción parecida a las hormonas de la mujer, para obtener el desarrollo de varios folículos, donde están contenidos los óvulos. Este proceso se controla midiendo los niveles de hormonas ováricas con análisis en sangre y/o realizando ecografías vaginales que informan del número y tamaño de los folículos en desarrollo. Además se utilizan otros medicamentos para evitar la ovulación espontánea y otros para conseguir la maduración final de los óvulos. Los óvulos se extraen mediante punción de los ovarios y aspiración de los

001530

JUNTA DE ANDALUCIA CONSEJERÍA DE SALUD

folículos, bajo control de ecografía y por vía vaginal. Una vez conseguida la fecundación, s selecciona el número de embriones a introducir en el interior del útero de la mujer.

La transferencia embrionaria es un procedimiento ambulatorio que habitualmente no precis anestesia ni ingreso. El depósito de los embriones en la cavidad uterina se realiza a través d la vagina. Con el fin de favorecer la implantación de los embriones se indican medicamento con efecto hormonal. En algunos casos no se puede efectuar esta técnica por no habe obtenido óvulos tras la punción o porque resulta imposible realizar la transferencia dentro de útero.

QUÉ EFECTOS LE PRODUCIRÁ:
Molestias que suelen remitir en horas, sobre todo en la obtención de los óvulos.
A veces, pueden aparecer trastornos psicológicos como síntomas de ansiedad y síntoma depresivos tanto en el hombre como en la mujer, que pueden dificultar la relación de pareja.

EN QUÉ LE BENEFICIARÁ:
En conseguir un embarazo que de forma espontánea no se ha conseguido.
El éxito de esta técnica dependerá de la causa de esterilidad. Globalmente está alrededor del 20% 30% de embarazos por ciclo.

OTRAS ALTERNATIVAS DISPONIBLES EN SU CASO:
El coito dirigido o la inseminación artificial que en su caso se ha desestimado y/o ha fracasado.

En su caso

QUÉ RIESGOS TIENE:
Cualquier actuación médica tiene riesgos. La mayor parte de las veces los riesgos no se materializan, y la intervención n produce daños o efectos secundarios indeseables. Pero a veces no es así. Por eso es importante que usted conozca lo riesgos que pueden aparecer en este proceso o intervención.

- LOS MÁS FRECUENTES:

- Embarazo múltiple: se producen con una frecuencia de 25 de cada 100 mujere aproximadamente.
- Síndrome de hiperestimulación ovárica: En ocasiones, la respuesta ovárica al tratamient es excesiva, se desarrolla un gran número de folículos y aumenta el tamaño ovárico Puede precisar hospitalización y tratamiento médico-quirúrgico y sólo excepcionalment se hace aconsejable la interrupción del embarazo.
- Embarazo ectópico: Consiste en la implantación del embrión fuera del útero habitualmente en las trompas. Excepcionalmente puede coexistir con un embaraz situado en el útero. Se produce en 3 de cada 100 casos.

- Aborto: La incidencia de abortos es discretamente superior a la observada en embarazos espontáneos, así como de defectos congénitos y alteraciones cromosómicas de los hijos. Puede ser aconsejable realizar alguna técnica de diagnóstico prenatal como ecografías, amniocentesis o biopsia corial.

- LOS MÁS GRAVES:
- Síndrome de hiperestimulación ovárica severa.
- Infección peritoneal.
- Hemorragia por punción accidental de vasos sanguíneos.
- Punción de un asa intestinal u otras estructuras.
- Torsión ovárica.

- LOS DERIVADOS DE SUS PROBLEMAS DE SALUD:

SITUACIONES ESPECIALES QUE DEBEN SER TENIDAS EN CUENTA:

Hay situaciones en las que este procedimiento no está indicado como en el caso de la existencia de enfermedades genéticas transmisibles, cuando existe patología ovárica o uterina, o cuando hay una inaccesibilidad ovárica o uterina para efectuar estos procedimientos.

La edad avanzada, el consumo de tabaco y las alteraciones importantes del peso corporal aumentan el riesgo de complicaciones durante el tratamiento, el embarazo y para la descendencia, y requerirán de adaptaciones en el tratamiento.
Pueden existir circunstancias que aumenten la frecuencia y gravedad de riesgos y complicaciones a causa de enfermedades que usted ya padece. Para ser valoradas debe informar a su médico de sus posibles alergias medicamentosas, alteraciones de la coagulación, enfermedades, medicaciones actuales o cualquier otra circunstancia.

OTRAS INFORMACIONES DE INTERÉS (a considerar por el/la profesional):

OTRAS CUESTIONES PARA LAS QUE LE PEDIMOS SU CONSENTIMIENTO:

- A veces, durante la intervención, se producen hallazgos imprevistos. Pueden obligar a tener que modificar la forma de hacer la intervención y utilizar variantes de la misma no contempladas inicialmente.

- A veces es necesario tomar muestras biológicas para estudiar mejor su caso. Pueden ser conservadas y utilizadas posteriormente para realizar investigaciones relacionadas con la enfermedad que usted padece. No se usarán directamente para fines comerciales. Si fueran a ser utilizadas para otros fines distintos se le pediría posteriormente el consentimiento expreso para ello. Si no da su consentimiento para ser utilizadas en investigación, las muestras se destruirán una vez dejen de ser útiles para documentar su caso, según las normas del centro. En cualquier caso, se protegerá adecuadamente la confidencialidad en todo momento.

