

Reproductive Care Center

Informed Consent for In Vitro Fertilization (IVF) And Related Procedures

Wife's Name: _____

Husband's Name: _____

We, the undersigned husband and wife, request, authorize and consent to the performance of in vitro fertilization (IVF) in an attempt to achieve our joint reproductive goal of conceiving and bearing a child.

- 1) We understand and consent to the following procedures:
 - a) Determination by standard tests that we are suitable candidates for the procedure.
 - b) The use of medications such as but not limited to gonadotropins, leuprolide, a GnRH antagonist, clomiphene citrate, aromatase inhibitors such as Letrozole, progesterone, human chorionic gonadotropin, antibiotics, and sedation medications. Most side effects are minor, such as nausea, hot flashes, headaches or visual halos.
 - c) Ultrasound examinations and blood tests.
 - d) The patient's semen specimen to be prepared for insemination of, or injection into, retrieved eggs.
 - e) Ultrasound-guided egg retrieval with insertion of a needle through the vaginal vault into the ovaries to obtain eggs. Number of eggs retrieved may vary from 0 to 60. On average, 70% will fertilize; but fertilization rates vary from 0 to 100%. In some, more eggs may be retrieved than will be utilized in a single cycle.
 - f) Embryo transfer.
- 2) We understand that any of the following may occur, which could prevent the successful completion of these procedures and prevent the establishment of the pregnancy:
 - a) Suboptimal response to medications.
 - b) Obtaining eggs from the follicles may be unsuccessful, or the eggs may not be normal. Occasionally, the ovaries cannot be reached transvaginally and a needle must be inserted through the abdomen with ultrasound guidance to get to the follicles. We understand that there is no guarantee that the ovaries contain any healthy eggs or that eggs will successfully be retrieved. We may not have eggs recovered because ovulation occurred before the time of retrieval.
 - c) Sperm from husband or donor may be abnormal.
 - d) The husband may not be able to collect a semen sample on the day of egg retrieval. If this is expected to be a problem it is suggested that semen cryopreservation be completed in advance so that a back-up sample is available. If the husband can not provide a semen specimen within a reasonable time on the day of egg retrieval (and no frozen sperm is available), he must make a decision regarding how to proceed. He can be sedated and sperm can be aspirated directly from the testicle (testicular sperm aspiration [TESE]), use donor sperm or discard the eggs without insemination. If TESE is required, intracytoplasmic sperm injection (ICSI) will also need to be done. The husband assumes all responsibility for providing a sperm sample on the day of egg retrieval.
 - e) Fertilization may not occur (1-3%) or may be abnormal in some or all of the eggs.
 - f) Cell division of the fertilized egg(s) may not occur, or embryo(s) may not develop normally.
 - g) The embryo transfer may be technically difficult or impossible.

Wife's Initials ____ / Husband's Initials ____

- h) Implantation of the embryo(s) into the wall of the uterus may not occur.
 - i) During the IVF process, it is possible that cell trauma or death of eggs, sperm or embryos could result from loss during normal handling, culture, 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 eggs, sperm or embryos.
- 3) We understand that in order to increase the chance of pregnancy, multiple embryos may be transferred to the uterus and could result in multiple gestations with increased risk of miscarriage, premature labor, cesarean section, blood loss, significant maternal, fetal or newborn health risks, and increased financial and emotional cost.
- 4) We understand that, even if a pregnancy is successfully established, multiple pregnancies, miscarriage, ectopic pregnancy, still birth, or birth defects may occur. In the event that any serious gestational abnormality is discovered, the various alternative courses of action should be discussed with an OB/GYN physician. Final decision on the course of action will reside with us. We understand there is no guarantee that this procedure will result in a successful pregnancy or a live birth.
- 5) We understand that the following are risks associated with the procedures:
- a) Infection.
 - b) Cramping.
 - c) Blood clots, pulmonary embolus and rarely death.
 - d) Hyperstimulation of the ovaries, which may require hospitalization. In rare cases, hyperstimulation could lead to the surgical removal of one or both ovaries or death.
 - e) Multiple gestations. If high-order (more than 2) multiple pregnancy does occur, the option of fetal reduction requires referral (usually out of state) and treatment at our expense.
 - f) Ultrasound-guided egg retrieval may result in mild-to-moderate discomfort. Potential serious complications include perforation of organs (such as bowel or bladder), bleeding (may require transfusion), or infection requiring hospitalization or major surgery.
 - g) Risks associated with anesthesia (local or IV sedation), including death. If the woman were to receive excess sedation, she could stop breathing and require resuscitation and transportation to the hospital. Rare heart arrhythmias (irregular heart beats) could also require transfer to a hospital and emergency care.
 - h) Allergic reaction which in rare cases may be severe or fatal.
 - i) Psychological distress is sometimes associated with ART procedures, particularly if pregnancy is not achieved.
 - j) Ovulation induction with gonadotropins and cancer risk data have not found a conclusive link between fertility drugs and ovarian or breast cancer. However, ovarian cancer risk may be slightly increased after gonadotropin injections in childless women, after extended follow-up of more than 15 years or for certain subtypes. The expected usual risk of a woman developing ovarian cancer during her lifetime is approximately 1%.
- 6) 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 intramuscular 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 the product labeling, all progesterone products recommended by our clinic are considered safe and effective during

pregnancy. Only one of the products has received specific approval by the FDA for use during pregnancy.

