

Delaware Valley Institute of Fertility & Genetics

6000 Sagemore Drive, Ste 6102

Marlton, NJ 08053

(856) 988-0072

FAX (856) 988-0056

Informed Consent to Donate Oocytes

I, _____ desire to participate in the oocyte donation program at Delaware Valley Institute of Fertility & Genetics (DVIF&G). I understand that there are several steps involved in this procedure and that beginning this process does not guarantee that I will complete the process. I understand that I will undergo medical and psychological screening to determine whether or not I will be accepted into the Ovum Donor program. I understand that acceptance or rejection is not necessarily a reflection of my psychological or medical health, but only an assessment of appropriateness for donation. I understand that I will receive medications to induce the maturation of several eggs and during this period, I will undergo intensive monitoring including blood work and ultrasound scans. I understand that many of the medications are given by self-administered injections. I understand that I will undergo a surgical procedure to retrieve my eggs and that the procedure is done under anesthesia by needle aspiration under ultrasound guidance. I understand that my eggs are being donated to a recipient that is unable to conceive. In this document the "recipient" may be a heterosexual or same-sex couple or a single man or woman. Specifically, I understand that my eggs are being donated for the purpose of allowing another individual to become pregnant and have a child. I knowingly donate my eggs for this purpose and relinquish all control of my eggs and recognize that any embryos or children that result are the sole property of the recipient and his/her partner. I understand that egg donation is a relatively new technology and that I am advised to seek legal counsel about my rights and responsibilities as a participant in this procedure.

If I am a known donor, I understand that I will be donating my eggs to:

(Recipient and spouse or partner).

Known donors should make special note of paragraph 13b on page 5.

I understand that each step in the process of oocyte donation carries some risk as detailed in the following paragraphs. I understand and explicitly accept such risks.

1. SCREENING - I understand that I, the egg donor, must provide a detailed history, including a comprehensive medical history looking for familial diseases before I will be allowed to enter the donor egg program. Additional screening may include:
 - a. Physical examination of the egg donor, including pelvic examination
 - b. Detailed social histories of each donor, including history of habits and substance ingestion. History of sexual relationships outside that of the immediate relationship will be privately discussed, and the conversation may be of a personal nature.

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- c. Screening for inheritable diseases according to history and ethnic background is performed.
- d. Psychological screening and interview of the donor with a qualified mental health professional is required. Multiple visits may be necessary.
- e. Screening generally includes, but is not limited to the following: Chlamydia & GC cervical or urine cultures, HepB, HepC, HIV I/II, RPR by FDA required labs; as well as, Complete blood count, Drug Screening, PT/PTT, ABO Rh and PAP smear.
- f. With respect to screening for contagious disease, it is understood that there are limitations to technology. Despite strict adherence to protocol, contagious disease may be transmitted from one individual to another, specifically from egg donors to egg recipients. The chances of this are unlikely, but exist nonetheless.
- g. Results of medical and psychological screening are shared with members of the DVIF&G staff for the purposes of matching. Results are not given to the donor.
- h. I understand that the risks of screening include, but are not limited to: learning information about myself that may require medical follow up, or that may cause me or my partner psychological distress.
- i. Non-identifying information obtained during the screening will be shared with the recipient.

2. MATCHING

- a. I understand that information gathered during the screening process will be shared with DVIF&G staff members for the purposes of matching me with a recipient couple. Some non-identifying information about me will be shared with the recipient and his/her partner. I understand that the recipient may not accept matches made by DVIF&G.

3. SYNCHRONIZATION - I understand that once I am matched with a recipient, synchronization with the recipient and start of the actual egg donation cycle may take a few weeks to a few months to coordinate. I may be placed on oral contraceptive pills to facilitate synchronization. Alternatively, my eggs may be frozen as part of an experimental protocol.

