#### **Department of Obstetrics and Gynecology**

Strong Fertility Center

Kathleen Hoeger, MD, MPH, Director Snigdha Alur-Gupta, MD Erin Masaba, MD John T. Queenan, Jr., MD Wendy Vitek, MD



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

This document describes the process and risks of cryopreservation and storage, and asks you to indicate your intention for the use of embryos from this IVF treatment cycle.

### **Description of Cryopreservation Process**

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 "suspended animation" until thawed.

# Risks of Cryopreservation and Storage

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 embryos 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 Strong Fertility Center or its laboratory. In accordance with its protocols, Strong Fertility Center makes reasonable efforts to handle and maintain its patients' embryos, including, but not limited to maintenance and monitoring of its equipment, materials and laboratory. Despite such efforts, I understand that as a result of one or more of these potential factors, my 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.

# Risk of Shipping to another facility

Some clinics do not offer long-term storage, so will ship your embryos to another facility after a period of time. 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, Strong Fertility Center, and any of Strong Fertility Center's physicians, employees, or agent except in the event of willful misconduct or gross negligence on the part of Strong Fertility Center, or any of Strong Fertility Center's physicians, employees, or agents.

# **Consent and Disposition**

I/We have chosen to have my/our embryos cryopreserved and stored for future use. There may be cases in which I/We do not use these embryos — due to death or some other reason. In such cases, I/we understand that there are generally 4 choices for the disposition of my embryos:

- 1. Give control of my embryos to my spouse or partner;
- 2. Discard the embryos;
- 3. Donate the embryos for approved medical research; or
- 4. Donate the embryos to another person/couple so they can try to have a child.

Please understand that the Strong Fertility Center cannot guarantee what the available or acceptable choices for disposition will be at any future date as this field is rapidly evolving both legally and medically. You may also wish to consult with a lawyer, together or individually, for each of you to understand your legal rights and any law that may apply to this Agreement or to your disposition choices. If any choice you select is not available for any reason, you are authorizing the Strong Fertility Center to thaw and discard ("discard") any currently cryopreserved embryos under this Agreement.

I/We are making one of the choices noted above on this form. I/We understand that I/we can change our choice at any time if I/we fill out and sign a new version of this Agreement. I/We also understand that I/We will need to sign a different consent when my embryos are thawed for use.

I/We also know that our marital status—now and later—can affect the future use of these embryos. I /We know that each clinic and each state has its own policies, which may affect my/our ability to use these embryos to try to have a child in the future.

Special note for embryos created with donated gametes: If your embryos were created with gametes (eggs and/or sperm) from a third-party donor, you cannot choose to donate embryos to anyone, for any reason, unless the gamete donor has agreed, in writing, to allowing their gametes (eggs or sperm) to be given to anyone besides you. This includes donation to try to have a child or for use in medical research or clinical training. Your 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 embryos will be discarded.

checked below (check only one box):
1. Please give complete control to Patient's Spouse or Partner, for any purpose, including implantation to achieve a pregnancy, donation to achieve pregnancy by someone else, donation for medical research or clinical training, or destruction and discard. This may mean keeping the cryopreserved embryos in storage. It may also mean that the CLINIC will be owed payment for these cryopreservation services.
2. Donate my embryos to a person and/or couple who wish to have a child who is either: a) selected by the CLINIC, or b) specifically named by me, below. This choice is controlled by the FDA and state laws. This means that I and my partner will need to be screened and tested. (choose option A or B):
A. Donate my embryos through the Strong Fertility Center, to an embryo bank or one or more recipients to receive the embryos to attempt a pregnancy, if this is practical, (as determined by the Strong Fertility Center in its sole discretion) and, if it is not possible, to discard the embryos.
B. Donate my embryos to the couple or person ("recipient(s)") named below (the "recipients). I understand that this means keeping the embryos in storage and requires both 1) payment by us or the named recipients of all storage fees and other payments due the Strong Fertility Center for these cryopreservation services, and 2) the Strong Fertility Center's ability to carry out this choice. I also understand that any future disposition of any unused embryos is under the sole control of the recipient(s) that he, she or they wish.  Donate to: Names  Address  Address
Phone Email
If your named recipients are unable or unwilling to accept the embryos, or your estate representative (Executor) does not carry out this choice, <b>you must check one of the boxes below</b> to indicate whether you <b>DO OR DO NOT</b> want the Strong Fertility Center to try to locate other recipients for donation, or if you want your embryos to be discarded. ( <b>Choose either option 1 or 2</b> ):
i. $\square$ Discard our embryos: Do not donate to other recipients, or an embryo bank.
ii. Donate our embryos to other recipients: The CLINIC will try to locate and donate to an embryo bank or one or more recipients to attempt a pregnancy if practical (as determined by the Strong Fertility Center in its sole discretion), and if this is not possible, discard our embryos.
3. Donate my embryos for medical research purposes, including but not limited to embryonic stem cell research, which may result in destroying the embryos. 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 embryos to medical research. I also accept that there may be no research study at the time of my death that will accept these embryos and that they may be discarded.
4. $\square$ Donate my embryos for clinical training, which may result in destroying the embryos. I accept that this choice will not result in the birth of a child.
5. Discard the embryos.
<b>6.</b> Other disposition (please specify); this option must also be initialed by an authorized representative of the Strong Fertility Center to be effective:
☐ Agreed upon: [insert name and title], authorized Strong Fertility Center representative:

