AGREEMENT AND INFORMED CONSENT TO CRYOPRESERVE AND STORE SPERM
(For use as Directed Donor)

PLEASE READ THE ENTIRE FORM CAREFULLY BEFORE SIGNING.

I authorize the SPERM/SEMEN CRYOPRESERVATION to be performed by a qualified lab staff member under the direction of Dr._____.

I am over eighteen (18) years of age. I am participating voluntarily in the Lucile Salter Packard Children's Hospital at Stanford ("LPCH") in vitro fertilization (IVF) or intrauterine insemination (IUI) program. LPCH is also signing this agreement and consent, under which it will cryopreserve (freeze) sperm collected from me.

I understand that the procedure may involve the use of a Food and Drug Administration (FDA) approved drug or device for a purpose not approved by the FDA. I understand that other medical care will not be withheld if I decide to withhold or withdraw my consent to this proposed treatment.

In addition to caring for patients, LPCH is affiliated with the Stanford University School of Medicine. As part of the medical education and training program, postgraduate fellows, residents, medical students, and approved health care practitioners may observe care, and if appropriately trained, participate in aspects of the procedure. These practitioners will be under the supervision of the attending doctor. The cryopreservation of sperm will be carried out by the practitioners identified on this form.

I understand that I have the right to be informed about my proposed care, treatment, services, medications, interventions, and its risks, benefits, side effects, potential problems related to recuperation, and the likelihood of achieving the care, treatment, and service goals.

I. Procedure and LPCH Responsibilities:

The LPCH cryopreservation program and procedures were explained to me by the physician named above. During this process, sperm are exposed to a cryoprotectant agent, which is a mixture of chemicals and proteins in solution that protects cells by modifying their response to freezing. The sperm are preserved in liquid nitrogen containers. The sperm considered suitable for clinical use can be used fo intrauterine insemination or IVF at LPCH.

The cryopreserved sperm will be stored at LPCH.

LPCH will use all reasonable efforts to protect patient privacy and confidentiality of patient records in accordance with the LPCH Notice of Privacy Practices and all applicable requirements. This includes the possibility that personal medical information will need to be disclosed to the Food and Drug Administration (FDA), state authorities that oversee tissue banks, clinics, and testing/screening practices, and/or other entities, as permitted or authorized by law.

II. Risks, Benefits and Alternatives:

Not all sperm will survive the freezing and/or thawing processes. The post thaw survival is largely dependent on the pre-freeze quality of the semen that is patient specific. For healthy sperm that survive there is not guarantee that a pregnancy or a live-birth will result since pregnancy and live-birth are based on many factors. Studies have not shown an increase in the rate of abnormalities in children born after cryopreservation and thawing of sperm; however, the possibility of presently unforeseen risks cannot be completely eliminated.

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II. Risks, Benefits and Alternatives:

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II. Risks, Benefits and Alternatives:

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Benefits of cryopreserving sperm/semen include: availability of sperm on the day of an Intrauterine insemination or oocyte retrieval for IVF due to travel, inability to produce and ejaculate on the day of the procedure, or absence of sperm in the ejaculate that you produce on the day of the procedure.

Alternatives to Sperm cryopreservation include cancellation of your treatment cycle, attempt at collection of a sample by masturbation or intercourse with a collection condom on the day of the procedure, testicular biopsy to obtain sperm (only applicable of undergoing In vitro Fertilization) or to freeze the eggs (only applicable if undergoing In vitro Fertilization).

As with any technique involving specialized equipment and procedures, technical problems or other failure may occur, including laboratory accidents, mechanical failure, improper freezing, maintenance, storage, withdrawal, thawing, and/or delivery, failure of utilities, fire, theft, earthquake, flooding, or other natural disaster.

III. Patient Responsibilities:

I understand that I am responsible for promptly notifying LPCH of any change in my address or telephone number. Any notice required by this agreement and informed consent form shall be hand delivered or sent by registered or certified mail, postage prepaid as follows:

To LPCH: Lucile Packard Children's Hospital
725 Welch Road
Palo Alto, CA 94304
Attn: REI/IVF Lab Staff

To Patient: _____

_____

Phone: _____

IV. Termination of Program

LPCH and its physicians reserve the right to terminate the sperm cryopreservation program at any time. In the event of termination of this program, LPCH will provide at least one month prior notice to permit me to locate another medical facility willing to accept the frozen sperm for storage. In the event that I do not make arrangements for transfer of the sperm to another facility during such notice period, LPCH will discard the sperm remaining in storage. In the absence of applicable instructions from me, any remaining sperm must be moved to another facility or it will discarded in accordance with LPCH policy.

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PATIENT/PROPERLY DESIGNATED REPRESENTATIVE:

By my signature below, I confirm that:

1. I have read and understand the information provided on this form, and the nature and purpose of the procedure have been explained to me. The risks and benefits of the procedure have been explained to me. In addition, the alternatives, the risks and benefits of these alternatives, and the risks of having no treatment have been explained to me. I have had the opportunity to ask questions and have received all the information I desire about the procedure.
2. I understand that in an emergency there may be different or further procedures required if the doctor believes they are necessary, and I consent to such procedures.
3. I consent to the taking of ultrasound images and pictures, videotapes, or other electronic reproductions of the sperm/semen and the use of the pictures, videotapes, or electronic reproductions for treatment or internal or external activities consistent with the hospital's mission of education and research, conducted in accordance with hospital policies.
4. I understand that this original consent form will be maintained in my medical record and a copy will be provided for me. I understand that this consent is an important document and should be maintained with other vital records.
5. I consent to the performance of the procedure designated above.

Date _____ Time _____ Signature _____

Signature of Translator or Name of Language Line _____

Date of Translation _____ Time of Translation _____ Language _____

❑ Telephone Consent Obtained by Practitioner
Second Witness to Telephone Consent: _____
Print Name of Second Witness to Consent: _____

Informed Consent Attestation:
I have discussed the procedures above, including the risks, benefits, and alternatives with the patient and their partner. I have also explained that with any procedure there is always the possibility of an unexpected complication, and no guarantees or promises can be made concerning the results of any procedure or treatment.

All questions were answered and the patient (and their partner, if applicable) consents to the procedures designated above.

Date _____ Time _____

Signature and Title of Practitioner _____ Print Name _____ Pager # _____

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Second Witness to Telephone Consent: _____
Print Name of Second Witness to Consent: _____

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Print Name of Second Witness to Consent: _____

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