CALIFORNIA'S STEM CELL AGENCY

TO: Members of the Intellectual and Industry Subcommittee

FROM: C. Scott Tocher, Ben Huang and James Harrison

DATE: January 26, 2017

RE: Consideration of initiation of process to adopt new Intellectual Property rules for new awards.

Executive Summary

To uphold Proposition 71's mandate to balance the opportunity of the State to benefit from patents and royalties with the need to assure essential medical research is not unreasonably hindered, CIRM continuously monitors and assesses its Intellectual Property rules to assure the balance is struck properly. From time to time, CIRM has updated these rules to provide greater clarity and account for the complex relationships and conditions that accompany drug and therapy development. To that end, the following changes to the IP rules are offered for discussion as a means to streamline the administration of the rules and simplify their application. Specifically, the proposal for discussion eliminates the distinctions between not-for profit and for-profit awardees; eliminates the concept of pre-commercial licensing revenue; and focuses revenue sharing on successful products and therapies.

I. Current IP Rules

A. Sections 100600-100611:

CIRM first adopted IP rules for its awardees in 2006 and has significantly amended them on two occasions since then. The regulations reflect several key principles: 1) CIRM does not own any inventions – IP is owned by the awardees; 2) awardees should make reasonable efforts to bring CIRM-funded IP to practical use – including data; 3) while there is no obligation to publish the results of CIRM-funded research, materials must be made available for California researchers after publication; and 4) the State shares in the success of CIRM research through revenue sharing, access and pricing regulations.

B. Revenue Sharing:

With respect to revenue sharing, the state shares in two types of revenue: licensing revenue (derived from our awardees when they license CIRM-funded technologies), and commercializing revenue (derived from awardees or third parties that commercialize a drug developed from CIRM-funded research). The primary determinant for which type of revenue is collected depends on the status of the awardee on the CIRM award: not-for-profit versus for-profit.

1. Not-for-Profits Awardee:

Licensing Revenue: A non-profit awardee must share either 15% or 25% of the licensing revenue (depending upon whether CIRM has funded 50% or more of the total costs of the project) it receives when it out-licenses a CIRM-funded invention or technology. Once the non-profit awardee receives licensing revenue exceeding $500,000, its obligation to share revenues with the State of California General Fund begins.

> Example: If University receives $1 million in licensing revenue and CIRM has funded 50% of the total project costs, the State General Fund would receive $125,000 (25% of $500,000). Conversely, if CIRM has funded less than 50% of the total project costs, the State General Fund would receive $75,000 (15% of $500,000).

The third party licensee has no revenue sharing obligation to the State General Fund or to CIRM.

2. For-Profit Awardee:

Licensing Revenue: A for-profit awardee may be required to share licensing revenue received by the awardee. However, because pre-commercial revenue and revenue arising from commercial sales are exempt, it is unlikely that an awardee will owe licensing revenue to the State General Fund.

Commercial Revenue: A commercializing entity (an awardee, licensee or collaborator)[1] that sells a product, drug, or service arising from CIRM-funded research must pay a royalty on commercial revenue to the State General Fund as follows: 0.1% per $1 Million in award funds, for the earlier of ten (10) years or 9x the award amount.

> Example: For an $8 million award, the commercializing entity (either the original CIRM awardee if it commercializes the drug, or a licensee who does so) will owe less than a one percent royalty (0.8%) on commercial revenue for ten years (unless payments reach $72 million before ten years have passed).

[1] A collaborator is defines as an entity that receives CIRM funding and obtains an ownership interest in a CIRM-funded invention or technology.

C. Summary of Challenges:

While certain aspects of CIRM's IP rules are fairly straight-forward, other provisions have created challenges for both CIRM and awardees in their implementation. This is due in part to the complexity of the provisions themselves, a lack of alignment between CIRM and its awardees, and opportunities to circumvent revenue sharing and other requirements.

For instance, the revenue sharing provisions hinge on the existence of a license between our awardees and downstream developers. However, some awardees do not license data, which often is the sole IP generated in late-stage preclinical and clinical awards. Moreover, even if licensed, the valuation of the license is up to the parties, which can leave the State with less than what might have been negotiated if CIRM was at the table.

In addition, calculating license revenue depends on the level of CIRM involvement, which can create disagreement about the level of CIRM's participation compared to other funding sources. In addition, the rules treat for-profit and not-for-profits differently. For instance, if Pharma licenses a CIRM-project from CIRM-funded University, Pharma pays nothing to the State when the drug is commercialized. But if Pharma licenses the same technology from CIRM-funded Company, a small biotech, the state receives up to nine times the CIRM award amount from Pharma based on commercial sales.

In light of the significant effort expended to administer the regulations and the challenges described above, the current IP rules should be reconsidered for new awards. Specifically, CIRM should ensure the regulations are clear and self-executing with a revenue-sharing formula which is objective and easy to calculate, and which minimizes the administrative burden to allow CIRM to focus resources on its mission to accelerate stem cell treatments to patients with unmet medical needs.

II. Proposed Revisions

The CIRM team has drafted revisions to the current IP regulations, which are attached as Exhibit A. The primary revisions address the problems identified above as follows:

1) Eliminate licensing revenue;
2) Treat Awardees the same regardless of profit status; and
3) Focus revenue sharing on successful drugs and therapies created through "regulatory use" of CIRM-funded research or successful non-drugs which have been exclusively licensed.

Additionally, the revisions clean up the invention reporting rules for awardees (100602) and address how to apply CIRM's regulations when more than one version may cover the development of a particular invention or technology.

