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MEMORANDUM

To: Members, Governing Board
California Institute for Regenerative Medicine

From: James C. Harrison

Date: March 9, 2012

Re: Proposed Amendment of CIRM Regulation to Adopt NIH Open Access Policy
for CIRM-Funded Publications (Our File No.: 2297-0)

Assemblymember Nancy Skinner's Office has contacted us to discuss the Assemblymember's interest in legislation that would 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. (*See* NIH Public Access Policy, Attachment A.)

Under CIRM's existing regulations (17 Cal. Code Regs., tit. 17, § 100603), 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.

Under the leadership of Vice Chair Torres, we have discussed the possibility of amending CIRM's regulations to incorporate the NIH Public Access Policy with Assemblymember Skinner's office. Through her staff, the Assemblymember has agreed that such an amendment would obviate the need for legislation.

We have prepared an amendment to CIRM's regulations to 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

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summary of their publications. (*See Attachment B.*) We believe that this proposal will advance CIRM's mission by making the results of CIRM-funded research widely available to the public.

Recommendation: Request Board approval to initiate rule-making process to incorporate the NIH Public Access Policy into CIRM's publication disclosure regulation.

Attachments

§ 100603. Publication Requirements.

(a) (1) A Grantee must provide for public access to any publication of a CIRM-Funded Invention or CIRM-Funded Technology, as provided in this section.

(2) 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.

(3) For publications other than those described in subsection (a)(2), including meeting abstracts, the Grantee must comply by providing the manuscript to CIRM no later than 12 months after the official date of publication.

(4) Grantees are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Regulation.

(b) Within 60 calendar days of the publication, Grantees shall notify CIRM of the Grant Number, Grantee Institution, Principal Investigator and the PubMed Central identification number for the manuscript.

~~Publication~~

~~Disclosure Form containing a 500-word abstract written for the general public that highlights the findings of the publication, as well as a brief statement of the Principal Investigator's biographical credentials. The abstract and biographical statement will be publicly available by CIRM.~~

~~(b) One copy of each publication or abstract must accompany the Publication Disclosure Form. The form will identify the Grant Number, Grantee Institution, Principal Investigator and provide space for information identified in subdivision (a) of this regulation.~~

(c) A Grantee must ensure that the final abstract or manuscript includes the URL of a website where a Materials Transfer Agreement (or similar document) can be accessed to facilitate requests for Publication-related Biomedical Materials.

(d) Any written or oral publication reporting a CIRM-Funded Invention or CIRM-Funded Technology must acknowledge CIRM funding. An example of an acknowledgement is:

“This research was made possible by a grant from the California Institute for Regenerative Medicine (Grant Number _____). The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of CIRM or any other agency of the State of California.”

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j),

Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research

Notice Number: NOT-OD-08-033

Update: The following updates relating to this announcement have been issued:

- October 30, 2009 - See Notice NOT-OD-10-009 Until further notice, only papers written in Latin script will be collected via the NIH Manuscript Submission System for the NIH Public Access Policy.
- August 12, 2009 - See Notice NOT-OD-09-136 Clarification on the Use of an NIHMSID to Indicate Compliance with the NIH Public Access Policy.
- March 19, 2009 - See Notice NOT-OD-09-071. The Omnibus Appropriations Act of 2009 Makes the NIH Public Access Policy Permanent.
- March 19, 2009 - See Notice NOT-OD-09-070. The intent of this Notice is to provide information on the following statutory provisions that limit the use of funds on National Institutes of Health (NIH) grant, cooperative agreement, and contract awards for FY2009.
- September 23, 2008 - See Notice NOT-OD-08-119. Reminder Concerning Grantee Compliance with Public Access Policy and Related NIH Monitoring Activities.
- March 7, 2008 - See Notice NOT-OD-08-057. Notice of Public Meeting: Seeking Comments on Implementation of the NIH Public Access Policy.

Key Dates

Release Date: January 11, 2008

Effective Date: April 7, 2008

Issued by

National Institutes of Health (NIH), (<http://www.nih.gov/>)

Department of Health and Human Services

Action

Notice; Revised Policy Statement

Summary

In accordance with Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008), the NIH voluntary Public Access Policy ([NOT-OD-05-022](#)) is now mandatory. The law states:

The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

Specifics

1. The NIH Public Access Policy applies to all peer-reviewed articles that arise, in whole or in part, from direct costs ¹ funded by NIH, or from NIH staff, that are accepted for publication on or after April 7, 2008.
2. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Policy.

3. PubMed Central (PMC) is the NIH digital archive of full-text, peer-reviewed journal articles. Its content is publicly accessible and integrated with other databases (see: <http://www.pubmedcentral.nih.gov/>).
4. The final, peer-reviewed manuscript includes all graphics and supplemental materials that are associated with the article.
5. Beginning May 25, 2008, anyone submitting an application, proposal or progress report to the NIH must include the PMC or NIH Manuscript Submission reference number when citing applicable articles that arise from their NIH funded research. This policy includes applications submitted to the NIH for the May 25, 2008 due date and subsequent due dates.

Compliance

Compliance with this Policy is a statutory requirement and a term and condition of the grant award and cooperative agreement, in accordance with the *NIH Grants Policy Statement*. For contracts, NIH includes this requirement in all R&D solicitations and awards under Section H, Special Contract Requirements, in accordance with the Uniform Contract Format.

Inquiries

Send questions concerning this Notice or other aspects of the NIH Public Access Policy to:

Office of Extramural Research
National Institutes of Health
1 Center Drive, Room 144
Bethesda, MD 20892-0152
Email: PublicAccess@nih.gov
Website: <http://publicaccess.nih.gov>

¹Costs that can be specifically identified with a particular project or activity. NIH Grants Policy Statement, Rev. 12/2003; http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part2.htm#_Toc54600040

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