

CONSENT FOR CRYOPRESERVATION OF EMBRYOS

We, _____ (Female Partner) and _____ (Partner, Spouse), as participants in the in vitro fertilization (IVF) program at the California Center for Reproductive Health (CCRH), understand that as a result of our participation in the IVF Program, more embryos may form than our physician recommend be transferred into the uterus in a single IVF cycle. Furthermore, we understand that certain clinical situations may arise with IVF that may necessitate the freezing of any resulting embryos. We understand that the purpose of cryopreservation (freezing) of embryos is to increase the possibility of achieving pregnancy at a future time. The purpose of this Consent and Agreement is 1) to give our permission to cryopreserve embryos, 2) to state our jointly agreed upon choices as to future disposition of these embryos, and 3) to outline our understanding of, and agreement as to, the terms under which our cryopreserved embryos will be maintained by CCRH or its affiliate laboratory. We understand that the embryos are subject to our joint disposition and therefore, all and any decisions about their disposal may be affected by applicable laws in the future or by any court having jurisdiction over these embryos. We understand we can jointly change any of the choices made herein by contacting the Medical Director at CCRH or its affiliate laboratory, and signing a new agreement incorporating any new choices and decisions which are available to us and on which we both agree.

Assisted reproductive techniques (ART) and the IVF process have been explained to us in detail and we have signed a separate informed consent form for ART, and if applicable, any additional consent form(s) related to the use of donor eggs or donor sperm.

Procedural Overview

Embryo cryopreservation is the freezing of embryos. As the IVF process may result in a supernumerary number of embryos above the number recommended for embryo transfer, or as specific indications may exist to avoid embryo transfer following IVF, cryopreservation of embryos allows for embryo transfer at a future time. Embryo cryopreservation is accomplished by placing embryos in specialized holding straws and then into liquid nitrogen (dry ice) at -190°C . At a future date, previously cryopreserved embryos are thawed for transfer and implantation in the uterus. We understand that there is no guarantee that thawed embryos will survive the freezing and/or thawing process, or that, if transfer occurs, pregnancy will result.

Transfer of cryopreserved embryos involves the thawing of a certain number of embryos, as determined by our physician in consultation with us, with the anticipated transfer of embryos into the female partner's (or recipient's) uterus. We understand that only embryos considered to be potentially viable using reasonable medical judgment will be transferred. We also understand and acknowledge that our physician or his/her affiliates are not obligated to proceed with embryo transfer if, on the basis of any new scientific, medical, or psychosocial evidence, it is their professional opinion that the risks of embryo transfer outweigh the benefits or a transfer is inadvisable. The transfer procedure is outlined more fully in Consent for Embryo Transfer, which we have reviewed, had explained to us and will have executed prior to the creation of any embryos.

Benefits and Risks

The benefit of cryopreservation of embryos are 1) the preservation of embryos for use during a future ART cycle, thereby lowering the risks of multiple pregnancies by limiting the number of embryos transferred following an initial IVF cycle, and 2) the preservation of embryos for future use when embryo transfer following IVF is not advisable (concerns for ovarian hyperstimulation syndrome, abnormal hormone profile during follicular stimulation, non-receptive uterus during follicular stimulation...). We understand that completing this consent for cryopreservation does not guarantee that there will be any embryos available for cryopreservation.

The risks of embryo cryopreservation are that the frozen embryos may not survive the freezing or thawing process or that a pregnancy will not occur. We also acknowledge that the freezing of embryos requires the use of mechanical support systems and the involvement of human technicians. We recognize that the practice of medicine is not an exact science and understand that techniques for embryo cryopreservation and thawing are relatively new, and are not universally established. We acknowledge that human error, equipment failure or unknown factors (i.e. catastrophic events such as earthquakes or fires...) could negatively affect the viability of the embryos. We specifically acknowledge and agree that CCRH, its affiliate laboratory, or any of its employees will not be liable for any destruction, damage, or loss to our embryos as a result of freezing, maintenance, storage, removal from storage, thawing, and/or delivery of the frozen embryos, or related services. We also acknowledge that any non-viable embryos, as determined by the embryology laboratory, may be discarded.

There may be a risk of infants having developmental problems or congenital birth defect as a result of any ART treatment, including embryo cryopreservation and thawing; however, initial human experience and extensive experience in domestic animal species have not yet demonstrated an increase in developmental or congenital anomalies in offspring born following cryopreservation beyond that observed in other ART treatments (such as IVF and embryo transfer).

Media utilized for ART treatments such as IVF and associated procedures (Assisted Hatching, Intracytoplasmic Sperm Injection, Embryo Transfer, etc.) may contain commercially obtained serum or serum components. While every effort to screen these products for hazards (e.g. HIV, hepatitis, etc.) has been made, the potential for unforeseen hazards is present and hereby acknowledged.

Treatment Alternatives

We recognize that the alternatives to freezing our embryos are: 1) implanting all fertilized eggs (embryos) into the female partner’s (or recipient’s) uterus, subject to our physician’s medical opinion as to maximum number; or 2) discarding the excess embryos not transferred in the initial cycle. We recognize that the alternative to transferring all frozen-thawed embryos in a future frozen embryo transfer (FET) cycle is to refreeze frozen-thawed embryos for future use, or to discard unused frozen-thawed embryos.

