

The Fertility Center of Colorado

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CONSENT FOR CRYOPRESERVATION AND STORAGE OF FERTILIZED EGGS

Patient Name _____ SS# _____

Partner Name _____ SS# _____

This agreement is a contract made and to be performed at Colorado Springs, Colorado, between _____ ("Patient"), _____ ("Partner"), and the Fertility Center of Colorado ("the Center").

RECITALS

Patient and partner wish to try to achieve a pregnancy by means of *in vitro* fertilization under the Center's Assisted Reproductive Technologies ("ART") Program and are enrolled therein. The Center offers its Cryopreservation Program ("the Cryo Program") to qualified ART patients as an option upon the terms and conditions of this agreement. The Center's ART and Cryo Programs are designed to aid couples that are infertile due to one or more conditions.

The Cryo Program uses liquid nitrogen to freeze, and thereby preserve, human pre-embryos (defined as fertilized eggs). This procedure is available when Patient and Partner produce multiple pre-embryos during their ART treatment cycle. The Cryo Program reduces the risk of multiple births, while creating opportunities for future pregnancy by transfer of concepti developed from frozen/thawed pre-embryos, sometimes avoiding additional egg retrieval procedures. Patient and Partner hereby contract and elect to enter the Cryo Program, and give their informed consent to the procedures, as explained below.

To enable the staff to focus on the mission of the Center and to help keep patient costs affordable, reasonable limitations must be placed upon liability. Paragraph 7 is included below to benefit all patients of the Center, including Patient and Partner.

Patient and Partner acknowledge that they have consulted or had opportunity to consult with such advisors as were necessary to enable them to decide to participate in the Cryo Program, to enter into this Agreement, and to sign the related consent forms.

In consideration of the premises and the rights and obligations created hereunder, Patient and Partner and the Center agree as follows:

PART I – AGREEMENT

- 1) The male Partner agrees to provide his sperm, and the female Patient agrees to provide her oocytes (eggs) to the Center to be used by the Center in accordance with this Agreement.

(If donated sperm or eggs are to be used, a separate form is required to be signed and attached hereto.) The Center shall use its laboratory procedures in an effort to achieve fertilization of one or more of the eggs. If more eggs fertilize than are desired to be currently transferred into the Patient, those fertilized eggs not being currently transferred will then be cryopreserved (frozen) at the Center for the primary purpose of preserving them for later transfer by the Center into the Patient. In cryopreserved form, such fertilized eggs are called "Cryopreserved Material" for the purposes of this Agreement. Patient and Partner acknowledge that the Cryopreserved Material will have no capacity to produce human life until by proper thawing and ascertainment of survival a pre-embryo has been produced and properly transferred into the Patient.

- 2) Neither Patient and Partner nor the Center shall have any rights or obligations concerning the Cryopreserved Material except as expressly created by this Agreement.
- 3) The Center will maintain and utilize or dispose of the Cryopreserved Material strictly as follows:
 - a) So long as Patient and Partner continue participation in the ART and Cryo Programs, the Cryopreserved Material shall be stored exclusively (i) to preserve the opportunity of thawing it, (ii) for completion of fertilization, and (iii) for transfer by the Center at the Center of any resulting pre-embryos into the Patient. Patient and Partner shall pay in a timely manner the Center's prevailing charges for participation in the Cryo Program. Unless otherwise directed (as for example, to thaw the Cryopreserved Material and transfer it into the Patient), the Center prefers to store the Cryopreserved Material for no longer than a period of 5 years, however will be maintained as long as storage fees are paid and current. It is the responsibility of the Patient and Partner to notify the Center when they would like to discontinue storage.
 - b) Upon termination of Patient and Partner's participation, as defined in Paragraph 4 below, in the Cryo Program, all further charges for storage of the Cryopreserved Material shall cease, and title to the remaining Cryopreserved Material will pass to the Center. At that time, and thereafter, the Center shall have the right to use or dispose of the Cryopreserved Material in any one or more of the following ways:
 - i) The Center may make the Cryopreserved Material available for pathological examination, research and/or training under duly authorized protocols of the Center;
or
 - ii) The Center may thaw and discard the Cryopreserved Material.
 - c) Notwithstanding the foregoing, the Center agrees to be governed, to the extent feasible, by any one of the foregoing ways selected by the Patient and Partner in a single writing signed by both of them in the presence of an authorized representative of the Center at or before termination of their participation, as defined in Paragraph 4 below.
 - d) If any court of competent jurisdiction shall award to either Patient or Partner all rights with respect to the Cryopreserved Material to the exclusion of the other partner, by an order or decree which is final and binding as to them, then the Center shall have the right thereafter, whether or not party to the proceedings giving rise to such order or decree, to deal exclusively with him or her to whom such rights were awarded ("the prevailing party") without liability or other accountability to the other of them, and in such event may (a) release their Cryopreserved Material to the prevailing party if the prevailing party fulfills conditions (i) through (ii) of Paragraph 5 below, (b) agree with the prevailing party for termination of participation, (c) proceed with ART under the direction of the prevailing party in any way agreeable to the Center in conformity with the protocols and policies then in effect with respect to ART, or (d) comply in any way with such decree.
- 4) Termination of Patient and Partner's participation shall occur upon:
 - a) Affirmative withdrawal by Patient and Partner from the Cryo Program which shall be deemed to occur upon the Center's receipt of (i) a writing, signed by both Patient and Partner, requesting termination of participation, or (ii) a writing, signed by both Patient or Partner, requesting termination of participation, together with a certified copy of an order entered by a court of competent jurisdiction, binding on both partners, and authorizing the requesting partner or either partner to terminate participation.

