

## **Fertility Centers of Illinois – FCI Consent to Donate Oocytes (Eggs)**

(Print Patient's full name)

(Print Partner's full name)

I understand that donating oocytes (eggs), whether to another woman, whether unknown or a relative or close friend, entails risks that are fairly well known from a medical perspective because components of the treatment cycle are medically identical to those which infertile women undergo. Some of the effects on a fertile woman of donating oocytes may not be identical, though, and the emotional and psychological risks to a woman and/or her partner and family of giving up her eggs to another woman are currently unknown.

I understand that the long-term emotional and psychological consequences of this form of family building are not known, especially when sisters or other close relatives have an on-going involvement in the life of the child/children.

### **MEDICATIONS TO STIMULATE OOCYTE PRODUCTION**

- Injections of the natural hormones FSH and/or LH (gonadotropins) to stimulate oocyte production
- Additional medications are used to prevent premature ovulation
- An overly vigorous ovarian response can occur, or conversely an inadequate response

Medications may include the following (not a complete list):

**Gonadotropins, or injectable “fertility drugs” (Follistim®, Gonal-F®, Bravelle®, Menopur®):** These natural hormones stimulate the ovary in hopes of inducing the simultaneous growth of several oocytes (eggs) over the span of 8 or more days. All injectable fertility drugs have FSH (follicle stimulating hormone), a hormone that will stimulate the growth of your ovarian follicles (which contain the eggs). Some of them also contain LH (luteinizing hormone) or LH like activity. LH is a hormone that may work with FSH to increase the production of estrogen and growth of the follicles. Luveris®, recombinant LH, can also be given as a separate injection in addition to FSH or alternatively, low-dose hCG can be used. These medications are given by subcutaneous or intramuscular injection. Proper dosage of these drugs and the timing of egg recovery require monitoring of the ovarian response, usually by way of blood tests and ultrasound examinations during the ovarian stimulation.

As with all injectable medications, bruising, redness, swelling, or discomfort can occur at the injection site. Rarely, there can be there an allergic reaction to these drugs. The intent of giving these medications is to mature multiple follicles, and many women experience some bloating and minor discomfort as the follicles grow and the ovaries become temporarily enlarged. Up to 2.0 % of women will develop Ovarian Hyperstimulation Syndrome (OHSS) [see full discussion of OHSS in the Risks to Women section which follows]. Other risks and side effects of gonadotropins include, but are not limited to, fatigue, headaches, weight gain, mood swings, nausea, Ovarian Torsion and clots in blood vessels.

Even with pre-treatment attempts to assess response, and even more so with abnormal pre-treatment evaluations of ovarian reserve, the stimulation may result in very few follicles developing, the end result may be few or no eggs obtained at egg retrieval or even cancellation of the treatment cycle prior to egg retrieval.

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

**GnRH-agonists (Leuprolide acetate) (Lupron®):** This medication is taken by injection. There are two forms of the medication: A short acting medication requiring daily injections and a long-acting preparation lasting for 1-3 months. The primary role of this medication is to prevent a premature LH surge, which could result in the release of eggs before they are ready to be retrieved. Since GnRH-agonists initially cause a release of FSH and LH from the pituitary, they can also be used to start the growth of the follicles or initiate the final stages of egg maturation. Though leuprolide acetate is an FDA (Federal Drug Administration) approved medication, it has not been approved for use in IVF, although it has routinely been used in this way for more than 20 years. Potential side effects usually experienced with long-term use include but are not limited to hot flashes, vaginal dryness, bone loss, nausea, vomiting, skin reactions at the injection site, fluid retention, muscle aches, headaches, and depression. No long term or serious side effects are known. Since GnRH-a are oftentimes administered after ovulation, it is possible that they will be taken early in pregnancy. The safest course of action is to use a barrier method of contraception (condoms) the month you will be starting the GnRH-a. GnRH-a have not been associated with any fetal malformations however you should discontinue use of the GnRH-a as soon as pregnancy is confirmed.

