Female Patient Name: _____ Social Security #: _____

Partner's Name: _____ Social Security #: _____

Karande & Associates, S.C.

InVia Fertility Specialists

ASSISTED REPRODUCTIVE TECHNOLOGIES PROGRAM (A.R.T.)
EMBRYO THAW AND TRANSFER CYCLE

Description, Explanation and Informed Consent

We, _____, being partners in a relationship, request and authorize INVIA FERTILITY SPECIALISTS to thaw our frozen embryos in an attempt to create a pregnancy. We understand that freezing (cryopreserving) of human embryos is a procedure that can be utilized to preserve embryos so that they may be transferred at a later date. We understand that the cryopreservation process requires the treatment of embryos with chemicals known as cryoprotectants and that these chemicals must be removed from the embryo(s) before transfer to the woman's uterus or fallopian tube(s). It is our understanding that thawing of our embryos will be performed at INVIA FERTILITY SPECIALISTS.

DESCRIPTION AND EXPLANATION OF THE PROGRAM

We understand that preparation for the transfer of cryopreserved embryos to the woman's uterus or fallopian tube(s) involves the following procedures:

1. Determination by standard infertility tests that we are suitable candidates for a frozen embryo transfer.
2. Ultrasound examinations combined with blood tests to determine the suitability of the uterine lining for reception of the embryos.
3. The use of "fertility medications" such as Lupron, an estrogen preparation (i.e. Estrace, Estraderm patches, or Estratiol valerate) and progesterone to prepare the uterine lining for embryo implantation and development.
4. Thawing of the cryopreserved embryo(s) and removal of cryoprotectants.
5. In some situations, a micromanipulation technique called Assisted Zona Hatching (A.Z.H.) is performed prior to embryo transfer to increase the likelihood of establishing a pregnancy.
6. Transfer the embryo(s) to the female patient's uterus or fallopian tubes by means of a plastic catheter (tube).
7. Obtaining blood samples and, if indicated, ultrasound evaluations several times in the subsequent 8-12 weeks to determine if pregnancy has occurred and is proceeding normally.

REASONS FOR ADVERSE RESULTS

We have been informed that embryo survival, becoming pregnant, or a successful outcome of pregnancy cannot be assured after cryopreservation procedures. We are aware and understand that the practice of medicine is not an exact science and that no guarantees have been made to us as a result of this procedure.

We have been informed that there are many complex and sometimes unknown factors that may limit pregnancy rates in frozen embryo transfer cycles. Some of the known factors that may prevent the establishment of a pregnancy or may lead to interruption of an attempt include:

- Irritation, redness, or swelling may result from the injection of medications necessary to prepare and maintain the uterine environment.

- Hemorrhage, hematoma and/or infection may result from frequent blood drawing.
- Administration of Lupron may cause localized redness, swelling, or itching at the injection site. In addition, some of the possible side effects include hot flashes, irritability, vaginal dryness, headaches, and sleep disorders.
- Administration of Progesterone may cause the woman to feel pregnant. Side effects include: bloating, nausea, depression, increased appetite, weight gain, fatigue, sleepiness, headache, and sleep disorders.
- Administration of Estrogen preparations is correlated with the method of administration. Patches may cause localized reactions, redness, swelling, and itchiness. Injections may cause bruising at the site, swelling, and redness.
- Some or all of the embryos may not survive freezing and thawing, or may survive but develop abnormally.
- Cell division (cleavage) of the embryos may occur.
- Embryo transfer into the uterus may be technically difficult or impossible or medically contraindicated or may be prevented by facility availability or personnel circumstances.
- If transfer occurs, the embryos may not implant and not continue to develop.
- If implantation occurs, the embryos may not grow or develop normally, or a multiple pregnancy, or an ectopic pregnancy or miscarriage may result.
- Equipment failure, infection, and/or human error or other unforeseen circumstances may result in loss or damage to the eggs, sperm, or embryos.
- If pregnancy and delivery occur, the child or children may be stillborn, have chromosomal abnormalities, and/or congenital (birth) defects.
- Psychological stress may result in anxiety and disappointment.
- A substantial amount of time and effort is required of participants in the program.
- Many of the standard products used in cryopreservation procedures and the growth of embryos are derived from biologic origins and, while these products are manufactured under strict quality control, INVIA FERTILITY SPECIALISTS cannot be responsible for unspecified product recalls.
- The long-term effects of cryopreservation on the offspring resulting from the technology are not known.

AGREEMENT AND CONSENT

Each of us understands and agrees that if the exercise of reasonable medical judgment the embryologists and physicians involved in A.R.T. program determine that any embryos are non-viable or otherwise not medically suitable for use or embryo transfer, such embryos will not be transferred in our A.R.T. cycle.

