Interim Regulation – Effective August 12, 2008

§ 100081. Exemption Petition for Lines Derived Prior to November 22, 2006.

For a covered stem cell line derived before November 22, 2006, the ICOC may find in public session that it is acceptably derived pursuant to the following procedure:

(a) A person or entity seeking ICOC approval for a covered stem cell line not otherwise acceptably derived under section 100080 of Title 17 of the California Code of Regulations shall submit a petition in a form as required by CIRM. That petition shall, at a minimum, provide the following information:

1. The name or designation of the covered stem cell line;

2. Information about the nature of the consents given by the donors of human gametes, embryos, somatic cells or tissue used to create the covered stem cell line, including copies of any such consents given;

3. Information about whether the donors of human gametes, embryos, somatic cells or tissue used to create the covered stem cell line received valuable consideration in exchange for their donation, including copies of any documents reflecting such exchanges;

4. Information about whether the donation of human gametes, embryos, somatic cells or tissue used to create the covered stem cell line was overseen by an IRB or equivalent, including copies of any documents reflecting such a review;

5. Information about whether the donors of human gametes, embryos, somatic cells or tissue used to create the covered stem cell line were reimbursed for the cost of

storage prior to donation, including copies of any documentation reflecting such reimbursements;

6. Information regarding ”best practices” at the time of donation of human gametes, embryos, somatic cells or tissue, including any documents substantiating those practices for each type of donation;

7. A statement describing the scientific and/or clinical necessity for granting the petition; and

8. Information submitted in connection with the petition that is of a confidential or proprietary nature as defined in H&S Code section 125290.30, subdivisions (e)(B) or (C), or that is protected from disclosure pursuant to other federal or state law shall not be subject to disclosure pursuant to those laws.

(b) Within 60 days of receipt of a complete petition, the President of CIRM will prepare a written recommendation to the ICOC, and provide a copy of that recommendation to the petitioner. The recommendation will describe the petition and the evidence without revealing confidential and proprietary information, will include an analysis of the petition, and a statement of reasons for granting or denying the petition.

(c) Within 30 days of receipt of the President's recommendation, the petitioner may submit a response to CIRM. Once that response is received, the petition will be placed on the agenda for the next regularly scheduled ICOC meeting.

(d) The President's recommendation and the petitioner's response shall be provided to the ICOC and the public (by posting on the CIRM website) at least ten days prior to the date of the meeting at which the ICOC will consider the petition.

(e) The ICOC must consider the merits of the petition in open session, and must vote to grant or deny the petition in open session. Members of the ICOC may request access to confidential and proprietary information in the petition during closed session before acting on the petition.

(f) The decision of the ICOC to grant or deny the petition is final and not subject to appeal.