Consent for Frozen Donor Oocyte In Vitro Fertilization and Embryo Transfer (Recipient)

Name of Patient: _____ Name of Partner: _____

We, the Patient and Partner (if applicable) named above, are each over the age of twenty-one (21) years. By our signatures below, I/we request and authorize the performance of in vitro fertilization and embryo transfer (IVF/ET) with frozen donor oocytes (Frozen Donor Oocyte IVF/ET). Frozen oocyte (egg) adoption will provide an opportunity for pregnancy for patients who could not otherwise conceive or, because of the risks of transmitting a genetic disorder, wishes not to conceive her/their own genetic child(ren). This will be accomplished by a procedure in which a fertile woman (referred to in this consent form as "the Donor") donates her oocytes, and the oocytes are frozen for subsequent fertilization and transfer to the patient. I/We have been unable to become pregnant and I/we are eager to have a child.

I/We understand and acknowledge that Regional One Health is a medical practice in reproductive endocrinology and operates a laboratory 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. I/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.

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

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

1. Determination by certain tests that I/we are suitable candidates for the procedure. The evaluations will include detailed medical histories, physical examinations, and laboratory tests including (but not limited to) tests for general health, HIV infection, and psychosocial assessment. The evaluation will minimize, though it cannot eliminate, the possibility of passing on a genetic or infectious disease. I/We represent and-warrant that, to the best of our knowledge and belief, all medical and genetic information I/we provide to Regional One Health and UT Regional One Physician, Inc. will be true, correct and complete.
2. A suitable donor has to be matched with us. With the assistance of Regional One Health and UT Regional One Physicians, Inc. and/or a third party donor recruitment agency, I/we may select an anonymous donor, whose identity will not be revealed to us and who will not be aware of our identity. A separate agreement with the Donor to donate her eggs will be exercised by the third party agency, which I/we have chosen.
3. Regional One Health and UT Regional One Physicians, Inc. make no representation or warranty, expressed or implied, as to the accuracy or authenticity of information furnished by the donor and/or the third party agency.
4. For our treatment cycle, the patient's endometrial (uterine lining) maturation will be induced with hormones (estrogen and progesterone) replacement to achieve the thickness needed for embryo implantation. Some of these hormone therapies might require the patient to perform self-injection on a daily basis. When the lining is adequately prepared, the oocytes will be thawed and fertilized with the partner's or sperm donor's sperm (if applicable).

5. The fertilization process requires performing Intracytoplasmic Sperm Injection (ICSI) - the process of inserting a single sperm into a mature egg - and a separate consent will be required. This procedure will allow for (i) optimization of the sperm's ability to fertilize an egg; (ii) putting a single sperm into a single egg overcomes failed fertilization due to sperm factor; (iii) overcoming concern of poor sperm attachment that may lead to failed fertilization. The risks of the procedure include: (i) death of the egg (less than 1 in 1000); (ii) inheritable male factor infertility (in select cases where the cause of infertility is an inherited sperm factor).
6. The embryologist at Regional One Health will perform the procedures that are deemed necessary to optimize the chance of successful implantation. Some of the procedures, described below, will be adopted and applied at the discretion of the physician and the embryologist at Regional One Health. These procedures may consist of one or more of the following:
    A. 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 1000); (2) identical or conjoined twinning (less than 1 in 100).
    B. 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.
7. The male partner will provide sperm specimen on the day of the oocyte thawing to be used for fertilization of the thawed Donor oocytes. If I/we have previously agreed that donor sperm will be used for fertilization, then this procedure will have been separately explained and a separate consent will be obtained.
8. Fertilizing the Donor's oocyte(s) by means of ICSI under controlled environmental conditions to allow conception to occur.
9. After fertilization, transferring the oocyte(s) into a controlled culture environment to optimize for growth. A successfully fertilized egg is referred to as an embryo.
10. After several days of growth, the patient will undergo an embryo transfer where the best embryo(s) will be placed into her uterus by means of a small catheter inserted through the cervix. The patient will continue her scheduled hormone replacement treatment to assist in implantation.
11. Pregnancy will be determined by a blood test within 14 days of embryo transfer.

I/We recognize and understand that a child conceived after frozen oocyte adoption and embryo transfer will not have the patient's genetic make-up, but will have that of the Donor and the male partner's (or sperm donor, if applicable).

Furthermore, I/we agree that the patient will be the legal mother for all purposes and the male partner will be the legal father for all purposes of any child born to the patient as a result of Frozen Donor Oocyte IVF/ET.

