# Recipient General Consent for Donated Embryos, EDI

## Assisted Reproductive Technologies

### Introduction:

This is to certify that we _____& _____ hereby agree to a form of treatment generally known as Embryo Donation.

We have medical problems, which are unresolved by conventional therapy. We understand that Embryo Donation provides a means by which some couples may conceive and bear children. After a detailed and complete discussion with our physician and/or his designee(s) at Embryo Donation International (EDI), we hereby request this therapy.

### General Steps:

The following is a general outline of the steps that may be required to perform Embryo Donation. Please realize that this list is not inclusive of all possibilities, but includes the most common concerns.

### Medications:

The use of "fertility drugs" such as Estrogen, Leuprolide (Lupron®) and Progesterone may be administered. Most of these hormones are the same as or very similar in structure to the natural hormones which are released during a normal menstrual cycle. The medications are sometimes administered by injection. Specific information about each drug will be provided. The frequency of administration varies, but there can be up to two injections each day.

### Blood/Urine Specimens:

When transferring donated embryos, urine testing is often requested twice each day. Endocrine blood tests are done less frequently. Bruising at the needle site may occur.

### Embryo Transfer:

The process of placing the fertilized donated embryos into the uterus or Fallopian tube is a low-risk procedure. Pelvic discomfort and vaginal bleeding may occasionally occur.

## Micromanipulation Techniques:

While certainly not intended, the micromanipulation techniques can occasionally result in partial or complete destruction of the embryos. This rarely occurs.

## Multiple Gestations:

Twins, triplets or more may occur when ART is used to achieve a pregnancy. The generally accepted risk near 40%, although seems to be significantly less with cryopreserved/thawed Donated Embryos. We understand that all multiple gestation pregnancies are exceedingly high risk with such complications as premature birth, the need for a surgical delivery and bed rest or hospitalization during the pregnancy. Options such as selective fetal reduction of some of the gestations may allow one, two or three of the infants to survive. We understand that we may need to leave Florida to find individuals skilled in this procedure. Once again, multifetal pregnancies involving triplets or more are infrequent with cryopreserved/thawed donated embryos.

## Abnormal Conception:

There has been a recent study (El-Chaar D, et al. Fertil Steril 2009;92:1557-61) that suggests there may be an increased chance of a major malformation (i.e., heart, intestine and skeletal) of around 1% higher in successful infertile patients than the rate seen from fertile parents (2.9% compared to 1.9%). This 1% increase seems to be present in those patients who simply took ovulation medications, had inseminations as well as those who had IVF. It is totally uncertain if this increased risk is due to the infertility treatment or simply a problem in the infertile population itself.

We offer no guarantee 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 in the more natural settings.

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 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.

As some families have cancer run through them while others heart disease, it is possible that some of the problems that caused subfertility of the Donating Parents could be inherited by their offspring. This would have been the case should you and your partner successfully conceived on your own.

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!

## Pregnancy Loss:

Any pregnancy may result in a spontaneous miscarriage and Embryo Donation is no exception. A stillbirth is also possible but does not seem to occur more frequently when ART is used when



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compared to the general population. Young women loose only 10% of their pregnancies while older women may loose up to 60% of established pregnancies. The loss rates will be proportional to the age of the egg donor and not the age of the uterus accepting the donated embryos.

## Ectopic Pregnancy:

The general incidence for an ectopic pregnancy, usually located in the fallopian tube, in patients using ART is 3%. Once pregnant, there is a 1:100-200 risk for having a concomitant intra-uterine and ectopic gestation called a **heterotopic** pregnancy. If this occurs, surgery is usually needed to remove the ectopic pregnancy while trying to conserve the intra-uterine pregnancy.

## Sexually Transmitted Infections:

To date, there has never been a case in which a Sexually Transmitted Infections (STI) was transferred via donated embryos. At the same time, the donating patients may not be available to updated testing to confirm their original negative STI laboratory findings.

Please understand that an embryo is very small and generally less than 100 cells in size. The transfer of STI's usually takes thousands or millions of infected cells. Nevertheless, there is a theoretic possibility that transferred donated embryos could also transfer a STI.

## Unexpected Events:

We understand that, despite reasonable precautions, any of the following may occur which would prevent the establishment of a pregnancy;

**General:**

- Realizing this is an elective procedure, my physician reserves the right to cancel my cycle at anytime if he feels my health is at risk.