- También puede hacer falta tomar imágenes, como fotos o videos. Sirven para documentar mejor el caso. También pueden usarse para fines docentes de difusión del conocimiento científico. En cualquier caso serán usadas si usted da su autorización. Su identidad siempre será preservada de forma confidencial.

001530

JUNTA DE ANDALUCIA CONSEJERÍA DE SALUD

1.2 IMÁGENES EXPLICATIVAS:

(En este espacio podrán insertarse con carácter opcional imágenes explicativas, esquemas anatómicos, pictogramas e que faciliten y permitan explicar de manera más sencilla la información al paciente.)

JUNTA DE ANDALUCIA CONSEJERÍA DE SALUD

CENTRO SANITARIO	SERVICIO DE OBSTETRICIA Y GINECOLOGÍA

2. CONSENTIMIENTO INFORMADO

(En el caso de INCAPACIDAD DEL/DE LA PACIENTE será necesario el consentimiento del/de la representante legal)

(En el caso del MENOR DE EDAD, cuando se considere que carece de madurez suficiente, el consentimiento lo darán sus representantes legales, aunque el menor siempre será informado de acuerdo a su grado de entendimiento y, si tiene más de 12 años, se escuchará su opinión. Si el paciente está emancipado o tiene 16 años cumplidos será él quien otorgue el consentimiento. Sin embargo, en caso de actuación de grave riesgo, según el criterio del facultativo, los representantes legales también serán informados y su opinión será tenida en cuenta para la decisión.)

2.1 DATOS DEL/DE LA PACIENTE Y DE SU REPRESENTANTE LEGAL (si es necesario)

APELLIDOS Y NOMBRE, DEL PACIENTE DNI / NIE

APELLIDOS Y NOMBRE, DEL/DE LA REPRESENTANTE LEGAL DNI / NIE

2.2 PROFESIONALES QUE INTERVIENEN EN EL PROCESO DE INFORMACIÓN Y/O CONSENTIMIENTO

APELLIDOS Y NOMBRE	FECHA	FIRMA
APELLIDOS Y NOMBRE	FECHA	FIRMA
APELLIDOS Y NOMBRE	FECHA	FIRMA
APELLIDOS Y NOMBRE	FECHA	FIRMA
APELLIDOS Y NOMBRE	FECHA	FIRMA

2.3 CONSENTIMIENTO

JUNTA DE ANDALUCIA CONSEJERÍA DE SALUD

Yo, D/Dña , manifiesto que esto
conforme con la intervención que se me ha propuesto. He leído y comprendido la información anterior. He
podido preguntar y aclarar todas mis dudas. Por eso he tomado consciente y libremente la decisión de
autorizarla. También sé que puedo retirar mi consentimiento cuando lo estime oportuno.

___SI ___NO Autorizo a que se realicen las actuaciones oportunas, incluyendo modificaciones en la form
de realizar la intervención, para evitar los peligros o daños potenciales para la vida o la salud, que pudiera
surgir en el curso de la intervención.
___SI ___NO Autorizo la conservación y utilización posterior de mis muestras biológicas para investigació
relacionada directamente con la enfermedad que padezco.
___SI___NO Autorizo que, en caso de que mis muestras biológicas vayan a ser utilizadas en otra
investigaciones diferentes, los investigadores se pongan en contacto conmigo para solicitarm
consentimiento.
___SI___NO Autorizo la utilización de imágenes con fines docentes o de difusión del conocimient
científico.
(NOTA: Márquese con una cruz.)

En a de de

EL/LA PACIENTE Consentimiento/Visto Bueno de EL/LA REPRESENTANTE LEGAL

Fdo.: Fdo.

CENTRO SANITARIO	SERVICIO DE OBSTETRICIA Y GINECOLOGÍA

2.4 RECHAZO DE LA INTERVENCIÓN

Yo, D/Dña. , no autorizo a la
realización de esta intervención. Asumo las consecuencias que de ello puedan derivarse para la
salud o la vida.

En a de de

EL/LA PACIENTE Consentimiento/Visto Bueno de EL/LA REPRESENTANTE LEGAL

Fdo.: Fdo.:

2.5 REVOCACIÓN DEL CONSENTIMIENTO

001530

JUNTA DE ANDALUCIA CONSEJERÍA DE SALUD

Yo, D/Dña , de forma libre y consciente he decidido retirar el consentimiento para está intervención. Asumo las consecuencias que de ello puedan derivarse para la salud o la vida.

En a de de

EL/LA PACIENTE Consentimiento/Visto Bueno de EL/LA REPRESENTANTE LEGAL

Fdo.: Fdo.:

12. 5. Sociedad Española de Fertilidad (SEF)

FECUNDACIÓN IN VITRO O MICROINYECCIÓN ESPERMÁTICA (FIV/ICSI) CON TRANSFERENCIA EMBRIONARIA Y CONGELACIÓN DE EMBRIONES

DOCUMENTO INFORMATIVO

SOCIEDAD ESPAÑOLA DE FERTILIDAD

I. ¿En qué consiste?

La **Fecundación in Vitro** es un tratamiento que consta de procedimientos médicos y biológicos destinados a facilitar la unión de óvulos (ovocitos) y espermatozoides en el laboratorio, y obtener embriones que serán introducidos en el útero para lograr la gestación.

