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## **MGH Fertility Center**

# ***Consent to Cryopreservation and Storage of Embryos, and Instructions for their Disposition***

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This document describes the process and risks of cryopreservation and storage and asks you to indicate your intention for the use of cryopreserved embryo(s) from this IVF treatment cycle.

<p>This Agreement is between you _____, the Patient,</p> <p style="text-align: center;">_____, your Partner (if applicable),</p> <p style="text-align: center;">and the MGH Fertility Center.</p> <p>The embryo(s) covered by this document are from any IVF treatment cycle started within one year of signing this form</p> <p style="text-align: right;">_____ (date of signature)</p>
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For the purposes of this agreement, Patient refers to the sole intended parent; the person who utilized their oocytes for embryo creation. If donor oocytes were used for embryo creation, patient refers to the individual who intends to transfer the embryo(s) to their uterus or the person who used their sperm for embryo creation.

### **Description of Cryopreservation Process**

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Cryopreservation (freezing) of embryos is a well-established procedure. Embryos are placed in special fluid to remove excess water then cooled to -196C in liquid nitrogen (or its vapor), which stops all metabolic activity. Once cryopreserved, embryos remain in this state until thawed.

### **Risks of Cryopreservation and Storage**

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The process of cryopreservation (freezing), storage, and thawing can damage cryopreserved embryos, and not all embryos will be successfully cryopreserved, or, if cryopreserved, successfully thaw, or be available for further treatment or implantation.

It is also possible that cryopreserved embryo(s) may be damaged, destroyed, lost or fail to develop, and therefore be unavailable for further treatment or implantation, due to a number of potential factors, including, but not limited to: patient-specific differences in tolerance of freezing; accidents; power outages; mechanical or equipment failure (including but not limited to loss of nitrogen or other tank failures); materials (including vials, straws and other containers used to freeze and store the samples and their labels); changes of any applicable law or regulations; human error; labelling errors; inventory record loss; natural and man-made disasters; sabotage; transportation or shipping accidents or other events which may be beyond the control of MGH Fertility Center or its laboratory. In accordance with its protocols, MGH Fertility Center makes reasonable efforts to handle and maintain cryopreserved

embryos, including, but not limited to maintenance and monitoring of its equipment, materials and laboratory. Despite such efforts, I understand that due to one or more of these potential factors, embryos may become unavailable for further treatment or implantation, or that the likelihood of a pregnancy resulting from any treatment or implantation may be reduced. There may be increased risk of complications in pregnancy or abnormalities in the offspring and the possibility of unforeseen risks cannot be eliminated. The maximum length of time embryos can be safely stored is unknown.

NOTE: In some cases, the MGH Fertility Center may not own or operate the laboratory responsible for storage of your embryo(s) and, therefore, cannot be responsible for laboratory processes beyond its knowledge and control. If this is true for your treatment, you may be asked to sign further documents with the laboratory. In the event my embryos are damaged, lost or destroyed, are otherwise unavailable for further treatment or implantation, or fail to result in a pregnancy, I hereby agree not to sue and agree to hold harmless, the MGH Fertility Center, and any of MGH Fertility Center's physicians, employees, or agent except in the event of willful misconduct or gross negligence on the part of MGH Fertility Center, or any of MGH Fertility Center's physicians, employees, contractors or agents.

### **Risk of Shipping to another facility**

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A patient(s) may require or choose to transfer embryo(s) to another facility for storage. In the event the embryos are lost, damaged or destroyed during transport, are otherwise unavailable for further treatment or implantation, or fail to result in a pregnancy, I hereby agree not to sue and agree to hold harmless, MGH Fertility Center, and any of MGH Fertility Center's physicians, employees, or agent except in the event of willful misconduct or gross negligence on the part of MGH Fertility Center, or any of MGH Fertility Center's physicians, employees, or agents.

### **Consent and Disposition**

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Embryos are commonly cryopreserved to be used for a subsequent embryo transfer. If cryopreserved embryo(s) are to be thawed and used for transfer, a separate consent will be required to be signed for the embryo(s) to be thawed. MGH Fertility Center and Massachusetts General Hospital are not obligated to proceed with attempted transfer of cryopreserved embryos if the MGH Fertility Center determines that the risks associated with doing so may outweigh the potential benefits. MGH Fertility Center 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 embryo(s) which have been cryopreserved remain in storage, Patient and Partner (if applicable) 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.

