

# Reproductive Care Center

## OOCYTE (EGG) DONATION RECIPIENT INFORMED CONSENT

### INTRODUCTION

In vitro fertilization (IVF) resulted in the world's first human birth reported in 1978. Donated female gametes (oocyte/egg donation) to treat certain types of female reproductive failure were used to produce a birth in 1984. The recipient couple must be married and the wife must be 18-55 years old without medical contraindications to pregnancy or labor and delivery of a pregnancy.

The egg donation process involves several steps for both the egg donor and the egg recipient.

- Recruitment and screening of egg donors followed by matching donors with recipients. In some cases, we perform screening tests after matching the donor with a recipient.
- Preparation of wife's uterus to achieve synchrony with the egg donor's stimulated cycle.
- IVF treatment of the egg donor.
- Sperm collection from the recipient woman's husband or sperm donor followed by insemination of eggs.
- Embryo culture and transfer into the recipient woman's uterus.
- Cryopreservation of surplus/excess embryos.
- The IVF process induces psychological stress and we refer patients for psychological counseling whenever patients request help or we feel it would be useful.

### EGG DONOR MATCHING

Reproductive Care Center (RCC) provided you with a list of egg donors available from our center. Information regarding the donors includes non-identifying medical, genetic and physical characteristics. Alternatively, recipients choose egg donors from other donor agencies or they bring their own known donor into the program. RCC cannot guarantee the accuracy of the information provided by the egg donors.

RCC's donor program includes sole-match cycles or split-match cycles. Each cycle type has different fees, responsibilities and obligations. A sole-match cycle matches one egg donor with one recipient woman. All eggs retrieved in that cycle become the property of the recipient woman and her husband. A split-match cycle matches one egg donor simultaneously with two recipient women. The retrieved eggs from a single split-match cycle are divided between the two recipient women and their husbands. In the event of very few eggs from retrieval, the recipient designated as the primary recipient becomes the owner of all the eggs.

### RISKS AND COMPLICATIONS

#### PREPARATION OF RECIPIENT WOMAN'S UTERUS

Hormone manipulation achieves synchrony between the donor and recipient's menstrual cycles. Controlled endometrial development (CED) describes the use of oral contraceptives (OC), GnRH agonists, estrogen, and progesterone hormones to achieve synchrony with the egg donor's cycle and stimulation of the endometrium to prepare it for implantation of an embryo. Transvaginal ultrasound and blood hormone levels monitor the endometrial response to CED. Occasionally, the endometrium does not respond to hormone stimulation and all the embryos must be cryopreserved.

#### DONOR IVF PROCEDURE

The IVF/ET process occurs in stages through outpatient visits. While the egg donor assumes the physical risks of IVF, you assume the risks associated with IVF that lead to low or poor egg formation. Consequently, the following summary of IVF focuses on aspects of the egg donors IVF cycle that affects you.

**Ovarian Stimulation:** The drugs and doses used for ovarian stimulation vary depending on medical and related factors. Most side effects are minor but an allergic reaction to any of the drugs is always possible. Rarely, a side effect could lead to cycle cancellation. RCC cannot guarantee the number or quality of eggs produced from stimulation.

Following embryo transfer (ET), we require progesterone supplements until the pregnancy test or for an additional 8 weeks if the woman is pregnant. Progesterone administration by injection often causes discomfort and swelling at the injection site for some weeks after stopping the injections. Vaginal progesterone may cause irritation and/or discharge. Despite some product labeling, all progesterone products recommended by our clinic are generally considered safe and effective during pregnancy. Only one of the products has received specific approval by the FDA for use during pregnancy.

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**Monitoring:** Transvaginal ultrasound examinations (TVE) determine the number and size of ovarian follicles (cysts) for the donor's cycle. Together with blood hormone levels, the medical staff determines whether to adjust the hormone dose and the correct time for egg retrieval. TVE also monitor the development of the recipient's endometrial lining. TVE does not usually hurt. Blood draws (phlebotomy) and injection of medications may cause mild discomfort and bruising, bleeding, infection, or scarring at the needle sites.

**Egg Retrieval:** We remove the eggs from the donor's body using ultrasound-guided egg retrieval. We do not guarantee that the ovaries contain any healthy eggs or that we will successfully retrieve them. We may not recover eggs because ovulation occurred before the time of retrieval (an unusual event).

## **IVF PROCEDURE - EMBRYOLOGY AND EMBRYO TRANSFER**

**Sperm collection:** The husband provides a semen specimen by masturbation on the day of the egg retrieval. Our staff processes the sperm for insemination of the eggs. We label each sperm specimen with several identifying marks such as name and chart number to ensure the correct sperm fertilizes the donor eggs.

If the man does not or cannot provide a semen specimen within a reasonable time on the day of egg retrieval, he must decide how to proceed. We can sedate the man and aspirate the sperm directly from the testicle or epididymis, use donor sperm or discard the eggs without insemination. The man assumes all responsibility for providing us with a sperm sample on the day of egg retrieval. We recommend that you notify the medical staff before you begin the treatment cycle if you believe that you may have trouble producing a sperm sample so that we can freeze a sample in advance.

**IVF Embryology:** Our staff combines the sperm and eggs following retrieval and then places them into an incubator to allow fertilization. If preliminary tests determine that the sperm will not naturally fertilize an egg, we insert the sperm directly into the egg (intracytoplasmic sperm injection - ICSI). We cannot guarantee fertilization regardless of the technique used to inseminate the eggs. Occasionally, eggs die in the incubator, other eggs fertilize abnormally resulting in embryos that cannot be transferred, and very rarely, none of the eggs fertilize or progress into embryos. When patients elect blastocyst transfer, they assume the risk that none of the embryos will become blastocysts; although, an embryo transfer of morula stage embryos may occur.

Equipment failure, infection, human error or other unforeseen factors may result in loss or damage to eggs, semen, and/or embryos. Unforeseen conditions (natural weather disasters, etc.) may make RCC facilities or other medical or laboratory support unavailable at the appropriate time for egg recovery.

**Embryo Transfer:** The patient(s) indicate in writing the number of embryos to be transferred and/or cryopreserved after discussion with a physician on the day of transfer. We transfer embryos into the uterus using a small catheter inserted through the cervix. Rarely, technical difficulties prevent ET requiring embryo freezing or the embryos are lost in the process of attempting a difficult ET. If more than one embryo is transferred, there is a risk of multiple gestations.

ET occasionally causes slight discomfort, a small risk of infection and/or bleeding. We recommend bed rest for the rest of the day following the ET. Intramuscular or intravaginal progesterone supplements enhance implantation of the embryos in the uterus. We recommend cryopreserving (freezing) excess embryos so that you have additional opportunities to become pregnant or to have another child if the fresh ET results in a successful pregnancy. You must sign a separate consent for embryo cryopreservation.

**Pregnancy:** We cannot guarantee implantation or a successful pregnancy from any IVF/ET procedure. Most infants born following human IVF appear normal at birth. Yet, congenital abnormalities, birth defects, genetic abnormalities, mental retardation, and/or other possible deviations from normal occur in children born following IVF as they do in children resulting from natural fertilization. Some studies suggest that IVF leads to greater risk of congenital anomalies than in natural conceptions.

Pregnancy following IVF/ET may end in a miscarriage, ectopic (tubal) pregnancy, or stillbirth. Multiple pregnancies (twins, triplets, etc.) occur with greater frequency than natural conceptions. Some pregnancy complications may occur more frequently following IVF than natural impregnation such as preterm labor and early delivery.

## **ALTERNATIVES TO EGG DONATION:**

Most clinicians recommend egg donation when the recipient woman is unlikely or unable to become pregnant with her own biologic child. Consequently, alternatives to egg donation include adoption, donor embryo transfer (if available), surrogacy, or childless living.

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## ACKNOWLEDGMENT OF INFORMED CONSENT/AUTHORIZATION

We, \_\_\_\_\_ (wife) and \_\_\_\_\_ (husband) hereby request donor egg IVF treatment (Program) at the Reproductive Care Center in hopes of having a child. We acknowledge reading and fully understanding this written material. All our questions concerning the Program have been fully answered to our satisfaction. We acknowledge receiving statistical information regarding success rates for donor egg IVF and related procedures.

We understand that legal principles may not be firmly established for egg donation. By participating in this Program, we accept the responsibilities, conditions, and risks involved as set out in this document and as explained to us by members of the IVF team. The references in this form to the RCC shall include such additional qualified physicians or scientists as are added to or assume responsibility for its activities from time to time and any assignee or other successor in interest of the RCC.

We understand that this is confidential process. Any deliberate attempt to seek an anonymous donor's identity will not be tolerated. In such instances, the cycle may be canceled at any time with no financial remuneration. This policy has been designed to protect both you and the donor.

We acknowledge that our acceptance and participation is at the sole discretion of the RCC. Correspondingly, we understand that we can withdraw from the Program at any time without affecting the availability of either present or future medical care at RCC. We represent that we are financially able to participate. We acknowledge our responsibility and willingness to pay for the costs of our care in the Program including other medical costs incurred by us at the RCC whether or not we produce embryos for transfer into the uterus.

It is possible that our participation in this Program may aid in the development of techniques that may help other infertile couples and/or provide new and useful medical information. Therefore, we consent to photographs and/or audiovisual taping of laboratory procedures involving our participation in the Program for the purpose of advancing medical education and research provided our identity is not disclosed. We agree that with our written prior consent, our identities may be disclosed.

We understand that information obtained about us during participation in this Program will be treated as confidential and that our identity will not intentionally be revealed without our prior consent. We have signed a separate Health Insurance Portability and Accountability Act (HIPAA) Authorization.

We understand and assume all risks of our participation. We make this choice with the knowledge that the practice of medicine and surgery is not an exact science and that no one promised or guaranteed the treatment or the results of treatment. We understand that the RCC has no policy for our compensation if complications occur. We agree that any possible dispute or claim involving us and the RCC shall be settled solely by arbitration by the American Arbitration Association (using its health care claim settlement arbitration rules). The locale for arbitration will be Salt Lake County, Utah, and the arbitrators' judgment may be entered in any appropriate court and shall be binding and enforceable.

We consent to disposal of eggs or embryos that, in the best judgment of RCC staff, are not viable, and are not transferred or frozen. In addition, we consent to the disposal or utilization of other cells, body tissues, or fluids that may have been obtained during the IVF process.

We understand that future questions about our participation in the Program can always be addressed to physicians and/or other members of the RCC staff.

This Informed Consent/Authorization dated this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, will be governed by the laws of the State of Utah.

\_\_\_\_\_  
Wife's signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness to wife's signature

\_\_\_\_\_  
Husband's signature (if applicable) Date

\_\_\_\_\_  
Witness to husband's signature

\_\_\_\_\_  
Reproductive Care Center

\_\_\_\_\_  
Date

# Reproductive Care Center

## Informed Consent for Intracytoplasmic Sperm Injection (ICSI)

**INFORMATION:** Injection of a single sperm into the oocyte (or egg) may be used to increase the chance of fertilization for couples that suffer from male-factor infertility or egg fertilization defects. It is recommended when couples are using frozen eggs, or are using sperm sorted using MicroSort technology for gender selection. ICSI is also usually recommended when preimplantation genetic diagnosis (PGD) testing is being done in order to minimize contamination from any extra DNA from other sperm that may be attached to the outside of the egg and subsequent embryo.

