



Embryo Donation Recipient General Information Southwest Florida Embryo Donation Program

What is embryo donation and who donates them?

Embryos were originally created through the Assisted Reproductive Technologies (ART). In order to minimize multiple pregnancies, the excess embryos were cryopreserved in liquid nitrogen for future use. Eventually, a caring and compassionate couple, the **Donating Parents**, decided to donate these frozen embryos. Rather than destroy the embryos or donate them to science, the Donating Parents thought their cryopreserved embryos deserved a chance at life and a needy couple a chance at parenthood.

In the future, we may consider moving abandoned embryos into the embryo donation process. For now, however, this ethical/legal issue requires further resolution.

What are the advantages of Embryo Donation over adoption?

Adoption is an excellent option for many couples. For some, however, Embryo Donation may be a preferred alternative:

1. Embryo Donation is quicker with delivery often within one year of the first visit.
2. Embryo Donation is often much less expensive than adoption.
3. Embryo Donation is usually less complicated and less expensive than many alternative ART procedures.
4. If there are enough Donated Embryos available, more than one child may be delivered by the **Donor Embryo Recipient**, all with similar genetic inheritance.
5. Unlike adoption, one has a tremendous amount of medical information regarding the mother and the true father of the Donated Embryos. At times in conventional adoption, the genetic father of the gestation is incorrectly identified leading to uncertainty and future custody/legal issues.
6. Unlike adoption, the Donor Embryo Recipient can choose the genetic traits they value by looking for Donated Embryos from specific genetic, social and religious backgrounds.
7. Unlike adoption, **the Donor Embryo Recipient** can protect and nurture the pregnancy minimizing prenatal exposure to drugs, poor nutrition and **Sexually Transmitted Infections (STI's)**.
8. Unlike adoption, the Donor Embryo Recipient may go to the Obstetrician of her own choice. In conventional adoption, the pregnant mother goes to the physician of her choice.
9. Embryo Donation offers a greater level of privacy compared to conventional adoption.

10. While quite variable, some insurance plans will cover for some aspects of the **Frozen Donor Embryo Transfer (FDET)** process while they will not cover adoption fees.

Adoption is still an excellent option for some couples while Embryo Donation has a number of interesting advantages.

Who are the potential Donor Embryo Recipients?

The following are some of the potential patients who are candidates for Embryo Donation:

- Both partners have significant fertility issues.
- Patients are seeking a less expensive alternative.
- Patients are unable to adopt (i.e., cancer survivor or couples in their 40's).
- Patients with a family history of genetic disease where direct reproduction is not desired.

In order to decide if you are a candidate for the program, you will be asked to forward all your medical records, laboratory tests, copies of prior operative procedures, radiology X-rays such as the hysterosalpingogram and any pertinent information on the evaluation of the partner prior to being seen by Embryo Donation International (EDI). Both the patient and partner will be encouraged to attend the first interview. Depending upon the age of the actual Donor Embryo Recipient, additional testing including an EKG, treadmill, psychological evaluation, mammogram, vaginal ultrasound and screening blood tests may be requested.

Significant medical conditions such as diabetes and recurrent pregnancy loss may exclude a Donor Embryo Recipient from participation in the program.

Occasionally, the Donating Parents may request that recipients be a certain race and religion. Some Donating Parents also prefer that the Donor Embryo Recipient live in a different city than the Donating Parents and their genetic offspring. In general, however, there are few if any restrictions regarding who may receive the donated embryos. Donating Parents may also have agreed to donate their embryos to single women and/or lesbian couples.

How do I choose the donated embryos?

You may choose your donated embryos using a number of parameters. Recipient Couples often try to match such characteristics as race, eye/hair color, height/weight, blood type, educational background and general interests. The updated Embryo Donation Data Base may be reviewed by visiting www.EmbryoDonation.com.

<i>Highly Desired</i> Donor Parent Characteristics	<i>Moderately Desired</i> Donor Parent Characteristics
<input checked="" type="checkbox"/> History of conception from the same batch of embryos (i.e., the fresh embryo transfer resulted in pregnancy of the Donor Parents and the excess cryopreserved embryos were donated) <input checked="" type="checkbox"/> Donating maternal age less than 34 at the time of ART <input checked="" type="checkbox"/> No family history of genetic diseases <input checked="" type="checkbox"/> No history of sexually transmitted diseases	<input checked="" type="checkbox"/> Maternal age was 35 to 40 years of age at the time of ART <input checked="" type="checkbox"/> Family history of genetic diseases <input checked="" type="checkbox"/> Past history of treated sexually transmitted disease*

*A Donated Embryo Recipient who already has Hepatitis may receive donated embryos from Donor Parents with Hepatitis.