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4. **OVULATION INDUCTION** - I understand that a variety of medications are available for the induction of ovulation including human menopausal gonadotropins (Pergonal, Humegon, Menopur) pure follicle stimulating hormone (urofollitropin, FSH, Fertinex), recombinant FSH (Follistim, Gonal-f) human chorionic gonadotropin (hCG), GnRH antagonists (Antagon and Cetrotide), and GnRH agonists (Lupron). I understand that some of these medications must be given by intramuscular injection, which may cause bruising or discomfort at the injection site. Very rarely, these medications may cause the ovaries to become over stimulated, leading to a condition called ovarian hyperstimulation syndrome (OHSS). I understand that in its most severe form this condition might require hospitalization for intravenous fluids and monitoring until the syndrome resolves. I also know that worldwide there have been rare reports of death following severe OHSS. I therefore understand the importance of maintaining close contact with the IVF team during the time that these medications are being used and for two weeks afterwards.
5. **MONITORING PROTOCOL** - I understand that while receiving the medications listed above, I will be closely monitored by the IVF team. I understand that this monitoring will include daily blood drawing, which carries the risk of mild discomfort and bruising at the puncture site. I understand that ultrasound examination of the ovarian follicles and the uterus will be performed frequently (usually every 1-3 days). These examinations may at times be uncomfortable, but there is no risk presently known to medical science. Occasionally, I may also be asked to collect urine samples for further hormone analysis. I understand that if monitoring suggests a low probability of successful egg retrieval that the stimulation cycle will be stopped and no egg retrieval will occur. In this case compensation will be reduced. I also understand that in certain circumstances after a cycle cancellation that I may be given the option of starting the ovarian stimulation again in a subsequent cycle.
6. **EGG RETRIEVAL** - I understand that at a time determined by the IVF team, that I will undergo a surgical procedure at DVIF&G to retrieve my eggs. I understand that in the vast majority of cases, ultrasound directed needle puncture of the follicles would be done. Very rarely, the retrieval may be done by laparoscopy under general anesthesia. I understand that the procedure involves the small risk of general anesthesia, risk of a reaction to antibiotics or other medications given, as well as injury to bowel, bladder, or blood vessels, which might require a large incision (laparotomy) to repair. I understand that there is a theoretical risk of death from egg donation, and that the risk of death is less than 1%. I understand that a separate informed consent will be obtained for a laparoscopic retrieval if it becomes necessary. With either type of egg retrieval, I understand that in rare cases there could be bleeding from the site where the ovaries were punctured. This may require laparotomy (a regular incision in the abdomen) if the bleeding cannot be controlled through the laparoscope. The risks of the procedure are similar to the risks of laparoscopy, including general anesthesia. I understand that a physician member DVIF&G team will perform the procedure: George S. Taliadouros

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7. AFTER THE RETRIEVAL - I understand that I must have a ride home and a companion to stay with me for 24 hours after the egg retrieval takes place. I understand that most complications occur soon after the retrieval and that it is important to comply with this requirement for my health and safety. I understand that one or more follow up visits are necessary after the retrieval to make sure I have recovered from any effects of the cycle upon my reproductive system. If I am an out-of-town donor, I must stay in NJ for 24 hours post retrieval; after that time I will be permitted to return home. DVIF&G carries medical insurance on all donors, which can be utilized at an outside facility such as the emergency room or hospital. This insurance is for procedure related visits only.

8. LONG TERM EFFECTS OF DONATION
 - a. I understand that egg donation is a relatively new technology and that the long term effects are not known.
 - b. I know that there is some information, which suggests that the lifetime risk for developing ovarian cancer may be increased by undergoing ovulation induction and that the link between ovulation induction and ovarian cancer remains an area of controversy and active research.
 - c. I understand that theoretically there could be a potential loss of fertility resulting from complications from donating my eggs, but to our knowledge no such loss has ever been reported.
 - d. I understand that the long-term psychological consequences of egg donation are unknown. There may be psychological distress associated with being an ovum donor. The Institute cannot be responsible for the adverse psychological consequences of entering into such an arrangement.
 - e. I understand that excess embryos resulting from my donation may be cryopreserved for future use. These embryos may then be further donated and utilized by other couples if the original recipient feels that their family is complete.

9. RESTRICTIONS ON ACTIVITY - I understand that for the protection of the health of all parties involved in the cycle (myself and the recipient couple) that I agree to certain restrictions on activity including, but not limited to the following list:
 - a. No intercourse once ovarian stimulation (ovulation induction) starts, until the menses after the egg retrieval or until cleared by the DVIF&G staff. I understand that I will be more fertile than usual during ovarian stimulation and the risk of unwanted pregnancy is great. In addition, the ovaries will be enlarged during stimulation and intercourse may increase the risk of cyst rupture and ovarian twisting (torsion).

