CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

MEMORANDUM

TO: Members of the ICOC

From: Elona Baum, Ben Huang and C. Scott Tocher

RE: Consideration of Amendments to CIRM's Intellectual Property Regulations

DATE: **AUGUST 16, 2013**

I. Background

Last September the ICOC initiated a rulemaking process to amend CIRM's Intellectual Property ("IP") regulations (sections 100600 – 100602, and 100608). The rulemaking, in pertinent part, addresses the reporting of licensing activities, provides a new revenue sharing formula that smooth out payment schedules, and addresses the treatment of pre-commercial revenues received by for-profit grantees. The ICOC, upon recommendation of the Intellectual Property and Industry Subcommittee, approved all of such recommendations after careful consideration and deliberation. These proposed changes are marked in red on Exhibit A. As part of this regulatory rulemaking process, staff is proposing addition changes highlighted in yellow on Exhibit A. These are discussed below.

II. Additional Proposed Amendments

The additional amendments staff is proposing are identified in yellow highlight on Exhibit A and provide, in pertinent part, the following:

A. Section 100601 -- Definitions

1. Exclusive Licensee, Exclusive License and License Agreement: These proposed changes are intended to ensure that the regulation has its intended effect by addressing negative covenants, such as covenants not to sue. For all practical purposes a covenant not to sue for patent infringement is similar to an actual license.

2. Licensing Revenue: When the ICOC last met, it agreed that licensing revenue would not include pre-commercial revenue such as development milestones

and upfront payments from For-Profit Grantees and For-Profit Collaborators. The proposed changes reflected on Exhibit A clarify the intent that such exclusion would not apply to passive licensors who have not or are not engaged in drug development.

3. Net Commercial Revenue: Three potential alternatives are suggested on Exhibit A. Staff is recommending the adoption of Option A. The other options were intended to regulate what is commonly referred to as the "reach through" of CIRM' revenue sharing requirements to various streams of revenue arising in whole or in part from CIRM funding. CIRM believes that to ensure greater clarity of purpose and intent it is best to address this issue in a subsequent rulemaking and/or in a statement of intent posted on the CIRM website as part of CIRM's Frequently Asked Questions.

B. Section 100608 – Revenue Sharing

- Subsection (a)(2) has already been approved by the ICOC but is marked with yellow highlight because this clause has been moved to the definition of Licensing Revenue.
- Other changes in this section are non-substantive; they either eliminate duplicative language or add a clarifying clause

II. Recommendation

Staff recommends the ICOC approve all changes identified in red on Exhibit A and highlighted in yellow, with the proviso that with respect to the yellow highlighted proposed amendments in the definition of Net Commercial Revenue, only Option A is approved.

EXHIBIT A

Amend Chapter 6, 17 Cal. Code of Regs. section 100600 to read:

Chapter 6 - Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees

§ 100600. Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees - Scope.

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,~~,~~ ~~except~~ 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.

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

Amend 17 Cal. Code of Regs. section 100601 to read:

§ 100601. Intellectual Property Regulations - Definitions.

The following definitions apply to the regulations in this chapter:

(a) Authorized Organizational Official. The individual, named by the applicant organization, who is authorized to act for the applicant organization and to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to applications and awards.

(b) Budget Period. The intervals of time (usually 12 months) into which a Project Period is divided for budgetary funding and reporting purposes as specified in the relevant NGA.

(c) CIRM-Funded Invention. An Invention, whether patentable or not, which arises from CIRM-Funded Research and is either:

(1) reduced to practice by a Grantee, Grantee Personnel and/or its Collaborator(s) during a CIRM-Funded Project or Activity; or

(2) conceived during a CIRM-Funded Project or Activity and reduced to practice by a Grantee, Grantee Personnel and/or its Collaborator(s) during a CIRM-Funded Project or Activity or within 12 months of the close of the Grant.

