



CONSENT FOR THE CRYOPRESERVATION OF HUMAN EMBRYO(S)

Version GFS100224

WE, THE UNDERSIGNED, being of legal age and desirous of participating, with the advice of our physician, in Gramercy Fertility Services' (GFS) Embryo Cryopreservation Program, hereby individually and jointly acknowledge, understand, agree and consent to the following:

1. EXPLANATION OF EMBRYO CRYOPRESERVATION

Reasons. Cryopreservation of embryos (embryo freezing) is a medical term describing the laboratory procedure by which supernumerary (excess) embryo(s) is/are frozen and stored for later thaw and use by patients to establish pregnancy. Excess embryos are the embryos over and above the number of embryos designated for fresh transfer. The number of embryos for fresh transfer is determined by our physician along with advice from the patients and the staff of GFS and taking into consideration the ASRM (American Society for Reproductive Medicine) guidelines for determining the maximum number of embryos for transfer.

Introduction. Cryopreservation techniques have become an increasingly important therapeutic strategy in assisted reproduction. It provides opportunities for patients to have repeated attempts at conception following a single drug stimulation cycle, preventing wastage of valuable genetic material and improving cumulative pregnancy rates.

Cryopreservation Process.

Vitrification of human embryos is an efficient and simple method of cryopreservation. It is a preferred alternative method to the traditional slow-cooling/rapid-thaw protocols, due to the lack of ice crystal formation and convenience. The radical strategy of vitrification results in the total elimination of ice crystal formation, both within the cells being vitrified (intracellular) and the surrounding solution (extracellular).

2. RISKS OF EMBRYO CRYOPRESERVATION

Risks of Birth Defects. We understand that several laboratories worldwide have demonstrated the ability to freeze and preserve human embryos and established pregnancies after transfer of thawed embryos into patient's uterus. Several hundred normal babies, worldwide, have been born subsequent to the transfer of such frozen/thawed embryos. We understand that studies of frozen/thawed human embryos and extensive investigations of cryopreserved animal pre-embryos have not demonstrated a significant increase in risk of abnormalities in offspring derived from these frozen/thawed embryos. We understand that this does not mean that this freezing/thawing procedure will not eliminate the normal risk of fetal abnormalities or the obstetric complications incidental to pregnancy and delivery. However, the cryopreservation of human embryos does not appear to create an increased risk to the mother or to the fetus, although the possibility of a presently unforeseen risk cannot be completely eliminated.

Risks of technical Procedures. The process of embryo cryopreservation however is in itself a very risky procedure for the human embryos. The embryos are subjected to chemicals and to temperatures that are very different from their natural environment. In addition, unforeseen technical problems and equipment failures may arise which preclude successful cryopreservation of embryos. Therefore, the possibility that all, some or none of the embryos may survive the freezing and thawing process may occur, resulting, on some occasions, in the cancellation of frozen embryo transfer.

3. SURVIVAL OF CRYOPRESERVED EMBRYO(S)

We understand that the probability of the embryos' survival of the freeze/thaw procedure is approximately 70%. We acknowledge the possibility that none of our embryos may survive the procedure and we are willing to take this risk.

4. BENEFITS OF EMBRYO CRYOPRESERVATION

Cryopreservation of embryos affords patients the additional possibility of initiating a successful pregnancy in future assisted reproductive technology cycle(s) which they elect to participate in. Additionally, freezing and storing excess embryos reduces the risk of multiple births in the patients' fresh IVF cycle and therefore reduce the attendant medical (obstetric) risks to the mother in undergoing multiple deliveries in a single IVF cycle. We understand that if we decide not to freeze and store our excess embryo(s), the embryo(s) will be discarded according to accepted laboratory procedures.

5. CONFIDENTIALITY

Any information obtained during these procedures that can be identified with us will remain confidential and will be described to individuals not connected to this project, only with our written permission. Furthermore, a government agency, including the FDA and the New York State Department of Health, may choose to review the cryopreservation data at any time to ensure compliance to their regulations. Any new information developed during the course of this investigation, which may affect our willingness to continue participation, will be promptly provided to us.

