Consent for In Vitro Fertilization with Donor Oocyte: Donor - Patient/Husband

Name of Patient: ______________________________ Name of Partner: ______________________________

I, the Patient, and my husband (if applicable) named above, are each over the age of twenty-one (21) years. I am a healthy female and request, authorize, and consent to donating my oocytes (eggs) for the performance of donor oocyte (egg) in vitro fertilization and embryo transfer (Donor Egg IVF/ET) intending to create pregnancy for a recipient. Donation of some of my eggs will provide an opportunity for pregnancy for individuals who could not otherwise conceive or, because of risks of transmitting a genetic disorder, wishes not to conceive their own genetic child.

I understand that the recipient is over the age of twenty-one (21) years. She/They have requested eggs from a donor to use at time of IVF/ET and is/are the intended parents of any child(ren) conceived and delivered through this procedure.

I understand and acknowledge that Regional One Health is a medical practice in reproductive endocrinology and will be managing my egg donation and performing my procedures. The Embryology laboratory at Regional One Health is responsible for my oocyte (egg) identification and micromanipulation, as indicated. I understand and agree that I will be evaluated for medical and psychological characteristics that might make me unsuitable as an egg donor. The evaluation will include a detailed medical history and physical examination, laboratory tests including tests for HIV, substance abuse, psychological evaluation, and genetic screening. The evaluation will enable Regional One Health to make an optimal recipient-donor match. I represent and warrant that, to the best of my knowledge and belief, all medical and genetic information I provide to Regional One Health will be true, correct and complete. I understand and agree that the physician in charge at Regional One Health will make the final approval of my egg donation to the recipient couple and her decision will supersede all other prior arrangements.

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

a. A detailed medical history and physical examination will be performed on me to determine if I am a suitable candidate for egg donation.

b. In addition, laboratory tests including (but not limited to) tests for HIV, substance abuse, and genetic disease as well as psychological evaluation will be performed to determine if I am a suitable candidate for egg donation. If I am married, my husband may be asked to attend the psychological evaluation and possibly be tested for infectious disease, as well.

c. The use of medications to stimulate and mature multiple eggs from my ovaries. Many of these medications will require me to perform self-injection on a daily basis. Before the eggs are released from the ovaries, collection (retrieval) of my egg(s) will be performed. I understand and acknowledge that Regional One Health is a medical practice in reproductive endocrinology and operates a laboratory responsible for my IVF cycle management and laboratory testing and services, including semen analysis, sperm preparation, oocyte (egg) identification and preparation, embryo culture, embryo micromanipulation, and cryopreservation. Blood work will be performed to monitor the growth of my ovarian follicle(s) containing the egg(s).

d. The performance of ultrasound examinations to assist in assessing the development of the follicles. Ultrasonography is a diagnostic procedure which uses sound waves to provide a "picture" of the ovaries and the growing follicle(s).

e. Retrieval of the eggs from my follicles, which may be done by one or more of the following methods:
   i. Ultrasound-guided trans-vaginal aspiration through a needle directed through the vagina into the follicle.
   ii. Ultrasound-guided trans-abdominal aspiration where the needle is directed through the skin of the lower abdomen and into the follicle.
   iii. Laparoscopy, a procedure, in which a tube containing a light and lenses is introduced through the navel to allow seeing the ovaries and tubes. This procedure has been separately explained, and a separate consent will be obtained as is routine.

f. After retrieval, my involvement is complete and all of my eggs will be retained by Regional One Health for donation to the recipient couple(s).

Because there is a possibility that I could become pregnant during or immediately after egg donation, I understand that unless I have undergone a form of permanent sterilization, I must properly use a barrier form of contraception (condom or diaphragm) or practice complete sexual abstinence during this time. No other form of contraception is acceptable during egg donation. Furthermore, I agree that if I inadvertently expose myself to unprotected sexual intercourse during egg donation, I will immediately inform my physician at Regional One Health.

