



FERTILITY COST WARRANTY PROGRAM INFORMED CONSENT AND AUTHORIZATION

We, the undersigned patient and partner 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 (FCWP). We are participating in the FCWP because we have been unable to conceive conventionally or by other available means.

For the purposes of this Informed Consent and Authorization, all references to FCWP shall include both the Fertility Cost Warranty Program and the Fertility Cost Warranty Program-Extended, but shall not include the Fertility Cost Warranty Program - Donor Oocyte.

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 the 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. EMBRYO TRANSFER (ET) is the placement of pre-embryos into the patient's uterus
- E. INTRACYTOPLASMIC SPERM INJECTION (ICSI) is a process by which sperm is injected directly into the egg.

II. IN VITRO FERTILIZATION

In order to stimulate multiple egg growth, the patient will be given, by injection, 2 hormonal medications: 1.) a gonadotropin releasing hormone agonist 2.) human menopausal gonadotropins. When, on the basis of hormone measurements and ultrasound scans, optimal maturity of eggs has been achieved, a third injection of hormones, human chorionic gonadotropin (hCG) will be given to induce final maturation of the eggs.

This process can sometimes result in temporary, and painful ovarian enlargement. Occasionally, this ovarian enlargement is severe and may result in a condition known as ovarian hyper-stimulation syndrome. This more serious, life-threatening variant may necessitate hospitalization. In our experience, severe ovarian hyper-stimulation occurs in less than 1% of all patients.

Mature eggs are retrieved under ultrasound guidance by placing a needle through the vagina into the ovary. Follicle sacs are entered individually and gentle suction is applied to remove the eggs and its surrounding fluid from the ovary. Complications of this are rare but can include excessive bleeding or injury to the surrounding bowel.

Following retrieval, the eggs and the 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 through a tiny plastic catheter.

In accordance with current FCWP guidelines, we understand that two to four pre-embryos, or as many pre-embryos as are available, if fewer, will be placed in the patient's uterus during each of the transfer procedures. We also understand that there is a risk of multiple pregnancy (see Section III), which has certain accompanying complications 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 IVF procedures in conjunction with the FCWP, and its alternatives. We freely and knowingly assume these risks.

Patient's initials _____

Partner's initials _____

III. 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 sub-specialist 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.

IV. CRYOPRESERVATION OF 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. These frozen pre-embryos will be stored and must be used before the next and subsequent ovarian stimulation cycles. In accordance with the FCWP 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. In the event that either of the patient or partner test positive for any of the infectious diseases, embryos cannot be stored at RMIA. The patient would become solely responsible for storage, transfer fees and any other related costs associated with an outside storage facility.

V. 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.

VI. USE OF DONOR SPERM

If we utilize donor sperm to fertilize a patient's eggs, we understand that we will be required to execute an Informed Consent for the Use of Donor Sperm provided by the selected sperm bank. RMIA does not maintain a donor sperm bank; therefore, all cost associated with the procurement of donor sperm shall be between patient/partner and the sperm bank in question. All benefits and limitations of liability given to the sperm bank by execution of the sperm bank's Informed Consent shall apply to RMIA to the same extent the benefits and limitations of liability apply to the sperm bank. We agree to bring no cause of action against RMIA connected to, or arising out of, our use of donor sperm.

VII. RMIA DISCRETION REGARDING MEDICAL TREATMENT AND PROCEDURES

We 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, we authorize RMIA and the personnel operating the FCWP to depart from the FCWP Current Guidelines if we are advised in advance of such a departure. We acknowledge that RMIA and the personnel operating the FCWP also reserve the right to terminate their participation in the FCWP at any time. In the event of such termination, and according to the wishes of the patient and partner, 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 patient and partner, 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

We acknowledge that there is no guarantee of a successful pregnancy under the FCWP 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.

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. We release the doctors, RMIA and the other personnel involved in the FCWP 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. 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.

X. COPY OF CONSENT FORM MADE AVAILABLE

We may request a copy of this consent form for our own records.

XI. 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.’

XII. 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

