FAMILY FERTILITY CENTER **www.familyfertility.com**
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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

Overview

Assisted reproductive technology (**ART**)

The Centers for Disease Control and Prevention (CDC) defines ART to include "all fertility treatments in which both eggs and sperm are handled. In general, ART procedures involve surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, and returning them to the woman's body or donating them to another woman." According to CDC, "they do not include treatments in which only sperm are handled (i.e., intrauterine—or artificial—insemination) or procedures in which a woman takes medicine only to stimulate egg production without the intention of having eggs retrieved."

In-vitro Fertilization (IVF)

The term IVF is often used interchangeably with ART because it is the most prevalent form of ART. IVF literally means allowing fertilization of the male and female gametes (sperm and egg) occur outside the female body. IVF is an established treatment for many forms of infertility. The first IVF baby in the world was born in 1978. The goal of IVF is to give a couple an opportunity to become parents, most commonly using eggs and sperm from a couple. There are many variations of the treatment depending on the medical indications and social circumstances, including use of donor eggs, donor sperm and/or gestational surrogates. It is an elective procedure designed to result in a pregnancy leading to a live birth 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 all participants in the process as well as the unborn child(ren). While best efforts have been made to disclose all known risks, there may be risks of IVF that are not yet clarified or even suspected at the time of this writing.

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. Furthermore, patient selection and treatment approaches differ among clinics. The Society for Assisted Reproductive Technology, SART, maintains and the Family Fertility Center concurs that a comparison of clinic success rates may not be meaningful.

Please place your initials at each page to indicate that you have read and understand the information provided. If you do not understand the information provided, please speak with our nurse and/or physician. There are a few locations within the consent form, specifically on pages 13, 16, 22, 26 and 27, where you are being asked to make a decision. Please initial your choice and sign where requested.

This form must be completed preferably before IVF treatment is started so that all your questions are answered before hand. At a minimum this form must be reviewed, completed with initials and signatures, and returned to our office no later than two days before egg retrieval so the laboratory has time to prepare for your case.

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Outline of Consent to Treatment with Assisted Reproductive Technologies

1. Name(s) of party/parties
   - A. Party/parties requesting ART or IVF treatment
     - a. Couple
     - b. Individual
   - B. Party/Parties participating in the process of ART or IVF treatment
2. Nature and purpose of IVF
3. Specific steps in IVF
   - A. Controlled ovarian stimulation
     - a. Purpose of controlled ovarian stimulation
     - b. Nature and side effect of medications for IVF
       - i. Gonadotropins
       - ii. GnRH-agonists
       - iii. GnRH-antagonists
       - iv. Human chorionic gonadotropin
       - v. Progesterone
       - vi. Oral contraceptive pills
       - vii Other medications
     - c. Other risks of medications for IVF
       - i. Ovarian hyperstimulation syndrome
       - ii. Cancer
   - B. Monitor ovarian or uterine response
   - C. Procurement of sperm sample
   - D. Oocyte retrieval
     - a. Nature of oocyte retrieval
     - b. Risks of oocyte retrieval
       - i. Infection
       - ii. Bleeding
       - iii. Trauma
       - iv. Anesthesia
     - c. Failure to obtain any egg
   - E. Fertilization of the eggs
     - a. Method of fertilization
       - i. Conventional in-vitro fertilization (IVF)
       - ii. Intracytoplasmic sperm injection (ICSI)
         - I. Indications for ICSI
         - II. Nature of ICSI
         - III. Purpose of ICSI
         - IV. Limitations of ICSI
         - V. Risks of ICSI
     - b. Number of eggs to be fertilized
   - F. Embryo culture
     - a. Nature of embryo culture

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

b. Embryo development
c. Limitations of microscopic examination of embryos

G. Other ART procedures in conjunction with IVF treatment
a. Assisted hatching
b. Embryo biopsy and pre-implantation genetic diagnosis
c. Embryo freezing

H. Embryo transfer
a. Number of embryos to transfer
b. Limits on the number of embryos to transfer
c. Single embryo transfer
d. Disposition of extra embryos

I. Hormonal support of uterine lining after embryo transfer

J. Determine if pregnancy has occurred

4. Risks of IVF
A. Failure to establish a pregnancy
B. Risks to the woman undergoing ovarian stimulation
C. Risks to the woman undergoing embryo transfer
a. Pregnancy resulting from IVF
b. Ectopic pregnancy

D. Risks to the child/children conceived with IVF
a. Overall risks
b. Birth defects
c. Imprinting disorders
d. Childhood cancers
e. Infant development
f. Risks of a multiple pregnancy
i. Preterm labor and delivery
ii. Prematurity
iii. Fetal death
iv. Additional risks to multiple fetuses
v. Option of selective reduction

5. Quality control in the IVF laboratory
6. Ethical and religious considerations in infertility treatment
7. Legal considerations and legal counsel
8. Psychosocial effects of infertility and its treatment
9. Alternatives to IVF
10. Reporting IVF outcome
11. References
12. Acknowledgement

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1. Name(s) party/parties

A. Party/parties requesting ART or IVF treatment

a. Couple

We,_____ and _____ of _____County, City of _____in the state of _____are _____(husband and wife or domestic partners) and are over the age of twenty-one years. We request and authorize Dr. H. Christina Lee, and/or such assistants as she may designate to use the services of the Family Fertility Center to perform assisted reproductive technologies (ART), also known as in-vitro fertilization (IVF), because we have been unable to become pregnant and/or have a child on our own, and other treatments have failed or are not appropriate.

b. Individual

I, _____, of _____County, City of _____ in the state of _____am over the age of twenty-one years. I request and authorize Dr. H. Christina Lee, and/or such assistants as she may designate to use the services of the Family Fertility Center to perform assisted reproductive technologies (ART), commonly known as in-vitro fertilization (IVF), because I have been unable to become pregnant and/or have a child on my own, and other treatments have failed or are not appropriate.

B. Party/Parties participating in the process of ART or IVF treatment

a. Oocyte or eggs will be extracted from _____
b. Sperm will be obtained from _____
c. Eggs from 1.B. a and sperm from 1.B.b will be fertilized in the laboratory.
d. The resulting normally fertilized eggs (embryo or embryos) will be placed into the uterus of_____.
e. Intended parents

i. Couples

_____and_____ are the intended parents of any and all child(ren) resulting from this procedure.

ii. Individual

_____ is the sole intended parent of any and all child(ren) resulting from this procedure.

2. Nature and purpose of IVF

IVF is an established treatment for many forms of infertility where an egg or eggs are extracted from the ovary or ovaries of a woman and mixed or injected with human sperm in the laboratory

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to achieve fertilization. After normal fertilization is achieved, the fertilized eggs are cultured in the laboratory for an appropriate period of time before they are placed inside a woman's uterus (womb) with the intent of making the woman pregnant.

An IVF cycle typically includes the following steps or procedures:
- controlled ovarian stimulation: use of medications to grow multiple eggs
- monitor ovarian and uterine responses
- procurement of sperm sample
- retrieval of eggs from the ovary or ovaries
- fertilization of eggs: insemination or injection of sperm into the egg
- culturing 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 facilitate and sustain pregnancy

In some cases, additional procedures are employed. These include:
- Intracytoplasmic sperm injection (ICSI) to increase the chance for fertilization
- Assisted hatching of embryos to potentially increase the chance of embryo attachment (implantation)
- Embryo Cryopreservation (freezing)
- Pre-implantation Genetic Diagnosis/Screening (PGD/PGS)

3. Specific steps in IVF

Before IVF can begin, suitability of all parties involved for this procedure will be determined by standard infertility evaluation, screening tests, psychological counseling and other medical procedures where required by federal, state or local law or deemed medically necessary by the treating physician.

