CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INITIAL STATEMENT OF REASONS FOR THE PROPOSED AMENDMENTS TO PUBLICATION REQUIREMENTS

HEARING DATE: None scheduled.

CLOSE OF PUBLIC COMMENT: November 19, 2012

SUBJECT MATTER OF PROPOSED REGULATIONS: IP Amendments

SECTIONS AFFECTED: The proposed amendments are to Title 17 of the California Code of Regulations, sections 100600, 100601, 100602 and 100608.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH AMENDMENT:

Because the three sections are essentially identical, and because the amendments to them are identical, the following discussion of "Purpose" and "Rationale" pertain to each section and the proposed amendment.

SECTION 100600 – INTELLECTUAL PROPERTY AND REVENUE SHARING REQUIREMENTS FOR NON-PROFIT AND FOR-PROFIT GRANTEES - SCOPE:

Purpose:

As amended, this section states that the regulations of this chapter apply to all California Institute for Regenerative Medicine ("CIRM") Grants awarded to Non-Profit and For-Profit Grantees on or after the effective date of these regulations. By accepting a CIRM Grant, the Grantee agrees to comply with these regulations. Any new or amended regulations of this Chapter subsequently adopted by the Independent Citizens Oversight Committee ("ICOC") will apply to CIRM-Funded Project(s) or Activities on the start date of the next Budget Period after the effective date of the regulations. Notwithstanding the foregoing sentence, amendments to Title 17, California Code of Regulations, sections 100606, 100607 and 100608, shall only apply to Grants awarded after adoption of the new or amended regulations unless the parties agree the amendments shall apply to existing Grants. All revisions to CIRM regulations will be posted on the CIRM website at www.cirm.ca.gov, which shall serve as notice to the Grantee or Authorized Organization Official of such revisions.

Rationale:

This section is necessary to define the circumstances and extent to which this chapter is to be applied. Because grants can exist over multiple numbers of years, it is necessary to indicate how revised grant regulations are to be applied to existing grants. The regulation addresses two types of grants – those which are "currently active" and those which are not. The regulation also informs recipients that the CIRM website will contain updates of regulations, which is aimed to inform recipients that the website can be relied upon to track potential amendments to these regulations and policies. The amendments provide the option of applying amendments to

sections 100606-100608 retroactively upon agreement. This will provide flexibility to grantees and CIRM to apply improvements and calibrations to existing grants where the parties agree to do so.

100601. INTELLECTUAL PROPERTY REGULATIONS - DEFINITIONS.

Purpose:

The following definitions shall apply to sections 100600-100611 of these regulations:

(h) Commercializing Entity. A For-Profit Grantee and its Collaborator or licensee that sells, offers for sale or transfers a Drug, product(s) or services resulting in whole or in part from CIRM-Funded Research.

(m) First Commercial Sale. The date upon which revenue is derived from the sale or transfer, but not the licensing or assignment, of a Drug, product or service in the United States or member country of the European Union.

(v) Licensing Revenue. The consideration received from the license of a CIRM-Funded Invention or CIRM-Funded Technology (provided however that with respect to a For-Profit Grantee or For-Profit Collaborator, Licensing Revenue does not include pre-commercial revenues such as development milestones and upfront payments). Licensing revenue excludes any additional grants, loans and other forms of research funding obtained to support the Project. Calculation: Revenue is calculated by subtracting a proportion of expenses reasonably incurred in prosecuting, defending and enforcing related patent rights equal to CIRM's percentage of support for development of such CIRM-Funded Invention and/or CIRM-Funded Technology from total consideration rendered, except to the extent that such expenses are recoverable from a third party as provided in Section 100605(c) or otherwise. In the case of non-profit Grantees and non-profit Collaborators Licensing Revenue is calculated by subtracting amounts due to the Inventor pursuant to existing institutional policies from total consideration rendered.

(x) Net Commercial Revenue. Income from the sale in any country or transfer (but not licensing or assignment) of a Drug, product(s) or services resulting in whole or in part from CIRM-Funded Research. Net Commercial Revenue excludes the following (as they pertain to the making, using or selling of products resulting from CIRM-Funded Research):
(1) import, export, excise and sales taxes, and customs duties;
(2) costs of insurance, packing, and transportation from the place of manufacture to the customer's premises;
(3) credit for returns, allowances or trades; and
(4) pre-commercial revenues received in connection with research and development and/or clinical activities, such as upfront and milestone payments.

Rationale:

To make specific the language and terminology used in formulating these regulations.

