Egg Donation
Process, Risk, Consent and Agreement

Donor Egg (DE) therapy has become an established treatment for infertility due to egg problems or certain genetic issues. The main goal of DE is to allow a patient the opportunity to become pregnant using eggs from a donor 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.

Egg Donation Process

Donor Screening

Potential egg donors undergo careful screening for genetic, psychological, hormonal and physical screening before being accepted as an egg donor. This screening process involves several office visits over a month or more to assess these factors.

Ovarian Stimulation

- Injections of the natural hormones FSH and/or LH (gonadotropins) are used to cause a group of eggs to develop to maturity.
- Additional medications are used to prevent premature ovulation
- An overly vigorous ovarian response can occur, or conversely an inadequate response

- “Fertility drugs” are used to stimulate the ovary in hopes of inducing the simultaneous growth of several oocytes (eggs) over the span of 8 or more days. Monitoring of your ovaries’ response by ultrasound is important. A typical pattern of office visits is shown below:
This process does not cause you to run out of eggs sooner in the future. The eggs that are induced to grow by these medications were already ‘linked’ to this cycle and would have been lost anyway had they not been induced to grow.

**Egg Retrieval**

- Eggs are removed from the ovary with a needle under ultrasound guidance
- Anesthesia is provided to make this comfortable
- Complications are rare

A transvaginal ultrasound probe is used to visualize the ovaries and the egg-containing follicles within the ovaries. A long needle is guided into each follicle and the contents aspirated. The aspirated material includes the egg.

For the egg donor, the retrieval is the last step. In about 2 weeks, your normal period will begin, and by that time your ovaries will often be back to normal size.

**Anesthesia:** Anesthesia will be administered by an anesthesiologist through your I.V. Anesthesia is rarely associated with unanticipated complications. These include, but are not limited to, allergy or anaphylaxis, IV problems, nausea, vomiting and aspiration, cardiac or pulmonary problems, neurological issues, and death. Your anesthesiologist will be with you throughout the procedure and treat any untoward event that may occur.

**Next**

Your eggs then become the property of the Recipient, to be used by her for procreation. Sperm are placed with your eggs, and one or two of the resulting embryos are transferred into a uterus (either hers or a gestational carrier’s). Extra embryos
can be frozen for later use. In some cases, the recipient is not yet identified at the time your eggs are removed; instead, your eggs can be frozen and stored to be used by someone to have a baby in the future.

Consent to Donate Eggs

Date: __________________________

Egg Donor Last Name: ______________________________ First Name: __________________

Date of Birth: ______________________________

Address: ______________________________________

____________________________________

Please check the appropriate choice and initial:

- The Pacific Fertility Center - Los Angeles may determine the recipient(s) (the person or persons who will receive the eggs) of these eggs.
  Donor’s initials: __________

- I designate the individual’s listed below as the recipient(s) of these eggs.
  Designee____________________________________________________________
  Donor’s initials: __________

I, the undersigned, request, authorize and consent to the donation of my eggs to Pacific Fertility Center - Los Angeles, and as appropriate, its employees, contractors, consultants and authorized agents, for use by an infertile couple or individual in their attempts to achieve a pregnancy.

How will the eggs be used?

I understand, agree and consent that the selection of the recipient will be determined at the sole discretion of the Pacific Fertility Center - Los Angeles, and as appropriate, its employees, contractors, and consultants, unless I have listed a specific designated recipient couple or individual below.

I understand, agree and consent that the eggs that I donate may be used fresh or frozen by the recipient (the couple or individual (female or male) who is using the eggs) and that once they have been retrieved, that I will have no further control over these eggs. The recipient may use them in any way they think is appropriate, and because of
confidentiality issues, I will not be notified of how they are used. I understand that the recipient may decide to discard the eggs, donate them to research or donate them to someone else in the future and that I will not be notified of that decision or asked for my approval. I understand that the eggs may first be frozen and stored in an Egg Bank before being used by a recipient, and that the recipient may not yet be identified at the time of my donation. Moreover, several different recipients may receive my eggs.