(d) CIRM-Funded Project or Activity. Those activities specified or described in an Application that are approved by the ICOC for funding and for which CIRM has issued an NGA, regardless of whether CIRM funding constitutes all or only a portion of the financial support necessary to carry them out.

(e) CIRM-Funded Research. All aspects of work conducted on a CIRM-Funded Project or Activity that is paid for, in whole or in part, with CIRM funds.

(f) CIRM-Funded Technology. Data, materials, research results or know-how whether patentable or not, that is ~~(1)~~ generated or conceived in the Project Period of a Grant~~,~~ and is paid for in whole or in part with CIRM-funds.

(g) Collaborator. Any person or entity other than a Grantee and Grantee Personnel who (1) receives directly or indirectly CIRM funding for work performed under a Grant, and (2) who obtains any ownership rights to a CIRM-Funded Invention or CIRM-Funded Technology during the Project Period.

(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.

(i~~h~~) Data. Scientific, clinical or technical recorded information derived during the Project Period of a Grant, regardless of form or the media on which it may be recorded, but not any of the following: financial, administrative, management data, other information incidental to contract administration, preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. "Data" excludes physical objects (e.g., laboratory samples).

(j~~i~~) Drug. (1) An article recognized in the official United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States, or National Formulary, or any supplement to any of them; (2) an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; or, (3) an article intended for use as a component of any article specified in subdivision (1) or (2). This term includes therapeutic products such as blood, blood products and cells, but excludes medical procedures and services relating thereto.

(kj) Exclusive License. A License Agreement that conveys to ~~the licensee~~ an individual or entity the sole right to make, use, sell, offer for sale and/or import ~~in one or more fields of use or territories, as to~~ a CIRM-Funded Invention or CIRM-Funded Technology, in any field of use or territory, or an agreement that ~~is not available~~ precludes conveyance of the right to make, use, sell, offer for sale and/or import, in any field of use or territory, a CIRM-Funded Invention or CIRM-Funded Technology to ~~be licensed to other entities or persons~~another.

(lk) Exclusive Licensee. Any individual or entity receiving ~~by license all rights~~ the sole right to make, use, sell, offer for sale and/or import ~~in one or more fields of use or territories~~ a CIRM-Funded Technology or a CIRM-Funded Invention in any field of use or territory.

(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.

(nl) For-Profit Organization. A sole-proprietorship, partnership, limited liability company, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners.

(om) Grant. A funding mechanism, other than a loan, providing money and/or property to an eligible entity to assist the recipient in carrying out all or any portion of a CIRM-Funded Project or Activity.

(pn) Grantee. The Non-Profit Organization or For-Profit Organization awarded a Grant by CIRM that is legally responsible and accountable for the use of the CIRM funds provided for the performance of the grant-supported project or activity. The Grantee is the entire legal entity, including Affiliates, even if only a particular division is designated in the Notice of Grant Award

("NGA"). An entity is an Affiliate of a Grantee if both entities share substantial common direction or control (either directly or indirectly), or if either entity owns (directly or through one or more entities) at least a 25% capital or profits interest in the other. All University of California Grantee campuses shall be considered as separate and individual Grantees.

(qo) Grantee Personnel. Grantee's Principal Investigator(s) and Grantee's employees, students and contractors working under the direct or indirect supervision of the Principal Investigator or a Co-Principal Investigator under the Grant.

(rp) Invention. A discovery that is conceived and/or reduced to practice, whether patentable or not.

(sq) Inventor. A person who is an inventor under the patent law of the relevant governing jurisdiction.

(tr) License Agreement. An agreement by which ~~an owner~~the holder of ~~a~~ rights in a CIRM-Funded Invention or CIRM-Funded Technology conveys to another individual or entity the right to make, use, develop, sell, offer to sell, and/or import a CIRM-Funded Invention or CIRM-Funded Technology ~~in exchange for consideration~~or precludes the holder of such rights from enforcing those rights against such other entity.

(us) Licensing Activities. Efforts of an owner or Collaborator of a CIRM-Funded Invention or CIRM-Funded Technology to negotiate, execute or enforce a License Agreement.

