

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
INITIAL STATEMENT OF REASONS FOR THE
PROPOSED AMENDMENTS TO PUBLICATION REQUIREMENTS

HEARING DATE: None scheduled.

CLOSE OF PUBLIC COMMENT: July 2, 2012

SUBJECT MATTER OF PROPOSED REGULATIONS: Publication Requirements

SECTIONS AFFECTED: The proposed amendments are to Title 17 of the California Code of Regulations, sections 100303, 100403, and 100603.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH AMENDMENT:

Because the three sections are essentially identical, and because the amendments to them are identical, the following discussion of “Purpose” and “Rationale” pertain to each section and the proposed amendment.

SECTION 100303 – GRANTS ADMINISTRATION POLICY:

Purpose:

The amendments state that for any manuscript that is peer-reviewed and accepted for publication in a scientific journal, the Grantee must ensure that an electronic version of the final peer-reviewed manuscript is submitted to PubMed Central or to CIRM to be made publicly available no later than 12 months after the official date of publication. The Grantee shall make reasonable efforts to comply with this requirement through submission to PubMed Central, including notifying CIRM of the PubMed Central identification number. If the Grantee is unable to submit the manuscript to PubMed Central, the Grantee may comply by providing the manuscript to CIRM, no later than 12 months after the official date of publication. In lieu of the final peer-reviewed manuscript, the Grantee may submit the final published article. Subdivision (c) states that for publications other than those described in subsection (b), including meeting abstracts, the Grantee must comply by providing the manuscript to CIRM no later than 12 months after the official date of publication. Finally, subdivision (d) is amended to state that Grantees are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Regulation. The remaining existing subdivisions are renumbered accordingly.

Rationale:

The amendments require grantees to provide an electronic copy of a publication arising from CIRM-funded research to CIRM to be made available to the public. The amendments are modeled on the National Institutes of Health Public Access Policy, which requires NIH-funded researchers to submit an electronic copy of final, peer-reviewed manuscripts upon acceptance for

publication to the National Library of Medicine's PubMed Central to be made publicly available no later than 12 months after the official date of publication. CIRM believes streamlining its publishing requirements to mirror those of federal grantees will harmonize the two different approaches and make compliance with CIRM requirements more familiar and therefore easier with which to comply. The proposed amendments require CIRM grantees to submit an electronic copy of publications to be made available to the public within 12 months of publication and to eliminate the requirement that grantees prepare a 500-word summary of their publications and instead provide a brief paragraph describing, in lay terms, the significance of the research findings. CIRM believes substituting a brief statement written in lay language of the impact of the research in lieu of a 500-word summary will advance the goal of educating the public about CIRM-funded research.

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.