



The Donor Egg Program

Dear Prospective Egg Recipient:

This packet contains information about the Donor Egg program. The program is designed for patients whose ovaries are not functioning well, who are unlikely to produce a pregnancy, or who are at risk of transmitting a genetic condition to their offspring,

Enclosed you will find for your review:

- **The donors:** a description of the donors, including the screening process
- **The process:** a timeline and detailed description of the steps involved
- **Your screening:** a list of the tests required
- **The risks:** a discussion of potential risks
- **A Recipient Questionnaire:** to be completed and mailed back to us prior to your first consultation
- **Recipient Information and Characteristics sheet:** to be completed and mailed back to us prior to your first consultation
- **Medical and Genetic History:** to be completed and brought back to us on your first consultation
- **Authorization to release information:** use this form to forward your medical records to us
- **Financial information:** an outline of the costs associated with the Donor Egg Program

Additionally, at the time of your orientation to the Donor Egg Program, consent forms will be provided to you so you can review them at home.

We hope you find the above material complete and informative. If after reviewing this material, you have additional questions or would like to pursue this opportunity further, please contact our **Donor Egg Coordinator at (516) 562-1763**.

In addition to answering any questions you may have, our Nurse will be able to start the initial registration process and discuss the next step with you, which is the review of your medical and infertility background. In order to conduct this review, we will need information about any prior medical visits, treatment and testing already performed. In this packet, you will find a release form for your medical records, which should be helpful in obtaining your medical records from other doctors that you have consulted with. Please note that we would like you to obtain a copy of your actual hysterosalpingogram (HSG) film, if possible.

Also, as part of this initial step, we will review the information that you'll provide to us on the Donor Egg Recipient Questionnaire, and the Recipient Information and Characteristics Profile form included in this packet. We recommend that you complete these forms and mail them back to us as soon as you decide to proceed.

Sincerely,

The Donor Egg Team

The Donors

Donors will be anonymous to you, unless you have agreed with someone you know to be your donor.

All egg donors, anonymous or known, will undergo extensive and elaborate screening to ensure their suitability to be egg donors. Their screening begins with a thorough review of their personal and family medical history. Donors with a family history of genetic diseases, or who have major medical or psychiatric conditions, will be excluded. A comprehensive questionnaire and follow-up interview are used to make this screening as complete as possible. The complete physical examination and psychological evaluation of the donor must be normal. The donor must be in good health and well adjusted, and have a good understanding of the process and the required anonymity.

Donors must have 2 ovaries, good ovarian functional reserve, and no evidence of drug use (negative urine drug screen), sexually transmitted diseases (gonorrhea, syphilis, chlamydia, and HIV) or hepatitis. Anonymous donors must be less than 35 years of age. Although there is no specific age limit for known donors, they must comply with all the above testing. Heavy smokers (more than a pack daily) are excluded.

Our current protocol includes screening all patients for cystic fibrosis and Fragile X. Additional genetic testing will be required based on ethnic background. These genetic tests may change based on updated recommendations of our Geneticist.

Qualifying donors are informed of potential side effects of their treatment, both known (e.g., bleeding, infection, ovarian hyperstimulation syndrome), and uncertain (eg., ovarian cancer). They are also informed that we will not disclose to them the identity of the egg recipient and whether a pregnancy was established. Donors sign an informed consent outlining these risks and the anonymity agreement. If married, the Donor's husband is also required to give consent.

Donors are informed that the identity of their recipients will never be disclosed. The consent forms, that donors are required to sign, stipulated that they will never seek the identity of the Recipient. Donors relinquish any parental rights to the offspring resulting from their eggs.

Donors are provided insurance to cover unanticipated medical expenses related to the complications resulting from their participation in the donor egg program.

Though the donation is anonymous, we will inform you of many pertinent details about the donor (see Donor Matching below). This is important for two reasons. First, it will enable you to make an informed choice about the suitability of the donor for you. Second, if you conceive successfully, you would already have the genetic record of your donor that may become important at some point in the future.