- b) Death of Patient or Partner – unless they've filed with the Center an agreement signed by both that the Survivor can remain in the Cryo Program.
 - c) Failure to pay prevailing charges of the Center for storage of the Cryopreserved Material, if such failure continues for a period of ninety days following written notice of nonpayment from the Center to the Patient and Partner at the latest address on file at the Center.
 - d) Termination pursuant to Paragraph 5 below, absent compliance with the requirements for transporting the Cryopreserved Material to another site.
- 5) Patient and Partner acknowledge that the Center, for medical reasons, recommends against the transporting of the Cryopreserved Materials to any other facility or location (except as may be necessary in the event the Center discontinues its Cryo Program). The parties hereto agree that the Center need only permit such transfers when the Patient and Partner (i) assume all risks and expenses; (ii) agree in writing to indemnify the Center from all cost, expense, and liability associated therewith; (iii) pay a fee for administrative and other costs (except when proceeding under Paragraph 6 below); and (iv) comply with such other condition as the Center may in its reasonable discretion impose.
- 6) It is intended that the Cryo Program operate indefinitely. However, the Center reserves the right to discontinue the operations of the Cryo Program upon reasonable notice in the event that scientific, financial, or other considerations lead it to do so. If the Center discontinues the Cryo Program for any reason while Patient and Partner are participants therein and their Cryopreserved Materials are in storage with the Center, the Center shall give written notice of the discontinuance to Patient and Partner by the United States Mail sent to their latest address on file at the Center. If the notice is returned for insufficient address or similar reason, or if no written response thereto is received within 30 days after mailing, or if the response so provides, it is agreed that the Center in any such event proceed as though there has been a termination of participation under Paragraph 4d above. However, if Patient and Partner do respond to such notice in writing signed by both of them and received at the Center within 30 days after mailing of the notice, the Center will, if so requested in the response, release to Patient and Partner jointly their Cryopreserved Material for transport elsewhere to a physician or clinic of their choice via approved portable refrigerator and container. All risks, costs, arrangements, and expenses for such transport and for the subsequent fate of the Cryopreserved Material shall be the sole responsibility of Patient and Partner. Failure of Patient and Partner to perfect and carry out the arrangements for such transfer within 30 days after agreeing to do so shall revert the parties to the provisions of Paragraph 3b.
- 7) In consideration of being accepted into the Programs of the Center, Patient and Partner waive, to the maximum extent permitted by law, any and all claims which they or either of them may hereafter be entitled to assert to recover damages from the Center, or any personnel thereof, for mental suffering, emotional distress, failure to achieve pregnancy, representations as to the likelihood or rate of success in achieving pregnancy, or any related cause of action or basis for liability. No assurance has been, or can be, given as to achieving the pregnancy of the Patient.
- 8) Patient and Partner agree to keep their most current mailing address on file at the Center at all times during their participation in the Cryo Program and for 5 years thereafter, and to advise the Center promptly in writing upon each change of address or prolonged absence from the last address on file. Unless and until superseded in writing, their current mailing address is the address shown below.
- 9) Patient and Partner agree that prior to the Center thawing any Cryopreserved Material incident to the transfer thereof to the Patient, both Patient and Partner must sign a separate written consent addressed to the Center, expressly requesting and authorizing the thawing and transfer for each attempt at achieving pregnancy.
- 10) If Patient or Partner or both of them shall make the Center or any of its officers a party to any litigation arising from any disagreement between Patient and Partner as to the rights of either or both of them hereunder as to each other or as to the Center, Patient and Partner shall be liable for the reasonable attorney's fees and other costs of the Center in such litigation unless the Center is found therein to have (i) breached this Agreement, (ii) acted