Costs and Expenses

We understand that there are costs associated with cryopreservation, storage and thawing which are separate from those associated with our infertility and other ART treatments, and that insurance coverage may not be available to cover those costs. We understand that the freezing process is intricate and time-consuming, and we acknowledge that we are personally responsible for all related expenses. We also understand that storage of embryos for any length of time involves expenses, for which we are responsible. We further understand that there are costs associated with the preparation of the uterus for implantation prior to thawing of embryos and transfer in a future FET cycle, for which we are fully responsible. Our failure to pay for any expenses associated with freezing, storage, thawing, and future FET cycle, will result in the termination of this agreement.

Inter-Program Transfer Option

At our request and upon reasonable advance written notice, CCRH’s affiliate laboratory will remove our frozen embryos in order to transfer them to a different designated IVF center or cryobank. In the event that we elect this option, we agree to assume full responsibility for any expenses and all liability incurred by CCRH and its affiliate laboratory in transferring our embryos to another IVF center or cryobank. At our request, frozen embryos may be released to us so that we may transport them to a designated IVF center or cryobank of our choice. In the event that we elect this option, we agree to assume all responsibility for the care of our frozen embryos and we indemnify CCRH and its affiliate laboratory from any damage, loss, expenses and any and all liability which may arise from self-transport. We acknowledge that other IVF centers or cryobanks may have different transport, handling, storage and/or thawing protocols for cryopreserved embryos than those of CCRH’s affiliate laboratory and that there is a risk of damage or destruction associated with the transport or thawing of embryos, for which we agree to hold CCRH, its affiliate laboratory, and its physicians, staff or associates harmless. We understand and agree that before any transfer will be performed, we will be required to execute a Release and Acknowledgement provided to us by CCRH’s affiliate laboratory.

Discontinuation of Operations

In the unlikely event that CCRH or its affiliate laboratory discontinues its cryopreservation program, we understand and agree that our embryos may be removed from storage, upon reasonable advance written notice to us at our last known address. If we do not respond within a reasonable time (three months after mailing to our permanent address as set forth herein) with specific directions for the disposition of embryos, any remaining embryos may be discarded. If so requested in a timely fashion (within three months of receipt of notice), CCRH’s affiliate laboratory will arrange for transport of our embryos to an alternative IVF center or cryobank of our choosing. However, we agree that in the event that time and circumstances prevent CCRH or its affiliate laboratory from contacting us at least three months before discontinuation of its cryopreservation program, or if no response is received from us in a timely fashion (within three months of receipt of notice), CCRH and its affiliate laboratory reserve the right to transfer our embryos to another IVF center or entity of its choice for continued storage. We recognize that if cryopreserved embryos are transferred to another IVF center or cryobank, handling and storage fees will apply per that facility’s fee schedule. If, within three months following written notification from CCRH or its affiliate laboratory of transfer of embryos to another facility, no response is received from us, CCRH or its affiliate laboratory may instruct any program or entity in possession of our embryos to discard them in accordance with this Agreement. We specifically agree to hold harmless CCRH, its affiliate laboratory, its physicians, staff or associated individuals from any liability for discarding or instructing another entity to discard our embryos as stated herein.

Responsibility for Informing CCRH of our Address

We understand that it is our responsibility to inform CCRH or its affiliate laboratory *in writing* of any change of address.

Our permanent address and telephone number are:

_____	_____
_____	_____
_____	_____

Legal Considerations

We understand that the legal status of cryopreserved embryos, and related issues of use, ownership, custody, inheritance, child support, and rights upon death, divorce, abandonment, or other contingencies are uncertain and may change. We understand that the issues may become even more complex if we are unmarried and/or if donor gametes have been used to create our embryos and/or if we elect to donate our embryos to an anonymous infertile couple. We have made the choices indicated below in order to define and govern, to the extent possible, disposition of our unused cryopreserved embryos in case any of the stated contingencies or other unexpected events occur. We reserve the right to jointly alter our instructions if the stated conditions (for example, unavailability, death, divorce)

have not yet occurred by delivering another duly signed and executed Agreement to CCRH and its affiliate laboratory, with different allowable instructions indicated therein.

We acknowledge, however, that CCRH and its affiliate laboratory cannot guarantee that the choices we have made here will be followed in every instance, since changes in laws, ethical standards, technologies, our circumstances, or program operation could change or limit the choices available over time and affect CCRH or its affiliate laboratory's ability to follow our stated preferences.

We acknowledge and agree that CCRH and its affiliate laboratory shall use its professional judgment with respect to the disposition of any unused cryopreserved embryos in any circumstances in which the choices contained in this form cannot, or in their professional judgment, should not be followed exactly, and release CCRH and its affiliate laboratory from any liability for such decisions, on behalf of ourselves, our heirs and successors. We further understand and agree that in the event of any conflict over disposition of the embryos, CCRH and its affiliate laboratory have the right to refuse to execute the choices made in this consent pending a court order resolving such conflict and may follow such court order without incurring any liability as a result. We understand that we may wish to consult an attorney on our behalf concerning these matters before completing this form and acknowledge that CCRH or its affiliate laboratory have not provided us with legal advice regarding these matters.