The recipient may decide to donate the eggs or embryos to research, including stem cell research. Neither I (the egg donor) nor the recipient of my eggs will receive any information about subsequent testing on the embryo or the resulting stem cells. Stem cell and cell lines may be kept for many years. It is possible the donated material may have commercial potential, but the donor will receive no financial or other benefit from any future commercial development. Stem cell research is not intended to provide direct medical benefit to the embryo donor. Embryos donated for research will not be transferred to a woman’s uterus, nor will the embryos survive the human pluripotent stem cell derivation process.

If I am not comfortable with unrestricted use described above, I may not be permitted to donate my eggs.

Non-Viable Eggs. I understand that some non-viable eggs may be used as a teaching aide for laboratory personnel before being discarded. We (I) understand that non-viable eggs and embryos will be discarded according to ASRM Ethical Guidelines.

Cells and Biological Materials that Would Normally Be Discarded. I understand that some cells (such as granulosa cells which are cells from the ovary that are retrieved along with eggs) and biological materials such as follicular fluid (the fluid that the egg is found in), which are normally discarded, may be used for research studies. These materials would never be used for any procedures that involve fertilization or creation of an embryo or a cell line without my written consent in advance. When these studies are completed, the materials will be discarded.

Research Use of Viable Eggs, I understand that the viable eggs will not be used for any research without my express written consent in advance. I understand that I would be asked to sign a separate consent to donate my eggs to research instead of donating them for use to produce a pregnancy.

Description of the Procedure:
The following is a general outline of the steps that may be required in the process of egg donation. I consent to the performance of these steps:

1. Complete history and physical examination, which will include questions about my age, medical, psychological, genetic and sexual history and my family medical and genetic history.
2. Administration of fertility drugs including but not limited to Gonal-F®, Menopur®, Bravelle®, Follistim® (also called gonadotropins) and other medications including but not limited to oral contraceptive pills (OCPs), GnRH agonists, GnRH antagonists (including but not limited to ganirelix and Cetrotide®), and hCG, to mature the eggs. Some of these drugs require daily injections.
3. The use of blood tests to monitor hormone levels, often on a daily basis.
4. Ultrasound examinations of the ovaries to monitor growth of the developing follicles. Ultrasonography is a diagnostic procedure using sound waves that provides a ‘picture’ of the ovaries and the growing follicles. This procedure may need to be performed daily.
5. Strict adherence to the medication injection and monitoring (blood tests and ultrasounds) schedule prescribed by the physicians.
6. Retrieving the eggs using ultrasound guided transvaginal egg retrieval. This procedure utilizes anesthesia and the insertion of a needle, through the vaginal wall, into the ovary (ovaries) to obtain the eggs.
7. The eggs may be used fresh or may be frozen for later use by the recipient (the couple or individual who is receiving the egg donation).
8. The use of antibiotics to reduce the risk of infection after the egg retrieval.
9. Federally mandated screening and testing for infectious diseases performed within 30 days of the egg retrieval.
10. Use of a condom throughout the treatment cycle to avoid pregnancy and possible disease transmission.
11. Abstain from any high impact activities starting from the day you start fertility hormone injections and until two weeks after egg retrieval.
12. Abstain from the use of any illicit drugs during the treatment process.

Situations that could make egg donation impossible

There are a number of reasons egg donation may not be possible:
1. Despite the fact that all instructions are followed faithfully, the ovaries may not respond to the medication and there may not be enough eggs developing and the cycle may need to be canceled before the egg retrieval. The ovaries may respond too well to the medications and this could lead to a potentially serious complication known as ovarian hyperstimulation syndrome (OHSS) and so the cycle may need to be cancelled before the egg retrieval.
2. Ovulation (release of the eggs) may occur spontaneously before the eggs can be retrieved.
3. In rare cases, no eggs may be retrieved.
4. The eggs may not be normal.
5. Infectious disease testing performed within 30 days of the retrieval may be positive.

