MPI # _____

REPRODUCTIVE ENDOCRINE ASSOCIATES OF CHARLOTTE, P.C.

Consent Form For Embryo Thaw

INFORMED CONSENT

We, _____(Female Patient)

And _____(Partner),

(Print names as appear on driver's license)

desire to have our frozen embryos thawed at REPRODUCTIVE ENDOCRINE ASSOCIATES OF CHARLOTTE, P.C. ("REACH") for the purpose of uterine transfer. We understand that there are a number of steps to this procedure, and that starting this process does not guarantee that we will complete the process, achieve pregnancy, or that a healthy child will be delivered. One of our physicians has discussed with us the nature of our condition and alternative therapies, if any, that are available. We understand that the Female Patient (or gestational carrier - if indicated) may receive medication to prepare the uterus for pregnancy and that when embryos survive the thaw process in adequate condition, they will be transferred into the uterus using an out-patient procedure.

A. General Description of The Procedure

We understand that _____ embryos are presently cryopreserved and we would like to have _____ embryos thawed with intent for uterine transfer, in accordance with that document titled 'Disposition Instructions For Cryopreserved Embryos'. Not all embryos may survive the cryopreservation and thawing process. If for whatever reason more embryos survive the thawing and culture process than requested or thought appropriate for uterine transfer , then such embryos may be refrozen. However, to be refrozen, the embryos must be of excellent morphological characteristics and this decision will be at the discretion of the embryologist team. We understand that in our case the embryologists may have to thaw additional embryos, if available, to obtain the desired number of viable embryos for the intended uterine transfer. In some cases, none of the embryos may survive the thawing process. Sometimes embryos only partially survive the thawing process. Such embryos may be healthy and able to develop into a normal pregnancy but the rate of success may be diminished. The embryologist will have to use his or her professional judgment regarding which embryos appear viable for uterine transfer, and which embryos appear non-viable to be discarded. The thaw survival rate of embryos may vary between attempts and may have little to do with changes in thaw procedure and can be the result of natural variance and sensitivity between embryos.

We understand that if our embryos were frozen in an IVF program other than REACH, or were transported to the laboratory, survival may have been affected by accidental thaw prior to the arrival in the laboratory at REACH. Also, embryos that come cryopreserved

and transported from other programs may have a lower prognosis than those fertilized and cryopreserved by the laboratory team at REACH. Survival rates of embryos from other programs are therefore unpredictable.

We understand that it is the general policy of this program to transfer a restricted number of embryos for IVF, in order to minimize the risk of multiple gestation (more than one baby) while maintaining high per-cycle success rates of the procedure. We understand that this ratio is dependent on the maternal age, the previous medical history, the number of embryos frozen and thawed, and the quality of the thawed embryos as judged by the embryologist after thaw. We also understand that the ability of an embryo to develop into a baby cannot be accurately determined by the embryologist. We understand that any excess cryopreserved embryos will be maintained in storage for us, we will continue to be our responsibility, and will be managed as directed in our original cryopreservation consent, if executed with REACH, or a new consent with REACH, if not original executed with REACH. We understand that although to date, there have been no observed generalized detrimental effects in children born from cryopreserved embryos as an independent factor, there can be no guarantee as to the normalcy of any pregnancy that develops following the transfer of a cryopreserved embryo.

B. Timing and Monitoring of Thaw and Transfer; the Preparation Cycle

We understand that the Female Patient will undergo one (1) of two (2) protocols for the preparation of the uterine lining prior to embryo thaw and transfer. The first protocol relies on the body's own stimulation of the lining during a natural (non-medicated) menstrual cycle. Using blood tests and ultrasound examinations, the physicians will determine the proper timing for the thaw and subsequent transfer of the embryos. Risks for this approach involve those of blood drawing only. Should the natural preparation of the lining be less than adequate, the embryos will remain cryopreserved and the transfer will be deferred to another cycle.

