

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
INITIAL STATEMENT OF REASONS FOR THE
PROPOSED AMENDMENTS TO MEDICAL AND ETHICAL STANDARDS

HEARING DATE: None scheduled.

CLOSE OF PUBLIC COMMENT: July 30, 2012

SUBJECT MATTER OF PROPOSED REGULATIONS: Publication Requirements

SECTIONS AFFECTED: The proposed amendments are to Title 17 of the California Code of Regulations, sections 100060 and 100070.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH AMENDMENT:

The following discussion of “Purpose” and “Rationale” pertain to each section and the proposed amendment as indicated below.

SECTION 100060 – SCRO COMMITTEE MEMBERSHIP AND FUNCTION:

Purpose:

The amendments delete the requirement that a non-scientist member of a SCRO committee not be appointed to or remunerated by the research institution.

Rationale:

The amendments delete the reference to remuneration and appointment to provide greater flexibility for stem cell research oversight committee operations.

SECTION 100070 – SCRO COMMITTEE REVIEW AND NOTIFICATION:

Purpose:

The amendments provide that CIRM-funded human subjects research, as defined by Title 45, Code of Federal Regulations, Part 46 (Protection of Human Subjects), revised June 23, 2005, and California Health and Safety Code section 24173, with the aim to create, from sources other than human gametes, blastocysts or embryos, or use a covered stem cell line may not commence without written notification of the SCRO committee. A statement from the designated institutional official (as defined in Title 17, California Code of Regulations section 100040, subdivision (b)(1)) may be provided in lieu of SCRO committee notification. The institutional official shall submit documentation of any required review of the proposed research by an IRB, IACUC, IBC or other mandated review.

Rationale:

The current regulation requires the stem cell research oversight committee to be notified of in vitro research involving the use of individually identifiable cells and tissue. The proposed amendment would allow a designated official to be notified in lieu of a SCRO committee for in vitro research involving identifiable cells and tissue. In vitro research involving the use of individually identifiable cells and tissue must also be reviewed and approved by an institutional review board (IRB). A designated institutional official is defined as a person *designated by the chancellor, chief executive or person with plenary authority*. This change provides flexibility and accounts for practical realities at smaller institutions.

SPECIFIC BENEFITS:

The proposed amendments align CIRM regulations with Grantee practice and experience and provide greater flexibility for Grantees to comply with CIRM policies.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS:

CIRM did not rely upon any specific technical, theoretical or empirical studies, reports or documents in proposing the amendments to these regulations.

MANDATE FOR SPECIFIC TECHNOLOGIES OR EQUIPMENT:

The proposed amendments do not mandate the use of specific technologies or equipment.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES:

In view of information currently possessed, no reasonable alternative considered would be more effective in carrying out the purposes for which the amendments are proposed, or would be as effective as the amendments proposed.

CIRM invites interested persons to present statements or arguments with respect to alternatives to the proposed amendments at the scheduled hearing or during the written comment period.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THAT WOULD LESSON ANY ADVERSE IMPACT ON SMALL BUSINESS:

CIRM has made the initial determination that the proposed amendments will not have an adverse impact on small business. The Non-Profit GAP applies to CIRM Grantees who are Academic Institutions and Non-Profit Institutions and who do not meet the definition of small business as defined in Government Code Section 11342.610.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS:

CIRM has made the initial determination that the proposed amendments will not have a statewide adverse economic impact.

**ECONOMIC IMPACT ANALYSIS REQUIRED BY GOVERNMENT CODE SECTION
11346.3, SUBDIVISION (b)**

CIRM has prepared the economic impact analysis required by Government Code section 11346.3, subdivision (b)(1).

**TECHNICAL, THEORETICAL, and/or EMPIRICAL STUDY, REPORTS, OR
DOCUMENTS RELIED UPON:**

“Economic Impact Analysis”

Copies of the documents referenced above are available at the offices of CIRM located at 210 King Street, San Francisco, California, 94107.