La Fecundación in Vitro puede realizarse mediante dos procedimientos diferentes: **Fecundación in Vitro convencional o FIV**, en la que el óvulo y espermatozoide se unen de forma espontánea en el laboratorio; y la **Microinyección Espermática o ICSI**, en la que la fecundación se realiza inyectando un espermatozoide en cada óvulo.

De la fecundación se obtienen los **preembriones**, que son el grupo de células resultantes de la división progresiva del óvulo desde que es fecundado hasta 14 días más tarde. Sólo deben generarse un número de preembriones en cada ciclo reproductivo que, conforme a criterios clínicos, garantice posibilidades razonables de éxito reproductivo de cada caso. Un número limitado (entre 1 y 3) de los preembriones obtenidos será transferido al útero para conseguir la gestación. El resto de embriones viables, si lo hubiera, serán congelados para ser destinados a los fines legalmente establecidos.

II. ¿Cuáles son las indicaciones?

Las indicaciones más frecuentes son:

- Trastornos de la fertilidad:
  - Ausencia, obstrucción o lesión de las trompas.
  - Disminución del número y/o movilidad de los espermatozoides o aumento de las alteraciones morfológicas de los mismos.
  - Endometriosis moderada o severa.
  - Alteraciones de la ovulación.
  - Fracaso de otros tratamientos.
  - Edad avanzada
  - Otras.
- Diagnóstico genético preimplantacional.

III. Procedimientos

La **Fecundación in Vitro y la Microinyección Espermática** comienzan habitualmente con la **estimulación de los ovarios** mediante el uso de fármacos, cuya acción es similar a la de ciertas hormonas producidas por la mujer. Los medicamentos empleados incluyen un prospecto que el paciente debe consultar, teniendo la posibilidad de solicitar al personal sanitario del Centro cualquier aclaración al respecto. La finalidad de este tratamiento es obtener el desarrollo de varios folículos, en cuyo interior se encuentran los óvulos. Con el fin de evitar la ovulación espontánea se asocian otros medicamentos con acción hormonal.

El proceso de estimulación ovárica se controla habitualmente con **análisis en sangre de los niveles de ciertas hormonas ováricas** y/o **ecografías vaginales** que informan del número y tamaño de los **folículos** en desarrollo. Si se obtiene el desarrollo adecuado, se administran otros medicamentos para lograr la maduración final de los óvulos.

Muchos de los medicamentos utilizados son inyectables, y su presentación permite la autoadministración por la paciente. Las dosis y pautas de administración se adaptan a las características clínicas de cada paciente, y la respuesta al tratamiento puede ser variable. Ocasionalmente se utilizan de forma asociada otros tipos de medicamentos.

Los óvulos se extraen mediante **punción de los ovarios** y **aspiración** de los folículos, bajo visión ecográfica y por vía vaginal. Esta intervención es realizada habitualmente en régimen ambulatorio y requiere **anestesia** y observación posterior durante un periodo variable.

Los **óvulos** (ovocitos) obtenidos se preparan y clasifican en el laboratorio. El número de óvulos que se extraen en la punción su madurez y calidad no puede predecirse con exactitud.

Una vez obtenidos los óvulos, el laboratorio deberá disponer de los **espermatozoides** procedentes de la pareja, o de u donante anónimo, en los casos que así proceda. El semen se prepara en el laboratorio con el fin de seleccionar lo espermatozoides más adecuados para la fecundación.

Si se realiza **Fecundación in Vitro (FIV)**, los óvulos y espermatozoides se cultivarán en el laboratorio conjuntamente e condiciones favorables para su unión espontánea (fecundación).

Si se realiza **Microinyección Espermática (ICSI)**, se inyectará un espermatozoide dentro de cada uno de los óvulos madur que se hayan recuperado.

Al día siguiente de la FIV o ICSI se determinará el número de **óvulos fecundados** y en los días sucesivos de cultivo s valorará el número y la calidad de los preembriones que continúen su desarrollo. Los preembriones se mantendrán en laboratorio por un periodo de 2 a 6 días tras los que se procederá a la **transferencia.**

La **transferencia embrionaria** consiste en el depósito de los embriones en la cavidad uterina a través de la vagina. Es u procedimiento ambulatorio que habitualmente no precisa anestesia ni ingreso. Con la finalidad de favorecer la implantació embrionaria se prescribe también un tratamiento hormonal.

El número de preembriones transferidos al útero no puede ser superior a tres en un ciclo, por mandato legal. Los paciente recibirán del equipo biomédico la información necesaria para decidir el número de embriones que se deben transferi con el fin de obtener el embarazo y evitar en lo posible la gestación múltiple.

Finalmente, en caso de existir **preembriones viables sobrantes** de un ciclo de Fecundación in Vitro se preservarán median congelación. **Los posibles destinos de los preembriones criopreservados se detallan en el apartado de información lega de este documento informativo (apartado VIII).**

En algunos casos, las técnicas habituales de FIV e ICSI pueden complementarse con otros procedimientos sobre lo gametos o embriones destinados a mejorar la capacidad de implantación embrionaria (eclosión asistida, extracció de fragmento, etc).

IV. Resultados

Los factores que condicionan la probabilidad de gestación son: la causa de la esterilidad, la edad de la paciente, el numer de ovocitos obtenidos y de embriones finales de buena calidad.

