

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 RECIPIENTS**

**Description, Explanation, and Informed Consent**

We, \_\_\_\_\_, have been informed that our infertility may be treatable by Assisted Reproductive Technologies (A.R.T.). The members of INVIA FERTILITY SPECIALISTS' 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 on the Assisted Reproductive Technologies Program.

**Description and Explanation of Program**

We understand that the A.R.T. Program involves the following procedures:

1. Determine by standard infertility tests that we are suitable candidates for donor oocytes (eggs).
2. Ultrasound examinations combined with blood tests to determine suitability of the uterine lining for reception of embryos.
3. Collecting and preparing sperm obtained for the Male Partner (by masturbation) for use in attempts to accomplish fertilization.
4. Mixing the sperm and egg(s) together in attempts to accomplish fertilization in the laboratory or in the recipient's (woman's) body. In situations where fertilization failure or reduced injection (I.C.S.I.) is performed in an effort to enhance fertilization.
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 recipient's (woman'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. Transfer the embryo(s) to the recipient's uterus or fallopian tubes by means of a plastic 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 it is proceeding normally.
8. 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 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 Donor Program, some of the known factors that may prevent the establishment of a pregnancy include:

1. Irritation, redness or swelling may result for the injection of fertility medications.
2. Follicles containing ripe eggs may not develop during the drug treatment (monitoring) cycle or response to the drugs may be inadequate thus preventing egg retrieval from the donor.
3. Pelvic scarring or adhesions and/or technical problems may prevent retrieval of one or more of the eggs from the donor.
4. Ovulation may occur prior to attempt to retrieve the egg, making obtaining an egg impossible.
5. One or more eggs may not be obtained after attempts to suction (aspirate) the follicle.
6. Hemorrhage or infection may occur during the attempt to aspirate the oocytes from the donor's follicles.
7. The sperm may not be able to be collected or processed.
8. Fertilization of the oocyte(s) to form embryos may not occur.
9. Cell division (cleavage) of the embryos may not occur.
10. Embryo transfer into the uterus may be technically difficult or impossible or medically contraindicated.
11. If transfer occurs, the embryos may not implant and continue developing.
12. 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.
13. Psychological stress may result in anxiety and disappointment and that a substantial amount of time is required by both of us.
14. Conditions may make primary laboratory facilities, an operating room, anesthesia or other medical support facilities unavailable at the appropriate time for obtaining eggs. However, once HCG is administered, we understand that an egg retrieval must be performed and that all attempts at locating alternate sites will be made available.
15. The eggs may not be normal.
16. Appropriate laboratory preparation of the sperm may be difficult or impossible.
17. Equipment failure, infection and/or human error or other unforeseen circumstances may result in loss or damage to the eggs, sperm, or embryos.
18. Each of us has been informed that many of the standard products used for development of the follicles and growth of the oocyte(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.

19. 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 cancer.

### **Agreement and Consent**

Each of us understands and agrees that if in the exercise of reasonable medical judgment by 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 embryos will not be utilized or transferred for our A.R.T. cycle.

Each of us 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 of us is required.

**Micromanipulation:** We have been informed that Intracytoplasmic Sperm Injection (I.C.S.I.) and Assisted Zona Hatching (A.Z.H.) are specialized procedures that may be indicated in addition to the Assisted Reproductive Technology procedure already described.

We understand that intracytoplasmic sperm injection is a procedure employed when previous cycles of A.R.T. have resulted in fertilization failure, a severely reduced fertilization rate of when semen parameters suggest that this may occur in the present A.R.T. cycle. The procedure involves the isolation of single sperm into an egg (oocyte) retrieved from the oocyte's donor. We have been informed that while I.C.S.I. is not longer considered experimental by the American Society of Reproductive Medicine (A.S.R.M.), the long-term effects of the procedure have not been evaluated. However, we acknowledge that the procedure is practiced in selected centers worldwide where the specialized equipment and expertise for the procedure is available and hundreds of children have been born as a result of the procedure. We understand that the use of the procedure cannot completely eliminate the risk of fertilization failure. We further understand that there may be some effects on the offspring, which at this time cannot be determined.

