

Reproductive Biology Associates
Agreement for Cryopreservation of Embryos and or Oocytes

I/We have consented to undergo in vitro fertilization (IVF) treatment and have signed the appropriate consent forms consenting to such treatment. As a result of drug stimulation of the ovaries, more than one embryo may be obtained after IVF. Alternatively, if I/We have consented to the use of donated oocytes (eggs) and have signed the appropriate consent forms consenting to such procedure, more than one egg or embryo may be obtained as a result of such procedure. When, as is usually is the case, an IVF treatment or egg donation procedure produces multiple eggs, it may be advantageous to freeze eggs prior to fertilization. Egg freezing allows patients to limit the number of embryos resulting from IVF and helps avoid the disposition problems that present when patients no longer want to use these remaining embryos to initiate pregnancy. When IVF treatment results in healthy eggs we do not want inseminated, I/We consent to cryopreservation (frozen storage) of the extra eggs. The number of eggs to freeze will be determined on an individual basis and will vary by patient and clinical circumstances. Many eggs are not mature and are incapable of fertilization. In some cases mature eggs have other abnormalities visible to the embryology team that make them unsuitable for freezing. In some cases, the medical team will advise me/us to inseminate all of my/ our eggs as a result of low egg number or quality. In these and other possible scenarios I/We understand that I/We may not be able to freeze eggs even though I/We had consented to the procedure. Alternatively, cases may arise where the medical team advises me/us to freeze all of the available eggs. I/We further understand that egg freezing is no guarantee of future success when the eggs are thawed and that it is possible for all my/our frozen eggs to die during the freeze/ thaw process.

Current data suggests that approximately 80% of eggs will survive the freeze/ thaw process. Surviving eggs then exhibit a 60-70% fertilization rate. Pregnancy rates for frozen egg treatment at RBA are currently above 70%, however, these pregnancies occurred in egg recipients. Little or no data on pregnancy outcome using frozen eggs in women over 30 using their own eggs is available. I/ We understand that RBA makes no representation regarding the viability of frozen eggs in women over 30 or in egg freezing in women using their own eggs. As this data becomes available, the RBA medical team will advise me/us of current outcomes.

When IVF treatment or egg donation procedure obtains more than the ideal number of embryos for replacement, I/We consent to cryopreservation (frozen storage) of the extra embryo(s). If the fresh embryos fail to lead to pregnancy, or if they do lead to pregnancy and I/we want to have an additional pregnancy, the frozen embryo(s) may be thawed and replaced in a later cycle. A disadvantage of cryopreservation is that about 30% of embryos do not survive the freeze, storage, or thaw procedure. Additionally, other embryos may be damaged with the loss of one or more cells. Cryopreservation of a single embryo may increase the total chance of birth by approximately 10%.

Procedures to be Followed: I/We understand that the following procedures will be performed to freeze my/our egg(s) or embryo(s). A chemical will be added to the culture medium. The **egg(s)** or **embryo(s)** will then be cooled in a biological cell freezer and stored at -196 Celsius in liquid nitrogen. I/ We understand that after thawing, an egg or embryo may degenerate and no longer be living. These eggs or embryos will be either discarded or possibly used for research, according to our wishes as set forth in this agreement. Other embryos may survive intact or lose some cells, but survive and possibly grow to implant and produce a pregnancy.

I/We intend to have these egg(s) or embryo(s) thawed and transferred back to (replaced into) the female partner's uterus at the proper moment in a later cycle. Replacement of embryos arising from both fresh insemination and egg thawing will require the administration of a pituitary suppressant, estrogen, and natural progesterone in injectable, suppository and/or oral forms on a prescribed schedule. Egg(s) are thawed and inseminated or embryo(s) are thawed and transferred at the appropriate time during this schedule. I/ We will sign a separate consent for this treatment.

Risks: The frozen egg(s) or embryo(s) may, upon thawing, degenerate. If this occurs, the egg(s) will not be inseminated or embryos(s) will not be replaced into the female partner's uterus. Animal research has demonstrated that early embryos are remarkably resistant to the insults of freezing, storage and thawing. It seems that eggs and embryos either survive unharmed or die. There is no indication at the current time that freezing of eggs or embryos increases birth defects. To date, the children born as the result of cryopreservation have not had increased rates of abnormalities. This is true also among the thousands of animals born each year from frozen embryos. It is possible that in the future more information in this area of concern may be learned.

There may be unforeseen risks for the female partner, the male partner, or the embryo(s), fetus (es), or child (ren) who develop from this treatment. While it is difficult to anticipate any such risks, I/We acknowledge that I/We have been notified of this possibility.

There may be other unforeseen complications, which have not been listed that may occur.

DISPOSITION OF FROZEN/THAWED EGG(S): I/We intend to freeze eggs and subsequently thaw them at a later date for insemination and embryo transfer to the female partner's uterus. Should I/ We change my/ our decision in this regard for any reason I/we understand that I/we have three options:

1. Eggs may be **DISCARDED**.
2. Eggs may be **DONATED** for use by another patient. RBA will determine if the frozen eggs are viable and meet FDA criteria for donation. In the case where the egg(s) are deemed ineligible for use, the eggs may not be donated anonymously. Directed donation to a **KNOWN** recipient will be acceptable and is a matter of informed consent covered in a separate consent form.
3. Eggs may be subject to **SCIENTIFIC STUDY**. Scientific investigation may include but is not limited to observation by microscopy, chemical treatment and or intentional disruption of cellular structures. Eggs **WILL NOT BE INSEMINATED** by any sperm source without our expressed, written consent.