Risks of Egg Donation

The following are risks and discomforts associated with this procedure:
1. Blood drawing and medication injections- mild discomfort and a risk of developing a bruise at the needle site.
2. Fertility drugs and other medications used to stimulate the ovaries may cause:
   a) Hyperstimulation - The fertility drugs/medications previously described may cause excessive ovarian enlargement (“hyperstimulation”), which may cause discomfort (because more than one follicle is growing). Hyperstimulation may result in ovarian enlargement requiring therapy including hospitalization and possible surgery with removal of an ovary.
   b) Cyst formation - The medications described above may result in large cysts forming on the ovaries. In the majority of cases, ovarian cysts induced by fertility drugs/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).
   c) Ovarian Hyperstimulation Syndrome (OHSS) - Fluid shifts within the body may require close observation and even hospitalization for further observation and treatment (1%-3% of cycles). The high levels of estrogen associated with the use of these medications may alter the way in which the body handles fluids. More specifically, the blood vessels may become “leaky” resulting in the accumulation of fluid within the abdominal cavity (ascites) or around the lungs (pleural effusion). This accumulation of fluid may result in abdominal distension and discomfort with associated shortness of breath (due to the diaphragm being pushed upward by the accumulation of fluid in the abdomen). In severe cases, removal of this fluid from the abdomen or from the space around the lungs may be required using a small needle (0.5% of cycles). The “leaky” vessels may also result in the individual becoming dehydrated because the fluid is in the wrong place, i.e. in the abdomen instead of in the blood vessels. Intravenous fluid administration may be required to maintain adequate blood flow to vital organs such as the kidneys. Severe dehydration could result in irreversible organ failure or blood clot formation leading to a pulmonary embolus (blood clots in the lung) or stroke (less than 0.1% of cycles). There are extremely rare reports in the literature of death occurring as a result of complications of OHSS. OHSS is a risk that is inherent to ovulation induction therapy; prevention cannot be guaranteed. At times, when monitoring shows that the risk of OHSS is unacceptably high, a cycle may be canceled. Severe OHSS will rarely occur if hCG administration is withheld. Close monitoring of your cycle by the clinic and following its instructions is imperative to reduce these risks.
d) **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 research studies of women taking fertility drugs. Since all of these cancers are more common in women with infertility, simply 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 the long-term impact fertility drugs may have on breast and ovarian cancer prevalence rates. For uterine cancer, the numbers are too small to draw conclusions.

e) **Adnexal Torsion (Ovarian Twisting)**: Less than 1 percent (1%) of the time, the stimulated ovary can twist on itself, cutting off its own blood supply. Surgery is required to untwist or even remove it.

3. Egg retrieval has risks including:
   a) Moderate discomfort after the procedure.
   b) Possibility of bleeding, infection, or injury to the abdominal organs that may require immediate major surgery with possible resulting loss of the uterus and/or ovaries, hospitalization for antibiotic therapy, blood transfusion or, in rare cases, death.
   c) The egg retrieval requires the use of anesthesia. Risks associated with anesthesia including nausea, difficulty breathing, respiratory distress or very rarely death.

4. The utilization of antibiotics at the time of egg retrieval may result in an allergic reaction, which may result in a rash. In its most severe form, an allergic reaction may be life threatening. The utilization of tetracycline/doxycycline is associated with an increased sensitivity to the sun and, therefore, caution should be taken to avoid prolonged sun exposure. The utilization of antibiotics may also be associated with nausea, vomiting, diarrhea, loss of appetite and vaginal yeast infections.

5. Federally mandated screening and testing for infectious diseases within 30 days of my egg retrieval may need to be repeated more than once to meet the timing requirements.