We have been informed that Assisted Zona Hatching (A.Z.H.) 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. The procedure is, however, rarely needed with donors. 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 during the procedure.

We understand that in general, medical history and results of the fertility evaluation obtained prior to the A.R.T. procedure will suggest if I.C.S.I. or 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 these techniques. Unless we have specifically indicated that we do not consent to the use of these procedures and will not be financially responsible for them, we hereby agree that the use of these procedures 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 the A.R.T. Program, and specifically through the use of the donor oocytes (eggs) obtained in this current A.R.T. attempt.

Each of us is voluntarily participating in the A.R.T. Donor 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 of our questions concerning the program have been fully answered to our satisfaction.

By participating in this 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 the techniques and procedures required to attempt to accomplish Assisted Reproductive Technologies as they have been described in this document and as they have been explained to us by the A.R.T. Program staff.

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

Each of us acknowledges and agrees that our acceptance into the A.R.T. Program and our continuing participation is at the discretion of the A.R.T. team. Correspondingly, we understand that we can withdraw from the A.R.T. Program at any time without affecting the availability of other, present, and future medical care at this institution. We are financially able to participate in the A.R.T. Program and for which we agree to be responsible. We also understand that we are responsible for any potential costs that may arise from unforeseen complications that may occur from the donor's oocyte recruitment or retrieval during the A.R.T. cycle.

It is possible that our participation in the A.R.T. Program may aid in the development of techniques that 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, for the purpose of observations, of other physicians and healthcare personnel during any medical procedures performed on us confidentially and that neither our identity nor specific medical details will be revealed without our consent. No information may be provided to the media by INVIA FERTILITY SPECIALISTS, without our prior written informed consent.

Each of us has been informed that if we or our oocyte donor should suffer any physical injury as a result of participation in this activity, all medical facilities are available for treatment. We understand, however, that we cannot expect to receive from the A.R.T. Team or INVIA FERTILITY SPECIALISTS or its employees any reimbursement for hospital expenses or any financial compensation for such injury.

The nature and purpose of the A.R.T. Donor Program, possible alternative methods of treatment, the risks involved and the possibility of complications have been explained to our satisfaction. Each of us had the opportunity to ask any questions we might have had about our participation. We understand that 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 consent at any time.

All of our questions regarding the above information in its entirety and in part, have been explained to us and answered to our satisfaction and understanding. We agree that we are voluntarily participating in the Assisted Reproductive Technologies Program with the use of Donor Oocytes at INVIA FERTILITY SPECIALISTS. Each of us has read this form and acknowledges receipt of a copy of this form.

We understand that if micromanipulation procedures are required for our A.R.T. cycle, we will be financially responsible for the additional costs incurred.

Female \_\_\_\_\_ Partner \_\_\_\_\_ As part of our A.R.T. cycle, we request that  
Initials                      Initials                      micromanipulation techniques, including intracytoplasmic  
sperm injection and/or assisted zona hatching, be used if  
indicated. We acknowledge that we have received  
information regarding the approximated and anticipated  
financial costs of such procedures and we accept all  
financial responsibility if our insurance does not cover  
these procedures, including any increased costs that may  
arise regardless of the success of such procedures.

Female \_\_\_\_\_ Partner \_\_\_\_\_ We decline the use of all micromanipulation techniques  
Initials                      Initials                      with our A.R.T. cycle.

“We hereby request and authorize the A.R.T. team to perform the procedures described herein which are deemed necessary for the A.R.T. Donor 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”

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|------|-----------------------------|---------------------|
| Date | Signature of Female Patient | Female Name – Print |
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| Date | Signature of Partner | Partner Name – Print |
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**All of our questions regarding INVIA FERTILITY SPECIALISTS consent on Assisted Reproductive Technologies (A.R.T.) Oocyte Recipients have been answered. Each of us has read the consent and acknowledges receipt of a copy of this consent.**

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| 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, by my signature indicate that the foregoing consent was read, discussed, and signed in my presence.**

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| 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 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.**

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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

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(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\_\_\_\_.

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(Notary Public)

(Notary Seal)