When relatives (sister, cousin) or other "known" donors are involved, the same screening process will be used. If the relative or friend is found unsuitable, we will not be able to tell you why your donor was rejected due to the confidential nature of the testing that the donor is required to undergo.

Donor Egg Agencies

Couples may choose to select a donor provided by a private egg donation agency. Such agencies specialize in the recruitment of donors, and can provide you with a list of donors, as well as, information about them.

Potential egg donors found through these outside donor agencies will have to meet the same strict standards we require of donors recruited directly by our program. Our program will help you evaluate the suitability of these potential egg donors for you, which will necessitate at least one visit by the potential donor to the Program during the screening process. Once accepted, we will coordinate the donor's care and management.

Most donor agencies are web-based and are located out of state. We will help coordinate and manage your egg donor’s off-site care with a local physician. When ready, your egg donor will have to travel to our facility to undergo the egg retrieval.

If you are interested in finding a donor through an agency, we can refer you to agencies. We encourage recipients to question agencies about their screening criteria, as well as, any additional costs that they may face, such as testing and travel fees.

The Consultation Visit

Whether or not you are already a patient at our Center, it will be important for you to have an initial consultation visit. This will give you the chance to learn about the egg donation process in great detail and to ask any questions you may have. At this visit, you will meet with a doctor and a nurse from the Donor Egg Team. If you are not an existing patient at our Center, you should have all of your relevant medical records, including x-rays and sonograms of the uterus available.

Your Screening

Our program has established a policy of screening designed to assess your health status in preparation for conception. We would like you to *carefully review the items below to determine which apply to you*

Needed	Test/Consult	Needed
<input type="checkbox"/>	hysterosalpingogram, hysterosonogram or hysteroscopy	within 6 months
<input type="checkbox"/>	Pap smear	within 1 year
<input type="checkbox"/>	mammogram	within 1 year over the age of 35.
<input type="checkbox"/>	electrocardiogram	within the year if you are over 45
<input type="checkbox"/>	total cholesterol level	everyone
<input type="checkbox"/>	fecal occult blood screening	everyone
<input type="checkbox"/>	preconception counseling	over 45, to review pregnancy risks with an obstetrician
<input type="checkbox"/>	general medical screening	over 45, or younger, but with a history of shortness of breath, have a heart murmur, or have an abnormal electrocardiogram, or high total cholesterol, or blood in your stools.
<input type="checkbox"/>	psychological screening	everyone
<input type="checkbox"/>	psychological counseling	Not required, but recommended
<input type="checkbox"/>	blood type and RH factor	everyone

The Pilot Cycle

The purpose of the “pilot cycle” is to mimic the actual treatment cycle where you will receive the embryos. This “rehearsal” allows us to better predict your response to the hormonal medications, and will therefore require both blood testing, as well as, ultrasounds of the uterus and an endometrial biopsy.

During the pilot cycle, you will take estrogen (tablets and/or patches) for about 4 weeks. Prior to starting the estrogen, you may be required to take additional medications either birth control pills or lupron injections. During the cycle, we will obtain several blood tests and vaginal sonograms.

Donor Matching

As soon as you are enrolled in our Program, we will start to seek an appropriate egg donor for you. Once your potential donor has been selected, we will provide you with the following info:

1. a medical questionnaire filled out by the donor
2. a genetics questionnaire
3. a report from our Geneticist
4. a report from our Psychologist
5. physical information on the donor including information on donor’s occupation and education attainments.

You will need to review this information and inform us about the acceptability of the proposed donor within a week. If you feel you’d like to know more about the donor, please call us quickly so we can complete the matching process expeditiously. If you decline the proposed donor, we will look for another, but we cannot guarantee when another donor will be available. Our program will allow you to decline 3 times. After which, your status will be moved down on the Recipient list.

Once you accept a donor, you will be given an approximate timetable for your cycle. This will partly depend on synchronization with the donor and yourself. In general, you should expect the donation to happen within 6 months after you have accepted a specific donor.

