UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

OFFICE OF THE VICE PRESIDENT - RESEARCH AND GRADUATE STUDIES

Research Policy Analysis and Coordination
1111 Franklin Street, 11th Floor
Oakland, California 94607-5200
Web Site: www.ucop.edu/research/rpac/
Tel: (510) 587-6031
Fax: (510) 987-9456

Submitted electronically through: ipregs@cirm.ca.gov

August 31, 2017

C. Scott Tocher
Deputy General Counsel
California Institute of Regenerative Medicine
1999 Harrison Street, Suite 1650
Oakland, CA 94612

SUBJECT: 2nd Notice of Proposed Regulation Amendments: Addition of Section 100650 to Chapter 6 of Title 17 of the California Code of Regulations, and the California Institute of Regenerative Medicine ("CIRM") IP Policy incorporated by reference into Section 100650

Dear Mr. Tocher,

The University of California ("UC") is grateful for CIRM's careful consideration of UC's previous comments submitted of May 8, 2017 as is evident in the revised IP Policy of August 17, 2017. Overall, CIRM's revisions address the majority of UC's concerns. UC respectfully submits the following additional comments along with proposed solutions for CIRM's consideration.

1. **At I. G. Collaborator**: As noted in UC's previous comment letter, it is critical that Awardees can properly identify those entities or persons meeting the definition of "Collaborator" early in time and without undue guesswork. UC presumes that CIRM intended the revised language to create a nexus between the first criterion (Invention or Technology ownership) and second criteria (CIRM funding or participation in a CIRM-funded Project) that trigger Collaborator status. Such a nexus is established as shown in the redlined partial paragraph below:

> ***Collaborator***. *Any person or entity other than an Awardee and Awardee Personnel who obtains any ownership rights to a CIRM-Funded Invention or CIRM-Funded Technology and (a) receives CIRM funding directly or indirectly under the Award; (b) knowingly participates in the Awardee's ~~a~~ CIRM-Funded Project; or (c)…*

The third criteria determinative of Collaborator status entails ownership rights in a CIRM-Funded Invention or CIRM-Funded Technology by way of licensee (direct) or sublicensee (indirect) status.

In the case of non-profit Awardees who license IP rights to commercial entities but do not commercialize themselves, the sublicense will be between the licensee and the sublicensee. The Awardee will not be a party to the sublicense. Including downstream sublicensees in the definition of Collaborator thwarts the goal of making Collaborators easily and proactively identifiable. Further, non-profit Awardees likely cannot meet their obligations under Section II.A[1] and II.D.6[2] with respect to entities who fall under the definition of Collaborator solely by means of sublicensee status. This concern can be remedied by removing "or indirect" from part (c) of the Collaborator definition. The fully revised paragraph would read as follows:

Collaborator. *Any person or entity other than an Awardee and Awardee Personnel who obtains any ownership rights to a CIRM-Funded Invention or CIRM-Funded Technology and (a) receives CIRM funding directly or indirectly under the Award; (b) knowingly participates in the Awardee's ~~a~~ CIRM-Funded Project; or (c)* receives such ownership rights in his or their capacity as a direct ~~or indirect~~ licensee of a CIRM-Funded Invention or CIRM-Funded Technology.

2. **At I.CC. Publication-Related Biomedical Materials**: The last sentence of this definition seems incongruously drafted as it excludes from the definition certain materials determined by Part IV, subdivision (E). Part IV. (E) waives an Awardee obligation applicable to Publication-Related Biomedical Materials. If certain materials are *not* included in the definition of Publication-Related Biomedical Materials, then the waiver of obligations applicable to such defined materials would not be necessary because the obligation would not exist. Deleting the last sentence of the definition would correct this inconsistency without posing any material alteration to the policy.

CC. Publication-Related Biomedical Materials. *Tangible research material of biomedical relevance first produced in the course of an Award including but not limited to unique research resources (such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data), as described in a published scientific paper as provided by Part III of this Policy. Specific examples include specialized and/or genetically defined cells, including normal and diseased human cells, monoclonal antibodies, hybridoma cell lines, microbial cells and products, viruses and viral products, recombinant nucleic acid molecules, DNA probes, nucleic acid and protein sequences, certain types of animals including transgenic mice and other property such as computer programs. ~~This term does not include tangible research material of biomedical relevance that is made commercially available by an Awardee, Awardee Personnel, Licensee or a Collaborator, as determined by Part IV, subdivision (E) of this policy.~~*

3. **At III. Publication Requirements, part B**: UC recommends inserting the number "12" before "months" in the first sentence clarifying the timeframe for submitting manuscripts for public access. This timeframe mimics the NIH Public Access Policy.[3] The sentence would then read:

[1] Section II.A.: "Prior to an NOA and continuing 12 months after the close of a Award, a Awardee must have written agreements with Awardee Personnel and Collaborators requiring prompt disclosure to the Awardee of any CIRM-Funded Invention."

[2] Section II.D.6: "Awardee shall have written agreements with its Awardee Personnel, Collaborators, licensees and transferees requiring such third parties to report to the Awardee information described in Part II.D."

[3] The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008) which states: *SEC. 218. 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*

"For any manuscript that is peer-reviewed and accepted for publication in a scientific journal, the Awardee 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."

4. **At III. Publication Requirements, part F**: The current language obligates Awardees to have a URL where a Material Transfer Agreement (or similar document) can be accessed to facilitate requests for material transfers. While some Awardees may not have a click-through MTA template directly available online, it is reasonable to expect Awardees to make available online *information* necessary to request an MTA. A suggested revision to the sentence is as follows:

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

   This slight edit would not lessen Awardee's obligation to share Publication-Related Biomedical Materials for research purposes in accordance with Section IV.

5. **At X. March-In Rights, part E**: This section states that an appeal is made by notifying the CIRM President of intent to appeal. UC was unclear on whether the notification, in itself, constitutes the appeal submission, or whether the notice to the President is a separate action from the written statement of reasons described in the second sentence of this Paragraph F.

6. Finally, while UC has not suggested any changes to the text of regulation §100650, UC requests confirmation regarding whether the original version of §100650 (dated 3/01/17) is the most recent version of the new regulation. If the regulation was modified in the course of the public review periods, please advise and share any later versions.

Thank you, Mr. Tocher, and your team for your diligent efforts to meet the concerns of institutes of higher education with respect to CIRM's proposed IP policy revisions. The UC system looks forward to continuing its long-standing collaboration with CIRM pursuing the acceleration of stem cell treatments to patients with unmet medical needs.

Sincerely,

Wendy D. Streitz
Executive Director
Research Policy Analysis and Coordination

---

after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.