



CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

TO: MEMBERS, GOVERNING BOARD
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

FROM: C. SCOTT TOCHER

SUBJECT: FINAL ADOPTION OF AMENDMENTS TO REGULATIONS CONCERNING CIRM-FUNDED PUBLICATIONS

DATE: OCTOBER 15, 2012

Executive Summary

At its March meeting earlier this year, the ICOC directed staff to begin the rulemaking process to align CIRM's publishing requirements with the NIH's Open Access Policy. That process, overseen by the Office of Administrative Law ("OAL") was begun in April and has almost concluded. CIRM circulated the proposed changes reviewed by the Board and has received no public comment. The proposed amendments are now ready for final adoption by the ICOC, after which the OAL will conduct a final review before going into effect. **Staff recommends adopting the proposed amendments.**

I. Background

Earlier this year Assemblymember Nancy Skinner's Office 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 was 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), 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. Through her staff, the Assemblymember has agreed that such an amendment of CIRM's regulations would obviate the need for legislation.

In March, the Board reviewed proposed amendments 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. Based on public comment at the time of the Board's approval of these amendments, the amendments did not include the proposal to eliminate the requirement that grantees prepare a 500-word summary of their publications (therefore that provision remains).

II. Amendments to Sections 100303, 100403 and 100603

Historically, CIRM adopted Intellectual Property regulations first for non-profit grantees (the 100300 series) and later adopted another set for for-profit grantees (the 100400 series). These two sets eventually were consolidated in the 100600 series. Throughout each series, the publication requirements remained virtually the same. While only the 100600 series has applied to grants since late 2009, CIRM still administers grants made before that time and which are bound by the earlier two series. Thus, the proposed amendments to section 100603 authorized by the ICOC in March were extended to 100603's counterparts in the earlier series (sections 100303 and 100403).

The amendments were circulated for public comment but none other than that which was made at the Board meeting in March was received. As posted, the draft aligns CIRM's regulations with the NIH as approved by the Board in March and retains the requirement for grantees to submit a short paragraph to CIRM describing the importance of the discovery.

III. Recommendation

Staff recommends the Board adopt the proposed amendments.

Attachments:

100303

100403

100603

1 Amend 17 Cal. Code of Regs. section 100303 to read:

2 **§ 100303. Publication Requirements.**

3 (a) A Grantee must provide for public access to any publication of a CIRM-Funded
4 Invention or CIRM-Funded Technology, as provided in this section. ~~Within 60 days of the~~
5 ~~publication of CIRM-funded research results in a scientific journal, PIs must submit to CIRM a~~
6 ~~500-word abstract written for the general public that highlights the findings of the published~~
7 ~~body of work. In addition, PIs must submit a biographical sketch to accompany the abstract.~~
8 ~~The abstract and the biographical sketch will be deposited into the publicly-accessible CELR, to~~
9 ~~be accessed via the CIRM website.~~

10 (b) For any manuscript that is peer-reviewed and accepted for publication in a scientific
11 journal, the Grantee must ensure that an electronic version of the final peer-reviewed manuscript
12 is submitted to PubMed Central or to CIRM to be made publicly available no later than 12
13 months after the official date of publication. The Grantee shall make reasonable efforts to
14 comply with this requirement through submission to PubMed Central, including notifying CIRM
15 of the PubMed Central identification number. If the Grantee is unable to submit the manuscript
16 to PubMed Central, the Grantee may comply by providing the manuscript to CIRM, no later than
17 12 months after the official date of publication. In lieu of the final peer-reviewed manuscript, the
18 Grantee may submit the final published article. ~~One copy of each publication resulting from~~
19 ~~work performed under a CIRM grant must accompany the mandatory annual progress report~~
20 ~~submitted to CIRM.~~

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

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

3 (e) Within 60 calendar days of the publication, Grantees shall notify CIRM of the Grant
4 Number, Grantee Institution, Principal Investigator and the PubMed Central identification
5 number for the manuscript. In addition, Grantees shall provide CIRM with a short paragraph,
6 written for the general public, describing both the importance of the discovery that is the subject
7 of the publication and the approach or methodology employed. Neither the publication abstract
8 nor the statement of public benefit submitted as part of the application satisfy this requirement.

9 (fe) In the final manuscript, authors must include the URL of a website where the CIRM
10 MTA (or similar document) can be accessed to facilitate requests for publication-related
11 materials.

12 (gd) CIRM grantees must acknowledge CIRM support of research findings in
13 publications, announcements, presentations, and press releases by the grantees. An example of
14 an acknowledgement is:

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

19 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
20 Safety Code. Reference: Section 125290.30, Health and Safety Code.