Fertilization of the Eggs

On the morning of your donor’s egg retrieval, your spouse will come to our Center. He will be directed to the Andrology Lab where he will provide his semen specimen for fertilization of the eggs. (A back-up specimen would have been frozen earlier in the cycle.)

While the most common source of sperm is the male partner of the recipient, it is not the exclusive source. Some couples elect to use donated sperm because the male partner does not produce sperm, produces defective sperm, or is the carrier of a genetic condition. Other recipients participating in the egg donor program may not have a male partner and will thus elect to use donated sperm. Donated sperm used by recipients come from an anonymous donor, which has to be pre-arranged by the program. Fertilization of the donated eggs by the partner’s sperm takes place in the embryology laboratory. Initial fertilization results will be available on the next day. Additional information will become available in the two subsequent days. Unexpected lack of fertilization may occur. In such circumstances your doctor will discuss the matter with you and appropriate diagnostic and/or therapeutic options will be offered. In cases where difficulty in fertilization is anticipated due to sperm quality or the male partner’s history, we may suggest the utilization of sperm injection directly into the egg intracytoplasmic sperm injection (ICSI), as described below.

The Embryo Transfer

The embryo transfer will be performed 3 or 5 days following egg retrieval, at the North Shore Center For Human Reproduction. You will first rest here, and then at home. You will be discharged home about an hour after the transfer, and will be advised to rest at home the following days.

The embryo transfer itself is usually performed without anesthesia and lasts only a few minutes. It is similar to an intrauterine insemination of sperm. Minor side effects may include cramping and minimal bleeding. Because of hospital policy, it will not be possible for your partner to be with you during the actual transfer. However, your partner will join you in our recovery room immediately afterwards.

After returning home, you will continue to take hormones. A pregnancy test will be done 12 days following the embryo transfer. If you are pregnant, you will continue to take your hormone medications for a several weeks after embryo transfer. Your pregnancy will be monitored closely by frequent blood tests and one or more ultrasounds. If not pregnant, these medications will be discontinued and your physician will see you for a follow up consultation.

Program Administration

Among those on the active list, priority is given to those who have been longer on the list. Couples who have never completed a donor egg cycle will be given priority.

In some cases, egg donors may produce a high number of mature eggs. In such cases, two recipients might be matched to the same donor. The recipient longer on the list, is designated "primary", the other recipient, "secondary". If the donor's response is unexpectedly poor, the few available eggs would go only to the "primary" recipient. You will be informed before you start the cycle, about sharing a donor, and whether you have been designated "primary" or "secondary" recipient.

If you get your donor through an outside agency, her eggs will not be split and she will be your exclusive donor for that cycle.

An Insurance Policy is required to cover the costs of complications of the Donor Egg process itself. The insurance, issued by Lloyd of London insurance company, covers medical complications of donors that occur within 90 days of the retrieval (up to \$100,000) that are attributed to their participation in the Donor Egg program. This insurance policy excludes costs related to a) psychological effects of egg donation; b) pregnancy in donor, and c) sexually transmitted diseases (including HIV).

Ancillary Procedures Available

In many cases, ancillary procedures may be of benefit to the overall success of donor egg attempt. These are listed below:

- **Embryo cryopreservation**

Embryo freezing, referred to as cryopreservation, enables us long-term storage of excess embryos above the number of embryos you wish to have transferred. This gives an added chance to achieve a pregnancy without having to undergo a completely new round of egg donation (and thus tremendous cost and time savings). After you sign an informed consent, healthy pre-embryos will be cryopreserved. Thawing and transfer of pre-embryos will be performed in the future, either on your natural cycle or more commonly on a "programmed" cycle, involving treatment with estrogen and progesterone.

You should be aware of the fact that some embryos may become non-viable following freezing and thawing, and may therefore not be available for transfer. Not all egg donation cycles will have sufficient embryos to allow freezing.

