

REPRODUCTIVE MEDICINE AND INFERTILITY ASSOCIATES
Woodbury Medical Arts Building
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(651) 222-6050

**FERTILITY COST WARRANTY PROGRAM –
DONOR OOCYTE**

**RECIPIENT COUPLE INFORMED CONSENT
AND AUTHORIZATION**

We, the undersigned recipient patient and partner, collectively referred to as the Couple, understand that we will be undergoing one or more procedures called in vitro fertilization (IVF) during our participation in Reproductive Medicine and Infertility Associates (RMIA) Fertility Cost Warranty Program-Donor Oocyte (FCWP-DO). This is done through the fertilization of donated eggs by the recipient partner's sperm and subsequent placement of any resulting pre-embryo(s) into the recipient patient's uterus. We are participating in the FCWP-DO because we have been unable to conceive conventionally or by other available means.

I. DEFINITIONS

- A. A PRE-EMBRYO is a fertilized egg, which prior to implantation in the uterus has divided to form a small number of simple, non-specialized cells. At this pre-embryo stage of development, each of these primitive cells is identical.
- B. CRYOPRESERVATION refers to preservation through freezing.
- C. IN VITRO FERTILIZATION (IVF) refers to the processes whereby egg growth is stimulated in the ovaries with the resultant eggs being retrieved and fertilized by sperm in the laboratory.
- D. INTRACYTOPLASMIC SPERM INJECTION (ICSI) is a process by which the sperm is injected directly into the egg.
- E. EMBRYO TRANSFER (ET) is the placement of pre-embryos into the patient's uterus.

II. DONOR SELECTION AND SCREENING

We understand that the donated eggs utilized in this procedure will be obtained from an anonymous donor, with final approval of any donor being made at the sole discretion of the RMIA physician. The American Society for Reproductive Medicine recommends, and RMIA requires, the following screening process for donors prior to the transfer of any reproductive tissue from one patient to another.



The screening process involves, but is not limited to, the following:

- a. Medical and genetic history
- b. Infectious disease screening (including sexually transmitted diseases)
- c. Physical examination
- d. Psychological examination

We understand that RMIA does not make any guarantee of the reliability of the information provided by the donor in the above-described screening process. We understand and agree that RMIA is not responsible for the accuracy or reliability of information obtained from donor during the screening process.

We also understand that RMIA cannot and will not assume any responsibility or liability for the donor's actions or inactions during the screening process.

Current guidelines for donor sperm require that the semen be quarantined for 180 days before being released for use. As no practical procedures exist, oocytes cannot be frozen and quarantined prior to use. Pre-embryo freezing is available, but not utilized in the FCWP-DO. Recipient couples entering into the FCWP-DO assume a low risk of acquiring HIV by using fresh pre-embryos, as the donated oocytes which are fertilized will **NOT BE FROZEN AND QUARANTINED**. The donor will be recalled and retested for HIV six months after oocyte donation.

III. IN VITRO FERTILIZATION

Medications will be used to coordinate the recipient patient's cycle with the availability of donor eggs. The risks of taking these medications have been explained to us in detail. It may take one or more trials of artificial cycles before actual pre-embryo placement. If pregnancy occurs, the recipient patient will need to continue taking these medications through the first trimester of pregnancy.

During the artificial cycle, the recipient patient will be closely monitored via ultrasound examinations and blood tests. Frequent tests may be administered through the remainder of the cycle to confirm hormone levels and determine if pregnancy has occurred.

Following retrieval, the donor eggs and recipient partner's sperm will be processed in the laboratory to accomplish fertilization. Based on the decision of the embryologist, some or all of the eggs will be injected with sperm via ICSI. Several days later, the fertilized eggs, now pre-embryos, will be transferred to the uterus of the recipient patient through a tiny plastic catheter.

In accordance with current FCWP-DO guidelines, we understand that two or three pre-embryos, or as many pre-embryos as are available, if fewer, will be placed in the recipient patient's uterus during each of the transfer procedures that are part of the FCWP-DO. We also understand that there is a risk of multiple pregnancy (see section IV), which has certain accompanying risks that have been explained to us. These include, but are not limited to, premature labor and premature birth, each of which can present substantial risk to the infant(s).

We have discussed with RMIA Doctor _____ the risks of the IVF procedures in conjunction with the FCWP-DO. We freely and knowingly assume these risks.

Patient's initials _____

Partner's initials _____

IV. RISK OF MULTIPLE PREGNANCY

Based on the experience of RMIA and published data, the risks of multiple pregnancies are significant. Approximately 15 to 30 percent of pregnancies conceived by IVF are multiple births. A patient's individual risk for a multiple pregnancy depends not only on her health history and age, but also on the number of pre-embryos transferred.

For example, RMIA has noted the following multiple pregnancy rates in patients under the age of 36 who have conceived through IVF:

3 pre-embryos transferred: twins 28 %, triplets 7 %.

Multiple pregnancies, in excess of twins, greatly increase the chance for infant mortality through premature birth. If a multiple pregnancy occurs, RMIA advises that the patient consult a subspecialist in maternal and fetal medicine, a perinatologist, to discuss the possibility of a selective reduction in the number of live fetuses. The patient retains the right to decline any medical recommendation regarding selective reduction.

V. CRYOPRESERVATION OF THE PRE-EMBRYOS

To reduce the need for multiple cycles of ovarian stimulation and egg retrieval, RMIA will freeze qualifying extra pre-embryos not utilized in any of the three ovarian stimulation/egg retrieval procedures under the FCWP-DO. These frozen pre-embryos will be stored and must be used before the next and subsequent ovarian stimulation cycles. In accordance with the FCWP-DO guidelines, pre-embryos will be thawed and transferred to the uterus in hormonally controlled cycles until no additional pre-embryos remain. We understand that only pre-embryos considered by RMIA doctors to be potentially viable will be used for transfer. Placement of the pre-embryos into the uterus requires a normal uterine lining and close synchronization to the normal process of embryo development. Such synchronization will require monitoring via blood tests and ultrasound examination(s). Pre-embryos will be thawed and placed in the uterus only if the cycle is determined by the RMIA doctor to be normal in all respects.

