



## Patient Information and Consent To Donate Embryos, EDI **Assisted Reproductive Technologies**

Embryo Donation International (EDI) is a subsidiary of Specialists in Reproductive Medicine and Surgery, P.A. (SRMS) and will be referenced throughout this document.

### What can I do with my cryopreserved embryos?

Your cryopreserved embryos can undergo the following:

<b>Example</b>	<b>Explanation</b>
1. Thaw with degeneration	The embryos are thawed and disposed of in a respectful manner. Some practices, such as ours, no longer provide this as an option when so many other excellent options listed below exist.
2. Thaw for scientific study	These embryos are often used for such activities as: ➤ Training laboratory personnel ➤ Used to test laboratory quality assurance
3. Donated for science	These embryos are donated to science. They may not be thawed and used right away. An example of this option is stem cell research. Unfortunately, this is not always possible.
4. Embryo Donation	Embryos are donated by the <b>Donating Parents</b> to <b>Embryo Donation Recipients</b> .

### What is Embryo Donation?

A caring and compassionate couple, the **Donating Parents**, decide to donate their frozen embryos. Rather than destroy the embryos or donate them to science, the **Donating Parents** often feel that their cryopreserved embryos deserve a chance at life and a needy couple a chance at parenthood.

### Who are the potential Donor Embryo Recipients?

The following are some of the potential patients who are **Donor Embryo Recipients**:

- Both partners have significant fertility issues.
- Couples who are seeking a less expensive alternative compared to other technologies and adoption.
- Couples who are unable to adopt (i.e., cancer survivor or couples in their 40's).

- Couples with a family history of genetic disease where direct reproduction is not recommended.
- The single patient may have difficulty conceiving.
- Same sex couples may have few reproductive options available.

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

### Can we stipulate who will get our embryos?

At times, the **Donating Parents** may decide to make stipulations regarding the **Donor Embryo Recipients**. Understand, however, the more stipulations that are made, the less likely it is that the embryos will find a qualified recipient couple and be transferred. Stipulations such as race and religion are occasionally requested. Stipulations are made, if desired, via the on-line application.

### What are my options in donating embryos to EDI?

You may donate them anonymously, you may approve of the recipients based on a psychological evaluation or you may have an open process. You will choose one of these options via the on-line application.

### How does the Approved Embryo Donation process work?

Once you have specified that this is your only choice, and the embryos have been accepted by EDI, we place the information about you and your embryos (without identifying information) onto the Embryo Database. Once a recipient has agreed to your request and any other stipulations you made also match, the following will occur:

- EDI will arrange for the recipient(s) to be screened by a Mental Health Professional (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 the recipients. EDI will review this document.
- The summary report will also have the contact information about the interviewer removed so confidentiality of the potential recipient cannot be breached.
- You will review the report and have ten business days to respond. If you agree, we will move forward with the recipient you approved.
- If you exclude the potential recipient, they may not re-apply with a new MHP's report.

If you have received a total of three different reports and you have excluded all individuals or the embryos are not placed on reserve for an approved donor within 24 months, EDI reserves the right to have your embryos shipped to another facility with you and EDI equally dividing the transportation fees. EDI will not be responsible for any charges by the other institution regarding the receiving and storage of your embryos.

### 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.

Once you have specified Open Embryo Donation as your only choice during the application process, your embryos will be tagged as an Open Embryo Donation set awaiting recipients to choose them. Once recipients have chosen them understanding the Open process has been requested, the following will occur:

- The embryo recipient application materials, without identifying information, will be sent to you for review. You will have ten business days to decide if you want to proceed.
- If you tentatively agree to learn more about these recipients and your embryos have not yet been transported, they will be sent to EDI. Because the Open process is complex and recipients more difficult to find, EDI may not request that your embryos be transported for storage until you have tentatively accepted a recipient in these early stages.
- Both you and the potential recipients will sign an agreement that will allow EDI to break confidentiality sharing identifying information between the two of you and will stipulate that the embryo transfer procedure will eventually take place here at EDI.
- You and the recipients will connect. If you both agree to move forward, both you and the recipients will be requested to obtain separate legal counsel. All of the subsequent fees are to be paid by the recipients 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 recipients will undergo laboratory testing. A copy of the lab reports will be provided to the other party.
- Both you and the recipients will undergo an evaluation by a Mental Health Professional with the reports exchanged with each other.
- The potential embryo recipient will undergo a recipient examination (i.e., home study). The report will be forwarded to you for review. You will have ten business days to accept or reject the potential recipients.
- Once the home study is completed and any remaining agreements signed, the embryo recipients will be prepared for transfer.
- 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.