- 7) Alternative treatments to IVF exist for most infertility problems. The success rates from non-IVF treatments are usually lower per treatment cycle. Success rates of alternative treatments vary depending upon the type and severity of the cause for infertility. Most couples possess some possibility of spontaneous conception without a physician's help. On the other hand, some infertility disorders require IVF for treatment such as when the woman does not have a uterus but she has her ovaries to supply eggs for IVF. We understand that alternatives to participation in this IVF program may include surgery, medical treatments, artificial insemination, adoption, or receiving no treatment and remaining child free by choice. We have been encouraged to discuss all alternatives to IVF treatment with an RCC physician.
- 8) We understand that insurance coverage for IVF and related procedures may not be available and that we are personally responsible for the expense of these treatments including clinic, laboratory, medication charges and professional fees. We hereby authorize RCC to release such information from our medical records as may be necessary for the settlement of all claims for payment of these charges.
- 9) We authorize RCC to release information from our medical records to our referring physician and to our obstetrician (if different) regarding our evaluation (including **all** infectious disease testing) and the IVF treatment cycle.
- 10) Data from our ART procedure will be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on us, the CDC applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308(d). This means that any information that CDC has that identifies us will not be disclosed to anyone else without our consent.
- 11) The overall success rate of IVF depends on many factors such as the age of the woman, follicle stimulating hormone (FSH) levels, the presence of fibroids, the presence of a hydrosalpinx (blocked fallopian tube), uterine cavity abnormalities, endometrial lining adequacy, the embryo quality and the number of embryos transferred. Recent success rates from IVF at RCC are available on the website (www.fertilitydr.com), through information submitted to the Society for Assisted Reproduction (SART – www.SART.org), the CDC (www.CDC.gov) and through discussion with our RCC physician.
- 12) Imprinting disorders have been reported in several small case series following IVF. Both genetic and epigenetic mutations occurred and involved the loss of imprinting of clusters of imprinted genes. There are at least 9 syndromes associated with imprinting but only three have been associated with ART: Beckwith-Wiedemann maternal hypomethylation syndrome and Angelman syndrome. A case series of 19 patients affected by imprinting disorders concluded that, except for the mother's who had taken ovarian stimulation drugs there was no common risk factor or link with IVF. Evidence from clinical reports suggests that the association between imprinting syndromes and ART may be restricted to syndromes where the imprinting change takes the form of hypomethylation on the maternal allele. In contrast, studies of gametes and early embryos suggest that ART can be associated with hypermethylation as well as hypomethylation, with imprinting changes occurring on paternal as well as maternal alleles. The health effects of ART-associated imprinting changes may also extend beyond the nine recognized imprinting syndromes.

- 13) Some studies suggest there is an increased risk of identical twinning after IVF, 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 <1-2% of the cases after IVF with embryo transfer at the cleavage stage. The expected rate after natural conception is <0.4%. Intracytoplasmic sperm injection (ICSI) and blastocyst embryo transfer (day 5) may also increase the risk.
- 14) We understand that available human data suggest that IVF does not significantly increase the risks of congenital anomalies (birth defects) in the resultant offspring. Although the risk of birth defects from embryos formed through IVF is similar to natural conceptions, RCC cannot guarantee a normal birth. The expected rate of major birth defects in the normal population is 2-4%. 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.
- 15) We agree that RCC shall be liable for loss, injury or damage to our eggs, sperm or 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, consortial, 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 eggs, sperm or embryos. In the event of loss, injury or damage to our eggs, sperm or embryos caused by RCC's gross negligence, liquidated damages shall be in the amount of:
- a) 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.
 - b) One Hundred Dollars (\$100) for each egg; provided that RCC's total liability for loss, injury or damage to Patients' embryos shall not exceed One Thousand Dollars (\$1,000) for all such eggs.
 - c) One Hundred Dollars (\$100) for each semen sample; provided that RCC's total liability for loss, injury or damage to Patients' semen samples shall not exceed Five Hundred Dollars (\$500) for all such semen samples.
- 16) We consent to allow RCC to dispose of bodily fluids or tissues, including any unfertilized or abnormally fertilized eggs, developmentally arrested, abnormal or undesired embryos. Such tissue and bodily fluids including any unfertilized or abnormally fertilized eggs, developmentally arrested, abnormal or undesired embryos may be photographed and used anonymously for presentation or publications. Unless otherwise requested in writing, 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.
- 17) 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, 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.

