

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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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 six (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-hysteroogram 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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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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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.familyfertility.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.