I/We understand that up to four (4) of our developing embryos may be transferred to the uterus. I/We have been told that this could result in multiple gestations (twins, triplets, etc.) with an increased risk of premature delivery, and an increased financial and emotional burden.

I/We acknowledge that a successful pregnancy after Frozen Donor Oocyte IVF/ET cannot be assured and that Regional One Health and/or UT Regional One Health Physicians, Inc. have made no such representation or guarantee. I/We understand that a number of occurrences may prevent the establishment of a successful pregnancy, including:

a. Frozen Donor's oocyte(s) may not be normal.
b. The male partner (or the donor, if applicable) may not be able to supply an adequate semen specimen.
c. Fertilization between frozen donor oocytes and the male partner's sperm may not occur.
d. Growth or cell division of any of our embryo(s) may not occur.
e. Our embryo(s) may not develop normally.
f. Implantation of the embryo(s) into the lining of the patient's uterus may not occur.
g. An unforeseen laboratory event may result in loss or damage of oocyte(s), sperm or embryo(s).

Patient's Initials _____
Partner's Initials _____

I/We understand that, if pregnancy is successfully established, there is a risk of miscarriage (approx. 1 in 6 to 8), ectopic (tubal) pregnancy (1 in 30), stillbirth and/or birth defects. At present, available research does not indicated a greater risk of birth defects following Donor oocyte IVF/ET as compared to equal-age women conceiving naturally. Nevertheless, I/we acknowledge that Regional One Health and/or 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. I/We understand that pregnancy after Frozen Donor Oocyte IVF/ET may be at increased risk of premature labor or delivery. This may lead to complications of prematurity for out child and its associated financial and emotional costs.

I/We understand that a number of risks and discomforts may be associated with this procedure, including:

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

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; (iii) if more than one embryo is transferred, that multiple pregnancy (twins, triplets, etc.) may occur; (Iv) that a pregnancy may occur in the tube (ectopic pregnancy), and require major surgery for treatment.

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.

I/We agree to assume complete responsibility for any embryo, fetus, or child developing from the donated oocyte(s), from the time of retrieval and all time thereafter. I/We agree to assume complete parental responsibility for any child born to the patient as a result of Frozen Donor Oocyte IVF/ET, regardless of the genetic make-up or physical or mental characteristics of the child at birth or at any time thereafter.

I/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 our eggs, sperm or embryo(s) cease to be viable while in the custody of Regional One Health or UT Regional One Physicians, Inc.

I/We fully understand that insurance coverage for any or all of the above procedures may not be available and that I/we will be personally responsible for all the expenses of this treatment including those associated with the Donor. The expenses may consist of medication costs, hospital fees, laboratory fees and/or physician professional fees.

I/We understand that Regional One Health or UT Regional One Physicians, Inc. will ***not*** voluntarily disclose to us the identity of the donor. Conversely, I/we understand that Regional One Health and UT Regional One Physicians, Inc. will ***not*** voluntarily disclose to the donor our identity or the identity of any child born to us as a result of egg donation. It is remotely possible, however, that Regional One Health and UT Regional One Physicians, Inc. could be compelled, through legal process, to disclose identities and I/we

Affix Patient Label

Patient's Initials _____
Partner's Initials _____

understand and acknowledge that absolute anonymity cannot be guaranteed. I/we agree that I/we will make no attempt to obtain the identity of the donor. I/We also understand that the donor will not be informed of pregnancy or childbirth as a result of her donated eggs, and has agreed to make no attempt to obtain the identity of any such child. The confidentiality of identities is not applicable to situations where the donor and I/we are already aware of each other's identities and our donor egg IVF/ET procedure is a result of direct prior arrangement with the donor.

I/We consent 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.

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 UTCRM 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).

I/We understand that all information about us obtained during the program will be handled confidentially and that neither our identities nor specific medical details will be revealed without our consent. Specific medical details may be revealed in professional publications as long as our identities are concealed.

The nature of Frozen Donor Oocyte IVF/ET has been explained to us, together with the known risks. I/We understand the explanation that has been given us and that there may be unknown risks.

I/We acknowledge that I/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, I/we consent to the medical procedures described in the consent form. I/We acknowledge that I/we understand all medical terminology contained in this consent and have had all our questions answered. I/We acknowledge and affirm that I/we have given our consent and signed this consent form without coercion or complication and of our own free will.

_____
Patient Signature Date

_____
Partner Signature Date

_____
Patient Printed Name

_____
Partner Printed Name

_____
Witness Signature Date

_____
Witness Printed Name

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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]

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Partner's Initials _____

[Notary Page for: Consent for Frozen Donor Oocyte In Vitro Fertilization and Embryo Transfer (Recipient)]

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 _____