Sin embargo, hay que tener presente que no todas las pacientes que inician el tratamiento logran el desarrollo folicul adecuado para ser sometidas a la punción, y ni todas las pacientes con punción ovárica tienen transferencia de embrione ya que en algunos casos fracasa la obtención de óvulos, la fecundación o el desarrollo embrionario precoz. Por ello, resultado del tratamiento se puede expresar como porcentaje de gestaciones sobre el total de ciclos iniciados, sobre ciclo con punción folicular y sobre ciclos con transferencia.

El Registro FIV/ICSI de la Sociedad Española de Fertilidad del año 2005 refería unas tasas de embarazo del 30.1% po ciclo iniciado, 33.9% por punción y 38.1% por transferencia.

El 80% de las gestaciones se obtienen en los tres primeros ciclos de FIV/ICSI con transferencia embrionaria satisfactori por lo que el fracaso hace necesario discutir con el equipo asistencial la conveniencia de emprender más tratamiento Entre un 40% y 60% de los pacientes obtienen embriones aptos para preservar mediante congelación, teniendo en cuent que solo serán congelados aquellos con características biológicas de viabilidad.

De estos embriones congelados, un 50-70% sobreviven tras la descongelación y son válidos para su transferencia a l cavidad uterina. La tasa de embarazo por transferencia de embriones congelados en el Registro FIV/ICSI de la Sociedad Española de Fertilidad del año 2005 es el 21.1 % por descongelación y 25.7% por transferencia.

V. Riesgos

Los principales riesgos de este procedimiento terapéutico son:

1) **Embarazo múltiple:** El riesgo de embarazo múltiple está relacionado con la edad de la mujer, el número de embriones transferidos al útero y la calidad de los mismos. En pacientes jóvenes y con embriones de buena calidad, la conducta más recomendable es transferir uno o dos embriones en los primeros intentos. La transferencia de tres embriones se suele indicar en pacientes de edad avanzada sin embriones de buena calidad, o ante fracaso de transferencias previas de menor número de embriones. En el Registro de la Sociedad Española de Fertilidad de 2005 la tasa de embarazos múltiples es del 26.1% con embriones frescos y 18.2% con congelados.

   La gestación de dos o más fetos supone un aumento de los riesgos médicos para la madre y los niños, tales como incremento de la patología del embarazo, prematuridad, bajo peso al nacimiento y complicaciones neonatales severas. La gravedad de esta complicación se incrementa de manera paralela al número de fetos.

   La gestación múltiple se acompaña igualmente de un aumento de las dificultades sociales, económicas y laborales de los padres.

2) **Síndrome de hiperestimulación ovárica:** En ocasiones, la respuesta ovárica al tratamiento es excesiva, se desarrolla un gran número de folículos, aumenta el tamaño ovárico y se eleva considerablemente la cantidad de estradiol en sangre. Además, el desarrollo de este síndrome tiene relación directa con la administración del fármaco necesario para la maduración final de los ovocitos (HCG) y la consecución de embarazo.

   Se clasifica en leve, moderada y severa, siendo esta última excepcional (menos de un 2 %) y se caracteriza por acumulación de líquido en el abdomen e incluso en el tórax, así como por alteraciones de la función renal y/o hepática. En casos críticos se puede asociar a insuficiencia respiratoria o alteraciones de la coagulación.

   Puede precisar hospitalización y tratamiento médico-quirúrgico y sólo excepcionalmente se hace aconsejable la interrupción del embarazo.

3) **Embarazo ectópico.** Consiste en la implantación del embrión fuera del útero, habitualmente en las trompas. Excepcionalmente puede coexistir con un embarazo situado en el útero. Se produce en un 3 % de los casos.

4) **Aborto:** La incidencia de abortos es discretamente superior a la observada en embarazos espontáneos (15.5% con embriones frescos y 30.1% con congelados en el Registro SEF de 2005).

5) **Edad avanzada, el consumo de tabaco y las alteraciones importantes del peso corporal** aumentan el riesgo de complicaciones durante el tratamiento, embarazo y para la descendencia, requieren adaptaciones en el tratamiento necesario para la estimulación ovárica y reducen las tasas de éxito.

6) **Defectos congénitos y alteraciones cromosómicas de los hijos:** los datos actuales sugieren que en los niños nacidos de FIV/ICSI puede incrementarse ligeramente el riesgo de anomalías congénitas y cromosómicas, sin que se haya podido establecer con exactitud la causa de este aumento. Por ello puede ser aconsejable realizar técnicas de diagnóstico prenatal como ecografías, amniocentesis o biopsia de corion.

7) **Riesgos psicológicos.** Pueden aparecer trastornos psicológicos como síntomas de ansiedad y síntomas depresivos, tanto en el hombre como en la mujer. En algunos casos, pueden surgir dificultades en la relación de pareja (sexual y emocional) y niveles elevados de ansiedad en el período de espera entre la aplicación de la técnica y la confirmación de la consecución o no del embarazo, así como ante los fallos repetidos de la técnica.

8) **Riesgos de la anestesia** que se detallan en el consentimiento informado específico.