Embryos are cryopreserved and stored for future use. However, there may be special circumstances, as described below, in which Patient and Partner (if applicable) do not use these embryos. In such cases, there are generally 4 choices for the disposition of the embryo(s):

1. Give control of my embryo(s) to my partner (if applicable);
2. Discard the embryo(s);
3. Donate the embryo(s) for approved medical research
4. Transfer the embryos to another facility for storage or for possible donation to another person so they can try to have a child.

If partnered, cryopreserved embryos are subject to joint disposition, except as otherwise provided in this Agreement (for example, embryos may be discarded due to nonpayment or failure to provide

updated contact information). Certain uses or dispositions of embryo(s) may also require approval by the MGH Fertility Center.

Please understand that the MGH Fertility Center cannot guarantee what the available or acceptable choices for disposition will be at any future date. You may wish to consult with a lawyer to understand your legal rights and any law that may apply to this Agreement or to disposition choices. If any choice you select is not available for any reason, you are authorizing the MGH Fertility Center to thaw and discard (“discard”) any currently cryopreserved embryos under this Agreement.

If the embryo(s) were created with gametes (eggs and/or sperm) from a third-party donor, you cannot choose to donate embryos for use in medical research or MGH Fertility Center quality assurance/training. The choices, here, to donate these embryos in the future must be consistent with all applicable direct agreements made with, or written authorizations from, the gamete donors and/or gamete bank. Without this prior written authorization, the embryo(s) will be discarded.

The following will delineate some special circumstances. These require disposition decisions in advance of cryopreserving embryo(s).

## **Death of Patient**

If Patient dies before using all embryos, the embryo(s) should be disposed of as checked below (check only one box):

1.  Please give complete control to Partner (if applicable), for any purpose, including implantation to achieve a pregnancy, donation to achieve pregnancy by someone else, donation for medical research or MGH Fertility Center training, or destruction and discard. This may mean keeping the cryopreserved embryo(s) in storage. It may also mean that the MGH Fertility Center will be owed payment for these cryopreservation services.
2.  Donate the embryo(s) for medical research or quality assurance/training purposes, including but not limited to MGH Fertility Center training or embryonic stem cell research, which may result in destroying embryo(s). I accept that this choice will not result in the birth of a child. I also understand that it may be restricted by state or federal laws. It is up to me to check the laws where I live about donating embryo(s) to medical research. I also accept that there may be no research study at the time of my death that will accept embryo(s) and that they may be discarded.
3.  Discard the embryo(s).

It is also agreed that if the selected disposition choice is not available or, in the MGH Fertility Center’s sole discretion, is not practical to implement; if the obligation to pay all storage and storage related fees when due are not upheld; or failure to preserve any choice made here as required by this Agreement or the MGH Fertility Center, authorization is given to the MGH Fertility Center to discard the cryopreserved embryo(s).

## **Death of Partner (If Applicable)**

If Partner dies before using all the embryos, we agree that the embryo(s) should be disposed of as checked below (check only one box):

1.  Please give complete control to Patient, for any purpose, including implantation to achieve a pregnancy, donation to achieve pregnancy by someone else, donation for medical research or MGH Fertility Center training, or destruction and discard. This may mean keeping the

cryopreserved embryo(s) in storage. It may also mean that the MGH Fertility Center will be owed payment for these cryopreservation services.

2.  Donate the embryo(s) for medical research purposes or quality assurance/training purposes, including but not limited to MGH Fertility Center training or embryonic stem cell research, which may result in destroying embryo(s). I accept that this choice will not result in the birth of a child. I also understand that it may be restricted by state or federal laws. It is up to me to check the laws where I live about donating embryo(s) to medical research. I also accept that there may be no research study at the time of my death that will accept embryo(s) and that they may be discarded.