- **Intracytoplasmic Sperm Injection (ICSI)**

Although most cases presenting with mild sperm abnormalities may still be successfully treated by “conventional” IVF, the development of ICSI has enabled us to break the sperm-egg barrier, thus allowing us to overcome most forms of male infertility. Indications for ICSI include:

1. Men with low sperm concentration, motility and/or morphology or anti-sperm antibodies.
2. Cases of partial or total fertilization failure in a previous IVF attempt.
3. Men presenting with absence of sperm in the ejaculate (azoospermia). These challenging cases include two main types of problems: (a) obstruction in the male genital tract (such as congenital bilateral absence of vas deferens, inflammatory occlusions, previous vasectomy, and other type of obstructions); and (b) patients presenting with different degrees of testicular insufficiency. The former cases can be successfully treated by new techniques of sperm aspiration from the epididymis or the vas deferens followed by ICSI. In the latter cases, sperm can sometimes be obtained from the testes by performing an open testicular biopsy or by needle aspiration, with the help of a urologist specially trained in such procedures.
4. In many cases, the possibility of freezing “extra” sperm obtained at the time of the urological intervention (prior to, or at the time of IVF-ICSI) should be considered. Frozen-thawed sperm may maintain viability and can therefore be used in future ICSI cycles. Sperm freezing is commonly done to maintain the reproductive potential prior to radical therapies in cases of cancer.

So far, most studies on babies resulting from ICSI have not shown a role of genetic or other major physical abnormalities higher than conventional IVF. However, since ICSI is a relatively new technology, more long-term follow-up studies are expected to be published in the future, shedding further light on this issue.

Genetic counseling is available to you through our program. You may choose to have chromosomal evaluation of your baby, either by CVS (chorionic villous sampling) or by amniocentesis.

- **Blastocyst Transfer**

Recent improvements in embryo culture conditions have allowed sustained embryo development to the blastocyst stage (the stage at which the embryo naturally arrives in the uterine cavity before implantation occurs). Not all embryos develop into blastocysts. Delaying the transfer to a more advanced stage enables us to transfer fewer embryos, thus lowering the risk of high-order multiple births. The transfer will usually occur 5-6 days after egg retrieval. Pregnancy rates may not be significantly different from day 3 transfer but chances for a multiple pregnancy of high order (triplets and above) are reduced. Excess blastocysts will be frozen at that stage. The IVF team will make the decision about whether you are a candidate for blastocyst transfer.

THE RISKS

Risks related to maternal age

On average, pregnancies are more apt to be complicated as the age of the pregnant woman increases. Some of this increase is due to the higher proportion of women who already have known medical problems such as high blood pressure, diabetes, and obesity. Healthy older women without overt medical disease are at somewhat decreased risk for complicated pregnancies, but the level of risk may still be above that seen at younger ages. For this reason, we have stressed preconceptual counseling to all prospective recipients over age 45 and a comprehensive medical evaluation for recipients 45 or older. We restrict the age of egg recipients to 50 years of age.

The most commonly observed complications have been blood pressure increases (hypertension and/or pre-eclampsia in up to 5%), and diabetes (in up to 20%). Other complications that are likely to occur more frequently at advanced maternal age are: slowed intrauterine fetal growth, bleeding problems (placenta previa) and premature delivery. The Cesarean section rate is higher. There may also be an increased risk of fetal death, and extremely rarely, maternal death.

Risks related to use of donor eggs per se

Since the eggs in this program are from young women, the risk of chromosomal abnormalities is not increased.

Though many donor egg recipients do in fact become (transiently) hypertensive during pregnancy, it is not clear whether this is due to age, to the immunological dissimilarity of the fetus, or both.

The risks of the development of an abnormal fetus are not yet fully known, but have not exceeded those normally seen to occur with other sorts of pregnancy.

It is possible that donors might transmit infections to you or your fetus by way of the eggs that they donate to you. Though not yet demonstrated to occur, we believe that we have taken all reasonable precautions to reduce the risk. Donors are screened before each cycle of egg donation for sexually transmitted diseases (gonorrhea, chlamydia, syphilis, hepatitis, and HIV).

Due to the anonymity of the process, it may not be possible to reliably learn of new medical problems in the donor's family after the donation has occurred. We cannot guarantee that such information will be brought to our attention.

