NOTICE OF PROPOSED REGULATION AMENDMENTS

California Code of Regulations
Title 17. – Public Health
Division 4 - California Institute for Regenerative Medicine
Chapter 6, Section 100650

Date: March 24, 2017
Deadline for Submission of Written Comment: May 8, 2017 – 5:00 p.m.
Public Hearing Date: April 11, 2017 at 11:00 a.m.

Subject Matter of Proposed Regulation:
Intellectual Property

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 May 8, 2017. Comments regarding this proposed action may also be transmitted via e-mail to ipregs@cirm.ca.gov or by facsimile transmission to 510-340-9159.

Public Hearing:
A public hearing to receive public comment, in oral or written form, will be held at CIRM's headquarters at 11:00 a.m., on Tuesday April 11, 2017. CIRM's offices are located at 1999 Harrison Street, Suite 1650, Oakland, California.

Sections Affected: The proposed regulatory action adds Section 100650 to Chapter 6 of Title 17 of the California Code of Regulations, and the document incorporated by reference into section 100650.

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 early 2005 with the passage of Proposition 71 (the "Act"), the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides $3 billion in funding for stem cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004, called for the establishment of 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 mission of the CIRM is to accelerate stem cell treatments to patients with unmet medical needs. A secondary goal is to strengthen California's biotechnology industry and create collateral economic benefits such as high-paying jobs and increased tax revenues.

To consider rules governing IP created with CIRM funding, one begins with Proposition 71's requirement regarding intellectual property, which is to strike a balance between the opportunity for the State to benefit from licensing revenues and royalties, versus the need to ensure that these requirements do not unreasonably hinder essential research and therapy development. It is this balancing test that has guided the agency's development of IP policies since 2005 and their periodic calibration since.

The core principles of the CIRM intellectual property regulations are unchanged:

First, CIRM does not take an ownership interest in any IP. Like the federal government, CIRM believes our awardees are more incentivized to exploit IP when they own their discoveries.

Second, although CIRM won't own IP, we want to make sure our awardees take reasonable steps to push IP forward and so we make that a requirement.

Third, we don't require that awardees publish their results, but if they do we maintain commonly accepted requirements that materials be made available for research purposes in California.

Finally, while the vast bulk of return to the state will be in the form of reduced health care costs and increased productivity resulting from therapies and cures, we have imposed direct return through pricing and access provisions, as well as revenue sharing – and it's revenue sharing that will be the focus of revisions.

Current revenue sharing provisions: 1) licensing revenue, or 2) commercial revenue. Licensing revenue is a cut that the state gets when our awardee licenses technologies to third parties and receives revenue down the road from that third party. It's important to note that licensing revenue is never collected from the third party but is only ever an obligation of our original grant recipient. How much our awardee must share depends on a formula that considers how great CIRM's involvement was during the project period of the grant – and the share will be either 15% or 25%. For-profit awardees are treated differently.

The other type of revenue sharing is commercial revenue: if our awardee licenses (or self-commercializes) a successful product, then we impose a royalty on net commercial revenues. What is important to understand about NCR is that this ONLY applies to for-profit awardees. So in essence, and again this a general rule, a non-profit awardee will share licensing revenues with the state. And a for-profit awardee, a commercializing entity – could be the awardee or it could be a pharma company down the road – will owe a royalty on commercial revenues.

Project goals: we want to ensure that our revenue sharing rules are clear and self-executing, where possible. Part of making that possible is ensuring that the rules use objective instead of subjective standards where possible. In other words, we should explicitly state an expected outcome as opposed to trying to require a type of behavior, such as "reasonable efforts."

CIRM has heard clearly from industry that they are less concerned about the given balance point or particular royalty rate, so much as they prize predictability of making that calculation in advance. Revenue sharing rules should be simple to calculate prior to taking an award and provide certainty and confidence in those calculations.

Finally, CIRM will have achieved its goals when CIRM team resources are focused on supporting CIRM's mission, rather than expending its efforts grappling with interpretation of our own rules and trying to enforce them on a case by case basis.

Proposed changes: In addition to refining reporting and other requirements, we primarily propose the following revisions:

1) Eliminate the disparate treatment of awardees and treat all awardees alike; AND

2) Eliminate the concept of licensing revenue for all awardees and focus instead on the "commercial revenue" concept currently applicable only to for-profit awardees.

3) In doing so, we intend to make no substantive changes to our current access and pricing provisions.

