Obstetrics and Gynecology

Agreement for Cryopreservation, Storage and Disposition of Egg or Sperm

MRN:
NAME:
BIRTHDATE:
CSN:

Note 1: As part of its operations, the Clinic, defined on <u>Exhibit A</u>, which is part of Michigan ("Hospital"), temporarily stores eggs and sperm for Clinic patients. As a Clinic patient and/or partner of a Clinic patient, you are requesting that the Hospital temporarily store your eggs or sperm (either, as applicable, a "Specimen"). You have been advised that other storage options are available and understand that the Hospital will only store your embryos subject to the terms and conditions of this Agreement. If, after review of this Agreement, you do not wish to temporarily store your Specimens at the Hospital, you must make other storage arrangements prior to the commencement of any services that will result in Specimens. All costs associated with the transfer to any such facility will be your responsibility. Upon execution, this Agreement is a legally binding document between you and/or your partner and the Hospital. If you need any assistance or support in reading or understanding this Agreement, please contact the Clinic.

Note 2: State and Federal law in this area is evolving and may change during the course of this Agreement. Currently, under Michigan law Specimens are considered to be personal property. Regardless of your marital status, the Hospital will consider the individual signing this Agreement to be the sole owner of the Specimen. It is very important that any post-humous dispositional choices you make in this Agreement are supported by your last will and testament and other estate planning documents. Lack of formal legal documentation that can be provided to the Clinic after your death may result in an inability of the Clinic to fulfill your dispositional choice in which event the Clinic shall dispose of the applicable Specimen.

Note 3: The Hospital is not in the business of cryopreservation and only stores Specimens on site for limited periods of time for clinical care reasons. As further outlined in this Agreement, executing this Agreement commits you to transferring or disposing of your Specimens once the conditions which merit storage by the Hospital no longer apply.

This Agreement is between:

- (a) the patient listed on Exhibit A hereto ("Patient"); and
- (b) the Clinic, as such term is defined on Exhibit A.

This Agreement pertains to Specimens from this day forward and nulls all prior contracts. Any updated Agreement will cover all specimen stored at the Center for Reproductive Medicine.

I. Storage Fees & Conditions of Storage.

- A. As noted above in *Note 3*, the Clinic temporarily stores Specimens for purposes of efficient clinical care to Clinic patients. The Clinic agrees to provide storage so long as the Patient:
- a. pays the Storage Fees indicated on <u>Exhibit C</u> in accordance with payment terms and protocols provided therein.

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- b. no less than one (1) time per year, provides Clinic with up-to-date contact information.
- c. affirmatively communicates to Clinic any changes to disposition instructions by executing a new copy of this Agreement which will replace the existing Agreement in its entirety; and
- d. agrees to and executes any required forms and contracts, and pays any required fees, in connection with the Clinic's transfer of the Specimens to a third-party storage vendor.
- B. Patient expressly understands, agrees, and authorizes the Clinic to discard the Specimens according to its normal laboratory procedures and applicable law without further notice to, or consent required by Patient fails to fulfill the requirements of Section 1(a), (b), (c) or (d).
- C. Clinic may, but is not required to, attempt to contact Patient periodically using reasonable efforts in accordance with Clinic's established policies and protocols to request that Patient cure a default under Section 1.
- D. In the event of a Patient defaults under this Section 1, Patient acknowledges and knowingly and completely releases any and all claims to the Specimens or to any additional notice from the Clinic as to the final disposition of the Specimens.
- E. Patient acknowledges that the Clinic provides only temporary storage and agrees to either (a) consent to a transfer to Clinic's third-party storage partner, including executing all forms and contract and paying any and all fees in connection therewith, or (b) in a timely manner, and at Patient's own cost and risk, arranging for a transfer of the Specimens to a storage facility of Patient's choice.
- Patient acknowledges that they have been fully advised concerning the state of the art of cryopreservation of specimens and understand that there can be no assurance or guarantee of any portion of the cryopreservation or thawing process, including ability to safely thaw the Specimen, normal embryonic development, etc., which risks are in addition to those outlined in applicable informed consent forms that relate to the medical procedures associated with any extraction, cryopreservation and/or implantation of Specimens and/or embryos. Patient understands and agrees that the Clinic's responsibilities shall be limited hereunder solely to the adequate cryostorage of said Specimens consistent with the state of the art at the date of entering into this Agreement. In any event, the total liability of the Clinic for failure to meet any of its responsibilities to the Patient (including, for example, for events outside of Clinic's control such as loss of Specimens due to power failure, etc.) shall be limited to a prorated cost of the procedure that created the Specimens. For example, the Clinic liability would be limited to 40% of the cost of the procedure that created the Specimens if 10 viable Specimens were created, 6 were used, and 4 were compromised due to the fault of Clinic. The parties agree that any claims relating to or arising out of the subject of this Agreement will be brought in the state courts of Michigan. In the event the Clinic terminates the operation of its storage facility, it may, upon 30 days written notice to Patient at their last known address, assign and transfer its obligations hereunder and the Specimens held on behalf of Patient to a storage facility.