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

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), through information submitted to the Society for Assisted Reproduction (SART – www.SART.org), the CDC (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.

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- (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.

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- 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

IVF & FROZEN EMBRYO TRANSFER FINANCIAL POLICIES

Each couple will need to meet with manager or billing staff to discuss fees and payment dates. Those couples with a combined income under \$60,000 may be eligible for an income based discount depending on their total assets. The Pre-IVF workup (ART checklist) needs to be completed before the medications for the treatment cycle can begin. Payment is expected at the time of service. **Medications are not included;** patients can purchase them through the pharmacy of their choice such as The Apothecary Shops, IVPCare, Freedom Drug or a similar infertility pharmacy.

PRE IVF TESTS

Wife

CBC/HCT
HIV-1&2 Ab
RPR
Hepatitis BsAg
Hepatitis C Ab
Rubella immunity screen
Gonorrhea by PCR
Chlamydia by PCR
Day 3 Follicle Stimulating Hormone (FSH)
Day 3 Estradiol (E2)
Anti-Mullerian Hormone (AMH)
Day 10 FSH (over 34, poor prior response, prior elevated FSH>7.9 or prior day 3 estradiol over 60)
Varicella immunity screen
Hysterosonogram (3D saline sonogram) – usually recommend this be completed at RCC

Husband

Semen analysis with Kruger strict morphology-at RCC
(\$178 - not included in Pre IVF package price)
HIV-1&2 Ab
Hepatitis BsAg
Hepatitis C Ab
RPR
Gonorrhea by PCR
Chlamydia by PCR

A hysterosonogram or HSG should be less than 1 year old at the time of embryo transfer in women over age 34. After a pregnancy or significant occurrence, some tests may need to be repeated.

Additional tests may be requested by your physician based on your individual circumstances.

The charge for the Pre-IVF follow-up visit will be determined by the amount of time spent with your physician developing a treatment plan.

To achieve the best results on the semen analysis with strict Kruger morphology the couple should abstain from sexual relations for at least two but not more than five days.

The total package price for the Pre IVF tests listed above is \$1,567 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 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 – We do not do this X-ray test of the uterus and fallopian tubes at our Center. 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 the RCC for review.

Cystic fibrosis mutation screening is recommended but may be declined by signing of a consent.

IVF COSTS

An **IVF Money Back Guarantee Package Plan** is available to patients that qualify. The charge is \$21,704 **plus** any premiums that are determined to apply. This “shared risk[®]” type plan includes up to 4 fresh IVF cycles with all the associated frozen embryo transfer cycles (potential value of >\$46,000). The contract is fulfilled with the delivery of a live baby. Two additional fresh 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 an “IVF Money Back Guarantee Plan Criteria Form”. In some circumstances, additional pre-IVF testing may be required to determine eligibility. Financing is available if qualified.

An **IVF Discounted Multiple Cycle Program** is available. This plan includes up to 2, 3 or 4 fresh IVF cycles (whichever option is chosen) with all the associated frozen embryo transfer cycles (potential savings of >\$25,000). The cost is \$15,285 for two, \$18,342 for three and \$20,380 for up to four fresh cycles. The contract is fulfilled with the delivery of a live baby or the completion of the purchased treatment cycles. No refund is available if a delivery does not occur. There are no additional premiums but it requires the medical approval of the primary physician. There are exclusions for medication and anesthesia charges. Associated procedures such as intracytoplasmic sperm injection (ICSI), testicular aspiration (needle) of sperm (TESE), preimplantation genetic diagnosis (PGD) or screening (PGS) and the use of a gestational surrogate are not included but can be purchased on a per cycle basis as needed. Please request a detailed handout about this program if interested. In some circumstances, additional pre-IVF testing may be required to determine eligibility.

Patients may also choose either the single cycle “**Global Single Cycle 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 (unless your insurance company has a global fee [S code] price structure). An upfront down payment will be required in advance. Patients with United Healthcare who have a covered IVF benefit should pay \$1630 as a down-payment. The amount due upfront for other insurance plans is a minimum of \$2705, but you may be required to pay more based on your expected plan coverage. 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 IVF insurance coverage.*** Blue Cross Blue Shield (BCBS) patients need to work carefully with billers regarding their particular situation.

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 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 IVF 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 IVF Fees	\$13,000	Cost of usual & customary IVF Fees	\$13,000	Cost of usual & customary IVF Fees	\$13,000
Your Safeguard payment	\$6,500	Your Safeguard payment	\$6,500	Your Safeguard payment	\$6,500
Insurer pays	\$11,000	Insurer pays	\$4,000	Insurer pays	\$0
Refund to patient	4,500	Refund to patient	\$0	Refund to patient	\$0
Net cost to patient	\$1,000	Net cost to patient	\$6,500	Net cost to patient	\$6,500

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 or other military 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.