6. COMPENSATION OF PROCEDURE

We acknowledge and understand that the aforementioned procedure is still experimental in nature and all risks and discomforts may not be presently known. There is no provision made for us to receive compensation or medical treatment at GFS or our physician's expense for physical harm suffered by us as a result this procedure.

7. VOLUNTARY PARTICIPATION

We understand that the purpose of this consent form is to advise us and to invite us to participate in the Cryopreservation of Embryo Project. We understand that participation in this project is voluntary, and will neither prejudice nor harm our current or future status or relationship with our physician and GFS, nor result in any penalty or loss of benefits to which we are otherwise entitled.

8. SUBSEQUENT OBSTETRIC AND POST-NATAL MEDICAL CARE

We understand that if a pregnancy is established with the transfer of frozen/thawed embryo(s), close observation by our physician or his/her designee is important and will be conducted throughout the pregnancy. The removal of a sample of fluids surrounding the baby (amniocentesis) may be advisable at 14 to 16 weeks of gestation or, alternatively, the clinical procedure known as chorionic villi sampling at 8 weeks of gestation may be performed, depending on maternal age. These two procedures may alert our physician to certain potential chromosomal abnormalities or major structural abnormality. If this is discovered, a geneticist and our physician will discuss with us the implication of these findings; and we, as patients, will make the decision whether or not the pregnancy should be continued. If we decide to terminate the pregnancy, we understand that the clinical and hospital costs and expenses incurred to that date, or resulting from that termination, will be borne by us. We will assume total financial responsibility for the medical care provided to us and/or our infant(s).

9. UNDERSTANDING THIS FORM

We hereby acknowledge that we have read and fully understand the contents of this consent form. We acknowledge that all procedures described in the form have been adequately explained to our satisfaction and that we understand them. We understand the risks, benefits and alternatives and we have had adequate time to reach our decision and have reached our decision voluntarily. All of our questions have been answered to our satisfaction.

10. INDEMNIFICATION

Each of us jointly and separately agrees for himself and herself and for his or her representatives, successors, heirs and assigns to hold harmless, reimburse and indemnify GFS, and its affiliates and subsidiary companies, including, but not limited to Metropolitan Diagnostic Laboratories, the owner(s) of the facility; our Physician(s) and their respective employees, contractors and agents for any loss, expense, cost or damage (including reasonable attorney's fees) paid or incurred by any member of the GFS that arises from a negligent or willful act or omission on the part of the Husband or the Wife, including, but not limited to, any failure by either of us to heed any warning, advice or recommendation or follow instructions, directions, or regimen given to either of us by any member of GFS and our physician.

11. INSURANCE

We are advised that GFS and its agents, or any other agency, provides no insurance coverage, compensation plan, or free medical care plan to compensate us if we or our embryo(s) are injured, harmed or destroyed by this cryopreservation procedure. We also understand that insurance coverage for the embryo cryopreservation procedure is not available at this time, and that we will be responsible personally for all costs involved in the embryo freezing. We have been provided with and have the current fee schedule for this procedure.

12. WAIVER

We acknowledge and understand that as with any technique necessitating mechanical assistance, equipment failure can occur. We agree that we shall not hold any member or members of GFS liable individually or jointly for the destruction or damage to our embryo(s) as a result of: any failure of utilities, any strike, cessation of services or other labor disturbance, any war, acts of public enemy or any other disturbance, any fire, wind, earthquake, water, act of God, or the failure of any laboratory that contracts with GFS for the provision of services.

13. COSTS

We acknowledge and understand that we are solely responsible for the costs of the cryopreservation of our embryo(s), and also for the costs associated with the storage of our frozen embryo(s). The staff of GFS provided the costs for the embryo cryopreservation and subsequent storage of frozen embryo(s) to us.