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**GnRH-antagonists (Ganirelix Acetate or Cetrorelix Acetate) (Antagon®, Cetrotide®):** These are another class of medications used to prevent premature ovulation. They tend to be used for short periods of time in the late stages of ovarian stimulation. The potential side effects include, but are not limited to, abdominal pain, headaches, skin reaction at the injection site, and nausea.

**Human chorionic gonadotropin (hCG) (Profasi®, Novarel®, Pregnyl®, Ovidrel®):** hCG is a natural hormone used in IVF to induce the eggs to become mature and fertilizable. The timing of this medication is critical to retrieve mature eggs. Potential side effects include, but are not limited to breast tenderness, bloating, and pelvic discomfort.

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

**Other medications:** Antibiotics may be given for a short time during the treatment cycle to reduce the risk of infection associated with egg retrieval. Antibiotic use may be associated with causing a yeast infection, nausea, vomiting, diarrhea, rashes, sensitivity to the sun, and allergic reactions. Other medications such as steroids, heparin, low molecular weight heparin or aspirin may also be included in the treatment protocol

### **Risks**

To increase the number of eggs that develop, a series of hormone shots are given. The hormones used in this regimen are known to have, or suspected of having a variety of side effects, some minor and some potentially major.

The most serious side effect of ovarian stimulation is ovarian hyperstimulation syndrome (OHSS). Its symptoms can include increased ovarian size, nausea and vomiting, accumulation of fluid in the abdomen, breathing difficulties, an increased concentration of red blood cells, kidney and liver problems, and in the most severe cases, blood clots, kidney failure, or death. The severe cases affect only a very small percentage of women 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 which can happen 10 to 15 days after retrieval. In a small number of OHSS cases, the ovary and Fallopian tube can twist (ovarian torsion), cutting off the blood supply. The treatment for ovarian torsion may include removal of the ovary and Fallopian tube.

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

### **TRANSVAGINAL OOCYTE RETRIEVAL**

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

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

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

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

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

**Anesthesia:** The use of anesthesia during the egg retrieval can produce unintended complications such as an allergic reaction, low blood pressure, nausea or vomiting and in rare cases death.

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

### **PARTICIPATION IN THE OOCYTE DONOR PROGRAM**

I understand and acknowledge that donating oocytes, whether to an anonymous or known recipient, entails medical risks that are identical to medical risks faced by an infertile women undergoing assisted reproduction. I also understand and acknowledge that there are additional known and unknown emotional and psychological risks to a woman and/or her partner and family when she donates her oocytes to another person. I acknowledge that I knowingly and willingly assume all known and unknown medical, emotional and psychological risks that are associated with the donation of my oocytes.

I hereby give permission to Fertility Centers of Illinois (FCI) to display my medical and genetic history, infectious disease testing results and photograph to potential oocyte recipients. I understand that **FCI** will only release the non-identifying health information that is necessary, in its sole discretion, to satisfy the requirements of the oocyte donation process.

I understand there is no guarantee that future laws or regulations will protect my anonymity in all instances, including disclosure of my identity to the oocyte recipient(s) and/or to any resulting child(ren).

I acknowledge and consent to the release of my non-identifying medical information to the oocyte recipient(s) only to the extent necessary to facilitate the oocyte donor selection process and/or coordinate the assisted reproduction treatment cycles between me and the oocyte recipient(s). I also consent to release my non-identifying medical information to any child(ren) that may result from my donated oocytes.

I certify that the genetic and medical history forms and risk assessment questionnaire I filled out are complete and accurate to the best of my knowledge. If at a future time I discover that I or someone in my family displays a hereditary condition, which was unknown at the time of my donation, I will notify **FCI** of such event. I understand that my identity will be kept anonymous.

I also certify that I have not, to my knowledge, contracted HIV or used intravenous drugs. I also verify that I am either not sexually active at this time, or that I am involved in a monogamous relationship and have not had sexual contact with someone with HIV/AIDS, or someone who used intravenous drugs. Furthermore, I agree not to have unprotected sexual intercourse from the time of the cycle start until the onset of my next menses.

It is understood that, even after signing this consent to donate oocytes, I may withdraw from the program without it affecting my future therapy or clinical care and there will be no penalty (except as herein outlined) or loss of benefits to which I am otherwise entitled.

