

**INFORMED CONSENT TO  
EMBRYO TRANSFER USING CRYOPRESERVED EMBRYO(S)  
WITH ASSISTED HATCHING**

**DEFINITIONS:**

As used in this Consent, the following definitions shall apply:

1. **Assisted reproductive technology (ART)** means those processes and procreative procedures which lead to and involve laboratory handling of human eggs or embryos, including, but not limited to, those processes and procedures associated with in vitro fertilization embryo transfer (IVF).
2. **The Reproductive Medicine Group IVF Program** refers to all processes and procedures fitting within the definition of ART (above) performed within or under the direction or guidance of the Reproductive Medicine Group, RMG ART Laboratories, Inc., RMG IVF/Surgery Center, Inc.
3. **Blastocyst** is the stage in the development of an embryo following initial cell division where the cells start differentiating usually achieved 5 – 6 days after fertilization.
4. **Cryopreservation** is preservation by freezing.
5. **Egg** means the unfertilized female reproductive cell.
6. **Embryo** means the product of fertilization of an egg by a sperm until the appearance of an embryonic axis.
7. **Embryo transfer** means the transfer of an in vitro fertilized embryo into a woman's uterus
8. **Follicle** means the fluid filled sac that contains the developing egg and cells surrounding the sac.
9. **Fertilization** means the initial union of an egg and sperm.
10. **Implantation** means the event that occurs when a fertilized egg adheres to the uterine wall for growth and development.
11. **In vitro fertilization (IVF)** refers to the processes whereby egg growth is stimulated in a woman, the eggs are obtained from her ovaries, and then fertilized by sperm in the laboratory, and the resulting embryos placed in her uterus.
12. **Providers** means The Reproductive Medicine Group, RMG ART Laboratories, Inc., RMG IVF/Surgery Center, Inc., and all personnel associated with the administration and delivery of services who are employed by The Reproductive Medicine Group, RMG ART Laboratories, Inc., RMG/IVF Surgery Center, Inc., the physicians, laboratory personnel, ambulatory surgery personnel and their employees, officers, agents, successors and assigns.
13. **Zona Pellucida** means the structure that functions as the covering or "shell" of the embryo.
14. **Zygote** means the conceptus in which the egg and sperm genetic material (pronuclei) have united.

**EXPLANATION OF PROCEDURES**

**Embryo Transfer Using Cryopreserved Embryo(s)**

Embryo transfer will be done by providing the recipient (individual) couple with their embryo(s) previously obtained by in vitro fertilization (IVF) and cryopreservation of embryo(s). In vitro fertilization, embryo transfer (IVF ET) involves the transfer of the embryo into the recipient female's uterus. In preparation for embryo transfer it is necessary to stimulate the uterine lining with hormonal drugs (usually estrogen and progesterone) prior to the transfer which will mimic the normal menstrual cycle. In the event the recipient female is having menstrual periods, the cycles may need to be regulated by medication (usually estrogen, progesterone, and sometimes Lupron) to prepare the uterus for embryo implantation. In both of these cases, it may require one or more trials of artificial cycles prior to the embryo transfer in order to determine the optimum treatment required for uterine development suitable for the transfer of the embryo(s).

In vitro fertilization- embryo transfer requires placement of the embryo(s) into the uterus by means of a small plastic tube inserted through the cervix. Blood samples will be obtained before and after embryo transfer to determine if hormone levels are normal and if pregnancy has occurred.

The aforementioned steps may not result in a pregnancy, even after several attempts. The number of human births from frozen embryos to this date has been less than fresh embryo transfer and most of these births have been normal. Currently, there does not appear to be an increased risk to the fetus by embryo freezing and thawing, but it cannot be quantified with certainty until more live births result from frozen embryos. There may be theoretical risks of congenital malformations associated with cryopreservation or long-term storage. If a pregnancy occurs from uterine placement of a cryopreserved embryo, close monitoring by a qualified obstetrician is recommended.

## **EXPLANATION OF PROCEDURES**

### **Assisted Hatching**

The cells that make up the early embryo are enclosed within a flexible membrane (shell) called the zona pellucida. During normal development, a portion of this membrane dissolves, allowing the embryonic cells to escape or “hatch” out of the shell. Only upon hatching can the embryonic cells implant within the wall of the uterus to form a pregnancy.

Assisted hatching is the laboratory technique in which an embryologist makes an artificial opening in the outer shell (zona pellucida) of the embryo. The hatching is usually performed on the day of the transfer, prior to loading the embryo into the transfer catheter. The opening can be made by mechanical means, making an incision in the embryo’s shell by the laser.

Some programs have incorporated artificial or “assisted hatching” into their treatment protocols because they believe it improves implantation rates, and ultimately, live birth rates although definitive evidence of this is lacking.