9) **Otros riesgos y complicaciones** que excepcionalmente se pueden producir:
   a) Reacciones adversa o intolerancia a la medicación.
   b) Infección peritoneal.
   c) Complicaciones de la punción folicular.
      * Hemorragia grave por punción accidental de vasos sanguíneos o del propio ovario.
      * Punción de un asa intestinal u otras estructuras.
   d) Torsión ovárica.
   e) Cancelación de la estimulación ovárica por ausencia o inadecuado desarrollo folicular o por excesiva respuesta a los tratamientos.

   f) No obtención de óvulos en la punción.
   g) No realización de la transferencia por:
      * Óvulos no adecuados para fecundación.
      * Ausencia de fecundación.
      * No obtención de embriones normales o viables.
      * Imposibilidad física de la transferencia por alteraciones anatómicas del útero.

VI. Riesgos Personalizados:

Las características médicas, sociales o laborales de cada paciente pueden suponer una modificación de los riesgos generales o aparición de riesgos específicos.

VII. Información económica (si procede)

Los precios que rigen en este centro se detallan en presupuesto adjunto, significándose la imposibilidad de concretar previamente de forma exacta el coste total, debido a que los tratamientos varían en cada paciente y, muy especialmente, en función de la respuesta a la estimulación ovárica de cada mujer.

El coste económico del mantenimiento de la congelación embrionaria deberá ser asumido por los pacientes, sea cual sea la decisión sobre el destino de los mismos.

VIII. Aspectos legales relacionados con la reproducción asistida

1.- De carácter general

El marco jurídico regulador de la reproducción humana asistida está constituido básicamente por la **Ley 14/2006 sobre Técnicas de Reproducción Humana Asistida.**

Las técnicas de reproducción asistida tienen como objetivo principal la solución de los problemas de esterilidad humana, para facilitar la procreación, cuando otras terapéuticas se hayan descartado por inadecuadas o ineficaces.

También pueden utilizarse en la prevención y tratamiento de enfermedades de origen genético o hereditario, cuando sea posible recurrir a ellas con suficientes garantías diagnósticas y terapéuticas y estén estrictamente indicadas.

Sólo pueden llevarse a cabo cuando haya posibilidades razonables de éxito y no supongan riesgo grave para la salud física o psíquica de la mujer o de la posible descendencia; y siempre en mujeres mayores de edad, con plena capacidad de obrar, con independencia de su estado civil y orientación sexual, que deben haber sido anterior y debidamente informadas de sus posibilidades de éxito, así como de sus riesgos y de las condiciones de dicha aplicación.

La mujer receptora de las técnicas podrá pedir que se suspendan en cualquier momento de su realización anterior a la transferencia embrionaria, debiendo atenderse su petición.

Cuando la mujer esté casada, se requerirá además el consentimiento del marido, a menos que estuvieran separados legalmente o de hecho y así conste fehacientemente. Si se trata de una pareja no casada, el consentimiento del varón será obligatorio si se usan sus espermatozoides en el tratamiento y voluntario si recurre al uso de semen de donante. En este último caos, si lo presta con anterioridad a la utilización de las técnicas, dicho consentimiento determinará la filiación paterna de la futura descendencia.

La mujer soltera, la viuda y la separada legalmente o de hecho, pueden ser receptoras o usuarias de las técnicas de reproducción asistida a título personal, valiéndose de semen procedente de donante, siempre que tengan más de 18 años, plena capacidad de obrar y hayan prestado su consentimiento escrito de manera libre, consciente y expresa.

2.- Información para el caso de utilización de gametos o embriones procedentes de donante

La donación de gametos y preembriones es un contrato gratuito, formal y confidencial concertado entre el donante y el centro autorizado. Tanto el banco de gametos, como los registros de donantes y de actividad de los centros, tienen obligación de garantizar la confidencialidad de los datos de identidad de los donantes.

Sin perjuicio de ello, las receptoras y los hijos nacidos tienen derecho a obtener información general de los donantes, que no incluya su identidad. Asimismo, en circunstancias extraordinarias que comporten peligro cierto para la vida o la salud del nacido, o cuando proceda de acuerdo con las leyes procesales penales, podrá revelarse la identidad de los donantes, con carácter restringido y sin que ello modifique nunca la filiación establecida previamente.

La elección de los donantes sólo puede realizarse por el equipo médico que aplica la técnica, y en ningún caso a petición de la receptora o la pareja. No obstante lo anterior, en todo caso el equipo médico deberá procurar la mayor similitud fenotípica e inmunológica posible con la mujer receptora.

Los donantes de los que procede el material genético han de tener más de 18 años, buen estado de salud psicofísica y plena capacidad de obrar. Su estado psicofísico debe cumplir las exigencias de un protocolo obligatorio de estudio de los donantes, que incluya sus características fenotípicas y psicológicas, así como las condiciones clínicas y determinaciones analíticas necesarias para demostrar que no padecen enfermedades genéticas, hereditarias o infecciosas transmisibles a la descendencia. A tal efecto se seguirá lo dispuesto en el R.D. 1301/2006.

Ni la mujer progenitora ni el marido, cuando hayan prestado su consentimiento formal, previo y expreso a determinada fecundación con contribución de donante o donantes, podrán impugnar la filiación matrimonial del hijo nacido como consecuencia de tal fecundación. De igual forma ocurrirá en estos casos con el varón no casado que hubiera firmado el consentimiento informado con anterioridad a la utilización de las técnicas.