The fee for the “Global Single Cycle Fresh IVF Fee” option is \$8,662 and is required to be paid before IVF medications begin. There is usually 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.

Global Low Stimulation Single Fresh IVF Cycle Fee package of \$5,197 (exclusions such as medication and anesthesia charges have been explained to us). This is a pre-paid cash discount package for a single low stimulation treatment cycle. There will be additional charges for additional specialized items such as intracytoplasmic sperm injection (ICSI) and extended culture. Some procedures such as cryopreservation and gestational surrogacy will not be done with this low cost package. Charges will not be itemized or billed to insurance. The entire payment is due prior to starting medications such as Femara or FSH in order to qualify for the pre-paid discount. The pregnancy rates per cycle are expected to be 20-40% below the regular cumulative IVF pregnancy rates due to the lower number of eggs retrieved and the resulting lower number of anticipated embryos to choose from for embryo transfer. See the “Low Stimulation IVF Financial Policies” handout for details.

Additional Charges per cycle that are not included in the Global Single Cycle Fresh IVF 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 either cashier's check, money order or cash. 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 for the second aspiration if two procedures are required for the same treatment cycle.

Open testicular Biopsy to obtain sperm \$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 that embryos are frozen.**

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, in women 38 or older, after thawing frozen embryos or as recommended by the physician.

Preimplantation Genetic Screening (PGS) testing for aneuploidy screening or gender selection using fluorescent in-situ hybridization (FISH) technology varies in cost depending on the laboratory used and the number of chromosomes tested (range from \$1,100 to \$3,500. This does not include the biopsy, biopsy supplies, shipping which is a separate fee. It should be considered when a woman is over the age of 35, has a history of recurrent miscarriages, desires selection of a specific gender or as recommended by the physician. This testing is usually provided through Reprogenetics, LLC. Fees are usually paid directly to the laboratory.

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. 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. 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).

Ovarian Hyperstimulation RCC Pre-Paid Coverage is \$290 for the regular IVF protocols (\$145 for the low stimulation protocol). On average 1-2% of IVF patients develop ovarian hyperstimulation (OHSS). Patients with irregular cycles or patients with large numbers of antral follicles (such as polycystic ovarian syndrome [PCOS]) are at even higher risk (up to 20-30%). RCC recommends that all patients purchase this coverage. If this complication occurs hydration with albumin and a procedure called culdocentesis with intravenous sedation may be needed to remove abdominal fluid. Generally one culdocentesis costs \$1,676. A patient may require multiple procedures (average 2-3 but may require up to 12). Pre-paid coverage is available (\$290/treatment cycle for a regular protocol (\$145/cycle for a low stimulation protocol) for OHSS treatment provided by RCC at the RCC (office evaluations, ultrasound, and culdocentesis as needed). This option does not include any coverage for treatment not provided at the RCC such as laboratory tests, hospitalization or emergency room care. Anesthetist fees are an additional charge. Due to the highly variable cost of obtaining albumin the cost of albumin needed for hydration is an additional cost (may be up to \$700 per treatment).

Insurance for complications of IVF within 1 year of the IVF cycle is \$525/cycle. It has been our experience that if a patient's insurance company does not cover IVF it will usually not cover complications of IVF. Thus, RCC recommends that patients who do not have insurance coverage for IVF consider purchase of insurance for complications of IVF. If insurance for complications of IVF has been purchased prior to the beginning of the cycle, patients will be covered up to \$250,000 with no deductible (for expenses not paid by your primary insurance company which will be billed first) and \$100,000 life insurance for death due to complications of the IVF cycle. This includes hospital and emergency room coverage. This insurance can be purchased by us for you through Brown & Brown Insurance. Details can be obtained through our business office. Information is also available at http://www.bbtexas.com/fertility_insurance_program_overview.php?file_id=87&link_id=45

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, after taking oral contraceptives 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 target date for the egg retrieval. Payment reserves your spot on the schedule.

If a patient's cycle is cancelled, an egg retrieval occurs but no embryos are available for transfer or the treatment cycle is delayed, the accumulated charges will be itemized and funds remaining will be credited to the patients for future treatment or will be refunded. If the patient paid the global cycle fee and does not have the egg retrieval, a maximum cancellation fee of \$4,331 for the regular IVF protocol (\$2,599 for the low stimulation protocol) or the itemized charges, whichever is less, will be charged. If an embryo transfer does not occur after an egg retrieval a minimum of \$1,000 (\$500 for a low stimulation protocol) will be credited or refunded.

