

Reproductive Care Center

Consents remain in effect for subsequent cycles

We have had the opportunity, but choose not to make any changes to the IVF consents that were signed on

Wife's Signature

Wife's Name Printed

Date

Husband's Signature

Husband's Name Printed

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

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.

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- (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"

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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