Consent for Frozen/Thawed 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, authorize, and consent to the performance of frozen/thawed embryo transfer (FET). We desire to become pregnant with cryopreserved (frozen) embryo(s). We have been unable to become pregnant and we are eager to have a child.

We understand and acknowledge that Regional One Health (ROH) is a medical practice in reproductive endocrinology and operates a laboratory responsible for our in vitro fertilization and embryo transfer (IVF/ET) cycle management and laboratory testing and services, including semen analysis, sperm preparation, oocyte (egg) identification and preparation, embryo culture, embryo micromanipulation, cryopreservation, and thawing. Regional One Health will be managing our care and performing the FET procedure, which involves embryo culture and preparation for transfer. We further understand that UT Regional One Physicians, Inc. is a faculty practice affiliated with the University of Tennessee and Regional One Health, and that Dr. Laura Detti is employed by UT Regional One Physicians, Inc.

We acknowledge and agree that we are both the intended parents of any and all live born children resulting from this embryo transfer procedure. If our biological sperm and/or oocytes (eggs) were not used to create these embryo(s), then we declare that we have the legal authority to utilize these embryo(s) for the purposes of pregnancy and childbirth.

We understand the following to be a general outline of the steps that may be required in this procedure. We consent to the performance of these steps:

a. Determination by certain tests that we are suitable for the procedure. The evaluations will include a detailed medical history, physical examination, and laboratory tests including, but not limited to, tests for general health, and HIV infection.
b. I (Patient) will begin a schedule of hormone (estrogen and progesterone) treatment to develop the uterine lining needed for embryo implantation. Some of these hormone therapies will require me to perform self-injection on a daily basis. The uterine lining is assessed by both blood tests and transvaginal ultrasound examinations.
c. Once the Patient's uterus has been prepared, she will be scheduled for the embryo transfer. We understand that the laboratory director at Regional One Health will determine the timing of embryo transfer so that it may be synchronized to the time of embryo thaw.
d. On the day of embryo transfer, the thawed embryo(s) will be placed into the Patient's uterus by means of a small catheter inserted through the cervix. This is immediately followed by 24 hours of bedrest.
e. Pregnancy can be determined by a blood test within 14 days of embryo transfer.

We understand that, based on age and other factors, up to three (3) of our thawed embryos may be transferred to the uterus. We have been advised that this could result in multiple gestation (twins, triplets). Multiple gestation is a higher risk pregnancy with an increased risk of premature delivery, other obstetrical complications, and an increased financial and emotional burden.

We acknowledge that a successful pregnancy after FET cannot be assured and that Regional One Health and/or UT Regional One Physicians, Inc. have made no such representation or guarantee. We understand that a number of occurrences may prevent the establishment of a successful pregnancy, including, but not limited to:

a. Patient may not respond to the medications.
b. The uterine lining may not develop normally.
c. The embryo thaw process may not be successful resulting in no viable embryo(s) for transfer.
d. Implantation of the embryo(s) into the uterus may not occur.
e. An unforeseen laboratory event may result in loss or damage of our embryo(s).

We understand that a number of risks and discomforts may be associated with this procedure, including but not limited to:

a. From the blood tests: mild discomfort and bruising at the needle site.