To overcome problems associated with fertilization, a single sperm is selected and injected directly inside an individual egg (Intracytoplasmic Sperm Injection, or "ICSI"). If viable sperm are available, the pregnancy rates are usually unaffected by the semen characteristics and sperm quality. ICSI can be performed in men without sperm in the ejaculate (azoospermia), if sperm can be harvested from the epididymis (collection system near the testicle) or the testicle (TESE).

Some studies have indicated an increase in the risk of sex chromosome abnormalities in ICSI pregnancies. The incidence of congenital birth defects may also be higher with ICSI, but it is unclear if this is due to the procedure itself, or to inherent problems with the sperm. It is well known that men with suboptimal semen parameters have a higher frequency of chromosomal abnormalities such as Klinefelters syndrome. Chromosome rearrangements and structural abnormalities may occur in up to 1% of pregnancies conceived after ICSI. Microdeletions of the AZF region of the Y chromosome have been found in up to 15% of men with low sperm counts. These microdeletions can be passed on to any male embryos that result. Men with low semen parameters are also more likely to have one of several cystic fibrosis gene mutations. We are aware that RCC recommends that men with low sperm counts be tested for the above mentioned abnormalities (such as karyotype or chromosome analysis, Y microdeletion assay, and Cystic Fibrosis mutation screening). If abnormalities are detected, genetic counseling is recommended. Genetic testing prior to embryo transfer (preimplantation genetic diagnosis), chorionic villi sampling or amniocentesis may be appropriate.

Some studies suggest there is an increased risk of identical twinning after ICSI, including situations where the fetuses are in the same fluid filled sac. When the fetuses are in the same sac (monochorionic and monoamnionic) there is an increased risk for miscarriage and late in pregnancy complications such as twin-twin transfusion can occur. Fortunately, this occurs in less than <2% of the cases after ICSI with embryo transfer at the cleavage stage. The expected rate after natural conception is <0.4%.

The potential advantages of selecting ICSI include: (1) enhancement of the fertilization rate thereby increasing the number of fertilized eggs available for transfer into the uterus or for freezing, (2) fertilization of eggs when the chance for successful fertilization under normal insemination protocols is anticipated to be low and (3) minimizing the likelihood of not getting any eggs to fertilize when the semen parameters are marginally abnormal. It is also possible that none of the eggs will fertilize, even with ICSI.

The potential disadvantages of ICSI include: (1) potential for unknown risks to the egg or embryo, (2) the process of ICSI itself may damage embryos or it may degenerate the egg immediately. If you or any of your offspring should require any medical treatment as a result of physical injury thought to arise from your use of ICSI, financial responsibility for such care will be yours.

Potential alternatives to the use of ICSI include: (1) trying basic in vitro fertilization (without the use of ICSI) with the possibility that very few and perhaps none of the eggs will fertilize, (2) use donor sperm from an approved sperm bank to fertilize the eggs or, (3) the couple could choose adoption or child-free living. Couples can also choose to not use frozen eggs, MicroSort sorted sperm or PGD.

**CONSENT:** We understand that ICSI involves an extra procedure fee in addition to charges associated with in vitro fertilization (IVF). We, the undersigned husband and wife, have decided to participate in the IVF program at the

Reproductive Care Center. We have read and understand the above and all our questions about ICSI have been answered. We have been encouraged to ask further questions at any time if doubts about our participation arise.

We acknowledge that neither the RCC, nor the physicians or staff have made any warranties with respect to: (1) the viability or successful fertilization of eggs after ICSI, (2) the establishment of pregnancy as the result of this treatment, (3) the lack of risk of a birth defect, miscarriage, tubal and/or ectopic pregnancy, multiple pregnancy or complication after embryo placement in the uterus.

We acknowledge the receipt of a copy of this agreement and agree by placing our initials next to the selection below as the method to be employed during IVF. We understand that we can change the options below with each subsequent IVF cycle if desired. This consent will remain in effect for 5 years from the date of signing or for up to 12 IVF cycles unless a new consent is signed by the couple and delivered to and acknowledged by RCC staff.

### **ICSI Preference**

\_\_\_\_\_ We desire ICSI to be performed on all of our eggs that are sufficiently mature and will pay for this in advance. This option is required when a couple is using frozen eggs, sperm sorted using MicroSort technology, or are using PGD for specific gene abnormalities when PCR is used.

\_\_\_\_\_ We desire ICSI to be performed on approximately 50% of our eggs that are sufficiently mature and will pay for this in advance. We desire that attempts be made to fertilize any remaining eggs using conventional IVF techniques. We acknowledge that there is no discount on the ICSI procedure in this situation due to the work involved.

\_\_\_\_\_ If we have chosen to not initially use ICSI despite the fact that it has been recommended due to the semen parameters, we desire that "rescue ICSI" be performed the day after egg retrieval if none of the eggs fertilize with normal IVF. We realize this has a much lower fertilization rate than ICSI on the day of the egg retrieval, but is occasionally successful in achieving a pregnancy. If rescue ICSI is done, we agree to pay the standard fees at the time of the procedure.

\_\_\_\_\_ We realize the sperm quality is borderline, and will pay for ICSI if the lab decides it is recommended based on the sperm collected the day of egg retrieval. If IVF is still recommended by the lab but no fertilization occurs, we desire rescue ICSI as described above. If ICSI is done, we agree to pay the standard fees at the time of the procedure.

\_\_\_\_\_ We understand that the sperm quality is considered adequate for IVF and that good fertilization (approximately 60-70% of the eggs fertilize on average) is anticipated. If no fertilization occurs (2-3% of cases with normal appearing sperm), we desire rescue ICSI as described above.

\_\_\_\_\_ We do not want ICSI to be done under any circumstances.

### **Donor Sperm Backup Preference**

We understand that despite the expectation, there may be a failure to obtain adequate sperm from the husband for ICSI. Even if sperm is obtained it may be immotile which makes it difficult to determine if it is viable. We acknowledge that even if ICSI is performed, fertilization may not occur. If no sperm are obtained and ICSI was planned, we:

\_\_\_\_\_ desire to use donor sperm, if available. We acknowledge that it is our responsibility to order and have delivered to Reproductive Care Center any donor sperm desired. We understand that only sperm from an approved sperm bank may be used. Donor sperm must be delivered to RCC prior to egg retrieval.

\_\_\_\_\_ do not desire to use donor sperm. We understand that in this case any eggs retrieved would not be able to be used and would be discarded.

## Genetic Testing Preference

\_\_\_\_\_ We desire and will ensure prior to proceeding with the treatment cycle that the husband have appropriate testing to include a chromosome analysis, Y microdeletion assay, and Cystic Fibrosis mutation screening. This is recommended for men whose sperm concentrations are less than 10 million/ml including when no sperm is in the ejaculate (azoospermia).

\_\_\_\_\_ We are aware of the risks but only desire the following test(s) on the husband which we will have completed prior to proceeding with the treatment cycle:

- chromosome analysis
- Y microdeletion assay
- Cystic Fibrosis mutation screening (recommended in all Caucasian couples attempting pregnancy)

\_\_\_\_\_ We are aware of the risks and do not desire testing on the husband for chromosome analysis, Y microdeletion assay, or Cystic Fibrosis mutation screening.

\_\_\_\_\_ Not applicable as the semen parameters are considered normal but we are using frozen eggs, MicroSort sorted sperm or we desire PGD.

We understand that payment for ICSI is an additional fee in addition to the basic IVF fees. We agree to pay this fee in advance if this is selected or on the day the ICSI is performed if it is determined to be indicated.

_____	_____
Husband's Signature	Date
_____	_____
Witness to Husband's Signature	Date
_____	_____
Wife's Signature	Date
_____	_____
Witness to Wife's Signature	Date

# Reproductive Care Center

## Informed Consent for Fresh Embryo Transfer

The number of embryos to be transferred should be agreed upon by the couple and their physician. Based on our experience at the Reproductive Care Center (RCC) and the guidelines set forth by the American Society for Reproductive Medicine (ASRM), the number chosen should optimize the chance for achieving a pregnancy while minimizing the likelihood of higher order multiple pregnancy. Multiple gestations (particularly triplet and higher order multiple pregnancy) are an undesirable consequence of assisted reproductive technologies. Multiple gestations lead to an increased risk of significant complications in both the fetuses and the mother. Patients should also be aware that even though the likelihood is low (<2%) it is possible for an embryo to split into “identical twins”. Thus even with the transfer of 1 embryo, twins could develop. Although multifetal pregnancy reduction can be performed to reduce fetal number, the procedure does not completely eliminate the risks associated with multiple pregnancies and can have adverse psychological consequences. We do not perform this procedure but can refer patients if needed. Fetal reduction may result in the loss of all fetuses (usually <5% risk) and even successful reductions may have adverse psychological consequences. If multifetal pregnancy reduction is not an acceptable option, we would usually recommend that you not transfer more than two embryos.

Embryos are cultured until ready for transfer, which is usually for three to six days. After culturing for 3 days the embryos have typically developed to the 6-8 cell stage and are called “cleavage stage” embryos. Two good cleavage stage embryos have usually been transferred on day 3 for many years at RCC with excellent pregnancy rates.

As the embryos continue to develop, they pass through several stages including blastocyst formation. Blastocysts are typically “stronger” than day 3 embryos. The strongest, and most fit, embryos will survive the additional two days in culture. Blastocysts have a higher implantation rate and are more likely to implant than day 3 embryos. Because of this increased viability, fewer blastocysts need to be transferred, thus potentially lowering the rate of high order (>2) multiple births.

However, even with the advantages of increased viability and lower multiple birth rates, blastocyst transfer is not for every couple (cycle). The longer the embryos are cultured the fewer the embryos that will remain viable for transfer (and or cryopreservation). For example, there are usually more embryos on day 1 than on day 3 or day 5 as some embryos stop growing or their growth slows during the culturing process. In addition, some studies of blastocyst transfer suggest there is an increased risk of identical twinning, including situations where the fetuses are in the same fluid filled sac. When the fetuses are in the same sac (monochorionic and monoamniotic) there is an increased risk for miscarriage and late in pregnancy complications such as twin-twin transfusion can occur. Fortunately, this occurs in less than 5% of the cases.

There must be enough viable embryos on day 3 to “risk” culturing to day 5. For example, if only two embryos are present on day 3, one or both could stop growing by extending culture to 5 or 6 days, which would result in the loss of the cycle. On the other hand, if more than 3 good 8 cell cleavage stage embryos are available on day 3, the chances are high that 2 or more will survive to day 5 making blastocyst transfer feasible. Whether or not the couple plans to cryopreserve some of their embryos will also influence the decision on whether to extend the culture.

The best comparative research studies demonstrated equivalent pregnancy rates and multiple birth rates to conventional IVF when transferring 2 blastocysts versus 3-4 embryos on day 3 after egg retrieval. The main difference between the two groups was that transfer of 2 blastocysts rarely resulted in triplets.