3.  Discard the embryo(s).

It is also agreed that if the selected disposition choice is not available or, in the MGH Fertility Center's sole discretion, is not practical to implement; if the obligation to pay all storage and storage related fees when due are not upheld; or failure to preserve any choice made here as required by this Agreement or the MGH Fertility Center, authorization is given to the MGH Fertility Center to discard the cryopreserved embryo(s).

### **Simultaneous Death of Patient and Spouse/Partner (If Applicable)**

If both, Patient and Partner, die at the same time (as defined by applicable state law) before using all the embryos, we agree that the embryo(s) should be disposed of as checked below (check one box only):

1.  Donate the embryo(s) for medical research purposes or quality assurance/training purposes, including but not limited to MGH Fertility Center training or embryonic stem cell research, which may result in destroying embryo(s). I accept that this choice will not result in the birth of a child. I also understand that it may be restricted by state or federal laws. It is up to me to check the laws where I live about donating embryo(s) to medical research. I also accept that there may be no research study at the time of my death that will accept embryo(s) and that they may be discarded.

2.  Discard the embryo(s).

It is also agreed that if the selected disposition choice is not available or, in the MGH Fertility Center's sole discretion, is not practical to implement; if the obligation to pay all storage and storage related fees when due are not upheld; or failure to preserve any choice made here as required by this Agreement or the MGH Fertility Center, authorization is given to the MGH Fertility Center to discard the cryopreserved embryo(s).

### **Divorce or Dissolution of Relationship (If Applicable)**

If the Patient and Partner are divorced or dissolve their non-marital relationship, we agree that the embryos should be disposed of as checked below (check one box only):

1.  Give complete control of embryo(s) to Patient, alone or with a new partner, for any purpose, including implantation to achieve a pregnancy, donation to achieve pregnancy by someone else, donation for research or MGH Fertility Center training, or destruction and discard. We understand that this Agreement does not discuss or decide whether any legal parent-child relationships will be created or not created, and that further legal action may be needed in the future.

2.  Give complete control of the embryo(s) to Partner, alone or with a new partner, for any purpose, including implantation to achieve a pregnancy, donation to achieve pregnancy by someone else, donation for research or MGH Fertility Center training, or destruction and discard.

We understand that this choice in this Agreement does not discuss or decide whether any legal parent-child relationships will be created or not created, and that further action may be needed in the future.

3.  Donate the embryo(s) for medical research purposes or quality assurance/training purposes, including but not limited to MGH Fertility Center training or embryonic stem cell research, which may result in destroying embryo(s). I accept that this choice will not result in the birth of a child. I also understand that it may be restricted by state or federal laws. It is up to me to check the laws where I live about donating embryo(s) to medical research. I also accept that there may be no research study at the time of my death that will accept embryo(s) and that they may be discarded.
4.  Discard the embryo(s).

It is also agreed that if the selected disposition choice is not available or, in the MGH Fertility Center's sole discretion, is not practical to implement; if the obligation to pay all storage and storage related fees when due are not upheld; or failure to preserve any choice made here as required by this Agreement or the MGH Fertility Center, authorization is given to the MGH Fertility Center to discard the cryopreserved embryo(s).

*NOTE: If there is any future question about disposing of the embryo(s) in the case of a divorce or dissolution of relationship, the MGH Fertility Center may require a valid, final, non-appealable court decree by a court of competent jurisdiction and/or settlement agreement (as determined in the MGH Fertility Center's sole discretion), which specifically tells the MGH Fertility Center how to make a final disposition of the embryo(s).*

### **Discontinuation of IVF Treatment When Partnered (If Applicable)**

If the Patient and/or Partner, agree to stop IVF treatment as a couple, we agree that any frozen embryos should be disposed of in the following manner (**check one box only**):

1.  Give complete control of embryo(s) to Patient, alone or with a new partner, for any purpose, including implantation to achieve a pregnancy, donation to achieve pregnancy by someone else, donation for research or MGH Fertility Center training, or destruction and discard. We understand that this Agreement does not discuss or decide whether any legal parent-child relationships will be created or not created, and that further legal action may be needed in the future.
2.  Give complete control of the embryo(s) to Partner, alone or with a new partner, for any purpose, including implantation to achieve a pregnancy, donation to achieve pregnancy by someone else, donation for research or MGH Fertility Center training, or destruction and discard. We understand that this choice in this Agreement does not discuss or decide whether any legal parent-child relationships will be created or not created, and that further action may be needed in the future.
3.  Donate the embryo(s) for medical research purposes or quality assurance/training purposes, including but not limited to MGH Fertility Center training or embryonic stem cell research, which may result in destroying embryo(s). I accept that this choice will not result in the birth of a child. I also understand that it may be restricted by state or federal laws. It is up to me to check the laws where I live about donating embryo(s) to medical research. I also accept that there may be no research study at the time of my death that will accept embryo(s) and that they may be discarded.
4.  Discard the embryo(s).