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II. General Terms Applicable to Disposition Choices

- A. Patient reserves the right, at any time subject to payment of all fees and penalties due pursuant to Section 1 and any fees or costs associated with such transfer, to personally arrange for the transfer of the Specimens to another storage facility. Patients shall execute any needed documentation in connection therewith and shall hold Clinic harmless with regard to any risks or damages related to such transfer.
- B. With regard to all the dispositional choices outlined in the below sections, Patient agrees and acknowledges that (a) if the selected disposition choice is not available or, in the Clinic's sole discretion, is not practical to implement; (b) if Patient defaults under Section 1 hereof; or (c) if Patient fails to preserve any choice made here as required by this Agreement or the Clinic, then Patient authorizes the Clinic to discard the Specimens.
- C. If Patient selects the option below indicating willingness to be contacted about potential opportunities to donate the Specimens for medical research, such research may include embryonic stem cell research, and any such research may result in the destruction of the frozen Specimens. Details of any particular research opportunity will depend on the specific research study. There may not be any research opportunities available. The Clinic is not aware of every research opportunity, and there may be opportunities that the Clinic does not contact Patient about. If the Clinic is aware of a research donation opportunity at the time of disposition and Patient have indicated willingness to be contacted, the Clinic will make reasonable efforts to contact Patient and refer Patient to the research study team for additional information about the research opportunity. If Patient is contacted about a potential research opportunity and referred to the research study team for more information, the research study team may still determine that the Specimens are not eligible to donate to the research study or Patient may choose to decline. By indicating willingness to be contacted, it is not a guarantee that Patient will be contacted or that there will be any research donation opportunities available to Patient. If the Patient has indicated a willingness to be contacted and the Specimen is not transferred to another storage facility within a reasonable amount of time after the time of disposition for any or no reason, because there are no research opportunities available or the Clinic is unable to contact Patient or any other reason, the Clinic will dispose of the Specimens without further notice to Patient. If you choose to be contacted regarding donation of the Specimens for clinical training, Patient acknowledges that such training may result in the destruction of the frozen Specimens and accepts that this choice will not result in the birth of a child. Similarly, if at the end of the storage period Specimens are not needed for clinical training purposes by the Hospital, Clinic may discard the Specimens without further notice to Patient. Please see further information on Exhibit B – Donation Information.
- D. If your Specimens are gametes (eggs and/or sperm) from a third-party donor, you cannot choose to donate Specimens 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 Specimens 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 applicable Specimens will be discarded.
- E. If patient wishes to make or change any disposition choice in the future, Patient acknowledges that they must complete and sign a new agreement and pay all storage and related fees to the Clinic.

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III. <u>Dispositional Choices</u>