Unfortunately, embryos unpredictably develop to the blastocyst stage. Approximately 40-50% of embryos successfully develop into blastocysts. If the starting number of embryos is low (less than 6 embryos), then we face a higher chance that none of the embryos remain viable by day 5-6. RCC may recommend embryo

transfer on day 3 rather than attempting blastocyst transfer when the embryo number is low or the quality is poor to avoid the possibility of no embryos for transfer on day 5.

The Reproductive Care Center cannot guarantee improved pregnancy rates or that any pregnancy will result from using blastocyst embryo transfer. IVF fails to produce any blastocysts in as many as 5-10% of cycles. It is generally assumed (but not known for sure) that embryos that die in laboratory culture would not have developed into normal pregnancies if they had been transferred into the uterus at an earlier stage.

The following updated guidelines were recommended by ASRM in 2006.

1. In patients under the age of 35, no more than two embryos should be transferred in the absence of extraordinary circumstances. For patients with a favorable prognosis, consideration should be given to transferring only a single embryo. The patients having the most favorable prognosis include those who are undergoing their first cycle of IVF, have good quality embryos as judged by morphologic criteria (appearance), and have embryos of sufficient quality and quantity to warrant cryopreservation (freezing). The patients who have had previous success with IVF should also be considered the most favorable prognostic category.
2. For patients between 35 and 37 years of age having a favorable prognosis, no more than two embryos should be transferred. All others in this age group should have no more than three embryos transferred. After extended culture no more than 2 blastocysts should be transferred.
3. For patients between 38 and 40 years of age with a favorable prognosis, no more than 2 blastocysts or 3 cleavage stage embryos should be transferred. For patients in this age group having a less favorable prognosis, no more than three blastocysts or 4 cleavage stage embryos should be transferred.
4. For most patients greater than 40 years of age, no more than three blastocysts or five cleavage stage embryos should be transferred.
5. For the patients with two or more previously failed IVF cycles and those having a less favorable prognosis, additional embryos may be transferred according to individual circumstances after appropriate consultation.
6. In donor egg cycles, the age of the donor should be used to determine the appropriate number of embryos to transfer.

We understand that we fit into category # \_\_\_\_\_ listed above. Special considerations for our case, if any, include (none) \_\_\_\_\_

We understand that transferring multiple embryos entails the risk of multiple pregnancies, which have much higher risks than single pregnancies. We have had an opportunity to discuss these risks with an RCC physician and accept the risks involved with this decision. We understand that transferring more than two embryos requires physician discussion.

RCC usually recommends that the couple plan to culture the embryos to day 5 or 6 after the egg retrieval and then transfer blastocysts if there are an adequate number of good quality embryos available on day 3. A day 2 transfer may be recommended if the number of embryos available for transfer is the same as the number of embryos desired for transfer (usually 2).

Please choose one option from the following two options:

**Option 1 day 3 (circle) – Yes No**

We desire a day 3 embryo transfer (do not want a day 5 (blastocyst) transfer and we plan to transfer the following number of cleavage stage embryos:

- \_\_\_\_\_ One cleavage stage embryo.
- \_\_\_\_\_ Two cleavage stage embryos.
- \_\_\_\_\_ Three cleavage stage embryos, if one is of poor quality.

**Option 2 day 5-6 (circle) – Yes No**

If in the opinion of RCC physicians and embryologists there is an **inadequate number** of quality embryos for extended culture we plan to transfer the following number of cleavage stage embryos on day 2 or 3:

- One cleavage stage embryo.
- Two cleavage stage embryos.
- Three cleavage stage embryos, if one is of poor quality.

**The following options are not usually recommended (extended culture would be preferred):**

- Four cleavage stage embryos, if two are of poor quality.
- Three good quality cleavage stage embryos.
- All cleavage stage embryos available.

If in the opinion of RCC physicians and embryologists there is an **adequate number** of quality embryos for extended culture we plan to transfer the following number of blastocysts on day 5 or 6:

- One blastocyst.
- Two blastocysts.
- Three blastocysts (**not usually recommended at RCC**).

\_\_\_\_\_  
Wife's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Husband's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Physician's Signature

\_\_\_\_\_  
Date

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**To be completed on the day of embryo transfer:**

Based on updated information provided on the day of embryo transfer, we desire to change the number of embryos transferred on this cycle to: \_\_\_\_\_.

We desire that extra embryos of adequate quality (#\_\_\_\_) be cryopreserved today (circle): Yes No

We desire that assisted hatching be performed today (additional cost): Yes No

We desire that extra embryos undergo extended culture (at additional cost) and if at least \_\_\_\_\_ blastocyst(s) of adequate quality develop we desire that they be cryopreserved (circle): Yes No

We desire that the embryos be frozen (circle): In groups (with no more than #\_\_\_\_ in a group) Individually

We request that RCC dispose of bodily fluids or tissues, including any unfertilized or abnormally fertilized eggs, developmentally arrested, abnormal or undesired embryos. Photographs may be made of any discarded tissues or fluids and may be used anonymously for presentation or publications. We also consent to allow RCC to use any bodily fluids, tissues, unfertilized or abnormally fertilized eggs, as well as any developmentally arrested, abnormal or undesired embryos that would otherwise be discarded, for medical research, quality control, training or teaching purposes.

\_\_\_\_\_  
Wife's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Husband's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Physician's Signature

\_\_\_\_\_  
Date:

# Reproductive Care Center

## Informed Consent for Cryopreservation, Storage and the Disposition of Human Embryos

### I. General Information: (Please Read Carefully)

#### Purpose of Cryopreservation

The purpose of cryopreservation in an Assisted Reproductive Technology (ART) program is to preserve surplus embryos, not replaced during the initial transfer procedure, for replacement at a later time. This procedure can be beneficial by eliminating the need for another ovarian stimulation and egg aspiration procedure when the initial in-vitro fertilization (IVF) fresh cycle (or frozen egg cycle) does not result in a pregnancy, or when additional pregnancy(s) are desired at a later time. The option of freezing embryos eliminates consideration of transferring too many embryos with high risk of multiple births or discarding embryos that might have become healthy babies.

#### Background on Cryopreservation

Reproductive Care Center (RCC) usually freezes 1-4 embryo(s) in cryo straws. Freezing embryos in groups minimizes the work and expense while usually allowing for the thaw of the appropriate number of desired embryos for transfer. During a frozen embryo transfer (FET) cycle, RCC thaws the best combination of frozen embryo groups in order to obtain the desired number of intact embryos for transfer.

If desired, Reproductive Care Center (RCC) can freeze each embryo individually (extra charge) in cryo straws. During a frozen embryo transfer (FET) cycle, RCC can serially thaw only the exact number of embryos necessary for your transfer. This practice may maximize the number of possible transfers from your retrieval cycle but adds additional time and cost to the procedure.

Embryos may survive the freeze-thaw process completely intact with all the cells (blastomeres) alive and healthy. However, most embryos lose one or more cells in the process. If at least 50% of the cells survive the thaw, we designate the embryo as surviving (intact). When less than 50% of the cells survive, we designate the embryo as partially surviving. All surviving embryos yield reasonable implantation rates, although the completely surviving embryos yield the highest implantation rates. Partially surviving embryos uncommonly lead to a successful pregnancy but because they occasionally do implant, we allow transfer of these embryos if the patient desires.

The success rate from FET cycles is less than from transfer of fresh embryos (embryos that have not been frozen yet). The overall success rate depends on the age of the woman when the embryos were formed, the embryo quality score, the status of the embryo at thaw and any other factor that would otherwise influence IVF success. Recent success rates from FET are available on our website ([www.fertilitydr.com](http://www.fertilitydr.com)), through information submitted to the Society for Assisted Reproduction (SART – [www.SART.org](http://www.SART.org)), the CDC ([www.CDC.gov](http://www.CDC.gov)) and through discussion with your RCC physician.

We understand that available human data as well as animal data do not suggest that embryo freezing increases the risks of congenital anomalies (birth defects) in the resultant offspring. Although the risk of birth defects from frozen human embryos is similar to natural conceptions, RCC cannot guarantee a normal birth. The expected rate of major birth defects in the normal population is 3-4%.

Prior to cryopreservation of embryo(s), and in compliance with the American Association of Tissue Banks, and RCC policies and procedures, the husband and wife are required to provide evidence of negative blood tests for Hepatitis B Surface Antigen, Hepatitis C antibody, HIV-1 & 2 antibody, syphilis, and gonorrhea and chlamydia within 24 months of the anticipated egg retrieval.

#### Risks to the Husband and Wife

While there are no known risks to the Husband or Wife from the cryopreservation procedure itself, when a thawed embryo(s) are placed in the uterus, the risks to the wife are the same as for a regular fresh IVF transfer, including but not limited to: infection, cramping, bleeding, ectopic pregnancy, miscarriage, multiple birth, and failure to achieve pregnancy.

#### Risks to the Embryo

Currently, 50%-70% of the embryos are anticipated to survive the freezing and thawing procedures. During the freezing and thawing process, it is possible that cell trauma or death of embryos could result from loss during normal handling, freezing, maintenance, storage, withdrawal, thawing, movement in the lab or between labs, malfunction of equipment, human error, natural disaster, or acts of a public enemy. Back-up systems are in place to decrease the likelihood of mechanical failure and malfunction, but circumstances beyond our control could develop and result in the loss or death of embryos. It is not known how long embryos can be stored without death or decreased viability, but you are encouraged to make early use of them.

# Reproductive Care Center

## **II. Informed Consent for the Cryopreservation of Human Embryos**

We, the undersigned Husband and Wife are legally married and agree to participate in the Reproductive Care Center's in vitro fertilization and embryo cryopreservation and storage program. We are, by this document, granting permission for one or more of our embryos to be frozen. We realize that there is no guarantee that any embryo(s) will be available for freezing or will survive the freezing or thawing process.

- (1) In the event that our embryos are initially assessed as unlikely to survive cryopreservation, we understand that it is the policy of the RCC to further culture such embryos. After additional culture, viability will be assessed. Those embryos considered to be viable may be cryopreserved at the later developmental stage (Blastocyst). If assessed as non-viable (either initially or after extended culture), we give consent for the RCC to discard such embryos.
- (2) We agree that prior to the RCC thawing any cryopreserved embryos for transfer thereof to the Wife, BOTH the Husband AND the Wife must sign a separate written consent (Informed Consent for Frozen Embryo Transfer) in the presence of the RCC (or notary public), expressly requesting and authorizing the thawing and transfer for each attempt at achieving pregnancy.
- (3) We understand that the policy of the RCC is not to transfer any embryos into (1) unmarried women, (2) women over the age of 50 (unless approved by RCC physicians after review), or (3) women who cannot safely carry a pregnancy according to the judgment of the physician transferring the embryos. Women who cannot safely carry a pregnancy could elect to use a gestational surrogate if desired.
- (4) The 1992 Fertility Clinic Success Rate and Certification Act requires the Centers for Disease Control and Prevention (CDC) to collect cycle-specific data as well as pregnancy outcome on all assisted reproductive technology cycles performed in the United States each year and requires them to report success rates using these data. Consequently, data from our IVF procedure with the use of frozen eggs will be provided to the CDC, and to the Society of Assisted Reproductive Technologies (SART) of the American Society of Reproductive Medicine (ASRM). The CDC may request additional information from the treatment center or contact us directly for additional follow-up. Additionally, our information may be used and disclosed in accordance with HIPAA guidelines in order to perform research or quality control. All information used for research will be de-identified prior to publication. De-identification is a process intended to prevent the data associated with our treatment being used to identify us as individuals.
- (5) It is intended that the RCC IVF and cryopreservation program option operate indefinitely. However, if the cryopreservation program at the RCC facility discontinues or ceases to operate then one or both of the following options may be exercised at our expense:
  - a) Transfer of embryos into the wife before closure of the facility;
  - b) Transfer to another storage facility.

