CONSENT FOR THE CRYOPRESERVATION (FREEZING) OF HUMAN EMBRYOS

Cryopreservation (freezing) of human embryos has one principal purpose: the preservation of embryos for later use. Usually only freshly produced embryos become available for cryopreservation, though on rare occasions embryos may be re-frozen after they had been thawed out and allowed to grow in the laboratory for a few days. Fresh embryos are frozen under only two circumstances: The most frequent situation is the production of more embryos during an in vitro fertilization (IVF) cycle than can, during that same cycle, safely be transferred into the female's uterus. Extra embryos are then frozen. A second possibility is the patient, whose ovaries are overstimulated during an IVF cycle, since embryo transfer in such circumstances may not be safe, all embryos may be frozen for transfer in a future month.

Responsible IVF programs cryopreserve only good quality embryos, which have a good chance to survive freezing and thawing intact. Many IVF cycles will, therefore, result in no cryopreservation. This consent is, therefore, presented for signature under the assumption that embryos will be available for cryopreservation, though nobody at CHR has made (or can make) representation that embryos will, indeed, be available for cryopreservation.

DESCRIPTION

The process of embryo freezing involves the use of chemicals, called cryoprotectants. Which cryoprotectants are used, depends on the freezing techniques utilized, and the developmental stage of the embryos [i.e., zygote (1-cell); early cleavage (2-8 cells) or blastocyst stage (32-64 cells)]. Once frozen, embryos are stored in liquid nitrogen tanks (-196 degrees C) in the laboratory of CHR and may remain there indefinite, as long as the tanks are properly maintained.

Once patient and physician decide on the potential use of frozen embryos, one or more embryos are thawed. Embryos are considered to have survived freezing and thawing if at least 50% of the original cells of an embryo have remained intact and/or the embryo continues normal division after thawing. Embryos, judged to have survived, are then transferred to the woman's uterus in an identical embryo transfer procedure as is utilized for freshly created embryos. While the percentage of surviving embryos can greatly vary, on the average approximately 60% of cryopreserved embryos are expected to survive thawing and becoming eligible for transfer into the uterus. Embryo survival is, at least in part, a reflection of embryo quality. Just like embryo quality cannot always be reliably assessed, embryo survival after freezing and thawing is also often unpredictable. In some instances NO embryos will survive. In others, ALL will.

The freezing of embryos is NOT part of a routine, fresh IVF cycle. Embryo cryopreservation, therefore, results in additional costs, but also offers additional pregnancy chances. CHR will freeze embryos only if so specifically instructed by patients. Patients signing this consent form, therefore, have to instruct CHR to follow one of the following options:
OPTIONS REGARDING THE CRYOPRESERVATION OF EMBRYOS: (Please indicate your choice by crossing the appropriate box and initialing your choice in the right margin. In case the embryos are the property of a couple, both partners have to initial the choice.) This choice should not be made until the whole consent form is read and all questions in regards to this choice were answered by CHR staff to your fullest satisfaction.

☐ CHOICE A: I/We want to cryopreserve our extra embryos, knowing that I/we will be charged a cryopreservation and 3-months initial storage fee, after which time we will be billed quarterly for storage fees, until CHR receives appropriate written instructions to remove these embryos from cryopreservation at CHR. If embryos are transferred to another IVF center, a transfer fee will become due prior to pick up of the embryos.

☐ CHOICE B: I/We do NOT want to cryopreserve embryos for our own use, but I/we want our extra embryos to be frozen, with the purpose of us donating these embryos anonymously to another infertile couple. With this choice, there will be no costs but I/we have to complete a history/profile form and have a few blood tests drawn approximately six months after embryo freezing.

☐ CHOICE C: I/We do NOT want to freeze any embryos under any circumstances, fully recognizing that this choice most likely will reduce our cumulative pregnancy chance from this IVF cycle.

O I/We still want all eggs fertilized, recognizing that this, most likely will result in excessive embryo numbers, requiring the ethical disposal of extra embryos.

O I/We want maximally 12 oocytes fertilized, attempting to avoid the creation of excessive embryos. I/We fully recognize that excessive embryos may still be created and that I/We will then have to face the question, whether to discard those ethically, or, after all, to decide to cryopreserve them.

O I/We want maximally ____________ oocytes fertilized, fully recognizing that this may result in an inadequately low number of embryos, reducing my/our pregnancy chance.
RISKS:
Embryo freezing and storage processes may result in damages to the embryos, which may not be immediately recognized and/or recognizable. Amongst potential damages to embryos from cryopreservation are the following:

• Damages to genetic material;
• Loss of some embryonic cells, which has been associated with decreased implantation and pregnancy potential after transfer into the uterus;
• Loss of complete embryo viability;
• Chromosomal abnormalities;
• Birth defects;
• Cryo-Injury;

Unspecified cryo-injuries have been a primary concern. The literature suggests, however, that these are only blamed for loss of viability during thawing. Available literature on children born from cryopreserved embryos does not suggest an increase in birth defects or chromosomal abnormalities over fresh IVF cycles. Long-term risks from human cryopreservation are, however, still unknown. Risk can also be technical in nature. For example:

• Mechanical support systems can fail;
• Equipment can fail;
• Human errors may occur;

Such technical risk can lead to embryo damage or complete embryo loss. Moreover, while eRR employs multiple back up security systems, such as a back up freezer system and/or liquid nitrogen holding facility, and a back up generator in order to minimize potential technical risks, unforeseen situations may occur.

