

**MASSACHUSETTS GENERAL HOSPITAL  
VINCENT REPRODUCTIVE MEDICINE AND IVF**

**INFORMED CONSENT TO EMBRYO FREEZING AND FROZEN EMBRYO DISPOSITION**

\_\_\_\_\_ (Patient) and \_\_\_\_\_ (Partner *as applicable*), having chosen to participate in the In Vitro Fertilization Program (the "IVF Program") at the Vincent Reproductive Medicine and IVF practice in Massachusetts General Hospital hereby enter into the following binding agreement with the Vincent Reproductive Medicine and IVF practice regarding the freezing and disposition of embryos produced by Patient and Partner through the IVF Program. This agreement (the "Agreement"), which is intended to be binding on the parties hereto, shall become effective as of \_\_\_/\_\_\_/\_\_\_, and shall remain in effect as provided herein.

(Date of signature)

**INTRODUCTION**

Not infrequently, the IVF process produces more embryos than the participants in that process (e.g., Patient and Partner) wish to have transferred as part of their IVF cycle. A process called embryo freezing (or "cryopreservation") has been developed as a means to attempt to save for possible future transfer to the patient's uterus those healthy embryos which are not transferred during a fresh IVF cycle. In the event the current IVF cycle does not result in a successful pregnancy, or if an attempt for another pregnancy is later desired, this freezing process allows for the possible transfer of a cryopreserved embryo to the patient at a later time.

For patients and partners who wish to preserve their extra embryos, the process for doing so generally begins after the fresh embryo transfer. In most cases, embryos are frozen 1-3 days after the transfer, at the blastocyst stage. However, in some cases the laboratory may decide to cryopreserve at the 6-8 cell stage which coincides with the day 3 transfer, or the pronuclear stage which coincides with the day of fertilization day 1. Only the healthy or viable embryos remaining from the IVF cycle will be frozen. The term "viable" refers to embryos that have displayed normal and appropriate cell division while in the incubator. Embryos that do not appear viable are not frozen for possible future fertility use.

A select group of patients will be electing to cryopreserve all of their embryos for the purposes of embryo banking. These embryos will be frozen at the earliest stage possible which is the pronuclear stage embryo, occurring the next day after the egg retrieval.

The cryopreservation procedure itself is complex. The embryos that are to be preserved are placed in a solution which contains special chemicals, called cryoprotectants, which help to protect the embryos during the freezing process. The embryos are then placed in tubes which are labeled with the patient's name, the patient's IVF number, the number of embryos in the tube, and the date of cryopreservation. The tubes are then placed in a computer controlled freezing unit and stored in a special tank filled with liquid nitrogen.

When the cryopreserved embryos are needed for transfer, they are warmed (or "thawed") in a solution and the cryoprotectant chemicals are removed. Typically, 70-80% of frozen embryos survive the entire process to be transferred. Each embryo is examined individually and any embryo that does not look viable will not be transferred. The actual procedure for embryo transfer following thawing of cryopreserved embryos is the same as the one used in a "fresh embryo" transfer.

In preparation for the transfer, hormones are given to the patient to control her menstrual cycle and to improve the receptivity of her uterine lining.

## **TERMS**

### **1. Duration of Cryopreservation**

All embryos which are cryopreserved pursuant to this Agreement will be frozen for a maximum period of 5 years from the date of the Patient's fresh embryo transfer. If Patient and Partner choose to store cryopreserved embryos, then they also must decide below (in section 6) about the disposition of any cryopreserved embryos that remain unused after the storage period. If Patient and Partner decide not to cryopreserve embryos, then they must indicate that below and decide on the disposition of any extra embryos (section 5).

### **2. Financial Terms**

There is no charge for the storage, by cryopreservation, for the first calendar year. At the end of the initial year, you will be billed an annual storage fee. Patient and Partner understand that insurance may not cover this cost and that, if continued storage is desired, Patient and Partner are responsible for the storage fee. Payment is due within 45 days of billing. In the event of nonpayment, MGH will try to contact Patient and Partner at the last known address by certified mail. If Patient and Partner do not respond within 45 days of the certified letter, MGH reserves the right to discontinue storage and discard the embryos.

### **3. Change of Address**

Patient and Partner understand that it is their responsibility to notify Vincent Reproductive Medicine and IVF promptly in writing of any change in their addresses or telephone numbers. Patient and Partner also understand that their embryos will be considered to be abandoned if (i) they have not paid in accordance with the Financial Terms above, or (ii) the maximum storage period (5 years) is approaching, and despite diligent efforts including certified mail, Vincent Reproductive Medicine and IVF is unable to contact them at their last known address. If Patient and Partner's embryos are considered to be abandoned, the Vincent Reproductive Medicine and IVF reserves the right to remove the embryos from storage and discard them.