3.- Sobre el destino de los embriones sobrantes criopreservados

Los **preembriones viables sobrantes** de un ciclo de fecundación in Vitro se criopreservarán en nitrógeno líquido, pues no todos los embriones no transferidos son aptos para la congelación. El destino posterior de los preembriones congelados puede ser:

a) La utilización por la propia mujer o, en su caso, su cónyuge femenino.
b) La donación con fines reproductivos.
c) La donación con fines de investigación.
d) El cese de su conservación sin otra utilización.

La **utilización por la propia mujer o su cónyuge** podrá efectuarse en cualquier momento mientras la mujer reúna los **requisitos clínicamente adecuados** para la realización de la técnica de reproducción asistida (lo que constituye el plazo máximo de conservación). En caso de pareja separada, si la mujer deseara utilizarlos para su reproducción personal habría de contar con el consentimiento del ex-marido para la nueva transferencia que hubiera de realizarse, ya que los hijos serían de ambos.

En la **donación con fines reproductivos** los embriones son donados a parejas estériles que los necesitan. La donación es **voluntaria, gratuita, anónima y altruista** y precisa de un **consentimiento escrito específico previo**. Las receptoras y los hijos nacidos tienen derecho a obtener información general de los donantes, que no incluya su identidad. En circunstancias extraordinarias que comporten peligro cierto para la vida o la salud del nacido, o cuando proceda de acuerdo con las leyes procesales penales, podrá revelarse la identidad de los donantes, con carácter restringido y sin que ello modifique nunca la filiación establecida previamente.

En la **donación con fines de investigación** los embriones se ceden de forma altruista para proyectos de investigación biomédica en centros especialmente autorizados y con proyectos concretos también autorizados. El ejercicio efectivo de esta opción conllevará la suscripción de un consentimiento adicional y específico en el que se expliquen los fines que se persigan con la investigación y sus implicaciones.

El **cese de su conservación sin otra utilización**, que en el caso de los preembriones y los ovocitos crioconservados sólo será aplicable una vez finalizado el **plazo máximo de conservación** establecido en la Ley sin que se haya optado por alguno de los destinos mencionados en los apartados anteriores. La crioconservación de los ovocitos, del tejido ovárico y de los preembriones sobrantes se podrá prolongar hasta el momento en que se considere por los responsables médicos, con el dictamen favorable de especialistas independientes y ajenos al centro correspondiente, que la receptora no reúne los requisitos clínicamente adecuados para la práctica de la técnica de reproducción asistida.

4.- Obligación de renovación del consentimiento respecto de los embriones criopreservados

Cada **dos años** como mínimo se solicitará de la mujer o de la pareja progenitora la **renovación o modificación del consentimiento**. Si al vencimiento de dos periodos de conservación consecutivos fuera imposible obtener de la mujer o la pareja progenitora la renovación del consentimiento correspondiente, habiendo sido previamente requerida por el centro de forma fehaciente (burofax con acuse de recibo, carta certificada con acuse de recibo, telegrama con acuse de recibo, carta notarial, etc.), los preembriones **quedarán a disposición de este centro**, que podrá destinarlos a cualquiera de los fines citados en el apartado 3, manteniendo las exigencias de confidencialidad y anonimato establecidas, así como la gratuidad y ausencia de ánimo de lucro.

5. En relación con la posibilidad de tener un hijo póstumo

En caso de fallecimiento del varón, sólo podrá determinarse legalmente la filiación si el material reproductor de éste se encontrase en el útero de la mujer en la fecha de la muerte, excepto si el marido o el varón no unido por matrimonio hubiesen prestado su consentimiento en el documento de consentimiento informado de las técnicas, en escritura pública, testamento o documento de instrucciones previas, para que su material reproductor pueda ser utilizado en los doce meses siguientes a su fallecimiento para fecundar a su mujer. Este consentimiento podrá ser revocado en cualquier momento con anterioridad a la realización de las técnicas.

Asimismo, previene la ley de reproducción que se entenderá otorgado el consentimiento del varón fallecido a la fecundación post mortem de su mujer (tanto si es pareja casada o no), cuando ésta hubiera estado sometida a un proceso de reproducción asistida ya iniciado para la transferencia de preembriones constituidos con anterioridad a la fecha de fallecimiento del marido. *Desde el punto de vista médico, se considera iniciado el tratamiento cuando la paciente recibe la primera dosis de la medicación necesaria para el procedimiento.*

IX. Alternativas ante el fracaso de la técnica

Si después de haber realizado uno o varios intentos de fecundación in vitro o microinyección espermática no se ha conseguido el embarazo, puede ser aconsejable adoptar, tras la oportuna reflexión, alguna de las siguientes alternativas:

- Volver a iniciar el tratamiento.
- Profundizar en estudios complementarios.
- Aplicar modificaciones a la técnica utilizada.
- Realizar un diagnóstico genético preimplantacional (DGP).
- Realizar nuevos tratamientos con gametos donados (óvulos y/o espermatozoides).
- Utilizar embriones donados.
- Desistir de los tratamientos de reproducción asistida.

El contenido del presente documento refleja el estado actual del conocimiento, y por tanto, es susceptible de modificación en caso de que así lo aconsejen nuevos hallazgos o avances científicos.