The second method of preparation involves the use of medication to suppress the body's normal stimulation of the ovaries, followed by the use of estrogen to specifically stimulate the growth of the uterine lining. The changing of the lining is followed by serial blood tests and ultrasound monitoring. Disadvantages to this approach include the possible need for daily injections of Leuprolide Acetate (Lupron). Lupron, when used for long periods of time, may induce symptoms similar to menopause. The use of this medication for the purposes of endometrial preparation does not pose this risk. Advantages of the medicated preparation method include the ability to prolong the period of accessibility of embryos by the uterus if the usual number of days of estrogen administration is insufficient. We understand that if monitoring of steroid administration suggests a low probability for successful pregnancy, then the preparation cycle will be stopped and no embryo thaw will occur. We also understand that we may be given the option of starting the preparation procedure again in a subsequent cycle.

C. Embryo Culture and Embryo Transfer

We understand that our embryos will be placed into the uterine cavity of the female patient (or gestational carrier – if indicated) immediately after thaw or alternatively one or

several days later. Timing of transfer is dependent on the stage at which the embryos were frozen. In some cases, embryos were frozen and stored at different stages of growth. This may result in several thaw sessions on different days. In general, only one attempt at embryo transfer will result, even though embryos may be at different stages. The choices made by clinicians and embryologist will depend on the stage of the embryos, their condition, the day of the preparation cycle and the uterine response. We know that some patients have embryos that develop slowly, or show different forms of microscopic anomalies, such as fragmentation and multi-nucleation, which may or may not be significant for the ultimate prognosis of such embryos causing pregnancy. Such observations may be due to a sensitivity of the embryos to the standard culture conditions in the laboratory, or may reflect inherent biologic issues of the embryo itself.

For an embryo transfer, a thin catheter will be passed through the cervix and into the uterus so the embryo may be deposited there. We understand that this procedure may involve some cramping and discomfort, and possibly a small amount of bleeding. Infection could be introduced at the time of the catheter insertion to the uterus, requiring antibiotic therapy. We understand there is no guarantee that any of the embryos thus transferred will result in a pregnancy.

We understand that the success of embryo thaw can often relate directly to the number of embryos transferred to the uterus. We also understand that this may significantly increase the risk for multiple gestation (more than one baby), and that this risk also correlates directly with either the number of embryos transferred, their development, the age of the female partner (or egg donor), the number of prior attempts, and other unknown factors. We also understand that in rare cases, an embryo may split by itself, thus resulting in multiple fetuses. (On occasion, this can mean that there are more identified fetuses than the number of embryos transferred.) There are distinct obstetric risks to multiple gestations, the most serious of which are pre-term labor and the delivery of premature infants who require intensive care. The number of embryos for uterine transfer is dependant on availability and factors such as maternal age, cycle attempt, and embryonic parameters.

D. Disposition of Unwanted or Unsuitable Embryos

We understand that certain of our embryos or their cells may be considered unwanted and abnormal when they do not survive, partially degenerate or, for any other reason, are unsuitable for embryo transfer. We understand that they may be observed to determine cellular inclusions, genes, gene mutation, proteins and chromosomes; and that such continued observation uses protocols that ultimately end all growth. We understand that these abnormal embryos or their cells will never be used for purposes other than those described herein and will never be offered to other individuals, couples, or institutions, for any intent of clinical use.

E. Use of Blood Products

Human serum albumin, a commercially prepared blood product for clinical laboratory use may be added to thaw and micromanipulation fluids. Careful screening is done by the manufacturers to reduce the likelihood of transmission of infectious diseases such as HIV, Hepatitis B and C. To date, there have been no documented cases of disease transmission

linked to human serum albumin usage at REACH. In spite of all these precautions, we understand and accept the risk that in extremely rare instances use of these blood products could result in the transmission of HIV, Hepatitis and/or other viral, or possibly as yet unknown non-viral, diseases.