1 Amend 17 Cal. Code of Regs. section 100403 to read:

2 **§ 100403. Publication Requirements.**

3 (a) A Grantee must provide for public access to any publication of a CIRM-Funded
4 Invention or CIRM-Funded Technology, as provided in this section~~Within 60 days of the~~
5 ~~publication in a scientific journal of CIRM-funded Research, the PI must submit to CIRM a 500-~~
6 ~~word abstract written for the general public that highlights the findings of the publication, as well~~
7 ~~as a brief statement of the Principal Investigator's biographical credentials. The abstract and the~~
8 ~~biographical statement will be deposited into the publicly-accessible CIRM electronic library~~
9 ~~repository, to be accessed via the CIRM website.~~

10 (b) For any manuscript that is peer-reviewed and accepted for publication in a scientific
11 journal, the Grantee must ensure that an electronic version of the final peer-reviewed manuscript
12 is submitted to PubMed Central or to CIRM to be made publicly available no later than 12
13 months after the official date of publication. The Grantee shall make reasonable efforts to
14 comply with this requirement through submission to PubMed Central, including notifying CIRM
15 of the PubMed Central identification number. If the Grantee is unable to submit the manuscript
16 to PubMed Central, the Grantee may comply by providing the manuscript to CIRM, no later than
17 12 months after the official date of publication. In lieu of the final peer-reviewed manuscript, the
18 Grantee may submit the final published article~~One copy of each publication of CIRM-funded~~
19 ~~Research must accompany the annual progress report submitted to CIRM pursuant to Title 17,~~
20 ~~California Code of Regulations, section 100402.~~

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

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

3 (e) Within 60 calendar days of the publication, Grantees shall notify CIRM of the Grant
4 Number, Grantee Institution, Principal Investigator and the PubMed Central identification
5 number for the manuscript. In addition, Grantees shall provide CIRM with a short paragraph,
6 written for the general public, describing both the importance of the discovery that is the subject
7 of the publication and the approach or methodology employed. Neither the publication abstract
8 nor the statement of public benefit submitted as part of the application satisfy this requirement.

9 (f) A Grantee must ensure that the final manuscript of any publication of CIRM-funded
10 Research includes the URL of a website where an MTA (or similar document) can be accessed to
11 facilitate requests for Publication-related Biomedical Materials.

12 (g) A Grantee must acknowledge CIRM funding of research in publications,
13 announcements, presentations, and press releases. An example of an acknowledgement is:

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

18 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
19 Safety Code. Reference: Section 125290.30, Health and Safety Code.

1 Amend 17 Cal. Code of Regs. section 100603 to read:

2 **§ 100603. Publication Requirements.**

3 (a) A Grantee must provide for public access to any publication of a CIRM-Funded
4 Invention or CIRM-Funded Technology, as provided in this section. ~~Within 60 calendar days of~~
5 ~~the publication in a scientific journal, or the publication of an abstract in connection with a~~
6 ~~scientific meeting, of a CIRM-Funded Invention or CIRM-Funded Technology, the Grantee must~~
7 ~~submit to CIRM a Publication Disclosure Form containing a 500-word abstract written for the~~
8 ~~general public that highlights the findings of the publication, as well as a brief statement of the~~
9 ~~Principal Investigator's biographical credentials. The abstract and biographical statement will be~~
10 ~~publicly available by CIRM.~~

11 (b) For any manuscript that is peer-reviewed and accepted for publication in a scientific
12 journal, the Grantee must ensure that an electronic version of the final peer-reviewed manuscript
13 is submitted to PubMed Central or to CIRM to be made publicly available no later than 12
14 months after the official date of publication. The Grantee shall make reasonable efforts to
15 comply with this requirement through submission to PubMed Central, including notifying CIRM
16 of the PubMed Central identification number. If the Grantee is unable to submit the manuscript
17 to PubMed Central, the Grantee may comply by providing the manuscript to CIRM, no later than
18 12 months after the official date of publication. In lieu of the final peer-reviewed manuscript, the
19 Grantee may submit the final published article. ~~One copy of each publication or abstract must~~
20 ~~accompany the Publication Disclosure Form. The form will identify the Grant Number, Grantee~~
21 ~~Institution, Principal Investigator and provide space for information identified in subdivision (a)~~
22 ~~of this regulation.~~

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

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

6 (e) Within 60 calendar days of the publication, Grantees shall notify CIRM of the Grant
7 Number, Grantee Institution, Principal Investigator and the PubMed Central identification
8 number for the manuscript. In addition, Grantees shall provide CIRM with a short paragraph,
9 written for the general public, describing both the importance of the discovery that is the subject
10 of the publication and the approach or methodology employed. Neither the publication abstract
11 nor the statement of public benefit submitted as part of the application satisfy this requirement.

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

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

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

21 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
22 Safety Code. Reference: Section 125290.30, Health and Safety Code.