By signing this consent form I/we acknowledge that I/we were informed of all potential risks associated with embryo cryopreservation and that all of my/our questions on this subject were answered to my/our fullest satisfaction. I/We have made above, on this page, noted decision about cryopreservation in full understanding of these risks.

TIME LIMITATIONS
I/We were advised, and fully understand, that, in case we instruct CHR via this consent form, to cryopreserve embryos, the validity of this instruction is limited to a time period of three (3) years from the date of this consent. This means that I/we must reissue new directions to CHR, as to what my/our wishes are in regards to my/our embryos, within this three (3) - year period. In other words, THIS CONSENT’S INSTRUCTION TO FREEZE EMBRYOS, AND MAINTAIN THEM IN CRYOPRESERVED STATUS AT CHR LABORATORIES, IS VALID FOR ONLY MAXIMALLY THREE YEARS. IF CHR HAS NOT RECEIVED APPROPRIATE WRITTEN INSTRUCTIONS (via one of CHR's correctly executed Cryopreserved Embryo Disposition Consent forms), MY/OUR EMBRYOS WILL BE CONSIDERED AS "ABANDONED", GIVING CHR THE LEGAL RIGHT TO DISPOSE OF THEM.

If CHR has not received appropriate new written instructions about the disposition of cryopreserved embryos within three (3) years from the execution of this consent form, CHR will make reasonable efforts to contact me/us. If such reasonable efforts are unsuccessful, CHR will have the legal right to ethically discard my/our embryos. I/We recognize that CHR can contact us only if I/we inform CHR in timely fashion of any changes in my/our addresses and/or telephone numbers. I/We herby commit to doing so.

DISPOSITIONs FOR EMBRYOS NOT IMMEDIATELY TRANSFERRED

Dispositions for extra fresh embryos:
Embryos from patients, who have chosen to cryopreserve their extra embryos, will be frozen, depending on clinical circumstances, either on days 1,3 or 5/6 after fertilization.

Extra embryos from patients, who choose, not to cryopreserve, will immediately after embryo transfer has taken place, be ethically destroyed. Patients who are uncomfortable with the ethical
destruction of human embryos, have three options, which should be carefully considered ahead of time: A first option would restrict the number of eggs for fertilization, thus minimizing the number of potential embryos, available for transfer. This option reduces the risk for extra embryos, and therefore, the potential need to discard embryos; but it also raises the risk of ending up with too few embryos for transfer, because fertilization rate and embryo development can never be predicted with great accuracy.

A second option would be the transfer of a larger embryo number into the uterus, than originally planned. This option would greatly increase the risk of multiple, or even high order multiple births, and, because of the associated risks to offspring, should NOT be considered.

A third, option would be a reconsideration of the decision not to freeze embryos.

Patients who for ethical, or religious, reasons are uncomfortable with the ethical disposal of embryos, should neither enter an IVF cycle, nor sign this, or any other related consent forms, until this issue is fully discussed with CHR staff, and resolved to the patient's fullest satisfaction.

Dispositions for cryopreserved embryos:

I/We are free to change my/our mind(s) about the status of my/our cryopreserved embryos at any time. However, even if I/we do not change my/our mind, and wish to maintain my/our embryos cryopreserved, I/we have to give CHR new instructions within three (3) years from the signing of this consent.

All instructions, regarding the disposition of cryopreserved embryos, have to be given to CHR in writing, using the Cryopreserved Embryo Disposition Consent. The options are as follows:

- Thaw out a specific number of cryopreserved embryos for the purpose of transferring them into the female's uterus, leaving (if there are any) remaining embryos frozen;
- Transfer embryos from CHR's cryopreservation elsewhere;
- Donate frozen embryos to CHR, for the exclusive use of anonymous donation to another infertile couple;
- Donate embryos "openly", in non-anonymous fashion, to a third party;
- Donate frozen embryo to CHR, for the exclusive use in medical research;
- Rave embryos in an ethical way discarded;

IN CASE OF DIVORCE/SEPARATION

Cryopreserved embryo unfortunately have become subject to litigation in cases of divorce and/or separation of alternative life style couples. In such cases, CHR will continue to honor this consent. If this consent indicates that two partners are "owners" of the embryos, only the signature of both partners, in regards to disposition orders for cryopreserved embryos will be honored. Where the custody of cryopreserved embryos is under dispute, CHR shall only abide by court rulings.

IN CASE OF DEATH

In case of death of an "owner" of cryopreserved embryos, CHR will be bound by a formal will, specifically addressing the desired fate of cryopreserved embryos, 'if such will is legally certified. In the absence of a last will, CHR will require a formal court ruling for instructions, as to the disposition of the embryos.

(Signatures on the next page of this consent)
I/We have read this consent and understand all the issues addressed in this document. All of my/our questions have been answered to my/our full satisfaction. I/We are also fully aware of all sperm storage fees charges by CHR and commit to timely payments. I/We have read this consent and acknowledge receipt of a copy.

______________________________________________________________________________________
Female Name     Female Signature    Date

______________________________________________________________________________________
Partner Name (where applicable)   Partner Signature    Date

WITNESSED BY:

______________________________________________________________________________________
Name       Signature      Date

If this consent is not witnessed within the offices of CHR, all signatures have to be notarized in the space below.

(Notary Seal)                                                                                      
Notary Public