Under such circumstances, we can be notified by certified mail at our latest address on file at the RCC. If the notice is returned for insufficient address or similar reason, or if no written response thereto is received within 30 days after mailing, we understand that the embryos will be at the sole discretion of the RCC, including donation or disposal.

- (6) We understand if our embryo storage fees become delinquent for more than 90 days, we will be sent a certified letter to our latest address on file. If there is no response and payment is not received within thirty days, RCC shall have the legal right to dispose of our embryos.
- (7) We agree to keep our most current mailing address on file at the RCC at all times during our participation in the IVF Program, while the cryopreserved material is being stored by the RCC, and for 1 year thereafter. We will advise the RCC promptly upon each change of address or prolonged absence (greater than 90 days) from the last address on file. Unless and until superseded in writing, our mailing address is the address currently shown on all forms. In the event that the RCC changes its mailing address, the RCC shall provide the same by way of certified mail, to those who currently have cryopreserved embryos stored, prior to such change. If we fail to notify the RCC within 90 days of change of address, the RCC shall retain the legal right to dispose of our embryos.
- (8) If either one or both of us shall make the RCC (or any of its directors, officers, employees, or agents) or assigns, a party to any arbitration or litigation between the RCC and us, as to the rights of either or both of us to the stored frozen embryos, we shall be liable for the reasonable attorney's fees and other costs of the RCC including loss of time incurred by the RCC personnel in such litigation, unless the RCC is found therein to have: (i) breached this agreement, (ii) acted arbitrarily and capriciously so as to justify being made a party to the legal proceedings, or (iii) committed a legal wrong against the Husband and/or Wife.
- (9) We understand that if either one or both of us declares any kind of bankruptcy, that our embryos stored at the Reproductive Care Center may be disposed of once the prepaid storage has elapsed.

# Reproductive Care Center

- (10) We understand that if we or any of our offspring should require any medical treatment as a result of physical injury thought to arise from our participation in this program, financial responsibility for such care will be our own, except for any matter involving gross negligence.

### **III. Pre-freeze Agreement for the Disposition of Cryopreserved Human Embryos**

We accept responsibility for the ultimate disposition of the cryopreserved embryos. However, we understand that this input cannot be an absolute right but must be consistent with the interests of ethical medicine, and applicable law. We agree that the ultimate use or disposition of cryopreserved embryos is subject to applicable laws and court decisions that affect the legal status or control of embryos. Certain situations may arise that could alter the original intent of the IVF-Cryopreservation procedure, that is, our joint reproductive goal of bearing a child. If the original intent can no longer be fulfilled, then one of the options listed below, for the disposition of cryopreserved embryos, must become operational.

We understand that the cryopreserved material is subject to our joint disposition and that all decisions about its disposition must be joint decisions, except where specified below. We may change our election at any time before disposition by execution of a "Change of Disposition Letter", signed by BOTH of us, notarized and sent by certified mail. Notice is not effective until received by the RCC, as evidenced by the return receipt, and documentation by the director of the RCC. Said letter shall remain in full force and effect unless and until superseded. In the absence of mutual consent by both signatures, this agreement remains binding. If we undergo further IVF cycles at RCC, this agreement regarding the disposition of cryopreserved embryos will apply to any future IVF cycles for 5 years from the date of signing or for up to 12 IVF cycles.

**Option 1:** Grant custody of the embryo(s) to the other spouse for responsibility and control of disposition.

**Option 2:** Transfer custody of the embryo(s) to a third party agent (family member or close friend), designated by both of us, who will be responsible for embryo disposition as if they were the biologic parent. Such third party must accept such responsibility by signing a Transfer of Custody of Cryopreserved Embryos document, along with us, in the presence of an RCC witness or notary public. If option 2 is requested but the Transfer of Custody of Cryopreserved Embryos document is not completed then option 3 will automatically apply.

**Option 3:** Transfer custody of the embryo(s) to the RCC for anonymous donation to a needful married couple.

We understand that **if** we have indicated our willingness to donate our embryos, that we must fill out a questionnaire on our physical characteristics, education, and the health of ourselves and our families. We consent to undergo genetic screening in order to determine if genetic defects exist. We fully understand that this screening may require having our blood drawn for confirmation of negative tests for specific diseases.

We consent (if required) to undergo testing at an FDA approved laboratory for blood borne and sexually transmitted diseases such as, but not limited to, syphilis, Hepatitis B and C, CMV (cytomegalovirus), chlamydia, gonorrhea and Human Immunodeficiency virus (HIV). We fully understand that this would require us to have our blood drawn and urine samples obtained within 30 days prior to or 7 days after the egg retrieval and that a second test requiring an additional blood specimen for HIV may be required six months later.

We fully understand that if abnormalities are found in the genetic, laboratory or psychological screening, we may not be allowed to donate the embryos.

We fully understand that we will not be compensated for the donation of our embryos. We agree to rely upon the discretion of the physicians and staff at RCC in the selection of a qualified recipient couple. We fully understand that all information concerning the identity of the recipients of our embryos is confidential. We agree not to attempt to discover the identity of the recipients of our embryos now, or at any time in the future. We understand that the recipient couple(s) agree(s) not to attempt to discover the identity of the donor couple now, or at any time in the future.

To the extent permitted by law potential adoptive parents will not have any access to our identities, but will receive the information from the questionnaire to assist in making their decision. We understand that donation of our embryos will be anonymous.

We forever hereafter relinquish any claim to or jurisdiction over offspring that may result from transfer of our embryo(s) to another woman. We consent to give up all maternal and paternal rights and responsibilities to any child(ren) conceived through these donated embryos. We understand that in such an event that we have indicated our wish for our embryos to be donated, and either after reasonable time and efforts have been expended, no recipient can be found, or if applicable future laws prohibit donation of embryos, that our embryos will be discarded.

# Reproductive Care Center

- Option 4:** Transfer custody of remaining cryopreserved embryos to the RCC for disposal.
- Option 5:** Transfer custody of remaining cryopreserved embryos to the RCC for medical research, laboratory training, quality control or disposal as deemed appropriate at the discretion of RCC.
- Option 6:** Grant custody to the wife for responsibility and control as to their use or disposition.
- Option 7:** Grant custody to the husband for responsibility and control as to their use or disposition.

As Husband and Wife, we jointly choose the indicated option for the following situations. (Please indicate one option for each situation by the **initials** and **date** of both Husband and Wife).

- (A) In the event of death, disability or legal incapacity of **one** of us, we hereby acknowledge and agree to:

Option # \_\_\_\_\_  
(1 through 5)                      Husband                      Wife                      Date

- (B) In the event of death, disability or legal incapacity of **both** of us, we hereby acknowledge and agree to:

Option # \_\_\_\_\_  
(2 through 5)                      Husband                      Wife                      Date

- (C) In the event of legal separation or divorce, we hereby acknowledge and agree to:

Option # \_\_\_\_\_  
(2 through 7)                      Husband                      Wife                      Date

- (D) In the event that we decide not to use any stored embryos in an attempt to initiate a pregnancy we hereby agree to:

Option # \_\_\_\_\_  
(2 through 7)                      Husband                      Wife                      Date

- (E) In the event there is a change in the physical condition of the Wife which renders her incapable of receiving a transfer or of carrying a pregnancy to term (including, but not limited to hysterectomy) and we are unwilling or unable to use a gestational surrogate we hereby acknowledge and agree to:

Option # \_\_\_\_\_  
(2 through 7)                      Husband                      Wife                      Date

We understand that if the wife has a hysterectomy or a serious change in health, the only chance for pregnancy would be for a gestational surrogate to carry the pregnancy. We understand that RCC will help arrange for a gestational surrogate if needed or we can provide a gestational surrogate of our choosing that could be used after appropriate consultation and screening. We understand that the expenses related to the use of a gestational surrogate would be our responsibility.

- (F) In the event that this contract is breached due to: (a) lack of payment for due or upcoming services [see Section II, paragraph 7, 8 and 10], (b) lack of a response following certified notification by mail which requires action on disposition of frozen stored embryos [see Section II, paragraph 7], or (c) failure to maintain current address on file with the RCC [see Section II, paragraph 8], then we hereby agree that RCC may dispose of the embryos.

## IV. Limits On Liability

We agree that RCC shall be liable for loss, injury or damage to our embryos only if such loss, injury or damage is directly caused by RCC's gross negligence in the performance of its duties. Furthermore, we agree that if RCC's gross negligence results in loss, injury or damage, RCC will only be liable for payment of Liquidated Damages as defined below. RCC will not be liable for punitive damages or consequential damages of any type, including but not limited to damages for mental, emotional, financial, consorsial, parental, societal injury and the like.

We agree with RCC that it would be impracticable and extremely difficult to fix actual damages for the loss, injury or damage of our embryos. In the event of loss, injury or damage to our embryos caused by RCC's gross negligence, liquidated damages shall be in the amount of Five Hundred Dollars (\$500) for each embryo, provided that RCC's total liability for loss, injury or damage to Patients' embryos shall not exceed Two Thousand Dollars (\$2,000) for all such embryos ("Liquidated Damages").

## V. Agreement of Husband and Wife to Participate

We acknowledge that we have carefully read and fully understand this document. We have had the opportunity to ask any questions and have them answered to our satisfaction. We have been given the opportunity to discuss this document with our

Wife's Initials \_\_\_\_\_ / Husband's Initials \_\_\_\_\_

# Reproductive Care Center

attorney. We voluntarily choose to participate. We understand that we may revoke our consent at any time prior to beginning the procedure and that our decision will not affect our relations with the RCC. By exercising the cryopreservation option, we accept the responsibilities, conditions and risks involved as set out in this document. In addition, we consent to the techniques and procedures required to attempt In Vitro Fertilization and Cryopreservation, embryo storage and a treatment cycle leading to a transfer of frozen thawed embryo(s). It is further expressly agreed that we hereby release the RCC and its personnel and medical staff from all responsibility and liability for the consequences, if any, resulting from participation in this procedure. We understand that all reasonable efforts to maintain confidentiality will be made, within the limits of billing, insurance and legal requirements.

Unless otherwise agreed to in writing, we agree that any possible dispute or claim in relation to services which we receive from RCC shall be settled solely by arbitration. Any arbitration proceeding will be conducted in accordance with the laws of the State of Utah. The locale will be Salt Lake County, Utah, and the arbitrators' judgment may be entered in any appropriate court and shall be binding and enforceable.