It is also agreed that if the selected disposition choice is not available or, in the MGH Fertility Center's sole discretion, is not practical to implement; if the obligation to pay all storage and storage related fees when due are not upheld; or failure to preserve any choice made here as required by this Agreement or the MGH Fertility Center, authorization is given to the MGH Fertility Center to discard the cryopreserved embryo(s).

## **Storage Fees**

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Maintaining embryos in a frozen state is labor intensive and expensive. Patients who have frozen embryos must: 1) pay fees associated with the storage of embryo(s) according to the MGH Fertility Center's storage and financial terms; and 2) stay in contact with the MGH Fertility Center with any change of address.

## **Time-Limited Storage of Embryos**

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The MGH Fertility Center will only keep cryopreserved embryos for a period of five years from the date of initial cryopreservation of embryo(s) created through in vitro fertilization. After that time, Patient and Partner (if applicable) select the following for the embryo(s) (check one box only):

1.  Donate the embryo(s) for medical research purposes or quality assurance/training purposes, including but not limited to MGH Fertility Center training or embryonic stem cell research, which may result in destroying embryo(s). I accept that this choice will not result in the birth of a child. I also understand that it may be restricted by state or federal laws. It is up to me to check the laws where I live about donating embryo(s) to medical research. I also accept that there may be no research study at the time of my death that will accept embryo(s) and that they may be discarded.
  2.  Discard the embryo(s).
  3.  Transfer the embryo(s) to a storage facility at personal expense and risk. Patient and Partner (if applicable) understand to complete and sign other documents as provided, or approved, by the MGH Fertility Center and any storage facility.
- If any other dispositional choice is desired in the future, Patient (and Partner), must both complete and sign a new dispositional agreement and pay all storage and related fees to the MGH Fertility Center.

## **Financial Terms**

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

## **Change of Address**

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Patient and Partner (if applicable) understand that it is their responsibility to notify MGH Fertility Center promptly in writing of any change in their addresses or telephone numbers. It is also understood that embryo(s) will be considered to be abandoned if (i) payment has not been made accordance with the Financial Terms above, or (ii) the maximum storage period (5 years) is approaching and despite diligent efforts including certified mail MGH Fertility Center is unable to make contact at the last known address to confirm intentions for continued cryopreservation. If embryo(s) are considered to be

abandoned, MGH Fertility Center reserves the right to remove the embryo(s) from storage and discard them.

**Patient and Partner (if applicable) expressly understand, agree, and authorize the MGH Fertility Center to reserve the right to discard embryo(s) according to its normal laboratory procedures and applicable law without further notice to, or consent required if:**

- 1) There is no contact by Patient and/or Partner (if applicable) with the MGH Fertility Center for a period of 5 years, or
- 2) There is failure to pay all fees for embryo storage within 45 days of billing and the MGH Fertility Center has made reasonable efforts to contact Patient and/or Partner (if applicable) according to its established protocols,

In such circumstances, it is also acknowledged that Patient and Partner (if applicable) knowingly and completely release any and all claims to embryo(s) or to any additional notice from the MGH Fertility Center as to the final disposition of the embryo(s).

