

# REPRODUCTIVE MEDICINE AND INFERTILITY ASSOCIATES

Woodbury Medical Arts Building  
2101 Woodwinds Drive, Suite 100  
Woodbury, MN 55125  
(651) 222-6050

## INFORMED CONSENT AND AUTHORIZATION FOR IN VITRO FERTILIZATION USING A KNOWN GESTATIONAL CARRIER

The undersigned patient and partner, collectively referred to as the Couple, have requested Reproductive Medicine and Infertility Associates (RMIA) perform one or more procedures called in-vitro fertilization (IVF). After IVF, the resulting pre-embryo(s) will be transferred to the undersigned gestational carrier (GC), selected by the Couple to carry their child. The Couple is utilizing IVF services and the gestational carrier because they have been unable to conceive conventionally or by other available means.

### I. DEFINITIONS

- A. A **GESTATIONAL CARRIER** is a woman who carries a Couple's child and has no genetic link to the developing child through the use of her own eggs. After IVF is performed pre-embryo(s) are transferred into the uterus of the gestational carrier.
- B. 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.
- C. **CRYOPRESERVATION** refers to preservation through freezing. Human pre-embryos are usually cryopreserved when they consist of 1 to 16 cells.
- D. **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.
- E. **EMBRYO TRANSFER (ET)** is the placement of pre-embryos into the patient's uterus.
- F. **INTRACYTOPLASMIC SPERM INJECTION (ICSI)** is a process by which the sperm is injected directly into the egg.

## II. SCREENING AND OPPORTUNITY FOR CRYOPRESERVATION AND QUARANTINE

The eggs and sperm used in the IVF procedure will be obtained from the Couple. The Couple, and the GC understand that the American Society for Reproductive Medicine recommends, and RMIA requires, the following screening process prior to the transfer of reproductive tissue from one patient to another.

The patient and partner must submit to and pass all screening tests and procedures required by the RMIA. 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

The GC understands that RMIA does not make any guarantee of the reliability of the information provided by the Couple in the above-described screening process. The GC understands and agrees that RMIA is not responsible for the accuracy or reliability of information obtained from the Couple during the screening process.

The GC also understands that RMIA cannot and will not assume any responsibility or liability for the Couple's actions or inactions during the screening process.

Current guidelines for donor semen 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 and quarantine is available upon request at an additional cost of \_\_\_\_\_. The GC should know that if the pre-embryo(s) to be transferred to her uterus are not frozen and quarantined for six months prior, she assumes a low risk of acquiring HIV. Neither the oocytes nor the sperm used to fertilize the oocytes will be frozen and quarantined prior to IVF.

I request RMIA to cryopreserve the Couple's pre-embryos and quarantine them for six months prior to transfer. I also request a mandatory retest for the Couple following the quarantine period.

I request RMIA to transfer the Couple's pre-embryos without cryopreservation or a six month quarantine period. I accept the risks described above for the transfer without quarantine and retesting of the Couple.

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Signature of Gestational Carrier

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Signature of Gestational Carrier

The GC understands that RMIA will perform the same or similar screening tests on her that will be performed on the Couple (see Section II).

The Couple understands that RMIA does not make any guarantee of the reliability of the information provided by the GC in the above-described screening process. The Couple understands and agrees that RMIA is not responsible for the accuracy or reliability of information obtained from the GC in the screening process.

The Couple also understands that RMIA cannot and will not assume any responsibility or liability for the GC's actions or inactions during the screening process.

### **III. IN VITRO FERTILIZATION**

#### **A. The Patient**

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.

#### **B. Gestational Carrier**

Medications will be used to coordinate the GC's cycle to the availability of pre-embryo(s) from the Couple. The risks of taking these medications have been explained to the GC in detail. It may take one or more trials of artificial cycles before actual pre-embryo placement. If a pregnancy occurs, the GC will need to continue to taking these medications through the first trimester of pregnancy.

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

C. Completion of IVF Process

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 of the GC through a tiny plastic catheter.

In accordance with current guidelines, we understand that two to four pre-embryos, or as many pre-embryos as are available, if fewer, will be placed in the GC's uterus during each of the transfer procedure. We also understand that there is a risk of multiple pregnancy (see Section IV), which has certain accompanying complications to the GC, which 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).

The Couple and the GC have discussed with RMIA Doctor \_\_\_\_\_ the risks of the IVF procedures. We freely and knowingly assume these risks.