Some religious faiths proscribe egg donation and/or in vitro fertilization in general. You may want to consult a member of your faith's clergy before proceeding (if appropriate).

Risks related to medications and monitoring procedures

The hormones that you will take during this process are similar to the hormones naturally present in a woman's body and are not known to have ill effects on your system or on a fetus. Some women experience skin irritation under the estrogen patch; many develop soreness in the area of progesterone injections or where blood has been drawn. Rarely, a woman will develop a severe reaction to a component of the medication, requiring that an alternative form be used. Reactions resolve upon discontinuation of the preparation.

Risks related to embryo transfer

Pelvic infection is a possible but a rare complication of the embryo transfer procedure. In order to minimize it, you will be asked to take an antibiotic around the time of embryo transfer.

Risks related to multiple pregnancy

Multiple pregnancies, the majority of which are twins, account for approximately 40% of all the pregnancies in our IVF program. The best way to reduce the chance for a high-order multiple pregnancy (triplets or more) is to reduce the number of embryos transferred.

Risks related to ectopic pregnancy

About 5% of all pregnancies resulting from assisted reproduction have been ectopic pregnancies (primarily in the tube). Many, but not all, of the ectopic pregnancies occur in women with prior diseases of the fallopian tubes, pelvic infection and scarring. Heterotopic pregnancies (simultaneous intrauterine and extrauterine pregnancies) may also occur, but are extremely rare. The management of ectopic pregnancies can be surgical or medical.

Risks related to laboratory procedures

The Embryology Laboratory defines its quality assurance policy as continuous improvement on a daily basis in every aspect of laboratory management and care. Given the nature of the material handled in the laboratory, working under optimal conditions is essential. Constant and consistent quality control to maintain this optimum is of the utmost importance. Our Embryology Laboratory oversees the following:

- Sterility and purity of the working environment supplies and solution
- Toxicity testing of all laboratory materials

- Optimal preventive maintenance on all laboratory equipment
- Daily function tests on all equipment
- Backup systems in the event of equipment malfunction
- Utilization of proven and reliable techniques
- Continuous consideration of laboratory safety and security

Of course, in any system that involves handling of microscopic material, human error may occur. The embryological techniques involved in your treatment require the laboratory to handle your gametes/pre-embryos on a daily basis. It is possible for a microscopic gamete (s) or embryo(s) to become lost or damaged during these procedures. The laboratory has made great effort to eliminate unnecessary handling and to make all necessary handling as safe as possible, but an absolute guarantee of gamete or embryo safety cannot be made. In addition to the human element, unforeseen conditions can occur within the laboratory environment (such as fire, unexpected devastating weather conditions or accident). Hazard plans are in effect with the hospital security department and most potential problems have been anticipated and prepared for, but again an unrestricted guarantee of gamete safety cannot be given.

An Approximate Timeline

The Initial Nursing Orientation to the Donor Egg Program

Receipt of returned materials from the Recipient
(questionnaire, medical records, hysterosalpingogram, patient information sheet and photo).
This orientation will review the components of the process; distribution and review of consent forms;
meeting with our Billing counselor to discuss financial coverage and our payment policy.

↓ Allow 1 – 4 weeks for the Initial Consultation Visit with the Physician

Consultation visit with the Physician

↓ Allow 1 – 3 weeks after consultation before the pilot cycle can begin.

Pilot Cycle

(may take 6 weeks to complete)

↓ Allow 1 – 2 weeks for test results to be received and reviewed.