Instructions as to Disposition of Unused Embryos

In the absence of contemporaneous instructions jointly provided by us in writing to, and acceptable to, CCRH and its affiliate laboratory, we have been asked to state our instructions for disposition of our unused embryos. We understand that any jointly agreed upon contemporaneous instructions, agreed to by CCRH and its affiliate laboratory, will override these instructions. We understand that, to the extent permissible by law, we have four options for disposition of unused cryopreserved embryos:

OPTION 1 "Discard Embryos": Discarding of our frozen embryos without further medical intervention.

OPTION 2 "Thaw for Observation and Discard": Thawing of our embryos with observation by the IVF laboratory staff of subsequent development up to a maximum of six days post-thaw, after which the embryos will become nonviable and be disposed of in accordance with CCRH and its affiliate laboratory's policy and procedure.

OPTION 3 "Transfer to Partner": Transfer to Female Partner or Male Partner as designated; or to new Female Partner, or to woman designated by Male Partner (if acceptable to CCRH and its affiliate laboratory), in the event of death of current Female Partner.

OPTION 4 "Donate Embryos": Donation to an anonymous infertile recipient(s) through CCRH and its affiliate laboratory to attempt to achieve a pregnancy. We understand that if we elect this option we will have no further right to information about the success of the donation or the identity of the recipient. We also understand we may be asked to provide non-identifying health and background information for the use of the recipient(s) and any child(ren) born as a result of our donation. In the event that after reasonable time and effort have been expended (not to exceed two years) and no recipient can be found, or if applicable future law or program policies prohibit donation, the embryos will be discarded per Option 1 ("Discard").



The following describes our current directives of what will be done with our unused cryopreserved embryos. Each selected directives must be initialed by BOTH partners.

DIRECTIVE 1. In the event of the DEATH of both of us, we wish to:

<input type="checkbox"/> Discard Embryos	<input type="checkbox"/> Thaw and Discard	<input type="checkbox"/> Donate Embryos
Female Partner Initials _____ Partner/Spouse Initials _____	Female Partner Initials _____ Male Partner/Partner Initials _____	Female Partner Initials _____ Male Partner/Partner Initial _____

DIRECTIVE 2. In the event of the DEATH of FEMALE PARTNER, we wish to:

<input type="checkbox"/> Discard Embryos	<input type="checkbox"/> Thaw and Discard	<input type="checkbox"/> Transfer to Partner**	<input type="checkbox"/> Donate Embryos
Female Partner Initials _____ Male Partner Initials _____			

**Transfer to Partner (Male Partner, New Female Partner if any and if so requested, or to a woman selected by Male Partner who agrees to carry a pregnancy on his behalf)

DIRECTIVE 3. In the event of the DEATH of the MALE PARTNER, we wish to:

<input type="checkbox"/> Discard Embryos	<input type="checkbox"/> Thaw and Discard	<input type="checkbox"/> Transfer to Partner	<input type="checkbox"/> Donate Embryos
Female Partner Initials _____ Male Partner Initials _____			

DIRECTIVE 4. In the event of DIVORCE, DISSOLUTION or LEGAL SEPARATION (as evidenced by a judicial order or decree), we wish to:

<input type="checkbox"/> Discard Embryos	<input type="checkbox"/> Thaw and Discard	<input type="checkbox"/> Transfer to Female Partner <input type="checkbox"/> Transfer to Male Partner	<input type="checkbox"/> Donate Embryos
Female Partner Initials _____ Male Partner Initials _____	Female Partner Initials _____ Male Partner Initials _____	Female Partner Initials _____ Male Partner Initials _____	Female Partner Initials _____ Male Partner Initials _____

We explicitly acknowledge that in the event of a judicial or other legal proceeding concerning the disposition of our frozen embryos, CCRH and its affiliate laboratory shall comply with that court order or decree and will not be liable to either of us in so doing. We further agree to hold harmless and indemnify CCRH and its affiliate laboratory for any action or inaction they undertake in compliance with such court order or decree, regardless of whether it was or was not a party to any court proceeding.

If CCRH terminates its gestational surrogacy program, we would cooperate with the transfer of embryos to another program that we jointly designate or the survivor of us designates for that purpose should we so request, under the same conditions as would apply to any inter-program transfer.

Initials

Certification of Informed Consent to Cryopreservation of Embryos

OUR SIGNATURES below evidence our agreement that: 1) we have read, understood, and agree to all terms of the agreement described above; 2) all such terms, medical procedures, risks, and benefits have been satisfactorily explained to us; and 3) that we have had sufficient time to seek additional information and make our decisions, and that we have all the information we desire. We hereby give our authorization and informed consent and agreement to cryopreservation of embryos according to the terms described above:

PATIENT NAME (print) PATIENT SIGNATURE DATE

PARTNER NAME (print) PARTNER SIGNATURE DATE

WITNESS (print) WITNESS SIGNATURE DATE