Print 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	Committee contact / Institutional official

Street address	City	State

ZIP / Post code	Daytime telephone	e-mail address

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

Name or Designation of Cell Line (please complete one form for each unique line)	CIRM Grant Number

SECTION III – Donor Consent Information	
Please check all statements that apply (check all that apply) to the cell line identified in Section II.	
Did the approved derivation protocol require **research donors** of human gametes, blastocysts or somatic cells to provided informed consent, as described in federal regulations at 45 CFR 46 (or a foreign equivalent).	☐ Yes ☐ No
Is the informed consent protocol for obtaining gametes, blastocysts or somatic cells from human subjects is consistent with California Code of Regulation section 100100 (CIRM Informed Consent Requirements).	☐ Yes ☐ No
Is a sample informed consent form (without donor identifiers) available to researchers wishing to utilize this cell line.	☐ Yes ☐ No
Was the cell line was derived from an embryo created for reproductive purposes with gametes provided by a third-party donor.	☐ Yes ☐ No
If yes, is there documentation that the original donor approved of the research use of the resulting embryo? Note, CIRM regulations section 100090(1) and 100081 address certain exceptions for embryos created before November 22, 2006.	☐ Yes ☐ No
Was the cell line was derived from any non-identifiable gametes or human somatic cells with no associated codes or links (exempt under 45 CFR 46 101.b). If yes, please describe below.	☐ Yes ☐ No

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

SECTION IV – Donor Reimbursement

The approved protocol for derivation of the human pluripotent stem cell line identified in Section II specified CIRM funds may be use to provide the following reimbursements to research donors.

☐ Research donors received no reimbursement, cash or in kind.

☐ Research donors received reimbursements. Indicate type in section below.

	Derivation source	Donor was reimbursed for "permissible expenses[1]"
☐	For blastocyst made specifically for research using IVF	☐ Oocyte donor ☐ Sperm donor
☐	For somatic cell nuclear transfer (SCNT) into human oocytes	☐ Oocyte donor ☐ Somatic cell donor
☐	Parthenogenesis using human oocytes	☐ Oocyte donor
☐	Somatic cell reprogramming (iPS)	☐ Somatic cell donor
☐	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
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		If available please provide month and year of: blastocyst formation	consent for research donation	cell line derivation
☐	Surplus IVF- or PGD-blastocyst made for reproductive purposes[2]			
☐	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 & Possible Restrictions	
Confirm donor consent was obtained consistent with the approved protocol described in Section III. Check all statements that apply to this derivation.	
☐	Donors of human gametes, blastocysts or somatic cells, used to create the cell line identified in Section II, provided informed consent, as described in federal regulations at 45 CFR 46 (or a foreign equivalent).
☐	The consent for obtaining gametes, blastocysts or somatic cells from human subjects was consistent with California Code of Regulation section 100100.
☐	45 CFR 46 requirements were not applicable to this derivation because the cell line was derived from non-identifiable gametes or human somatic cells with no associated codes or links (exempt under 45 CFR 46 101.b).

[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.

Are there any restrictions or limitations on the use of derived cell lines? If yes, describe any restriction or limitations on the use of derived lines.	☐ Yes ☐ No

SECTION VIII Optional Information – Link to Donor & Medical History	
For the derived pluripotent cell line, do any links exist to gamete or somatic cell donor(s)?	☐ Yes ☐ No
Is there a donor medical history associated with this stem cell line?	☐ Yes ☐ No

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
Signature	**Date**

Addition Comments