**PART II – INFORMED CONSENT FOR
CRYOPRESERVATION OF HUMAN PRE-EMBRYOS**

- A. We (the undersigned Patient and Partner) understand that cryopreservation is a clinical procedure performed under the direction of the Fertility Center of Colorado ("the Center"). It is designed to initiate a successful pregnancy after cryopreservation of pre-embryos, which are fertilized eggs. We understand that participation in this clinical procedure is voluntary. If we elect not to participate, our decision will not affect our relations with the Center or result in any penalty or loss of benefits to which we are otherwise entitled.
- B. We have read this document carefully and know we should ask questions about anything which is unclear before we decide whether to be participants in this procedure.
- C. The Cryo Program is used in the event that we produce excess pre-embryos during our IVF treatment cycle. Any excess embryos of suitable quality may be cryopreserved. We understand that any pre-embryos believed to be of poor quality or abnormal will not be cryopreserved.
- D. We further understand that this procedure is intended to benefit us personally by reducing the risk of multiple births and their obstetric complications, while at the same time creating additional opportunities for the initiation of pregnancy at a later date with the transfer of concepti developed from frozen/thawed pre-embryos. As an alternative we may elect to inseminate up to five eggs in this cycle and donate or discard any excess eggs.
- E. Laboratories worldwide now have the ability to cryopreserve human pre-embryos and to establish pregnancy after transfer. Many babies have been born subsequent to the transfer of such frozen/thawed pre-embryos. Studies of these pre-embryos and extensive investigations of cryopreserved animal pre-embryos suggest no increase in risk of abnormalities in offspring that had been cryopreserved. This does not mean that cryopreservation eliminates the normal risk of obstetric complications or fetal abnormalities but rather that cryopreservation does not appear to create an increased risk, although the possibility of a presently unforeseen risk cannot be completely eliminated.
- F. Any information obtained during these procedures that can be identified with us will remain confidential and will be described to individuals not connected with this project only with our written permission. We understand that photographs or videotapes may be taken of the pre-embryos during the cryopreservation procedures as a permanent record and for possible use at a medical meeting or with the lay public for educational purposes. We understand that confidentiality will be maintained. We understand that we have the right to review these records at any time, and we authorize any appropriate government agency to do so.
- G. We understand that with any technique necessitating mechanical support systems, equipment failure can occur. Neither the Center nor its directors, employees, or consultants are to be held liable for any destruction, damage, loss, or improper freezing, maintenance storage, withdrawal, thawing, and/or delivery caused by or resulting from any malfunction of the storage tank, failure of utilities strike, cessation of services or other labor disturbance, any fire, wind, earthquake, water, or other acts of God, or the failure of any other laboratory equipment.
- H. We are advised that the Center provides no insurance coverage, compensation plan, or free medical care plan to compensate us if we or our pre-embryos are harmed in any way by this cryopreservation procedure. If we believe that we have been harmed, we may contact the Center which will be glad to review the matter with us.

Signed:

Patient Signature _____ Date _____

Witness Signature _____ Date _____

Partner Signature _____ Date _____

Witness Signature _____ Date _____

PART III – STATEMENT OF DISPOSITION

1. In the event of the death of the male partner, we wish the cryopreserved fertilized eggs to be:

- Transferred to the custody of the female partner if she wishes. _____
Initials Patient/Partner
- Donated to another couple, understanding that an additional consent would need to be completed by the female partner along with final blood testing of the female partner or the embryos would be discarded. _____
Initials Patient/Partner
- Discarded, understanding that an additional consent would need to be completed by the female partner in order to prevent storage costs from accruing. _____
Initials Patient/Partner

2. In the event of the death of the female partner, we wish the cryopreserved fertilized eggs to be:

- Transferred to the custody of the male partner if he wishes. _____
Initials Patient/Partner
- Donated to another couple, understanding that an additional consent would need to be completed by the male partner along with final blood testing of the male partner or the embryos would be discarded. _____
Initials Patient/Partner
- Discarded, understanding that an additional consent would need to be completed by the male partner in order to prevent storage costs from accruing. _____
Initials Patient/Partner

3. In the event of both of our deaths, we understand that the cryopreserved fertilized eggs would be discarded. Female Partner Initials _____ Male Partner Initials _____

4. In the event of our divorce, we wish the cryopreserved fertilized eggs to be:

- Donated to another couple, understanding that an additional consent would need to be completed by both partners along with final blood testing of both partners or the embryos would be discarded. _____
Initials Patient/Partner
- Discarded, understanding that an additional consent would need to be completed by both partners in order to prevent storage costs from accruing. _____
Initials Patient/Partner
- Placed at the disposal of the _____ (female partner or male partner) and we agree that if the above designated person becomes unable or unwilling to assume responsibility for the cryopreserved fertilized eggs, indicated by failure to make payments for storage, responsibility for disposition will revert to the other partner if she or he so desires. If that person is not willing to assume ownership, indicated by failure to make payments for storage, we agree that the cryopreserved fertilized eggs will be discarded. _____ Initials Patient/Partner

Signed:

Patient Signature _____ Date _____

Witness Signature _____ Date _____

Partner Signature _____ Date _____

Witness Signature _____ Date _____

Please Print

Names of Patient and Partner

Street Address

City State Zip Code

Home Phone Work Phone

The Fertility Center of Colorado:

Authorized Representative Date _____