**Special Considerations in Egg Donation:**

**Infectious Disease Testing Of The Egg Donor.** I understand and consent that I must be subjected to federally mandated infectious disease testing within 30 days of the egg retrieval and then again after the retrieval. I understand and agree that if I test positive for any of the infectious diseases mandated by federal law that my eggs cannot be donated and that the eggs must be disposed of according to American Society of Reproductive Medicine (ASRM) Ethical Standards. I further understand that if I do not come for the testing required for these infectious diseases within 30 days of the retrieval, the eggs cannot be used and will be discarded and this might cause severe stress for the recipient.

**Donor Screening and Testing.** I understand and agree that as an egg donor, I have been asked extensive questions about my age, medical, genetic, psychological, sexual and family history. My truthful answers to these questions are critical to the health and safety of the recipient and the child that may be conceived as a result of this egg donation. I agree to answer these questions truthfully. I agree to notify The Pacific Fertility Center - Los Angeles of any medical condition or disease, particularly genetic diseases, which may arise in my immediate family or in me. I agree to provide medical updates and relevant information to the Pacific Fertility Center - Los Angeles should the Pacific Fertility Center - Los Angeles contact me in the future.

**Unknown Family History.** I understand and agree that if I do not have knowledge about my genetic parent’s medical history (for example if I was adopted or conceived with donor gametes) that my eggs may not be suitable for donation to produce a pregnancy.

I further acknowledge and consent that medical, psychological, genetic/infectious disease, technical or other considerations may contraindicate or preclude (make impossible) the donation of these eggs to a recipient despite my request. I agree that the disposition of these eggs will ultimately rely on the best medical judgment of the Pacific Fertility Center - Los Angeles.

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www.pfcla.com
Fertility Center - Los Angeles, and as appropriate, its employees, contractors, consultants and authorized agents, at the time of the potential donation.

Identity of the Donor and the Recipient(s).

Unless I have designated the recipient(s) of my eggs above, I understand that I will not be informed of the identity (identities) of the recipient(s) by the Pacific Fertility Center - Los Angeles. I also understand that the Pacific Fertility Center - Los Angeles will protect my identity and will not intentionally reveal it to the recipient(s) or to any child or children born from this donation, except as allowed below or if a court orders otherwise.

I understand that my identity might be revealed independently of the Pacific Fertility Center - Los Angeles by, for example, through advances in Internet searches or by my own choice by my registering voluntarily with a website.

I understand that if a child born from this donation has a medical or psychological need that might be met by me, that the Pacific Fertility Center - Los Angeles may elect to contact me to make a request that my identity be revealed. Such requests may be for a medical need such as a bone marrow transplant or to obtain family history based, for example, on newly discovered genetic information.

Because of the potential medical or psychological need of a child born from this donation, I also agree to promptly provide the Pacific Fertility Center - Los Angeles with any changes of address and/or contact information for me over the next 18 years.

I understand that once any child or children born from this donation are deemed legal adults, they may request to know the identity of the egg donor (me). I understand that I am under no obligation to agree to respond or reveal my identity pursuant to any request.

At this time, I am indicating my willingness to do the following (please check all that apply):

- I agree to provide non-identifying information limited to medical and biographical information to the Pacific Fertility Center - Los Angeles.
- I agree to have non-identifying contact with the child when the child becomes a legal adult if both the child and I agree to the disclosure.
- I agree to have identifying contact with the child when the child becomes a legal adult if both the child and I agree to the disclosure.

Donor’s initials: __________

I understand that I am under no obligation to agree to any request and that I am free to change my choices in writing in the future. My choices indicated on this form will remain valid unless and until I submit a change in my choices in writing to the Pacific Fertility Center - Los Angeles. I also understand that any choices I have indicated herein may be altered or voided by changes in the law or by court orders.

Parental Rights and Responsibilities. I understand that all rights and responsibilities for the care of any child resulting from the donation of my eggs will be the responsibility of the recipient(s). This includes any financial responsibilities and obligations associated with the care and upbringing of such a child.

