Consent for In Vitro Fertilization and Embryo Transfer

Name of Patient: _____ Name of Partner: _____

We, the Patient and Partner named above, are each over the age of twenty-one (21) years. By our signatures below, we request and authorize the performance of in vitro fertilization and embryo transfer (IVF/ET). We have been unable to become pregnant and we are eager to have a child.

We understand and acknowledge that Regional One Health is responsible for our IVF/ET cycle management and laboratory testing and services, including semen analysis, sperm preparation, oocyte (egg) identification and preparation, embryo culture, embryo micromanipulation and cryopreservation.

We acknowledge that Regional One Health and UT Regional One Physicians, Inc., and their physician and employees have explained the process and procedures involved with IVF/ET and we will manage our expectations and hopes given the realistic understanding of what can be achieved by IVF/ET. We acknowledge that we have been encouraged to ask questions and ask further clarification regarding the process and procedures described in this consent if we desire.

We acknowledge that the following process and procedures involving IVF/ET have been explained to us fully:

1. Patient will be instructed to self-administer injectable medications, such as gonadotropins (Lupron, Antagon, Cetrotide, Repronex, Bravelle, Gonal-F, Follistim), and human chorionic gonadotropin (hCG). These are intended to stimulate the ovaries to produce more than one egg and to optimize implantation. In addition, injectable progesterone, progesterone suppositories and baby aspirin may be used. In some cases, Heparin may be used.
2. The progress of follicle development will be monitored by blood tests and ultrasounds that are performed in the morning over the course of several days.
3. A transvaginal procedure will be done to retrieve eggs from the ovaries.
4. If eggs are retrieved, they will be fertilized with the partner's sperm provided at the same time of the egg retrieval (or with donor sperm if applicable to the patient's circumstances). Sperm may be obtained by masturbation, PESA (Percutaneous Epididymal Sperm Aspiration), TESE (Testicular Sperm Extraction) or by other means. In the event the fresh sample obtained on the day of retrieval is sufficient or of poor quality, the frozen back-up (if obtained) semen specimen will be used. In select cases where the patient and the partner have been counseled and have given prior informed consent, a carefully marked specimen of frozen human sperm obtained from a sperm bank for the purpose of in vitro fertilization will be used. The sperm will undergo laboratory preparation and will be used for in vitro fertilization.
5. If the eggs fertilized, the embryo(s) will be placed into the uterus and the uterine lining will be supported with progesterone. The embryologist at Regional One Health will perform procedures that are deemed necessary to optimize the chance of successful implantation. Some of the procedures, described below, will be adapted and applied at the discretion of the physician and the embryologist at UTCRM-Regional One Health. These procedures may consist of one or more of the following:

    A. Intracytoplasmic Sperm Injection (ICSI) - the process of inserting a single sperm into a mature egg.
    Benefits: (1) optimizes the sperm's ability to fertilize an egg; (2) putting a single sperm into a single egg overcomes failed fertilization due to sperm factor; (3) overcomes concern of poor sperm attachment that may lead to failed fertilization.
    Risks: (1) death of the egg (less than 1 in 1,000); (2) inheritable male factor infertility (in select cases where the cause of infertility is an inherited sperm factor).

    B. Assisted Hatching (AH) (also known as Zona Drilling (ZD)) - the process of drilling a hole through the outer shell of the embryo.
    Benefits: (1) improves hatching of embryo; (2) enhances implantation in the uterus.
    Risks: (1) injury of embryos (less than 1 in 1,000); (2) identical or conjoined twinning (less than 1 in 100).

    C. Cryopreservation - in the event of numerous embryos, those of high quality that are not transferred to the uterus may be cryopreserved. Signed informed consent is **required** prior to cryopreservation of embryos.

Affix Patient Label

Patient's Initials _____
Partner's Initials _____

We further acknowledge that the IVF/ET process contains several complicated steps and resultant risks, which have been explained to us fully, including:

1. The development of eggs may not be adequate, indicated either by low estrogen levels or lack of follicle development (identified by ultrasound).
2. Development may go too slowly, increasing the likelihood of eggs that will not fertilize.
3. Development may proceed normally, but ovulation may begin before the procedure can be scheduled. This a rare event if a patient is taking Lupron, but may be more common in a "flare" or antagonist protocol.
4. Development may occur in an ovary which is not accessible.

If any of the above circumstances occur, we understand that it may be recommended that the stimulation cycle be stopped and we will need to await another cycle. In that event, we will discuss these circumstances with Regional One Health, its physicians and employees, and they will outline plans for another attempt, if feasible. We understand that the physician's goal in this phase is to try to ensure that if Patient undergoes egg retrieval, the physician will have the best possible chance to retrieve fertilizable eggs. Patient's chance of going to retrieval in a particular cycle once Patient has begun the stimulation program is over 90%. If Patient has retrieval, her chance of successful retrieval of eggs is more than 99%. We also understand the following risks and potential outcomes as it relates to said process and procedures:

1. It is possible that retrieval no eggs will be obtained (less than 1% probability).
2. It is possible that eggs will be retrieved, but none of them will fertilize (3% probability).
3. It is possible that eggs will fertilize, but then will not develop into embryos (less than 1% probability).
4. Unexpected difficulty may occur in the attempt to transfer the embryo(s) to the uterus.
5. After the embryo(s) are transferred, it/they may fail to implant and pregnancy, therefore, will not occur.
6. Equipment failure is a remote possibility, but could possibly interfere with any of the steps in this process or make it impossible to successfully cryopreserve excess embryos.