Risks that may be associated with assisted hatching include damage to the embryo resulting in loss of embryonic cells, or destruction or death of the embryo. Artificial manipulation of the zygote may increase the rates of monozygotic (identical) twinning which are significantly more complicated pregnancies. There may be other risks not yet know.

## **RISKS AND HAZARDS**

Certain risks and hazards are associated with embryo transfer using cryopreserved embryos. Among these are:

1. Blood tests may cause mild discomfort. There is a risk of developing a bruise and/or infection at the needle site.
2. Any of the medications used (antibiotics, hormones, steroids and prenatal vitamins) may cause allergic or unforeseen reactions involving, but not limited to: skin, gastrointestinal, neurological or respiratory systems.
3. The embryos may implant in the fallopian tube resulting in an ectopic (tubal) pregnancy. Ectopic pregnancy may require major surgery for removal and may require removal of the involved tube(s).
4. Transferring the embryo(s) into the uterus may cause discomfort and a risk of developing an infection or bleeding.
5. The transfer of multiple embryos into the uterus may result in a multiple pregnancy with an inherent increased risk of multiple births and significant adverse outcomes including: miscarriage, premature labor and delivery which may result in fetal death, cerebral palsy and other infant defects, and increased maternal risks including Cesarean section, death and other complications; and increased financial and emotional burden. For high order multiple pregnancy, selective reduction of some fetuses may be available to reduce but not exclude some of the aforementioned risks, however, its availability cannot be guaranteed and decisions regarding it can result in psychological anguish for some couples. In rare instances, selective reduction can result in the loss of all fetuses and be associated with complications such as bleeding and infection.
6. Assisted reproductive technologies may be associated with psychological anguish or distress.
7. It is possible that a fetus conceived by assisted reproductive technologies could be abnormal or have congenital defects which may not always result in spontaneous abortion or be detectable by prenatal tests.
8. Other risks to you or an offspring conceived with an ART procedure, may exist which are not clear at the present time, or which may be unknown such as: disease risks associated with blood, blood products or other biological products which may be used in culturing embryos.

Certain risks and hazards are associated with assisted hatching. Among these are:

1. It is a technique that has not had a long duration of outcome follow-up and while the literature reports successful live birth with its use with no apparent increase in congenital defects, there may be unknown risks to the egg or developing embryo, including loss of embryonic cells.
2. Artificial manipulation of the zygote may increase the rates of monozygotic (identical) twinning which are significantly more complicated pregnancies.
3. Increased implantation rates may contribute to an increased multiple pregnancy rate with the inherent risks associated with multiple pregnancy.
4. While evidence does not currently suggest it to be the case, laboratory manipulations may result in abnormal embryos. Assisted Hatching may also result in embryo death or degeneration. Technical problems may prevent successful Assisted Hatching.
5. Other risks may exist which are not clear or which may be unknown at the present time. The Reproductive Medicine Group will not take responsibility for such events.

### **ABSENCE OF GUARANTEE**

The Providers do not and cannot guarantee freedom from disease, injury or risks, or that pregnancy will occur, even after several attempts. The reasons the procedure may fail to result in pregnancy include, but are not limited to, the following:

1. The cryopreserved embryos may not survive the thaw, may be damaged during the thaw or may not result in a normal infant; there may be a theoretical risk of congenital malformations associated with cryopreservation or long-term storage.
2. After surviving the thaw, the cryopreserved embryos may not develop sufficiently or normally to be transferred;
3. The embryo(s) may not be able to be placed in the uterus at IVF; complications such as bleeding, cramping or infection may result;
4. Implantation of the embryo(s) into the uterus may not occur; the embryo(s) may not be genetically or functionally competent to implant into the uterus even with morphologically normal (higher grade) embryos.
5. A laboratory mishap may result in the loss or damage to the embryo(s).

The Reproductive Medicine Group Program and Providers will take reasonable steps to reduce the possibility of technical failure in the various ART processes. However, it is possible that technical failure, theft, an act of nature or other events could occur. In consideration for participation in this program, we agree that The Reproductive Medicine Group IVF Program and Providers will not be held responsible for any loss or damage to any cryopreserved embryos, or any other laboratory storage events. We release The Reproductive Medicine Group IVF Program, its employees and the physicians from associated liability.

Even if pregnancy is achieved, there is a risk of early or late miscarriage, tubal pregnancy, genetic or other birth defects or stillbirth. These risks do not appear to be significantly higher due to assisted reproductive techniques, but may be increased related to multiple pregnancy if it occurs.

### **ACKNOWLEDGEMENTS**

We (I) understand that neither the undersigned physicians(s) and his/her associates nor any employee or agent of The Reproductive Medicine Group IVF Program has made any express or implied guarantee or warranty to us (me) regarding the outcome of the assisted reproductive technology that we (I) are about to undergo.

We (I) acknowledge that our physician has counseled us regarding alternative medical treatments or procedures that may be available to us (me), including non-medical options such as adoption and non-treatment.