If Patient dies before using all of the embryos, I/We agree that the embryos should be disposed of as

If Spouse/Partner dies before using all the embryos, I/We agree that the embryos 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 research or clinical training, or destruction and discard. This may mean keeping the embryos in storage. It may also mean that the Strong Fertility Center will be owed payment for these cryopreservation services.
2. Donate my embryos to a person and/or couple who wish to have a child who is either: a) selected by the CLINIC, or b) specifically named by me, below. This choice is controlled by the FDA and state laws. This means that I and my partner will need to be screened and tested. (choose either option A or B):
A. Donate my embryos through the Strong Fertility Center, to an embryo bank or one or more recipients to receive the embryos to attempt a pregnancy, if this is practical, (as determined by the Strong Fertility Center in its sole discretion) and, if it is not possible, to discard the embryos.
B. Donate my embryos to the couple or person ("recipient(s)") named below. I understand that this means keeping the embryos in storage and requires both 1) payment by us or the named recipients of all storage fees and other payments due the Strong Fertility Center for these cryopreservation services, and 2) the Strong Fertility Center's ability to carry out this choice. I also understand that any future disposition of any unused embryos is under the sole control of the recipient(s) that he, she or they wish.  Donate to: Names
PhoneEmail
If your named recipients are unable or unwilling to accept the embryos, or your estate representative (Executor) does not carry out this choice, you must check one of the boxes below to indicate whether you DO OR DO NOT want the Strong Fertility Center to try to locate other recipients for donation, or if you want your embryos to be discarded.  If the named person or couple is unable or unwilling to accept the embryos, I/We direct Strong Fertility Center as checked below (choose either option 1 or 2):
i. Discard our embryos: Do <b>no</b> t donate to other recipients, or an embryo bank.
ii. Donate our embryos to other recipients: The CLINIC will try to locate and donate to an embryo bank or one or more recipients to attempt a pregnancy if practical, (as determined by the Strong Fertility Center in its sole discretion), and if this is not possible, discard our embryos.
3. Donate my embryos for medical research purposes, including but not limited to embryonic stem cell research, which may result in destroying the embryos. 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 embryos to medical research.
4. Donate my embryos for clinical training, which may result in destroying the embryos. I accept that this choice will not result in the birth of a child.
5. Discard the embryos.
<b>6.</b> Under disposition (please specify); this option must also be initialed by an authorized representative of the Strong Fertility Center to be effective:
Agreed upon: [insert name and title], authorized Strong Fertility Center representative:

If both of us, Patient and Patient's Spouse/Partner, die at the same time (as defined by applicable state law) before using all the embryos, I/we agree that the embryos should be disposed of as checked below (check only one box):
1. Discard embryos.
2. Donate our embryos to a person and/or couple who wish to have a child who is either: a) selected by the CLINIC, or b) specifically named by me, below. This choice is controlled by the FDA and state laws. This means that we will both need to be screened and tested when the embryos are created. (choose either option A or B):
A. Donate our embryos through the Strong Fertility Center, to an embryo bank or one or
more recipients to receive the embryos to attempt a pregnancy, if this is practical, (as determined by the Strong Fertility Center in its sole discretion) and, if it is not possible, to discard the embryos.
B. Donate our embryos to the couple or person ("recipient(s)") named below. I/we understand that this means keeping the embryos in storage and requires both 1) payment by us or the named recipients of all storage fees and other payments due the Strong Fertility Center for these cryopreservation services, and 2) the Strong Fertility Center's ability to carry out this choice. I/we also understand that any future disposition of any unused embryos is under the sole control of the recipient(s) that he, she or they wish.  Donate to: Names
Phone Email
If your named recipients are unable or unwilling to accept the embryos, or your estate representative (Executor) does not carry out this choice, you must check one of the boxes below to indicate whether you DO OR DO NOT want the Strong Fertility Center to try to locate other recipients for donation, or if you want your embryos to be discarded.  If the named person or couple is unable or unwilling to accept the embryos, I/We direct Strong Fertility Center as checked below (choose either option 1 or 2):
i. $\square$ Discard our embryos: Do <b>no</b> t donate to other recipients, or an embryo bank.
ii. Donate our embryos to other recipients: The CLINIC will try to locate and donate to an embryo bank or one or more recipients to attempt a pregnancy if practical, (as determined by the Strong Fertility Center in its sole discretion), and if this is not possible, discard our embryos.
3. Donate our embryos for medical research purposes, including but not limited to embryonic stem cell research, which may result in destroying the embryos. 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 embryos to medical research. I also accept that there may be no research study at the time of my death that will accept these embryos and that they may be discarded.
<b>4.</b> Donate our embryos for clinical training, which may result in destroying the embryos. I accept that this choice will not result in the birth of a child.
<b>5.</b> Other disposition (please specify); this option must also be initialed by an authorized representative of the Strong Fertility Center to be effective:
Agreed upon: [insert name and title], authorized Strong Fertility Center representative:

# Divorce or Dissolution of Relationship

If the Patient and Spouse/Partner are divorced or dissolve their non-marital relationship, I/We agree that the embryos should be disposed of as checked below (check only one box):
1. Give complete control of our embryos to Patient, alone or with a new partner or spouse, for any purpose, including implantation to achieve a pregnancy, donation to achieve pregnancy by someone else donation for research or clinical 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 our embryos to Spouse/Partner, alone or with a new partner or spouse, for any purpose, including implantation to achieve a pregnancy, donation to achieve pregnancy by someone else, donation for research or clinical training, or destruction and discard. We understand that this choice in this Agreement does not discuss or decide whether any legal parent-child relationship will be created or not created, and that further action may be needed in the future.
3. Donate our embryos to a person and/or couple who wish to have a child who is either: a) selected by the CLINIC, or b) specifically named by me, below. This choice is controlled by the FDA and state laws. This means that we will both need to be screened and tested when the embryos are created. (choose either option A or B):
A. Donate our embryos through the Strong Fertility Center, to an embryo bank or one or more couples or individuals to achieve a pregnancy if this is practical (as determined by the Strong Fertility Center's sole discretion), and, if it is not, to discard the embryos.
B. Donate our embryos to the couple or individual ("recipients") named below to achieve a pregnancy. We understand that this may mean keeping the embryos in storage and requires both 1) payment by us or the named recipients of all storage fees and other payments due the Strong Fertility Center for these cryopreservation services, and 2) the Strong Fertility Center's ability to carry out this choice. I/we also understand that any future disposition of any unused embryos is under the sole control of the recipient(s) that he, she or they wish.  Donate to: Names  Address  Address
Phone Email  If your named recipients are unable or unwilling to accept the embryos, or your estate representative (Executor) does not carry out this choice, you must check one of the boxes below to indicate whether you DO OR DO NOT want the Strong Fertility Center to try to locate other recipients for donation, or if you want your embryos to be discarded.  i. Discard our embryos: Do not donate to other recipients, or an embryo bank.  ii. Donate our embryos to other recipients: The CLINIC will try to locate and donate to an embryo bank or one or more recipients to attempt a pregnancy if practical, (as determined by the Strong Fertility Center in its sole discretion), and if this is not possible, discard our embryos.
<ul> <li>4. Donate our embryos for medical research purposes, including but not limited to embryonic stem cell research, which may result in destroying the embryos. We accept that this choice will not result in the birth of a child. We also understand that it may be restricted by state or federal laws. It is up to us to check the laws where we live about donating embryos to medical research. I also accept that there may be no research study available at the time of my death that will accept my embryos and that they may be discarded.</li> <li>5. Donate our embryos for clinical training, which may result in destroying the embryos. We accept that this choice will not result in the birth of a child.</li> <li>6. Discard the embryos.</li> </ul>

NOTE: If there is any future question about disposing of the embryos in the case of a divorce or dissolution of relationship, the Strong 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 Strong Fertility Center's sole discretion), which specifically tells the Strong Fertility Center how to make a final disposition of the embryos.