### **4. Risk Factors**

The parties to this Agreement acknowledge that it is possible that some or all of the embryos which are frozen and stored pursuant to this Agreement are not healthy embryos and/or will not survive the process required for cryopreservation. The parties further acknowledge that it is possible that one or more embryos will be damaged or lost while frozen, or will not survive the

thawing process. The parties also acknowledge the possibility that, if transferred following thawing, the embryos may not result in a viable pregnancy.

Patient and Partner have been informed that, although studies of pregnancies resulting from the transfer of frozen embryos have not demonstrated an increased risk of complications in pregnancy or abnormalities in the offspring of these procedures, the possibility of unforeseen risks cannot be eliminated. They have also been informed that the maximum length of time embryos can be safely stored is unknown.

The parties understand and accept that, with a technique such as cryopreservation, which requires mechanical support systems, equipment failure and technical problems could occur, damaging the embryos or compromising the prospect of a viable pregnancy. Vincent Reproductive Medicine and IVF including its employees and agents, shall not be held liable for any damages, loss or problems due to improper freezing, maintenance, storage, withdrawal, thawing, and/or delivery caused by malfunction of the storage tank, the failure of utilities, a strike by workers, cessation of services or other labor disturbances, or other disturbances.

### 5. Decision Relating to Freezing/Cryopreservation of Extra Embryos

Patient and Partner hereby make the following decision with respect to those extra embryos (following our fresh embryo transfer) which have been assessed as healthy and viable by the IVF Program Staff.

 <i>Choose One</i> 	_____	_____	<b>YES</b>	We consent to have the extra embryos frozen. These will be stored for up to 5 years, provided that Patient and Partner pay applicable storage fees and notify Vincent Reproductive Medicine and IVF of any changes of address or telephone number.
	Patient's Initials	Partner's Initials		
	_____	_____	<b>NO</b>	We do not wish to freeze embryos.
	Patient's Initials	Partner's Initials		

*If you choose yes, proceed to #6*  
*If you choose no, check one of two boxes below*

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_____	_____	<input type="checkbox"/>	Please check one box to show your choice regarding the disposition of embryos that are not frozen:  1. We would like to donate the embryos for use in research, or in activities related to improving assisted reproductive therapies (ART).  ▪ The research and activities related to improving ART may include, for example, studies of ways to improve techniques or fertility success rates or studies that may improve our understanding of infertility and reproductive medicine.  ▪ The research also may include embryonic stem cell research. In this case, MGH would contact us to provide more information about a particular study and to ask whether or not we consent to donate embryos to the study. MGH would retain a link between my/our embryos and limited information about me/us in order to contact us about such research.
Patient's Initials	Partner's Initials		
_____	_____	<input type="checkbox"/>	2. We request that all extra embryos be discarded.
Patient's Initials	Partner's Initials		

6. **Decision Relating to Disposition of Frozen Embryos**

The parties agree that the frozen embryos are subject to Patient’s and Partner’s joint disposition, except as otherwise provided in this Agreement (for example, embryos may be discarded as a result of nonpayment or failure to provide updated contact information). The parties further understand and agree that all decisions about the disposition of the frozen embryos must be joint decisions by Patient and Partner, except where such disposition may be affected by applicable laws or by any court with jurisdiction over them. Patient and Partner can, together and by mutual agreement, change any of these decisions at any time before action has been taken in reliance on such decisions, by contacting Vincent Reproductive Medicine and IVF and signing a new Agreement, specifying their decisions. Patient and Partner further understand that certain uses or dispositions of embryos may also require approval by Vincent Reproductive Medicine and IVF. Vincent Reproductive Medicine and IVF and Massachusetts General Hospital are not obligated to proceed with any attempted embryos transfer of any embryos if the IVF Program determines that the risks associated with doing so may outweigh the potential benefits. Vincent Reproductive Medicine and IVF also retains the right to terminate this Agreement upon written notice for other reasons that they consider appropriate. In any circumstances of termination of this Agreement where embryos which have been cryopreserved remain in storage, Patient and Partner will be contacted and all reasonable efforts will be made to arrange for disposition of such embryos in accordance with Patient’s and Partner’s desires at such time.

**Disposition of Frozen Embryos After Storage Period:**

Patient and Partner hereby make the following decision regarding the **final disposition** of frozen embryos that are stored in accordance with this agreement and not used for a later pregnancy. Please choose one of the three options and initial it.

