Freezing & Storage of Sperm or Eggs,

and Instructions for their Disposition

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DESCRIPTION

This document informs patients of the risks of freezing and storage, and records their decision regarding disposition of eggs and sperm under various situations.

TARGET

* All patients who might freeze eggs or sperm

RELEASE NOTES

* This is the 3rd revision of this document
* Adds language about freezing and storage risks
* Broadens applicability to both gametes – eggs and sperm
* Signature page allows for Witness as well as Notary verification.

TO DO

* Omit disposition options not available in your practice (for instance, some clinics do not offer donation to research or clinical training, and others don’t have a time or age limit to use frozen eggs).
* Replace “CLINIC” with your program’s name throughout
* Enter the number of years in storage or age of patient that your CLINIC will use as limits.
* Modify this document according to local needs and preferences.
* Get legal review to assure conformance with State and local laws and regulations

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Consent for Freezing and Storage of Eggs or Sperm, and Instructions for their Disposition

This document describes the process and risks of freezing and storage of eggs or sperm, and asks you to indicate your intention for the use in certain situations.

This Agreement is between you, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and the CLINIC, and covers a specific instance of freezing.

The eggs or sperm covered by this Agreement are due to be frozen on or about:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(planned / predicted date of freezing).*

Contact Information:

* Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Cell phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Process of Freezing

Freezing of sperm and/or eggs is now a well-established procedure. Once frozen the cells remain in “suspended animation” until thawed. The sperm to be frozen can be from ejaculates, epididymal aspirates or testicular biopsies. Eggs are typically in the form of individual eggs obtained by follicle aspiration. This document is directed at all these types of cells.

Risks

The process of freezing, storage, and thawing can damage eggs or sperm, and not all eggs or sperm will be successfully frozen, or, if frozen, successfully thaw, fertilize (if eggs), or be available for further treatment or implantation.

It is also possible that frozen eggs or sperm may be damaged, destroyed, lost or fail to survive, 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 CLINIC or its laboratory. In accordance with its protocols, CLINIC makes reasonable efforts to handle and maintain its patients’ eggs, sperm, and embryos, including, but not limited to maintenance and monitoring of its equipment, materials, and laboratory. Despite such efforts, I understand that because of one or more of these potential factors, my eggs and/or sperm may become unavailable for further treatment or implantation, or that the likelihood of a pregnancy resulting from any treatment or implantation may be reduced.

In addition, there is a very small potential risk that gametes or embryos that are frozen may not be properly labeled or transferred to the individual(s) who stored them. This can arise from human error in fertilizing eggs or human or mechanical errors in labeling and storing eggs, sperm or embryos. While every SART clinic and embryology lab has protocols designed to avoid such errors through reasonable efforts to properly identify, label, store, thaw, and transfer reproductive tissue, errors in these steps are possible and patients understand and accept the risks inherent in such steps.

*If you choose to freeze eggs or embryos, you MUST complete the Disposition of Embryos (or Eggs) Agreement before freezing. This statement may need to be notarized. The statement explains the choices you have for disposing of the eggs or embryos in a variety of situations that may arise. You can submit a new statement later if you change your mind about your choices. For frozen embryos, any change requires that both parties — you and your partner-- agree in writing to the change.*

Risk of Shipping to another Facility

In some cases, the clinic may not own or operate the laboratory responsible for freezing or storage of your eggs or sperm 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. Some clinics do not offer long-term storage, so will ship your embryos to another facility after a period.

Consent to Freeze and Store, and Instructions for Disposition

I have chosen to have my eggs or sperm frozen and stored for future use. There may be cases in which I do not use my eggs or sperm—due to my death or some other reason. In such cases, I generally have three choices for the disposition of my eggs or sperm.

1. Give control of my eggs or sperm to my partner or spouse;
2. Donate the eggs or sperm to a specific person; or
3. Discard the eggs or sperm;

I am making one of the above choices on this form. I understand that I can change my choice at any time if I fill out and sign a new version of this consent. I also understand that I will need to sign a different consent when my eggs or sperm are thawed for use.

