

## REPRODUCTIVE BIOLOGY ASSOCIATES

### Recipient Consent for Oocyte Donation by Anonymous Donor

I, \_\_\_\_\_ (“Recipient”) and \_\_\_\_\_ (“husband/partner”) agree to a form of treatment known as oocyte (egg) donation, in vitro fertilization (IVF), and embryo transfer (ET) (the “Treatment”). We have an infertility problem that is unresolved by conventional therapy. We understand that egg donation provides a means by which infertile couples may conceive and bear children. We request this Treatment, and after detailed and complete discussion with our physician listed below, we understand that the following is an outline of the steps required in this Treatment, as well as the material risks and potential benefits of this Treatment. We have been advised that, in addition to the material risks explained in this consent form, there may be other risks involved in this therapy.

I (We) further understand that the egg donor shall remain anonymous through the services of Reproductive Biology Associates (“RBA”), \_\_\_\_\_ MD (“Physician”) or associates or staff involved in the RBA Egg Donor Bank Program.

**Nature and Purpose of Treatment:** The purpose of the Treatment is to allow me, as the Recipient, to carry and deliver a child that I could not otherwise conceive. This allows me to experience pregnancy, childbirth, and motherhood through the use of egg donation. Child(ren) conceived by this method will not have my genetic material but will have that of the egg donor and my husband/partner. Regardless of the outcome, however, I will be the mother of any child(ren) born to me as a result of egg donation and hereby accept all the legal responsibility required of a parent with regard to her child(ren).

**Diagnosis Indicating Treatment:** I (We) have been diagnosed with an infertility problem that is unresolved by conventional therapy.

**Procedures to be Followed:** RBA will obtain one or more eggs from an egg donor. I (We) have been advised that the egg donor has been carefully screened by RBA to be a suitable donor from a psychological and physical standpoint, having been tested for infectious diseases, and screened and questioned in regards to familial genetic diseases, and emotional stability. I (We) understand that RBA is neither giving nor making any guarantee or warranty about the reliability of the history of the egg donor. RBA will make an effort to match the general physical characteristics of the egg donor with the Recipient’s general physical characteristics.

Ovulation stimulating agents, including pituitary hormones called gonadotropins, will be used to stimulate multiple egg production in the egg donor. The pituitary is the master gland at the base of the brain. Modification and control of the donor’s pituitary hormones will be induced by drugs, administered by injection daily for up to 28 days, which modify the gonadotropin releasing hormone from the base of the brain. Two different approaches may be used, GnRH agonists or antagonists. Human chorionic gonadotropin (HCG) which mimics the pituitary hormone LH, is used to trigger ovulation. This injection is given once approximately 36 hours prior to egg retrieval.

The egg donor will have blood samples collected and undergo ovarian ultrasound examination, in which high frequency sound waves are used to form an image of the follicles, the fluid filled

areas where eggs develop. The purpose of these tests is to identify the time at which eggs are suitable for recovery. Surgery to retrieve the eggs will be scheduled near the time of projected ovulation. Vaginal ultrasound guided egg retrieval is the method of egg retrieval, which involves the introduction of a specially designed needle through the vaginal wall under local anesthesia and intravenous sedation.

Recipients will have the option of inseminating all the mature eggs available OR cryopreserving a portion of the eggs prior to insemination. **There are advantages to cryopreservation of eggs before fertilization. First, this approach limits the number of excess embryos for which a patient becomes responsible. Secondly, egg cryopreservation allows patients to donate the eggs back to RBA at later date without the ethical or emotional concerns surrounding the donation of one's own gametes. Other unanticipated advantages to egg freezing may also exist. In the event we choose to cryopreserve any of the donor eggs, we understand that we may not sell or return the eggs to any person, business interest or institution other than RBA. However, we understand that circumstances may arise in which we desire to return some or all frozen eggs to RBA and that RBA reserves the right to accept or refuse returned eggs on a case by case basis.**

**There are potential disadvantages to egg freezing as well. Eggs may die as a result of the freeze and thaw procedures. Fertilization potential may be impaired and may result in low or no normal embryos. RBA has thusfar been successful with egg freezing but there are no large data sets that detail average pregnancy rates or risks to patients and any resulting offspring. Unanticipated disadvantages to the egg freezing procedure, including abnormal pregnancy, abnormal delivery or impaired offspring may exist.**

The female partner will undergo the administration of hormones during the donation cycle in order to synchronize her cycle with the egg donor's cycle and to prepare her uterine lining. Modification and control of the female partner's pituitary hormones will be induced by drugs, administered by injection daily for up to 28 to 35 days, which modify the gonadotropin releasing hormone from the base of the brain. Estrogen and progesterone will be administered by injection, vaginally or orally. The female partner will have blood samples collected and undergo ovarian ultrasound examination, in which high frequency sound waves are used to form an image of the uterine lining. The purpose of these tests is to identify the time at which the uterus is suitable for embryo transfer.