A. **Transfer:** We (Patient and Partner) will arrange for transfer of remaining embryos to another facility for storage or possible donation to another person.

\_\_\_\_\_  
Patient’s Initials

\_\_\_\_\_  
Partner's Initials

B. **Research or Activities Related to Improving Assisted Reproductive Therapies (ART):**

\_\_\_\_\_  
Patient’s Initials

\_\_\_\_\_  
Partner's Initials

- The research and activities related to improving ART may include, for example, studies of ways to improve techniques or fertility success rates or studies that may improve our understanding of infertility and reproductive medicine.
- The research also may include embryonic stem cell research. In this case, MGH would contact us to provide more information about a particular study and to ask whether or not we consent to donate embryos to the study. MGH would retain a link between my/our embryos and limited information about me/us in order to recontact us about such research at a future time.

C. **Discard:** We would like the embryos to be discarded.

\_\_\_\_\_  
Patient’s Initials

\_\_\_\_\_  
Partner's Initials

*Choose One*

In the event of special circumstances, as explained below, Vincent Reproductive Medicine and IVF and MGH will dispose of the embryos as specifically indicated below.

(i) In the event of SEPARATION or DIVORCE of Patient and Partner, Patient and Partner wish the embryos to be:

\_\_\_\_\_  
Patient's Initials

\_\_\_\_\_  
Partner's Initials

A. Owned and controlled by the Patient if she is able and willing to assume such ownership and control; otherwise the embryos will be thawed and discarded. *(patient owns embryos)*

**or**

\_\_\_\_\_  
Patient's Initials

\_\_\_\_\_  
Partner's Initials

B. Owned and controlled by the Partner if he or she is able and willing to assume such ownership and control; otherwise the embryos will be thawed and discarded. *(partner owns embryos)*

**or**

\_\_\_\_\_  
Patient's Initials

\_\_\_\_\_  
Partner's Initials

C. Owned and controlled by the Patient and the Partner jointly, but if one is unable to assume such ownership and control, then by the other solely; and if both are unable or unwilling to assume such ownership and control, the embryos will be thawed and discarded. *(both jointly own)*

**or**

\_\_\_\_\_  
Patient's Initials

\_\_\_\_\_  
Partner's Initials

D. Used for research or activities related to improving assisted reproductive therapies. *(used for research)*

**or**

\_\_\_\_\_  
Patient's Initials

\_\_\_\_\_  
Partner's Initials

E. Thawed and discarded. *(discarded)*



(ii) In the event of DEATH OF THE PATIENT, Patient and Partner wish the embryos to be:

\_\_\_\_\_  
Patient's Initials

\_\_\_\_\_  
Partner's Initials

A. Owned and controlled by the Partner if he or she is able and willing to assume such ownership and control; otherwise the embryos will be thawed and discarded.

**or**

\_\_\_\_\_  
Patient's Initials

\_\_\_\_\_  
Partner's Initials

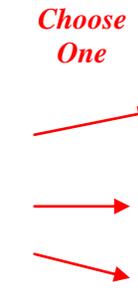
B. Used for research or activities related to improving assisted reproductive therapies.

**or**

\_\_\_\_\_  
Patient's Initials

\_\_\_\_\_  
Partner's Initials

C. Thawed and discarded.



(iii) In the event of DEATH OF THE PARTNER, Patient and Partner wish the embryos to be:

*Choose One*



\_\_\_\_\_  
Patient's Initials

\_\_\_\_\_  
Partner's Initials

A. Owned and controlled by the Patient if she is able and willing to assume such ownership and control; otherwise the embryos will be thawed and discarded.  
**or**



\_\_\_\_\_  
Patient's Initials

\_\_\_\_\_  
Partner's Initials

B. Used for research or activities related to improving assisted reproductive therapies.



\_\_\_\_\_  
Patient's Initials

\_\_\_\_\_  
Partner's Initials

**or**  
C. Thawed and discarded.

7. General Acknowledgement by Patient and Partner.

Patient and Partner acknowledge that they have read this document and have been given the opportunity to ask questions, which have been answered to their satisfaction. Patient and Partner further acknowledge that they understand that they can change any of the decisions reflected in this Agreement before action has been taken in reliance on such decisions, by contacting the Vincent Reproductive Medicine and IVF practice and signing a new or modified Agreement or an amendment to this Agreement.

\_\_\_\_\_  
Signature of Patient

\_\_\_\_\_  
Signature of Partner (*as applicable*)

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date of Birth

\_\_\_\_\_  
Date of Birth

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date