****I/WE UNDERSTAND THAT IF I/WE CHOOSE TO MAINTAIN OUR EGGS IN CRYO-STORAGE THAT I/WE ARE RESPONSIBLE FOR ANY AND ALL RECURRING CHARGES OR STORAGE FEES AS COVERED IN RBA'S FEE SCHEDULE.**

I/We have the principal responsibility to decide the disposition of my/ our eggs. While I/We are alive our frozen egg(s) will not be released from storage for the purpose of donation to another couple, disposal, or scientific study without written consent of me/ us . I/We may determine to have my/our egg(s) removed from cryopreservation at any time. If egg(s) are cryopreserved and I/We determine to have them removed, then our options are as previously explained as being egg donation, disposal, or scientific study of the eggs.

The possibility of one or both of our deaths, disappearance, incapacity, inability to agree on disposition in the future, or any other unforeseen circumstance that may result in neither of us being able to determine the fate of any stored egg(s) requires that I/We now indicate my/ our wishes. I/We understand that one of three decisions explained above must be made. In the event I/we are unable to make a decision later, I/we now indicate my/our desire to have any or all of our embryos in frozen storage disposed as follows:

_____ **A. EGG DONATION**

Female partner's signature

Male partner's signature

_____ **B. CELL CULTURE AND DEGENERATION/DISPOSAL**

Female partner's signature

Male partner's signature

_____ **C. SCIENTIFIC STUDY**

Female partner's signature

Male partner's signature

I/We understand that one of two decisions explained above must be made for any poor quality egg(s) which either may not be of sufficient quality to inseminate or may have been frozen and once thawed may not survive the thaw. I/We now indicate my/our desire to have any or all of my/our poor quality eggs disposed as follows:

_____ **A. DISPOSAL**

Female partner's signature

Male partner's signature

_____ **B. SCIENTIFIC STUDY**

Female partner's signature

Male partner's signature

In the event of divorce, separation, or marriage dissolution I/We understand the legal ownership of any stored egg(s) reverts to the female partner

I/We understand that I/We retain the right at all times during storage of the egg(s) to contact RBA by written consent of us both to change any directions for the disposition of our cryopreserved eggs.

I/We understand that scientific study of our egg(s) may result in treatments, procedures or products that have commercial value. I/We further understand that I/We will not receive any compensation for any future commercial use resulting from the scientific study of My/Our egg(s).

DISPOSITION OF EMBRYO(S): We intend to have these embryos thawed and transferred back to the female partner's uterus. However, if we should change our decision in this regard for any reason, we understand that we have three options:

1. **EMBRYO DONATION:** Embryo(s) will be donated to another couple.
2. **CELL CULTURE AND DEGENERATION/DISPOSAL:** Embryo(s) will be thawed and discarded.
3. **SCIENTIFIC STUDY:** the embryo(s) will be observed and studied scientifically in the laboratory at RBA by microscope or other means. The embryos will not be maintained for more than one week of further development.

We have the principal responsibility to decide the disposition of our embryo(s). While we are alive our frozen embryo(s) will not be released from storage for the purpose of donation to another couple, disposal, or scientific study without the written consent of us both. We may determine to have our embryo(s) removed from cryopreservation at any time. If embryo(s) are cryopreserved and we determine to have them removed, then our options are as previously explained as being embryo donation, disposal, or scientific study of the embryos.

The possibility of one or both of our deaths, disappearance, incapacity, inability to agree on disposition in the future, or any other unforeseen circumstance that may result in neither one of us being able to determine the fate of any stored embryo(s) requires that we now indicate our wishes. We understand that one of three decisions explained above must be made. In the event we are unable to make a decision later, we now indicate our desire to have any or all of our embryos in frozen storage disposed of as follows:

_____ **A. EMBRYO DONATION**

Female partner's signature

Male partner's signature

_____ **B. CELL CULTURE AND DEGENERATION/DISPOSAL**

Female partner's signature

Male partner's signature

Contact Information: I/We understand that it is our responsibility to inform RBA of any change in address or telephone numbers listed below as long as I/We have **egg(s)** or **embryo(s)** in storage at that facility. After a period of five (5) years has elapsed without contact with RBA and RBA continues to store our egg(s) or embryo(s) at such time, if I/We fail to keep such information current with RBA, and after diligent search by registered letter to our last known address, and calls to our last known phone number, and our contact person listed below, RBA will consider my/our egg(s) or embryos(s) abandoned. At such time as RBA determines my/our egg(s) or embryo(s) abandoned, I/We understand that RBA has the right to dispose of these egg(s) or embryo(s). In such instance, RBA's policy is that it will neither donate the egg(s) or embryo(s) to another couple nor use them for scientific study. I/We further understand that if I/We fail to pay our storage fees when due, after diligent efforts as listed above to contact us, RBA has the right to dispose of these embryos. In such instance, RBA's policy is that it will neither donate the egg(s) or embryo(s) to another couple nor use them for scientific study.

