Consent to Cryopreservation (Freezing) and/or Storage of Oocytes: Cancer Patients

I, _____ (Patient), wish to use the services and facilities of the in vitro fertilization (IVF) laboratory at Regional One Health (ROH) for collecting, culturing, in vitro maturation (IVM), freezing, storing and/or keeping custody of my oocytes (eggs) for my future use in fertility treatments, on the conditions set forth in this agreement:

I hereby consent and agree that the employees of the IVF laboratory at Regional One Health (ROH), under the supervision of the Laboratory Director, shall have such authority and control over access to my oocytes as may be necessary for the performance of their duties, relative to the freezing and custody of my oocytes.

I desire to cryopreserve my oocytes because I will be undergoing chemotherapy and/or radiation therapy treatments to treat my medical condition, such as cancer or rheumatologic diseases. Although not all chemotherapy and/or radiation treatments affect fertility (my ability to become pregnant), the treatments I will receive may affect my ovaries and may cause me to undergo menopause after therapy is finished. In order to preserve my future ability to become pregnant, egg banking must take place before my treatment begins.

I acknowledge and recognize that mature eggs can successfully be removed from my ovaries, frozen and subsequently thawed and fertilized with sperm using a technique called in vitro fertilization (IVF). Such fertilized eggs (embryos) have been transferred to the uterus of women who have stored their eggs in this way, and pregnancies have resulted. Results indicate that the infants born from these pregnancies are no more likely to have birth defects than infants conceived naturally.

I understand that this process will require me to undergo an oocyte (egg) retrieval, where my eggs will be harvested from my ovaries, then frozen and stored. The stored eggs will be available to me at any time after the storage procedure if I wish to try to become pregnant. I may also, at any time, elect to have the eggs discarded or donated for research purposes. Any such research will not involve fertilizing the eggs with sperm.

I do hereby agree to be evaluated to confirm that the egg retrieval process will not present an increased risk to me by virtue of my disease or my general state of health. I will also require a blood test to measure my serum follicle stimulating hormone (FSH) to confirm that my ovaries are likely to yield health eggs. I agree to be assessed by my oncologist, the reproductive endocrinologist at UTROP and will meet with a clinical psychologist to ensure that the risks I incur during the process will be acceptably low. These assessments will require one (1) or two (2) additional office visits, each lasting between thirty (30) to sixty (60) minutes.

I have been made aware that egg banking and the subsequent use of my frozen oocytes is regulated by the Food and Drug Administration (FDA). In order to comply with current tissue banking regulations and to be prepared for any future changes in regulations while my eggs are in storage, I agree to be tested and screened for infectious diseases prior to banking to include HIV I, HIV II, Hepatitis B, Hepatitis C and PRP for Syphilis as well as thirty (30) days after the egg retrieval. In doing so, if for any medical reason I may not be able to carry a pregnancy from my own eggs in my uterus, it will still be possible to have my own genetic child/children to be carried by another individual such as a gestational carrier/surrogate, as long as results from both screens are negative.

In order to permit the harvesting of as many oocytes as possible, I acknowledge and accept that I will be treated with a series of hormone injections (gonadotropin) to stimulate my ovaries to develop many follicles with eggs in them simultaneously. Normally, only one (1) follicle with an egg develops in a menstrual cycle. The injections will be given under my skin on a once or twice daily basis for about ten (10) days. My response to these medications will be monitored by blood tests and vaginal ultrasound examinations, possibly resulting in dosage changes during the course of my ovarian stimulation process. Once these monitoring examinations show that my eggs are mature, I will be scheduled for the egg retrieval.

This egg retrieval is an outpatient procedure taking approximately fifteen (15) to thirty (30) minutes during which time I will be given intravenous (IV) administration of pain medication and relaxants (including, but not limited to, fentanyl, versed, Propofol, and/or diazepam) designed to keep me comfortable. These medications usually cause a patient to doze off from time to time, but should not prevent communication between myself and the individuals performing the procedure. The retrievals are done in a procedure room adjacent to the IVF laboratory located at ROH.

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I understand that once sedation has been established, my ovaries will be visualized using an ultrasound probe inserted into my vagina. And that under this ultrasound guidance, a needle will be passed into the ovaries and the follicles to suction the fluid (which contains the egg) out of each, one by one, until all of the follicles have been emptied of fluid. This fluid is then scanned, with the use of a microscope in the IVF Laboratory, to search for the eggs to be frozen, After all follicles are emptied, the procedure will be terminated and the effects of the sedation should be completely gone later that same day.

I understand that my mature harvested eggs will be frozen within a few hours of the egg retrieval. Any harvested eggs that are not mature will be cultured in special fluids (media) in the IVF laboratory for one (1) to two (2) more days in hopes they will mature, at which time they can also be frozen. Although care will be taken, I understand that damage to my oocytes may occur during any part of the cryopreservation (freezing) and storage process and that such risks are inherent in the nature of the process and are beyond the control of the IVF laboratory at ROH.

I hereby release the Regional One Health, UT Regional One Physicians, Inc., and their respective employees, agents, directors, officers, and contractors ("the Releasees") from any claim for injury or damage, known or unknown, that might result should my frozen oocytes cease to be viable while in the custody of the IVF laboratory at ROH.