We (I) understand that the Providers and the physicians are not obligated to proceed with assisted reproductive technology procedure (s) when in their opinion the risks associated with so doing outweigh the potential benefits.

We (I) understand that if pregnancy is achieved, follow-up obstetrical care will be required. This may be undertaken by the obstetrician of our (my) choice and might require careful biochemical and biophysical monitoring (ultrasound examination, hormone tests, amniocentesis, etc.) to determine the well-being of the fetus and/or the mother.

If we are lawfully married, we acknowledge that any child/children born to us who was conceived by in vitro fertilization, artificial insemination or by use of donated eggs or sperm or embryos will in all respects be irrebuttably presumed to be our natural child/children. (This presumption does not apply to unmarried couples or in cases of gestational surrogacy. Legal counsel is recommended).

We (I) understand that the undersigned physician(s), his/her associates, and the other Providers, unless required by law, will make all reasonable efforts to keep information about us (me) during the course of our (my) treatment confidential. We (I) agree that specific medical details may be revealed in professional publications, as long as our (my) confidentiality is maintained. We (I) understand that our (my) names and identities will not be revealed to the media or to any other person without our authorization, unless required by law.

We (I) understand the Providers must fulfill federal reporting requirements and provide data to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that 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, the CDC applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Services 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. In addition, as professional members of the Society of Assisted Reproductive Technology we report information to this professional organization in a non-identifiable manner.

We (I) understand insurance coverage for all or any part of the total procedure may not be available, and we (I) acknowledge jointly and severally (individually and as partners) our (my) personal responsibility for payment of the costs of this treatment. Such costs shall include, but may not be limited to, facility charges; laboratory charges; and physicians' professional fees. The costs explained are only for routine participation in an uncomplicated assisted reproductive technology procedure. Complications requiring unexpected treatment and/or hospitalization will result in additional costs for which we (I) understand we (I) are fully responsible.

We (I) understand future legislation or common law may develop which would invalidate or render illegal portions or all of this consent.

**CONSENT AND RELEASE:**

We (I) consent to the thawing of \_\_\_\_\_ embryos or a sufficient number of embryos for placement of up to \_\_\_\_\_ (viable embryos) into the uterus/fallopian tube (circle one or both). We (I) realize there is no guarantee that the thaw will result in the number of embryos we (I) wish to replace, or that placement will result in pregnancy. We (I) further understand that multiple pregnancy may occur with its attendant risks which are known to us (me).

Physician Instructions for ART Laboratory:

We (I) have read this Embryo Transfer Using Cryopreserved Embryo with Assisted Hatching consent form and have been afforded the opportunity to ask questions and received answers to our (my) satisfaction. We (I) understand the procedures and the potential risks and hazards associated with the procedures, and that alternative procedures may be available. We (I) sign this form freely and voluntarily. By our (my) signatures below, we (I) hereby consent to the embryo transfer using cryopreserved embryo with assisted hatching procedures. We (I) elect and agree to the process of embryo hatching of all available embryos.

We (I) authorize The Reproductive Medicine Group IVF Program, its personnel, the physician, any person under the physician's direction or responding to his/her orders to perform all necessary tests and procedures and to administer all necessary medications and treatments required in the embryo transfer using cryopreserved embryo(s).

**RELEASE AND INDEMNIFICATION**

We (I) understand the assisted reproductive technologies discussed herein are clinical procedures with unknown risks that may be related to pregnancy attempted or achieved by this method or to the mental or physical health of any child/children so produced. We (I), therefore, do jointly and severally, in consideration of the opportunity to participate in The Reproductive Medicine Group IVF Program, release the Providers from any and all liability, claims, demands, costs, expenses, and loss of any nature for any reason incurred as the result of our participation in The Reproductive Medicine Group IVF Program, including but not limited to those: associated with the birth of a child/children, in any way related to any child/children produced, any cryopreserved embryos or eggs or semen held, maintained, or handled by The Reproductive Medicine Group IVF Program, or in any way related to our participation in The Reproductive Medicine Group IVF Program.

We (I) agree to and shall indemnify The Reproductive Medicine Group IVF Program and the Providers for any attorney's fees, court costs, damages, judgments, or any other losses or expenses incurred by The Reproductive Medicine Group IVF Program and Providers or for which The Reproductive Medicine Group IVF Program and Providers may be responsible with respect to any "third party" claim, legal action or defense thereto, arising out of the in vitro fertilization herein contemplated, including, but not limited to any claim or legal action brought by the child/children resulting from the in vitro fertilization process.

\_\_\_\_\_  
Patient Printed Name Date

\_\_\_\_\_  
Partner Printed Name Date

I have consulted with and explained the contents of this consent form to the couple (individual) who have signed above.

\_\_\_\_\_  
Treating Physician Printed Name Date