Affix Patient Label

Patient's Initials _____
Partner's Initials _____

b. From the medications: (i) mild discomfort and bruising at the needle site of self-injected medications; (ii) the possibility of an increased risk of developing ovarian tumors later in life has been proposed in women who have been exposed to long-term 'fertility drugs'. Although recent studies do not demonstrate any association of tumors with fertility treatment, this risk has not been conclusively disproved. (iii) Estrogen therapy may cause nausea. Long-term administration of estrogen has been associated with gall bladder disease, blood clots, liver disease, and heart attacks. In postmenopausal women, long-term administration of estrogen has also been associated with breast cancer. Since the doses in this procedure are low and administration is short-term, such side effects are unexpected, but cannot be ruled out. Natural estrogens given during pregnancy have not been associated with birth defects; however the potential for increased incidence of birth defects with artificial estrogen is unknown. (iv) Progesterone therapy may cause mood swings and water retention. Long-term administration is associated with elevation of cholesterol. Since the doses in this procedure are low and administration is short-term, such side effects are unexpected, but cannot be ruled out. Recent studies do not demonstrate any association of natural progesterone given during pregnancy with birth defects, but this risk has not been conclusively disproved.
c. From the transfer of the embryo(s) into the uterus: (i) mild discomfort; (ii) the small (1 in 400) risk of developing infection and possible bleeding.
d. From psychological stress. We understand there may be a greater psychological risk to us than in a naturally conceived pregnancy because of the manner in which our pregnancy was achieved and the fact that the oocyte was donated by another woman. In addition, information revealed during the psychological evaluation may cause stress for our relationship and to our mental well-being.

We understand that, if pregnancy is successfully established, there is a risk of miscarriage (approximately 1 in 6 to 8), ectopic (tubal) pregnancy (1 in 30), stillbirth, and/or birth defects. At present, available research does not indicate a greater risk of birth defects following FET as compared to equal-age women and conceiving naturally. Nevertheless, we acknowledge that Regional One Health and UT Regional One Physicians, Inc. cannot guarantee the genetic, physical, and mental characteristics of the child, nor that the child will be born free of physical or mental abnormality, disease, or defect. We understand that pregnancy after FET may be at increased risk of premature labor or delivery. This may lead to complications of prematurity for our child and its associated financial and emotional costs.

We hereby release Regional One Health and UT Regional One Physicians, Inc. and their respective employees, agents, directors, officers, and contractors, from any injury or damage, known or unknown, that might result should the embryo(s) cease to be viable while in the custody of Regional One Health or UT Regional One Physicians, Inc.

We shall indemnify Regional One Health and UT Regional One Physicians and its physicians for any attorneys' fees, court costs, damages, judgements, or any other losses or expenses incurred by any of them or for which any of them may be responsible with respect to any claim, legal action, or defense thereto arising out of the FET hereby requested, including any claim or legal action brought by the child or children resulting from the embryo transfer. We fully understand that insurance coverage for any or all of the above procedures may not be available and that we may be personally responsible for the expenses of this treatment. The expenses may consist of hospital charges, laboratory charges, and/or physician professional fees.

We consent to the photographing or televising of any laboratory procedure(s) to be performed for medical, scientific, or educational purposes, provided my identity is not revealed by the pictures or by descriptive text accompanying them.

The Centers for Disease Control (CDC) is a "public health authority" and is authorized by law (PL 102-493) (HR 4773) to collect data on assisted reproductive technologies in the United States. In the interest of public health, we understand and acknowledge that Regional One Health is required, under the Fertility Clinic Success Rate and Certification Act of 1992, to submit information about our assisted reproductive treatment to the CDC. Furthermore, data collected by the Society of Assisted Reproductive Technologies (SART) is used to generate statistics published annually in medical and scientific publications and for selected research projects. For such activities, our data is de-identified (stripped of information that could potentially lead to revealing the subject of the information).

Affix Patient Label

Patient's Initials _____
Partner's Initials _____

We each acknowledge that we have fully reviewed and comprehend the contents of this consent form for FET. The nature of FET has been explained to us, together with the known risks. We understand the explanation that has been given us and understand that there may be unknown risks. We acknowledge that we have had the opportunity to ask any questions about the procedures and services discussed herein and those questions have been answered to our satisfaction. We acknowledge that FET is being performed at our request and with our consent.

We understand that we may elect not to continue with the procedure at any time and that this decision will not affect any other present or future medical care and treatment from Regional One Health and UT Regional One Physicians, Inc.

With full knowledge and understanding of the attendant risks and consequences of our decision, we each consent to the medical procedure described in this consent form. We each acknowledge that we understand all medical terminology contained in this consent and have had all our questions answered. We each 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 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 _____

[Notary Page for: Consent for Frozen/Thawed 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 _____