Micromanipulation: We have been informed that Assisted Zona Hatching (A.Z.H.) is a specialized procedure that may be indicated <u>in addition</u> to the Assisted Reproductive Technology procedure already described.

We have been informed that Assisted Zona Hatching is a micromanipulation procedure performed on embryos immediately prior to transfer to the uterus of the woman. We are aware that in this procedure, a small opening is made in the outer shell of the embryo (zona pellucida) to enhance the possibility that the embryo will hatch out of its shell and implant in the uterus. We acknowledge that the procedure has been demonstrated to enhance implantation in some cases and has resulted in many live births worldwide, although the long-term risks are unknown. We understand that a potential adverse reaction is damage to the embryo or total loss of the embryo during the procedure.

We understand that, in general, medical history and results of the fertility evaluation obtained prior to the A.R.T. procedures will suggest if A.Z.H. is appropriate; but that in some cases, observations made by the A.R.T. team during the cycle itself may cause re-evaluation of the need

to utilize this technique. **Unless we have specifically indicated that we do <u>not</u> consent to the use of this procedure and will not be financially responsible for it, we hereby agree that the use of this procedure is at the discretion of the A.R.T. team.**

Each of us represents that we will acknowledge our parentage of any child born to us through this A.R.T. cycle at INVIA FERTILITY SPECIALISTS.

Each of us is voluntarily participating in the A.R.T. program in hopes of having a child through this technique. We acknowledge that we have read and fully understand this consent form and that all our questions concerning the program have been fully answered to our satisfaction.

By participating in this A.R.T. program, we accept the responsibilities, conditions, and risks involved as set out in this document and as explained to us by members of the A.R.T. team. In addition, we consent to all the described techniques and procedures.

Each of us understands that, depending upon the basis of our continued infertility, alternative means of conceiving a child may not be available. However, if alternative means do exist, we have been made aware of those means and the risks inherent in each. We still desire to use the here described A.R.T. technique as our treatment method of choice. We make this choice with the knowledge that the practice of anesthesia, medicine, and surgery is not an exact science and acknowledge that no one at INVIA FERTILITY SPECIALISTS has given us promises or guarantees about treatment, care or outcomes as a consequence of this treatment.

Each of us acknowledges and agrees that our acceptance into the A.R.T. program and our continuing participation is at the discretion of INVIA FERTILITY SPECIALISTS' A.R.T. team. We also understand that we can withdraw from the treatment at any time, without affecting the availability of other, present or future medical care at INVIA FERTILITY SPECIALISTS.

We have been advised and understand that freezing and thawing of embryos has been utilized in hundreds of centers in the world, where specialized equipment and expertise are available, and that thousands of pregnancies and live births of normal infants have resulted. However, we also understand that there may be some effects on the offspring which, at this time, cannot be determined, including risks of genetic abnormalities and birth defects.

The potential benefits from this procedure may be an increased chance of pregnancy without the necessity of multiple surgical interventions for oocyte recovery.

We understand that freezing and thawing may result in damage to the embryo(s), including damage to embryonic genetic material, loss of some embryonic cells or loss of viability of the embryo as a while. We understand that the ability of an embryo to survive freezing and thawing is related to the quality of the embryo prior to cryopreservation.

Female _____ Initials	Partner _____ Initials	As part of our Embryo Thaw and Transfer Cycle, we request that Assisted Zona Hatching be used, if indicated. We acknowledge that we have received information regarding the approximate and anticipated financial costs of the procedures and we accept the full financial responsibility, if our insurance does not cover this procedure, including any increased costs that may arise regardless of the success of the procedure.
Female _____ Initials	Partner _____ Initials	We decline the use of Assisted Zona Hatching (A.Z.H.) during our Embryo Thaw and Transfer cycle.

We are financially able to participate in INVIA FERTILITY SPECIALISTS' A.R.T. program. We acknowledge that we have been given a full description of the costs of our care in the A.R.T. program and agree to be fully responsible for all costs. We also understand that we are

financially responsible for any related medical, professional, or laboratory fees, and any unanticipated costs existing from this cycle.

We agree to disclose such financial information as is required to determine our financial ability to pay for all usual procedures. We understand that delinquent accounts may be referred to an attorney or collection agency and agree to pay reasonable attorney fees, collection costs, and other costs related to collection of delinquent accounts.