100602. INVENTION AND LICENSING REPORTING REQUIREMENTS.

Purpose:

...

(c) This new subdivision states that within 60 calendar days after a Grantee executes an exclusive license agreement, non-exclusive license agreement, material transfer agreement, research collaboration agreement, or any other agreement conveying rights in CIRM-Funded Inventions or CIRM-Funded Technology, a Grantee shall notify CIRM of the execution of such agreement(s) and submit to CIRM a copy of the executed agreement. The notification and agreement(s) shall be marked "Confidential" in accordance with Health and Safety Code section 125290.30, subdivision (e)(2)(B).

The amendments also delete section (c)(4) pertaining to reporting of licensing agreements.

Rationale:

Part of CIRM's ongoing responsibility is to gauge the effectiveness of CIRM's IP regulations and assess our Grantees' efforts to exploit CIRM technology. A primary tool at CIRM's disposal is the ability to gain visibility into various license and other agreements conveying rights between our Grantees and third parties to CIRM-funded technologies. Currently, while Grantees are required to notify CIRM on an annual basis when such agreements are entered into, Grantees are not required to provide CIRM with copies of such documents.

To address this lack of visibility and to make clearer CIRM's requirements going forward, staff proposes amendments to section 100602 to require provision of such agreements within 60 days of their execution. CIRM will hold the documents in confidence in accordance with Proposition 71. (The deleted language in (c)(4) is superfluous in light of the proposed amendments.)

100608 – REVENUE SHARING:

Purpose:
As amended, the following subdivisions state:

(a) Licensing Revenue. A Grantee and Collaborator must share with the State of California a fraction of Licensing Revenue arising in whole or in part from a CIRM-Funded Invention, CIRM-Funded Technology, or results of CIRM-Funded Research, as follows:

(1) In the event that CIRM funds at least one half of the total cost of the CIRM-Funded Project resulting in the licensed or transferred CIRM-Funded Invention, CIRM-Funded Technology or results of CIRM-Funded Research, then the amount owed is 25 percent of Licensing Revenue received in excess of $500,000 and shall be payable to the State of California for deposit into the State's General Fund (such payments to be used by the State of California in a manner consistent with Title 35 United States Code, Section 202, subdivision (c)(7)). The threshold amount of $500,000 (in the aggregate) shall be adjusted annually by a multiple of a fraction, the denominator of which is the Consumer Price Index, All Urban Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the Bureau of Labor

Statistics of the United States Department of Labor and published for the month of October 2009, and the numerator of which is such Index published for the month in which the Grantee accepts the Grant. In the event that CIRM funds less than one half of the total cost of the CIRM-Funded Project resulting in the licensed or transferred CIRM Funded Invention, CIRM Funded Technology or results of CIRM-Funded Research then the amount owed is 15 percent of Licensing Revenue in excess of the threshold amount described above.

(2) Notwithstanding the forgoing, in the event that a Commercializing Entity is making royalty payments pursuant to subsection (b) below, For-Profit Grantees and For-Profit Collaborators will have no obligation to share with the State of California, any Licensing Revenues they derive as a result of the same commercial revenue stream.

(b) Net Commercial Revenue. A Commercializing Entity must share with the State of California for deposit in the State's General Fund a fraction of Net Commercial Revenue that results in whole or in part from CIRM-Funded Research (regardless of whether a CIRM- Funded Invention or CIRM-Funded Technology is involved) as follows:

(1) A royalty on Net Commercial Revenue at a rate of 0.1% per $1 million of CIRM Grant(s) for the earlier of Ten (10) years from the date of First Commercial Sale or nine times the amount of the Grant(s); (By way of example, Grants totaling $15 million will result in royalty payments of 1.5% of Net Commercial Revenues.)

(2) In addition, upon satisfaction of the obligation in subsection (b)(1) above, a 1% royalty shall be owed on Net Commercial Revenues in excess of $500 million per year, until the last to expire patent covering a CIRM Funded Invention, if any, that generates, or plays a role in the generation of, in whole or in part said Net Commercial Revenue; provided at least $5 million in CIRM Grant or Grants were made in support of such CIRM-Funded Research, CIRM Funded Technology or CIRM Funded Inventions

(3) For purposes of subdivision (c) of this section, the royalty rate calculation shall apply only to Grants made to For-Profit Grantees and which were awarded subsequent to the effective date of this section, as amended.

(4) Royalty payments owed pursuant to this section shall be paid 60 days following the end of each calendar quarter.