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

a. From the blood tests: (i) mild discomfort and bruising at the needle site; (ii) anxiety and stress from the revelation of underlying disease not previously known to me.
b. From psychological evaluation: (i) anxiety and stress from the questions asked during the examination; (ii) marital stress if my spouse is asked questions during the examination.
c. From the self-injected medications: (i) mild discomfort and bruising at the needle site; (ii) a small risk (1 in 200 women) of developing ovarian hyper-stimulation syndrome (OHSS), the consequences of which may be serious and, if untreated, include stroke and death; (iii) the possibility of an increased risk of developing an ovarian tumor 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 ovarian tumors with fertility treatment, this risk has not been conclusively disproved.
d. From ultrasound-guided egg retrieval or the laparoscopy: (i) the moderate discomfort after the procedure; (ii) the risk (1 in 400) of bleeding, infection, or injury to the abdominal organs that may require immediate major surgery; (iii) the risks associated with the general or local anesthesia; and (iv) the risk of having blood in the urine for a few days after the procedure.
e. Psychological stress.

I understand and agree that I will immediately notify my physician at Regional One Health in the event of any changes in my medical condition or of any new medications that I will be taking other than prescribed by my physician at Regional One Health. I agree that from the time I am accepted as an egg donor until my eggs are retrieved, I will not ingest or inhale any nicotine product.

I understand and agree to waive any and all rights I might otherwise have with regard to any egg(s) recovered by the procedures described in this Consent Form. If applicable, my husband also agrees to waive any and all rights he might otherwise have with regard to any of my egg(s) recovered by the procedures described in this Consent Form. The physician in charge at Regional One Health shall have the sole right to possession of the egg(s) and to determine who the recipient(s) will be.

By my agreement to participate, I hereby waive any and all parental rights I might otherwise have with regard to any child born to the recipient patient as a result of my egg donation. At the moment of embryo transfer to the recipient patient and at all times thereafter, full parental rights will be vested in the intended parents, the recipient patient and her husband, if applicable. Furthermore, I agree that I will not have any right or otherwise be entitled to custody, visitation, or any other incident of parenthood, nor will I be entitled to know the identity of the recipient parents or their child(ren), absent their consent.

I understand and acknowledge that one-half of the genetic make-up of any child conceived as a result of my egg donation will be attributed to me. It is possible, though unintended and highly unlikely, that I (or my husband, if applicable) may incur legal responsibilities which are as yet unforeseeable due to the lack of legal precedent. This may include, but is not limited to, the establishment of legal parentage, child support, or custody obligations.

If I am participating as an anonymous donor, I agree that I will make no attempt to obtain the identity or address of the intended parents. I also understand that I will not be informed of pregnancy or childbirth as a result of my donated eggs, and I agree to make no attempt to obtain the name or address of any such child(ren).

I understand that I will not be financially compensated for my time, effort, and expenses by Regional One Health or UT Regional One Physicians, Inc. and that compensation will be honored by a third party agency as set forth in a separate consent/contract. I agree that under no circumstances explicitly seek financial compensation directly from the recipient couple.

Patient’s Initials ________

Partner’s Initials ________

Notwithstanding any provision in this agreement or in any agreement of a third-party agency, all payments to me are contingent upon my timely compliance with all responsibilities explicitly imposed upon me by the terms of this agreement.

I understand that Regional One Health will not be charging me or my health insurance company for tests and procedures needed for egg donation. I am aware that the recipient couple is required to purchase a medical insurance policy to cover unanticipated and unforeseen complications or injury to me resulting from egg donation. Since this policy will only pertain to complications and injuries sustained as a direct result of egg donation, I acknowledge and agree that I have been strongly advised by Regional One Health to maintain my own medical insurance before, during and after egg donation in order to cover medical expenses not related to egg donation or that may be required to treat medical conditions discovered during my evaluation.

If I withdraw from egg donation for any reason, I understand and agree to immediately return any unused medications and supplies or be charged for the costs of the same.