# Discontinuation of IVF Treatment

If the Patient and her Spouse/Partner both agree to stop IVF treatment as a couple, I/We agree that any frozen
embryos should be disposed of in the following manner (check only one box):
1. Give complete control of our embryos to Patient, alone or with a new partner or spouse, for any purpose for any purpose, including implantation to achieve a pregnancy, donation to achieve
pregnancy by someone else, donation for research or clinical training, or destruction and discard. We understand that this document 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.
2. Give complete control of our embryos to Spouse/Partner, alone or with a new partner or
spouse, for any purpose, including implantation to achieve a pregnancy, donation to achieve pregnancy by someone else, donation for research or clinical training, or destruction and discard. We understand that this choice in this document does not discuss or decide whether any legal parent-child relationships will be created or not created, and that further action may be needed
3. Donate our embryos to a person and/or couple who wish to have a child who is either: a) selected by the CLINIC, or b) specifically named by me, below. This choice is controlled by the FDA and state laws. This means that we will both need to be screened and tested when the embryos are created. (choose either option A or B):
A. Donate our embryos through the Strong Fertility Center, to an embryo bank or one or
more couples or individuals to achieve a pregnancy if this is practical (as determined by the Strong Fertility Center's sole discretion), and, if it is not, to discard the embryos.
B. Donate our embryos to the couple or individual ("recipients") named below to achieve a pregnancy. I /we understand that this may mean keeping the embryos in storage and requires both 1) payment by us or the named recipients of all storage fees and other payments due the Strong Fertility Center for these cryopreservation services, and 2) the Strong Fertility Center's ability to carry out this choice. I/we also understand that any future disposition of any unused embryos is under the sole
control of the recipient(s). That he, she or they wish.
Donate to: Names Address
Phone Email
If your named recipients are unable or unwilling to accept the embryos, or your estate representative (Executor) does not carry out this choice, <b>you must check one of the boxes below</b> to indicate whether you <b>DO OR DO NOT</b> want the Strong Fertility Center to try to locate other recipients for donation, or if you want your embryos to be discarded.
i. $\square$ Discard our embryos: Do <b>no</b> t donate to other recipients, or an embryo bank.
ii. Donate our embryos to other recipients: The CLINIC will try to locate and donate to an embryo bank or one or more recipients to attempt a pregnancy if practical, (as determined by the Strong Fertility Center in its sole discretion), and if this is not possible, discard our embryos.
C. Donate our embryos for medical research purposes, including but not limited to embryonic stem cell research, which may result in destroying the embryos. We accept that this choice will not result in the birth of a child. We also understand that it may be restricted by state or federal laws. It is up to us to check the laws where we live about donating embryos to medical research.
D. Donate our embryos for clinical training, which may result in destroying the embryos.  We accept that this choice will not result in the birth of a child.
4. Discard the embryos.
5. Other disposition (please specify); this option must also be initialed by an authorized representative of the Strong Fertility Center to be effective:
☐ Agreed upon: [insert name and title], authorized Strong Fertility Center representative:

I/We also agree that if: our selected disposition choices are not available or, in the Strong Fertility Center's sole discretion, are not practical to implement; if I/we do not uphold our obligation to pay all storage and storage related fees as and when due; or fail to preserve any choice I/we have made here as required by this agreement or the Strong Fertility Center, I/we authorize the Strong Fertility Center to discard our embryos.

#### **Storage Fees**

Maintaining embryos in a frozen state is labor intensive and expensive. Patients/couples who have frozen embryos must: 1) pay fees associated with the storage of their embryos according to the Strong Fertility Center's storage and payment protocol; and 2) stay in contact with the Strong Fertility Center at least once a year to inform the Strong Fertility Center of their wishes.