It is possible that our participation in INVIA FERTILITY SPECIALISTS' A.R.T. program may aid in the development of new techniques which may help other infertile couples and/or that new and useful information in medical science may be obtained. Therefore, we consent to the taking and publication of photographs and/or audiovisual taping of laboratory procedures involving our participation in the program for the purpose of advancing medical education and research, provided our identity is not disclosed or apparent from the materials. We also consent to the admittance, for the purpose of observation, of other physicians and healthcare personnel during any medical procedures performed on us during our participation in the A.R.T. program. All information obtained during the procedure will be handled confidentially and that neither our identity nor specific medical details will be revealed without our consent. No information about our medical care may be provided to the media by INVIA FERTILITY SPECIALISTS without our consent, if such information endangers the confidentiality of our medical record.

Each of us has been informed that, should we suffer any physical injury as a result of participation in INVIA FERTILITY SPECIALISTS' A.R.T. program medical facilities are available for treatment. We understand, however, that we cannot expect to receive from either INVIA FERTILITY SPECIALISTS, its employees, or any other related third parties, any reimbursement for hospital expenses or any financial compensation for such injury, nor will we make choice to any such entitlement.

We understand the risks/reasons for any potential adverse results. All of our questions about the possible risks/reasons for adverse results of embryo cryopreservation and thaw procedures have been answered to our full satisfaction. The nature and purpose of INVIA FERTILITY SPECIALISTS' A.R.T. program, this specific treatment cycle, possible alternative methods of treatment, the possible risks involved and the possibility of complications have been also explained to our full satisfaction.

Each of us had the opportunity to ask any questions we might have about our participation. We understand that any future questions can always be addressed to members of the A.R.T. team. Our participation is purely voluntary and we understand that we may withdraw our consent at any time.

Federal law requires that all A.R.T. programs report cycle specific data to the Centers for Disease Control (C.D.C.). We understand that to collect these data, it may be necessary for INVIA FERTILITY SPECIALISTS to contact us for follow up after completion of our A.R.T. cycle. We understand that all personal identifiers, submitted with cycle specific data, would be protected under the Federal Privacy Act. However, we further understand that we can elect to **not** have any personal identifiers reported.

Female _____ Initials Partner _____ Initials We authorize the use of personal identifiers in cycle specific data for submission to the Centers for Disease Control.

By participating in INVIA FERTILITY SPECIALISTS' A.R.T. program, we accept the responsibilities, conditions, and risks involved, as set out in this document and as was explained to us by members of INVIA FERTILITY SPECIALISTS' A.R.T. team. In addition, we consent to the techniques and procedures as they have been described in this document, and as INVIA FERTILITY SPECIALISTS' A.R.T. program staff has explained them repeatedly.

We each hereby request and authorize the A.R.T. team to perform the procedures described herein which are deemed necessary for the A.R.T. program. If in the preparation for the procedures contemplated herein, other conditions are discovered or arise, which in the best judgment of any member of the A.R.T. team, make a change or an extension of the original procedure necessary or advisable, we each authorize and request that the A.R.T. team perform such extended or revised procedure or procedures. We each hereby authorize the A.R.T. team to undertake such services and care necessary in conjunction with the procedures which we have authorized the A.R.T. team to perform in relation to the A.R.T. program.

All of our questions regarding INVIA FERTILITY SPECIALISTS' Frozen Embryo Thaw Consent have been answered. Each of us has read and acknowledges receipt of a copy of this consent.

_____	_____	_____
Date	Signature of Female Patient	Female Name – Print
_____	_____	_____
Date	Signature of Partner	Partner Name – Print

As one of the members of InVia Fertility Specialists, by my signature indicate that the foregoing consent was read, discussed and signed in my presence.

_____	_____	_____
Date	Signature of Witness (Female Patient)	Witness Name – Print
_____	_____	_____
Date	Signature of Witness (Partner)	Witness Name – Print

NOTE: If you or your partner are unable to have this consent witnessed by a staff member at INVIA FERTILITY SPECIALISTS or FULL UNDERSTAND THIS CONSENT, please notify the INVIA FERTILITY SPECIALISTS medical staff. We will provide you with further information and a witness. If you wish to sign the consent outside of INVIA FERTILITY SPECIALISTS, please have the consent notarized.

State of _____, County of _____ss., I, the undersigned, a Notary Public in and for

the said County in the State aforesaid; DO HEREBY CERTIFY that

_____
(Female Patient/ Partner)

personally known to me as the same persons whose names are subscribed to the foregoing document before me this day in persons, and acknowledged that he and she signed, sealed and delivered the said document at his and her free and voluntary act, for the use and purposes therein set forth.

Given under my hand and official seal this _____ day of _____, 20_____,

Commission expires on: _____, 20_____.

_____
(Notary Public)

(Notary Seal)