Donor Match

Donor identified, matched and accepted (may take several months; usually shorter)

↓ Allow a month or two for cycle synchronization

Egg donation Treatment and Retrieval

(takes about 4 weeks)

Fertilization of eggs and Transfer

(total of 5 days)

Pregnancy Testing

(2 weeks after transfer. Continue hormonal medication for 10 full weeks, if pregnant)

RECIPIENT QUESTIONNAIRE

RECIPIENT'S NAME: _____ DATE: ____/____/____

RECIPIENT'S BIRTHDATE: ____/____/____ RECIPIENT'S SS#: ____ - ____ - ____
WEIGHT: _____ lbs. HEIGHT: _____ ft. _____ inches

ADDRESS: _____ CITY: _____ STATE: _____ ZIP: _____

HOME PHONE: (____) ____ - ____ CELL PHONE: (____) ____ - ____ MAY MESSAGES BE LEFT? YES NO

PARTNER'S NAME: _____

PARTNER'S BIRTHDATE: ____/____/____ PARTNER'S SS#: ____ - ____ - ____

GYNECOLOGIST'S NAME: _____ PHONE #: (____) ____ - ____

ADDRESS: _____ CITY: _____ STATE: _____ ZIP: _____

PLACE OF YOUR EMPLOYMENT: _____ WORK #: (____) ____ - ____
WORK JOB TITLE: _____
ADDRESS: _____ CITY: _____ STATE: _____ ZIP: _____

PLACE OF YOUR PARTNER'S EMPLOYMENT: _____ WORK #: (____) ____ - ____
WORK JOB TITLE: _____
ADDRESS: _____ CITY: _____ STATE: _____ ZIP: _____

WOULD YOU LIKE AN INSURANCE PRE-AUTHORIZATION DONE FOR YOUR DONOR EGG TRANSFER? YES NO
NAME OF YOUR PRIMARY INSURANCE COMPANY: _____

ADDRESS: _____ ID#: _____ GROUP#: _____

SUBSCRIBER'S NAME: _____

NAME OF YOUR SECONDARY INSURANCE COMPANY: _____

ADDRESS: _____ ID#: _____ GROUP#: _____

SUBSCRIBER'S NAME: _____

PREVIOUS DONOR EGG OR IN-VITRO FERTILIZATION? NO YES IF YES, NAME OF PROGRAM: _____

HOW MANY PREGNANCIES HAVE YOU HAD? _____ HOW MANY LIVING CHILDREN? _____
WHAT MEDICAL CONDITION IS THE INDICATION FOR YOU TO ENTER THE DONOR PROGRAM: _____

Recipient Information and Characteristics Profile

RECIPIENT'S NAME _____ PARTNER'S NAME _____

	<u>RECIPIENT</u>	<u>PARTNER</u>
DATE OF BIRTH	_____	_____
RACE	_____	_____
BLOOD TYPE/RH	_____	_____
HAIR COLOR	_____	_____
EYE COLOR	_____	_____
HEIGHT	_____	_____
WEIGHT	_____	_____
COMPLEXION	_____	_____
<u>MEDICAL HISTORY:</u>		
DIABETES	_____	_____
HYPERTENSION	_____	_____
ARTERIOSCLEROSIS	_____	_____
INHERITABLE EYE DEFECTS	_____	_____
CONGENITAL ABNORMALITIES	_____	_____
CYSTIC FIBROSIS	_____	_____
TAY-SACHS	_____	_____
COOLEY-ANEMIA OR THALASSEMIA	_____	_____
ANY KNOWN GENETIC DISEASE	_____	_____
AIDS TESTING	_____	_____
<u>PERSONAL HISTORY</u>		
MARRIED	_____	_____
CHILDREN	_____	_____
RELIGION	_____	_____
ETHNIC BACKGROUND	_____	_____

Recipient Photos
MAY BE A JOINT PHOTO

Recipient 's Name _____

Attach Photo of Recipient here.

Recipient Partner's Name _____

Attach Photo of Partner here.



**RECIPIENT and RECIPIENT COUPLE
MEDICAL AND GENETIC HISTORY CERTIFICATION**

We certify that the above information is, to the best of our knowledge, **true and complete**, and we have not intentionally omitted or withheld any information required to be given in this questionnaire.

We also acknowledge that we have asked the meaning of any term that we were not familiar with.

Recipient's Printed Name

Recipient Partner's Printed Name

Recipient's Signature

Recipient Partner's Signature

Date

Date

Witness' Printed Name Witness' signature Date