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- b. No medications other than the ones prescribed by DVIF&G unless cleared by the DVIF&G staff. This includes all over-the-counter medications, and herbal remedies. Many of these items can have adverse effects on the stimulation of the eggs.
- c. No illicit drugs or smoking during the screening and cycling periods. Random drug and Nicotine testing will be performed throughout your cycle. Positive results may lead to a reduction in compensation.
- d. No body piercing or tattooing during the 12 months prior to the cycle. These procedures carry a risk of hepatitis and HIV, which can be transmitted to the recipient or the resulting child.
- e. I understand that I must be available to the DVIF&G staff for testing on a daily basis once injectable medications start until the retrieval of the eggs takes place. I may not need to have testing every day, but the exact schedule cannot be completely predicted prior to the cycle and the success of the cycle relies upon very precise timing of medications, tests and procedures. I understand that I must be able to accommodate possible changes in the predicted schedule and that participation in the egg donation program requires a time commitment and may inconvenience me. Missed appointments or missed medication dosages will result in a reduction in compensation.

10. ACCESS TO DONOR RECORDS - I relinquish all rights to any information obtained during the evaluation process and donor egg procedure including psychological, medical and other testing.

11. OWNERSHIP OF EMBRYOS RESULTING FROM EGG DONATION

- a. I understand that once eggs are removed from me, I relinquish all control of those eggs to DVIF&G for the above-agreed purposes. The eggs and resulting embryos belong to the recipient couple and /or the DVIF&G Program and I will have no responsibilities or rights of any kind in relation to such eggs or embryos.
- b. I understand that the eggs may be split between more than one recipient couple (if applicable), that excess eggs or embryos may be frozen for use at a later date, donated to another couple (if the recipient couple desires), donated for research purposes or discarded and that these procedures may occur without the knowledge or the consent of myself or my spouse.
- c. I also understand that bodily fluids or tissue, such as fluid aspirated from the ovaries at the time of the egg retrieval may be utilized for diagnostic, research or teaching purposes at the discretion of DVIF&G.

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12. OFFSPRING RESULTING FROM EGG DONATION

- a. I understand that offspring resulting from egg donation are the children of the recipients. I understand that I may not claim any responsibility or parenting rights for or obligations to those children, even if I am related to the egg recipient.
- b. I understand that the recipient couple is fully responsible for all offspring, regardless of the outcome of the pregnancy, until the child reaches the age of consent. Because of the newness of egg donation, this is an area with limited legal precedence and I understand that DVIF&G cannot assure recipients or donors of the enforceability of this situation.

13. ANONYMITY

- a. I understand that my general physical characteristics, medical information and biographical information provided by me, would all be available to the egg recipient. The anonymity of all parties will be strictly maintained to the best of DVIF&G ' ability, unless a court of law orders DVIF&G otherwise or unless the law requires such disclosure. Neither the name nor identifying information of the donor will be given to the recipient under any circumstances, nor entered in the hospital record of the recipient. However, there is the possibility that insurance claims or other records may reveal the identity of one or both parties. While DVIF&G will avoid this disclosure to the extent possible, the recipient and the donor assume the risk of identification. The DVIF&G Program will keep a separate, confidential record. The donor will receive no other information about the recipient, the outcome of the donation procedure or the resulting pregnancy should one occur. Any information obtained about any of the individuals involved (donor, donor's partner, recipient, recipient's partner) will remain confidential and will only be disclosed with the consent of that individual. I further agree that I will make no effort to ascertain the identity of the recipient and/or the partner and/or any resulting offspring.
- b. I understand that if I am a donor not recruited by DVIF&G (known donor, donor contracted via an agency, donor recruited by the recipient) I may have a non--anonymous arrangement, by prior agreement among all parties involved. All parties involved in such an arrangement (donor and spouse, recipient and spouse) are required to seek separate legal counsel and to consider separate legal documentation of the agreement to donate and accept eggs. Because of the newness of egg donation, this is an area with limited legal precedence and DVIF&G cannot assure recipients or donors of the enforceability of these agreements.