I/We expressly understand, agree, and authorize the Strong Fertility Center to discard our embryos according to its normal laboratory procedures and applicable law without further notice to, or consent required by us (Patient or Spouse/Partner) if:

- 1) There is no contact by me/one of us (Patient and/or Spouse/Partner) with the Strong Fertility Center for a period of 5 years, or
- I/We fail to pay all fees for embryo storage for a period of 5 years and the Strong Fertility Center has made reasonable efforts to contact Patient and Spouse/Partner according to its established protocols,

In such circumstances, I/we also acknowledge that I/we knowingly and completely release any and all claims to our embryos or to any additional notice from the Strong Fertility Center as to the final disposition of the embryos.

# Time-Limited Storage of Embryos

	ong Fertility Center will only keep cryopreserved embryos for a period of one year(s). After that time, bose to do the following with our embryos (check only one box):
1	Donate our embryos for medical research, including but not limited to embryonic stem cell research, which may result in the destruction of the frozen embryos. I/we accept that this choice will not result in the birth of a child. I/we also understand that it may be restricted by state or federal laws. It is up to us to check the laws where we live about donating embryos to medical research.
(	Donate our embryos for clinical training purposes which may result in the destruction of the frozen embryos. We accept that this choice will not result in the birth of a child.
	Discard the frozen embryos.
	Transfer our embryos to a storage facility at my/our expense and risk. We understand that we will be required to complete and sign other documents as provided, or approved, by the Strong Fertility Center and any storage facility.

• If we wish to make any other dispositional choice in the future, we know that we must both complete and sign a new dispositional agreement and pay all storage and related fees to the Strong Fertility Center.

#### Age-Limited Storage of Embryos

	inderstand that the Strong Fertility Center will not transfer embryos into any woman to produce a ancy after age 54 years. After this age, I/we choose to do the following with our embryos <b>(check only one</b>
ŕ	Transfer our embryos into one of us that has not reached that age, or into a gestational carrier, so that we may have a child.
	Donate our embryos for medical research, including but not limited to embryonic stem cell research, which may result in the destruction of the frozen embryos. We accept that this choice will not result in the birth of a child. We also understand that it may be restricted by state or federal laws. It is up to us to check the laws where we live about donating embryos to medical research.
	Donate our embryos for clinical training purposes which may result in the destruction of the frozer embryos. We accept that this choice will not result in the birth of a child.
	Discard the embryos.
	Transfer our embryos to a storage facility at my/our expense and risks. I/we understand I/we will be required to complete and sign other documents as provided, or approved, by the Strong Fertility Center and any storage facility.

• If we wish to make any other dispositional choice in the future, we know that we must both complete and sign a new dispositional agreement and pay all storage and related fees due to the Strong Fertility Center.

#### Donation of Frozen Embryos for Research Purposes

If you selected the option "award for research purposes" under any of the preceding circumstances, as a donor of human embryos to research, including but not limited to stem cell research, you should 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 your wishes, no guarantees can be given that embryos will be used for research or
  donated to another couple. In these instances, if after 5 years no recipient or research project can be
  found, or your embryos are not eligible, your embryos will be destroyed and discarded by the lab in
  accordance with laboratory procedures and applicable laws.
- The embryos 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 embryos 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 woman's uterus, nor will the embryos survive the human pluripotent stem cell derivation process. Embryos will be handled respectfully, as is appropriate for all human tissue used in research.
- If the donated embryos were formed with gametes (embryos) from someone other than the patient and her spouse or partner (those who sign this document), the gamete donors may be required to provide a signed, written consent for use of the resulting embryos for research purposes.

# **Legal Issues and Legal Counsel**

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

Sign on the next page to indicate your consent:

By signing below, I/We consent to the cryopreservation and storage of my embryos. I/We also consent to the shipping of embryos to another facility if my Clinic does not offer long-term storage. I/We acknowledge and accept the risks outlined above. I/We affirm my dispositional choices as indicated above. I/We understand that I/We can change those choices in the future. This will require a written and notarized agreement. I/We also understand that if none of my choices is available, the Clinic may discard my frozen embryos.

X			
Patient Signature		Date	
Patient Name		Date of Birth	
Notary Public			
Sworn and subscribed before me on this	day of	·	
Notary Signature		Date	
X			
Spouse / Partner Signature		Date	
Spouse / Partner Name		Date of Birth	
<b>Notary Public</b> Sworn and subscribed before me on this	day of		
Notary Signature		Date	
If signed in the office:  Statement by Witness (must be employed) I declare that the person who signed this descund mind and acting of his or her own from the or her) this document in my presence.	locument is pers	onally known to me and appea	
Witness Name:			
Witness Signature:			