**After Thawing;**

- An average of 1 out of 4 thawed embryos will not survive. The embryos lost are thought to be genetically abnormal and don't survive the rigors of the freeze/thaw process.
- Even if cell growth and division occurs, the embryo may not develop normally.
- If the embryo transfer is delayed, it may not be possible to maintain the life of the embryo.
- Loss or damage to the embryos may occur during the actual transfer process.
- Even if the embryos develop and are placed back into the uterine cavity, actual implantation of the embryos on the walls of the uterus may not occur.
- While the most extreme of precautions is taken, a laboratory accident may result in the loss or damage of the embryo(s).
- The physician(s) and staff of EDI will not be held accountable for acts of God (i.e., hurricane), which do not allow for any of the ART procedures to take place.

## Psychological Concerns:

We are aware that the preparation for, and the ART procedures themselves, may have serious psychological consequences with respect to, but not limited to, the mother-child, the father-child, mother-father and parent-family relationships. Psychological counseling is always available upon request. Issues regarding disclosure to the offspring are often important to the Embryo Recipient.



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## Legal Concerns:

Should EDI be sued and/or be held liable or responsible for any monies due to third parties (including any child or children resulting from ART procedures) on any claims, we will indemnify (pay back) all such monies to EDI. This includes, but is not limited to, damages, judgments, court costs, attorney fees or any other monetary losses which are claimed or adjudged against EDI for any medical procedures performed by or on EDI's behalf as contemplated in this Agreement.

We understand that under Florida law the donor(s) of the embryos is(are) relieved of all legal rights to and responsibilities for the donated embryos. We further understand that as recipients we become the legal owners of the donated embryos, and as potential parents, have legal rights to and responsibilities, under all circumstances (i.e. inheritance, divorce, etc.), for the donated embryos and offspring as though the donated embryos were genetically ours.

We understand that EDI recommends that we seek legal advice from an attorney familiar with reproductive law, if we have any concerns about our rights as embryo recipients.

## Education, Publication and Confidentiality Concerns:

It is possible that our participation in this program may aid in the development of techniques that will assist other couples and that new and useful information may be obtained from our procedures. Therefore, realizing that our identity will **not** be disclosed, we agree to the taking and publication of photographs, slides or videotapes and/or the active/passive participation of medical/laboratory guests EDI. We realize that specific medical details maybe included in medical discussions or publications without our consent as long as reasonable efforts are made to conceal our identity. Only with prior consent will our identity be purposefully disclosed. These photographs may be used for general documentation of the medical records or for educational purposes, i.e., publications and/or lectures at a national, state or local level.

The confidentiality of the medical records will be maintained in accordance with Florida law. EDI is mandated by Federal statutes to obtain confirmation of all delivery data on the ART pregnancies. We agree to forward any needed information to fulfill the Federal statutes including, but not necessarily limited to, a copy of the birth certificate & a copy of the birth announcement, the newborn sex, newborn weight and any information regarding pregnancy, delivery and newborn complications. We agree that our records may be reviewed by outside agencies including, but not necessarily limited to, the Federal Food and Drug Administration (FDA) or the Society of Assisted Reproductive Technologies (SART). Upon occasion, we understand that these same agencies may contact us to confirm the pregnancy outcome.

## Alternatives of Care:

We understand that there may be other alternatives in obtaining a child rather than ART such as, but not limited to, adoption. In spite of the other alternatives, we request that ART be used.

## General Concerns:

We understand that the practice of medicine is not an exact science and while our physician has recommended ART for our condition, **there is no guarantee that the procedures will result in a successful pregnancy and delivery.**



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We understand that we may elect not to continue with the ART procedures at any time and that this decision will not affect present or future medical care at EDI. Likewise, we acknowledge that our acceptance and continued participation in the program is at the sole discretion of the ART team.

We have read the above materials and understand the possible complications of the proposed procedures. We have had the opportunity to ask questions and to inquire about the risks and benefits of the ART program. Our questions have been answered to our satisfaction and we understand the information given to us.

We understand that this Recipient Consent For Donated Embryos is to be considered valid for **all** future ART procedures, unless specifically revoked by us.

Frequently, the **Donor Parents** would like to know if the procedure worked. We stipulate the following:

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

All of the blanks in this consent have been filled prior to the signing of the signatures below:

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| _____ | _____ | ___/___/___ |
| Recipient's Signature | Recipient's Name (print) | Date |
| _____ | _____ | ___/___/___ |
| Partner's Signature | Partner's Name (print) | Date |
| _____ | _____ | ___/___/___ |
| EDI Coordinator's Signature | EDI Coordinator's Name (print) | Date |
| _____ | _____ | ___/___/___ |
| Practitioner's Signature | Practitioner's (print) | Date |


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