I acknowledge and agree that, in the event loss, damage or destruction of the oocytes occurs for any reason whatsoever, except as provided in the paragraph above, my actual damages as a result thereof would be impracticable or extremely difficult to determine. Accordingly, I agree that in the event any or all of my stored oocytes are lost, damaged or destroyed for any reason, including equipment failure or unforeseeable natural disasters, but without limitation as a result of the negligence of ROH, I shall be entitled to liquidated damages in the amount equal to the storage fee paid for the term of the storage agreement in which such loss, damage, or destruction occurred.

I further release, discharge, indemnify, and hold harmless the Releasees from any and all liability and responsibility of any nature whatsoever that may result from complications of pregnancy, childbirth, or 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 cryopreservation (freezing) of my oocytes as authorized herein.

I am aware and understand that my oocytes will be kept in the andrology laboratory at ROH up to one (1) year. If I still have stored oocytes remaining after the expiration of the one-year period, they will be shipped by Regional One Health to Fairfax Cryobank (or other cryopreservation storage facility chosen by us) provided that we have (i) signed a storage agreement with the cryopreservation storage facility; (ii) paid the applicable fee for storage to the cryopreservation storage facility; and (iii) ROH has received of notification of such from the cryopreservation storage facility. We understand it is our responsibility to maintain the storage agreement and pay the applicable fee to the cryopreservation storage facility.

I understand that I may choose an entity other than Fairfax Cryobank to provide cryopreservation storage. I further understand and agree that my protected health information (PHI) may be disclosed to the cryopreservation storage facility and I consent to such disclosure.

In the event I have not secured an external cryopreservation storage facility for the cryopreserved oocytes within the one-year period, **I understand that the cryopreserved oocytes will be considered abandoned**. If the cryopreserved oocytes are determined to be abandoned by ROH, I request the following (**initial beside your choice and cross out the other choice**):

_____ _____ a. all the cryopreserved oocytes shall be donated the oocytes for research to the University of Tennessee Health Science Center (UTHSC) for research purposes. Any research performed shall be conducted pursuant to applicable federal and state guidelines Research on embryo(s) will not be continued beyond the 14th day of development and will not be transferred to attempt pregnancy. This disposition releases any and all rights we may have in the cryopreserved embryo(s) and any cell lines, intellectual property, or royalties that may be derived from such work. If state or federal guidelines prohibit such research or if remaining embryo(s) are unused, all embryo(s) may be thawed and destroyed.

_____ _____ b. thaw and destroy all cryopreserved oocytes. This disposition directs ROH to dispose of cryopreserved oocytes in a manner consistent with any federal and state laws one (1) year from the date of cryopreservation.

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I understand there is no limit as to how long my oocytes may be stored at the applicable storage facility, but upon a specified notice time to the applicable storage facility, I can have my cryopreserved oocytes transferred to any future IVF laboratory for the purpose of trying to attain a pregnancy.

I am aware and understand that the long-term safety or viability of cryopreserved oocytes is not completely known. However, oocyte freezing has resulted in the births of hundreds of babies worldwide. Even though this knowledge is present, I acknowledge that my oocytes may not survive the freezing and/or thawing process, or that pregnancy may not result when my oocytes are ultimately used. It has been recommended to me that stored oocytes be thawed and used in fertility treatments within five (5) years of cryopreservation. However, due to my age at the time of the egg retrieval, freezing and storage, I understand that longer storage time may be necessary until I become of age to begin fertility treatments and that studies have shown that some oocytes thawed after five (5) years have been successful when used in fertility treatments. Nonetheless, I understand my storage contract for my oocytes is based on an annual renewal.

If I should die or become mentally incompetent while any of my cryopreserved, stored oocytes are still in possession f the IVF laboratory at ROH, I hereby authorize, direct and consent to the taking of the action I have marked below. I hereby consent thereto (**initial next to your choice and cross out the other choices**):

_____ _____ a. my surviving, mentally competent and legal spouse or partner at the time of my death or incompetence shall have authority to direct oocyte usage and storage;

_____ _____ b. donate all stored oocytes to UTHSC for research purposes as describe in the paragraph above; or

_____ _____ c. thaw and dispose of all stored oocytes in accordance with applicable federal and state laws.

I fully understand that insurance coverage for any or all of the above procedures may not be available and that I will be personally responsible for the expenses of this treatment and the annual storage fee. The expenses may consist of hospital charges, laboratory charges, and/or physician professional fees.

I understand that all information obtained about me during the program will be handled confidentially and that my identity will not be revealed without my consent. However, specific medical details may be revealed in professional publications as long as my identity is concealed.

I understand it is my responsibility to inform the IVF laboratory at ROH of any future changes in my mailing address. My current mailing address is:

_____ (street)

_____ (city, state, zip)

I acknowledge that I have fully reviewed and comprehended the contents of this consent form. The nature of oocyte cryopreservation has been explained to me, together with the known risks. I understand the explanation that has been given me and that there may be unknown 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 oocyte cryopreservation and/or storage is being performed at my request and with my consent. I acknowledge and affirm that I have given my consent and signed this consent form without coercion or compulsion and of my own free will.

Affix Patient Label

Patient's Initials _____

_____ _____
Patient Signature* Date Parent or Guardian's Signature Date

_____ _____
Patient's Printed Name Parent or Guardian's 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 _____

[Notary Page for: Consent to Cryopreservation (Freezing)
and/or Storage of Oocytes: Cancer Patients]

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" or parent or guardian of "Patient".

My commission expires: _____ .

_____
Notary Public

Affix Patient Label

Patient's Initials _____