### **Age-Limited Storage of Embryos**

Patient and Partner (if applicable) understand that the MGH Fertility Center will not transfer embryo(s) into the uterus of Patient and/or Partner, if applicable, to produce a pregnancy after the 49<sup>th</sup> year of birth is complete. After this age, Patient and Partner (if applicable) choose to do the following with our embryo(s) **(check one box only)**:

1.  Transfer the embryo(s) into one of us that has not reached that age, or into a gestational carrier, so that we may have a child.
  2.  Donate the embryo(s) for medical research purposes or quality assurance/training purposes, including but not limited to MGH Fertility Center training or embryonic stem cell research, which may result in destroying embryo(s). I accept that this choice will not result in the birth of a child. I also understand that it may be restricted by state or federal laws. It is up to me to check the laws where I live about donating embryo(s) to medical research. I also accept that there may be no research study at the time of my death that will accept embryo(s) and that they may be discarded.
  3.  Discard the embryo(s).
  4.  Transfer the embryo(s) to a storage facility at personal expense and risk. Patient and Partner (if applicable) understand to complete and sign other documents as provided, or approved, by the MGH Fertility Center and any storage facility.
- If we wish to make any other dispositional choice in the future, we know that I, and a spouse/partner) must both complete and sign a new dispositional agreement and pay all storage and related fees due to the MGH Fertility Center.

### **Donation of Frozen Embryos for Research Purposes**

If the option “award for research or quality assurance purposes” was selected under any of the preceding circumstances, as a donor of human embryos to research, including but not limited to stem cell research, be aware of the following:

- Donating embryos for research may not be possible or may be restricted by law. While efforts will be made to abide by personal wishes, no guarantees can be given that embryo(s) will be used for research. In these instances, if no research or quality assurance project can be found,

or the embryo(s) are not eligible, the embryo(s) will be destroyed and discarded by the lab in accordance with laboratory procedures and applicable laws.

- The embryo(s) may be used by MGH Fertility Center for quality assurance or training purposes.
- The embryo(s) may be used to derive human pluripotent stem cells for research and the cells may be used, at some future time, for human transplantation research.
- All identifiers associated with the embryo(s) will be removed prior to the derivation of human pluripotent stem cells.
- Donors to research will not receive any information about subsequent testing on the embryo or the derived human pluripotent cells.
- Derived cells or cell lines, with all identifiers removed, may be kept for many years.
- It is possible the donated material may have commercial potential, but the donor will receive no financial or other benefit from any future commercial development.
- Human pluripotent stem cell research is not intended to provide direct medical benefit to the embryo donor.
- Donated embryos will not be transferred to a person's uterus, nor will the embryos survive the human pluripotent stem cell derivation process. Embryo(s) will be handled respectfully, as is appropriate for all human tissue used in research.
- If the embryo(s) were created with gametes (eggs and/or sperm) from a third-party donor, you cannot choose to donate embryos for use in medical research or MGH Fertility Center training.

## **Legal Issues and Legal Counsel**

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Patient and Partner (if applicable) understand that the laws on embryo cryopreservation, thawing, and use may be unclear where Patient and Partner (if applicable) live. They may also be unclear on the parent-child status of any resulting child. The MGH Fertility Center has not given any legal advice, and Patient and Partner (if applicable) are not relying on them to do so. Patient and Partner (if applicable) may need to speak to a lawyer who is an expert in this area to understand legal rights and obligations. In the event oocytes are combined with sperm to form embryos, marital status may affect the ability to use the embryos in the event of a dispute. The policy of the MGH Fertility Center or state may also affect my ability to use my embryos.

Sign on the final page to indicate your consent:

By signing below, Patient and Partner (if applicable) consent to the cryopreservation and storage of embryo(s). Patient and Partner (if applicable) acknowledge and accept the risks outlined above, affirm dispositional choices as indicated above and understand that choices regarding change in choices can be made in the future. This will require a written and notarized agreement. Patient and Partner (if applicable) also understand that if none of the choices are available, the MGH Fertility Center may discard the frozen embryo(s)

X

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Patient Name

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

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X

\_\_\_\_\_  
Partner Signature (if applicable)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Partner Name (if applicable)

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

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X

\_\_\_\_\_  
Legal Guardian Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Legal Guardian Name

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

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*If Patient is a minor (less than 18 years of age):*

**Parent/Parents or Legal Guardian Signature is Required:**

X

\_\_\_\_\_  
Parent or Legal Guardian Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Legal Guardian Name

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

X

\_\_\_\_\_  
Parent or Legal Guardian Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Legal Guardian Name

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