CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Petition to Designate a Covered Stem Cell Line as Acceptably Derived

The Independent Citizens Oversight Committee (ICOC) has determined that covered stem cell lines will be considered acceptably derived if they meet the requirements of section 100090 of Title 17 of the California Code of Regulations. Alternatively, an applicant may petition the ICOC to find that a covered stem cell line derived before November 22, 2006 was acceptably derived. The complete regulation governing a petition may be found at the following link: http://www.cirm.ca.gov/reg/pdf/Reg100081.pdf. The following information must be provided:

SECTION I – Applicant Information

Name of contact person		Name of entity submitting petition
Street address	City	State / Country
ZIP / Post code	Daytime telephone	e-mail address

SECTION II – Covered Stem Cell Line Information

Name or designation of covered stem cell line		Alternate Names

Name of person or entity where derived
Check this box if same as applicant information ☐

Street address	City	State / Country
ZIP / Post code	Daytime telephone	e-mail address
Derivation source (check one below)	Derivation Date	Date embryo originally created

- ☐ Surplus IVF-embryo
- ☐ PGD embryo
- ☐ Embryo created for research
- ☐ Parthenogenesis
- ☐ Other (describe)

SECTION III – Information About the Nature of Donor Consent (check all that apply)

Indicate which gamete donors provided consent specifically for research use.

- ☐ Consent for research use provided by each gamete donor
- ☐ Consent for research use provided by oocyte donor only
- ☐ Consent for research use provided by sperm donor only
- ☐ Consent for research provided by individuals with dispositional authority

Provide any additional information about the nature of consents given by donors, attach redacted copies of consent forms or explain why such documents are not provided.

SECTION IV – Information About Payments (Valuable Consideration) to Donors

Did the donors of gametes receive payments of any kind or other valuable consideration for providing sperm or oocytes? Describe any payments and attach redacted copies of the payment protocol/contract or explain why such documents are not provided.

Were donors reimbursed for the cost of embryo or gamete storage prior to donation? If yes, include copies of any documentation describing such reimbursements.	☐ Yes ☐ No

SECTION V – Information IRB or Equivalent Oversight

Was the derivation protocol approved by an institutional review board (IRB) or, in the case of a foreign source, an IRB-equivalent?	☐ Yes ☐ No

Provide any additional information about the nature of review and oversight, attach documents reflecting protocol approval or explain why such documents are not provided.

SECTION VI – Best Practices and Scientific and/or Clinical Necessity

Provide any additional information regarding "best practices" at the time of donation of human gametes, embryos, somatic cells or tissue, documents substantiating those practices for each type of donation, or explain why such documents are not provided.

Provide a statement explaining the scientific and/or clinical necessity for granting this petition for the cell line identified on page 1.

SECTION VII – CONFLICT OF INTEREST DISCLOSURE

In order to comply with the Conflict of Interest policies under which CIRM operates, this section must be completed by any applicant that is a **for-profit** organization.

For-Profit organizations means: a sole-proprietorship, partnership, limited liability company, corporation or other legal entity that is organized or operated for the profit or financial benefit of shareholders or other owners.

Related business entity means: (1) a for-profit organization that owns 50% or more of the Applicant's voting shares; (2) a for-profit organization subsidiary in which the Applicant owns 50% or more of the voting shares; or (3) a for-profit organization with which the Applicant shares management and control; shares resources, or shares a controlling owner.

Please list each related business entity.

(1)

(2)

SECTION VIII – CERTIFICATION

Under penalty of perjury of the law of the state of California, I certify that the statements herein are true and complete to the best of my knowledge.

Name	Signature	Date

Electronic submissions may be made by sending this form to cell_line@cirm.ca.gov. For submissions by mail, send to:

Submit by Email

Print Form

CIRM
Attn: MES Working Group
210 King Street 3rd Floor
San Francisco, CA 94107