14. BENEFIT - I understand that there is no medical benefit to myself from egg donation.

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15. FINANCIAL RESPONSIBILITY

- a. The recipient couple understands that they are responsible for the charges incurred as part of the egg donation procedure. This includes but is not limited to physician, laboratory and hospital charges. The recipient's insurance company may cover all or part of these charges, but the recipient couple is solely responsible for any unpaid monies.
- b. We are obliged to inform you about the Program's policy in the unlikely event that physical injury occurs. If, as a result of your participation, you experience physical injury from known or unknown risks of the donation procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available. No monetary compensation, however, is available. The DVIF&G Program will help to bill the appropriate insurance company for any additional expenses but the DVIF&G Program will not be responsible for the costs of such care.
- c. In the event that the donor has a complication directly related to the egg donation stimulation or procedure which manifests itself within 60 days of the egg donation that is not covered in full by any insurance any and all costs incurred by the donor will be the responsibility of the recipient who has been advised of this fact. However, DVIF&G cannot guarantee that the recipient will in fact pay such costs.
- d. In addition, the anonymous donor identified by the DVIF&G Program will be compensated for her time, risk and inconvenience the sum of \$8,000. If you are a donor represented by an agency, you will not receive any compensation from DVIF&G and will be compensated fully by your agency according to your previously agreed upon terms.
- e. This amount will be pro-rated should cancellation occur for reasons beyond the donor's control. A follow-up visit and return of any unused medications is required before payment.
- f. This consent does not instruct the Donor on the issue of taxation of any payment contemplated under this consent, and this consent is not dependent on any particular tax characterization of any payment made hereunder. The Donor is advised to consult with a tax specialist in order to determine her own tax-related responsibilities and duties.

16. SUMMARY

- a. I acknowledge that I have been given an opportunity to undergo medical, psychological and legal counseling, which has been met with my satisfaction.

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- b. I understand and agree that my acceptance into the Oocyte Program and my continued participation is within the sole discretion of DVIF&G.
- c. I understand that the law in this area is uncertain. DVIF&G makes no representation as to the law in this area. In addition, DVIF&G cannot guarantee the following:
 - i. That the Oocyte Donor will produce viable ova.
 - ii. That the recipients will honor any agreement with the Oocyte Donor and/or her husband.
 - iii. That the recipients will accept physical custody and financial responsibility of any child born from such arrangement.
 - iv. That the recipients will be financially responsible for any medical complications to the Donor resulting from the Oocyte donation.
- d. The Oocyte Donor represents she is a healthy, legally competent, individual over the age of twenty-one (21) years who to the best of her knowledge is capable of producing normal, healthy ova without any unreasonable risk to her physical or mental health or to that of any resulting child, and who desires to enter into an arrangement by which she will have ova removed from her ovaries for the purpose of donating such ova to the Intended Parents for their use in conception of a child. If the Oocyte Donor is under the age of 21, approval from the medical director is required.
- e. The prospective Oocyte Donor voluntarily enters into this arrangement with the intention and desire that the intended, recipient parents of any child born as the result of this donation have physical and, to the extent permitted by law, legal custody of such child, and the extent permitted by law, be recognized as the child's parents for all lawful purposes.
- f. It is the intention of the Oocyte Donor that she is entering into this arrangement to donate oocytes to the intended mother and the genetic/intended father for the purposes of allowing the recipients to have a child and not for the purpose of having a child who the Oocyte Donor will raise or with whom she will have a legal relationship.
- g. I understand the Procedures agreed to by this consent are relatively new and that the newness means that it cannot be guaranteed what the Court system will do in response to any questions or requests brought to it as a result of the arrangement.
- h. Therefore, it is understood by the parties to this consent that no one can guarantee whether, or to what extent, the appropriate legal authorities will sanction or enforce this consent or any agreement you have with the intended parents or any of its provisions or any aspect of the procedures contemplated therein. Further, no one

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can guarantee to what extent, the appropriate legal authorities will recognize or enforce the parental rights of the Intended Parents.

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I acknowledge that I have an adequate understanding of the ovum donation process as described above and that the physicians and their associates have provided me with all the required information that I have requested. I have been made aware of the usual and most frequent risks and hazards inherent in the procedures, and the treatment associated with it. I understand that there may be some risks that are not known at this time. I explicitly accept and acknowledge all these risks both known and unknown. I have had the opportunity to ask all pertinent questions and these have been answered to my satisfaction. I understand that I may at any time prior to retrieval decide to withdraw from participation without prejudice.

Oocyte Donor's Signature

Date

DVIF&G Staff Member

Date

Physician Signature

Date