

CENTER FOR ADVANCED REPRODUCTIVE SERVICES

OVERVIEW OF EMBRYO DONATION FOR RECIPIENTS AND DONORS

EMBRYO DONORS

Some patients who undergo treatment with In Vitro Fertilization (IVF) have excess embryos frozen. These embryos are stored for future use in liquid nitrogen in vials containing one or two embryos each. When these patients have completed building their families and do not wish to pursue another pregnancy they may choose to:

1. Discard these embryos according to the American Society for Reproductive Medicine Ethical Guidelines;
2. Donate the embryos to research, or;
3. Donate the embryos to other infertile persons for conception attempts;
4. Transfer to long term storage facility.

All of the options listed above require written consent from the persons for whom the embryos were made. The Center for Advanced Reproductive Services (CARS) requires separate consent forms for each of these options.

Who is eligible to donate embryos?

Anyone who has frozen embryos may consider donating the embryos to another infertile person or couple, but the actual donation cannot occur until six months has passed from the birth of the last desired child or the ending of treatment after unsuccessful cycles. Everyone who wishes to donate embryos must be willing to undergo a rigorous medical, psychological and genetic history screening. In doing so, embryo donors must attest that all information has been truthfully and fully submitted. This information will be shared anonymously with prospective embryo recipients. In addition, embryo donors are also tested for infectious diseases, genetic disorders and blood typing by having a sample of blood drawn.

Embryos can also be donated to someone the donor knows. Except that this is not anonymous, all other steps in this process are the same as for anonymous donation.

Qualifying criteria to be considered as an embryo donor:

- Have a minimum of 2 embryos frozen.
- Embryos frozen at the blastocyst stage must have been frozen after November 2001
- The egg provider must have been no older than 39 at the time of egg retrieval.

- A minimum period of 6 months of cryopreservation after last unsuccessful cycle or after birth of last intended child prior to release of embryos for donation

-Documented absence of communicable disease

Overview of Embryo Donation

The donor/donor couple¹ must undergo donor screening. Donors must sign a Consent for Screening and Preliminary Embryo Selection. Screening includes, but is not limited to, review of medical and lab records, verbal interviews, written questionnaires, and psychological screening and counseling. All of this will occur at no financial cost to the donors, but does require time and effort. If at this point the donors qualify, they will be put on a “preliminary donor list” and their profiles (or those of their egg or sperm donors) will be anonymously shared with potential recipients.

After recipients choose a profile the embryo donor(s) will be required to undergo further screening, including infectious disease testing. It is not until all screening and infectious disease testing is complete that a final selection can be determined. *Until such time, the embryos remain the property and responsibility of the embryo donors.* Responsibility includes storage fees up until the calendar quarter embryos are accepted into the Preliminary Donor List and all custodial rights until a final selection is made. At the time of the final selection, appropriate consents will be executed and the embryos will be donated to the Center for Advanced Reproductive Services for donation to recipients for conception attempts.

Screening tests for embryo donors

As of May 25, 2005, the FDA recommends, when possible, that the testing and screening of sexually intimate partners who later decide to donate embryos should take place *before transfer of the embryo(s) to the recipient.* It is CARS policy to appropriately test all embryo donors prior to embryos being transferred to a recipient

Required testing for embryo donors (both egg and sperm providers) includes, but is not be limited to, HIV I and II, Hepatitis B Surface Antigen and Hepatitis B Core Antibody, Hepatitis C, RPR and blood typing. The sperm provider must also be tested for HTLV I and II and CMV. If potential recipients desire any additional testing (such as testing for cystic fibrosis or other genetic disorders), the embryo donors may be asked to consent and all additional testing would be the financial responsibility of the recipients.

If donor sperm from an approved sperm bank was used, the sperm donor will have been appropriately screened by the sperm bank, and the sperm quarantined accordingly. If donor oocytes were used, the appropriate screening guidelines regarding oocyte donation were followed and available to CARS staff for review. In the case of donated gametes (eggs and sperm), we will only work with embryo donors who have worked with a sperm banks approved by CARS or that have utilized a CARS egg donor.

¹ We will use the term “donor” to refer to single women or to both members of a couple that agreed to create embryos for their own conception attempts. This might be a married couple, an unmarried couple, or a lesbian couple. For the rest of this document, all these persons will be referred to as “the donor” or “donors”.

