

Female Patient's Name: _____ Social Security #: _____

Partner's Name: _____ Social Security #: _____

**Karande & Associates, S.C. doing business as
InVia Fertility Specialists**

**ASSISTED REPRODUCTIVE TECHNOLOGIES PROGRAM
OOCYTE CRYOPRESERVATION - CONSENT
Description, Explanation and Informed Consent**

We, _____, understand that cryopreservation (freezing) of human oocytes is a procedure that can be utilized to preserve oocytes so that they may be fertilized and transferred at a later time. The members of INVIA FERTILITY SPECIALISTS's staff, along with affiliated Professional Staff, are known as the "A.R.T. Team". We understand that by signing this form, we evidence our consent to the use, by the A.R.T. Team, of assisted reproductive technology procedures in connection with our participation in the Assisted Reproductive Technologies Program. It is our understanding that cryopreservation will be performed by the embryologists at InVia Fertility Specialists.

Description and Explanation of Program

Embryos have been successfully cryopreserved in fertility clinics throughout the past decade. More recently, oocyte cryopreservation has been performed with variable success.

Oocyte cryopreservation provides patients with the option of "oocyte banking", or freezing their eggs for use at a later date. This is especially beneficial for oncology patients or patients wishing to postpone pregnancy until later years. It will also allow oocyte donors to be stimulated independent of recipients. Oocyte cryopreservation also benefits those patients who wish to fertilize only a limited number of oocytes due to religious or ethical reasons. Oocyte cryopreservation may also be employed if for some unexpected reason the male partner cannot produce a semen specimen during the day of egg retrieval.

All cryopreserved oocytes will be frozen using a medically appropriate protocol in the laboratories of Karande and Associates. They will be stored in liquid nitrogen (-196 degrees C) in the laboratories of InVia Fertility Specialists until that time that they will be thawed for attempts at fertilization for transfer into the uterus.

We understand that the Oocyte Cryopreservation involves the following:

1. Determine that we are suitable candidates for oocyte cryopreservation or determine by standard infertility tests that we are suitable candidates for donor oocytes.
2. Collection of oocytes from the Woman's (donor's) ovary(s) by placing a needle into the ovary and aspiration of follicular contents using ultrasound guidance.
3. Collection and preparation of sperm obtained from the Male Partner (by masturbation) for use in attempts to accomplish fertilization.
4. Injecting the sperm into the egg(s) using a micromanipulation procedure called intracytoplasmic sperm injection (I.C.S.I.) after oocyte thawing, in attempt to accomplish fertilization in the laboratory.
5. If fertilization occurs, to permit growth of the embryo(s) for several cell divisions until the embryologist and physicians determine that it (they) can be transferred back to the Woman's (recipient's) uterus or fallopian tubes. In some situations, a micromanipulation technique called Assisted Zona Hatching (A.Z.H.) is used prior to embryo transfer to increase the chances of pregnancy.
6. Ultrasound examinations combined with blood tests to determine suitability of the uterine lining for the reception of embryos.
7. Transfer of the embryo(s) to the recipient's uterus or fallopian tubes by means of a plastic tube.
8. Obtaining blood samples and, if indicated, ultrasound evaluations several times in the subsequent 8-12 weeks to determine if pregnancy has occurred and it is proceeding normally.
9. The use of "fertility medications" including but not limited to Lupron, Estrace and Progesterone.

Reasons for Adverse Results

Each of us has been informed that neither becoming pregnant nor a successful outcome of the pregnancy can be assured as a result of Assisted Reproductive Technology procedures. We have also been informed that we may not have any embryos available for transfer to the uterus after the thawing of the oocytes. We have been informed 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 also been informed that although there are many complex and sometimes unknown factors that may limit pregnancy rates in the Oocyte Cryopreservation Program, some of the known factors that may prevent the establishment of a pregnancy include:

1. Poor or no survival of the oocytes after undergoing the thawing.
2. The sperm may not be able to be collected or processed.
3. Poor or no fertilization of the thawed oocytes.
4. Poor or no development of the resultant fertilized embryos.
5. The eggs and/or embryos may not be genetically normal.
6. One or more oocytes may not be obtained after follicular aspiration.
7. Equipment failure, infection and/or human error or other unforeseen circumstances may result in loss or damage to the eggs, sperm or embryos.
8. Embryo transfer into the uterus may be technically difficult or impossible or medically contraindicated.
9. If transfer occurs, the embryos may not implant and continue developing.
10. If pregnancy occurs, each of us has been informed that it may result in multiple gestation or an ectopic pregnancy, or a pregnancy, which ends in miscarriage.
11. Psychological stress may result in anxiety and disappointment and that a substantial amount of time is required by both of us.
12. Each of us has been informed that many of the standard products used for development of the follicles and growth of the oocytes(s), and/or embryo(s) are derived from biologic origins, and while these products are manufactured under the strictest guidelines of the Federal Drug Administration, INVIA FERTILITY SPECIALISTS cannot be held responsible for any potential unspecified product recalls.
13. Each of us understands that the long-term effects of the administration of fertility drugs are not known. We acknowledge that the long-term health effects of fertility drugs are still being evaluated including the potential long-term risk of ovarian or endometrial cancers.