(vt) Licensing Revenue. The consideration received ~~from~~ for the grant of rights (including license ~~of~~ rights) in or an agreement to not enforce rights to make, use, develop, sell, offer to sell, and/or import 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~~, excluding the following: (1) any additional grants, loans and other forms of research funding obtained to support the Project; (2) consideration received prior to commercialization of the CIRM-Funded Invention or CIRM-Funded Technology, such as development milestones and upfront payments, by For-Profit Grantees and/or For-Profit Collaborators who have expended, or are expending, their own funds on developing the CIRM-Funded Invention or CIRM-Funded Technology; and (3) consideration derived from Net Commercial Revenue upon which CIRM has received payment from a Commercializing Entity pursuant to Section 100608(b).

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, subdivision (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.

~~rendered to an owner or Collaborator of a CIRM-Funded Invention or CIRM-Funded Technology pursuant to a License Agreement, but excludes subsequent research funding. In the case of Non-Profit Grantees only, Licensing Revenue is calculated by subtracting amounts due to the Inventor pursuant to existing institutional policies from total consideration rendered. For all owners of a CIRM-Funded Invention or CIRM-Funded Technology, Licensing 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 Invention and 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.~~

(w~~u~~) Material Transfer Agreement ("MTA"). An agreement that governs the transfer of tangible research material between a Grantee and/or its Collaborator and an individual or entity ("Recipient") and defines the rights of the Grantee and the rights and limitations of the Recipient with respect to the materials and any derivatives therefrom.

(x~~v~~) Net Commercial Revenue.

{Option A: [~~Income from~~Gross amounts invoiced for the sale in any country or transfer~~,~~ (but not licensing or assignment)~~,~~ of a Drug, ~~or~~ product(s) or services resulting in whole or in part from CIRM-Funded Research.**]**

Option B: [Gross amounts invoiced by an Exclusive Licensee or its affiliates (and their respective sublicenses) for the sale or transfer of a Drug, product(s) or services resulting, in whole or in part resulting, in whole or in part, from the CIRM-Funded Invention or CIRM-Funded Technology that is the subject of the Exclusive License to such Exclusive Licensee.**]**

Option C: [Gross amounts invoiced by an Exclusive Licensee or its affiliates (and their respective sublicenses) for the sale or transfer of a Drug, product(s) or services, the creation or development of which resulted, in whole or in part, from the CIRM-Funded Invention or CIRM-Funded Technology that is the subject of the Exclusive License to such Exclusive Licensee.**]}**

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.

(yw) Non-Exclusive License. A License Agreement under which the rights transferred or conveyed in a CIRM-Funded Technology or a CIRM-Funded Invention to the licensee remain available to be licensed to one or more entities.

(zx) Non-Exclusive Licensee. Any individual or entity that obtains the right to make, use, sell, offer for sale and/or import in a specific field of use or territory, CIRM-Funded Technology or a CIRM-Funded Invention, through a Non-Exclusive License.

(aay) Non-Profit Organization. A university or other institution of higher education or another organization of the type described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501 (c)(3)) and is exempt from taxation under 501 (a) of the Internal Revenue Code (26 U.S.C. 501 (a)) and California Revenue and Taxation Code section 23701d.

(bbz) Notice of Grant Award ("NGA"). The document that notifies the Grantee and others that an award has been made, contains or references all terms and conditions of the award as well as the Grantee's and Principal Investigator's agreement to those terms and conditions, and documents the commitment of CIRM funds.

(ccaa) Principal Investigator. The Principal Investigator ("PI") is an individual designated by the Grantee to direct CIRM-Funded Research. He or she is responsible and

accountable to the Grantee and CIRM for the proper conduct of the project or activity. References herein to "Principal Investigator" include Co-Principal Investigators as well.

(ddbb) Project Period. The amount of time over which CIRM funds a a specific Grant.

(eeee) Public Funds. Funds belonging to the State of California or of any county, city, city and county, or other municipal corporation or subdivision thereof, or any public agency therein.