I am aware that there are or may be laws in the state of California or other applicable states governing the legitimacy and legal status of children born following the use of donor eggs.
By my signature below, I give up all rights to use or make decisions about my donated eggs following this procedure. Should a child be born as a result of my egg donation, by my signature(s) below, I give up any and all rights and claims I have or may be deemed to have to such a child.

It is also possible that laws may be enacted in the future that would require the Pacific Fertility Center - Los Angeles to reveal my identity to the recipient couple (woman) or resulting child. If such laws are enacted, the CENTER might be required to adhere to those requirements. I understand that I might not be notified in such circumstances.

Information on all cycles of Assisted Reproductive Technology treatment, along with data identifying recipients and women who undergo ART with their own eggs, is currently collected into a national database under the 1992 Fertility Clinic Success Rate and Certification Act. As part of this process, the Society for Assisted Reproductive Technology plans to begin to collect identifying information on all egg donors. As with recipient cycles and cycles for women using their own eggs, this information may be used to track outcomes. For this purpose, certain donor identifying information such as name, date of birth, and social security number will be reported to a Registry by SART member clinics for data aggregation. ASRM guidelines currently require permanent records be kept for all egg donation cycles. Efforts to collect this information are intended to respect donation confidentiality and not to disclose confidential identifying information to recipients, donors, or offspring. Control of such information in the future may, however, depend on applicable law.

The Pacific Fertility Center - Los Angeles does not offer legal advice on these matters and if I need or want legal advice I must consult an attorney with expertise in family law related to assisted reproductive technologies.

Responsibilities of the Egg Donor. I understand and agree that additional responsibilities and requirements described in the “Egg Donor Agreement” must be met as part of the egg donation process. I further understand that adherence to the terms of that agreement will not affect the medical care that I receive, as described in this consent.

I may change my mind at any time prior to the point at which the eggs have been retrieved and donated.

Other Considerations:

Confidentiality. I understand the confidentiality of medical records, including any photographs, X-rays or recordings, will be maintained in accordance with applicable state and federal laws. Anonymous data from the ART procedure will also be provided to the Centers for Disease Control and Prevention (CDC) in compliance with the 1992 Fertility Clinic Success Rate and Certification Act, which requires that CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data.

I expect this procedure to be performed with not less than the customary standard of care. I understand the risks and benefits as outlined, and further understand and agree that the Pacific Fertility Center - Los Angeles shall be responsible only for acts of negligence on its part and the part of its employees, contractors, consultants and authorized agents.

I have had the opportunity to review this treatment and ask questions of our (my) physician concerning the alternative options to utilization of donated eggs, including adoption and no treatment. The full egg donation process has been explained to us (me), together with the known risks. I understand the explanation that has been given to us. I have had the opportunity to ask any questions I might have and those questions have been answered to my satisfaction. Any further questions may be addressed to the Pacific Fertility Center - Los Angeles staff. I acknowledge that utilization of donated eggs is being performed at my request and with my consent.
Egg Donor Signature

Date

Egg Donor Name

Date of Birth

Notary Public
Sworn and subscribed before me on this _____ day of __________, __________.

____________________________
Notary Signature

Date

Spouse Signature (if applicable)

Date

Spouse Name

Date of Birth

Notary Public
Sworn and subscribed before me on this _____ day of __________, __________.

____________________________
Notary Signature

Date
Anonymous Egg Donor Agreement

Date: ___________________________

Egg Donor Last Name: ___________________________ First Name: ___________________________

Date of Birth: ___________________________

Address: ______________________________________

I, the undersigned, have executed (signed) an informed consent to act as an Anonymous Egg Donor (AED) in the program of the Pacific Fertility Center - Los Angeles. I understand that the consent describes the medical aspects, some legal issues and the risks of the treatment that I will receive as part of acting as an Anonymous Egg Donor.

I understand that this document (called an agreement) describes the specific responsibilities and requirements to which I have agreed in acting as an egg donor. I understand that I will be compensated for my time and effort only if I meet these responsibilities.

By signing this agreement, I state again that I have been completely truthful in all the information I have given in my application to be an egg donor regarding my age, personal medical, psychological, sexual and genetic history and that of my family where requested.