We acknowledge that neither the RCC nor its IVF team have made any warranties or representations with respect to: (I) the pre or post thaw viability of our embryos, (II) the successful establishment of pregnancy following uterine placement of our previously frozen embryos, (III) the lack of risk of a birth defect, miscarriage, tubal and/or ectopic pregnancy, multiple pregnancy, or pregnancy complication after embryo placement in the uterus or (IV) the infallibility of the liquid nitrogen-cooled storage refrigerators or any other IVF equipment or procedure.

We do hereby consent to having our embryos frozen and stored at the Reproductive Care Center for possible future use. There is a charge for embryo cryopreservation (freezing). If we desire that each embryo be frozen individually there is an additional charge above the basic freezing fee. These costs have been explained to us and we have received a copy of the current "IVF Financial Policy" document for review. **This freezing charge is applicable for each day that embryos are frozen.** The freezing charge is the same regardless of the number of embryos available for freezing on that particular day or the day of freezing (day 1-7). If embryos from the same cycle are frozen on separate days (such as day 3 cleavage embryos and day 5 blastocysts) then there will be a separate charge for each day embryos are cryopreserved.

**We desire that our embryos be (select one):**

\_\_\_\_\_ Frozen in groups

\_\_\_\_\_ Frozen individually

This selection (regarding freezing in groups or individually) will apply to any future IVF cycles with embryo cryopreservation for 5 years from the date of signing or for up to 12 IVF cycles unless we request a change in writing. We accept responsibility for the payment of fees to store the embryos. Storage fees are billed on an annual basis at the end of each calendar year for the upcoming year. We understand that if we fail to pay our storage fees within thirty days of a certified notice that such payments are due, our embryos may be discarded. We acknowledge that if either of us have a significant viral infectious disease, as determined by an RCC physician, that we may be required to store our embryos at another facility. There will be additional charges for shipping and separate outside facility storage fees in this situation.

We accept the potential risks and benefits of the freezing, storing, and thawing including failure of the embryos to survive the process or initiate a pregnancy.

\_\_\_\_\_  
Husband's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness to Husband's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Wife's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness to Wife's Signature

\_\_\_\_\_  
Date

Note: Please deliver this consent form to the office of the Reproductive Care Center, 10150 Petunia Way, Sandy, Utah 84092. We suggest that you keep a copy in your safety deposit box or another place in which you keep important documents and that, if you have a personal attorney, he/she also be given a copy. You may wish to execute this document formally before a notary public, but notarization is not required by the RCC.

# Reproductive Care Center

## Cystic Fibrosis Information and Consent

Cystic fibrosis (CF) is a life-long illness that is usually diagnosed in the first few years of life. The disorder causes problems with digestion and breathing. CF does not affect intelligence or appearance. Recent advances in genetics have resulted in the recommendation that couples be offered testing for CF. About 1 out of 30 white people in the USA is a carrier for CF, and if two of these carriers marry each other, the risk that any children from them will have CF is one out of four. One out of about every 2,500 babies born to parents with European Caucasian ancestry is born with the disease. Other ethnic groups have lower chances. Couples considering pregnancy can be tested to see if they are carriers, and pregnant women can have tests done on their fetus to see if it is affected. These tests are usually not covered by insurance but they can give helpful information for a couple deciding if they want to have a child together. There are more than 1,000 genetic alterations that can cause cystic fibrosis. The screening tests currently recommended detect 25-30 of the most common alterations. In some circumstances (such as one spouse is already a known carrier) it may be of benefit to test for a more extensive panel of 80-90 alterations. If both the husband and wife are carriers of CF, preimplantation genetic diagnosis can usually be performed to help prevent transmission of the disease (prior to implantation of the embryos). After conception has been achieved your obstetrician can perform or refer you for prenatal testing such as chorionic villi sampling or amniocentesis.

We understand that testing for cystic fibrosis is recommended for people with European Caucasian ancestry (higher chance of passing this disease on to their offspring), and offered to all couples contemplating conception or childbirth. We have had the opportunity to discuss this disease with our physician, and all of our questions have been addressed. It is our desire to:

- \_\_\_\_\_ Have basic (25-30 most common mutations) cystic fibrosis preconception screening, This is usually done through ARUP or ReproMedix. Recommended screening for Caucasian couples. (Least expensive option)
- \_\_\_\_\_ Have comprehensive (more than 90 of the more common mutations) cystic fibrosis preconception screening. This is usually done through Genzyme Genetics or ReproMedix. This is recommended if the spouse is a known carrier or if the husband has congenital absence of the vas deferens.
- \_\_\_\_\_ Have complete (gene sequencing) cystic fibrosis preconception screening.
- \_\_\_\_\_ Not have cystic fibrosis screening at this time.

\_\_\_\_\_  
Wife's name spelled out

\_\_\_\_\_  
Wife's signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Husband's name spelled out

\_\_\_\_\_  
Husband's signature

\_\_\_\_\_  
Date



# Reproductive Care Center

## Donor Egg IVF & Frozen Embryo Transfer Financial Policy

Each couple needs to meet with the office manager or billing staff to discuss fees and payment dates. The Pre-Donor Egg IVF workup and the ART checklist needs to be completed before the medications for the treatment cycle can begin for either the donor or the recipient. Payment is expected before the cycle medications begin. **Medications are not included;** patients can purchase them through the pharmacy of their choice. Medications for the donor will be billed to the recipient directly through The Apothecary Shops, IVPCare, Freedom Drug or a similar national infertility pharmacy.

### Basic Pre Donor Egg IVF Tests

#### Wife (if <45 years old)

CBC/HCT  
HIV-1&2 Ab  
Hepatitis BsAg  
Hepatitis C Ab  
RPR  
Chlamydia and Gonorrhea (PCR)  
Blood type & Rh  
Rubella Ab IgG immunity screen  
Varicella Ab IgG immunity screen  
Hysterosonogram (3D saline sonogram) - This test should be done at RCC

#### Husband

Semen analysis with Kruger strict Morphology (at RCC)  
HIV-1&2 Ab  
Hepatitis BsAg  
Hepatitis C Ab  
RPR  
Chlamydia and Gonorrhea (PCR)

We require that pre-IVF lab work be less than 1 year old at the time of embryo transfer. After a pregnancy or significant occurrence, some pre-IVF tests may need to be repeated on a more frequent basis. Additional tests may be requested by your physician based on your individual circumstances.

**The total pre-paid package price for the Pre Donor Egg IVF tests listed above for men and women <45 years old that includes a 3D saline sonogram and semen analysis performed at RCC is \$1,809** and is due prior to testing.

If patient desires to bill insurance in most circumstances we will provide you with the appropriate lab request forms and ask you to have them drawn at the preferred lab provider suggested by your insurance company (such as Quest, LabCorp or an IHC facility). We apologize for any inconvenience this may cause you but you should be aware that for most lab tests that we draw and send out for testing the insurance company reimburses us less than our costs. If we agree to bill the insurance company, the charges will be itemized at our normal fee for service price. The amount the insurance company does not pay will be the patient's responsibility if we are not a contracted provider. Safeguard prices are usually available for testing if we are not a contracted provider.

Hysterosalpingogram- Evaluates the uterine cavity and fallopian tubes and may be requested instead of a saline sonogram if approved by your physician. We do not do this X-ray test of the uterus and fallopian tubes at our Center. If requested by your physician, we will provide you with orders to have this done by a Radiologist (available at most hospitals). This should be scheduled after menstrual bleeding has finished but before ovulation occurs (usually recommend before day 11 of the cycle. A copy of the report and the x-ray films should be sent to RCC for review.

The recipient couple is required to consult with an approved psychologist or licensed clinical social worker prior to proceeding with treatment. The cost for this is paid by the recipient couple and is not included in the RCC screening package noted above.

Cystic fibrosis mutation screening is recommended for the husband for Caucasian couples but may be declined by signing a consent.

**For women over age 44** – In addition to the above, RCC requires a Chem 12, fasting glucose, lipid profile, urinalysis, and recent general physical exam by an internist, family physician or obstetrician. This testing is not included in the package price.

**For women over age 49** – In addition to the above, RCC requires a cardiac evaluation (including EKG and treadmill test), mammogram and chest x-ray (CXR). This testing is not included in the package price.

### Donor Egg IVF Costs

A **\$510 non-refundable “matching” fee** is assessed at the time that an anonymous egg donor is selected. This initial payment will be applied to any of the options noted below.

An **IVF Donor Egg Money Back Guarantee Package Plan** is available to patients that qualify. The basic fee charge is \$34,570. **plus** any premiums that are determined to apply **plus** additional charges for the egg donor expenses. Options for paying the additional egg donor expenses include a refundable, multiple cycle egg donor cycle fee of \$12,992 for up to four fresh sole (1 recipient is matched with 1 egg donor for each cycle) match donor egg cycles. A nonrefundable, donor egg single cycle fee option is also available for a sole match (\$4,331/cycle), or known or anonymous donors provided by the recipient or a donor egg agency not affiliated with RC may participate for a nonrefundable fee of \$2,170/cycle. This plan includes up to 4 fresh IVF cycles with all the associated frozen embryo transfer cycles. Two additional fresh donor egg IVF treatment cycles (6 total) can be included for an additional premium. There are exclusions for medication and anesthesia charges. Please request a detailed handout about this program if interested. Billing office staff can review this option with you and determine the total charge including any applicable premiums **after** your physician has completed a “Donor Egg IVF Money Back Guarantee Plan Criteria Form”. In some circumstances, additional Pre Donor Egg IVF testing may be required to determine eligibility.

Patients may choose either the single cycle **“Global Single Cycle Donor Egg Fresh IVF Fee”**, **“Insurance”** or the **“Safeguard”** option for each treatment cycle.

The **“Insurance”** option will have all charges itemized and billed to insurance for the services rendered. A fee of \$7,133 is required prior to starting the treatment cycle, or if we are a preferred provider, a \$4,076 fee is required in advance. Any itemized amount not covered by insurance will be the responsibility of the patient to pay. ***This can often be more expensive for the patient if they do not have good Donor Egg IVF insurance coverage.*** Blue Cross Blue Shield (BCBS) patients need to work with billers regarding their particular situation because BCBS pays the patient directly.

### Safeguard Payment Plan for Non-Contracted Commercial Health Insurance Carriers\*

Reproductive Care Center (RCC) recognizes that patient co-pays and deductibles are an increasing part of your health care dollar. In addition, because the rules of managed care plans often vary depending on the status of the health services provider, such as whether they are in “in network” or “out of network,” we know that it is often difficult for patients to understand how much they will ultimately be asked to pay. We developed the Safeguard Payment Plan so it would be clear—upfront—the maximum amount that you would be financially responsible for.

If we are not contracted with your insurance company as a preferred provider and if we determine that you should be eligible for out of network infertility treatment benefits that cover the anticipated costs associated with a donor egg IVF treatment cycle you may select the Safeguard Payment Plan. You pay 50% of the total expected insurance charges of your treatment upfront. This is the amount we have calculated as the patient payment average including all balance bills, co-pays, and deductibles. If you pay that amount, RCC will not hold you responsible for any additional cost. RCC will work with your insurance company to obtain payment for the insurer’s share. If we receive more than 100% of our usual and customary fees from the combination of the safeguard payment plan and the reimbursement from the insurance company, we will refund you the difference.