We further understand that additional complications and adverse complications and adverse reactions may occur as a result of the above described process and procedure, including establishing an abnormal pregnancy. We understand that complications and adverse reactions could include, but are not limited to, the following:

1. Patient may have a reaction to the medication used. These may range from allergic reactions, bloating, emotional symptoms and/or hot flashes, to pain, abdominal swelling and over-stimulation of the ovaries.
2. Patient may have bruising or infection at the site of blood sampling or at the site of injection.
3. Patient may have problems during the retrieval. These may include reactions to a drug, difficulty breathing, or cardiac arrest. The procedure could damage a blood vessel, the bladder, or an organ inside the abdomen. Patient could have bleeding or infection, or patient might need an emergency surgery to correct any of these conditions.
4. An unforeseen laboratory event may result in loss of or damages to our egg(s), sperm, or embryo(s).
5. If Patient becomes pregnant, the pregnancy could miscarry (20% of pregnancies) or could be an ectopic pregnancy (outside the uterus - 2% of pregnancies). The risk of a congenital defect is the same as the background rate of the general population.
6. Patient may become pregnant with more than one gestation. The risk depends on the quality of and the number of embryos transferred. This will be discussed with us prior to the embryo transfer so that **we** may choose how many embryos to transfer, if within the guidelines from the American Society for Reproductive Medicine, which Regional One Health, UT Regional One Physicians, Inc., and their physicians and employees obey.
7. These fertility drugs have been used for decades with no known life threatening risks, but the long-term health risks of infertility treatment and ovulation-enhancing drugs are constantly under study.

Patient's Initials _____
Partner's Initials _____

We further understand that data from our Assisted Reproductive Technology (ART) procedure will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that the CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Data collected by the Society of Assisted Reproductive Technologies (SACT) is used to generate statistics published annually in medical and scientific publications and for selected research projects. Because sensitive information will be collected, CDC and SART applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308(d). We understand that this means that any information that CDC has that identifies us will not be disclosed to anyone else without our consent.

Although Regional One Health is not able to guarantee success, it will make every effort to assist us in achieving our goal of having a healthy infant. To induce the Regional One Health, UT Regional One Physicians, Inc., and the physician to render the services herein requested, we agree that:

1. We acknowledge that no action or inaction on the part of Regional One Health, UT Regional One Physicians, Inc., their physicians, or other employees or agents, in providing artificial insemination can either assure Patient's health or well-being or the health and well-being of the child or children during or after pregnancy or childbirth or determine the physical and/or mental status of any child or children born as a result of the procedure. We understand and acknowledge that pregnancy and childbirth both involve risks that are independent of whether conception occurs through IVF/ET or otherwise.
2. Although reasonable safeguards will be employed, we acknowledge that there is a risk of being infected by diseases, including HIV/AIDS.
3. We acknowledge our obligation to care for, support, education and otherwise treat and consider any child or children born as the result of IVF/ET in all respects as though they were our natural child or children. We will never allege in any proceeding that the child or children born is/are other than legitimate, and as such, will be our lawful child or children and legal heir(s).
4. We accept the risks described above and hereby release, indemnify and forever hold harmless Regional One Health, UT Regional One Physicians, Inc., and their respective employees, agents, directors, officers, and contractors (the "Releasees") from any and all liability and responsibility of any nature whatsoever that may result from complications of pregnancy, childbirth, delivery or from the birth of an abnormal infant or infants in any respect, or from the heredity or hereditary tendencies of such infant or infants, or from any other adverse consequences that may arise in connection with or as a result of the process and procedures herein authorized.
5. We further release, discharge, indemnify and forever hold harmless the Releasees from any claim for injury or damage, known or unknown, that might result should our eggs, sperm, or embryo(s) cease to be viable while in the custody of the Releasees.
6. We understand that insurance coverage for any or all of the above procedures may not be available and that we, individually and jointly, will be responsible for all charges for services rendered for this treatment. The expenses may include hospital charges, laboratory charges, and/or physician professional fees.
7. We agree to the photographing or televising of any laboratory procedure(s) to be performed for medical, scientific, or educational purposes, provided our identities are not revealed by the pictures or by descriptive text accompanying them.

We acknowledge that we have been given an opportunity to ask questions about the proposed procedure and that all of our questions have been answered to our satisfaction. With full knowledge and understanding of the attendant risks and consequences of our decision, we consent to the medical procedure described in this consent form. We acknowledge that we understand all medical terminology contained in this consent and have had all our questions answered. We acknowledge and affirm that we have given our consent and signed this consent form without coercion or compulsion and of our own free will.

Patient's Initials _____

Partner's Initials _____

_____ _____
Patient Signature Date Partner Signature Date

_____ _____
Patient Printed Name Partner Printed Name

_____
Witness Signature Date

_____
Witness Printed Name

Physician Attestation

The above mentioned Patient and Partner (if applicable) have been informed and counseled by me and others regarding the risks and benefits of the relevant treatment options, including non-treatment. The Patient and Partner (if applicable) expressed understanding of the information presented during the discussion.

_____
Physician Signature Date

_____
Physician Printed Name

[Notary Page to Follow]

Affix Patient Label

Patient's Initials _____
Partner's Initials _____

Consent for In Vitro Fertilization and Embryo Transfer

[Notary Page for: Consent for In Vitro Fertilization
and Embryo Transfer]

STATE of _____)
) :SS
COUNTY of _____)

The foregoing instrument was acknowledged before me this _____ day of _____, 20____, by _____, referred to in this consent form as "Patient".

My commission expires: _____ .

_____
Notary Public

STATE of _____)
) :SS
COUNTY of _____)

The foregoing instrument was acknowledged before me this _____ day of _____, 20____, by _____, referred to in this consent form as "Partner".

My commission expires: _____ .

_____
Notary Public

Affix Patient Label

Patient's Initials _____
Partner's Initials _____