En _____ a ____ de _____ de _____

Fdo. El/La Médico/a (Col.nº _____) *Fdo. Dª.* *Fdo. D.*

FECUNDACIÓN IN VITRO O MICROINYECCIÓN ESPERMÁTICA (FIV/ICSI), CON TRANSFERENCIA Y CONGELACIÓN EMBRIONARIA

DOCUMENTO DE CONSENTIMIENTO

SOCIEDAD ESPAÑOLA DE FERTILIDAD

Dña._____

mayor de edad, con DNI/Pasaporte nº_____, estado civil _____, y

D/Dña._____

mayor de edad, con DNI/Pasaporte nº _____, estado civil _____, y

con domicilio en la Ciudad de _____,

calle_____ nº _____ C.P._____

País _____, concurriendo como (matrimonio/pareja de hecho/mujer sin pareja)_____

DECLARO/DECLARAMOS:

1) Tener plena capacidad de obrar.
2) En este acto, de manera libre, consciente y expresa, presto/prestamos nuestro consentimiento escrito a la utilización de técnicas de reproducción asistida:
   - □ Con semen de la PAREJA.
   - □ Con semen de DONANTE.
3) Haber recibido, anteriormente a este acto, información verbal y escrita, esta última a través del "***Documento Informativo sobre Fecundación In Vitro o Microinyección Espermática (FIV/ICSI), con Transferencia Embrionaria y Congelación de Embriones***", el cual ha sido leído, comprendido y suscrito. En consecuencia, he/hemos recibido información sobre las siguientes cuestiones:
   - — Información y asesoramiento sobre las técnicas de reproducción asistida en sus aspectos biológicos, jurídicos y éticos. En caso de utilizar semen de donante, también sobre su utilización y en especial, sobre la relevancia jurídica de la firma de este consentimiento informado por el marido o varón no casado en orden a la determinación con el mismo de la filiación paterna respecto de la descendencia que se consiga, que será considerada legalmente como propia a todos los efectos.
   - — La indicación, procedimiento, probabilidades de éxito, riesgos, contraindicaciones y complicaciones del tratamiento propuesto y de la medicación empleada.
   - — La disposición del personal sanitario para ampliar cualquier aspecto de la información que no haya quedado suficientemente aclarado.
   - — Los destinos de los posibles embriones viables que quedarán criopreservados en el banco del centro por no haber sido transferidos al útero en el ciclo de tratamiento.
   - — Los posibles riesgos que se pueden derivar de la maternidad a una edad clínicamente inadecuada, tanto para la mujer durante el tratamiento y el embarazo, como para la descendencia.
   - — La obligación de renovar o modificar periódicamente nuestro consentimiento respecto de los embriones criopreservados, así como de comunicar al centro cualquier cambio de domicilio o circunstancia personal que pueda afectar a su destino (separación, fallecimiento o incapacidad sobrevenida de uno de los cónyuges, etc.).
   - — Información relativa a las condiciones económicas del tratamiento.
4) Que, según el equipo médico, para mi/nuestro proyecto reproductivo, es adecuado un tratamiento de reproducción asistida a través de la técnica denominada: Fecundación in Vitro con _____ y dentro de las alternativas de tratamiento expuestas, he/hemos comprendido que la técnica más adecuada en nuestro caso es la que aquí consentimos.
5) Conocer que, en cualquier momento anterior a la transferencia embrionaria, puedo/podemos pedir que se suspenda la aplicación de las técnicas de reproducción asistida, y que dicha petición deberá atenderse.
6) El equipo médico me/nos ha informado también de los siguientes riesgos relacionados con nuestras circunstancias personales: _____.
   Además, he/hemos sido informado/s de la conveniencia de consultar el prospecto de los medicamentos prescritos para conocer con más detalle los posibles riesgos asociados a su utilización, sin perjuicio de poder también solicitar las aclaraciones adicionales que estime convenientes al equipo médico.
7) Autorizo/Autorizamos y consiento/consentimos la transferencia de un máximo de _____ (uno, dos ó tres) embriones.
8) Respecto a la posibilidad de generar embriones que no vayan a ser transferidos al útero en el mismo ciclo y **en base a nuestro proyecto reproductivo de futuro**: (marque lo que proceda)
   - □ Deseo/deseamos **que se generen TODOS los embriones posibles** como consecuencia de la inseminación o microinyección de todos los ovocitos obtenidos, asumiendo la obligación de congelar los embriones viables no transferidos, y consentimos la misma.
   - □ Deseo/deseamos **que se genere un NÚMERO LIMITADO de embriones**, consecuencia de la inseminación o microinyección de..... (número) ovocitos, asumiendo la obligación de congelar los embriones viables no transferidos. El resto de ovocitos serán:
     - O Vitrificados
     - O Desechados
   - □ Deseo/deseamos **que NO se genere NINGÚN EMBRIÓN** que no vaya a ser transferido, por lo que autorizo/autorizamos la inseminación o microinyección de un máximo de..... (número) ovocitos. El resto de ovocitos serán:
     - O Vitrificados
     - O Desechados
9) Que el destino que deseo/deseamos dar a los posibles ovocitos y/o preembriones congelados sobrantes sería (marcar lo que proceda):
   - □ Uso propio, es decir utilización por la propia pareja, mujer o, en su caso, su cónyuge femenino.
   - □ Donación con fines reproductivos (*si la mujer es ≤ 35 años*).
   - □ Donación con fines de investigación (*en base a un proyecto debidamente presentado y autorizado por las autoridades sanitarias competenies, previo informe favorable del órgano competente y consentimiento escrito de la pareja o de la mujer*).
   - □ Cese de su conservación sin otra utilización al finalizar el plazo máximo de conservación (*cuando la receptora no reúna los requisitos clínicamente adecuados para realizar la técnica de reproducción asistida*).

