CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE (CIRM)

INITIAL STATEMENT OF REASONS FOR THE
PROPOSED ADOPTION OF CIRM MEDICAL AND ETHICAL STANDARDS
SECTION 10081 – EXEMPTION PETITION FOR CELL LINES

HEARING DATE: None Scheduled.

SUBJECT MATTER OF PROPOSED REGULATIONS: Exemption Petition for Lines Derived Prior to November 22, 2006.

SECTIONS AFFECTED: The proposed action adopts section 100081 of Chapter 2 of Title 17 of the California Code of Regulations.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH AMENDMENT:

SECTION 100081 – EXEMPTION PETITION FOR LINES DERIVED PRIOR TO NOVEMBER 22, 2006:

Purpose: The purpose of Section 100081 is to augment and to clarify the stem cell lines that may be used in CIRM-funded research. The regulation states that the ICOC may find in public session that a cell line derived before November 22, 2006, is acceptably derived pursuant to the procedure described as follows:

Subdivision (a): This subdivision describes the contents of a petition by a person or entity seeking ICOC approval of a stem cell line pursuant to the regulation. The petition is attached as Appendix A. The Petition must provide the following info:

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;
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.

Subdivisions (b), (c) and (d): These subdivisions describe how a petition will be processed by CIRM and how CIRM will go about making a recommendation on the petition.

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.

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.

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.

Subdivisions (e) and (f): These subdivisions describe how the ICOC will process a petition submitted pursuant to the regulation.

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.

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

Rationale:

Subdivision (a): In the case of hESC lines derived before the effective date of the regulations, there may be an ongoing need to evaluate materials for use in CIRM-funded research. This evaluation might include “grandfathering” lines deemed appropriate or “disqualifying” lines deemed inappropriate. It is anticipated that the universe of lines subject to evaluation would be limited to a small number of lines with scientific significance or unique ethical concerns.

Considerations relating to the decision to approve or disqualify a particular hESC line would likely be unique to the specific line. Under these conditions a regulatory remedy may not be practical. Rather, an administrative evaluation procedure that enables consideration of the unique considerations relating to a specific line is advisable. Administrative remedies shall include a process where lines were evaluated against scientific and ethical considerations in a consistent and transparent manner.

The evaluative process must include the elements described in the subdivision to ensure a full and fair review of the petition. The information identified is deemed the most relevant and pertinent to a decision on the merits of the request.

Subdivisions (b), (c) and (d): These subdivisions are necessary to indicate to the public and the petitioner how a petition will be processed by the CIRM and what a petition may expect with respect to a recommendation by the President of CIRM. The timelines involve preserve the ability of CIRM to conduct a thoughtful evaluation of a petition while also preserving the ability of the petitioner to conduct research in a timely fashion.

Subdivisions (e) and (f): These subdivisions are necessary to indicate how the ICOC will finally determine the merits of a petition and the process for doing so. The timelines involve preserve the ability of the ICOC to conduct a thoughtful evaluation of a petition while also preserving the ability of the petitioner to conduct research in a timely fashion. By subjecting a petition to the review of both the CIRM and ICOC, the public can be assured that the process is open and fair.

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