The husband/partner will provide a fresh sperm specimen collected by masturbation or other means, or a sperm donor can be used, to inseminate the eggs by intracytoplasmic sperm injection (ICSI). ICSI is performed when there is known or suspected defective sperm production, or when low numbers of eggs (less than 5) are recovered at egg retrieval. A single sperm in these cases is picked up in a fine hollow needle and injected into the body of the egg. The micromanipulation itself, the actual insertion, or the result of it, may cause immediate degeneration of the egg, or may yield abnormal embryo(s). Technical problems might exist which may make successful sperm injection impossible. If embryos resulting from ICSI are replaced, the Recipient will take corticosteroids by mouth for 5-15 days.

I do \_\_\_\_\_ / do not \_\_\_\_\_ consent to the use of intracytoplasmic sperm injection (ICSI) if it is recommended.

\_\_\_\_\_  
Recipient's initials

\_\_\_\_\_  
Husband/partner's initials

A clinical method for potential enhancement of pregnancy during IVF, known as assisted hatching, involves micromanipulation of the zona pellucida (soft shell surrounding the embryo) after fertilization and prior to replacement of embryo(s) into the uterus. A small hole will be made in the zona pellucida by micromanipulation using an acidic medium or laser to "drill" through this outer shell. This technique may facilitate the hatching ability of embryo(s) to improve the ability of the embryo(s) to implant. If hatched embryos are placed in the Recipient's uterus, the female will take corticosteroids and antibiotics by mouth for 5-15 days.

I do \_\_\_\_\_ / do not \_\_\_\_\_ consent to the use of assisted hatching if it is recommended.

\_\_\_\_\_  
Recipient's initials

\_\_\_\_\_  
Husband/partner's initials

Once the eggs have been inseminated or exposed to the husband/partner's sperm, the eggs become the property of Recipient and male partner. **Any eggs frozen prior to insemination are held in storage for my/our future benefit but are the property of RBA. We understand that we are responsible for storage fees for frozen eggs maintained on our behalf.**

After 3 days, if fertilization takes place as planned, at the 4- to 8-cell stage, early embryo(s) may be placed into the Recipient's uterus. This transfer will be made through the Recipient's cervix via a small catheter. In some cases the embryo(s) will be cultured in vitro for a total of five days, until the blastocyst stage.

Almost all IVF procedures produce eggs which do not fertilize. After 24 hours it is clear that these will not benefit the attempt to conceive. Most of these eggs are discarded, but in some cases the eggs may be studied to investigate the science of human reproduction, subject to your consent. Some of this knowledge could be of benefit to future patients.

I do \_\_\_\_\_ / do not \_\_\_\_\_ consent to the utilization of our unfertilized eggs for scientific research.

\_\_\_\_\_  
Recipient's initials

\_\_\_\_\_  
Husband/partner's initials

There are usually some eggs which appear to fertilize normally. During the 3-5 days of incubation it becomes clear that a certain percentage of embryos cease to develop. These embryos are composed of degenerating cells which are no longer dividing. These embryos are discarded. However, from time to time, scientific observations can be made on these embryos which could help us to understand human reproduction and infertility, subject to your consent. None of these embryos would be monitored in culture beyond 14 days.

I do \_\_\_\_\_ / do not \_\_\_\_\_ consent to the utilization of our abnormal embryos or embryos that cease to develop for scientific research.

\_\_\_\_\_  
Recipient's initials

\_\_\_\_\_  
Husband/partner's initials

**Reasons for Possible Failure:**

- A. The time of ovulation may be misjudged or may be unpredictable, or may not occur at all in the monitored cycle, thus precluding any attempt at obtaining an egg.
- B. An attempt at egg retrieval may be unsuccessful.
- C. The egg(s), if obtained, may not be normal.
- D. The husband/partner may be unable to obtain a semen specimen or may produce no sperm.
- E. Eggs may not survive the thawing procedure.
- F. Fertilization may not occur.
- G. Cleavage, or cell division, of the fertilized egg(s) may not occur.
- H. The embryo(s) may not develop normally.
- I. It will not be possible to maintain the life of the embryo if the Recipient does not return for transfer.
- J. Implantation may not occur.
- K. Loss or damage of the fertilized eggs or embryo(s) may occur during the procedure.
- L. There may be other reasons that are not understood by the scientists.

Realizing the difficulty and the low likelihood of success of this Treatment, it is still our wish to attempt this Treatment.

**Note: Complications from some of the problems listed below may lead to serious permanent disability or death.**

**Material Discomforts and Risks:** The following are some of the risks and discomforts associated with the embryo transfer procedure:

- A. **Blood drawing:** Discomfort and the possibility of developing a painful bruise at the needle site may occur. A blood clot in the vein may occur.
- B. **Ultrasound:** This examination involves the use of a form of energy (sound waves) which at high energy levels may produce heat and tissue damage. At the extremely low energy levels utilized in diagnostic ultrasounds, no adverse effects have been observed to date.
- C. **Medications:** Some of the risks associated with taking hormones to recreate the menstrual cycle are common. Women may experience none to all of the following symptoms: nausea, vomiting, slight weight gain or loss, breast tenderness and enlargement, occasional vaginal bleeding, changes in skin pigment on the upper lip, under the eyes, or on the forehead, yeast infections of the vagina, vaginal discharge and

wetness, hot flashes, night sweats, menstrual period cramping, headaches, fluid retention and mood swings. Much less common side effects include appetite changes, nervousness and fatigue, and changes in sex drive. More serious but rare side effects include hypertension (high blood pressure), gall bladder disease, blood clots developing in the legs, lungs, eyes, brain, heart or elsewhere, heart attacks and strokes. I have been advised that I am at more risk for developing heart problems and blood clots if I smoke, or have in the past.