Donated embryos will frequently differ in **quality** based on the following:

1. If the original fresh transfer resulted in conception, the entire batch of embryos will tend to be excellent.
2. The larger the number of cryopreserved Donated Embryos, the greater the likelihood for success.
3. The more advanced the embryo in development at the time of cryopreservation (i.e., morula or blastocyst stage cryopreserved donor embryos), the healthier the embryos and the greater the likelihood of implantation.
4. The larger the number of cryopreserved Donated Embryos, the more likely the recipients can have more than one child from the same Donor Parents.
5. The younger the female Donor Parent, the better the implantation rates.
6. The younger the female Donor Parent, the less likely that a genetic amniocentesis will need to be performed during a successful FDET pregnancy.

EDI will try to give the cryopreserved donated embryos a “letter grade” to make the process of choosing healthy Donated Embryos somewhat easier. Visit www.EmbryoDonation.com to review the embryos currently available for donation.

What are my options in receiving embryos at EDI?

You may choose the Anonymous, Approved or the Open Embryo Donation procedures. The embryo donors may only chose one of these three options while you have the option of any or all of the options.

How does the Approved Embryo Donation process work?

Let us assume that you have found some embryos on the database that you think would be great and the donor as stipulated an Approved Embryo Donation process. Realizing at times, the donor wants to more about you, a psychological evaluation by a qualified Mental Health Professional (MHP) is probably the best way to do this. The MHP may ask you questions about the embryo donation process itself as well as questions involving your current relationships and overall life philosophies. We suggest that you see this as an opportunity to discuss important issues such as disclosure to an embryo donor offspring, what you will tell friends and family and if you have truly worked out the issues an embryo donor conception. You will be required to meet only once for at least one hour. If you have a partner, your partner will be required to be present. A predetermined fee will be due at the time of your service unless this is a covered service on your insurance plan and the provider takes your insurance.

Once you have agreed to an Approved Embryo Donation process and any other stipulations by the donor match, the following will occur:

- EDI will arrange for you to be seen by a MHP. This MHP will be prompted before the interview to make certain they will ask questions pertinent to the embryo donation process.
- Once the interview has taken place, the MHP will be responsible for creating a summary report without any specific identifying information about you. EDI will review this document.
- The summary report will also have the contact information about the interviewer removed so your confidentiality cannot be breached.
- The donor will have ten business days to review the report. If they approve, you will continue to move forward though the embryo donation process.

If the donor excludes three total reports on different recipients, EDI will ask the donor to split the costs for having their embryos transferred to a different facility.

You may use this same MHP report to apply for other Approved Embryo Donation embryos. You may see a new MHP for each set of embryos you apply for. You will not be allowed to re-apply by seeing a new MHP for the same set of embryos following a “no thank you” response by a donor.

How Does The Open Embryo Donation Process Work?

Some donors and recipients want to have a relationship prior to, during and perhaps even after the embryo donation procedure. If a child is born, they may also want to continue a relationship. This process is not for everyone. No one knows if this results in better or worse outcomes but emotions run high on the adoption front regarding disclosure issues, so the Open Embryo Donation process has proponents.

If you want to receive embryos that are stipulated for Open Embryo Donation, the following will occur:

- Your embryo recipient application materials, without identifying information, will be sent to donor for review. They will have ten business days to decide if they want to proceed.
- If the donors tentatively agree, both the donors and recipients will sign an agreement that will allow for EDI to break confidentiality sharing identifying information between the two of you. The contract will also stipulate that the embryo transfer procedure will eventually take place at EDI.
- You and the donors will connect. If you both agree to move forward, both of you will need to obtain separate legal counsel. You are responsible for all of the subsequent fees unless otherwise agreed. At each level, we will request that both parties agree to move forward.
- Legal documents will be drafted and signed by each party. EDI is to receive a copy of these legal documents to review for completeness.
- Both you and the donors will undergo laboratory testing. A copy of the lab reports will be provided to the other party.
- You and the donors will undergo evaluation by a Mental Health Professional with the reports exchanged between the donors and recipients.
- If still moving forward, you will undergo a recipient examination (i.e., home study). The report will be forwarded to the donors for review. They will have ten business days to accept or reject you as the embryo recipients.
- If everyone is still moving forward and any final agreements are signed, you will then begin be prepared to accept the donated embryos.
- The pregnancy test results will be communicated to both parties unless otherwise stipulated.

