

Female Patient Name: _____ Social Security # _____

Male Patient Name: _____ Social Security # _____



**THE CENTER FOR HUMAN REPRODUCTION (CHR)—ILLINOIS/NEW YORK CITY*
ASSISTED REPRODUCTIVE TECHNOLOGIES PROGRAM (A.R.T.)
CRYOPRESERVATION OF HUMAN EMBRYOS
Description, Explanation and Informed Consent**

We, _____ understand that cryopreservation (freezing) of human embryos is a procedure that can be utilized to preserve embryos so that they may be transferred at a later date. Cryopreservation may be employed in the event that assisted reproductive technology procedures produce more embryos than may be used in a treatment cycle. It can also be employed to preserve embryos for later use if it is determined that, because of unexpected complications, it is not medically advisable to perform an embryo transfer during the same treatment cycle as the egg retrieval that provided eggs for these procedures. We understand that executing this consent does not guarantee that embryo freezing will be performed unless the special circumstances listed above are met. It is our understanding that cryopreservation, if employed, will be performed by the embryologists at The Center for Human Reproduction.

DESCRIPTION AND EXPLANATION OF THE PROGRAM

We have been informed that to prepare embryos for cryopreservation, embryos must be treated with chemicals known as cryoprotectants. These chemicals include propylene glycol (1,2-propanediol) and glycerol. The type of cryoprotectant used depends upon the developmental stage at which the embryos are cryopreserved.

We have also been informed that embryos can be frozen at various stages of development and that embryos are routinely frozen as zygotes (a single cell with two pronuclei), early cleavage stage embryos (2 to 8 cell embryos) and blastocysts (32-64 cells).

We have been informed that all cryopreserved embryos will be stored in liquid nitrogen (-196 degrees C) in the laboratories of the Center for Human Reproduction (CHR) until physicians at CHR determine that conditions are appropriate for transfer of the embryos to the woman's uterus. At that time, one or more of the embryos will be thawed and examined to determine if the embryo(s) have survived (defined as at least 50% of the original embryonic cells remaining intact) the freezing and thawing process. When it is deemed medically appropriate, potentially viable embryos will be transferred to the woman's uterus by means of a plastic catheter (tube). In some situations, transfer of embryos to the uterus through the cervix may be impossible or it may be deemed by the physician that it is warranted to instead transfer the embryos after thaw into the fallopian tubes by means of laparoscopy.

We understand we must agree to one of the following options:

Choice A: We want to cryopreserve embryos.

We understand there will be a fee (\$754.00) due at the time of the in-vitro fertilization retrieval for initial freezing and 3 months of storage. Thereafter, storage fees will be billed quarterly.

** Your cryopreserved (frozen) embryos can at any time be transferred to another IVF program. Should you instruct us to prepare them for such a transfer, a transfer fee will be accessed which will be due upon pick up of the embryos for transfer.*

Choice B: We do not want to cryopreserve embryos for our own use but would like embryos generated and frozen for anonymous donation to another couple.

There will be no storage or freezing fees due if this option is chosen. It will, however, be necessary that you and your partner have a blood test drawn in 6 months and complete a history/profile form in a timely fashion.

Choice C: We do not want to cryopreserve embryos.

* Per NY State Law doing business as the Medical Offices for Human Reproduction (MOHR)

RISKS/REASONS FOR ADVERSE RESULTS

We have been advised that cryopreservation of embryos has been utilized in hundreds of centers in the world where specialized equipment and expertise are available, and that thousands of pregnancies and live births of normal infants have resulted. The potential benefits from this procedure may be an increased chance of pregnancy without the necessity of multiple surgical interventions for oocyte recovery.

We understand that, if we do not consent to cryopreservation and allowing the embryology staff of the Center for Human Reproduction to attempt to fertilize all oocytes, we may be limiting our chances to achieve pregnancy. In allowing for cryopreservation of excess embryos, we may have the opportunity of additional embryo transfers at a later date, if we so choose to proceed with a frozen embryo transfer cycle sometime in the future.

We understand that freezing and long-term storage may result in damage to the embryos including damage to embryonic genetic material, loss of some embryonic cells or loss of viability of the embryo as a whole. We understand that, although thousands of children have been born worldwide as a result of this technology, there may be some effects on the offspring, which, at this time cannot be determined, including risks of chromosomal abnormalities and congenital malformations. The primary concern with the use of cryopreservation is thought to be unspecified cryo-injury; however, according to published reports, cryo-injuries are only blamed for loss of viability during the thaw procedures. The long-term risks associated with human embryo cryopreservation are, however, still unknown at present.

We understand that, as with any technique that requires mechanical support systems, equipment failure can occur. We also note that, while backup freezer systems and/or liquid nitrogen holding facilities are used in an effort to diminish the potential damage, which may be caused by any malfunction, unforeseen situations may occur.