I acknowledge that my partner is fully aware of my intent to donate oocytes and understands the need for protected sexual intercourse during my oocyte donor cycle..

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I understand that my donated oocytes will be used in an attempt to create an embryo(s) that can be used to establish a pregnancy in a known or anonymous oocyte recipient(s). **(Please choose one option)**

\_\_\_\_\_ I agree to donate all my oocytes at the time of oocyte retrieval to the following known recipient for the purpose of establishing a pregnancy in the following recipient:

\_\_\_\_\_  
Name of oocyte recipient

\_\_\_\_\_ I agree to donate all my oocytes at the time of oocyte retrieval to \_\_\_\_\_ anonymous recipients for the purpose of establishing a pregnancy in each anonymous recipient. The manner in which my oocytes are to be shared between or among the anonymous recipients will be at the sole discretion of **FCI**.

**DISPOSITION OF UNUSED OOCYTES**

As the oocyte donor, I acknowledge that I have the right to direct how my unused oocytes will be used by the oocyte recipient(s).

\_\_\_\_\_ I **AGREE** that the oocyte recipient(s) may dispose of any unused oocyte(s) as follows:

**(Please initial your choice for each disposition option)**

**YES    NO**

- |       |       |   |
|-------|-------|---|
| _____ | _____ | Donate to a research/quality control program determined by <b>FCI</b> at its sole discretion  |
| _____ | _____ | Donate to other person(s) or couple for the purpose of establishing a pregnancy, and further agree to allow such other person(s) or couple to re-donate any unused oocytes to another person(s) or couple for the purpose of establishing a pregnancy; and I agree to continue to permit re-donation until such time as there are no unused oocytes remaining |
| _____ | _____ | Discard according to generally accepted laboratory practices  |
| _____ | _____ | Cryopreservation storage, at the oocyte recipient(s) expense  |
| _____ | _____ | Restrictions (please include any restrictions you wish to place on any of the choices above):   |
- 

**DONATION OF EMBRYOS CREATED WITH MY DONATED OOCYTES**

Because the law in this area is unsettled, as the oocyte donor, I acknowledge that if I am determined to have the right by applicable law to direct how unused embryo(s) created with my donated oocytes will be used by the oocyte recipient(s), I **AGREE** that the oocyte recipient may dispose of any embryo(s) created with my donated oocyte(s) as follows:

**(Please initial your choice for each disposition option)**

**YES    NO**

- |       |       |  |
|-------|-------|--|
| _____ | _____ | Donate to a research/quality control program determined by <b>FCI</b> at its sole discretion   |
| _____ | _____ | Donate to other person(s) or couple, for the purpose of establishing a pregnancy, and further agree to allow such other person(s) or couple to re-donate any unused embryos created with my donated oocytes to another person(s) or couple for the purposes of establishing a pregnancy; and I agree to continue to permit re-donation until such time there are no unused embryos created with my donated oocytes remaining |
| _____ | _____ | Discard according to generally accepted laboratory practices   |
| _____ | _____ | Cryopreservation storage, at the oocyte recipient(s) expense   |
| _____ | _____ | Restrictions (please include any restrictions you wish to place on any of the choices above)   |
-

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In the event the original oocyte recipient(s) and/or embryo owner(s) determines to re-donate my donated oocyte(s) or embryo(s) created with my donated oocyte(s) to other oocyte recipient(s) or embryo recipient couple, it may be necessary to release my non-identifying medical information to the potential oocyte and/or embryo recipient(s) only to the extent necessary to facilitate the oocyte and/or embryo selection process. **(Please choose one option)**

\_\_\_\_\_ I **AGREE** to the release of my non-identifying medical information

\_\_\_\_\_ I **DO NOT AGREE** to the release of my non-identifying medical information

**FINANCIAL CONSIDERATIONS**

In the case of anonymous oocyte donation, I will receive a stipend of \$\_\_\_\_\_ upon completion of the cycle for the inconvenience, time, travel expenses, and possible loss of income because of my medical services. If the cycle is cancelled by FCI for medical reasons, through no fault of mine, prior to retrieval and after beginning medications, I will receive \$\_\_\_\_\_. If I withdraw from the program at any time, for non-medical or personal reasons, I will receive no reimbursement.

