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EMBRYO DONATE TO STEM CELL RESEARCH

San Diego Fertility Center – IVF and Andrology Laboratories

I/We have:

_____ Embryo(s) that I/We no longer want to continue to store, and
want to Donate to Stem Cell Research

I/We wish to donate to stem cell research (check one):

- All embryo(s) in storage
- Specific embryos(s) (i.e. date, donor code, other): _____

Reason embryo(s) is no longer needed: _____

I/We no longer want the cryopreserved material maintained in storage. Please donate to stem cell research according to SDFC IVF protocol. Note: SDFC will use frozen material 30 days (or more) from receipt of this form unless a written and signed letter of revocation is received. If donor tissue was used and/or cryopreserved, I/We warrant that I/We have no other contractual obligations to the donor that conflict with the intentions expressed in this document. After signatures are obtained, please return this consent ASAP.

X _____
Patient Signature

Date

Patient Printed Name

Date of Birth

X _____
Partner Signature

Date

Partner Printed Name

Date of Birth

Notary

Date

For Internal SDFC use:		
EO closed: _____	Remove Cryo Inv: _____	Lab Director: _____

CONSENT TO DONATE HUMAN EMBRYOS AND EMBRYONIC CELLS
San Diego Fertility Center: donation of frozen embryos

Clinic Name: San Diego Fertility Center
Clinic Address: 11425 El Camino Real
 San Diego, Ca 92130
Clinic Phone: (858) 720-3136

You are considering donation of embryos that were produced for you in pursuance of fertility treatment. These embryos are now frozen. Your decision whether to donate them for research rests on you having decided that you no longer need them for your fertility treatment.

Before agreeing to donate the embryos for research, it is important that you read and discuss this document to understand what will happen with the embryos. You should feel free to ask questions of the person who is discussing this consent form with you. The information in the form and the discussion of it may help you to decide whether you want to make this donation. If you do, you will need to sign this consent form reflecting your decision.

I. What is the purpose of the research that will be done with donated embryos?

Researchers will briefly culture the embryos in a dish to derive human embryonic stem cells from the embryos and/or analyze cells from the embryos to better understand the individual cell types present and how they communicate to allow successful embryo implantation. Stem cells are cells with the unique capacity to divide with no known limit, and to develop into most of the different types of cells or tissues of the body. Those stem cells will be the focus of research for learning about human development, testing new pharmaceuticals and therapeutic uses.

II. What is going to happen if you decide to donate embryos for research?

If you decide to donate, the donated embryos will not be transferred to a woman’s uterus.

Researchers will briefly culture the embryos in a dish to make cell lines and/or perform gene activity analysis using deep sequencing on cells from the previously frozen embryo. Cells will come either from the inner cell mass or from the outer lining (trophectoderm) of the embryo, and are not themselves able to develop into embryos. For stem cell derivation, cells will be cultured in specialized conditions in the dish into either a human trophoblast or a human pluripotent stem cell line. A “cell line” means a group of cells that can live and divide outside of the body, can be frozen for storage for an indefinite period of time and can be used for future research. “Pluripotent” means that the cell line is capable of developing into a wide variety of cell types. The cells or cell lines created may be kept for many years.

The embryos will not survive after the culture or stem cell derivation. Embryos will be cultured for 7 days or less as allowed per the California Code of Regulations (Guidelines for Human Stem Cell Research, Health and Safety Code §125118, 2018). However, the donated embryos will be handled respectfully, as is appropriate for all human tissue used in research.

III. What are the risks of donating embryos for research?

By agreeing to donate your excess frozen embryos, you will no longer have those embryos available for transfer.

IV. What are the benefits of donating embryos for research?

There will be no direct medical benefit to you. Instead, others may benefit in the future through what is learned from the research. This study will advance scientific and medical knowledge. Unless relevant to your clinical care, you will not be given information about what is learned from working with the embryos you donate or the cells or cell lines created.

