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Certification Form for Human Pluripotent Stem Cell Line Derivation

Title 17 California Code of Regulations Section 100080(f) designates all human pluripotent stem cell lines derived in accordance with the CIRM regulations as "acceptably derived." Derived cell lines may be used in CIRM funded research. Lines derived in accordance with the CIRM regulations conform to the *2008 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research*.

This form is designed for researchers or institutions seeking designation of a human pluripotent stem cell line as "acceptably derived." The information provided herein will be utilized to support the registration and designation of human pluripotent stem cell lines as "acceptably derived."

- **Part A** is to be completed by the SCRO committee or equivalent.
- **Part B** may be completed by a SCRO committee, researcher or other institutional official.

Part A: To be completed by the SCRO committee or equivalent.

SECTION I – Research Oversight Committee

Oversight committee name	Committee contact / Institutional official
University of California, San Francisco - Gamete Embryo and Stem Cell Research Committee (GESCR)	Bernard Lo, M.D. - GESCR Committee Chair

Street address	City & State
512 Parnassus Ave., Room C-126, Box 0903	San Francisco, CA

ZIP / Post code	Daytime telephone	e-mail address
94143-0903	415-476-5370	bernie@medicine@ucsf.edu

Is this committee constituted in a manner consistent with California Code of Regulations Section 100060?	☒ Yes ☐ No

SECTION II – Derived Cell Line Information

The oversight committee identified in Section I reviewed and approved the protocol for derivation of the human pluripotent stem cell line identified in this section.

Institution or Entity Deriving Cell Line	Principal Investigator
University of California, San Francisco	Susan Fisher, Ph.D.

Name or Designation of Cell Line	CIRM Grant Number
UCSFB-8	RL1-00648-1

SECTION III – Donor Consent Information	
Does the approved protocol require <u>each donor</u> of human gametes or somatic cells, used to create the cell line identified in Section II, to provide informed consent for the <u>research use</u> of their biological material for cell line derivation?	☒ Yes ☐ No
Was the original procurement protocol for obtaining gametes, blastocysts or somatic cells from human subjects approved by an IRB, as described in federal regulations at 45 CFR 46.107, (or a foreign equivalent)?	☒ Yes ☐ No
Was the consent protocol for obtaining gametes, blastocysts or somatic cells from human subjects consistent with California Code of Regulation section 100100?	☒ Yes ☐ No
Is the consent form available?	☒ Yes ☐ No

Additional comments or information regarding human subjects status or donor consent:

See Section VII below.

SECTION IV – Donor Payments

The approved protocol for derivation of the human pluripotent stem cell line identified in Section II specified the following payments or reimbursements may be provided to donors.

☒ Original donors of gametes, blastocysts or somatic cells received no payments, cash or in kind.

☐ Original donors received reimbursements and/or payments. Indicate type in section below.

	Derivation source	Donor was reimbursed for direct "permissible expenses[1]"	Donor received payments in excess of direct expenses
☐	For surplus IVF- or PGD-blastocyst made for reproductive purposes	☐ Oocyte donor ☐ Sperm donor	☐ Oocyte donor ☐ Sperm donor
☐	For blastocyst made specifically for research using IVF	☐ Oocyte donor ☐ Sperm donor	Gamete donor may not receive payments
☐	For somatic cell nuclear transfer (SCNT) into human oocytes	☐ Oocyte donor ☐ Somatic cell donor	Gamete donor may not receive payments
☐	Parthenogenesis using human oocytes	☐ Oocyte donor	Gamete donor may not receive payments
☐	Somatic cell reprogramming (iPS)	☐ Somatic cell donor	Somatic cell donor may not receive payments
☐	Other (describe)		

☐ Payment status for gamete, embryo or somatic cell donation could not be determined.

SECTION V – Certification For Part A

I certify that the statements herein are true and complete to the best of my knowledge.

Name	Title
Bernard Lo, M.D.	Professor, Department of Medicine Chair, Gamete, Embryo and Stem Cell Research Committee
Signature	**Date**

[1] Direct "permissible expenses" may include, but are not limited to, costs associated with travel, housing, childcare, medical care, health insurance and actual lost wages. See Title 17 California Code of Regulations section 100020(h).

Part B to be completed by a SCRO committee, researcher or other institutional official.

SECTION VI – Derivation Source and Date of Derivation				
Derivation source		Month and year of: blastocyst formation	consent for research donation	cell line derivation
	Surplus IVF- or PGD-blastocyst made for reproductive purposes[2]	REDACTED ON FILE	REDACTED ON FILE	11/08
	Blastocyst made specifically for research using IVF			
	Somatic cell nuclear transfer (SCNT) into oocytes			
	Parthenogenesis			
	Somatic cell reprogramming (iPS)			
	Other (describe)			

SECTION VII – Verification of Donor Consent

Confirm donor consent for applicable source of human pluripotent cells.

(1) For any blastocyst created using IVF.

- ☒ Consent for research use provided by all gamete donors
- ☐ Consent for research use provided by oocyte donor only
- ☐ Consent status for gamete donor(s) unknown
- ☐ Other (describe):

(2) For SCNT or parthenogenesis.

- ☐ Consent for research provided by all gamete and somatic cell donors.
- ☐ Other (describe): No consent for SCNT or parthenogenesis

(3) For Somatic cell reprogramming (iPS)

- ☐ Consent for research provided by all somatic cell donors
- ☐ Other (describe): No consent for somatic cell reprogramming (iPS)

[2] The purpose of blastocyst formation was for reproductive use. The individual(s) with custody of the embryo determined it was no longer required for reproductive use.

SECTION VIII – Link to Donor, Medical History & Restrictions	
Is/are the donor(s) gametes or somatic cells identifiable – does a link exist between the donor(s) and the derived human pluripotent cell line?	☒Yes ☐No
Is there a donor medical history associated with this stem cell line?	☒Yes ☐No
Did the donor(s) consent to being contacted?	☒Yes ☐No
Are there any restrictions or limitations on the use of derived cell lines?	☒Yes ☐No

If yes, describe any restriction or limitations on the use of derived lines.

An identifiable link exists between the IVF Tissue Bank and the donors, but the embryos were de-identified before being given to Dr. Fisher.

No SCNT permitted.

SECTION IX – Certification For Part B

By signing this document I certify that this cell line was derived in a manner consistent with the protocol described in Part A, and the statements herein are true and complete to the best of my knowledge.

Name	Title
Elena Gates, M.D. Susan Fisher, Ph.D.	Professor, Department of OB/GYN & Repro.Sci Director, UCSF IVF Tissue Bank Professor, Department of OB/GYN & Repro Sc
Signature	Date

Addition Information