

CIRM Pluripotent Stem Cell Line Certification Form



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

University of California, San Francisco - Gamete Embryo and Stem Cell Research Committee (GESCR)

Committee contact / Institutional official

Bernard Lo, M.D. - GESCR Committee Chair

Street address

512 Parnassus Ave., Room C-126, Box 0903

City & State

San Francisco, CA

ZIP / Post code

94143-0903

Daytime telephone

415-476-5370

e-mail address

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

University of California, San Francisco

Principal Investigator

Susan Fisher, Ph.D.

Name or Designation of Cell Line

UCSF3

CIRM Grant Number

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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Was the consent protocol for obtaining gametes, blastocysts or somatic cells from human subjects consistent with California Code of Regulation section 100100?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is the consent form available?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Additional comments or information regarding human subjects status or donor consent:	
<p style="color: blue;">See Section VII below.</p>	

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
<input type="checkbox"/> For surplus IVF- or PGD-blastocyst made for reproductive purposes	<input type="checkbox"/> Oocyte donor <input type="checkbox"/> Sperm donor	<input type="checkbox"/> Oocyte donor <input type="checkbox"/> Sperm donor
<input type="checkbox"/> For blastocyst made specifically for research using IVF	<input type="checkbox"/> Oocyte donor <input type="checkbox"/> Sperm donor	Gamete donor may not receive payments
<input type="checkbox"/> For somatic cell nuclear transfer (SCNT) into human oocytes	<input type="checkbox"/> Oocyte donor <input type="checkbox"/> Somatic cell donor	Gamete donor may not receive payments
<input type="checkbox"/> Parthenogenesis using human oocytes	<input type="checkbox"/> Oocyte donor	Gamete donor may not receive payments
<input type="checkbox"/> Somatic cell reprogramming (iPS)	<input type="checkbox"/> Somatic cell donor	Somatic cell donor may not receive payments
<input type="checkbox"/> 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	4/09
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 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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is there a donor medical history associated with this stem cell line?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Did the donor(s) consent to being contacted?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Are there any restrictions or limitations on the use of derived cell lines?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
If yes, describe any restriction or limitations on the use of derived lines.	
<p>An identifiable link exists between the IVF Tissue Bank and the donors, but the embryos were de-identified before being given to Dr. Fisher.</p>	
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	