### **If we ask for our embryos to be donated, will they automatically be placed in the Embryo Donation Program?**

The short answer is, *no*. While not an easy decision, EDI reserves the right to refuse to take some embryos into the **Embryo Donation Program**. Here are some of the reasons EDI may refuse to take the embryos:

1. If the embryos came from the eggs of a 40-year-old woman, the likelihood that the embryos will be chosen is reduced.
2. If a single embryo is offered, it is unlikely that it is chosen.
3. If there is a family history of genetic disease, they may not be chosen.
4. Embryos of poor quality will not be accepted.

5. If the facility that froze the embryos originally have poor success rates for their frozen embryo transfer procedures, the donated embryos may not thaw well and survive.

If EDI refuses to take the embryos, the couple is free to find another location to take the embryos, although few facilities are willing to take embryos for Embryo Donation.

### [Will we have to pay anything to donate our embryos?](#)

All transport and processing fees for the donated embryos to be packaged and sent to EDI will be paid for by EDI. You will not incur any expense through the Embryo Donation process.

### [Are we paid for our embryos?](#)

You agree to donate your embryos by your own free will and you will **not** be compensated by EDI for your kindness. While EDI does want to encourage couples to donate their embryos, we do not want to entice them in an unethical fashion.

### [Can we get our embryos back?](#)

You will have the option to request that your Donated Embryos be returned. Please do not do this without significant cause since an **Embryo Recipient Couple** may be counting on your embryos and be very close to the actual transfer process. These last minute cancellations can be extraordinarily disappointing to the **Recipient Couple**. The **Donating Parents** will pay the fees involved in processing and transport of these embryos to the location of your choice.

If the donated embryos have not been used within five years of arriving to EDI, the final disposition of the embryos will have to be decided upon. Rather than being sent back after five years, you will also have the option to thaw them, donate them to science or have them transferred to the location of your choice. If you so choose, the **Donating Parents** will pay the fees involved in processing and transport of these embryos to the location of your choice. If mutually decided upon, EDI may choose to keep them in the Embryo Donation Program, but it is clearly understood that EDI cannot routinely be responsible for holding Donated Embryos indefinitely that are not chose within five years by qualified Embryo Recipients.

### [Will we have to undergo any future testing?](#)

When your embryos are chosen, EDI will review the data on your family history you submitted in the original materials. Standards-of-care genetic screening issues may need to be further addressed. If you agreed to potential future blood testing in the original consents, you will be contacted and asked to undergo additional laboratory testing (i.e., hepatitis, HIV and genetic studies) at no charge. Any significant information found from the screening tests will be communicated directly to you. We promise to make this step as convenient as possible.

### [What are the success rates for Embryo Donation?](#)

Please visit the [www.EmbryoDonation.com](http://www.EmbryoDonation.com) and follow the links to the statistics section.

### [Do we have any legal responsibilities to the Donor Embryo offspring?](#)

Currently, you will not have any Parental responsibilities to the offspring from embryo donation here in the state of Florida.

### **Can the Donor Embryo offspring ever find us?**

Our Embryo Donation program is most often 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. Appropriate legal means would be drawn upon to protect all parties.

If offspring from Donated Embryos needs to contact you for medical reasons (i.e., bone marrow or kidney transplant because of significant disease) and upon request by the Recipient Couple, EDI would act as a neutral entity to assist all parties in appropriate communication while keeping confidentiality intact.

We do offer Open Embryo Donation where both the donors and recipients form at least a temporary relationship. In this situation, it is quite likely that the offspring will know who the donating individuals are.

### **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.

EDI commits to placing the Embryo Donation data for at least five years from the day of arrival to the facility. At the end of five years, you will be contacted and the embryos will then either undergo thaw and disposal, thaw for scientific study or will be shipped to the location of your choosing.

If you do not return the five-year notification consent, EDI will assume full control of the embryos. They will be left on the Embryo Donation list & eventually donated, thawed and disposed of, thawed for scientific study or donated to science. EDI simply cannot continue to indefinitely freeze large numbers of abandoned embryos.

### **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 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 any given donor.

Given the fact that some of the embryos placed up for Embryo Donation are coming from out of the area, it becomes even more unlikely that the siblings could ever meet. It becomes astronomically unlikely.

***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.***

### **What are the psychological affects of the Embryo Donation process?**

Embryo donation is clearly new, 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 and psychological counseling will always be available upon request. If you desire counseling, we can help you find a provider close to your home. It goes to reason, however, that many couples will prefer the embryos be transferred rather than destroyed.