A. Controlled ovarian stimulation

The party named in Section 1.B.a will self administer by injection combinations of medications including: Leuprolide acetate (Lupron®), Cetrorelix acetate (Cetrotide®), Ganirelix acetate follicle stimulating hormone and/or luteinizing hormone (Menopur®, Bravelle®, Follistim® or Gonal-F®), human chorionic gonadotropin (hCG) (Ovidrel®, Novarel®, Pregnyl®) and progesterone (Endometrin®, Crinone®, or Prometrium®) for the purposes as described in Sections 3.A.a and 3.A.b below.

a. Purpose of controlled ovarian stimulation

The success of IVF largely depends on growing multiple eggs at once. Injection of the natural hormones, also called gonadotropins or more specifically follicle stimulating hormone (FSH), and/or luteinizing hormone (LH), 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 may occur.

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

b. Nature and side effect of medications for IVF

i. 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 as described in Section 3.C.

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) as described in Section 3.B.c.i. below. 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.

Despite pre-treatment attempts to assess response, and particularly when pre-treatment evaluation indicates an abnormal 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.

ii. 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 (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) 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.

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

iii. GnRH-antagonists (ganirelix acetate or cetrorelix acetate) (Ganirelix, 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 of ovarian stimulation. The potential side effects include, but are not limited to, abdominal pain, headaches, skin reaction at the injection site, and nausea.

iv. Human chorionic gonadotropin (hCG) (Novarel® or 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 mature eggs. Potential side effects include, but are not limited to breast tenderness, bloating, and pelvic discomfort.

v. 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®, 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, and allergic reaction. If progesterone is given by intra-muscular injection, there is 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.

vi. 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 bleeding, headache, breast tenderness, nausea, swelling and the risk of blood clots or stroke.

vii. Other medications

Antibiotics may be given for a short time during the treatment cycle or at the time of egg retrieval 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. Occasionally, anti-anxiety medications or muscle relaxants may be recommended prior to the embryo transfer. The most common side effect is drowsiness. Where indicated, other medications such as steroids, heparin, low molecular weight heparin or aspirin may also be included in the treatment protocol.

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c. Other risks of medications for IVF

i. Ovarian hyperstimulation syndrome (OHSS)

The most serious side effect of ovarian stimulation with fertility medications is 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 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.

ii. 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 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 indeed cause some increased risk of uterine cancer.

B. Monitor ovarian or uterine response

The party named in Section 1.B.a will undergo serial ultrasound examinations and blood testing for reproductive hormones to assist in predicting the time of expected ovulation. As described in Section 3.B.b.i above, sometimes when the stimulation results in very few follicles, few or no eggs may be obtained at egg retrieval or treatment cycle may be cancelled prior to egg retrieval.

The party named in Section 1.B.d will undergo serial ultrasound examinations and blood testing for reproductive hormones to assist in preparation of the uterine lining to maximize implantation success. If this party is not the same person named in Section 1.B.a, she will also self administer hormones to prepare the uterine lining in preparation for embryo transfer.

C. Procurement of sperm sample

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

Unless other arrangement is made, on the day of egg retrieval, party named in Section 1.B.b. will produce by masturbation a sperm specimen which will undergo laboratory preparation for fertilization.

If donor sperm is used for fertilization, the sperm must be procured and sent to the Family Fertility Center prior to the day of retrieval. Furthermore, the sperm sample must be determined eligible according to rules and regulations set forth by the Code for Federal Regulations for human cells, tissues and cellular and tissue-based products (CFR , title 21, part 121 HCT/P) and enforced by the Food and Drug Administration (FDA), as well as deemed acceptable by the Family Fertility Center.

In cases where previous semen analysis showed no live sperm, sperm isolation will be attempted from specimen procured by a urologist in a separate procedure, called testicular biopsy or epididymal aspiration on the party named in Section 1.B.b.

D. Oocyte retrieval

The party named in Section 1.B.a will undergo oocyte retrieval when eggs are removed from the ovary with a needle under ultrasound guidance. Anesthesia is provided to make this comfortable.

a. Nature of oocyte retrieval

Oocyte retrieval is the removal of eggs from the ovary. An ultrasound probe is placed vaginally 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. Generally all follicles greater than 12 mm in diameter will be aspirated. But it is within the discretion of the physician to determine which particular follicle will be aspirated. Rarely, the ovaries are not accessible via the vaginal route and laparoscopy or transabdominal retrieval may be necessary. Anesthesia is generally used to reduce, if not eliminate, discomfort.

b. Risks of oocyte retrieval

i. Infection

Bacteria normally present in the vagina may be transferred inadvertently 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 routinely used immediately prior to egg retrieval procedure at the Family Fertility Center to reduce the risk of pelvic or abdominal infection. Despite the use of antibiotics, there is no way to eliminate this risk completely.

ii. Bleeding

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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. When blood accumulates inside the abdomen, symptoms of lower abdominal pain or cramping, inability to take deep breathes, and pain in the right shoulder or right upper abdomen may develop. On occasion, such symptoms are so severe it may require removal of the accumulated blood with another needle aspiration or, rarely, by a laparoscopy under general anesthesia.

The incidence of major bleeding problems has been estimated to be less than 0.1%. Major bleeding may require surgical repair, possibly loss of the ovary, or the need for blood transfusion. Although very rare, review of the world experience with IVF indicates that unrecognized bleeding has lead to death.

iii. 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.

iv. 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.

c. Failure to obtain any egg

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

E. Fertilization of the eggs

a. Method of fertilization

i. Conventional in-vitro fertilization (IVF)

In conventional IVF sperm and eggs are mixed together in a culture dish with specialized conditions (culture media, controlled temperature, pH (acidity), humidity and light) to permit the sperm to fertilize the eggs on their own ability.

ii. Intractyoplasmic sperm injection (ICSI)

In the alternative, fertilization is achieved by injecting a single sperm into an egg using a technique called intractyoplasmic sperm injection (ICSI)

I. Indications for ICSI

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

ICSI is performed if no or low fertilization was observed in a previous IVF attempt, fertilization with conventional IVF is anticipated to be poor because of poor semen or sperm quality, sperm quality or oocyte quantity is borderline so ICSI is performed to maximize the number of embryos available for transfer, or other indications, e.g. viral infection in the party from whom sperm is used for fertilization.

II. Nature of ICSI

ICSI involves the direct injection of a single sperm into the interior of an egg using an extremely thin glass needle. Manipulation of the egg requires specialized equipment specifically designed to perform the very small intricate movements utilized during the procedure. Prior to injection of the sperm, eggs have to be treated with a solution containing hyalurondiase, an enzyme which removes the cumulus cell surrounding the egg so as to allow visualization of the egg itself. The egg will be held in place with a small glass pipette while a micro glass needle, previously loaded with a single viable sperm, is introduced through the shell (zona pellucida) into the egg. The sperm is released from the micro needle into the inside of the egg. After the egg is injected with the sperm, it is rinsed in fresh culture medium and cultured as described in Section 3.F.a.i above

III. Purpose of ICSI

ICSI is an effective treatment for male factor infertility because the technique delivers the sperm directly into the egg, bypassing the shell around the egg (zona pellucida) and the egg membrane (oolemma), thereby increasing the chance of fertilization when fertilization rates are anticipated to be lower than normal. As long as viable sperm are available, the negative effects of abnormal semen characteristics and sperm quality on fertilization can be overcome with ICSI.