CONTACT INFORMATION:

Female Partner _____
(Please include name,
address,telephone, _____
Cell,e-mail address)

Male Partner _____
(please include name,
address,telephone,cell _____
pager, email address)

Contact Person: _____
(please list a person
Who will know how to _____
Contact you and include
Name address,telephone _____
Cell,pager, email address)

Equipment Failure: I/We understand that with any technique necessitating mechanical support systems, equipment failure can occur. Neither RBA, nor its directors, employees, agents or consultants, are to be held liable for any destruction, damage, misuse, or improper testing, freezing, maintenance, storage, withdrawal, thawing, and/or delivery caused by or resulting from any gross negligence, malfunction of the storage tank, failure of utilities, strike, cessation of service, war, acts of a public enemy, or other disturbances, or any fire, wind earthquake, water, or other acts of God; or the failure of any other laboratory.

Financial Responsibility There will be a fee charged at the time of cryopreservation of the egg(s) or embryo(s) for freezing and storage for the first two years. Thawing procedures performed before the anticipated transfer of frozen egg(s) or embryo(s) to the female partner's uterus will involve additional expense for which we are responsible whether transfer is performed or not. I/We will get a separate fee sheet from RBA as to the amount of these additional expenses. There is an additional charge for the insemination and transfer of frozen thawed egg(s), if this transfer is done. There is an additional charge for the transfer of the frozen embryo(s), if this is done. We will be responsible for any direct medical expenses incurred for this therapy, including the cost of complications at the prevailing fee schedule, other than RBA physician fees for treating whatever complications may arise.

If any egg(s) or embryo(s) will be stored beyond 24 months from the date of cryopreservation we will pay a fee annually, which increases each year, to RBA for such long-term storage. If all egg(s) or embryo(s) in storage are thawed prior to the conclusion of the 24 month period I/ We will be reimbursed a portion of the fees already paid for storage. The period of embryo storage at RBA will be no more than 5 years from the date of this agreement, after which time other storage or disposition options of the egg(s) or embryo(s) will be discussed with us. The fee will be payable in advance on the first day of the month in which the 24-month period begins. An invoice will be sent to us when payment is due.

Current Status of Cryopreservation Therapy Success and % Risk of Multiple Pregnancy:
Please ask your IVF nurse for the current CDC and RBA statistics handout.

Alternative Procedures: I/We understand that we may refuse to have egg(s) or embryo(s) cryopreservation. Our alternative options would be to limit the number of eggs retrieved in IVF treatment or donated in an egg donation procedure (and thereby limit the number of embryos replaced) or to have all embryos that develop from an IVF treatment or egg donation procedure replaced into the female partner's uterus at one time. I/We may elect these egg(s) or embryo(s) be destroyed or donated for scientific study. I/We understand that it cannot be predicted how many eggs are necessary to result in at least one embryo.

Records/Confidentiality: I/We understand that strict confidentiality will be maintained with respect to all information which identifies us to the extent permitted by law.

Inquiries: Questions regarding this treatment will be answered by Hilton I. Kort, M.D., Carlene W. Elsner, M.D., Dorothy E. Mitchell-Leef, M.D., Daniel B. Shapiro, M.D., Andrew A. Toledo, M.D., David I. Keenan, M.D., Scott M. Slayden, M.D., Robert J. Straub, M.D. or one of their assistants. They can be reached at 404-843-3064.

Voluntary Consent: I/ We have read and understand this agreement and consent form. I/We understand that some of the language in this agreement and consent form may be technical. I/We certify that I/We understand the nature of the cryopreservation and consent to have our egg(s) or embryo(s) cryopreserved. I/We have been given an opportunity to ask any questions I/We may have. All questions and inquiries have been answered to my satisfaction. I/We have been informed that I/We may contact the office of Reproductive Biology Associates at 404-843-3064 regarding further questions about this procedure and my rights as relating to this procedure. I/We am /are 18 years or older.

In light of what is known about the possible reasons for our infertility, I/We accept this treatment option as a potential tool to enhance the possibility of establishing pregnancy. By signing this agreement, I/We attest that I/We have indicated my/our wishes for disposition of our egg(s) or embryo(s) above. I/We further attest that I/We have been given the opportunity to ask questions and the physicians and staff of RBA have answered, to my satisfaction and within the limitation of current knowledge, all my questions.

FEMALE PARTNER:

Female partner's printed name

Female partner's signature

DATE

Witness signature

DATE

MALE PARTNER:

Male partner's printed name

Male partner's signature

DATE

Witness signature

DATE

I, the undersigned, have defined and fully explained the cryopreservation of egg(s) or embryo(s) to the female partner and the male partner named above and I have answered all of their questions. To the best of my knowledge, the individuals signing this agreement and consent form understand the procedure involved and the benefits and risks involved in this procedure.

Physician Signature

DATE

**Cryo Egg/Embryo
Revised 1/08**