Both the donors and recipients need to be dedicated to this more complicated process. Once again, it is uncertain if an Open process is better for all parties, including the offspring. Future research will hopefully begin to answer these important questions.

What kind of screening did the Embryo Donors receive?

All Donating Parents underwent intensive screening processes including a history and physical exams as well as detailed genetic histories and extensive laboratory testing for communicable diseases. Please remember that these couples had medical problems just like you, so their medical histories were not perfect. Nearly all of them will have some reproductive issues.

Per standard of care, all Donating Parents underwent various evaluations including screening for STI's including hepatitis, syphilis and HIV. Ideally, the Donating Parents should be re-screened for STI's before the Donated Embryos are transferred. This is not always possible and adds further costs to the Recipient Couple. The likelihood for ART patients, such as you, to be negative for HIV just prior to ART, only to turn positive later, is quite low. EDI simply has a very low risk population for these types of concerns. We must always keep perspective on this issue since conversion to an active infection is extraordinarily unlikely.

In addition, it should always be remembered that you are considering the transfer of very minute quantities of tissue (i.e., multi-celled embryos) compared to organ and blood donation where billions of cells are donated. Even if the Donating Parents were positive for a STI, the chances of transferring HIV or Hepatitis to a Recipient Couple are astronomically small, and perhaps, only a theoretical concern. It is of interest that the cryopreservation process itself may also render some underlying infections harmless.

If you desire re-testing of the Donating Parents, please discuss these issues with EDI. Some of the parents will have agreed to be retested upon request, although doing so will increase the costs of the Embryo Donation procedure.

In summary, the probability for transmission of disease is quite remote and is minimized through the original screening laboratory testing of the Donating Parents.

Was genetic screening performed on the Donating Parents?

Routine genetic screening laboratory tests, including Sickle Cell for African-American patients and Tay Sachs for Jewish patients, were inevitably offered to the Donating Parents during their original ART cycle. If there was a significant history for other genetic diseases, testing for these diseases were also offered. Offered does not necessarily mean that they were done.

Changing recommendations regarding genetic screening now make the FDET process more complex. For example, Caucasian couples considering conception are now to be offered genetic testing for the gene that causes Cystic Fibrosis. A Caucasian woman is estimated to have a 1/29 risk for carrying the abnormal gene, which can result in Cystic Fibrosis in one out of every 3,400 deliveries (<http://www.cff.org/>). It is an uncommon disease, but genetic testing is now offered to couples considering conception.

In all likelihood, the Donating Parents did not have this level of genetic screening. If the Donating Parents are currently available and willing, this genetic test can be performed in addition to the updating of other STI's. Once again, if requested, this will increase the costs to you. Genetic screening and repeat testing for STI's will, therefore, remain optional to the Recipient Couple assuming the consent for retesting by the Embryo Donors.

Are the children born via Embryo Donation different than other children?

Gestations that result from the Frozen (Donor) Embryos are essentially the same to children conceived through a more "natural" process. There are, however, a few potential exceptions:

1. If the embryos were created from subfertile parents, the offspring may have similar reproductive issues when they reach adulthood. For example, there does seem to be genetic

- predisposition to gynecologic diseases (i.e., endometriosis) much as the way that cancer and heart disease may run in various families.
2. Along the same lines, additional data has been published that indicates some male-factor problems may be passed on to the children. This seems to occur at a very low rate, but can occur. The overall outcome is usually similar to that of the father (i.e., reproductive issues). Fertility and other medical issues may occur to the male child or the female offspring may carry a generic problem that could eventually affect her children. Once again, the medical outcomes are usually no different than the male partner who originally provided the sperm.
 3. Please keep in mind that what ever brought you to the FEDT process may have been transmitted to your *genetic* offspring. In addition, these concerns generally pale in comparison to conventional adoption, where much less are known about the genetic parents and their family.
 4. There have been some studies which indicate the average ART pregnancy will deliver somewhat earlier with a smaller-for-gestational-age baby compared to those conceived through natural means. This is probably due to the fact that the patients are simply at higher risk for problems due to the issues that made them subfertile in the first place.