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.

IV. Limitations of ICSI

Despite ICSI, failure to establish a pregnancy may result because of the following reasons: (1) inability of the eggs to withstand the injection procedure, (2) failure of the sperm to activate the egg in spite of injection inside the egg, (3) poor egg quality resulting in inability of the egg to achieve normal fertilization or subsequent cell division or growth, and/or (4) failure of the embryo to implant.

V. Risks of ICSI

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,

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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 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 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 chromosome 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 chromosomal abnormality in a sperm may not be the same as those seen when tested by a blood test.

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

b. Number of eggs to be fertilize

The probability of a successful IVF is to a large extent proportionate to the number of fertilized eggs. It is generally recommended to fertilize all the eggs retrieved with conventional IVF or to fertilize all the mature eggs with ICSI. However, some couples/individuals may wish to limit fertilization to a pre-determined number of eggs because of concern regarding the disposition of extra embryos.

_____ (name(s) of intended parent(s) named in Section 1.B.e) decide to (initial ONE of the following choices)

i. Fertilize all the eggs retrieved. Initials:_____

ii. Fertilize some (please specify a number) _____of the eggs retrieved and discard all the unfertilized eggs. Initials:_____

iii. Fertilize some (please specify a number) _____ of the eggs retrieved and freeze all the unfertilized eggs. Initials:_____. A separate consent to freeze the remaining unfertilized eggs is required .

iv. Fertilize some (please specify a number)_____ of the eggs retrieved and donate all the unfertilized eggs to the Family Fertility Center solely for the purpose of laboratory quality control. No embryo will be created with any of the unfertilized eggs. Initials: _____

F. Embryo culture

a. Nature of embryo culture

Eggs or fertilized eggs are kept in conditions that support their needs and growth. They are placed in small dishes 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 eggs or embryos are placed inside incubators which tightly control the temperature, atmospheric gases, pH (acidity) and humidity the embryos experience.

b. Embryo development

Microscopic examination of the eggs and embryos are carried out at specific time after insemination or ICSI to determine whether the eggs are fertilized normally and the fertilized eggs or embryos are developed normally.

The day after the eggs have been inseminated or injected with a single sperm, they are examined under the microscope for signs that the process of fertilization is underway. At this stage, normal development is evident by the still single cell having two nuclei; this stage is called a zygote. Two days after insemination or ICSI, normal embryos have divided into about 4 cells. Three days after insemination or ICSI, normally developing embryos contain about 8 cells. Five to six days

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after insemination or ICSI, normally developing embryos have developed to the blastocyst stage, which is an embryo that now has 80 or more cells, with an inner fluid-filled cavity and a small cluster of cells called the inner cell mass.

c. Limitation of microscopic examination of embryos

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 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. Until other proven and non invasive techniques become available in the future, visual appearance is the most common and useful guide in the selection of the best embryo(s) for transfer.

G. Other ART procedures in conjunction with IVF treatment

a. Assisted hatching

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 a laboratory technique in which an embryologist makes an artificial opening in the shell of the embryo to enhance its ability to hatch and thus implant after transfer. It has been theorized that this outer shell becomes thicker and hardened with culturing in the laboratory and/or aging of the oocyte. Assisted 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.

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.

Available published evidence does not support the routine or universal application of assisted hatching in all IVF cycles at this time. Family Fertility Center follows the guidelines on assisted hatching set forth by the Practice Committee of the Society for Assisted Reproductive Technology (SART) of the American Society for Reproductive Medicine (ASRM) (Fertility and Sterility Vol 90, Suppl 3, Nov 2008). Assisted hatching is offered only for patients with a poor prognosis, including those with more than two failed IVF cycles, poor embryo quality AND women older than 38 years old.

b. Embryo biopsy and Pre-implantation genetic diagnosis

See Consent for Embryo Biopsy and pre-implantation genetic diagnosis.

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

c. Embryo freezing

See Consent to Cryopreservation and Storage of Human Embryos.

H. Embryo transfer

After a few days of development when the requisite cell divisions have occurred, a pre-determined number of embryos will be selected for transfer into the uterus of the party named in Section 1.B.d. with a thin tube (catheter). Ultrasound guidance may be used to help guide the catheter and confirm placement of the embryos at a proper location in 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.

a. Number of embryos to transfer

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. The number of embryos to be transferred must be determined and agreed upon by the physician and the parties named in Section 1.B.d and Section 1.B.e before oocyte retrieval is done.

b. Limits on the number of embryos to transfer

In an effort to curtail the problem of multiple pregnancies, some countries have enacted law regulating the number of embryos to transfer. At the moment of this writing, no such law has been enacted in the U.S. at the federal, state or local level. Because multiple pregnancies (see Section 4.D.e.) can be devastating to the health of both mother and children, national guidelines published by the Practice Committee of the Society in Assisted Reproductive Technologies (SART) of the American Society for Reproductive Medicine (ASRM) in 2006 recommend limits on the number of embryos to transfer (see Tables below). All clinics, including the Family Fertility Center, which are members of SART are to follow these guidelines or risk losing their membership with SART. 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

Favorable means previous successful IVF outcome, first IVF cycle, good embryo quality, or excess embryos available for freezing.

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

c. Single embryo transfer

While there is no absolute guarantee to avoid multiple pregnancy, single embryo transfer is the only option to minimize the possibility of multiple pregnancy and its inherent risks to the health of mother and children and is the recommended choice for favorable prognosis as noted in Section 3.I.b. _____ (name(s) of intended parent(s) in Section 1.B.e) decide to have (write the number of embryo(s) to be transferred, then place initials after the number)

_____embryo(s) transferred on 2nd to 3rd day after fertilization, or

_____embryo(s) transferred on 5th to 6th day after fertilization.

d. Disposition of extra embryos

In cases where additional embryos remain after the transfer is completed, depending on its developmental normalcy, it may be possible to freeze (cryopreserve) them for later use.

(**Additional costs associated with freezing and future transfer of excess embryo(s) will be incurred. A separate consent to freeze and store human embryos must be signed before egg retrieval.)**

For all remaining embryos that are not transferred, _____ (name(s) of intended parent(s) named in Section 1.B.e) decide to (initial ONE of the following choices)

i. _____freeze (cryopreserve) the excess embryos and store for later decision,

ii. _____ discard the excess fertilized eggs,

iii. _____ donate the excess fertilized eggs to Family Fertility Center solely for the purpose of quality control use, or

iv. _____ describe any other option.

I. Hormonal support of the uterine lining after embryo transfer

Successful implantation or 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 sometimes estradiol may be necessary too. Progesterone is given by the intramuscular, oral or vaginal route. Estradiol is given by the oral, vaginal, dermal or intramuscular route. The duration of this support is from 2 to 10 weeks.

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J. Determine if pregnancy has occurred

Following transfer of the fertilized eggs, blood samples from party named in Section I.B.d will be obtained to determine if pregnancy has occurred and if it is progressing normally.

4. Risks of IVF

A. Failure to establish a pregnancy

The success rate of a single IVF cycle of treatment varies from less than 10% live birth per cycle in women 42 years old or older to over 50% live birth rate per cycle in women under 35 years old, especially among women with good quality eggs. The national average live birth rate for all women undergoing IVF between 2006 and 2008 is about 30% per cycle of treatment.