(c) Grantees and Collaborators shall include provisions within any license of a CIRM-Funded Technology or CIRM-Funded Invention ensuring that a Commercializing Entity, whether a licensee or sub-licensee, directly owes payments to the State pursuant to subdivision (b) of this Section, where applicable.

(d) Revenues due the State according to this Section shall be paid to the California State Treasurer's Office, Division of Cash Management.

Rationale:

Subdivision (a): The amendments to section 100608(a) simplify the calculation of the Proportionality Reduction. Instead of tracking dollar for dollar other funding sources to determine the proportionality of CIRM funding for a given invention, the amendments provide that in the event that CIRM funds 50% or more of a CIRM Funded Project then the State of California will receive 25% of the Grantee's licensing revenue which arises from the licensing of CIRM Funded Technology (e.g. data) or CIRM Funded Inventions resulting in whole or in part from the CIRM Funded Project. In the alternative, if CIRM funded less than 50% of the Project, the State will receive 15% of the Grantee's licensing revenues.

By virtue of an amendment to the definition of Licensing Revenue, For-Profit Grantees will not be required to share pre-commercial revenues such as upfront payments and development milestone payments. This is consistent with recent amendments to the Loan Administration Policy which recognize that pre-commercial revenue is akin to a payment in arrears for prior investments.

For-Profit Grantees and Collaborators will be required to share licensing revenues with California which, for example, arise from the licensing of methods, but in order to avoid double payments arising from the same income stream, For-Profits will not have an obligation to share with CIRM any royalty income they receive if CIRM is receiving a royalty on the same revenue stream from a Commercializing Entity pursuant to section 100608(b).

Subdivision (b): The "self-commercialized" revenue provisions of the current regulatory scheme are revised to smooth out the payment obligation and to extend the obligation to commercializing entities. This provision will apply to commercial sales revenues (not licensing revenues) received by a "Commercializing Entity" to the extent the CIRM funded Drugs, products or services resulted in whole or in part from CIRM grants to a For-Profit Grantee. It amends the revenue sharing formula as follows:

Sets the rate of payout owed to California to one-tenth of one percent (0.1%) per one million dollars ($1 Million) in Grants provided to For-Profit Grantee(s) for the lesser of (i) 10 years or (ii) nine times (9x) the Grant; and

Includes a follow-on 1% royalty where Net Commercial Sales exceed $500 million per year and where CIRM grant(s) aggregate more than $5 million and involve a patented CIRM-Funded Invention or patented CIRM Funded Technology.

Subdivision (c): The amendments approved by the IP subcommittee create new obligations on third party "commercializing entities." CIRM proposes the revenue sharing requirements ensure that third party licensees (who may ultimately be "commercializing entities") of CIRM-funded technologies have an affirmative obligation to CIRM and the State to abide by these revenue sharing obligations when they apply to the third party licensees.

Subdivision (d): CIRM also proposes to clarify the revenue sharing obligations of Section 100608 by indicating that the revenues due under the regulations are payable to the State Treasurer's Office, Division of Cash Management. This amendment provides clarity on how to fulfill revenue sharing obligations.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS:

A. Documents or Laws:

None.

B. Public Input:

Discussion and public input received at the following public meetings conducted by the Intellectual Property and Industry Subcommittee on 06/11/12; and ICOC on 09/05/12.

MANDATE FOR SPECIFIC TECHONOLOGIES OR EQUIPMENT:

The proposed amendments do not mandate the use of specific technologies or equipment.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES:

In view of information currently possessed, no reasonable alternative considered would be more effective in carrying out the purposes for which the amendments are proposed, or would be as effective as the amendments proposed.

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.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THAT WOULD LESSON ANY ADVERSE IMPACT ON SMALL BUSINESS:

CIRM has made the initial determination that the proposed amendments will not have an adverse impact on small business. The intellectual property regulations apply to CIRM Grantees who are Academic Institutions and Non-Profit Institutions and who do not meet the definition of small business as defined in Government Code Section 11342.610.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS:

CIRM has made the initial determination that the proposed amendments will not have a statewide adverse economic impact.

ECONOMIC IMPACT ANALYSIS REQUIRED BY GOVERNMEND CODE SECTION 11346.3, SUBDIVISION (b)

CIRM has prepared the economic impact analysis required by Government Code section 11346.3, subdivision (b)(1).

TECHNICAL, THEORETICAL, and/or EMPIRICAL STUDY, REPORTS, OR DOCUMENTS RELIED UPON:

"Economic Impact Analysis"

Copies of the documents referenced above are available at the offices of CIRM located at 210 King Street, San Francisco, California, 94107.