RMIA does not provide long-term storage of cryopreserved pre-embryos. Patients with pre-embryos remaining in storage after completion of IVF will have the remainder of their pre-embryos transferred to ReproTech, Ltd., a company specializing in long-term storage of cryopreserved pre-embryos. Those pre-embryos not sent to ReproTech Ltd. will be sent to a similar storage facility. This transfer will occur approximately 1 year from the date of cryopreservation and is contingent upon each patient's desire to continue storage of their pre-embryos as an alternative to disposal. Prior to transfer, patients will be asked to execute a pre-embryo storage agreement with ReproTech Ltd.

VI. RIGHT TO TRANSFER CRYOPRESERVED PRE-EMBRYOS

We understand that we have the right to transfer any frozen pre-embryos at any time to a storage bank not under the control or supervision of RMIA, and that we must pay a transfer fee of \$360.

VII. RMIA'S DISCRETION REGARDING MEDICAL TREATMENT AND PROCEDURES

The Couple understand that RMIA is not obligated to proceed if, on the basis of scientific evidence, and sound medical judgment, the risks of proceeding with services outweigh the benefits. Furthermore, the Couple authorize RMIA and the personnel operating the FCWP-DO to depart from the FCWP-DO Current Guidelines if advised in advance of such a departure. We acknowledge that RMIA and the personnel operating the FCWP-DO also reserve the right to terminate their participation in the FCWP-DO at any time. In the event of such termination, and according to the wishes of the Couple, all reasonable efforts will be made to arrange for the use or disposal of remaining pre-embryos. However, in the absence of a directive from the Couple, frozen pre-embryos will be properly disposed at the discretion of RMIA.

VIII. NO GUARANTEE OR WARRANTY REGARDING CRYOPRESERVATION OF PRE-EMBRYOS, PREGNANCY, OR THE HEALTH AND CHARACTERISTICS OF ANY CHILD CONCEIVED IN THE FCWP-DO

We acknowledge that there is no guarantee of a successful pregnancy under the FCWP-DO and that failure may occur in stimulation of the ovaries, gathering of the eggs, fertilization in the laboratory, transfer to the uterus or pregnancy itself. Furthermore, we understand that neither the doctors nor RMIA make or have made any promises or warranties that the pre-embryos will survive cryopreservation. Mechanical failures can occur at any point during the process resulting in loss of pre-embryos. Regarding the results of the cryopreservation procedure, we understand that there is no guarantee or warranty as to health and characteristics of any child or children conceived while we are in the FCWP-DO.

We agree and understand that the doctors and RMIA shall not, and cannot, be held responsible for the physical or mental characteristics of any child or children conceived while we are in the FCWP-DO. We release the doctors, RMIA and the other personnel involved in the FCWP-DO from any and all liability and responsibility of any nature whatsoever for:

- a. Complication of pregnancy,
- b. Childbirth or delivery,

- c. The birth of a child or children abnormal in any respect,
- d. The genetic, or hereditary tendencies of an abnormal child or children,
- e. Multiple pregnancy and premature birth,
- f. Ovarian hyper-stimulation syndrome,
- g. Any other adverse consequence that may arise in connection with, or as a result of, the procedures authorized by signing this form.

IX. OTHER MATTERS

We accept and acknowledge our obligation by agreeing to support, and otherwise treat a child born as a result of our participation in the FCWP-DO as if it were our natural born child.

We have been assured that all information regarding our treatment will to the extent allowed and required by law, be kept confidential. Furthermore we have also been assured that neither our identity nor specific medical details concerning us will be revealed without our consent. Specific medical details may be revealed in professional publications as long as our identity is concealed.

We also understand that insurance coverage for any or all of the above procedures may not be available and that we will be held personally responsible for the expenses of this treatment.

X. SEVERABILITY

In the event that any part of this Informed Consent and Authorization is declared by any court or other judicial administrative body to be null, void, or unenforceable, the said provision shall survive to the extent it is not so declared, and all of the provisions of this agreement shall remain in full force and effect.

XI. COPY OF CONSENT FORM MADE AVAILABLE

The Couple may request a copy of this consent document for their own records.

XII. REPORTING OF ASSISTED REPRODUCTIVE TECHNOLOGY TREATMENT

The notice below has been provided to us from the Society of Assisted Reproductive Technologies (SART) Executive Council for distribution to all patients undergoing Assisted Reproductive Technologies treatment. Please note that we are required to Report the data from your treatment cycle as directed below.

'Data from your ART procedure will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that the CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on you, CDC applied for and received an 'assurance of confidentiality' for this project under the provisions of the Public Health Service Act, Section 308(d). This means that any



information that CDC has that identifies you will not be disclosed to anyone else without your consent. We will comply with RMIA to obtain all the necessary information required by the CDC associated with our IVF treatment cycles.

XIII. OPPORTUNITY FOR LEGAL REPRESENTATION

We acknowledge by our signatures below that we have read the foregoing, all questions have been answered to our satisfaction and that we have each been advised to, and have had the opportunity to consult with legal counsel of our own choosing. We have been advised and understand that we, as partner and patient, may have conflicting interests and should, if either of us desires, each seek our own independent legal counsel.

Having been fully informed, we freely and voluntarily sign below:

Patient Printed Name

Clinic ID

Patient signature

Date

Partner Printed Name

Clinic ID

Partner signature

Date

Address

Witness

Date