I understand and acknowledge that Regional One Health and UT Regional One Physicians, Inc. has no responsibility for any psychological, social, medical, or economic consequences which occur secondary to the identification of any medical or psychological abnormality or condition from Regional One Health's evaluation of me or my husband (if applicable) which is not a complication, injury, or pregnancy caused by egg donation.

I 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.

I further understand that data from my Assisted Reproductive Technology (ART) procedure (egg donation) will also 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. 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. 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). I understand that this means that any information that CDC has that identifies me will not be disclosed to anyone else without my consent.

I understand that the results of my medical tests and other protected health information will be revealed to me but are otherwise subject to the Privacy Notice of UTCRM-ROH created in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Regional One Health and/or UT Regional One Physicians, Inc. will disclose my protected health information to the recipient couple. I understand and acknowledge that, in extraordinary and unforeseen circumstances and with my consent, Regional One Health and UT Regional One Physicians, Inc. may provide only my pertinent genetic and medical information to medical providers of a child conceived through my egg donation, to allow for optimal medical treatment of that child. This information will not include my personal identity unless otherwise required by law. In addition, I agree that specific medical details may be revealed in medical and scientific publications as long as my identity is concealed.

I understand that Regional One Health or UT Regional One Physicians, Inc. will ***not*** voluntarily disclose the identities of the recipient(s) or any child born to the recipient(s) as a result of my egg donation. Conversely, I understand that Regional One Health and/or UT Regional One Physicians, Inc. will ***not*** voluntarily disclose my identity to the recipient couple or any child born to the recipient patient as a result of my 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 my identity and I understand and acknowledge that absolute anonymity cannot be guaranteed. If I am participating as an anonymous donor, I agree that I will make no attempt to obtain the identity of the intended parents. I also understand that I will not be informed of pregnancy or childbirth as a result of my donated eggs, and I agreed to make no attempt to obtain the identity of any such child. The confidentiality of identities is not applicable to situations where the recipient couple and I are already aware of each other's identities and my egg donation is a result of direct prior arrangement with the recipient couple.

Patient's Initials ________

Partner's Initials ________

I understand that my participation in egg donation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which I might otherwise be entitled. I am under no obligation to continue to participate as an egg donor and can freely and immediately withdraw before the beginning of any treatment cycle. If I withdraw after the start of ovarian stimulation but prior to egg retrieval, however, I acknowledge an increased risk of ovarian hyperstimulation (1 in 200 patients) and pregnancy.

I understand that my acceptance as an egg donor is conditioned upon my adherence to the terms and conditions of this consent form, and agree to at all times abide by its terms and conditions. In the event that I withdraw from participation as an egg donor as provided above, I will remain bound by the terms and conditions of this consent form with regard to all events occurring either prior to or after such withdrawal, notwithstanding discontinuation of my active participation. I intend that the terms and conditions of this consent form will be binding on me and my husband, respective heirs, executors, administrators, representatives, and assigns.

I acknowledge that I have fully reviewed and comprehend the contents of this consent form. The nature of egg donation has been explained to me, together with known risks. I have had the opportunity to ask any questions I might have and those questions have been answered to my satisfaction. I acknowledge that egg donation is being performed at my request and with my consent. I understand that I may elect not to continue with the procedure at any time and that this decision would not affect any other present or future medical care and treatment from either Regional One Health and/or UT Regional One Physicians, Inc..

With full knowledge and understanding of the attendant risks and consequences of my participation, I consent to the medical procedures described in this consent form and agree to participate as an egg donor. I acknowledge and affirm that I have given my consent and entered into this consent form without coercion or compulsion and of my 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.

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Physician Signature Date

____

Physician Printed Name

[Notary Page to follow]

Patient’s Initials ________

Partner’s Initials ________

[Notary Page for: Consent for In Vitro Fertilization with
Donor Oocyte: Donor - Patient/Husband]

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 “Husband”.

My commission expires: ____ .

____
Notary Public