



## INFORMED CONSENT AND AUTHORIZATION FOR IN VITRO FERTILIZATION

We, the undersigned, as patient and partner understand that we will be undergoing one or more procedures called in vitro fertilization (IVF). We are utilizing the IVF services of Reproductive Medicine and Infertility Associates (RMIA) 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 the pre-embryo stage of development, each of these simple cells is identical.
- b. CRYOPRESERVATION refers to the preservation through freezing. Human pre-embryos are usually cryopreserved when they consist of 1 to 16 cells.
- 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. Several days later, the fertilized eggs, now pre-embryos, will be transferred to the uterus through a tiny plastic catheter.

We understand \_\_\_\_\_ 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 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 prematurity. 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**

If the patient and her partner do desire, RMIA will freeze and store for a limited period of time any qualifying pre-embryos not utilized at the initial embryo transfer. This will reduce the need for multiple cycles of ovarian stimulation and egg retrieval. The cryopreserved pre-embryos will be used according to the directive of the patient and her partner. We understand that only pre-embryos considered by RMIA doctors to be of potential medical use will be transferred. Unless otherwise specified, the same transferring guidelines will be used as for the “fresh” embryos. 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 attending 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. 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 the patient or partner, tests positive for any of the infectious diseases, embryos cannot be stored at RMIA. The patient would become solely responsible for storage, transfer fees and 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 \$ 360.00.

#### **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'S 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. RMIA also reserves the right to terminate IVF services 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**

We acknowledge that there is no guarantee of a successful pregnancy by using IVF 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 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 through IVF procedures.

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 through IVF. We release RMIA, and the physicians, other personnel, and agents involved in IVF services from any and all liability and responsibility of any nature whatsoever for:

- a. Complications 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 procedure authorized by signing this form.

## **IX. SEVERABILITY**

In the event that any part of this Informed Consent and Authorization is declared by any court of competent jurisdiction to be null, void, or unenforceable, the said provision shall survive to the extent it is not so declared, and all other 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 described 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 the 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 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 patient and partner, 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

