


CIRM Pluripotent Stem Cell Line Certification Form

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|  | Certification Form for Human Pluripotent Stem Cell Line Derivation |
| <p>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 <i>2008 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research</i>.</p> <p>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."</p> <ul style="list-style-type: none"> ❖ 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 | |
| UCLA Embryonic Stem Cell Research Oversight Committee | | Committee Contact: Steven Peckman Institutional Official: James Economou, Vice | |
| Street address | City | State | |
| 615 C. E. Young Drive South, 477 | Los Angeles | California | |
| ZIP / Post code | Daytime telephone | e-mail address | |
| 90095-7357 | 3108254958 | speckman@mednet.ucla.edu | |
| Is this committee constituted in a manner consistent with California Code of Regulations Section 100060? | | | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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 |
| UCLA | Jerome Zack, PhD & Amander Clark, PhD |
| Name or Designation of Cell Line (please complete one form for each unique line) | CIRM Grant Number |
| UCLA 1, 2, and 3 | RL1-00636-1 |

| SECTION III – Donor Consent Information | |
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| 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). | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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). | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |
| Is a sample informed consent form (without donor identifiers) available to researchers wishing to utilize this cell line. | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |
| Was the cell line was derived from an embryo created for reproductive purposes with gametes provided by a third-party donor. | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |
| <p>If yes, is there documentation that the original donor approved of the research use of the resulting embryo?</p> <p>Note, CIRM regulations section 100090(1) and 100081 address certain exceptions for embryos created before November 22, 2006.</p> | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |
| <p>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).</p> <p>If yes, please describe below.</p> | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |
| <p>Additional comments or information regarding human subjects status or donor consent:</p> <div style="border: 1px solid black; padding: 10px; margin-top: 10px;"> <p>The oocyte donor is not identifiable to the embryo donors or to the investigators. The oocyte donor was NOT paid for contribution of the gametes to research. Rather, the oocyte donor was paid four years prior to the research for her contribution to the clinical IVF process. The oocyte donor provided written permission for the use of residual clinically embryos to be used for research.</p> </div> | |

| SECTION IV – Donor Reimbursement | | |
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| <p>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.</p> | | |
| <p><input checked="" type="checkbox"/> Research donors received <u>no reimbursement</u>, cash or in kind.</p> | | |
| <p><input type="checkbox"/> Research donors received <u>reimbursements</u>. Indicate type in section below.</p> | | |
| | Derivation source | Donor was reimbursed for “permissible expenses”¹ |
| <input type="checkbox"/> | For blastocyst made specifically for research using IVF | <input type="checkbox"/> Oocyte donor <input type="checkbox"/> Sperm donor |
| <input type="checkbox"/> | For somatic cell nuclear transfer (SCNT) into human oocytes | <input type="checkbox"/> Oocyte donor <input type="checkbox"/> Somatic cell donor |
| <input type="checkbox"/> | Parthenogenesis using human oocytes | <input type="checkbox"/> Oocyte donor |
| <input type="checkbox"/> | Somatic cell reprogramming (iPS) | <input type="checkbox"/> Somatic cell donor |
| <input type="checkbox"/> | Other (describe) <input style="width: 400px; height: 20px;" type="text"/> | |
| <p><input type="checkbox"/> Payment status for gamete, embryo or somatic cell donation could not be determined.</p> | | |

| SECTION V – Certification For Part A | |
|--|--|
| <p>I certify that the statements herein are true and complete to the best of my knowledge.</p> | |
| <p>Name</p> <input style="width: 90%; height: 20px;" type="text" value="Steven Peckman"/> | <p>Title</p> <input style="width: 90%; height: 20px;" type="text" value="Associate Director"/> |
| <p>Signature </p> | <p>Date</p> <input style="width: 90%; height: 20px;" type="text" value="10/8/10"/> |

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 |
| <input checked="" type="checkbox"/> | Surplus IVF- or PGD-blastocyst made for reproductive purposes ² | 2005 | March 2009 | August 2009 |
| <input type="checkbox"/> | Blastocyst made specifically for research using IVF | | | |
| <input type="checkbox"/> | Somatic cell nuclear transfer (SCNT) into oocytes | | | |
| <input type="checkbox"/> | Parthenogenesis | | | |
| <input type="checkbox"/> | Somatic cell reprogramming (iPS) | | | |
| <input type="checkbox"/> | 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. | |
| <input checked="" type="checkbox"/> | 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). |
| <input checked="" type="checkbox"/> | The consent for obtaining gametes, blastocysts or somatic cells from human subjects was consistent with California Code of Regulation section 100100. |
| <input type="checkbox"/> | 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.

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| 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>hESC recipients must provide documentation of ESCRO, IRB, or equivalent ethical review for the research planned with the requested lines.</p> | |

| 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)? | <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 |

| 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 |
| Amander Clark, PhD | Assistant Professor |
| Signature | Date |
|  | 10/8/10 |
| Addition Comments | |
| <div style="border: 1px solid black; height: 100px;"></div> | |