



IVF PHOENIX

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**HUMAN EMBRYO CRYOPRESERVATION
AGREEMENT OF UNDERSTANDING AND
ACKNOWLEDGEMENT OF INFORMED CONSENT**

We/I, _____ and _____, the undersigned, agree to submit some ____ or all ____ of the embryos that remain from in vitro fertilization or micromanipulation to the process of cryopreservation/freezing. I am/We are aware that this process cools an embryo to -40 C under laboratory conditions directed by Dr. John Couvaras and IVF Phoenix Laboratory. The embryo(s) remain stored in a frozen state until the couple request a transfer of the embryos into the uterus or advise IVF Phoenix to destroy them. Upon notification of a desire to transfer the embryos, the physician will monitor the woman's cycle until optimum conditions are achieved for transfer to occur. If, after thawing, the embryo does not survive or does not grow, it will be appropriately discarded and not transferred back into the woman's uterus.

The purpose of embryo freezing is to save embryos that are the product of an IVF/ART cycle. This allows the couple to use the embryos obtained from one IVF/ART cycle for future transfer to the uterus without the need to repeat another ovarian superovulation cycle.

Worldwide experience has resulted in several clinical pregnancies and normal live births. I am/We are aware that not all of the embryos will survive the freeze-thaw process: Approximately 50% are expected to be viable after the thawing process. I/We understand that neither the physician nor IVF Phoenix can guarantee the results of this procedure.

As with any technique that requires mechanical support systems, equipment failure can occur for which IVF Phoenix can not be liable. Backup systems are available to decrease the likelihood of serious malfunction, but unforeseen situations could occur which are out of the control of IVF Phoenix.

Embryo freezing has been used in cattle and laboratory animals with no known adverse results in the offspring, but long term effects with human embryo freezing are unknown at the present time. I/We have been informed that the rate of congenital anomalies or malformations in the offspring of fresh assisted reproduction pregnancies is the same as that of the general population.

If pregnancy does occur, referral to a qualified physician for amniocentesis (removal of a sample of the fluid surrounding the fetus) or chorionic villus sampling (sampling of the tissue that makes up the placenta) is suggested. Both procedures are effective in identifying certain chromosomal (genetic) abnormalities and major structural abnormalities of the central nervous system. If an abnormality is identified through amniocentesis or chorionic villus sampling, the geneticist and the physician working with IVF Phoenix will discuss the implications of the findings, and I/we will be given an opportunity to decide whether to terminate or continue the pregnancy. If the decision to terminate the pregnancy is made, I/we agree to accept financial responsibility for that procedure.

Legal principles and requirements regarding IVF and embryo freezing have not been firmly established. Currently, there are no Arizona State Laws dealing specifically with these issues. It

is

generally accepted that each embryo resulting from the fertilization of woman's egg by a man's sperm shall remain the joint legal property of both. If anonymous donor sperm is used, ownership of the

embryo(s) will remain with the couple, unless there is no legal marriage then ownership of the embryo will reside solely with the woman signing this consent form. If there is dissolution of the marriage, release or disposal of the embryos will require the signed consent of both partners. I/We understand that legal requirements may be established by the state and guidelines may change at any time.

As the owner(s) of any and all such embryos, the consent of all participants will be required concerning their use and disposition. Such consent must be obtained from all owner(s) **prior** to cryopreservation. Certain use or disposition may also require approval by the IVF Phoenix team.

Should circumstances arise whereby embryo(s), fresh or frozen, remain that are not used for the purpose of attempting to initiate a pregnancy in the woman, the embryo(s) may be donated to another infertile couple, or otherwise handled in such a fashion to be determined by the IVF Phoenix team in accordance with established policies. Disposition may also be controlled by the final decision of a court or other governmental authority having jurisdiction there over.

I/We wish to have the embryo(s) disposed of in the following fashion: (**Only one of the three paragraphs must be initialed "YES"; initial the other paragraphs "NO".**)

- 1.) The embryo(s) be used by other infertile couple(s), if otherwise permissible by law.

YES _____/_____ NO _____/_____

- 2.) The embryo(s) be handled in accordance with the policies of the IVF/ART program at IVF Phoenix in a manner consistent with professional and ethical standards, and applicable legal requirements.

YES _____/_____ NO _____/_____

- 3.) Physical possession of the embryo(s) will be transferred back to the owner(s). All transfer costs or arrangements will be the responsibility of the owner(s).

YES _____/_____ NO _____/_____

I/We understand that this decision is binding. I/We will retain the right to change my/our decisions regarding the disposition of the embryos until all embryos are used or disposed of. A change in disposition will require written notice to the IVF Phoenix team at which time a new contract will be drafted and signed by all owners of such embryo(s). The ultimate disposition of these embryos will also be subject to applicable laws and court decisions, e.g., decree of dissolution, in the event of a change in our marital status or other events interfering with the fulfillment of our present intentions.

In the event of the death of both husband and wife or all owners of the embryo(s), I/we direct the embryo(s) be disposed of in the following fashion: (**only one of the two paragraphs must be initialed "YES"; initial the other paragraph "NO".**)

- 1.) The embryo(s) may be used by other infertile couples, if otherwise permissible by law.