Neither the embryo donors nor CARS, make any guarantee as to the quality or condition of the embryos being donated. Embryo donors have had their medical, psychological, genetic and family history recorded and screened.

Significant findings and the potential implications of these findings for the well being of any child resulting from these embryos will be thoroughly discussed with recipients. Even with this screening, it is possible for a child to be born with a major congenital malformation (birth defect) or health problem. The Center cannot guarantee any characteristics of a child resulting from the embryo donation process, including, but not limited to, blood type, eye color, hair color, height or intellectual ability.

Risks and disadvantages to embryo donors

Embryo donor(s) must fully understand that in donating these embryos, they will be unavailable for their own use if they later change their minds. Donors may also experience some level of emotional distress in the future regarding donated embryos. We require that potential embryo donors have a psychological consultation to consider these issues. Physical risks include the possibility of tenderness and/or bruising at the puncture site following blood tests.

Advantages to embryo donors

For some people, donating embryos to research, or discarding them, are not comfortable options. By donating embryos to an infertile recipient, the embryo donors will be making an altruistic gesture that may help others become parents.

Relinquishment of rights by embryo donors

There currently are no statutes in the state of Connecticut concerning embryo donation. When donors sign Consent to Donate Embryos, they give up all rights and responsibilities for the embryos and for any children conceived from those embryos.

Compensation

Embryo donors receive no compensation, monetary or otherwise, for the donation of their embryos. *While they will not be charged for required tests directly related to the embryo donation process*, they will not be reimbursed for any previous medical expenses, or for embryo storage costs pre-dating eligibility for the Preliminary Donor List.

Waiting period

A minimum period of 6 months of cryopreservation must be observed after the last unsuccessful cycle or after the birth of the last intended child prior to release of embryos for donation.

EMBRYO RECIPIENTS

Who is eligible to receive embryos?

Female recipients, who are in generally good health and able to carry a pregnancy and who will not reach their fiftieth (50th) birthday by the time of the embryo transfer may be eligible to receive donated embryos. All recipients will need to meet with a CARS

program psychologist to discuss embryo donation. This important step is to allow the discussion of potential emotional issues with an expert in the field and is an extension of the informed consent process.

Alternatives to embryo donation

Embryo recipients are choosing to receive donated embryos because they are unable to conceive using their own sperm and eggs. They may actually need the donation of both sperm and eggs, or they may need only one but choose to proceed with embryo donation.. Potential recipients could also choose to adopt, or to not have children.

Screening tests of embryo recipients

In addition to infectious disease screening, we will also check the female recipient's thyroid function, prolactin, and rubella status. The female recipient will also have cervical cultures done to test for gonorrhea and Chlamydia infections. It is important that the female recipient be up to date with her general health care, including yearly PAP smears for all ages, mammograms for women over 40 years old, and EKG and diabetes screening for women over 45 years old. These tests can be arranged with your primary care provider or we can schedule them for you. Either a hysterosalpingogram (HSG) or sonohysterogram needs to be performed within 1 year of embryo transfer to rule out uterine and/or tubal abnormalities. If these tests are needed, the recipient will be informed of the specific tests required.

Chance of success

The probability of conceiving using cryopreserved donated embryos is directly related to the age of the female donor (or her egg donor) at the time the eggs were retrieved, as well as the stage of development at which the embryos were frozen. There are other factors that impact the chance of pregnancy as well, including the endometrial lining of the recipient, the number of embryos available for transfer, and the quality of the embryos at the time of freezing and thawing. Recipients will be informed if a specific batch of embryos resulted in a pregnancy for the embryo donors. It is important to realize, however, that even if a fresh IVF cycle did not result in pregnancy, a frozen cycle may still have a positive outcome. In general, the age of the recipient does not affect the pregnancy rate, but may affect the risk of complications during a pregnancy (pre-term labor, diabetes, etc).

Responsibility of embryo recipients

There are both financial and legal obligations to receiving donated embryos. ***Embryo recipients are responsible for paying for all program costs, regardless of the outcome, including (but not limited to) donor screening and all recipient costs (see detailed fee schedule).*** Once a donor is selected, if the recipients choose to keep the embryos frozen for greater than six months, they will be charged for storage on a quarterly basis (see fee schedule). A total cost estimate of the embryo transfer process will be provided for the recipients' review, with the understanding that actual costs may be different from what has been estimated.