As part of my continued participation as an egg donor, I agree to:

- Submit to any urine, cervical cultures or blood tests or physical examinations required.
- Continue to truthfully disclose aspects of my age, medical, psychological, genetic, sexual and family history.
- Refrain from smoking.
- Refrain from use of recreational drugs.
- Respond to requests for follow-up information in a timely fashion.
- Keep all scheduled appointments and arrive promptly.
- Follow all instructions precisely and ask for assistance if I do not understand those instructions.
- Refrain from any attempt to learn the identity of the recipients.
- If I tell others that I am an egg donor, I will not share the exact timing of my cycle or the day of my egg retrieval (except with those that live with me and the person that transports me to and from my egg retrieval).

I understand that, from the beginning of my drug treatment with GnRH agonist, antagonist or birth control pills, I must:

- Refrain from intercourse or if I have intercourse, use a condom to avoid both pregnancy and disease transmission.
- Avoid high impact and strenuous activities such as running.
- Take all medications at the prescribed time.
• Have blood tests and ultrasounds at intervals determined by the physicians, which may be daily for several weeks.
• Be available for egg retrieval on the day determined by the physicians, on 36 hours notice.

I understand that:
• As an anonymous egg donor and patient of the Pacific Fertility Center - Los Angeles, I will receive medical care according to the standards set by SART.
• All reasonable efforts will be made to maintain my confidentiality and protect my identity unless at some time in the future I agree to reveal it.
• There are or may be laws in the state of California or other applicable states governing the legitimacy and legal status of children born following the use of donor eggs. It is also possible that laws may be enacted in the future that would require the Pacific Fertility Center - Los Angeles to reveal my identity to the recipient couple (individual) or resulting offspring. If such laws are enacted, the Pacific Fertility Center - Los Angeles might be required to adhere to those requirements.
• The Pacific Fertility Center - Los Angeles does not offer legal advice on these matters and if I need or want legal advice I must consult an attorney with expertise in family law related to assisted reproductive technologies.
• I will be treated with respect and care throughout the process.

I understand that:
• If I require any additional treatment for any complications that arise, I may be covered by short-term oocyte donor health insurance that will be provided to me by the program within the terms, limits and conditions of the plan. (I have been given a copy of limitations of that policy and understand that conditions that do not directly relate to egg donation may not be covered).
• I am solely responsible for the cost of any additional treatment required that is unrelated to my egg donation (that is, treatment outside of the terms, limits and conditions of the short-term oocyte donor health insurance plan provided to me by the Pacific Fertility Center - Los Angeles).
• Treatment will be provided to me by a member of the Pacific Fertility Center - Los Angeles medical team or other physician as indicated.
• I will be responsible for all costs associated with all deductible, co-payments and other amounts related to non-covered services (services unrelated to my donation of eggs).

I understand that in exchange for the time and effort I expend during this cycle, the Recruiting Program will control my reimbursement if they recruited me.
I have read this agreement, understand my responsibilities and agree to these conditions of being an Egg Donor. I have received a copy of this agreement.

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<th>Egg Donor Signature</th>
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<tr>
<td>Egg Donor Name</td>
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Risks to Recipient and Offspring

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.

After eggs are retrieved, they are transferred to the embryology laboratory where they are kept in conditions that support their needs and growth. The embryos are placed in small dishes or tubes containing "culture medium," which is special fluid developed to support development of the embryos made to resemble that found in the fallopian tube or uterus. The dishes containing the embryos are then placed into incubators, which control the temperature and atmospheric gasses the 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. Three days after insemination or ICSI, normally developing embryos contain about 8 cells. Five 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, and a small cluster of cells called the inner cell mass.

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
- 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 (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 who provided the eggs, and the appearance of the developing embryo, have the greatest influence on pregnancy outcome and the chance for multiple pregnancy.