I understand that if required FDA lab results for infectious disease testing as abnormal and/or positive, I will not qualify as an oocyte donor and the current oocyte donation cycle will be canceled. I understand that in this situation, I will not receive reimbursement.

**RELINQUISHMENT OF ALL RIGHTS TO THE OOCYTES AND ANY RESULTING EMBRYOS OR OFFSPRING**

I understand that FCI is not providing legal advice regarding the legal rights and obligations of the parties involved, including the rights of the embryo(s) and infant(s) born as the result of the donor oocyte service, and the ramification of any resulting embryo transfer procedure. I understand that the laws in this area are unsettled and have not been fully addressed in state or federal legislation or court decisions. I understand that the law may change and no warranties as to the ultimate cost, liability or obligations of the involved parties can be made. I understand that I am required to seek legal counsel and represent that I have done so before signing this consent. In that connection, I have provided a letter from legal counsel verifying the execution of the legal contract. I have also had the opportunity to consult with a physician, and psychologist/counselor.

I have considered all of the information provided to me, from various sources, and knowingly relinquish all rights of any kind to the oocytes and to any resulting embryo(s) or child(ren), except where applicable law or this consent requires otherwise, or where a court has acquired jurisdiction over the embryos.

I hereby acknowledge that I have been given the opportunity to read and understand the ASRM Third Party Reproduction Pamphlet. I have conferred with my physician and medical team, during which time we have discussed (1) the risks and benefits of ART treatment and (2) my individual medical circumstances.

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

I agree to waive, release and relinquish any and all rights, claims or causes of action of any kind, whether known or unknown and whether now existing or occurring in the future, over and against **FCI** its physicians and their staff, employees, affiliates, agents, officers and directors and agree to defend, hold harmless and indemnify such parties from and against any expenses, claims, actions, liabilities, attorney fees, damages, losses, penalties, fines and interest of any kind, including death of or injury to persons or embryos and damage to property that may arise, directly or indirectly, with the oocyte donation, cryopreservation (freezing) of the oocyte or embryos, oocyte and /or embryo(s) disposition and including any liability relating to the child(ren) resulting from the use of my donated oocytes.

I have read this consent carefully and fully understands its contents. I have had the opportunity to speak to my healthcare provider and ask questions and have all questions answered to my satisfaction.

I have made this decision free of coercion and agree to proceed with donating my oocytes as stated above.

I have been fully advised of the risks and benefits of oocyte donation, as well as ART generally, and understand them. I have made the decision to be an oocyte donor free of coercion and agree to proceed with donating my oocytes as stated above. I

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understand that this consent signed at the time of treatment at FCI supersedes any other consent signed by me with other agencies.

\_\_\_\_\_  
Oocyte Donor

\_\_\_\_\_  
Date

\_\_\_\_\_  
Partner, if applicable

\_\_\_\_\_  
Date

**Photo Identification**

(F)Type: \_\_\_\_\_ Date: \_\_\_\_\_

\_\_\_\_\_  
Witness Name Signature and Title Date: \_\_\_\_\_

**Signature of consenting party must be notarized if the consent is signed outside the presence of a Center employee.**

**Patient**

State of \_\_\_\_\_

County of \_\_\_\_\_

I certify that I know or have satisfactory evidence that \_\_\_\_\_ is the person who appeared before me, and said person acknowledged that he/she signed this instrument and acknowledged it to be him/her free and voluntary act for the uses and purposes mentioned in the instrument.

Dated \_\_\_\_\_

\_\_\_\_\_  
Notary Signature

\_\_\_\_\_  
Title

My appointment expires \_\_\_\_\_

**Physician Attestation**

The above mentioned woman/couple has been informed and counseled by me and others regarding the risks and benefits of the relevant treatment options, including non-treatment. The woman/couple appeared capable of understanding the information presented as demonstrated by our discussion and the responsive nature of the participation of the woman/couple.

\_\_\_\_\_  
Physician Date