Any of the following may occur during an IVF treatment which would prevent the establishment of a pregnancy:

a) Abnormal response to fertility drug, the time of ovulation may be misjudged or it may not be predictable which would preclude the attempt to secure an egg;

b) the attempt to recover an egg may be unsuccessful;

c) the recovered egg may not be normal;

d) the party named in Section I.B.b may be unable to provide a suitable sperm specimen;

e) fertilization may not occur;

f) cleavage or cell division of the fertilized egg may not occur;

g) the embryo may not develop normally;

h) implantation may not be successful;

i) a laboratory accident may result in loss or damage to the egg, the sperm or the fertilized egg;

j) 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, or

k) other unforeseen circumstances may prevent any step of the procedure to be performed or prevent the establishment of pregnancy.

B. Risks to the woman undergoing ovarian stimulation

a. Ovarian hyper stimulation syndrome-See Section 3.B.c.i
b. Cancer-See Section 3.B.c.ii

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

C. Risks to the woman undergoing embryo transfer

a. Pregnancy resulting from IVF

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. 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)
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. *Please note that most experts believe the rate of Cesarean delivery to be well above the 26.7% rate quoted here.

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. 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 cases.

b. Ectopic pregnancy

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.

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

D. Risks to the child/children conceived with IVF

a. 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.

b. 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 difference is seen predominately in singleton males. Studies to date have not been large enough to prove a link between IVF treatment and specific types of birth defects.

c. 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.

d. 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.

e. Infant development

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

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.

Potential Risks in Singleton IVF Pregnancies

	Absolute Risk (%) in IVF Pregnancies	Relative Risk (vs. non-IVF Pregnancies)
Preterm birth	11.5%	2.0 (1.7--2.2)
Low birth weight (< 2500 g)	9.5%	1.8 (1.4--2.2)
Very low birth weight (< 1500 g)	2.5%	2.7 (2.3--3.1)
Small for gestational age	14.6%	1.6 (1.3--2.0)
NICU (intensive care) admission	17.8%	1.6 (1.3--2.0)
Stillbirth	1.2%	2.6 (1.8--3.6)
Neonatal mortality	0.6%	2.0 (1.2--3.4)
Cerebral palsy	0.4%	2.8 (1.3--5.8)
Genetic risks		
-imprinting disorder	0.03%	17.8 (1.8--432.9)
-major birth defect	4.3%	1.5 (1.3--1.8)
-chromosomal abnormalities (after ICSI):		
-of a sex chromosome	0.6%	3.0
-of another chromosome	0.4%	5.7

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.

f. Risks of a multiple pregnancy

i. Preterm labor and delivery

The most important maternal complications associated with multiple gestation are preterm labor and delivery, pre-eclampsia, and gestational diabetes (see Section 4.C.a Risks of pregnancy). 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.

ii. Prematurity

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

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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.

iii. Fetal death

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 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.

iv. Additional risks to multiple fetuses

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.

Placenta previa (placenta extends over the cervical opening) and vasa previa (where one or more of the blood vessels extends over the cervical opening) are more common complications in multiple gestations. Abruptio placenta (premature separation of the 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.

v. 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

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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 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%)

5. Quality control in the IVF laboratory

Quality control in the IVF laboratory is extremely important to optimize the fertilization, growth and development of the embryos in an environment outside of the human body. 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 Family Fertility Center 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 Family Fertility Center to use your eggs, sperm or embryos for research purposes. Please initial your choice below:

_____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.

_____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.

6. 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

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pregnancy (triplets or more). You are encouraged to consult with trusted members of your religious or ethics community for guidance on your infertility treatment.

7. Legal considerations and legal counsel

In cases when embryos are frozen for later use or when a third party is involved in the process of IVF, the law regarding parent-child status, rights of sperm or egg donors, gestational surrogate and child(ren) resulting from this treatment is, or may be, unsettled in the state in which either partner or spouse, or any donor currently or in the future lives, or in the state of Pennsylvania where Family Fertility Center is located.

Family Fertility Center has not given you legal advice, nor should you rely on the Family Fertility Center to give you any legal advice. You are strongly advised to consult a lawyer who is experienced in the areas of reproductive law if you have any questions or concerns about the present or future status of your embryos, your individual or joint access to them, your individual or joint parental status as to any resulting child(ren), or about any other aspect of this consent and agreement.

8. Psychosocial effects of infertility and its 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 an individual or couple 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. In addition to working with our health care team to minimize the emotional impacts of infertility treatments, you are encouraged to seek counseling 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 time, 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)

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- 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

Our health care team can assist you to identify a local qualified mental health professional who is familiar with the emotional experience of infertility.

9. Alternatives to IVF

There are alternatives to IVF treatment including using donor sperm, donor eggs, adoption, or not pursuing any active treatment. 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. Sperm freezing has been an established procedure for many decades. Exciting advances have been made in the area of egg freezing. Although officially considered an experimental procedure by the ASRM several years ago, the Family Fertility Center offers egg freezing as one of the treatment options in the expanding field of ART.

10. Reporting IVF outcome

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 your 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). The CDC may request additional information from the Family Fertility Center or contact you directly for additional follow-up. Additionally, your 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 your treatment from being used to identify you as individuals.

11. References

General IVF overviews available on the internet

http://www.sart.org/

http://www.cdc.gov/art/

Number of Embryos to Transfer

Guidelines on number of embryos transferred. The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology. Fertil Steril 2006; 86 (suppl 4): S51-S52.

Initials_____/_____

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

Culturing Embryos to the Blastocyst Stage

Blastocyst culture and transfer in clinical-assisted reproduction. The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology. Fertil Steril 2006; 86 (suppl 4): S89-S92.

Intracytoplasmic sperm injection

Genetic considerations related to intracytoplasmic sperm injection (ICSI). The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology. Fertil Steril 2006; 86 (suppl 4): S103-S105.

Embryo hatching

The role of assisted hatching in in vitro fertilization: a review of the literature. A Committee opinion. The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology. Fertil Steril 2006; 86 (suppl. 4): S124-S126.

Ovarian Hyperstimulation

Ovarian hyperstimulation syndrome. The Practice Committees of the American Society for Reproductive Medicine. Fertil Steril 2006; 86 (suppl 4): S178-S183.

Risks of pregnancy

Infertility, assisted reproductive technology, and adverse pregnancy outcomes. Executive Summary of a National Institute of Child Health and Human Development Workshop. Reddy UM, Wapner RJ, Rebar RW, Tasca RJ. Obstet Gynecol 2007; 109(4):967-77.

Risks to offspring

Infertility, assisted reproductive technology, and adverse pregnancy outcomes. Executive Summary of a National Institute of Child Health and Human Development Workshop. Reddy UM, Wapner RJ, Rebar RW, Tasca RJ. Obstet Gynecol 2007; 109(4):967-77.

Multiple pregnancy associated with infertility therapy. The Practice Committees of the American Society for Reproductive Medicine Fertil Steril 2006; 86 (suppl 4): S106-S110.

Imprinting diseases and IVF: A Danish National IVF cohort study. Lidegaard O, Pinborg A and Anderson AN. Human Reproduction 2005; 20(4):950-954.

12. Acknowledgement

(If Section 1.B.e.ii is completed where an individual is the sole intended parent, the words we, us, our, or ours will be replaced by I, me, my and mine.)

We accept the IVF procedure as our own voluntary act and acknowledge that the child or children produced are our own legitimate children and, as our heir or heirs, with all the rights and privileges accompanying such status.

We understand that neither Dr. H. Christina Lee, nor the Family Fertility Center and its staff, can be responsible for the physical and mental characteristics of the child or children produced by this method.

Initials_____/_____

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

We, on behalf of ourselves, on behalf of offspring born as a result of this procedure, and on behalf of their heirs, executors, administrators, successors and assigns, hereby fully release and discharge Dr. H. Christina Lee, the Family Fertility Center, and its staff from all claims and actions that we, our offspring and their above mentioned successors now or hereafter may have arising out of the proposed IVF.

We, jointly and severally, hereby agree to indemnify and hold harmless Dr. H. Christina Lee, the Family Fertility Center, its staff, and their successor, assigns, heirs and executors and administrators from and against any and all liability, in connection with any claim brought by us, our offspring, or any other person or entity in connection with the IVF procedure.

We understand that, with any technique necessitating mechanical support systems, equipment failure can occur. Dr. H. Christina Lee, the Family Fertility Center, and its staff are not to be held liable for any destruction or damage to our sperm, egg(s) and/ or embryo(s) caused by or resulting from any malfunction of equipment, failure of utilities, fire, wind, earthquake, water, or other acts of God.

We consent to the photographing or televising of the procedures to be performed, including the eggs, the sperm, our fertilized eggs, portions of the body for medical, scientific or educational purposes, provided that our identity is not revealed by the pictures or any accompanying text.

We understand that insurance coverage for all or any part of this total procedure may not be available and acknowledge, jointly and severally, our personal responsibility for payment of all costs of this treatment, including hospital charges, laboratory charges and physician's professional fees, as well as costs incurred as a result of any complication which may occur.
.
We have had the opportunity to read and ask questions about the contents of this document and all the components of IVF treatment. We understand the information provided and our questions have been answered to our satisfaction. We execute this consent form freely and voluntarily. We have not relied on any inducements, promises, or representations made by Dr. H. Christina Lee, the Family Fertility Center or its staff.

_____

Print Name Signature Date

_____

Print Name Signature Date

Initials_____/_____

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CONSENT TO TREATMENT WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

Initial below to indicate which components of IVF treatment you agree to undertake in your upcoming treatment cycle.

Elements of IVF Treatment	Initials	Date	Initials	Date
In-vitro fertilization (IVF)				
Intracytoplasmic Sperm Injection (ICSI)				
Assisted Hatching				
Embryo Freezing*				
Egg Freezing*				
Sperm or Testicular Freezing*				
Embryo Biopsy*				
Pre-implantation Genetic Diagnosis*				

*Separate consent forms must be completed for these additional procedures.

The foregoing was read, discussed, and signed in my presence, and in my opinion the person signing did so freely, and with full knowledge and understanding.

_____

Print Name of Witness Signature of Witness Date

I have explained to the above couple/individual the nature and purpose of the procedure; the potential benefits, and possible risks associated with participation in this procedure. I have answered all questions that have been raised by the above couple/individual.

.

_____

H. Christina Lee, M.D., J.D., H.C.L.D. Date

Initials_____/_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (HUSBAND)

Personal History

Name_____Date of Birth_____

Home Address_____

Home Phone_____Work Phone_____

Type of Employment_____

Social Security #_____Medical Insurance_____

Marital Status_____Religion_____

Highest education degree (high school, college, graduate school, etc.)_____

Ethnic background (check all that applies)

Northern European Caucasian (specify)_____

Greek_____

Middle Eastern_____

Italian_____

Jewish_____

African American_____

Hispanic_____

Southeast Asian_____

Asian Indian_____

American Indian_____

Other ethnic group (specify)_____

Height_____Weight_____

Natural hair color_____Eye color_____

Complexion (Fair, Medium, Dark)_____Blood type (if known)_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (HUSBAND)

Medical History

Medical illness_____

_____

_____

Medications taken within the last 30 days_____

_____

Drug allergies_____

Surgeries in the past (list all surgeries and why done)_____

_____

_____

Number of pregnancy sired by you_____Number of living children_____

Coffee (cups/day)_____ # Cigarettes per day_____

Alcohol consumption (type, quantity, and frequency)_____

Recreational drug use (type, quantity, and frequency)_____

Intravenous drug use (type, quantity, and frequency)_____

Hobbies_____

_____

Reasons for requesting anonymous oocyte (egg) donation_____

_____

_____

_____

_____

_____

_____

_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (HUSBAND)

Family History

CHILDREN

Living

	Name	Sex	Age	Health status
1.				
2.				
3.				
4.				
5.				
6.				

NOTES:_____

_____

_____

Deceased (including neonatal & childhood deaths)

	Name	Sex	Age at Death	Cause of Death
1.				
2.				

NOTES:_____

_____

_____

_____

_____

_____

_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (HUSBAND)

Family History

(If you are adopted, do not complete this section and proceed to page 8)

Father (if living) age:_____ Health status:_____

_____

if deceased, age at death:_____ Cause of death:_____

Mother (if living) age:_____ Health status:_____

_____

if deceased, age at death:_____ Cause of death:_____

Paternal grandfather
(if living) age:_____ Health status:_____

_____

if deceased, age at death:_____ Cause of death:_____

Paternal grandmother
(if living) age:_____ Health status:_____

_____

if deceased, age at death:_____ Cause of death:_____

Maternal grandfather
(if living) age:_____ Health status:_____

_____

if deceased, age at death:_____ Cause of death:_____

Maternal grandmother
(if living) age:_____ Health status:_____

_____

if deceased, age at death:_____ Cause of death:_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (HUSBAND)

Family History

BROTHERS AND SISTERS

Living

Name Sex Age Health status

1._____

2._____

3._____

4._____

5._____

6._____

7._____

8._____

NOTES:_____

_____

_____

Deceased (including neonatal & childhood deaths)

Name Age at Death Cause of Death

1._____

2._____

3._____

4._____

NOTES:_____

_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (HUSBAND)

Family History

PATERNAL UNCLES AND AUNTS

Living

Name Sex Age Health status

1._____

2._____

3._____

4._____

5._____

6._____

NOTES:_____

_____

Deceased (including neonatal & childhood deaths)

Name Age at Death Cause of Death

1._____

2._____

NOTES:_____

_____

_____

PATERNAL FIRST COUSINS

Neonatal death?_____ Cause(if known)_____

Birth Defects?_____ Specific Defect_____

NOTES:_____

_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (HUSBAND)

Family History

MATERNAL UNCLES AND AUNTS

Living

Name Sex Age Health status

1._____

2._____

3._____

4._____

5._____

6._____

NOTES:_____

_____

_____

Deceased (including neonatal & childhood deaths)

Name Age at Death Cause of Death

1._____

2._____

NOTES:_____

_____

_____

MATERNAL FIRST COUSINS

Neonatal death?_____ Cause(if known)_____

Birth Defects?_____ Specific Defect_____

NOTES:_____

_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (HUSBAND)

Do you have a personal or family history of the following conditions: (if yes to any of the questions, please explain at the end of this section)

Condition	Yourself		Family		Comments (Indicate which family member and age of onset)
1. Congenital malformation					
Cleft lip	yes	no	yes	no	
Cleft palate	yes	no	yes	no	
Club foot	yes	no	yes	no	
Congenital heart disease	yes	no	yes	no	
Spina bifida	yes	no	yes	no	
Others	yes	no	yes	no	
2. Children with					
Down's syndrome	yes	no	yes	no	
Other chromosomal abnormalities	yes	no	yes	no	
Mental retardation	yes	no	yes	no	
Learning Delay	yes	no	yes	no	
Congenital birth defect	yes	no	yes	no	
3, Hemophilia or Bleeding disorder	yes	no	yes	no	
4. Albinism	yes	no	yes	no	
5. Retinitis Pigmentosa	yes	no	yes	no	
6. Cystic fibrosis	yes	no	yes	no	
7. Muscular Dystrophy	yes	no	yes	no	
8. Huntington's chorea	yes	no	yes	no	

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (HUSBAND)

Do you have a personal or family history of the following conditions: (if yes to any of the questions, please explain at the end of this section)

Condition	Yourself		Family		Comments (Indicate which family member and age of onset)
9. Thalassemia	yes	no	yes	no	
10. Sickle cell disease	yes	no	yes	no	
11. Tay Sach's disease	yes	no	yes	no	
12. Neurofibromatosis	yes	no	yes	no	
13. Marfan syndrome	yes	no	yes	no	
14. Colon cancer	yes	no	yes	no	
15. Leukemia or Lymphoma	yes	no	yes	no	
16. Childhood cancer	yes	no	yes	no	
17. High blood pressure	yes	no	yes	no	
18. Diabetes	yes	no	yes	no	
19. High cholesterol	yes	no	yes	no	
20. Heart attack	yes	no	yes	no	
21. Obesity	yes	no	yes	no	
22. Stroke	yes	no	yes	no	
23. Embolism or Thromboplebitis	yes	no	yes	no	
24. Seizure disorders	yes	no	yes	no	
25. Blindness	yes	no	yes	no	
26. Deafness	yes	no	yes	no	
27. Ulcerative colitis	yes	no	yes	no	
28. Crohn's disease	yes	no	yes	no	
29. Thyroid disease	yes	no	yes	no	
30. Rheumatoid Arthritis	yes	no	yes	no	

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (HUSBAND)

Do you have a personal or family history of the following conditions: (if yes to any of the questions, please explain at the end of this section)

Condition	Yourself		Family		Comments (Indicate which family member and age of onset)
31. Lupus	yes	no	yes	no	
32. Jaundice	yes	no	yes	no	
33. Hepatitis	yes	no	yes	no	
34. Blood transfusion	yes	no	yes	no	
35. Anemia	yes	no	yes	no	
36. Asthma	yes	no	yes	no	
37. Kidney disease	yes	no	yes	no	
38. Depression	yes	no	yes	no	
39. Schizophrenia	yes	no	yes	no	
40. Drug addiction	yes	no	yes	no	
41. Alcoholism	yes	no	yes	no	
42. Sexually transmitted diseases					
Gonorrhea	yes	no	yes	no	
Chlamydia	yes	no	yes	no	
Syphilis	yes	no	yes	no	
Condyloma	yes	no	yes	no	
Genital herpes	yes	no	yes	no	
Human Immunodeficiency Virus (HIV)	yes	no	yes	no	
43. Infertility	yes	no	yes	no	
44. Radiation or Chemotherapy	yes	no	yes	no	
45. Hospitalization	yes	no	yes	no	

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (HUSBAND)

Do you have a personal or family history of the following conditions: (if yes to any of the questions, please explain at the end of this section)

Condition	Yourself	Family	Comments (Indicate which family member and age of onset)

46. Other medical conditions not listed_____

Explanation for any of the conditions above:_____

_____

_____

_____

_____

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_____ _____
Signature of Husband or Male Partner Date

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (WIFE)

Personal History

Name_____Date of Birth_____

Home Address_____

Home Phone_____Work Phone_____

Type of Employment_____

Social Security #_____Medical Insurance_____

Marital Status_____Religion_____

Highest education degree (high school, college, graduate school, etc.)_____

Ethnic background (check all that applies)

Northern European Caucasian (specify)_____

Greek_____

Middle Eastern_____

Italian_____

Jewish_____

African American_____

Hispanic_____

Southeast Asian_____

Asian Indian_____

American Indian_____

Other ethnic group (specify)_____

Height_____Weight_____

Natural hair color_____Eye color_____

Complexion (Fair, Medium, Dark)_____Blood type (if known)_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (WIFE)

Medical History

Gynecologic history

Age at first period _____ Interval between periods_____

Duration of period _____Bleeding between periods (yes/no) _____

Methods of birth control used now and in the past _____

_____

Current frequency of intercourse (weekly) _____

Obstetrical history

Number of previous pregnancy _____

How many of your pregnancies have resulted in:

Miscarriage _____

Abortion _____

Stillbirths _____

Tubal pregnancy _____

Live births _____

Past medical history

Medical illness_____

_____

_____

Medications taken within the last 30 days_____

_____

Drug allergies_____

Surgeries in the past (list all surgeries and why done)_____

_____

_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (WIFE)

Hobbies _____

Coffee (cups/day)_____ # Cigarettes per day_____

Alcohol consumption (type, quantity, and frequency)_____

Recreational drug use (type, quantity, and frequency)_____

Intravenous drug use (type, quantity, and frequency)_____

Recreational drug use in current and/or past sexual partner(s) (type, quantity, and frequency) _____

_____

Intravenous drug use in current and/or past sexual partner(s)(type, quantity, and frequency) _____

_____

Reasons for requesting anonymous oocyte (egg) donation_____

_____

_____

_____

_____

_____

_____

_____

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_____

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_____

_____

_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (WIFE)

Family History

CHILDREN

Living

	Name	Sex	Age	Health status
1.				
2.				
3.				
4.				
5.				
6.				

NOTES:_____

_____

_____

Deceased (including neonatal & childhood deaths)

	Name	Sex	Age at Death	Cause of Death
1.				
2.				

NOTES:_____

_____

_____

_____

_____

_____

_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (WIFE)

Family History

(If you are adopted, do not complete this section and proceed to page 8)

Father (if living) age:_____ Health status:_____

_____

if deceased, age at death:_____ Cause of death:_____

Mother (if living) age:_____ Health status:_____

_____

if deceased, age at death:_____ Cause of death:_____

Paternal grandfather
(if living) age:_____ Health status:_____

_____

if deceased, age at death:_____ Cause of death:_____

Paternal grandmother
(if living) age:_____ Health status:_____

_____

if deceased, age at death:_____ Cause of death:_____

Maternal grandfather
(if living) age:_____ Health status:_____

_____

if deceased, age at death:_____ Cause of death:_____

Maternal grandmother
(if living) age:_____ Health status:_____

_____

if deceased, age at death:_____ Cause of death:_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (WIFE)

Family History

BROTHERS AND SISTERS

Living

	Name	Sex	Age	Health status
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				

NOTES:_____

_____

_____

Deceased (including neonatal & childhood deaths)

	Name	Age at Death	Cause of Death
1.			
2.			
3.			
4.			

NOTES:_____

_____

_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (WIFE)

Family History

PATERNAL UNCLES AND AUNTS

Living

Name Sex Age Health status

1._____

2._____

3._____

4._____

5._____

6._____

NOTES:_____

_____

Deceased (including neonatal & childhood deaths)

Name Age at Death Cause of Death

1._____

2._____

NOTES:_____

_____

_____

PATERNAL FIRST COUSINS

Neonatal death?_____ Cause(if known)_____

Birth Defects?_____ Specific Defect_____

NOTES:_____

_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (WIFE)

Family History

MATERNAL UNCLES AND AUNTS

Living

	Name	Sex	Age	Health status
1.				
2.				
3.				
4.				
5.				
6.				

NOTES:_____

_____

_____

Deceased (including neonatal & childhood deaths)

	Name	Age at Death	Cause of Death
1.			
2.			

NOTES:_____

_____

_____

MATERNAL FIRST COUSINS

Neonatal death?_____ Cause(if known)_____

Birth Defects?_____ Specific Defect_____

NOTES:_____

_____

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IN-VITRO FERTILIZATION WITH DONATED OOCYTES
COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (WIFE)

Do you have a personal or family history of the following conditions: (if yes to any of the questions, please explain at the end of this section)

Condition	Yourself		Family		Comments (Indicate which family member and age of onset)
1. Congenital malformation					
Cleft lip	yes	no	yes	no	
Cleft palate	yes	no	yes	no	
Club foot	yes	no	yes	no	
Congenital heart disease	yes	no	yes	no	
Spina bifida	yes	no	yes	no	
Others	yes	no	yes	no	
2. Children with					
Down's syndrome	yes	no	yes	no	
Other chromosomal abnormalities	yes	no	yes	no	
Mental retardation	yes	no	yes	no	
Learning Delay	yes	no	yes	no	
Congenital birth defect	yes	no	yes	no	
3, Hemophilia or Bleeding disorder	yes	no	yes	no	
4. Albinism	yes	no	yes	no	
5. Retinitis Pigmentosa	yes	no	yes	no	
6. Cystic fibrosis	yes	no	yes	no	
7. Muscular Dystrophy	yes	no	yes	no	
8. Huntington's chorea	yes	no	yes	no	

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Do you have a personal or family history of the following conditions: (if yes to any of the questions, please explain at the end of this section)

Condition	Yourself		Family		Comments (Indicate which family member and age of onset)
9. Thalassemia	yes	no	yes	no	
10. Sickle cell disease	yes	no	yes	no	
11. Tay Sach's disease	yes	no	yes	no	
12. Neurofibromatosis	yes	no	yes	no	
13. Marfan syndrome	yes	no	yes	no	
14. Colon cancer	yes	no	yes	no	
15. Leukemia or Lymphoma	yes	no	yes	no	
16. Childhood cancer	yes	no	yes	no	
17. High blood pressure	yes	no	yes	no	
18. Diabetes	yes	no	yes	no	
19. High cholesterol	yes	no	yes	no	
20. Heart attack	yes	no	yes	no	
21. Obesity	yes	no	yes	no	
22. Stroke	yes	no	yes	no	
23. Embolism or Thromboplebitis	yes	no	yes	no	
24. Seizure disorders	yes	no	yes	no	
25. Blindness	yes	no	yes	no	
26. Deafness	yes	no	yes	no	
27. Ulcerative colitis	yes	no	yes	no	
28. Crohn's disease	yes	no	yes	no	
29. Thyroid disease	yes	no	yes	no	
30. Rheumatoid Arthritis	yes	no	yes	no	

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Do you have a personal or family history of the following conditions: (if yes to any of the questions, please explain at the end of this section)

Condition	Yourself		Family		Comments (Indicate which family member and age of onset)
31. Lupus	yes	no	yes	no	
32. Jaundice	yes	no	yes	no	
33. Hepatitis	yes	no	yes	no	
34. Blood transfusion	yes	no	yes	no	
35. Anemia	yes	no	yes	no	
36. Asthma	yes	no	yes	no	
37. Kidney disease	yes	no	yes	no	
38. Depression	yes	no	yes	no	
39. Schizophrenia	yes	no	yes	no	
40. Drug addiction	yes	no	yes	no	
41. Alcoholism	yes	no	yes	no	
42. Sexually transmitted diseases					
Gonorrhea	yes	no	yes	no	
Chlamydia	yes	no	yes	no	
Syphilis	yes	no	yes	no	
Condyloma	yes	no	yes	no	
Genital herpes	yes	no	yes	no	
Human Immunodeficiency Virus (HIV)	yes	no	yes	no	
43. Infertility	yes	no	yes	no	
44. Radiation or Chemotherapy	yes	no	yes	no	
45. Hospitalization	yes	no	yes	no	

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COMPREHENSIVE HISTORY OF RECIPIENT COUPLE (WIFE)

Do you have a personal or family history of the following conditions: (if yes to any of the questions, please explain at the end of this section)

Condition	Yourself	Family	Comments (Indicate which family member and age of onset)

46. Other medical conditions not listed_____

Explanation for any of the conditions above:_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____ _____
Signature of Wife or Female Partner Date

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Information for Recipient of Donor Oocytes

Introduction

Thank you for expressing an interest as an oocyte recipient in our oocyte donation program at the Family Fertility Center. Our successful program was established since 1994 and is directed by H. Christina Lee, M.D., J.D. She has been board certified in both the specialties of Reproductive Endocrinology, and Obstetrics & Gynecology since 1991.

Indications for Oocyte Donation

Many successful pregnancies have been achieved with the use of anonymous oocyte donors in the in-vitro fertilization program at the Family Fertility Center. Treatment of infertility using donor oocyte is indicated for the following conditions.

A. To treat infertility in women with premature ovarian failure or gonadal dysgenesis. This includes women with

1. congenital gonadal dysgenesis or absence of ovaries,
2. idiopathic (unexplained) or autoimmune premature ovarian failure,
3. ovaries destroyed by chemotherapy and/or radiation therapy, and
4. ovaries surgically removed.

B. To avoid transmission of a significant genetic defect with which the recipient is known to be either affected or to be a heterozygote, or to have a family history of a condition, the carrier status of which cannot be detected.

C. To assist in pregnancy establishment in women with declining or absent ovarian function. These women with otherwise normal fertility factors become pregnant more often and are more likely to reach full term with the use of donor oocytes.

D. To assist in pregnancy establishment in individuals with persistently poor oocyte and/or embryo quality during assisted reproductive technologies.

Screening of Oocyte Donor

There is no absolute method of completely ensuring that infectious agent or genetic defect will not be transmitted by oocyte donation. Guidelines as set forth by the American Society for Reproductive Medicine, (ASRM), and the regulatory rules of the United States Food and Drug Administration, (FDA), are followed at the Family Fertility Center to make that possibility remote.

A. Oocyte donors are volunteers who are between 21 and 33 years of age. Donors with established fertility are desirable but not an absolute requirement.

B. Psychological counseling will be required for all oocyte donors.

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Information for Recipient of Donor Oocytes

C. Risk factors recognized for human immunodeficiency virus (HIV) infection, such as intravenous drug use, multiple sexual partners, and sexual partner(s) who is bisexual, uses intravenous drugs, or HIV infected are reasons for disqualification as potential oocyte donors.

D. Medical History

The donors are in good health and give no history to suggest hereditary and familial disease. A complete sexual history is obtained to exclude as donors individuals who might be at high risk for sexually transmitted diseases as stated above.

E. Physical Examination

Donors are required to have a complete physical examination including a pelvic examination, cervical culture, and Pap smear.

F. Genetic History

On the basis of a genetic history, all oocyte donors are screened for, but not limited to, the following:

a. Donor must be generally healthy and have no major Mendelian disorder such as hemophilia.
b. Donor must not have any major malformation of complex cause (multifactorial/polygenic), such as spina bifida or heart malformation. A major malformation is defined as one that carries serious functional or cosmetic handicap.
c. Donor must not be heterozygous for an autosomal recessive gene known to be prevalent in the donor's ethnic background. Where indicated, testing for traits prevalent in the donor's background will be performed. This includes α-thalassemia in Southeastern Asians and Filipinos, β-thalassemia in Mediterranean populations, sickle cell disease in African-Americans, and Tay-Sachs disease in Jews of Eastern European descent and certain other population isolates.