I know that my marital status—now and later—can affect my use of these eggs or sperm if they have been used to create embryos. Also know that each clinic and each state has its own policies. This may affect my ability to use these eggs or sperm if embryos have been formed.

# MY CHOICE is indicated below:

# In the event of my death

If I die before using all my eggs or sperm stored at the CLINIC . . . (check only one box):

❑ Discard the eggs or sperm. I understand that if I am under the age of 18 that this is likely the only option available.

❑ Give control over the use of my eggs or sperm to my spouse or partner named below. He or she will have complete control for any purpose. This includes fertilization and implantation for purposes of them parenting any resulting child, donation for medical research, or discard. This may mean keeping the frozen eggs or sperm in storage. It may also mean that the CLINIC will be owed payment.

Partner:  Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

                        Phone \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❑ Donate my eggs or sperm to the couple or person named below. I know that this choice is controlled by the FDA and state laws. That means that I will need to be screened and tested for certain infectious diseases around the time my sperm or eggs are frozen. I understand this person must be someone who would use the gametes for their own reproductive purposes and not donate them to someone else.

Donate to:  Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

                     Address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

                        Phone \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: If the couple or person named above cannot or will not accept the eggs or sperm, the CLINIC will discard them.

# In the event I don’t pay for storing frozen eggs or sperm

Keeping eggs or sperm frozen requires that I pay storage fees. You must also contact the CLINIC at least once a year. That way they will know your wishes for the eggs or sperm. Your eggs or sperm may be discarded if:

* You have not contacted the CLINIC for \_\_\_\_ years
* You have not paid your storage fees for \_\_\_\_ years, and the CLINIC cannot reach you

Before discarding the eggs or sperm, the CLINIC will contact you by registered mail at your last known address. You must pay the overdue storage fees within 30 days from the date of the mailing. If you do not, you are giving your permission for the CLINIC to proceed with discard.

Legal Issues and Legal Counsel

I understand that the laws on egg and sperm freezing, thawing, and use may be unclear where I live. They may also be unclear on the parent-child status of any resulting children. This CLINIC has not given me any legal advice, and I am not relying on them to do so. I 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 eggs or sperm have been used to form embryos, a separate disposition agreement or legal ruling will control the use the embryos in the event of a dispute. The policy of my CLINIC or state may also affect my ability to use my eggs or sperm.

Sign on the appropriate following page to indicate your consent / assent:

By signing below, I consent to the freezing and storage of my eggs or sperm. I also consent to the shipping of eggs or sperm to another facility if my Clinic does not offer long-term storage. I understand I will be asked to sign additional consents by the receiving facility. I acknowledge and accept the risks outlined above. I affirm my dispositional choice as indicated above. I understand that I can change those choice in the future. This will require a written and notarized agreement. I also understand that if my choices is unavailable, the Clinic will discard my frozen eggs or sperm.

*If signed out of the office:*

X

Patient Signature Date

Patient Name Date of Birth

**Notary Public**

Sworn and subscribed before me on this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_.

X

Notary Signature Date

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*If signed in the office:*

**Statement by Witness (must be employee at least 18 years old)**

I declare that the person who signed this document is personally known to me and appears to be of sound mind and acting of her own free will. He or she signed this document in my presence.

Witness Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

FOR PATIENTS UNDER AGE 18:

By signing below, we (patient and parent / guardian) agree to the freezing and storage of my eggs or sperm. We also consent to the shipping of eggs or sperm to another facility if my Clinic does not offer long-term storage. We acknowledge and accept the risks outlined above. We affirm my dispositional choice as indicated above. We understand that we can change those choice in the future; this will require a written and notarized agreement. We also understand that if our choice is unavailable, the Clinic will discard my frozen eggs or sperm**.**

PATIENT ASSENT (between ages 14 and 17)

X

Patient Signature Date

Patient Name Date of Birth

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PARENT / GUARDIAN CONSENT:

X

Parent / Guardian Signature Date

Parent / Guardian Name Date of Birth

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CLINIC REPRESENTATIVE:

X

Clinic Representative Signature Date