Me comprometo/nos comprometemos a acudir a la clínica para formalizar la renovación o cambio de destino del material criopreservado (ovocitos, espermatozoides o embriones) y asumir en todo caso el coste económico del material criopreservado durante el tiempo que aquél esté depositado en el centro.

10) He/Hemos comprendido toda la información que considero/consideramos adecuada y suficiente, por parte del Dr./Dra._____.

Firma de los interesados

11) De igual forma en la consulta médica he/hemos afirmado:

- No padecer enfermedades congénitas, hereditarias o infecciosas transmisibles con riesgo grave para la posible descendencia.
- No haber omitido o falseado ningún dato de tipo médico o legal que pudiera incidir en el tratamiento o sus consecuencias.
- Comprometerme/Comprometernos a notificar al centro los cambios de circunstancias personales (defunción, separación, divorcio,…).
- Obligarme/Obligarnos a comunicar los cambios de domicilio en caso de existir embriones congelados.

Y una vez debidamente informada/os,

AUTORIZO/AUTORIZAMOS:

A la aplicación de los procedimientos de tratamiento y control necesarios para el tratamiento de Fecundación in Vitro (FIV) / Microinyección Espermática (ICSI), transferencia de embriones y congelación embrionaria si procede.

El contenido del presente documento refleja el estado actual del conocimiento, y por tanto, es susceptible de modificación en caso de que así lo aconsejen nuevos hallazgos o avances científicos.

Según lo establecido en la Ley Orgánica 15/1999, de protección de datos de carácter personal, sus datos de carácter personal y sanitario quedarán registrados en un fichero propiedad del centro _____, pudiendo ser utilizados y cedidos única y exclusivamente a los efectos de la actuación encargada, gozando de los derechos de acceso, rectificación, cancelación y oposición. Todos los datos que se derivan del proceso quedarán reflejados en la correspondiente historia clínica, que será custodiada en las instalaciones de la entidad para garantizar su correcta conservación y recuperación.

NOTA: La clínica hará todo lo posible para mantener el almacenaje de las células/tejidos en condiciones óptimas, pero no se hará responsable de la pérdida de viabilidad de los mismos debido a desastres naturales u otras emergencias que estén fuera del control de la clínica. Debe conocer que sus embriones podrían ser trasladados a una localización alternativa en caso de una situación de emergencia (inundaciones, disturbios, fuego, situaciones violentas –armas-, amenazas/ataques terroristas, gas u otras explosiones, terremotos, etc).

En_____ a _____ de _____de 20_____

Fdo. ..... Fdo. .....

D.N.I. ..... D.N.I. .....

Fdo. .....

D.N.I. .....

(El Director del CENTRO o delegado)

ANEXO para el esposo/pareja o para el varón no casado:

D_____, mayor de edad, provisto de DNI nº_____ en este acto presto mi consentimiento a que en el caso de que falleciera con anterioridad a que mi material reproductor se halle en el útero de Dña_____ _____, pueda ésta, en los 12 meses siguientes a mi fallecimiento, proceder a fecundarse con el mismo, y que se determine la filiación del hijo nacido conmigo.

En _____ a ____ de _____ de _____

Fdo. D/Dª._____

Firma del Médico

ANEXO para la VARIACIÓN del destino de los embriones criopreservados

Dña_____, mayor de edad, provista de DNI/pasaporte nº_____ y domicilio en la calle/plaza _____ de _____,
D._____, mayor de edad, provisto de DNI/pasaporte nº_____ y domicilio en la calle/plaza _____ de _____,

en este acto solicitamos la modificación del destino de nuestros embriones sobrantes / criopreservados y consentimos en que el nuevo destino sea:

- O Utilización por la propia mujer.
- O Donación con fines reproductivos (*si la mujer es ≤ 35 años*).
- O Donación con fines de investigación (*en base a un proyecto debidamente presentado y autorizado por las autoridades sanitarias competentes, previo informe favorable del órgano competente y consentimiento escrito de la pareja o de la mujer*).
- O Cese de su conservación sin otra utilización una vez finalizado el plazo máximo de conservación (*cuando la receptora no reúna los requisitos clínicamente adecuados para realizar la técnica de reproducción asistida*).

Me comprometo/nos comprometemos a acudir a la clínica para formalizar la renovación o cambio de destino del material criopreservado (ovocitos, espermatozoides o embriones), y a asumir en todo caso el coste económico de la criopreservación durante el tiempo que aquél esté depositado en el centro.

En _____ a ____ de _____ de _____

Fdo. Dña _____Fdo. D _____

Firma del Médico:

ANEXO para la REVOCACION del presente consentimiento

D/Dña_____ _____, mayor de edad, provista de DNI/pasaporte nº_____ y domicilio en la calle/plaza _____ _____ de _____, en este acto solicito la SUSPENSIÓN de la aplicación de la técnica de reproducción asistida a la que me estoy sometiendo.

Fdo. D/Dña _____

Firma del Médico: