

# 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](http://www.fertilitydr.com)), through information submitted to the Society for Assisted Reproduction (SART – [www.SART.org](http://www.SART.org)), the CDC ([www.CDC.gov](http://www.CDC.gov)) and through discussion with 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.

18) 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.

19) Our signatures below constitute our acknowledgment:

- a) That we have read, understood and agreed to the foregoing.
- b) That the proposed procedure(s) have been satisfactorily explained to us, and we have all the information that we desire.
- c) That we have received a copy of this consent and have been given the opportunity to discuss this document with our physician and/or attorney prior to signing.
- d) That if we undergo further IVF cycles at RCC, this agreement will apply to any future IVF cycles for 5 years from the date of signing or for up to 12 IVF cycles.
- e) That we agree to keep our most current mailing address on file at the RCC at all times during our participation in the IVF Program and for 1 year thereafter if we achieve a pregnancy. We will advise the RCC promptly upon each change of address or prolonged absence (greater than 90 days) from the last address on file. We agree to notify the RCC of the outcome of all pregnancies that are achieved.
- f) That we hereby request the treatment prescribed above and give our authorization and consent.

Wife's Signature	Date
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Witness to Wife's Signature (Notary or RCC Representative)	Date
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Husband's Signature	Date
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Witness to Husband's Signature (Notary or RCC Representative)	Date
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State of \_\_\_\_\_ )  
 ) ss.  
 County of \_\_\_\_\_ )

The foregoing instrument was acknowledged before me on the \_\_\_\_ day of \_\_\_\_\_, 20\_\_ by \_\_\_\_\_.

\_\_\_\_\_  
 Notary Public  
 Residing at:

My commission expires: \_\_\_\_\_