14. STORAGE TERMS

We acknowledge and understand that once our embryo(s) are frozen, the embryo(s) will require storage in a cryotank filled with liquid nitrogen in order to stay viable and that we are solely responsible for the costs associated with the storage of our frozen embryo(s). We acknowledge and understand that our frozen embryo(s) will be stored at GFS for up to the first six (6) months. This is to allow enough time to use the frozen embryo(s) in a succeeding cycle in case the fresh cycle was not successful in achieving a viable pregnancy. After the first six (6) months, we may elect to either: (a) transfer the frozen embryos for long-term storage; (b) donate the embryos for research; (c) dispose the embryo(s) according to acceptable procedures as mentioned above; or (d) notify GFS to keep the frozen embryos in the facility for the near future Frozen Embryo Transfer procedure that we will be undergoing. We understand and acknowledge that we are responsible for the storage fees as detailed in GFS' fee schedule provided to us.

15. TRANSFER OF FROZEN EMBRYOS TO LONG TERM STORAGE FACILITIES

We acknowledge and understand that our frozen embryos will be stored at GFS for up to the first six (6) months. After the initial six (6) months have elapsed, we have the option to transfer our frozen embryo(s) to another facility and we undertake the obligation of notifying GFS if I/we chose such option.

Furthermore, we understand and agree that we are responsible for the costs incurred in the transfer, transport, and further storage of our embryo(s) at the facility of our choice. We also understand that we do not have to be physically present in the facility to witness the transfer of our frozen embryo(s), however, we may elect to do so by notifying GFS. Upon transfer for long-term storage, we understand that we will be notified by GFS within thirty (30) days of occurrence via mail and/or telephone.

16. DISPOSAL OPTIONS (for Consent for Embryo Cryopreservation version GFS100224)

Disposal options for frozen embryos will be noted in the Consent for The Storage of Reproductive Tissues

17. AUTHORIZATION

In light of careful consideration of the potential risks and benefits of embryo cryopreservation and subsequent embryo thawing and frozen embryo transfer, I/we, the undersigned, being of legal age, and desirous of having a child, hereby individually and jointly consent to participate in GFS's Embryo Cryopreservation Program and voluntarily request, authorize and direct GFS, the facility, the Physicians and their respective employees, contractors and agents to perform any and all procedures necessary for embryo cryopreservation, as well as any such additional procedures that any of them may deem necessary. We acknowledge that we have previously executed Consent for In-Vitro Fertilization, and that this Consent for Embryo Cryopreservation version GFS100224 is in addition to, and supplements such other Consents. Further, we understand that the contents and terms of all GFS Consent Forms that we have signed apply to this consent and are incorporated herein by reference.

We understand that the interpretation and effect of this Consent for Embryo Cryopreservation version GFS100224 shall be governed by the laws of the state of New York.

_____ Female Patient's Name	_____ Signature	_____ Date
_____ Husband/Partner's Name	_____ Signature	_____ Date
_____ Witness' Name	_____ Signature	_____ Date

GRAMERCY FERTILITY SERVICES

139 East 23rd Street, 2nd Floor, NY, NY 10010 (212) 677-5118 (212) 677-5338 fax

CONSENT FOR THE STORAGE OF FROZEN REPRODUCTIVE TISSUES

I/We, THE UNDERSIGNED, being of legal age and desirous in keeping my / our frozen reproductive tissues for a longer period of time for future ART, hereby acknowledge, understand, agree and consent to the cryostorage of my / our frozen tissues at Gramercy Fertility Services (GFS) located at 139 E23 St, 2Fl, NY NY 10010 and to the following:

1. Type and Source of frozen reproductive tissues: The type and source(s) of the reproductive tissues for storage is/are:

() **EMBRYO(s)** Source of Egg: [] Patient’s own, name: _____
[] Directed Donor, print name: _____
[] Anonymous Donor: donor code: _____
(print tissue bank name) _____
(tissue bank address & phone) _____

Source of Sperm: [] Intimate partner / Husband _____
[] Directed Donor, print name: _____
[] Anonymous Donor: donor code: _____
(print tissue bank name) _____
(tissue bank address & phone) _____