F. Use of Chemical Substances, Disposable Items and Mechanical Devices During the Procedures

A large number of chemical substances (sugars, salts, enzymes, proteins), mechanical devices (incubator chambers, microscopes, air handling systems, filters, standard laboratory equipment) and disposable items (pipettes, Petri dishes, flasks, micro tools) are used during and after the thaw. There may be unknown risks associated with the use of any of these items that cause your thaw procedure to fail, even though checks and quality control measurers are performed on a regular basis. Thus far, we do not know of any association between the use of these materials, those used during freezing, and anomalies of pregnancy and fetal development, but underlying unidentified problems may nevertheless exist.

G. Risks Associated With Embryo Thaw / Transfer Procedures

Based on current medical knowledge, we understand there does not appear to be a higher incidence of birth defects associated with thaw procedures of embryos resulting from IVF or ICSI. However, there is not at present sufficient statistical data available to definitively conclude that this is so. Therefore, we understand that embryo thawing may impose risks to the fetus during development. We also understand that because more than one embryo may be transferred, there may be a higher incidence of multiple births. An embryo may split when inside the uterus, forming monozygotic twins and there may be other associated anomalies. In certain cases, fetal reduction may be considered if more embryos implant than can be medically (or personally) deemed advisable to carry through a pregnancy. We also understand that it is possible for ectopic or tubal pregnancies to occur despite placement of embryos into the uterine cavity. These associated potential clinical complications can produce increased financial and emotional burdens.

H. Success Rate and Outcome

In synopsis of the above descriptive material, we understand that failure to obtain a pregnancy may result from many reasons, including the following:

(1) The gametes obtained from either partner or donor may have been abnormal, with subsequent development of abnormal embryos.

(2) The embryos may not survive the thaw.

(3) The embryos may only partially survive thaw. Some of these embryos may be judged abnormal and not transferable, others may be considered partially viable. The success rate of partially viable embryos is low.

(4) Growth of the embryo(s) after thaw may not occur at all or the embryo(s) may not develop normally.

(5) The embryo(s) may become infected by viral or bacterial contaminants in the laboratory, or an unforeseen laboratory accident may result in loss or damage to the embryo(s).

(6) The embryo(s) may become contaminated by viruses or bacteria in the vagina, cervix or uterus.

(7) Some thawed embryos may not develop well even when in approved commercial culture medium in spite of standard testing.

(8) Implantation of the thawed embryos(s) in the uterus after embryo transfer may not occur, or an early pregnancy loss may occur after an initial positive result.

(9) Even if a pregnancy is established, we understand that delivery of a child may not occur due to miscarriage, ectopic pregnancy (outside the uterus), stillbirth, or other complications associated with pregnancy and delivery.

(10) There may be unknown side-effects from any of the procedures used resulting in abnormal pregnancy or abnormal fetal development.

(11) Clinically un-useful and discarded material from our procedure may be observed or studied for research purposes.

We understand that the members of the IVF team cannot guarantee that a pregnancy will result from this thaw procedure. Even in normally fertile couples, the chance of pregnancy is approximately twenty-five percent (25%) in a natural menstrual cycle. If no pregnancy occurs, we may be offered participation in future cycles when assessment by the IVF team reveals no contra-indications. We understand that the IVF team cannot guarantee the normality of any child resulting from this procedure.

I. Confidentiality

We understand that we may at any time decide to withdraw from participation in this program without prejudice. Any information obtained during this procedure and identified with us will remain confidential and will be disclosed only with our permission. Any publications resulting from this procedure will not identify us individually. Representatives of The Food and Drug Administration (FDA), The Center for Disease Control (CDC), and The Department of Health of North Carolina may inspect the records.

J. Execution of Consent

By signing this form below you expressly indicate and certify the following:

(1) That you have read and understand each and every provision herein;

(2) That you have been given the opportunity to review this document with any and all third parties of your choosing;

(3) That you have been given an opportunity to ask any and all questions;

(4) That for each question you have asked, you have received a satisfactory answer;

(5) That you know that you may ask additional questions at any time in the future;

(6) That you may discontinue this program at any time in the future; and

(7) That you are over the age of twenty-one (21).

_____ _____

Female Patient's Signature Date

_____ _____

Partner's Signature Date

_____ _____

REACH representative verifying completion of consent Date

_____ _____

Witness – if signed outside of REACH Date