**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 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.

**Additional Elements and their risk**

**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

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 close 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 slightly higher risk of birth defects. Whether any association is due to the ICSI procedure itself or to inherent sperm defects, however, 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.

**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 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.

**Cryopreservation**

- Freezing of eggs and embryos can provide additional chances for pregnancy.
- 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 the clinic on an annual basis.

Freezing (or “cryopreservation”) of eggs or embryos is a common procedure. Since multiple eggs (oocytes) are often produced during ovarian stimulation, on occasion there are 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.

**Risks of Pregnancy**

Pregnancies that occur with IVF are associated with increased risks of certain conditions. 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 risks related to the IVF procedure per se, but it is difficult to assign the relative contributions.

Multiple gestations, which account for 30% of IVF pregnancies, increase the risk of pregnancy complications. The most important maternal complications associated with multiple gestations are preterm labor and delivery, high blood pressure (pre-eclampsia or toxemia), and gestational diabetes.

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.
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. 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.

**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 some may be due to the underlying infertility issues.

**Childhood cancers.** Most studies have not reported an increased risk with the exception of a retinoblastoma, a rare eye tumor.

**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**

Currently more than 30% of IVF pregnancies are twins or higher-order multiple gestations (triplets or greater), and about half of all IVF babies are a result of multiple gestations. Identical twinning occurs in 1.5% to 4.5% of IVF pregnancies.

Premature delivery accounts for most of the risk. Twins deliver on average three weeks earlier and weigh 1,000 gm less than singletons. Triplet (and greater) pregnancies deliver before 32 weeks (7 months) in almost half of cases. 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.

Long-term consequences of prematurity can include cerebral palsy, vision problems, and lung disease. 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 decreases some of these risks.
IVF, egg donation, and cryopreservation all present the possibility that more eggs or embryos will be created than can be used in a fresh cycle, or used by the original recipient for their own procreation. Decisions must be made as to the ultimate disposition of any excess eggs or embryos remaining at the time the original recipient completes their medical treatment. There are three potential dispositions, each of which is outlined below. As a donor, it is important that I understand and consent to whom may control dispositional choices of any excess eggs or embryos.

DISPOSITION OF EXCESS EGGS or EMBRYOS:

1) DISCARD: Any recipient of donor eggs must have the option to discard unused eggs or embryos. I understand that any decision regarding discard is for the recipient and/or medical program to make and that I have no control over, nor will I be informed of, any such decision or discard.

2) DONATION FOR RESEARCH: The recipient may decide to donate the eggs or embryos to research, including stem cell research. Neither I (the egg donor) nor the recipient of my eggs will receive any information about subsequent testing on the embryo or the resulting stem cells. Stem cell and cell lines may be kept for many years. It is possible the donated material may have commercial potential, but the donor will receive no financial or other benefit from any future commercial development. Stem cell research is not intended to provide direct medical benefit to the embryo donor. Donated embryos will not be transferred to a woman’s uterus, nor will the embryos survive the human pluripotent stem cell derivation process.

3) DONATION FOR PROCREATION: The recipient may decide to donate the eggs or embryos for procreation (pregnancy and childbirth) to another individual or couple, or to an entity that locates such individuals or couples (“secondary donation”). I will not receive any information regarding such decision or ultimate disposition of eggs or embryos, and will have no control over any such decision.

Except as and to the extent specifically limited herein, I understand, agree and consent that the eggs that I donate may be used fresh or frozen by the recipient (the couple or individual who is using the eggs) and that once they have been retrieved, that I will have no further control over these eggs. The recipient may use them in any way they think is appropriate and, because of confidentiality issues; I will not be notified of how they are used. I understand that the recipient may decide to discard the eggs, donate them to research or donate them to someone else in the future.

☑ YES: I approve of DONATION FOR RESEARCH
☑ NO: I do NOT approve of DONATION FOR RESEARCH

☑ YES: I approve of secondary DONATION FOR PROCREATION
☑ NO: I do not approve of secondary DONATION FOR PROCREATION