() **OOCYTE(s)** Source: [] Patient’s own, name: _____
[] Directed Donor, print name: _____
[] Anonymous Donor: donor code: _____
(print tissue bank name) _____
(tissue bank address & phone) _____

() **SEMEN** Source: [] Patient’s own / Client Depositor: _____
[] Directed Donor, print name: _____
[] Anonymous Donor: donor code: _____
(print tissue bank name) _____
(tissue bank address & phone) _____

() **TESTICULAR TISSUE** Source: [] Patient’s own / Client Depositor: _____
(tesa/tese/mesa) [] Directed Donor, print name: _____
[] Anonymous Donor: donor code: _____
(print tissue bank name) _____
(tissue bank address & phone) _____

() _____ Source: [] Patient’s own, name: _____
[] Directed Donor, print name: _____
[] Anonymous Donor: donor code: _____
(print tissue bank name) _____
(tissue bank address & phone) _____

2. Amount of frozen reproductive tissues for storage.

If known, # of embryos/oocytes: _____, and/or # of straws or vials: _____

I/We acknowledge that the above stated amount of straws or vials or other materials used for the cryopreservation of my/our tissues are correct to the best of my/our knowledge and I/we understand that unless the tissues were processed and frozen by GFS, its partners and/or affiliates, GFS does not have the exact knowledge of the contents of the cryocontainers and can only account for the number of cryocontainers and base the contents on the statements and records of the tissue bank that processed and froze the tissues. I/We will take full responsibility on the contents of the cryocontainers and will not hold GFS, its affiliates, agents, staff and physicians, responsible for any discrepancies that may arise.

3. **Storage Process.** The frozen reproductive tissues contained in straws, vials or other cryocontainers will be transferred into storage tanks containing liquid nitrogen to maintain the storage temperature of between -123°C to -196°C (-321°F). Unless the tissues were frozen at GFS, it is my/our responsibility to ensure that liquid nitrogen levels are maintained at required levels to preserve the integrity of the reproductive tissues prior to being received by GFS.

4. **Reasons.** The purpose of freezing and storage of my/our reproductive tissues is to have the tissues available for future ART procedures at GFS or other ART centers where these can be later thawed and used by me/us to establish pregnancy.

5. **Donor Tissues.** I/We understand GFS's policy of accepting and storing frozen reproductive tissues obtained from donors only from tissue banks licensed by the New York State Dept. of Health Tissue Resources Program. To obtain an exemption from this, the following documentation has to be provided to GFS, which would be submitted to the NYS Health Department for their approval:

1. donor's test results for sexually transmitted diseases including, but not limited to, HIV 1, HIV 2, HTLV I, HTLV II, Hepatitis A, B and C, syphilis, Chlamydia and gonorrhea. Test results should be as recent as one month of the donation process and testing conducted at a laboratory permitted by the NYS DOH to do donor serology (if out-of-state, the lab must be accredited by that state's licensing arm or by the Health Care Financing Authority).
2. donor's comprehensive personal and family background and health history.

6. **Survival.** I/We understand that GFS cannot and does not guarantee survival of the reproductive tissues due to certain factors including but not limited to the cryopreservation process and the transportation process and I/we understand that none of the tissues may survive.

7. **Storage Terms.** I/We understand that I/we am/are solely responsible for the costs of storage of my/our frozen reproductive tissues.

The current cost for storage of frozen reproductive tissues at Gramercy Fertility is **\$450 for six (6) months or \$600 for one (1) year. This fee schedule is subject to change without prior notification.** Payment is due on the day the tissues are received for storage. I/we understand and agree that I/we will provide a valid credit card information to be kept on GFS's file which will then be charged once the storage expires. The credit card information will be updated whenever necessary to ensure its validity.

I/We acknowledge and understand that my/our frozen reproductive tissues will be stored at GFS for up to the first six (6) months. This is to allow enough time to use the frozen tissues for an assisted reproductive procedure (ART). After the first six (6) months, we may elect to either:

- (a) notify GFS to keep the frozen reproductive tissues in their facility for the near future ART procedure that I/we will be undergoing;
- (b) transfer the frozen reproductive tissues for long-term storage;
- (c) donate the frozen reproductive tissues for research; or
- (d) dispose the frozen reproductive tissues according to acceptable procedures.

