

NOTICE OF PROPOSED REGULATION AMENDMENTS

California Code of Regulations

Title 17. – Public Health

Division 4 - California Institute For Regenerative Medicine

Amendments to Sections 100303, 100403 and 100603

Date: May 18, 2012

Deadline for Submission of Written Comment: July 2, 2012 – 5:00 p.m.

Public Hearing Date: None Scheduled

Subject Matter of Proposed Amendments: Amendments to Publication Requirements

Sections Affected: The proposed regulatory action amends sections 100303, 100403 and 100603 of Title 17 of the California Code of Regulations.

Authority: Article XXXV of the California Constitution and Health and Safety Code Section 125290.40, subdivision (j).

Reference: Section 125290.30, Health and Safety Code.

Informative Digest/Policy Statement Overview:

The California Institute for Regenerative Medicine (“Institute” or “CIRM”) was established in 2005 after the passage in 2004 of Proposition 71 (the “Act”), the California Stem Cell Research and Cures Initiative. The statewide ballot measure established a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities. The Independent Citizens’ Oversight Committee (“ICOC”) is the 29-member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California’s leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry. The Act charges the ICOC with developing standards and criteria to make grant awards and to develop standards and criteria for proper oversight of awards. (§ 125290.50.) To that end, CIRM has adopted rules regarding Intellectual Property and specifically a regulation governing publications of CIRM-funded research.

Assemblymember Nancy Skinner’s office has expressed interest in amending CIRM’s section 100603 to require CIRM grantees to provide an electronic copy of a publication arising from CIRM-funded research to CIRM to be made available to the public. The Assemblymember’s proposal is 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.

Under CIRM's existing regulations (17 Cal. Code Regs., tit. 17, § 100603, 100403, and 100303), CIRM-funded researchers are required to submit a publication disclosure form to CIRM, along with a 500-word public summary of the article and a copy of the publication, within 60 days of publication. The regulation does not require that grantees submit an electronic copy of the publication, and neither the publications nor the public summaries are currently available on CIRM's website.

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.

Specific Benefits:

The proposed amendments align disclosure requirements from CIRM funding with those of the federal National Institutes of Health. By harmonizing CIRM's rules with federal policy, Grantees will find compliance easier and will no longer have to manage two distinct policy approaches when receiving both CIRM and federal funds. In addition, the proposed amendments increase the public's access to publicly-funded research results.

Impact on Existing State Regulations:

CIRM has determined that the proposed amendments have no effect on existing state regulations. Therefore, the proposed regulations are neither inconsistent nor incompatible with existing state regulations.

DISCLOSURES REGARDING THE PROPOSED AMENDMENTS:

CIRM has made the following initial determinations:

Mandate on local agencies and school districts: None.

Submittal of Comments:

Any interested party may present comments in writing about the proposed amendments to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on July 2, 2012. Comments regarding this proposed action may also be transmitted via e-mail to GAPComments@cirm.ca.gov or by facsimile transmission to (415) 396-9141.

Public Hearing:

At this time, no public hearing has been scheduled concerning the proposed regulations. If any interested person or the person's representative requests a public hearing, he or she must do so in writing no later than June 18, 2012.

Effect on Small Business:

CIRM has determined that the proposed amendments will have no impact on small businesses. The regulation implements conditions on awarding and administering grants for stem cell research. This research is conducted almost exclusively by large public and private nonprofit institutions. As such, the amendments to the regulation are not expected to adversely impact small business as defined in Government Code Section 11342.610.

Impact on Local Agencies or School Districts:

CIRM has determined that the proposed amendments do not impose a mandate on local agencies or school districts, nor do they require reimbursement by the state pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code because the amendments do not constitute a “new program or higher level of service of an existing program” within the meaning of Section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed amendments.

Costs or Savings to State Agencies:

CIRM has determined that no savings or increased costs to any agency will result from the proposed amendments.

Effect on Federal Funding to the State:

CIRM has determined that no costs or savings in federal funding to the state will result from the proposed amendments.

Effect on Housing Costs:

CIRM has determined that the proposed amendments will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:

CIRM has made an initial determination that the proposed amendments will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:

CIRM has made an initial determination that the adoption of these amendments will not have a significant cost impact on representative private persons or businesses. CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed amendments.

Results of Economic Impact Analysis:

The above analysis is based on that fact that the proposed amendments do not impose new requirements on existing business operations or functions of other agencies or individuals, but implement standards for seeking and using state grant funds for scientific research. In most cases, such grants include funds to cover overhead and other indirect costs of the research, including most compliance activities. CIRM has made an initial determination that it is unlikely the proposed amendments will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently

doing business within the State of California, nor directly impact the health and welfare of California residents, worker safety, and the state's environment.

Consideration of Alternatives:

In accordance with Government Code Section 11346.5, subdivision (a)(13), CIRM must determine that no reasonable alternative it considered, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of the law than the proposal described in this Notice. 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.

Availability of Statement of Reasons and Text of Proposed Regulations:

CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed amendments, all of the information upon which the amendments are based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:

After holding the hearing and considering all timely and relevant comments, CIRM may adopt the proposed amendments substantially as described in this notice. If CIRM makes modifications that are sufficiently related to the originally proposed text of the amendments, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before it adopts the regulations as amended. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact:

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the amendments; and inquiries regarding the rulemaking file may be directed to:

Scott Tocher
Counsel to the Chairman, ICOC
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
(415) 396-9100

Questions on the substance of the proposed regulatory action may be directed to:

Amy Cheung
California Institute for Regenerative Medicine
(415) 396-9110

The Notice of Proposed Regulatory Amendment, the Initial Statement of Reasons and any attachments, and the proposed text of the amendments and existing regulation are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons:

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code Section 11346.9, subdivision (a), may be obtained from the contact person named above.

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