In summary, ART conceptions are not more prone to significant abnormalities. We offer no guarantee, however, that the child will be normal, but tens of thousands of children have been created by the IVF process and the children are generally as healthy as those conceived through a more “natural” means.

To reiterate, it is very important that the Donor Embryo Recipients not try to seek “perfection” in finding the “ideal” Donated Embryos. It is doubtful that your own genetic children would have been perfect given the issues that have brought you to the point of considering Embryo Donation. ***Please keep your perspective!***

What are the success rates for Embryo Donation?

As data accumulates, these success rates will be published on the EDI web site located at www.EmbryoDonation.com.

Do the Donating Parents have any legal rights to the Donor Embryo offspring?

Currently, there are no parental rights of the Donating Parents to the offspring from embryo donation here in the state of Florida. As with blood and other organs, once donated, the donor loses all legal rights to the tissues.

The Donating Parents are free to change their mind and request that their Donated Embryos be returned up to the point of the actual thaw and transfer, although this expected to rarely, if ever, occur. We allow this to encourage patients to consider Embryo Donation, but do not want them to feel that they could not reclaim their embryos should their own children pass away. Once the embryos are transferred to the Embryo Recipient, the Embryo Donors will lose any legal rights to the offspring.

Will we ever meet the Donating Parents?

With anonymous and approved embryo donation procedures, the process remains anonymous and the donors and recipients will not meet. If you have agreed to an open process, it is feasible that you may potentially meet the donors.

Can the children ever find the Donating Parents?

The Embryo Donation program is anonymous. In addition, EDI is required to keep medical charts for only seven years, so requests made years in the future may not be able to be honored. EDI intends to honor the contracts that specified anonymity so appropriate legal means would be drawn upon to protect all parties.

If an offspring from Donated Embryos needed to find the Donating Parents for medical reasons (i.e., bone marrow or kidney transplant) and upon request, EDI would act as a neutral entity to assist all parties while keeping confidentiality intact.

Are the Donating Parents paid for their embryos?

The Donating Parents have donated by their own free will and were not compensated for their decision. Upon occasion, any remaining cryopreservation fees have been waived when the parents decide to donate the embryos. EDI does this to encourage couples to consider donating their embryos, but do not want to entice them inappropriately to do so. This may eventually change given the fact that sperm and egg donors are paid for their services.

How Long Can The Donated Embryos Stay Frozen?

We really do not know the limit of the cryopreservation process. Animal research has shown that offspring are possible after many years of cryopreservation. More research will need to be done before this question can be adequately answered. We will not hold donated embryos indefinitely and will certainly encourage their transfer as quickly as possible.

Will you send the Donated Embryos to other ART facilities?

These embryos were donated to EDI because of our success with ART. The Donated Embryos will only be used here at EDI and will not be shipped out of the area.

Will you accept donated embryos from other ART facilities?

In short, we will accept some cryopreserved Donated Embryos from other facilities. We will not accept all embryos offered and will have to evaluate each donation on a case-by-case basis. Below are some of the reasons why EDI will reserve the right to refuse to accept the transport of Donated Embryos:

1. The ART facility that is called upon to transfer Donated Embryos has very poor Frozen Embryo Transfer success rates.
2. The embryos originated from women with advanced maternal age.
3. Very few embryos are available.
4. The embryos originated from minority combinations that are rarely represented in our patient population.

Please understand that our goal is to accept the transport of embryos likely to be chosen by our patient population. We are certainly not biased towards or against any individuals or programs. We simply do not want to become an international storage facility, but would like to offer the option of embryo donation to couples that would otherwise choose to destroy their healthy embryos.

It should be noted that in the past we have had difficulty in estimating the success rates for (donated) frozen embryos from other programs. It would appear that the success rates are somewhat dependent on the quality of the facility that froze the donated embryos. In addition, the post-thaw and embryo

transfer procedures (i.e., the techniques used here at EDI) also influence the success rates. While not actually certain, the take-home-baby rates will probably be somewhere in between the rates for the two ART facilities.