Patient's initials \_\_\_\_\_

Partner's initials \_\_\_\_\_

GC'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 GC'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 GC 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 recipient patient retains the right to decline any medical recommendation regarding selective reduction

RMIA strongly advises that the Couple and the GC (with the aid of legal counsel) draft an advance agreement detailing, what action will be taken in the event of a multiple pregnancy in excess of twins.

## **V. CRYOPRESERVATION OF PRE-EMBRYOS**

To reduce the need for multiple cycles of ovarian stimulation and egg retrieval, RMIA will freeze extra pre-embryos not utilized in any of the three ovarian stimulation/egg retrieval procedures. These frozen pre-embryos will be stored and may be used before the next and subsequent ovarian stimulation cycles. 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. Patients are asked to execute a pre-embryo storage agreement with ReproTech Ltd. in advance. In the event that either patient or partner tests positive for any of the infectious diseases, embryos cannot be stored at RMIA. The patient would be solely responsible for storage, transfer fees, and other related costs associated with an outside storage facility.

## **VI. RIGHT TO TRANSFER CRYOPRESERVED PRE-EMBRYOS**

The Couple understands that they 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 they must pay a transfer fee of \$360.

## **VII. USE OF DONOR SPERM**

If the Couple utilize donor sperm to fertilize the patient's eggs, it is understood that both the Couple and the GC 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 the Couple, the GC, 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. The Couple and the GC agree to bring no cause of action against RMIA connected to, or arising out of, our use of donor sperm.

## **VIII. 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 and the GC authorize RMIA and its operating personnel to depart from the current guidelines if advised in advance of such a departure. We acknowledge that RMIA and its operating personnel also reserve the right to terminate their participation 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.

## **IX. NO GUARANTEE OR WARRANTY REGARDING CRYOPRESERVATION OF PRE-EMBRYOS, PREGNANCY, OR THE HEALTH AND CHARACTERISTICS OF ANY CHILD CONCEIVED**

The Couple acknowledges that there is no guarantee of a successful pregnancy using a GC 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, the Couple understands 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, the Couple understand that there is no guarantee or warranty as to health and characteristics of any child or children conceived using a GC.

The Couple agrees and understands that the doctors and RMIA shall not, and cannot be held responsible for the physical or mental characteristics of any child or children conceived. The Couple and the GC release and hold harmless the doctors, RMIA and its operating personnel 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.

**X. PARENTAL RIGHTS OF RESULTING OFFSPRING.**

The Couple are the intended parents of any offspring resulting from the IVF procedures contemplated in this Informed Consent for In Vitro Fertilization Using a Known Gestational Carrier. However, because this is an area with limited legal precedence, RMIA cannot assure the Couple of the enforceability of their legal parental rights. RMIA requires a copy of the GC agreement or a letter from the attorney that the Couple has been advised of their legal rights and respectfully declines to draft the GC agreement.

**XI. 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.

**XII. COPY OF CONSENT FORM MADE AVAILABLE**

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

### **XIII. 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.’

### **XIV. OPPORTUNITY FOR LEGAL REPRESENTATION.**

The Couple and the GC acknowledge by their signatures below that they have read the foregoing and all questions have been answered to their satisfaction and that they have each been advised to, and have had the opportunity to, consult with legal counsel of their own choosing. The Patient, the partner, and the GC have been advised and understand that they, as a patient and a partner, and as a gestational carrier, may have conflicting interests and should, if any of them so desires, each seek their own independent legal counsel.

RMIA advises that the parties seek independent legal counsel and enter into a written agreement, which thoroughly addresses all areas of agreement, concern, and conflict.

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

\_\_\_\_\_  
Patient's Printed Name ID # \_\_\_\_\_

\_\_\_\_\_  
Patient's signature Date \_\_\_\_\_

\_\_\_\_\_  
Partner's Printed Name ID # \_\_\_\_\_

\_\_\_\_\_  
Partner's Signature Date \_\_\_\_\_

\_\_\_\_\_  
Address

\_\_\_\_\_  
Gestational Carrier's Printed Name ID # \_\_\_\_\_

\_\_\_\_\_  
Gestational Carrier's Signature Date \_\_\_\_\_

\_\_\_\_\_  
Address

Witnessed: \_\_\_\_\_  
Date \_\_\_\_\_