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 Single Cycle Fresh IVF Option

The following tests and procedures are **included** in the Global Single Fresh IVF Cycle Fee:

Group education class	Usual stimulation monitoring (US & E2 blood tests)
Pre-IVF focused physical exam	Egg retrieval and embryo culture for up to 3 days
Baseline ultrasound (US) scan if needed	Embryo transfer with ultrasound guidance if needed
Single suppression check (US & E2 blood test)	One quantitative pregnancy blood test

Post cycle review (within 6 months)

One pregnancy US 2 weeks after positive HCG

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

Initial physician consultation fees	Follow-up consult fees prior to starting IVF
Pre IVF testing charges including trial transfer if needed	Any medications needed for the cycle
Hysterosalpingogram or 3D saline sonogram	Cyst checks with US
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)
Clinical care related to ovarian hyperstimulation syndrome	Culdcentesis related costs
Clinical care related to evaluation and treatment of complications of IVF	
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 st ultrasound)	
Treatment for unrelated medical conditions	
Surgeries not related to the IVF cycle	
MicroSort sperm sorting for gender selection (additional non-refundable fee per cycle)	
Preimplantation Genetic Diagnosis (PGD) testing with associated biopsy fees	
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. \$275 to be paid to the anesthetist prior to the day of egg retrieval. Payment needs to be either check, cashier's check, money order or cash on the day of cycle fee payment.

Frozen embryo transfer cycle (FET)

If the patient has frozen embryos then we usually recommend a controlled endometrial development (CED)" Frozen Embryo Transfer Cycle (FET). The medications for a CED FET cycle generally cost approximately \$200-\$450. The Global Single CED FET cycle fee is \$2,935. 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. If a saline sonogram, trial transfer or other evaluation test needs to be completed, this would be an additional charge.

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, in women 38 or older, after thawing frozen embryos especially if using blastocysts or as recommended by the physician.

Preimplantation Genetic Screening (PGS) testing for aneuploidy screening or gender selection using fluorescent in-situ hybridization (FISH) technology varies in cost depending on the laboratory used and the number of chromosomes tested (range from \$1,100 to \$3,500. This does not include the biopsy, biopsy supplies, shipping which is a separate fee. It should be considered when a woman is over the age of 35, has a history of recurrent miscarriages, desires selection of a specific gender or as recommended by the physician. This testing is usually provided through Reprogenetics, LLC. Fees are usually paid directly to the laboratory.

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. 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. 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.

Gestational Surrogate if needed is an additional \$320.

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	One 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	Any 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 st ultrasound)	
Treatment for unrelated medical conditions or surgeries not related to the FET cycle	
Preimplantation Genetic Screening (PGS) or Diagnosis (PGD) testing with associated biopsy fees	
Collection and shipping charges for blood tests sent to RCC	

Reproductive Care Center

IVF PAYMENT AGREEMENT

We have chosen to start an IVF cycle in _____ of 2009 or to begin our IVF Money Back Guarantee Package Plan or our IVF Discounted Multiple Cycle Program with our first cycle beginning _____ of 2009 and have had the payment options explained to us. We understand that we must choose from the following options:

- (1) **IVF Money Back Guarantee Package Plan.** We have selected and qualify to participate in the IVF 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 \$21,705 (base price) **plus any premiums that are determined to apply.** 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. Income based discounts are not available for this treatment protocol.
- (2) **An IVF Discounted Multiple Cycle Program.** We have selected and qualify to participate in the IVF Discounted Multiple Cycle Program. The program includes up to 2, 3 or 4 fresh IVF cycles (whichever option is chosen) with the associated frozen embryo transfer cycles (potential savings of >\$25,000). The cost is \$15,285 for two, \$18,342 for three and \$20,380 for up to four fresh cycles. The contract is fulfilled with the delivery of a live baby or the completion of the purchased treatment cycles. No refund is available if a delivery does not occur. There are no additional premiums but it requires the medical approval of the primary physician. There are exclusions for medication and anesthesia charges. Associated procedures such as intracytoplasmic sperm injection (ICSI), testicular aspiration (needle) of sperm (TESE), preimplantation genetic diagnosis (PGD) or screening (PGS) and the use of a gestational surrogate are not included but can be purchased on a per cycle basis as needed. Please request a detailed handout about this program if interested. In some circumstances, additional pre-IVF testing may be required to determine eligibility. Income based discounts are not available for this treatment protocol.
- (3) **Global Single Fresh IVF Cycle Fee** package of \$8,662 (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. There will be additional charges for additional specialized items such as intracytoplasmic sperm injection, extended culture, and cryopreservation. Charges will not be itemized or billed to insurance. The entire payment is due prior to starting medications such as Lupron or FSH in order to qualify for the pre-paid discount. Income based discounts are available for this treatment protocol.
- (4) **Global Low Stimulation Single Fresh IVF Cycle Fee** package of \$5,197 (exclusions such as medication and anesthesia charges have been explained to us). This is a pre-paid cash discount package for a single low stimulation treatment cycle. There will be additional charges for additional specialized items such as intracytoplasmic sperm injection (ICSI) and extended culture. Some procedures such as cryopreservation and gestational surrogacy will not be available with this low cost package. Charges will not be itemized or billed to insurance. The entire payment is due prior to starting medications such as Femara or FSH in order to qualify for the pre-paid discount. Pregnancy rates are expected to be 20-40% lower than with the regular cumulative IVF cycle treatment rates. Income based discounts are not available for this treatment protocol.
- (5) **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 anesthetist 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.

Reproductive Care Center

- (6) **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 \$8,662 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.
- (7) **Safeguard Payment Plan** of \$6,500. 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 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 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 understand that if we choose the Global Single Fresh IVF Cycle Fee, Global Low Stimulation Single Fresh IVF Cycle Fee, IVF Money Back Guarantee Package Plan or the IVF Discounted Multiple Cycle Program option that RCC will not help us bill our insurance company. We understand the pre-paid cycle plans are 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 Single Fresh IVF Cycle Fee, Global Low Stimulation Single Fresh IVF Cycle Fee, IVF Money Back Guarantee Package Plan and the IVF Discounted Multiple Cycle Program 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 Single Fresh IVF Cycle Fee option nor the Global Low Stimulation Single Fresh IVF Cycle Fee if the insurance company pays less than anticipated.

Reproductive Care Center

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

Paid at Signing

- | | |
|---|-----------------|
| 1. <input type="checkbox"/> IVF Money Back Guarantee Package Plan with premiums: | \$ _____ |
| 2. IVF Discount Multiple Cycle Fresh IVF Fee | |
| a. <input type="checkbox"/> Two fresh cycle package - \$15,285 | \$ _____ |
| b. <input type="checkbox"/> Three fresh cycle package - \$18,342 | \$ _____ |
| c. <input type="checkbox"/> Four fresh cycle package - \$20,380 | \$ _____ |
| #1 and #2 above include embryo cryopreservation (groups), storage and all associated frozen embryo transfers as outlined in the contract. | |
| 3. <input type="checkbox"/> Global Single Cycle Fresh IVF Fee (basic) - \$8,662 | \$ _____ |
| 4. <input type="checkbox"/> Global Low Stimulation Single Cycle Fresh IVF Fee (basic) - \$5,197 | \$ _____ |
| 5. Insurance Company _____ | |
| a. <input type="checkbox"/> Contracted carrier estimated basic co-payment | \$ _____ |
| b. <u>Non-contracted</u> carrier with confirmed IVF infertility benefit | |
| i. <input type="checkbox"/> Downpayment (basic) for non-contracted carrier | \$ _____ |
| ii. <input type="checkbox"/> SafeGuard Payment Plan (basic) for a non-contracted carrier as per section 5 above | \$ _____ |
| c. Anesthetist fee with insurance (choose one) | |
| <input type="checkbox"/> Anesthetist fee (separate check to Wayne Riding) - \$275 | \$ _____ |
| <input type="checkbox"/> Anesthetist fee (please have them bill insurance) | \$ _____ |
| 6. Common additional applicable fees or co-payments needed: | |
| a. <input type="checkbox"/> Anesthetist fee (separate check to Wayne Riding) - \$275 | \$ _____ |
| b. <input type="checkbox"/> Personal IVF training (if unable to attend group class) - \$153 | \$ _____ |
| c. <input type="checkbox"/> Intracytoplasmic sperm injection (ICSI) - \$1,200 | \$ _____ |
| d. <input type="checkbox"/> Testicular aspiration (TESE) (needle) - \$1,131* | \$ _____ |
| e. <input type="checkbox"/> TESE (open biopsy) - \$1,630* | \$ _____ |
| f. <input type="checkbox"/> Preimplantation Genetic Diagnosis (PGD) – variable* | \$ _____ |
| g. <input type="checkbox"/> Embryo biopsy and shipping charges for PGD - \$2,000* | \$ _____ |
| h. <input type="checkbox"/> Extended embryo culture - \$204 | \$ _____ |
| i. <input type="checkbox"/> Assisted Hatching - \$300 | \$ _____ |
| j. <input type="checkbox"/> Sperm cryopreservation for backup - \$336 | \$ _____ |
| k. <input type="checkbox"/> Embryo cryopreservation (groups) - \$650* | \$ _____ |
| l. <input type="checkbox"/> Embryo cryopreservation (single embryo) - \$840* | \$ _____ |
| m. <input type="checkbox"/> Embryo storage (1 year) - \$430* | \$ _____ |
| n. <input type="checkbox"/> Gestational Surrogate* - | \$ _____ |
| o. <input type="checkbox"/> OHSS treatment coverage after regular IVF- \$290 - | \$ _____ |
| p. <input type="checkbox"/> OHSS treatment coverage after Low Stim IVF- \$145 - | \$ _____ |
| q. <input type="checkbox"/> Complications of IVF Insurance - \$525 | \$ _____ |
| r. <input type="checkbox"/> Other _____ | \$ _____ |
| s. Total | \$ _____ |

*Not available in the "Global Low Stimulation Single Cycle Fresh IVF Fee"

Reproductive Care Center

We have had the risks of IVF and specifically of ovarian hyperstimulation (OHSS) explained to us. We are aware that patients with Polycystic ovarian syndrome (usually have irregular cycles and/or a large number of antral follicles (>20) at baseline) are at increased risk for OHSS. It has been our experience that if a patient's insurance company does not cover IVF it will usually not cover complications of IVF. Thus, RCC recommends that patients who do not have insurance coverage for IVF consider purchase of insurance for complications of IVF. Payment must be received prior to starting stimulation medications.

- We decline additional pre-paid or insurance coverage.
- We desire treatment coverage (\$290/treatment cycle [\$150/treatment cycle for the low stimulation protocol]) for OHSS treatment provided by RCC at the RCC (office evaluations, ultrasound, and culdocentesis as needed). This is needed in 1-3% of all IVF patients and up to 20% of patients at high risk.. This option does not include any coverage for treatment not provided at the RCC such as hospitalization or emergency room care. Anesthetist fees and laboratory tests are an additional charge.
- We accept supplemental insurance coverage for complications of IVF through the Brown & Brown Co. and will pay \$525/treatment cycle. We understand that our primary insurance company will be billed first. This includes coverage for hospitalization (occurs in less than 1% of all IVF patients). Payment must be received and submitted to Brown & Brown Co prior to starting medications for the treatment cycle.

Options available with the IVF Money Back Guarantee Package Plan. This fee will be refunded if pregnancy and delivery does not occur as per the contract.

- We accept the pre-paid coverage option (\$744/treatment cycle) for OHSS treatment provided by RCC at the RCC (office evaluations, ultrasound, and culdocentesis as needed). This is needed in 1-3% of all IVF patients and up to 20% of patients at high risk... This option does not include any coverage for treatment not provided at the RCC such as hospitalization or emergency room care. Anesthetist fees and laboratory tests are an additional charge. This fee will be refunded if pregnancy and delivery does not occur as per the contract.
- We accept insurance coverage for complications of IVF through the Brown & Brown Co. (\$1,389) as an additional fee to the IVF Money Back Guarantee Package Plan. This includes coverage for hospitalization (occurs in less than 1% of all IVF patients). This fee will be refunded if pregnancy and delivery does not occur as per the contract. Payment must be received and submitted to Brown & Brown Co prior to starting medications for the first treatment cycle.

We have received and reviewed a current copy of the Reproductive Care Center, PC (RCC) "IVF and Frozen Embryo Transfer Financial Policies" and/ or "Low Stimulation IVF 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

Reproductive Care Center

LOW STIMULATION IVF FINANCIAL POLICIES

Each couple will need to meet with manager or billing staff to discuss fees and payment dates. Income based discounts are not available for this treatment protocol. The Pre-IVF workup (ART checklist) needs to be completed before the medications for the treatment cycle can begin. Payment is expected at the time of service. **Medications are not included;** patients can purchase them through the pharmacy of their choice such as Southwood Apothecary Shop, IVPCare, Freedom Drug or a similar infertility pharmacy.

PRE IVF TESTS

Wife

CBC/HCT

Rubella immunity screen

Day 3 Follicle Stimulating Hormone (FSH)

Day 3 Estradiol (E2) and AMH (anti-mullerian hormone)

Day 10 FSH (over 34, poor prior response or prior elevated FSH>7.9)

Varicella immunity screen unless the patient has a history of chickenpox

Hysterosonogram (3D saline sonogram) – usually recommend this be completed at RCC

A hysterosonogram or HSG should be less than 1 year old at the time of embryo transfer in women over age 34. After a pregnancy or significant occurrence, some tests may need to be repeated.

Additional tests may be requested by your physician based on your individual circumstances.

Husband

Semen analysis with Kruger strict morphology-at RCC

(\$178-not included in Pre IVF package price)

The charge for the Pre-IVF follow-up visit will be determined by the amount of time spent with your physician developing a treatment plan.

To achieve the best results on the semen analysis with strict Kruger morphology the couple should abstain from sexual relations for at least two but not more than five days.

The total package price for the Pre IVF tests listed above is \$1,067 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 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 – We do not do this X-ray test of the uterus and fallopian tubes at our Center. 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 the RCC for review.

Cystic fibrosis mutation screening is recommended but may be declined by signing of a consent.