G. Family History

On the basis of a family history, the donor's first-degree relatives (parents or offsprings) must be free of

a. major malformations
b. major Mendelian disorders that fall into the following categories
    1. autosomal dominant or X-linked disorders in which age of onset extends beyond the age of the donor, such as Huntington's disease
    2. autosomal dominant inheritance with reduced penetrance
    3. autosomal recessive inheritance, if the disease has a high frequency in the population

H. Infectious and Genetic Diseases Testing

1. Serological testing will be performed for blood type and Rh factor.

2. The following tests, in addition to adequate history-taking and exclusion of individuals at high risk for relevant communicable diseases, are required by the FDA.
    a. Antibodies against HIV 1 and HIV 2,
    b. PCR for HIV and hepatitis C viruses,

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c. Hepatitis B surface antigen,
d. Total antibody against Hepatitis B core antigen,
e. Antibodies against Hepatitis C,
f. Serologic tests for syphilis, and
g. Cervical smear or urine for gonorrhea and chlamydia.

3. Genetic testing including a chromosomal analysis and ethnic specific genetic diseases such as cystic fibrosis for Caucasians, Tay Sachs disease for donors of Jewish descent, sickle cell disease for African-American donors, and certain ethnic specific hemoglobinopathies will be performed.

I. Consent of Oocyte Donor

Oocyte donor is required to sign a consent form, spelling out a firm denial of recognized risk factors for HIV.

Limitation on the number of oocyte donations for the oocyte donor

One concern with oocyte donation is the possibility of subsequent occurrence of an inadvertent consanguineous marriage. In addition, there is still uncertainty regarding to the long term risks of gonadotropins and oocyte retrievals to the oocyte donor. Family Fertility Center follows the guidelines set by the ASRM that no single oocyte donor will undergo more than 6six (6) cycles of oocyte donation per her lifetime.

Screening for Recipient Couple

A. Comprehensive medical, family and genetic history will be taken from both husband and wife, or partners of the recipient couples.

B. Husband or the male partner must undergo a complete semen analysis within three months prior to the treatment cycle.

C. Within one month prior to the treatment cycle, a complete physical examination on the wife, female partner or the designated gestational surrogate, including an evaluation of the uterine cavity with a hysteroscopy, hysterosalpingogram, or hydro-hysterogram with ultrasound, and a mock embryo transfer will be performed.

D. Recipient couples must undergo similar laboratory tests as the oocyte donor. Laboratory tests include blood type, Rh factor, rubella titers, serologic test for syphilis, testing for hepatitis B antigen, hepatitis C antibody, gonorrhea, chlamydia and HIV screening.

E. Because of the potential for adverse emotional and psychological consequences as a result of in-vitro fertilization using donor oocyte, formal psychological screening and counseling with a licensed psychologist, psychiatrist, or social worker is strongly recommended prior to treatment cycle.

F. In view of the lack of knowledge about the physiological effects and risks for establishing pregnancy in women of advanced age, potential recipients over the age of 40 are required to undergo a thorough evaluation including cardiovascular screening and high-risk obstetrical consultation before being approved to receive donated oocytes.

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Information for Recipient of Donor Oocytes

G. While no specific age has been recommended above which pregnancy is universally detrimental, Family Fertility Center reserves the right to approve any individual to be a recipient of oocyte donation in the anonymous oocyte donation program.

Match Between Oocyte Donor and Recipient

Recipient couples are encouraged to list the characteristics that they desire in a prospective donor While there is no guarantee that a potential oocyte donor has all the characteristics desired by an oocyte recipient couple, every attempt will be made to match oocyte recipient couple and oocyte donor for physical characteristics including race, height, body build, complexion, eye color and hair colors and texture, ethnic background, family medical history, educational background and personality characteristics. Consideration will be given to blood type and Rh factor, particularly with Rh negative recipients.

To maximize the likelihood of success, it is highly recommended to choose a donor who is under 35. Most egg donors are between the ages 21-30. Other factors related to likelihood of success are having previously carried a pregnancy to term, or having previously completed an egg donor cycle with good results.

Procedures for Oocyte Donor

The basic steps in an in-vitro fertilization cycle using donor oocyte for the oocyte donor are:

1. suppression of menstrual cycle with a gonadotropin releasing hormone agonist (GnRHa)
2. ovulation enhancement (stimulate development of more than one egg in a cycle), and
3. oocyte retrieval or egg harvest.

Procedures for Oocyte Recipient Couple

The basic steps in an in-vitro fertilization cycle with donor oocyte for the recipient couple are:

1. if wife of recipient couple is premenopausal, suppression of menstrual cycle with a gonadotropin releasing hormone agonist (GnRHa)
2. estrogen replacement after adequate suppression by GnRHa
3. fertilization of donor oocytes with sperm from husband of recipient couple
4. embryo culture
5. embryo transfer, and
6. estrogen and progesterone replacement to support implantation

Freezing and Quarantining of Oocytes or Embryos

Current FDA guidelines require that donor semen be quarantined for 180 days before being released for use. Quarantining sperm is feasible because sperm can tolerate freezing much better than eggs. Although embryo freezing has been an established procedure, success with frozen embryo transfer still lags behind fresh embryo transfer. Emerging reports of live birth rates using vitrified donor oocytes comparable to fresh donor oocytes are very encouraging. At this time, Family Fertility Center elects to offer fresh donor oocytes until vitrification of donor oocytes becomes a more acceptable practice.

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Information for Recipient of Donor Oocytes

Identity Release and Disclosure Policy

Generally all egg donations with anonymous donors are performed anonymously. Recipient couple agrees never to attempt to discover the identity of the oocyte donor and waives all rights to see or copy records concerning the oocyte donor that may be kept by the physician or the Family Fertility Center. At some point, all records and information concerning the donor will be destroyed to protect her identity.

But we are committed to creating egg donation arrangements that fit the personal needs of both donor and recipients. Some donors and recipients are interested in meeting each other and we support that process, if all parties are willing. Usually this meeting is completed without exchange of any identifying information like last names, addresses, or telephone numbers, so that anonymity of the arrangement is maintained. If desired, the meeting can be facilitated in our office.

Standards for the Practice of Oocyte Donation

Under the federal statute, 21CFR 1271 HCTP, FDA has established regulatory rules on the screening and testing procedures for donors of eggs, sperms and embryos. In addition guidelines are established by the American Society for Reproductive Medicine, (ASRM), on the practice of oocyte donation.

Legal Concerns

Oocyte donors and recipient couples are required to execute documents that state their commitment, on the part of the donor, to give up all rearing rights and duties to any offspring, and on the part of the recipient couple, to take on all rights and duties of legal parents.

In Pennsylvania, the woman who delivers the baby is the legal mother unless a pre-birth court order has been obtained as in pre-arranged gestational carrier arrangements. Thus, for women using egg donation to in order to conceive, there is no need to file any legal documents to establish the parentage of the child. Laws regarding the use of donor egg vary in different states and countries. You are strongly urged to consult with a family law attorney to further clarify your legal concerns.

How to Begin

If you have one of the medical indications for the use of in-vitro fertilization using donor oocyte and wish to be a recipient, please call (610) 868-8600 to make an appointment for your initial consultation. Go to www.familyfertilty.com for more information on Egg Donation Program for Recipient. Complete this form along with History of Recipient Couple (Wife), History of Recipient Couple (Husband), and Consent to treatment with assisted reproductive technologies. Bring these forms and, where applicable, your medical records regarding previous infertility testing and treatment to your first visit.