YES _____/_____ NO _____/_____

2.) The embryo(s) should be handled in accordance with the policies of the IVF/ART program at IVF Phoenix in a manner consistent with professional and ethical standards, and applicable legal requirements. YES _____/_____ NO _____/_____

I, the female partner, understand that a decision regarding the disposition of the stored embryos must be made no later than the time I enter natural menopause. I understand the presumption of menopause will be at age 50 unless IVF Phoenix is provided written notice to the contrary. If, at that time, we do not want the embryo(s) used by anyone else or handled in accordance with the policies of IVF Phoenix, we will arrange for their transportation to a suitable location elsewhere. If, however, arrangements are not made by that time, the IVF Phoenix team will have the right to handle the embryo(s) in accordance with their standard policy, in a manner consistent with professional and ethical standards, and applicable legal requirements.

The fee for cryopreservation includes storage for the first year from the date of the initial cryopreservation. After one year, a yearly fee (that is subject to change) will be assessed. If I/we, the owner(s) of the embryo(s) decide to donate the embryo(s), I/we will notify the IVF Phoenix team as soon as possible and storage charges will be discontinued. We will maintain a correct address on file with IVF Phoenix and will notify them of changes in our marital status, menopausal status, or health condition that would preclude further attempts at achieving a pregnancy.

I/We understand that prior to donating embryo(s) to other infertile couples, I/we must have documented HIV testing, Hepatitis B and C screening, RPR, and maternal blood type and Rh. Without such testing information, the agreement and option of donating embryo(s) for transfer into someone other than the female owner is void and the default option is for disposal of such embryo(s) if they are not to be used by the female owner.

Failure to pay for continued storage or failure to provide current information to the IVF Phoenix team will result in disposition of the embryo(s) in accordance with the policies of IVF Phoenix.

If the embryo(s) are donated, confidentiality will be maintained. The current legal opinion is that the offspring of any successful pregnancy will attain the legal status of adopted children without legal ties to the biological parent(s).

In any circumstances where the IVF Phoenix program is terminated and there are embryo(s) that remain in storage, I/we will be contacted and all reasonable efforts will be made to arrange for disposition of such embryo(s) in accordance with my/our desires at that time.

Each of us hereby agrees and acknowledges that any sperm, ova, or embryos that belong to me/us that is determined to be non-viable or otherwise medically unsuitable for transfer as judged by the IVF Phoenix team will be disposed of in accordance with program policies. I/We will be notified prior to the disposal of any such embryo(s).

I am/We are voluntary participants and are free to withdraw my/our consent regarding the disposition of our embryos and can discontinue my/our participation in the program by written request. I am/we are free to relocate of any embryos to another suitable location at any

time without prejudice.

If pregnancy occurs, close observation by the IVF Phoenix team is important and will continue throughout the pregnancy unless I/we notify the IVF Phoenix team in writing of our objections to such observation. I/we understand that if I/we or any of my/our offspring should require medical treatment as a result of physical injury arising from my/our participation in this process, financial responsibility for such treatment will be my/our own. Therefore, payment of all medical costs associated with my/our participation will be my/our responsibility. IVF Phoenix will not be held responsible for conditions related to this procedure.

IN THE EVENT OF INJURY RESULTING FROM THIS PROCEDURE, IVF PHOENIX IS NOT ABLE TO OFFER FINANCIAL COMPENSATION OR ABSORB THE COSTS OF MEDICAL TREATMENT, HOWEVER, IT WILL ASSURE THAT THE NECESSARY FACILITIES, EMERGENCY TREATMENT AND PROFESSIONAL SERVICES WILL BE AVAILABLE.

MY SIGNATURE BELOW ACKNOWLEDGES MY VOLUNTARY PARTICIPATION IN THIS PROCEDURE, BUT IN NO WAY RELEASES THE MEDICAL STAFF FROM THEIR PROFESSIONAL AND ETHICAL RESPONSIBILITY TO ME.

I/We shall indemnify IVF Phoenix and all its participants for any attorney's fees, court costs, damages, judgments, or any other losses or expenses incurred by the program for which they may be responsible with respect to any claim, legal action or defenses thereto arising out of the Human Embryo Cryopreservation process, herein contemplated, including, but not limited to, any claim or legal action brought by the child or children resulting from the Human Embryo Cryopreservation process of their offspring.

In signing this agreement, I am /we are aware that this procedure may have serious psychological consequences with respect to, but not limited to, the parent/child and husband/wife relationship. I/We hereby release IVF Phoenix from all liability and responsibility whatsoever for any psychological consequences of this procedure.

I/We understand the confidentiality of the data will be maintained within legal limits. My/Our questions regarding these procedures have been answered to my/our satisfaction. My/Our participation is completely voluntary. I/We understand that I/we may withdraw my/our consent at any time prior to the procedure. I/We have read and understand the implications of this consent and have received a copy. If I/we have additional questions at a later date, I/we understand that I/we can contact IVF Phoenix, Dr. Couvaras, and/or his associate at (602) 765-2229

Patient signature

Date

Witness

Date

Partner/Spouse signature

Date

Witness

Date

Revised 2/8/02