IVF COSTS

Patients may also choose only the single cycle “**Global Single Cycle Fresh IVF Fee**” for each treatment cycle. Insurance billing and the money back guarantee program is not available for the low stimulation IVF package plan.

The fee for the “Global Single Cycle Fresh Low Stimulation IVF Fee” option is \$5,197 and is required to be paid before IVF medications begin. There is usually 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.

Additional Charges per cycle that are not included in the Global Single Cycle Fresh IVF 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 either cashier’s check, money order or cash. 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).

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).

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

Ovarian Hyperstimulation RCC Pre-Paid Coverage is \$145. On average <1% of IVF patients develop ovarian hyperstimulation (OHSS) with a low stimulation protocol. Patients with irregular cycles or patients with large numbers of antral follicles (such as polycystic ovarian syndrome [PCOS]) are at higher risk (up to 20-30%). RCC recommends that all patients purchase this coverage. If this complication occurs hydration with albumin and a procedure called culdocentesis with intravenous sedation may be needed to remove abdominal fluid. Generally one culdocentesis costs \$1,676. A patient may require multiple procedures (average 2-3 but may require up to 12). Pre-paid coverage is available (\$145/treatment cycle) for OHSS treatment provided by RCC at the RCC (office evaluations, ultrasound, and culdocentesis as needed). This option does not include any coverage for treatment not provided at the RCC such as laboratory tests, hospitalization or emergency room care. Anesthetist fees are an additional charge. Due to the highly variable cost of obtaining albumin the cost of albumin needed for hydration is an additional cost (may be up to \$700 per treatment).

Insurance for complications of IVF within 1 year of the IVF cycle is \$525/cycle. It has been our experience that if a patient’s insurance company does not cover IVF it will usually not cover complications of IVF. Thus, RCC recommends that patients who do not have insurance coverage for IVF consider purchase of insurance for complications of IVF. If insurance for complications of IVF has been purchased prior to the beginning of the cycle, patients will be covered up to \$250,000 with no deductible (for expenses not paid by your primary insurance company which will be billed first) and \$100,000 life insurance for death due to complications of the IVF cycle. This includes hospital and emergency room coverage. This insurance can be purchased by us for you through Brown & Brown Insurance. Details can be obtained through our business office. Information is also available at http://www.bbtexas.com/fertility_insurance_program_overview.php?file_id=87&link_id=45

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.

Cycle fees are due prior to starting any medication for the treatment cycle. Usually this is at least 6 weeks before target date for the egg retrieval. Payment reserves your spot on the schedule.

If a patient’s cycle is cancelled, an egg retrieval occurs but no embryos are available for transfer or the treatment cycle is delayed, the accumulated charges will be itemized and funds remaining will be credited to the patients for future treatment or will be refunded. If the patient paid the global cycle fee and does not have Low Stim IVF Financial Policies v3
Prices subject to change without notice.

the egg retrieval, a maximum cancellation fee of \$2,599 or the itemized charges, whichever is less, will be charged. If an embryo transfer does not occur after an egg retrieval a minimum of \$500 will be credited or refunded.

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

Global Single Cycle Low Stimulation Fresh IVF Option

The following tests and procedures are **included** in the Global Single Fresh IVF Cycle Fee:

Group education class	Usual stimulation monitoring (US & E2 blood tests)
Pre-IVF focused physical exam	Egg retrieval and embryo culture for up to 3 days
Baseline ultrasound (US) scan if needed	Embryo transfer with ultrasound guidance if needed
Single suppression check (US & E2 blood test)	One quantitative pregnancy blood test
Post cycle review (within 3 months)	One pregnancy US 2 weeks after positive HCG

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

Initial physician consultation fees	Follow-up consult fees prior to starting IVF
Pre IVF testing charges including trial transfer if needed	Any medications needed for the cycle
Hysterosalpingogram or 3D saline sonogram	Cyst checks with US
ICSI (intracytoplasmic sperm injection)	
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)
Clinical care related to ovarian hyperstimulation syndrome	Culdocentesis
Clinical care related to evaluation and treatment of complications of IVF	
MicroSort sperm sorting for gender selection (additional non-refundable fee per cycle)	
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 st ultrasound)	
Treatment for unrelated medical conditions	
Surgeries not related to the IVF 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. \$275 to be paid to the anesthetist prior to the day of egg retrieval. Payment needs to be either check, cashier's check, money order or cash on the day of the cycle payment.

The following procedures will not be done during a low stimulation IVF cycle treatment:

- TESE (testicular sperm aspiration)
- Cryopreservation of embryos
- Preimplantation Genetic Diagnosis (PGD) testing
- Use of a gestational surrogate or an egg donor

The pregnancy rates per cycle are expected to be 20-40% below the regular cumulative IVF pregnancy rates due to the lower number of eggs retrieved and the resulting lower number of anticipated embryos to choose from for embryo transfer.