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	
Vickie Sheckler	Novocell, Inc.	
Street address	**City**	**State / Country**
3550 General Atomics Ct.	San Diego	California
ZIP / Post code	**Daytime telephone**	**e-mail address**
92121	858-380-7787	vsheckler@novocell.com

SECTION II – Covered Stem Cell Line Information

Name or designation of covered stem cell line	Alternate Names	
Novocell CyT49	CyT49	

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**
	November 2005	January 2001

- ☒ 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.

The Cyt49 embryo was created for the couple seeking fertility treatment using sperm from the husband and an oocyte from a third party donor. Consent for stem cell research (Novocell/Cythera Stem Cell Research Consent, Attachment 1a) was obtained from the donating couple following the IRB approved Novocell protocol. Consent for use of the oocyte (Third Party Oocyte Donor Consent, Attachment 1b) was given for achieving a pregnancy and giving up all rights for resulting embryos to the couple (recipient and her husband).

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.

No payment or other valuable consideration was provided to the couple for donation of the embryo. No payment or other valuable consideration was provided by Novocell to the oocyte donor for donation of the oocyte.

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.

Original IRB approval was obtained May 4, 2004 and an annual continuing review was approved April 19, 2005 (Attachment 2). IRB Review encompassed Principal Investigator qualifications, procedures for the following: obtaining informed consent, embryo transfer to Novocell, maintaining patient confidentiality, and cell line derivation and disposition (Attachment 3). Please note that although an expedited review form was used, a full IRB board review was performed.

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.

Best practices at the time of donation included protection of human subjects via IRB approval of procedures and informed consent. Additional guidance was obtained from the 2005 National Academy of Sciences Guidelines for Research on Human Embryonic Stem Cells. Please refer to attachments 1 through 3 for documentation.

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

Concerning scientific utility, the CyT49 human ES cell line has a propensity to differentiate towards primitive streak derivatives (endoderm and mesoderm), a valuable property that is not scientifically understood at this time. In addition Novocell has been able to adapt CyT49 to single cell passaging and achieved scale up that would allow clinical entry. The cell line has been differentiated to pancreatic lineages and extensively tested in rodent models. In addition pilot tumorgenicty studies have been conducted with CyT49s.

CyT49 was derived under clinical manufacturing conditions, has passed FDA Points to Consider (PTC) safety testing (refer to Attachment 4), and it is anticipated that the cell line will be used to produce a cell therapy product for clinical trials approximately 2011-2013. There are very few hES cell lines derived under conditions that would allow the line to be used clinically in human subjects. To isolate and qualify another cell line to the same standards would most likely delay entry into the clinic by at least 2 years (this would not include differentiation procedure optimization as discussed below).

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) Novocell, Inc.

(2) Cythera, a wholly own subsidiary of Novocell, Inc.

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
Vickie Sheckler		September 4, 2008

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