If, after thawing, an embryo does not grow, then that embryo will not be transferred back into the woman's uterine cavity and, instead, will be disposed of in an ethically-accepted manner according to the Center for Human Reproduction Guidelines and the American Society for Reproductive Medicine Ethical Standards.

We further understand that if any of the following situations occur, the embryos will be disposed of in an ethically-accepted manner according to the Center for Human Reproduction Guidelines and the American Society for Reproductive Medicine Ethical Standards:

1. In the exercise of reasonable medical judgment, the embryologists and physicians determine that sperm, oocytes or embryos (either fresh or frozen-thawed) are non-viable or otherwise not medically suitable for use or embryo transfer.
2. If one or more of the cryopreserved embryos remain in cryopreservation after expiration of the three-year period, during which we must direct the use or disposition of cryopreserved embryos (see below for further explanation).

In addition, we agree that the staff of the Center for Human Reproduction is not obligated to transfer these embryos at any point in the future if medical evidence and/or experience indicate that the risk of transfer of frozen embryos outweighs the benefits.

USE OR DISPOSITION OF CRYOPRESERVED EMBRYOS:

We understand that the Center for Human Reproduction limits the term of storage of cryopreserved embryos to three (3) years. We understand that we must redirect the use or disposition of cryopreserved embryos no later than three (3) years after cryopreservation. **We understand that we do not need to make a selection at this time regarding the use or disposition of cryopreserved embryos and that this may be decided upon at a later date.** During this 3-year period, we have the following options with respect to each cryopreserved embryo:

- The thaw and, under medically appropriate circumstances, the **transfer** of these embryos to the uterus of the woman, unless we designate in writing that we wish to continue maintaining these cryopreserved embryos in storage. If we elect to maintain these embryos in storage after the initial three- (3) year period, we must state so in writing and continue to pay for storage fees.
- The use of all existing embryos for Institutional Review Board-approved medical **research** according to the Center for Human Reproduction Guidelines and the American Society for Reproductive Medicine Ethical Standards. We understand that, if this is our choice, we must so designate, in writing, accompanied by a notarized witness signature to both (if applicable) of our signatures.
- The **disposal** of all existing embryos in an ethically-accepted manner according to the Center for Human Reproduction Guidelines and the American Society for Reproductive Medicine Ethical Standards. We understand that, should we choose this option, we must accompany this written request with a notarized witness signature affixed to both, if applicable of signatures.
- The **donation** of any/all existing embryos for use by an anonymous or designated recipient in accordance with the regulations and policies in force at the Center for Human Reproduction at the time of donation. This option is called the **Embryo Adoption** option.

In the event that prior to the expiration of the three-year period, we are no longer participating in the Center for Human Reproduction Program as a couple and the program has in its possession embryos created by reason of our participation in the program, we hereby agree that the program's disposition of such embryos shall be determined only by applicable terms of any legally binding written agreement between us, signed by each of us or on our behalf and delivered to the program.

In the event of divorce, and if embryos are remaining in storage, we acknowledge that by signing this consent, we cannot expect disposition of the embryo custody to be the responsibility of the Center for Human Reproduction. We fully understand that we retain custody of any existing cryopreserved embryos, and should we pursue dissolution of our marriage, the custody of the embryos shall be decided in a court of law. The Center for Human Reproduction shall abide by the court's ruling.

In the event that one of us dies while the program has in its possession such embryos, the survivor shall have the right to determine use of disposition of such embryos, unless stated otherwise in this consent form.

In the event that both of us die while the program has in its possession such embryos, we hereby designate our wishes by initialing the one option we choose:

- | | | |
|-----------------|------------------|--|
| _____
Female | _____
Partner | Option #1: We wish to donate the embryos to the Center for Human Reproduction for disposal according to the Center guidelines. |
| _____
Female | _____
Partner | Option #2: We wish to donate the embryos to The Center for Human Reproduction for research per the Center guidelines. |

CHOICE A: We do agree and consent to cryopreservation and, therefore, we have to choose one of the options as stated below:

AGREEMENT AND CONSENT:

- We hereby give consent for cryopreservation of extra embryos resulting from assisted reproductive technology procedures.
- We request that these embryos be stored for subsequent transfer to the female partner's uterus or other such use as is permitted by this consent.
- We understand that embryos not claimed by us within three (3) years after the date of cryopreservation may be disposed of in an ethically acceptable manner.
- We acknowledge that we are financially responsible for the freezing and storage of these embryos and, should we fail to keep this financial account current (within 90 days), the embryos will be disposed of in an ethically acceptable manner with prior written notice to us. We agree to disclose such information as is required to determine our financial status and ability to pay for cryopreservation.
- We understand that the fees associated for the cryopreservation of embryos and the storage of these embryos are usually not a covered benefit by an insurance company and will therefore be our responsibility.
- We understand that delinquent accounts may be turned over to any attorney or collection agency for collection of delinquent amounts.
- We acknowledge it is our responsibility to notify the Center for Human Reproduction of any change of address.