By eliminating licensing revenue and focusing on commercial successes, we believe we can optimize CIRM's remaining resources which will allow the team to focus on CIRM's strategic mission. By simplifying our revenue sharing rules, we will make them easier to understand, explain and administer. As a result, potential applicants will be able to more accurately predict the cost of CIRM money and thus, likely make CIRM's programs more attractive to follow-on investment and commercialization.

In summary, Proposition 71 requires CIRM to adopt intellectual property standards that provide for a return to the State. CIRM's existing regulations fulfill that charge by providing for return to the state and mechanisms to ensure CIRM is able to monitor the development and commercial success of IP generated with state funds. IP reporting provides CIRM with the necessary visibility into development activities and march-in provisions ensure there is an enforcement mechanism for compliance. Pricing, access and revenue sharing satisfy the requirement of return to the state and materials sharing ensures broad access for research results funded with public dollars. Each of those elements is carried forward with this set of revisions, with changes primarily designed to eliminate license revenue sharing and treat all awardees uniformly.

Anticipated Benefits of the Proposed Regulation:
To the extent the regulation facilitates use of the funds and encourages development of intellectual property and return to the state as required by law, and to the extent California institutions apply for and receive research funds, such requirements are indirectly attributable to increased economic activity spurred by the investment research funds in the state and resultant

positive business and employment development. Also, to the extent the regulation makes it possible for the expenditure of research funds in the state, and to the extent that research results in medical treatments and cures for chronic disease and injury, the regulation indirectly benefits the health and welfare of California residents who will benefit from such treatments and cures.

Consistency and Compatibility with Existing State Regulations:
CIRM has conducted an evaluation for any other regulations on this area and has concluded that this is the only regulation concerning intellectual property for CIRM-funded research projects. Therefore, the proposed regulation is neither inconsistent nor incompatible with any other existing state regulations.

Incorporated by Reference Documents: The following sections as contained in the September 1, 2017 version of the "Intellectual Property Policy for CIRM Awards," sections "I" through and including "XII."

DISCLOSURES REGARDING THE PROPOSED AMENDMENTS:
CIRM has made the following initial determinations:

Mandate on local agencies and school districts: CIRM has determined that the proposed regulation does 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 regulation does 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.

Effect on Small Business:
CIRM has determined that the proposed amendment will have no impact on small businesses. The regulation implements terms on awarding grants for stem cell research. This research is conducted almost exclusively by large public and private 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 there are no costs to any local agency or school district that are required to be reimbursed pursuant to Government Code section 17500 et seq.

Other Nondiscretionary Cost or Savings to Local Agencies:
CIRM has determined that there are no other nondiscretionary cost or savings imposed upon local agencies that will result from the proposed regulation.

Costs or Savings to State Agencies:
CIRM has determined that no savings or increased costs to any agency will result from the proposed regulation, other than increased efficiency and resultant savings from CIRM the reduced administrative burden on CIRM.

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 regulation.

Effect on Housing Costs:
CIRM has determined that the proposed regulation will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:
CIRM has made an initial determination that the proposed regulation 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 is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed regulation.

Results of Economic Impact Analysis:
The Economic Impact Analysis is based on that fact that the proposed regulation does not impose new requirements on existing business operations or functions of other agencies or individuals, but implements standards for 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. However, to the extent the regulation facilitates use of the funds and encourages invention and return to the state as required by law, and to the extent California institutions apply for and receive research funds, such requirements are indirectly attributable to increased economic activity spurred by the investment research funds in the state and resultant positive business and employment development. Also, to the extent the regulation makes it possible for the expenditure of research funds in the state, and to the extent that research results in medical treatments and cures for chronic disease and injury, the regulation indirectly benefits the health and welfare of California residents who will benefit from such treatments and cures.

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 than the proposed action 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 submit statements or arguments with respect to alternatives to the proposed amendments 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 regulation is 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 considering all timely and relevant comments, CIRM may adopt the proposed regulation substantially as described in this notice. If CIRM makes modifications that are sufficiently related to the originally proposed text of the regulation or policy incorporated thereby, it will make the modified text (with the changes clearly indicated) available to the pubic for at least 15 days before it adopts the regulation or policy 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:

C. Scott Tocher
Deputy General Counsel
California Institute for Regenerative Medicine
1999 Harrison Street, Suite 1650
Oakland, CA 94612
(510) 340-9159

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

Ben Huang
California Institute for Regenerative Medicine
(510) 340-9138

The Notice of Proposed Regulatory Amendment, the Initial Statement of Reasons and any attachments, and the proposed text of the proposed regulation 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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