### Examples

Cost of usual & customary Fees	\$22,418	Cost of usual & customary Fees	\$22,418	Cost of usual & customary Fees	\$22,418
Your Safeguard payment	\$11,209	Your Safeguard payment	\$11,209	Your Safeguard payment	\$11,209
Insurer pays	\$21,000	Insurer pays	\$9,000	Insurer pays	\$0
Refund to patient	9,791	Refund to patient	\$0	Refund to patient	\$0
<b>Net cost to patient</b>	<b>\$1,418</b>	<b>Net cost to patient</b>	<b>\$11,209</b>	<b>Net cost to patient</b>	<b>\$11,209</b>

If we collect nothing from your insurer, you are only responsible for the Safeguard Payment amount—guaranteed. You do not have to select the Safeguard Payment Plan. If you do not, RCC will bill your insurance

company for our usual and customary fee, and you will be held responsible for the difference between the amount paid by insurance and our fee.

*\*Commercial Health Insurance includes most PPO and traditional indemnity insurance programs. Commercial Health Insurance does not include Medicaid, Medicare, and Champus insurance plans. Commercial Health Insurance also excludes Exclusive Provider Organizations (EPO's.) Call our Patient Billing Advocate to see if your Commercial Health Insurance qualifies you to participate in the Safeguard Payment Plan. Patients without Commercial Health Insurance are not eligible for the Safeguard Payment Plan.*

### **Global Fee Options:**

**Global Sole Match Single Cycle Donor Egg Fresh IVF option:** The fee for the sole match (couple receives all of the eggs retrieved) "global" option is **\$18,342** and is required before IVF medications begin. A nonrefundable \$510 deposit is included in the fee and will be collected at the time a potential recipient is matched with an anonymous donor. There is no discount off the global fee if a patient has lab work or other tests completed elsewhere, as it requires extra time and effort for our staff to obtain and review the results. The patient will be responsible to pay for all services performed at any outside facility. If a **known donor** is used the cost is **\$15,795** but the charges for screening the donor (estimate \$1,500-\$2,500) will be charged directly to the recipient and the recipient will be responsible for any payments to the donor for participation. Cycle bills are generated at the time of matching and are due and payable on receipt. If covered by insurance, the appropriate deposit will be required. If there is no insurance coverage, payment in full is expected within seven days of receipt of donor match.

**Global Split Donor Single Cycle Donor Egg Fresh IVF option:** The fee for the **split donor** "global" option is **\$12,738**. The eggs retrieved from a single egg donor are divided between two recipient women and their husbands. At the start of the cycle, one recipient is identified as the primary recipient and one recipient as the secondary recipient. The egg donor must have a minimum of 8 mature eggs for both the primary and secondary recipient to participate in the split egg donor program. A fee of **\$12,738** will be **billed to each recipient**; A nonrefundable \$510 deposit is included in the fee and will be collected at the time a potential recipient is matched with an anonymous donor. The primary recipient will pay the entire cost of the anesthetist fee. If the secondary egg donor recipient does not receive any eggs (this should happen infrequently) then the amount of money spent on medications and monitoring will be applied to the next treatment cycle and the recipient will automatically become the primary recipient.

## **Additional charges per cycle that are not included in the global fee**

**Intravenous sedation by Nurse Anesthetist** is \$275 to be paid to the anesthetist prior to the day of egg retrieval. Payment needs to be with cash, cashier's check, or money order. Personal checks may be used if paid prior to the day of the procedure. Credit cards are not accepted.

**Intracytoplasmic sperm injection (ICSI)** if needed is \$1,200

**Extended Embryo Culture (day 4-7 in attempt to grow blastocysts)** if desired is \$204 (same price for up to 4 days of culture).

**Testicular or epididymal sperm aspiration (TESE)** is \$1,131 for first procedure and \$566 if two procedures are required for the same treatment cycle.

**Open testicular biopsy to obtain sperm** is \$1,630.

**Back-up sperm cryopreservation** is \$336. This is recommended if the husband has difficulty producing a semen sample or will be unavailable on the day of egg retrieval. If unable to produce a semen sample on the day of egg retrieval and a back-up sample is not available, testicular aspiration of sperm and ICSI can be performed (\$2,331 plus \$275 anesthetist fee).

**Cryopreservation** of excess embryos is \$650 for freezing the embryos in groups and \$976 for freezing the embryos individually. The fee is the same regardless of the number of embryos frozen, if they are frozen on the same day. If embryos are frozen on separate days (such as day 3 cleavage cell embryos and day 5 or day 6 blastocysts), then **an additional cryopreservation fee will be assessed for each day those embryos are frozen.**

**Embryo storage** is \$430 a year and will be billed on a calendar year basis. It will be prorated for the first calendar year (when embryos are frozen) and for the year in which the frozen embryo transfer cycle is completed.

**Assisted Hatching** is \$300. It should be considered in cases of an abnormal zona pellucida (thick shell), 2 prior failed cycles, in women 38 or older, after thawing frozen embryos or as recommended by the physician.

**Additional ultrasounds during pregnancy** if needed are at least \$275 with additional charges for multiple sacs, physician consult or blood work.

**Preimplantation Genetic Diagnosis (PGD)** testing for specific gene disorders such as cystic fibrosis using polymerase chain reaction (PCR) technology is available. Various laboratories can be used.

1) Reproductive Genetics Institute (RGI) in Chicago, Illinois. See: [www.ReproductiveGenetics.com](http://www.ReproductiveGenetics.com). A current list of the genetic tests available is on their website. RGI will usually supply the embryologist for ICSI and biopsy. They will bill the patient directly for all associated costs including ICSI, biopsy, biopsy supplies, shipping, and testing as applicable.

2) Testing is also available through Genesis Genetics Institute (Dr. Mark Hughes) in Detroit, Michigan. See: [www.GenesisGenetics.org](http://www.GenesisGenetics.org). Genesis Genetics Institute will bill the patient directly for the testing (and development if needed) costs and the physician interpretation fees. Embryo biopsy is not usually included. Reproductive Care Center will bill the patient for the costs of the embryo biopsy, supplies and shipping.

**Embryo biopsy (or egg polar body)** is \$2,038. If additional biopsies are performed during the same treatment cycle a 50% discount will apply to the 2nd and 3rd biopsy if needed.. This includes the biopsy, biopsy supplies and shipping (unless unusual shipping needs such as on holidays or some weekends are required).

**Additional ultrasounds during pregnancy** if needed or desired are at least \$280 with additional charges for multiple sacs, physician consult or bloodwork.

**Additional ultrasounds and hormone assays.** If patients are not adequately suppressed (high estradiol or large ovarian cysts) at their initial baseline ultrasound (after suppression with Lupron or on day 2-3 of the cycle), additional itemized fees for repeat ultrasound and/or blood testing will be required.

**Gestational Surrogate** – see separate pricing handout.

**Cycle fees are due prior to starting any medication for the treatment cycle.** Usually this is at least 6 weeks before the target date for egg retrieval. Payment reserves your spot on the schedule. If a cycle is cancelled, charges will be itemized and remaining credit will be refunded to patient or applied to a future cycle.

We accept cash, checks, and most major credit cards.

For patients who choose the insurance option and have a credit balance remaining after the completion of treatment, the credit amount will be refunded to the patient.

## Global Cycle Option

The following tests and procedures are **included** in the global cycle if an anonymous donor from RCC is used:

For Egg Donor & Recipient	For Donor Only	For Recipient Only
Education class	Routine medical, infectious disease and psychological screening tests	Endometrial lining monitoring (US and E2 blood tests)
Pre-IVF focused physical exam	Stimulation monitoring (US and E2 blood tests)	Embryo culture
Baseline ultrasound (US) scan if indicated	Egg retrieval	Embryo transfer with ultrasound guidance if needed
Suppression check (US and E2 blood test)	Egg Donor Insurance coverage for complications	<b>One</b> quantitative pregnancy blood test
	Clinical care related to ovarian hyper stimulation syndrome	One pregnancy US 2 weeks after positive HCG
	Fee paid for the donor	Post-cycle review within 6 months

The following are **excluded** in the global cycle fee:

- |  |  |
|--|--|
| Initial physician consultation fees  | Follow-up consult fees prior to starting |
| Pre IVF recipient testing charges including trial transfer                                 | Any medications needed for the cycle     |
| Hysterosalpingogram (HSG) or 3D saline sonogram  | Cyst checks with US (recipient)          |
| ICSI (intracytoplasmic sperm injection)  | TESE (testicular sperm aspiration)       |
| Cryopreservation of embryos  | Embryo storage                           |
| Hospitalization for any reason   | Any test or treatment not done at RCC    |
| Services performed by any third party without exception                                    | Extended embryo culture (day 4-6)        |
| Special testing requests for the egg donor   | Assisted hatching                        |
| Preimplantation Genetic Screening (PGS) or Preimplantation Genetic Diagnosis (PGD) testing |  |

- Embryo or egg biopsy
- Clinical care related to evaluation and treatment of complications of the donor egg IVF for the recipient
- Additional ultrasounds or blood tests necessary to evaluate an abnormal pregnancy
- Treatment for a miscarriage or an ectopic pregnancy
- Clinical care related to pregnancy (other than the initial HCG and 1<sup>st</sup> ultrasound)
- Treatment for unrelated medical conditions
- Surgeries not related to the Donor Egg IVF cycle
- MicroSort sperm sorting for gender selection (additional non-refundable fee per cycle)
- Frozen embryo transfer cycle fees
- Embryo thawing for frozen embryo transfer cycles
- Collection and shipping charges for blood tests sent to RCC

**Intravenous sedation by Nurse Anesthetist is \$275** to be paid to the anesthetist prior to the day of egg retrieval. Payment needs to be with cash, cashier's check, or money order. Personal checks may be used if paid prior to the day of the procedure. Credit cards are not accepted.

**Cancellation Fees:** Refunds will be based on the Sole Match Donor Egg Cancellation Policy and the Split Donor Egg Cycle Cancellation Policy forms attached.

## Frozen embryo transfer cycle (FET)

If the patient has frozen embryos then we recommend a controlled endometrial development (CED) Frozen Embryo Transfer Cycle (FET). The medications for a CED FET cycle generally cost approximately \$450. The Global Single CED FET cycle fee is \$2935. A cancellation fee equal to half the Global Fee charge or the "fee for service" charges for services rendered, whichever is less, will be assessed.

### Additional Charges per cycle that are not included in the Global Single Cycle CED FET fee

**Extended Embryo Culture (day 4-7 in attempt to grow blastocysts)** if desired is \$204 (same price for up to 4 days of culture).