Could the children from Embryo Donation inadvertently meet their siblings and reproduce (Inadvertent Consanguinity)?

It is quite common to be concerned about the potential for related siblings raised in different families meeting and reproducing.

Similar concerns have existed and have been examined in detail for egg and/or sperm donation cycles. According to existing guidelines, it is recommended that we limit a single egg/sperm donor from producing no more than 15 offspring per 500,000 population. Please recall that we here at EDI cater to a large population here in Southwest Florida conservatively estimated at over 1,000,000, not even including the other states and countries we service. According to the guidelines, we could easily have over 30 offspring residing in Southwest Florida per egg/sperm donor before retiring the donor.

We here at EDI will try to limit an embryo donation couple to no more than six successful donated offspring within the Southwest Florida Region. Where possible, we will also list the location of the donor parents and encourage the use of donated embryos in different cities and counties.

What are the psychological affects of the Embryo Donation process?

Embryo donation is clearly a new path to parenthood, bringing with it the potential for complex psychological, social, emotional, and ethical considerations. We have neither significant long-term experience nor psychosocial research to draw upon. While possible, it seems unlikely that there will be any significant psychological impacts to all parties involved, but this is uncertain.

The issues regarding disclosure to friends, family and the offspring are important. We will attempt to cover some of these topics at the web site. It is also encouraged for all interested parties to discuss these issues with qualified personnel. Psychological counseling will always be available upon request.

How do we get started?

1. It is strongly recommended that a health practitioner see you here at EDI to make certain you are a candidate for Embryo Donation. Alternatives to Embryo Donation will be discussed so that the couple will be able to make an informed decision.
2. We have an eligibility form that must be completed. You may call us at (239) 275-8118 and we will mail or fax the form. This needs to be completed and sent back to us. Once reviewed and you are seen to fulfill the minimal Requirements, will be happy to send you a packet of information, although you might want to access the information directly through the internet at www.EmbryoDonation.com.
3. If you desire any legal assistance, an attorney's name will be provided to you. One source is www.LegalSurrogacy.com.
4. A financial meeting will be available to you to discuss the financial issues of Embryo Donation. It can become a bit complicated, so this will be encouraged.
5. If you desire any emotional assistance, counseling will be made available to you. The ART team may occasionally require that the couple undergo psychological counseling. Refusal to

undergo counseling upon request will be grounds for exclusion from the EDI Embryo Donation Program.

6. Screening laboratory tests will be obtained on you and, when appropriate, your partner.
7. A final visit with your practitioner will be made to review the issues regarding genetic testing and the repeat testing of STI's of the Donating Parents.
8. If requested, additional laboratory tests will be obtained on the donating parents.
9. When completed, your case will be reviewed by the EDI ART team who will make a final decision regarding your Frozen Donated Embryo Transfer (FDET) protocol.

What is the general evaluation of the recipient couple?

The exact evaluation will be tailored to your specific clinical situation. A couple aspects of the evaluation are fairly constant:

1. A hysteroscope or uterine sound may be placed into the uterus during in the months prior to the FDET cycle to make certain the uterine cavity is normal and to document the precise depth in which the embryos will be placed into the uterus. This is called a "Trial Transfer".
2. Screening laboratory studies for infections will be obtained. If there are maternal health concerns, additional testing may be requested to make certain the recipient female will be safe during a pregnancy.

Other evaluation steps will be covered in detail by the staff of EDI.

What happens during the month of the FDET?

Essentially, if you ovulate regularly, we simply track your ovulation carefully and transfer the thawed Donated Embryos into the uterus very close to the time of expected implantation. If you do not ovulate on a regular basis, we will take control of your menstrual cycle and replace the necessary hormones to prepare the uterus for the FDET. These concerns are covered in detail in other materials.

How many embryos will be thawed?

The number of embryos to be thawed and transferred will vary depending upon the following:

1. How many embryos are stored in a single cryopreserved vial or straw container
2. Quality of the embryos
3. Previous implantation rates with the original fresh transfer
4. Age of the eggs at the time of ART
5. What would be the maternal consequences of a multiple pregnancy?
6. Would the recipient couple consider fetal reduction should a multi-fetal pregnancy (triplets or more) occur?
7. What are the personal preferences of the Donor Embryo Recipient?