We do agree and consent to cryopreservation and, therefore, we have to choose one of the options as stated below:

I understand that if this is my choice and I have resulting embryos in excess of the number that is designated to be returned to the female patient's uterus these embryos will be cryopreserved for our future use. I acknowledge that I have received information regarding the approximate cost of such cryopreservation and I am aware that such costs are estimates and may increase at any time. I accept and acknowledge financial responsibility for the freezing and the storage fees of any/all excess embryos.

Option # 1: Have sperm added to ALL retrieved oocytes in an attempt to create fertilization. We agree to cryopreserving any excess embryos.

Option # 2: Have sperm only added to 12 oocytes maximum in an attempt to try and avoid creating excess embryos after an embryo transfer. We agree to cryopreserving any excess embryos.

We have chosen to cryopreserve—(initial the option you both agree to):

		Option #1. Attempt to fertilize ALL retrieved oocytes.
Female	Partner	

		Option #2. Attempt to fertilize up to 12 oocytes.
Female	Partner	

CHOICE B: We have chosen to allow for cryopreservation of excess embryos NOT for our own use but for the use in CHR’s Donor Embryo Program for anonymous donation to another couple. Please initial below.

AGREEMENT AND CONSENT:

- We hereby give consent for the cryopreservation of extra embryos resulting from assisted reproductive technology procedures.
- We request that these embryos be donated to CHR’s **Embryo Adoption Program** for use by an anonymous couple.
- We understand that we are consenting to relinquish all parental rights to these excess embryos.
- We understand that both partners will need to complete a donor profile that discloses family/medical history in accordance with the regulations and policies in force at the Center for Human Reproduction at the time of donation.
- We understand that both partners will need to have blood tests 6 months after the embryos are cryopreserved in order to complete the donation of the embryos to the **Embryo Adoption Program**. (CHR will pay for the cost of the laboratory tests.)
- We understand there will be no storage or freezing fees due if this option is chosen and we complete our above stated obligations.

We understand that CHR has the option to dispose of all embryos according to The Center for Human Reproduction Guidelines and The American Society of Reproductive Medicine Ethical Standards if the embryos are determined not to be acceptable for cryopreservation and/or for the **Embryo Adoption Program**.

I understand that, if this is my choice, and I have embryos in excess of the number that is designated to be returned to my uterus on the day of embryo transfer, these excess embryos will be cryopreserved. The cryopreserved embryos will be used in accordance to the guidelines of CHR’s **Embryo Adoption Program** for anonymous adoption by fertility patients in the program.

We have chosen to allow cryopreservation of excess embryos for CHR’s Embryo Adoption Program. Partners must initial to acknowledge you both agree.

Female Partner

CHOICE C: We do NOT agree or consent to cryopreservation and therefore we have to choose one of the options as stated below. Please initial the option you have chosen.

Female Partner **Option #1: Have sperm added to only 12 oocytes in an attempt to create fertilization.** If there are any excess embryos after my embryo transfer I agree to allow the Center for Human Reproduction to discard these excess embryos according to Center guidelines in an ethical manner.

Female Partner **Option #2: Have sperm added to _____ oocytes (MAXIMUM 6) and then transfer all viable embryos to the woman’s uterus per the Center for Human Reproduction guidelines.**

All of our questions regarding the Center for Human Reproduction consent on Assisted Reproductive Technologies Program (A.R.T.) Cryopreservation of Human Embryos have been answered. Each of us has read the consent and acknowledges receipt of a copy of this consent.

Date Signature of Female Patient Female Name – Print

Date Signature of Partner Partner Name – Print

As one of the members of The Center for Human Reproduction, by my signature indicate that the foregoing consent was read, discussed and signed in my presence.

Date Signature of Witness (Female Patient) Witness Name – Print

Date Signature of Witness (Partner) Witness Name – Print

NOTE: If you or your partner are unable to have this consent witnessed by a staff member at CHR or FULLY UNDERSTAND THE CONSENT, please notify the CHR medical staff. We will provide you with further information and a witness. If you wish to sign the consent outside of CHR, please have the consent notarized.

State of _____, County of _____ ss., I, the undersigned, a Notary Public in and for the said County in the

State aforesaid; DO HEREBY CERTIFY that _____
(Female Patient / Partner)

personally known to me as the same persons whose names are subscribed to the foregoing document appeared before me this day in persons, and acknowledged that he and she signed, sealed and delivered the said document as his and her free and voluntary act, for the use and purposes therein set forth.

Given under my hand and official seal this _____ day of _____, 20 _____,

Commission expires on: _____, 20_____.

(Notary Public)

(Notary Seal)