8. **Transfer From and To Other Storage Facility.** I/We understand that it is my/our responsibility to make all arrangements for the transfer of the frozen reproductive tissues between GFS and the source tissue bank including the rental of the transport tank. I/We understand that we will notify GFS in advance about the impending transfer of tissues in order to get all necessary documentation including consent forms and associated records in order.

I/We acknowledge and understand that my/our frozen reproductive tissues will be stored at GFS for up to six (6) months. After the first six (6) months have elapsed, I/we also have the option of transferring my/our frozen reproductive tissues to another facility of my/our choice for long-term storage and I/we undertake the obligation of notifying GFS beforehand about such arrangements.

Furthermore, I/we understand and agree that I/we am/are responsible for the costs incurred in the transfer and further storage of my/our reproductive tissues at the long-term storage facility of my/our choice. I/We also understand that I/we do not have to be physically present at GFS nor at the long-term storage facility to witness the transfer of my/our frozen reproductive tissues. However, I/we may elect to do so by notifying GFS. Upon transfer to another facility for long-term storage, I/we understand that I/we will be notified by GFS or by the long-term storage facility within thirty (30) days of occurrence via mail and/or telephone.

9. **Confidentiality.** Any information obtained during these procedures that can be identified with me / us will remain confidential and will be described to individuals not connected to this project, only with my / our written permission.

10. **Waiver.** I/We acknowledge and understand that as with any technique necessitating mechanical assistance, equipment failure can occur. I/We agree that I/we shall not hold any member or members of Gramercy Fertility Services, its affiliates, agents, staff and physicians, liable individually or jointly for any destruction, damage, any failure of utilities, any strike, cessation of services or other labor disturbance, any war, acts of public enemy or any other disturbance, any fire, wind, earthquake, water, act of God, or the failure of any laboratory equipment that contracts with GFS for the provision of services.

11. **Indemnification.** I/We agrees for himself and herself and for his or her representatives, successors, heirs and assigns to hold harmless, reimburse, and indemnify GFS, and its affiliates, representatives, agents, and subsidiary companies, the owner(s) of the facility, my/our Physician(s) and their respective employees, contractors and agents for any loss, expense, cost or damage (including reasonable attorney's fees) paid or incurred by any member of GFS that arises from a negligent or willful act or omission on my/our part, including, but not limited to, any failure to heed any warning, advice or recommendation or follow instructions, directions, or regimen given to me/us by any authorized member of GFS.

12. **Disposal Options:** I/We understand that the reproductive tissues will be stored at GFS on the elected terms of storage. I/We understand that it is my/our responsibility to notify GFS of any change of address or other contact information that I/we may have in the future including the valid credit card information for which monthly charges will be collected from. I/We, being the owner(s) of the frozen reproductive tissues, have the principal responsibility of deciding the disposition of the frozen reproductive tissues and the said tissue(s) will not be released from storage for any purpose without my/our written consent unless the following events occur;

A. In the event that I/we cannot be located (lost contact) within at least 6 months, after reasonable attempts to reach me/us, at the most recent contact information GFS has in my/our file, via telephone and certified mail with return receipt, the frozen reproductive tissue should be:

_____ discarded
_____ donated for research (final outcome is destruction of tissues)

B. **For sole owner only, no need to fill in C, D, and E.** In the event of my death as sole owner, the frozen reproductive tissue should be:

_____ discarded
_____ donated for research (final outcome is destruction of tissues)

C. In the event of death of any one of us as joint owners, the frozen tissues should be:

_____ discarded
_____ donated for research (final outcome is destruction of tissues)
_____ surviving partner decides

D. In the event of death of both of us as joint owners

_____ discarded
_____ donated for research (final outcome is destruction of tissues)

E. In the event of divorce as joint owners

_____ discarded
_____ donated for research (final outcome is destruction of tissues)