(ffdd) Publication-Related Biomedical Materials. Tangible research material of biomedical relevance first produced in the course of CIRM-Funded Research 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 Title 17, California Code of Regulations, section 100603. 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 a Grantee, Grantee Personnel, Licensee or a Collaborator, as determined by CIRM pursuant to Title 17, California Code of Regulations section 100604, subdivision (e).

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

Amend 17 Cal. Code of Regs. section 100602 to read:

§ 100602. Invention and Licensing Reporting Requirements.

(a) Prior to an NGA and continuing 12 months after the close of a Grant, a Grantee must have written agreements with Grantee Personnel and Collaborators requiring prompt disclosure to the Grantee of any CIRM-Funded Invention.

(b) Within 60 calendar days after a CIRM-Funded Invention has been disclosed to a Grantee, the Grantee must notify CIRM of the CIRM-Funded Invention through the use of the CIRM Invention Disclosure Form, which will be received in confidence by CIRM. The Invention Disclosure Form shall identify the Grant under which the CIRM-Funded Invention was made, the Inventor(s) and the Principle Investigator. The Disclosure shall be sufficiently complete in technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose, operation, and physical, chemical, biological or electrical characteristics of the CIRM-Funded Invention. If the CIRM-Funded Invention has been submitted for publication or presentation, then the Disclosure shall identify the publication, the date of the abstract or manuscript or presentation, the submission date and if relevant any publication dates, including publication via the internet.

(c) Within ~~60~~ 90 calendar days after a Grantee executes a~~n exclusive~~ license agreement (exclusive or non-exclusive)~~, 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~~ those parts of the agreement that address license revenue, including but not limited to upfront and milestone payments, royalties, income and equity. The notification and ~~agreement(s)~~ disclosures made pursuant to this

subdivision by a Grantee may be made without identifying the licensee, and shall be marked "Confidential" in accordance with Health and Safety Code section 125290.30, subdivision (e)(2)(B). In lieu of the disclosure process described in this subdivision, CIRM and a Grantee may agree to an alternative method of conveying the information described in this subdivision.

(~~d~~e) A Grantee must submit annually to CIRM during, and for 15 years after, the Project Period of the Grant, an Invention Utilization Report containing the following information:

(1) Grantees must report all patent applications filed which claim, or cite to publications concerning, CIRM-Funded Inventions, including the countries in which application(s) were filed, application serial number(s), status and detailed description(s) of the CIRM-Funded Invention(s); and

(2) Grantees must report the issuance or abandonment of any patent applied for that claims, or cites to publications concerning, CIRM-Funded Invention, including the patent number and date of issuance or abandonment and the countries in which the applications have issued or have been abandoned; and

(3) Grantees must report the total funding from all sources that directly contributed to a CIRM-Funded Invention disclosed or claimed in the patent application, including each co-funder's identity, the dollar amounts each contributed and the dates of contribution. CIRM may audit all such co-funding reports; and

~~(4) A Grantee must report to CIRM the execution of all Exclusive License Agreements, Non-Exclusive License Agreements, Material Transfer Agreements or Collaborative Agreements conveying rights in CIRM-Funded Inventions or CIRM-Funded Technology; and~~

(4) A Grantee must report to CIRM the execution of all Material Transfer Agreements or Collaborative Agreements conveying rights in CIRM-Funded Inventions or CIRM-Funded Technology; and

(5) In the event that a CIRM- Funded Invention or CIRM-Funded Technology generates revenue or other consideration (whether from a License Agreement or otherwise), a Grantee must report such revenue or consideration received during the preceding 12 month period or since the last report, whichever is longer.

(6) A Grantee must report the following key progress toward commercialization of a CIRM-Funded Invention or CIRM-Funded Technology including the following:

(A) Initiation of clinical testing;

(B) Initiation of pivotal studies; and

(C) Application for marketing approval.