### **Will we be contacted if the Recipient Couple conceives?**

With the permission of the Donor Embryo Recipients and your own personal desire to be contacted, we will contact you regarding the success of the Embryo Donation process. It is important that if you move that you please contact the facility as to your change in address.

### **Will the Embryo Recipient receive all of our donated embryos?**

Once pregnancy occurs in the Embryo Recipient, they may reserve *some* of the remaining cryopreserved donated embryos for further use. If a large number of embryos remain, however, 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 very 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, we will not allow any **Donor Embryo Recipient** to “re-donate” the donated embryos with ***new stipulations***. It is important that any restrictions that you placed on the original set of donated embryos will remain intact and not be modified during a theoretical second embryo donation process.

### **Why donate them to EDI?**

While there may be other programs which may accept your donated embryos; here are a few reasons why you might want to consider sending your Donated Embryos to EDI:

- There are very few Embryo Donation programs currently available.
- EDI does not charge a “middle-man” fee, thereby decreasing the costs to the desperate Recipient Couple.
- EDI has a history of being an “Embryo Advocate” by discussing the fate of abandoned embryos and trying to change current standards regarding the automatic disposal of the abandoned embryo.
- EDI will allow you to have your embryos returned upon request, assuming that they have not been used.

- EDI agrees to help all parties keep track of newly diagnosed genetic problems in the Embryo Donor family or the Embryo Recipient offspring.
- EDI has an excellent success rate in a large number of ART procedures.
- EDI has an extraordinarily organized Embryo Donation Program, which will help to make certain that all steps of the Embryo Donation process run smoothly.
- The EDI Embryo Donation Program is easily accessible through the web site at no charge to the recipients. This increases the likelihood that the embryos will be chosen by qualifying recipients and find a wonderful home.
- Florida has excellent legal statutes that protect many sets of circumstances, which make it a safe haven in which to donate and receive embryos.

If you have any questions regarding the Embryo Donation Program, we suggest you contact us and we will try to answer your questions.

### Why can't the needy couple simply adopt?

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

1. Embryo Donation is quicker with delivery often within one year of the first visit.
2. Embryo Donation is usually significantly 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 (i.e., brothers and sisters) may be delivered by the Recipient Couple 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 issues.
6. Unlike adoption, the Recipient Couple can choose the genetic traits they value to some degree 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 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.

### How do we get started?

1. If you have not received the entire Embryo Donation packet, we ask that you call and request this information.
2. Visit <http://www.dreamababy.com/embryo-donation.htm> for additional information and to review the embryos currently available for donation.

3. If you have questions, an appointment will be made or a telephone conference will be set up with the Embryo Donation Coordinator.
4. If you desire answers to any legal questions, an attorney's name will be provided to you. One potential place is [www.LegalSurrogacy.com](http://www.LegalSurrogacy.com).
5. You will be asked to review and complete the Embryo Donation Packet. All consents will have to be signed and sent to us.
6. After the consents are signed, EDI will contact the laboratory where the embryos are stored and obtain information on the number and quality of the embryos stored.
7. EDI will then grade the embryos and decide if the embryos will be accepted into the Embryo Donation Program.
8. EDI will then pay all handling and shipping fees to the EDI laboratory.
9. The information on the Donated Embryos will be placed on the EDI web site.

**Will we be told of the success/failure of the embryo donation procedures?**

Understanding that once the embryos are donated, it is up to the Embryo Recipients to agree for EDI to notify us, in an anonymous fashion, of the success or failure of the Donor Embryo Transfer procedures:

- We **agree** to have SRMS-EDI notify us of the success/failure of the Donor Embryo procedures.
- We prefer that SRMS-EDI **not** notify us of the success failure of the Donor Embryo Transfer procedures.

**Summary:**

The Embryo Donation Program is a wonderful option for your embryos. If you feel these embryos deserve a chance at life and that an infertile couple has a chance at parenthood, then Embryo Donation is a wonderful alternative.

Our questions have been answered to our satisfaction. All of the blanks in this consent have been filled prior to the signing of the signatures below:

_____	_____	___/___/___
Woman's Signature	Woman's Name (print)	Date
_____	_____	___/___/___
Partner's Signature	Partner's Name (print)	Date
_____	_____	___/___/___
EDI Nurse Coordinator Signature	EDI Nurse's Name (print)	Date
_____	_____	___/___/___
EDI Physician's Signature	EDI Physician's Name (print)	Date

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Initials:	Date:
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