**D. Risks to Us:** As with any transfer of embryo(s), the risk of tubal or ectopic pregnancy or miscarriage exists. Pregnancy may not occur, and this will lead to personal disappointment. Corticosteroids will be given by mouth to the Recipient for five days and the following side effects may occur in rare cases. It may mask signs of infection, and new infections may appear during use. High blood pressure, salt and water retention, and increased excretion of potassium and calcium may occur. These effects may cause mood swings, insomnia, depression, psychotic manifestations, muscle weakness, impaired wound healing, increased sweating, headache, or dizziness.

If the Recipient is over 50 years of age, there is a significantly increased risk (as much as 10-fold) of preeclampsia and gestational diabetes when compared to women less than 50 years of age.

The use of antibiotics may result in nausea, vomiting, diarrhea, loss of appetite, and rashes. Also in uncommon or rare cases, sensitivity to the sun, hypersensitivity reactions resulting in shock, or blood diseases including reduced platelets or fractured red cells with anemia or bleeding may occur.

**E. Embryo transfer:** This procedure may cause discomfort and may lead to infection or ectopic or tubal pregnancy which could result in hemorrhage, or excessive bleeding or death.

**F. Risk to Potential Children:** There are theoretical risks of the procedure which potentially could damage the embryo and result later in defects in the child. It is not known if the risk with this procedure (egg donation) is higher or lower than the risks associated with children conceived naturally. The normal filtering effect of the female reproductive tract selects against certain types of abnormal sperm. Since this filter is lost in IVF, abnormal sperm could be responsible for fertilization of the egg and to fertilization with more than one sperm and potential genetic abnormality.

Although the early embryo is thought to be highly resistant to environmental damage, the laboratory culture conditions may induce previously unknown problems.

Some studies of outcomes of assisted reproduction show no apparent increase of developmental defects. Two articles indicate double the normal rates of low birth rate and major birth defects. In 2002, research indicated that low birth weight occurred at double normal rates in IVF offspring, for reasons which were unknown. Birth defects were noted in IVF babies of almost 3%, about double normal rates. It is possible that the characteristics of the parents are the origin of these problems. A group of patients with specifically identified increased risk of abnormalities is the group of male factor patients, particularly those with extremely low sperm production. In the event that we should

become pregnant following transfer of embryos after ICSI, you have advised us to consider further tests to establish the genetic normality of our fetus.

There may be unforeseen risks for the Recipient, the husband/partner, or the embryo(s), fetus(es), or child(ren) that develop from this Treatment. While it is difficult to anticipate any such risks, we acknowledge that we have been notified of this possibility.

**G. Controversial Ethics:** Certain aspects of the ethics of this Treatment are controversial. Some members of the community, including our own family or friends, may not approve of this Treatment. This disapproval may damage interpersonal relations between us and our family and/or friends.

**H. Multiple Pregnancies:** Replacement of more than one embryo increases the chance of pregnancy. The goal of the procedure is to obtain multiple embryos for transferring to the uterus and leading to pregnancy. Transfer of more than two (2) embryos at a time increases the risk of multiple pregnancy.

These rates are much higher than in natural pregnancy. Multiple pregnancy has an increased risk for premature birth, birth defects, maternal hypertension, low birth weight, and many other complications. Pregnancies with triplets or more fetuses always deliver prematurely - about 4 to 6 weeks early for triplets, and 6 to 8 weeks early for quadruplets. Such severely premature infants are at risk for many complications including long term neurological and other handicaps and death.

Multiple pregnancies may lead to emotional and financial strain for you and prolonged hospitalization of the Recipient before birth and of both the Recipient and infants after birth. Deaths of babies around the time of delivery and the number of babies born with long-term handicaps are several times more common in multiple births than in single births. The major problem is that the babies are born before they are fully mature.

Some of the disorders and other factors that are responsible for increased illness and death of infants of multiple pregnancies include: premature delivery, unequal blood flow to the developing twins, placental infarcts (portions of the placenta lose their blood supply), and premature separation of the placenta and compression of the cord. Also, higher numbers of birth defects occur in offspring of multiple-fetus pregnancies. These problems are even more frequent in sets of identical twins.

A procedure known as fetal reduction of pregnancy has been proposed for some women whose pregnancies involve 3 or more fetuses. More information on this controversial procedure is available on an individual basis.

If pregnancy is established, miscarriage, tubal or ectopic pregnancy, stillbirth, or birth defects may occur.

**I. Failure to Achieve Pregnancy:** The Treatment may fail to produce a pregnancy. If the Treatment does not succeed, you could be disappointed. You could experience frustration, anxiety, and depression which may be severe.