We understand that while several babies have been born world wide as a result of this technology, there may be some effects on the offspring, which at this time cannot be determined, including the risks of chromosomal abnormalities and congenital malformations. The long-term risks associated with human oocyte cryopreservation are unknown at present.

If, after thawing, an oocyte does not fertilize, the oocyte will be disposed of in an ethically accepted manner according to InVia Fertility Specialists' guidelines and the American Society for Reproductive Medicine Ethical Standards.

We also understand that if any of the following situations occur, the oocytes/embryos will be disposed of in an ethically accepted manner according to InVia Fertility Specialists' guidelines and the American Society for Reproductive Medicine Ethical Standards:

1. In the exercise of reasonable medical judgment, the embryologists and physicians determine that sperm, oocytes, or embryos (either fresh or frozen-thawed) are non-viable or otherwise not medically suitable for use or embryo transfer.
2. If none of the oocytes survive the thawing procedure.
3. Fertilized thawed oocytes that do not cleave (divide) to form viable embryos as assessed by the ART team.

In addition, we agree that the Staff of Karande and Associates, S. C. is not obligated to transfer the resultant embryos at any point in the future if medical evidence and/or experience indicate that the risk of transfer of frozen embryos outweighs the benefits.

Agreement and Consent

We have reviewed and executed the form captioned Consent to the Cryopreservation of Human Embryos in Assisted Reproductive Technologies. With regard to the cryopreservation of oocytes:

- _____ _____ Option #1 I agree that all of the oocytes collected for use in oocyte donation at Karande and Associates will be cryopreserved for later use in a suitable recipient couple.
- _____ _____ Option #2 I agree that all retrieved oocytes will be frozen for my future Use.
- _____ _____ Option #3 I/We agree that the donated oocytes obtained from the donor designated for use in this cycle will be divided into primary and secondary recipient. As primary recipient we will receive approximately 8-10 oocytes (as determined by the ART team.) The remaining unfertilized oocytes will be cryopreserved for later use by the secondary recipient. **We understand that the expenses will be divided appropriately between InVia Fertility Specialists and the primary recipient couple.**
- _____ _____ Option #4 I/We agree to fertilize only _____ oocytes. We agree to have the remaining oocytes cryopreserved at Karande and Associates for later use by us.
- _____ _____ Option #5 I/We agree to fertilize only _____ oocytes. We agree to the cryopreservation of the remaining oocyte(s), [please circle one option]:
a.) for use by another infertile couple.
b.) for use by InVia Fertility Specialists for research purposes.
- _____ _____ Option #6 I/We agree, due to failure of obtaining a sperm sample on the day of egg retrieval, to cryopreserve all retrieved oocytes for later use.

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

Each of us further understands that if pregnancy occurs, miscarriage, ectopic pregnancies, stillbirth, congenital abnormalities or multiple pregnancy may result. We have been informed that the process of Assisted Reproductive Technologies can be very psychologically stressful, and may result in anxiety and disappointment and that a substantial amount of time by both us is required.

"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. Oocyte Cryopreservation Program. If in the preparation for, during, or following 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."

The signing of this consent does not guarantee that you will have oocytes frozen. Oocyte freezing will be performed on a per case basis, based on the number of oocytes retrieved, oocyte quality, and the number of oocytes wishing to be inseminated.

All of our questions regarding INVIA FERTILITY SPECIALISTS consent on Assisted Reproductive Technologies Program (A.R.T.) Oocyte Cryopreservation have been answered. Each of us has read the consent and acknowledges receipt of a copy of this consent.

Date	Signature of Female Patient	Female Name – Print
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Date	Signature of Partner	Partner Name – Print
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As one of the members of INVIA FERTILITY SPECIALISTS, my signature indicates that the foregoing consent was read, discussed and signed in my presence.

Date	Signature of Witness (Female Patient)	Witness Name – Print
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Date	Signature of Witness (Partner)	Witness Name – Print
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NOTE: If you or your partner are unable to have this consent witnessed by a staff member at INVIA FERTILITY SPECIALISTS or do not FULLY UNDERSTAND THE 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.

Notary Public

State of _____, County of _____, 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 appeared before me this day in persons, and acknowledged that he and she signed, sealed and delivered the said document as 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 Seal) (Notary Public)