Recipients accept the responsibilities for the care of any child resulting from the embryo donation process, and intend to be the legal parent(s) of any child that results, with all the

rights and responsibilities that come with parenting. Under no conditions will recipients seek financial aid from embryo donors or CARS.

Neither CARS nor the donors will assume any financial responsibility for the upbringing of any child resulting from the embryo donation process.

The process for the recipient

After being counseled and signing the appropriate consent forms the recipient will select donated embryos. As part of the selection process, recipients may anonymously review all available non-identifiable information on embryo donor(s) (unless this is a known donation, and then the information is not anonymous). This may include a health questionnaire, personal characteristics form, and psychological and genetics reports.

Recipients will have an appointment with one of our nurses or physicians, who will prepare a treatment plan, which will include prescriptions, and instructions on how to administer medications. Hormones will be administered to prepare the lining of the uterus. The process will be monitored with ultrasounds and blood tests. The donated embryos will be thawed and prepared for transfer using a small catheter placed through the cervix and into the uterus.

Risks associated with embryo donation

There is no guarantee that any of the donated embryos will survive the thawing process, or that the transfer of thawed embryos will result in a conception or a successful pregnancy. The chances of success, as well as the risk of miscarriage, are related to many factors, including the age of the egg provider at the time the eggs were retrieved, as well as the embryo quality. Our physicians will discuss most of the factors that may affect the success of embryo donation with the recipients.

The transfer of more than one embryo into the uterus may result in a multiple pregnancy (twins, triplets or more), with an increased risk of miscarriage, premature labor and premature birth.

Benefit to embryo recipient

If the procedure is successful, recipients may become pregnant and potentially be able to achieve parenthood through an alternative option.

ISSUES FOR BOTH EMBRYO DONORS & RECIPIENTS

Confidentiality & Anonymity

Embryo donation is typically anonymous and neither the donors nor the recipients shall be advised of each others' identities. However, there are some cases where the donors and recipients choose to be known to each other. If you have been designated as a recipient for embryos from a donor known to you, aspects of your medical care and conditions and that of the recipient may be revealed and/or discerned as part of the treatment process. Moreover, in known embryo donor situations we require all parties meet with an attorney and execute legal contracts. CARS will refer patients to local attorneys with expertise in this area.

If your embryo donor(s) is anonymous, you pledge that you will never seek his/her/their identity, except as allowed below or if a court orders otherwise. The Center will protect the recipient's identities except as allowed below or if a court orders otherwise. However, if a child born from this donation has a medical or psychological need that might be met by the donor prior to the child turning 18, the parents may contact the Center and ask the Center to contact the donor to ask for help. Such requests may be for a medical need such as a bone marrow transplant, but can only be requests that cannot wait until the child is a legal adult.. **Once any child or children born from this donation are legal adults**, the child may contact the Center and ask the Center to convey a request to the donor. This request may be for something that can be provided anonymously (such as an update on the donor's medical history) or it may be a request to meet or talk with the donor. ***The embryo donor is under no obligation to consent to any request.*** Embryo donors may ask if there has been a pregnancy as a result of their donation.

Reporting requirements

The confidentiality of medical records, including any photographs, X-rays or recordings, will be maintained in accordance with applicable state and federal laws. Embryo donors and recipients may request records be released to other physicians. Data from donor embryo transfer cycles will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires the CDC to 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, the 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 the CDC has that identifies you will not be disclosed to anyone else without your consent.

Emotional Distress

Infertility is often distressing. Feel free to talk to any one of our nurses or physicians regarding how you are feeling. There are some support groups available such as RESOLVE and the American Fertility Association. We also have program psychologists who are available to embryo donors and recipients, as well as outside counselors that we work with, who specialize in fertility and family issues.

Right to legal counsel & Connecticut state law

Embryo donation is a new, developing and gray area of the law and few states have laws regulating the transfer or donation of embryos. The legal relationship between such child(ren) and the donors and recipients has not been determined under Connecticut law.

Before signing the consent forms, both embryo donors and recipients should ensure that all procedures have been satisfactorily explained to them, and all questions answered.