The final decision of how many embryos will be thawed will be made with input from the recipient couple, the physician and the laboratory Ph.D.'s.

What will happen after the Donated Embryos are thawed?

Approximately 75% of the embryos will survive the thaw process. The 25% of the embryos that do not survive are generally thought to be genetically abnormal and are selected against through the freeze/thaw process. These donated embryos were probably not going to result in viable pregnancies.

There are laboratory techniques that may improve the success rates of the FDET:

Microsurgical Assisted Hatching (AH)

Human embryos actually have to “hatch” from the zona pellucida before implanting into the endometrial lining. The outside covering called the zona pellucida may become slightly rigid making it more difficult for the embryos to escape from the outer covering and implant. AH involves the careful opening of a small segment of the zona making it easier for the embryo to escape and implant.

Anywhere from two to four surviving Donated Embryos will usually be loaded into a very thin catheter and placed directly into the uterus through the cervical canal. This is a relatively painless procedure and will be done without premedication. The patient will then be asked to rest for about 30 minutes. The patient is encouraged to bring something to read, music to listen to or a DVD to watch.

Will we get ALL the embryos frozen from the Donating Parents?

Once pregnancy occurs, you may reserve *some* of the remaining cryopreserved donated embryos for further use until your pregnancy reaches nine weeks. After nine weeks gestational age, any remaining embryos will be made available to other patients. If you sustain a pregnancy loss before nine weeks, you will be able to extend your reservation of these remaining embryos for an additional five months. There is no guarantee, however, that there will be any embryos left following your transfer. If a large number of embryos remain, EDI reserves the right to portion out the remaining embryos so that the largest number of families will benefit from the Embryo Donation process. Since there is often a long waiting list for Embryo Donation, we simply do not want one couple hoarding a large number of unused embryos while another needy couple could be enjoying parenthood.

In addition, you will not be allowed to “re-donate” the Donated Embryos. It is important that any restrictions that were originally placed on the Donated Embryos (i.e., race, religion) will remain intact and not be modified or lost during a “second” donation process.

What about lodging for out-of town guests:

Many of our patients travel great distances to seek care here at EDI. We have connections with various hotels to provide you with the best rates. Vacation packages can also be arranged to make your visit to Southwest Florida as enjoyable as possible. Please discuss these arrangements with the front office staff well ahead of your visit here. Our web site at www.EmbryoDonation.com also has a number of valuable links regarding Southwest Florida.

Summary:

The Embryo Donation program is a wonderful opportunity for a patient who desires a child but who is unable to do so through other means. The program is often the only hope for such patients.

Miscellaneous Frequent Questions

What general restrictions are necessary during the month of FDET?

We ask that you check before taking **any** additional medications other than regular or extra strength Tylenol. Prenatal vitamins will be prescribed. Smoking, herbal medications, over-the counter medications, recreational drug use and alcohol must be eliminated. If another physician prescribes you a medication, please have the physician contact us and we will clear the use of the desired medication or provide alternative treatments.

What is my activity level after a embryo transfer?

We ask that with any embryo transfer that the woman continues bedrest for the day of and the day following transfer. This involves lying in bed and lying on the couch. It is allowed that she shower and go to the bathroom. She is to be pampered!

Light activity should follow for the following five to seven days wherein normal activity may be resumed.

We suggest that you abstain from vaginal intercourse for seven days following the embryo transfer. To be honest, it is doubtful that intercourse would “dislodge” an embryo and result in a negative pregnancy test. Even so, guilt regarding early sexual relations following a negative pregnancy test can become somewhat overwhelming. That stated, there is absolutely no data available that states that vaginal intercourse is harmful to the early gestation following implantation. Once again, we suggest that you use good common sense.

Also during the month of transfer, strenuous activity is to be avoided and new physical activities should not be initiated. We ask our patients to use good common sense. When deciding what is strenuous and what is not, please discuss the “grey” areas with the IVF coordinator. Once again, please use good common sense.

Do we really need to buy or borrow an answering machine?

It is **imperative** that our patients be available by phone or answering machine to receive instructions regarding medications and appointments for monitoring. The accurate predication of the impending ovulation is crucial. The inability to contact you may result in the cancellation of your cycle.

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