**Repeat Cryopreservation of embryos** is \$650 for freezing the embryos in groups and \$976 for freezing the embryos individually. The fee is the same regardless of the number of embryos frozen, if they are frozen on the same day. If embryos are frozen on separate days (such as day 3 cleavage cell embryos and day 5 or day 6 blastocysts), then **an additional cryopreservation fee will be assessed for each day that embryos are frozen.**

**Continued Embryo storage** is \$430 a year and will be billed on a calendar year basis. It will be prorated for the year in which the frozen embryo transfer cycle is completed.

**Assisted Hatching** is \$300. It should be considered with an abnormal zona pellucida (thick shell), 2 prior failed cycles, after thawing frozen embryos especially if using blastocysts or as recommended by the physician.

**Preimplantation Genetic Diagnosis (PGD)** testing for specific gene disorders such as cystic fibrosis using polymerase chain reaction (PCR) technology is available. Various laboratories can be used.

1) Reproductive Genetics Institute (RGI) in Chicago, Illinois. See: [www.ReproductiveGenetics.com](http://www.ReproductiveGenetics.com). A current list of the genetic tests available is on their website. RGI will usually supply the embryologist for ICSI and biopsy. They will bill the patient directly for all associated costs including ICSI, biopsy, biopsy supplies, shipping, and testing as applicable.

2) Testing is also available through Genesis Genetics Institute (Dr. Mark Hughes) in Detroit, Michigan. See: [www.GenesisGenetics.org](http://www.GenesisGenetics.org). Genesis Genetics Institute will bill the patient directly for the testing (and development if needed) costs and the physician interpretation fees. Embryo biopsy is not usually included. Reproductive Care Center will bill the patient for the costs of the embryo biopsy, supplies and shipping.

**Embryo biopsy (or egg polar body)** is \$2,038. If additional biopsies are performed during the same treatment cycle a 50% discount will apply to the 2nd and 3rd biopsy if needed.. This includes the biopsy, biopsy supplies and shipping (unless unusual shipping needs such as on holidays or some weekends are required).

**Additional ultrasounds during pregnancy** if needed or desired are at least \$280 with additional charges for multiple sacs, physician consult or bloodwork.

**Additional ultrasounds and hormone assays.** If patients are not adequately suppressed (high estradiol or large ovarian cysts) at their initial baseline ultrasound (either after suppression with Lupron or on day 2-3 of the cycle), additional itemized fees for repeat ultrasound and/or blood testing will be required.

The following tests and procedures are **included** in the Global Single CED FET Cycle Fee:

Injection training update if needed	Embryo thaw
Single suppression check (US & E2 blood test)	Embryo transfer with ultrasound guidance if needed
Endometrial lining check	<b>One</b> quantitative pregnancy blood test
	One pregnancy US 2 weeks after positive HCG

The following are **excluded** in the global FET cycle fee:

Pre FET testing charges including trial transfer (if needed)	Medications for the FET cycle
Hysterosalpingogram or 3D saline sonogram	Cyst checks with US
Repeat cryopreservation of embryos	Continued Embryo storage
Hospitalization for any reason	Any test or treatment not done at RCC
Services performed by any third party without exception	Embryo culture after thaw
Clinical care related to evaluation and treatment of complications of FET	
Additional ultrasounds or blood tests necessary to evaluate an abnormal pregnancy	
Treatment for a miscarriage or an ectopic pregnancy	
Clinical care related to normal pregnancy (other than the initial HCG and 1 <sup>st</sup> ultrasound)	
Treatment for unrelated medical conditions or surgeries not related to the FET cycle	

## Sole Match Donor Egg Cancellation Policy

A Sole Match Donor Egg cycle has one anonymous Egg donor matched with one recipient woman

<b>Reason for Cancellation</b>	<b>Recipient Fee</b>
Recipient chooses to cancel after the donor starts Lupron	\$2,935
Recipient chooses to cancel after the donor has taken FSH for < 5 days	\$3,889
Recipient chooses to cancel after the donor has taken FSH for $\geq$ 5 days	\$7,557
Medical cancellation occurs due to donor cycle response (ie. Drop in Estrogen >30%, LH surge)	\$3,081
Recipient decides to repeat cycle using same donor after a medical cancellation	\$1,541
Recipient chooses to cancel participation in cycle because donor response is 1-3 follicles equal to or above 15mm prior to HCG	\$4,182*
Recipient chooses to cancel participation in cycle because donor response is 4-6 follicles equal to or above 15mm prior to HCG	\$6,053
No viable eggs are obtained on the day of retrieval.	\$4,182
Cycle is canceled due to inability of donor to initiate a cycle (ie. Donor is pregnant, positive infectious disease screening at start of cycle, donor withdraws)	No charge
Cycle is canceled when the recipient develops a MAJOR medical complication during cycle. (Must be approved by an RCC physician.)	No charge if donor has not started medications <b>OR</b> \$4,182 if donor has initiated FSH

\* If the recipient decides to continue the cycle and no pregnancy is established, the recipient will receive a 30% discount on a future fresh donor egg IVF cycle. This discount does not apply to any frozen embryo transfer associated with the discounted donor cycle.

The \$510 matching fee is included in the total "recipient fee" noted above.

If an egg donor has not undergone ovarian stimulation previously and the initial stimulation cycle is cancelled due to low follicular development or medical cancellation and in the opinion of the RCC physicians the egg donor would be expected to stimulate well in the future with a repeat attempt then if the recipient couple is willing to try again with the same egg donor RCC will waive the recipient fee noted above.

The recipient couple is responsible for the cost of any additional medications for future donor egg cycle attempts.

In the event of a cancellation, the balance of the cycle fees paid by the recipient will be refunded.

## Split Donor Egg Cycle Cancellation Policy

At the time of cycle match, recipients will approve their participation in the cycle as either the primary or secondary recipient. If either recipient withdraws from the cycle after the cycle is initiated, the remaining recipient will continue in the cycle at the fee structure for the Primary Recipient in a Split Donor Egg Cycle. If either recipient withdraws from the cycle after the match process but prior to the initiation of medications for the cycle, the remaining recipient will be given the opportunity to continue the cycle as a SOLE MATCH donor cycle at the cycle fees designated for that program, or may delay the initiation of the cycle until a second recipient who desires a split donor cycle with the chosen donor is identified.

Reason for Cancellation	Primary Recipient Fee	Secondary Recipient Fee
Recipient chooses to cancel after the donor starts Lupron	\$2,038	\$2,038
Recipient chooses to cancel after the donor has taken FSH for < 5 days	\$2,700	\$2,700
Recipient chooses to cancel after the donor has taken FSH for $\geq$ 5 days	\$5,248	\$5,248
Medical cancellation occurs due to donor cycle response (ie. Drop in Estrogen >30%, LH surge)	\$2,140	\$2,140
Recipient decides to repeat cycle using same donor after a medical cancellation	\$1,070	\$1,070
Recipient chooses to cancel participation in cycle because donor response is 1-3 follicles equal to or above 15mm prior to HCG	\$2,904*	\$0.00 *
Recipient chooses to cancel participation in cycle because donor response is 4-6 follicles equal to or above 15mm prior to HCG	\$4,203*	\$0.00 *
No viable eggs are obtained on the day of retrieval.	\$2,904	\$2,904
Cycle is canceled due to inability of donor to initiate a cycle (ie. Donor is pregnant, positive infectious disease screening at start of cycle, donor withdraws)	No charge**	No charge**
Cycle is canceled when the recipient develops a MAJOR medical complication during cycle. (Must be approved by an RCC physician.)	No charge if donor has not started medications <b>OR</b> \$2,692 if donor has initiated FSH	No charge if donor has not started medications <b>OR</b> \$2,692 if donor has initiated FSH

\* If the recipient decides to continue the cycle and no pregnancy is established, the recipient will receive a 30% discount on a future donor cycle. This discount does not apply to the frozen embryo transfer associated with the discounted donor cycle.

The \$510 matching fee is included in the "recipient fee" noted above.

If an egg donor has not undergone ovarian stimulation previously and the initial stimulation cycle is cancelled due to low follicular development or medical cancellation and in the opinion of the RCC physicians the egg donor would be expected to stimulate well in the future with a repeat attempt then if the recipient couple(s) are willing to try again with the same egg donor RCC will waive the recipient fee noted above.

The recipient couples are responsible for the cost of any additional medications for future donor egg cycle attempts.

In the event of a cancellation, the balance of the cycle fees paid by the recipient will be refunded.

## **RCC Egg Donor Recommended Screening**

### **Initial and then as recommended:**

- CBC with platelets
- Blood Type and Rh
- Hemoglobin electrophoresis
- Day 3 estradiol and FSH
- Anti-mullerian hormone (AMH)
- Psychological screening
- Physical exam
- Pap smear
- Chlamydia/Gonorrhea urine PCR or swab based testing\*
- Cystic fibrosis (DNA mutation testing for carrier status)

### **Testing to be repeated before each donation**

- HIV-1, 2 & O Ab
- Hepatitis BsAg
- Hepatitis C Ab
- VDRL/RPR
- Nucleic acid testing (NAT) for HIV-1 by PCR
- Nucleic acid testing (NAT) for HCV by PCR
- Nucleic acid testing (NAT) for West Nile Virus by PCR
- GC/CT Urine PCR or Cx Culture

### **Ethnic specific genetic testing,**

- Jewish
  - Tay Sachs
  - Canavan
- Black/African American
  - Sickle cell screening – Hemoglobin electrophoresis
- Mediterranean (Greek or Italian), Chinese and Southeast Asian ancestry
  - Thalassemia screening – Hemoglobin electrophoresis
- Other as indicated

### **Optional**

#### **Additional extensive screening can be completed as an additional cost to the recipient**

- Alpha 1 antitrypsin
- Fragile X syndrome
- Karyotype – peripheral blood
- Lipid panel (includes cholesterol)
- HIV 2 by PCR
- HTLV 1 & 2 by PCR
- Renal ultrasound
- Jewish extensive screening
  - Bloom Syndrome
  - Familial Dysautonomia (FD)
  - Fanconi Anemia (type c)
  - Gaucher Disease (type I)
  - Glycogen Storage (type 1a)
  - Maple Syrup Urine Disease
  - Mucopolipidosis (Type IV - ML IV)
  - Niemann-Pick Type A

# Reproductive Care Center

## DONOR EGG PAYMENT AGREEMENT

We have chosen to start a donor egg cycle in 2009 or to begin our Donor Egg Money Back Guarantee Package Plan with our first cycle beginning in 2009 and have had the payment options explained to us. We understand that we must choose from the following options:

- (1) **Donor Egg Money Back Guarantee Package Plan.** We have selected and qualify to participate in the Donor Egg Money Back Guarantee Package Plan. Exclusions such as medication and anesthesia charges have been explained to us. We understand that the minimum price will be \$34,570 (base price) **plus any premiums that are determined to apply.** We understand that if we chose the nonrefundable donor egg single cycle fee an additional fee will be assessed for each fresh donor egg IVF cycle. We understand that if we have not been honest in fully disclosing any known risk factors, that our contract can be cancelled with no refund.
- (2) **Global Donor Egg Single Fresh IVF Cycle Fee** package of \$18,342 (exclusions such as medication and anesthesia charges have been explained to us). This is a pre-paid cash discount package for a single treatment cycle. Charges will not be itemized or billed to insurance. The entire payment is due prior to starting medications such as Lupron or FSH.
- (3) **Global Donor Egg Single Fresh IVF Split Cycle Fee** package of \$12,738 (exclusions such as medication and anesthesia charges have been explained to us). We understand that we may be the primary or the secondary recipients. This is a pre-paid cash discount package for a single treatment cycle. Charges will not be itemized or billed to insurance. The entire payment is due prior to starting medications such as Lupron or FSH.
- (4) **Insurance billing (RCC contracted Health Insurance Carrier).** All appropriate charges will be itemized and billed to insurance. RCC requires a down payment, which is determined based on our estimated insurance coverage. We will be responsible for any amount that the insurance company does not pay that RCC is not required to write off due to contracts for discounted fees that RCC may have with the insurance company. Anesthesia does not contract with any insurance carriers. The anesthesia fees will be billed through their separate billing company. The itemized anesthesiologist fees are approximately \$600. Depending on our insurance coverage and required co-pay, it may be less expensive to pay the prepaid cash price of \$275.
- (5) **Insurance billing (RCC non-contracted Health Insurance Carrier offering applicable infertility treatment benefits).** All appropriate charges will be itemized and billed to insurance. Depending on our insurance coverage and required co-pay, it may be less expensive to pay the prepaid cash price of \$18,000 or we may want to consider the Safeguard Payment Plan. We will be responsible for any amount that the insurance company does not pay unless we choose the Safeguard Payment Plan.
- (6) **Safeguard Payment Plan** of \$11,209. Reproductive Care Associates, PC (RCA) and Reproductive Care Center, PC (RCC) are separate and distinct legal entities that offer different services and have different tax identification numbers. Our physicians are contracted employees with each separate company to provide specific services. Patients are allowed to select the safeguard option for advanced reproductive services offered by RCC because RCC (and their physician employees) is not contracted with their insurance company. The safeguard price is only available to patients whose insurance company is not contracted with RCC but have infertility benefits for full coverage of Donor Egg IVF and associated procedures. Due to the difficulty in determining in advance what percent of the usual charges many insurance companies will cover for advanced reproductive services this option enables patients in this situation to determine in advance the maximum anticipated costs so they can decide whether to initiate treatment. We understand that the payment is due in advance. Our insurance company may send us an explanation of benefits (EOB) that tells us that RCC is contracted and that RCC is required to write off a certain amount of the charges. **By**

**signing this agreement we are accepting the fact that RCC is not contracted with our insurance company as noted above and RCC will not be responsible for nor be bound to a contract that they have not made.** We also agree that we have had the opportunity to discuss this with a financial staff member at Reproductive Care Center and all of our questions have been answered.

We agree to the guidelines stated above and we have selected:

1.  Donor Egg Money Back Guarantee Package Plan with premiums: \$ \_\_\_\_\_
  - a. Donor egg cycle fees due with each cycle (if applicable):
    - i. Refundable option to cover up to 4 fresh cycles - \$12,991 \$ \_\_\_\_\_
    - ii. Non-refundable option for 1 sole match fresh cycle - \$4,131 \$ \_\_\_\_\_
    - iii. Non-refundable option for 1 anonymous fresh cycle when donor is provided by the recipient or a known egg donor - \$2,170 \$ \_\_\_\_\_

Includes embryo cryopreservation (groups), storage and all associated frozen embryo transfers as outlined in the contract.

  - b. Initial anesthetist fee (separate check to Wayne Riding) - \$275** \$ \_\_\_\_\_  
**An additional fee will be required for each sedation needed.**
2.  Global Donor Egg Single Fresh IVF Fee Cycle (basic) - \$12,738 \$ \_\_\_\_\_
  - a.  Primary (owes anesthetist fee)
  - b.  Secondary (anesthetist fee not required)
3.  Global Split Donor Egg Single Fresh IVF Fee Cycle (basic) - \$18,342 \$ \_\_\_\_\_
4. Insurance Company \_\_\_\_\_ \$ \_\_\_\_\_
  - a.  Contracted carrier estimated basic co-payment - \$4,076 \$ \_\_\_\_\_
  - b. **Non-contracted** carrier with confirmed IVF infertility benefit
    - i.  Downpayment (basic) for non-contracted carrier - \$7,133 \$ \_\_\_\_\_
    - ii.  SafeGuard Payment Plan (basic) for a non-contracted carrier as per section 5 above - \$11,209 \$ \_\_\_\_\_
  - c. Anesthetist fee with insurance (choose one)
    - i.  **Anesthetist fee (separate check to Wayne Riding)- \$275** \$ \_\_\_\_\_
    - ii.  **Anesthetist fee (please have them bill insurance)** \$ \_\_\_\_\_
5. Common additional applicable fees or co-payments needed for #2, #3 or #4 above:
  - d.  Anesthetist fee (separate check to Wayne Riding) - \$275 \$ \_\_\_\_\_
  - e.  Credit for paid matching fee if applicable - \$510 \$ \_\_\_\_\_
  - f.  Credit for use of a known donor if applicable - \$2,547 \$ \_\_\_\_\_
  - g.  Personal IVF training (if unable to attend class) - \$ \_\_\_\_\_
  - h.  Intracytoplasmic sperm injection (ICSI) - \$1,200 \$ \_\_\_\_\_
  - i.  Testicular aspiration (TESE) (needle) - \$1,131 \$ \_\_\_\_\_
  - j.  TESE (open biopsy) -\$1,630 \$ \_\_\_\_\_
  - k.  Preimplantation Genetic Diagnosis (PGD) - variable \$ \_\_\_\_\_
  - l.  Embryo biopsy for PGD - \$2,038 \$ \_\_\_\_\_
  - m.  Extended embryo culture - \$204 \$ \_\_\_\_\_
  - n.  Sperm cryopreservation for backup - \$336 \$ \_\_\_\_\_
  - o.  Embryo cryopreservation (groups) - \$650 \$ \_\_\_\_\_
  - p.  Embryo cryopreservation (single embryo) - \$976 \$ \_\_\_\_\_
  - q.  Embryo storage (1 year) - \$430 \$ \_\_\_\_\_
  - r.  Gestational Surrogate - \$ \_\_\_\_\_
  - s.  Other \_\_\_\_\_ \$ \_\_\_\_\_
  - t. Total** \$ \_\_\_\_\_

We understand that if we choose the Global Donor Egg Single Fresh IVF Cycle Fee or Donor Egg Money Back Guarantee Package Plan option that RCC will not help us bill our insurance company. We understand the discounted pre-paid Global Donor Egg Fresh IVF Cycle Fee price is available because significant administrative costs are saved when charges are not itemized and insurance billed. We accept responsibility for payment of services that are excluded from the Global Donor Egg Single Fresh IVF Cycle Fee or Donor Egg Money Back Guarantee Package Plan that we have had or will have rendered.

We understand that if we select the Insurance option (contracted carrier) that we must pay our down payment (estimated co-pays and deductibles) to RCC prior to starting medication such as Lupron or FSH. If we select the Insurance option (non-contracted carrier) we must pay our down payment or the SafeGuard Payment Plan to RCC prior to starting medications. If the insurance pays us directly we agree to immediately pay RCC for the charges we are responsible for. If payment is not received within 30 days of our receipt of the payment from the insurance company interest will be assessed at 18% APR (from the date medication was started). Additionally we understand that if we select the insurance option without the SafeGuard plan, we cannot switch to the pre-paid Global Donor Egg Single Fresh IVF Cycle Fee option if the insurance company pays less than anticipated.

We have received and reviewed a copy of the Reproductive Care Center, PC (RCC) "Donor Egg and Frozen Embryo Transfer Financial Policy" and all of our questions have been answered.

Wife \_\_\_\_\_

Date \_\_\_\_\_

Husband \_\_\_\_\_

Date \_\_\_\_\_

Administrative \_\_\_\_\_

Date \_\_\_\_\_

# Reproductive Care Center

## Informed Consent for Assisted Hatching (AH)

Hatching of the embryo at the blastocyst stage is a critical step in the sequence of physiological events culminating in the implantation of the embryo. Failure to hatch may be one of the many factors limiting human reproductive efficiency.

Assisted hatching involves the artificial thinning or opening of the zona pellucida or shell of the embryo. It has been proposed as one technique to improve implantation and pregnancy rates following in vitro fertilization. An increased implantation rate following mechanical opening of the zona pellucida or shell was first reported in 1990. Since these early reports many assisted reproductive technology programs have incorporated the use of assisted hatching in selective instances in efforts to improve clinical outcomes.

The assisted hatching procedure is generally performed on the day of embryo transfer. The procedure includes the creation of an opening in the zona or shell of the embryo using either mechanical techniques, acidified solutions or more recently the use of a laser.

The assisted hatching procedure may rarely be associated with complications independent of the IVF procedure including damage to the embryo and damage to individual blastomeres or cells with subsequent reduction of embryo viability. In addition, assisted hatching has been associated with a slightly increased risk of monozygotic twinning.

The success rates following the use of assisted hatching in different IVF programs have varied considerably. Differences in patient populations, operative experience, hatching techniques, and study design have made it difficult to compare reports directly from the different centers. A comprehensive review and meta-analysis of the available randomized controlled trials have demonstrated a possible improvement in clinical pregnancy rates following assisted hatching in patients with prior failed IVF cycles, in older women, when only fair or poor quality embryos are available for transfer or after embryo cryopreservation. However, overall live birth rates in the groups are not significantly different. The number of live births reported in studies this far did not allow a confident conclusion regarding the clinical efficacy of the assisted hatching procedures. Results have also been inconclusive regarding the best method for assisted hatching however most embryologists now believe that the use of the laser is the safest and probably best method.

The available published evidence does not support the routine universal application with assisted hatching in all IVF cycles. **Assisted hatching may be clinically useful and is recommended at RCC in patients with a poor prognosis, including those with at least two prior failed IVF cycles, fair or poor embryo quality, embryos with a thick zona pellucida (shell), embryos formed from frozen eggs, women at least 38 years of age, and after embryo cryopreservation.**

We understand that assisted hatching involves an extra procedure fee above normal IVF or the frozen embryo transfer fee. We the undersigned, husband and wife, have requested that assisted hatching be performed on;

- All of our embryos just prior to embryo transfer (fresh transfer) or on the day the embryos are thawed if extended culture is planned.
- Approximately 50% of our embryos prior to embryo transfer or on the day the embryos are thawed if extended culture is planned.
- Embryos that have a ‘thick zona pellucida (shell)’ on the day of embryo transfer or the day they are thawed.
- None of our embryos (we do not want assisted hatching)

We have read and understand the above and all of our questions about assisted hatching have been answered.

We acknowledge that neither the Reproductive Care Center nor the physicians or staff have made any warranties with respect to the assisted hatching procedure or the outcome of any pregnancy as the result of this treatment.

\_\_\_\_\_  
Wife's Signature

\_\_\_\_\_  
Wife's Name Printed

\_\_\_\_\_  
Date/Time

\_\_\_\_\_  
Husband's Signature

\_\_\_\_\_  
Husband's Name Printed

\_\_\_\_\_  
Date/Time