(7) Grantee shall have written agreements with its Grantee Personnel, Collaborators, licensees and transferees requiring such third parties to report to the Grantee information described in this subdivision (c).

(ed) The Invention Utilization Report shall be marked "Confidential" in accordance with Health and Safety Code section 125290.30, subdivision (e)(2)(B).

(fe) CIRM reserves the right to itself and its agents to conduct an audit of the Grantee and Collaborators to ensure compliance with this Chapter. Grantee and Collaborators must maintain and provide such documentation as is necessary to establish compliance. Further, Grantee must ensure that its Collaborators, Grantee Personnel and all Exclusive and Non-Exclusive Licensees maintain such documentation as is necessary to establish compliance.

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

Amend 17 Cal. Code of Regs. section 100608 to read:

§ 100608. Revenue Sharing.

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

~~(1)~~ In ~~Subject to subdivision (a)(2) of this regulation and to adjustments made in accordance with~~ 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 ~~provisions hereof,~~ 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 foregoing, 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.

~~(2) If any funding sources other than CIRM (including those of the Grantee or Collaborator, as the case may be) directly contributed to the development of said CIRM- Funded Invention or CIRM-Funded Technology, then the return to the State of California on Licensing Revenue in excess of the threshold amount described in subdivision (a)(1) of this regulation shall be proportionate to the support provided by CIRM, as follows: The amount of CIRM funding of the CIRM-Funded Invention or CIRM-Funded Technology shall be divided by the total of funding provided by all sources, and that fraction shall be multiplied by 25. That numeral is the percentage due to the State of California of Licensing Revenue.~~

~~(b)~~ A Commercializing Entity ~~Grantee and Collaborator~~ must share with the State of California for deposit in the State's General Fund a fraction of ~~any~~ Net Commercial Revenue ~~that results in whole or in part it receives from a self-commercialized product it commercializes itself and which resulted from its CIRM-Funded Research (regardless of whether a CIRM-Funded Invention or CIRM-Funded Technology is involved)~~ as follows:

(1) A royalty ~~Grantees and Collaborators must pay royalties to the State of California for deposit into the State's General Fund~~ on Net Commercial Revenue ~~exceeding the threshold amount described in subdivision (a)(1) of this regulation. Total payments under this subdivision (b)(1) shall equal and not exceed three times the total amount of the CIRM Grant or Grants that led to the product. The rate of payback of the royalty shall be~~ at a rate of 0.1% per $1 million of

CIRM Grant(s) for the earlier of Ten (10) years ~~three (3) percent of the annual Net Commercial Revenue~~ from the ~~product~~date of First Commercial Sale ~~or~~ of the applicable Drug, product or service, or until such royalty equals nine times the ~~.~~

~~(2) In addition, if Net Commercial Revenue from a product commercialized by the Grantee, or Collaborators and which resulted from its CIRM-Funded Research exceeds the milestone of $250 million in any calendar year, a one-time payment of three times the total~~ amount of the Grant(s); (By way of example, Grants totaling $15 million ~~awarded shall be paid to the State of California. In addition, if Net Commercial Revenue exceeds the milestone of $500 million in any calendar year, an additional one-time payment of three times the total amount of the Grant(s) awarded shall be paid to the State of California.~~

~~(3) In addition to any amounts due under any other provision of this regulation, where a CIRM-Funded Invention(s) or CIRM-Funded Technology is involved in the achievement of Net Commercial Revenue realized by a Grantee or Collaborator equivalent to or greater than $500 million in any year, and where a CIRM Grant or Grants amounting to more than $5 million (in the aggregate) were made in support of CIRM-Funded Research that contributed to the creation of Net Commercial Revenue, the Grantee or Collaborator~~ will result in royalty payments of 1.5% of Net Commercial Revenues.)~~pay the State of California one percent annually of Net Commercial Revenue in excess of $500 million for the life of any patent covering such patented CIRM-Funded Invention or patented CIRM-Funded Technology.~~

(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 (~~e~~b) 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.

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