At some point in the future, and at the discretion of Dr. Parast, the study leader, cells from the embryos you donate will be used for basic science experimentation, which may include genetic manipulation, and animal or human transplantation. In addition, the embryos collected from you and the DNA, RNA or protein that they contain may also be used in additional research to be conducted by others, either within or outside University of California San Diego, collaborating in this research, including whole genome sequence analysis. These specimens, DNA, and their derivatives may have significant therapeutic or commercial value. You consent to such uses, except as indicated below:

V. What are the alternatives to donating embryos for research?

If you choose not to donate these embryos, they will continue to be stored or otherwise handled according to the routine practice. This may include, at your direction and if medically appropriate, donation of the embryos to other persons for IVF treatment, donation of the embryos for other future research, continued storage, or disposal.

VI. Who will learn information about you if you donate embryos for research?

A randomly generated identification number will be assigned to the tissues. All the information that identifies the embryos you donate as having been created by you (e.g., your name, address or other identifying information) will be protected and will not be provided to researchers. If the research results in the publication of scientific papers, no

information that identifies you or could link the cells or cell lines that you provided tissues for will be published. If the research results in a therapy, no information that identifies you or could link the cells or cell lines that you provided tissues for will be made available.

VII. What are the payment arrangements?

Donation of embryos created during your fertility treatment involves no extra cost to you. Your only costs are those that have been part of your IVF medical care. You will not be paid for the donation of embryos should you choose to make such a donation. In addition, if you choose to make this donation, you will not be reimbursed for storage costs prior to the time of embryo donation.

If discoveries are made as a result of this research, such discoveries may be commercialized, for example, resulting in the development of a cell line that could be used to make a product or to become part of a procedure. While you will be informed of findings relevant to your clinical care, you will not be paid or provided other benefits as a result of a discovery based on the use of your cells.

VIII. What happens if you choose to withdraw your consent to donate embryos?

You are free to donate or to decide not to do so. There is no penalty if you decide not to donate the excess frozen embryos. No one will hold this against you and it will not affect the quality of clinical care you receive.

If you decide to donate, you may withdraw this consent up until the time the embryos are transported to the researchers. Once that occurs, you will not be able to retrieve the embryos you had donated and the cells will continue to be available for research as described above.

To withdraw your consent, you must contact the clinic at the address provided above.

IX. Consent to the use, sharing and storage of your cells.

By signing this consent form, you give permission for the researchers to use and to store the cells or cell lines, from the embryos you donate for research. In addition, your consent will allow the cells or cell lines from the embryos you donate to be kept for so long as the research continues. The derived cells or cell lines, with all identifiers removed, may be kept for many years, and may be shared with multiple research institutions.

By signing this consent form, you give permission for the researchers at UCSD to share the cells or cell lines from the embryos you donate among researchers, with other non-profit institutions, and/or with commercial entities and their end users.

X. For questions about the research or for any problems that arise, you may contact:

____ Dr. Louise Laurent _____
____ 9500 Gilman Drive, MC 0695 _____
____ La Jolla, CA 92093 _____
____ (858) 336-6882 _____

If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the UCSD Human Research Protections Program office at (858) 246-4777 for more information about this, or to inquire about your rights as a research subject, or to report research-related problems.

XII. DISPOSITION OF EMBRYOS—SIGNATURE(S) REQUIRED

A copy of this consent form will be given to you. Please keep a copy of the form as it contains important information.

I have read this consent form. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction.

- I hereby voluntarily consent to donate for research _____ frozen embryos created during my/our fertility treatment that are now in excess of or inappropriate for my/our clinical need.
- Please continue to store these embryos as per IVF laboratory protocols.
- Please *discard* these embryos as per IVF laboratory protocols.

Name of Donor #1

Signature of Donor #1

Date

Name of Donor #2

Signature of Donor #2

Date

I would like to be contacted to further discuss this study; please contact me at the following number: _____

I do not wish to be contacted to further discuss this study. I understand all the points discussed above and wish to proceed with donation of my excess embryos.

To Study Personnel: If the patient wishes to be contacted, please fill out the below:

I have explained this consent form and have answered the questions asked about the form and the information in it.

I hereby attest that the above-signed has voluntarily agreed to donate the number of frozen embryos indicated above for research purposes and that, to the best of my knowledge, the requirements under California law for informed consent have been satisfied.

Name of Person Discussing Consent with Donor(s)

Signature of Person Discussing Consent with Donor(s)

Date