A. Time-Limited Storage of Specimens. Absent extenuating circumstances, the Clinic will only store cryopreserved Specimens for a period of up to eighteen (18) months. Clinic has the sole discretion to determine shorter storage periods. After that time, Patient chooses to do the following with the Specimens (check one box only):
☐ Be contacted regarding donating the Specimens for medical research;
☐ Be contacted regarding donating the Specimens for clinical training purposes;
☐ Donate the Specimens for any other purpose, which shall require transfer to a storage facility that
Patient has identified and contracts with separately for donation purposes;
☐ Dispose of the Specimens; or
☐ Transfer the Specimens to a storage facility at Patient's expense and risk.
B. Death of Patient. If the Patient listed on <u>Exhibit A</u> dies before using all of the Specimens, Patient agrees that the Specimens should be disposed of as checked below (check only one box):
☐ Complete control to be given to the individual listed as Beneficiary on Exhibit A. Beneficiary will be required to execute a new agreement with only Beneficiary listed as a signatory thereto indicating dispositional choices. The Clinic may require Patient's final will to specifically indicate this dispositional choice and to indicate Patient's understanding that the Specimen may result in the post-humous birth of a child.
□ Donate the Specimens outside of the Clinic, which shall require transfer to a storage facility that Patient has identified and contracts with separately for donation purposes, all of which must be arranged for in advance of Patient's death with copies of all required documents provided to Clinic in advance;
☐ Dispose of the Specimens; or
☐ Transfer the Specimens to a storage facility at Patient's expense and risk, all of which must be arranged for in advance of Patient's death with copies of all required documents provided to Clinic in advance.
As stated above, if a disposition instruction requires steps to be taken in advance of the Patient's death and such steps are not taken (i.e., contracts not signed, invoices not paid, etc.), then the Clinic shall dispose

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of the Specimens.

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IV. Additional Provisions

- A. Patient acknowledges they are making the choices noted above on this form and that they may change their choice(s) at any time by executing a new version of this Agreement. Patient also acknowledges they may need to sign a different consent if/when they wish to thaw the Specimens for use;
- B. Patient acknowledges that its marital status—now and later—can affect the future use of these Specimens. Patient acknowledges that each clinic and each state has its own policies, which may affect their or, if applicable, their spouse or partner's, ability to use these Specimens to try to have a child in the future.
- C. If there is any future question about disposing of the Specimens in the case of a divorce or dissolution of relationship, the Clinic may require a valid, final, non-appealable court decree by a court of competent jurisdiction and/or settlement agreement (as determined in the Clinic's sole discretion), which specifically tells the Clinic how to make a final disposition of the Specimens.
- D. Patient acknowledges that the laws on Specimen cryopreservation, thawing, and use may be unclear where they live and where the Clinic is located. They may also be unclear on the parent-child status of any resulting child. This Clinic has not given me any legal advice, and Patient acknowledges they are not relying on them to do so. Patient acknowledges they may need to speak to a lawyer who is an expert in this area to understand their legal rights and obligations.
- E. In the event any federal, state or local legislative, regulatory or judicial action or determination or an actual or threatened decision, finding or action by any governmental or private agency or third party, limits the ability of either party to take a required action under this Agreement, the parties agree to negotiate in good faith to amend this Agreement to comply with such law or other change.

35-10287

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The parties hereby enter into this Agreement as of the Effective Date.

	Date:
Signature of Patient or Legally Authorized Representative (if patient is unable to sign)	
Printed Name of Legally Authorized Representative (if patient is unable to sign) Relationship: Spouse Parent Next-of-Kin Legal Guardian DPOA for Healthcare	

The Regents of the University of Michigan

Printed Name: David Miller, M.D., MPH

Title: President, University of Michigan Health, Executive Vice Dean of Clinical Affairs

Date: August 3, 2022

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Exhibit A

Defined Term	Term
Patient	
Beneficiary	
Clinic	The Regents of the University of Michigan, a Michigan constitutional corporation, Ann Arbor, Michigan, doing business as the Center for Reproductive Medicine
Effective Date	Date of last signature hereto

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Exhibit B

Additional Information Regarding Donation of Frozen Specimens for Research Purposes

If you selected the option "[d]onate for . . . medical research" or "[d]onate for clinical training purposes" under any of the preceding circumstances, as a donor of human Specimens to research, including but not limited to stem cell research, you should be aware of the following:

- Donating Specimens 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 Specimens will be used for research. In these instances, if no recipient or research project can be found, or your Specimens are not eligible, your Specimens will be destroyed and discarded by the lab in accordance with laboratory procedures and applicable laws.
- The Specimens 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 Specimens 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 Specimen 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 Specimen donor.
- Donated Specimens will not be transferred to a woman's uterus, nor will the Specimens survive the human pluripotent stem cell derivation process. Specimens will be handled respectfully, as is appropriate for all human tissue used in research.
- If the donated Specimens were formed with gametes (Specimens) 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 Specimens for research purposes.

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Exhibit C

Storage Fees and Payment Terms

See attached.