A. Eliminate License Revenue:

From adoption of the first CIRM IP policy in 2006, CIRM has in one way or another attempted to derive revenue for the State from our awardees when they license CIRM-funded IP to third parties. For less valuable or early-stage technologies, the existing $500,000 revenue threshold (before the obligation to share licensing revenue kicks in) necessary to cover patent prosecution and other costs means that, in most cases, revenue is unlikely ever to be shared. At the other end of the spectrum, for late stage awards where significant IP may already have been developed and the output of the award is data, awardees may be disinclined to license the data or license it for nominal value. And in any event, the valuation of a data license even if pursued is entirely up to the awardee and the licensor, who may already have underlying financial arrangements to compensate for licensing pre-existing IP.

For example, an academic Grantee may license a pre-existing non-CIRM-Funded patent to a biotech for development and commercialization several years into a CIRM grant. If the Grantee does not include data or know-how in the patent license but transfers CIRM-Funded data to the biotech without a license, CIRM and the Grantee would have to negotiate to ensure the Grantee entered into a separate data license for the CIRM-Funded data. However, if the Grantee merely transfers the existing milestones from the patent license to the data license without incorporating the royalty, then the State's maximum return on the data license will be a fraction of the CIRM funding, and all the royalties for this CIRM-Funded Project (if any) will be kept by the academic Grantee.

Reviewing applicants' IP plans to assess efforts to license for value potential CIRM IP, attempt to negotiate adjustments to these third-party agreements, and then monitor them requires significant, ongoing effort. In light of the limited potential for a return from license revenue sharing, eliminating licensing revenue and focusing on commercial sales likely will be a net-positive from a resource standpoint.

B. Similar Treatment of Awardees:

As shown above, awardees are treated differently based on profit status. When the IP rules were amended in 2014 to create the concept of tapping commercial revenue from successful products, that concept was limited to for-profit awardees and their licensees. Since its adoption, the concept has not proven to be an undue obstacle to generating interest in licensing CIRM-funded technologies by pharma or a roadblock to for-profit entities applying for CIRM funding. In light of this, the distinction in treatment of awardees is difficult to justify and eliminating it will streamline application of CIRM's IP rules, making them easier to understand and follow.

C. "Regulatory Use":

As discussed earlier, the primary hook for revenue sharing under current rules is via a license between our awardee and a third party. For instance, current rules governing commercial revenue only apply to our awardee, a collaborator, or a *licensee*. Without a license, no commercial revenue can ever be collected from a third-party pharma partner. To ensure the State receives its fair share for drugs developed by third-parties with CIRM funding, the revisions introduce the concept of "Regulatory Use," which is the use of the output of CIRM-funded research in an FDA (or other equivalent body) submission.[2] Thus, a commercializing entity that makes "regulatory use" of CIRM-funded technology will be liable to the State for the proscribed revenue sharing regardless of whether there is a license between the entity and CIRM's original awardee though CIRM still anticipates the licensing process to be the vehicle for a heavy majority of the payments to the State. (See draft 100601, subdivision (gg).)

III. Requested Action: The CIRM team requests the subcommittee's approval of a recommendation to the ICOC to commence the regulatory adoption and public comment process.

Attachments:

Ex. A – Draft revisions.

[2] Regulatory use does not include a reference or citation to publicly available publication that describes or references CIRM-funded research and technology.

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, amendments to Title 17, California Code of Regulations, sections 100606, 100607 and 100608~~This regulation~~,~~ shall only apply to ~~Grants~~ Awards ~~awarded~~ approved after the adoption of ~~the new or amended regulations~~this regulation unless the parties agree this regulation, including any amendments, ~~e amendments shall apply~~applies to ~~existing Grants~~Awards funded in whole or in part prior to the effective date of these regulations, or as provided in section 100612 if applicable.~~.~~ 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) Award. CIRM funding in the form of an Award, Grant, Loan, or contract that is based on an approved application and budget.

(c) Awardee. An organization that is the Recipient of an Award and that is legally responsible and accountable for the use of the funds provided and for the performance of the CIRM-funded Project or Activity. The Awardee is the entire legal entity even if a particular component is designated in the Notice of Award. Campuses of the University of California shall be considered as separate and individual Awardees.

~~(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 NGANOA.~~

(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 ~~Grant~~Awardee, ~~Grant~~Awardee 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 ~~Grant~~Awardee, ~~Grant~~Awardee Personnel and/or its Collaborator(s) during a CIRM-Funded Project or Activity or within 12 months of the close of the ~~Grant~~Award.

(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~~NOA, 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 generated or conceived in the Project Period of a Grant~~Awardarises from CIRM-Funded Research ~~and is paid for in whole or in part with CIRM funds~~.

(g) Collaborator. Any person or entity other than a ~~Grant~~Awardee and ~~Grant~~Awardee 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. Any (1) ~~A For-Profit Grant~~Awardee ~~and its Collaborator or licensee that sells, offers for sale or transfers a Drug product(s) or service(s) resulting in whole or in part from CIRM-Funded Research.~~(1) Any entity that sells, offers for sale or transfers a Drug: (a) resulting in whole or in part from Regulatory Use; or (b) that consists, in whole or in part, of a CIRM-Funded Invention; or~~.~~ (2) ~~Any~~ Awardee, Collaborator, or Exclusive Licensee who commercializes a non-Drug product or service resulting in whole or in part from CIRM-Funded Research.

(i) Data. Scientific, clinical or technical recorded information derived during the Project Period of an ~~Grant~~Award, 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) 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.

(k) Exclusive License. A License Agreement that conveys to an individual or entity the sole right to make, use, sell, offer for sale and/or import a CIRM-Funded Invention or CIRM-Funded Technology in any field of use or territory, or an agreement that 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 another.

(l) Exclusive Licensee. Any individual or entity receiving the sole right to make, use, sell, offer for sale and/or import 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~~.

(n) 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.

~~(o) Grant~~Award. ~~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.~~

~~(p) Grant~~Award~~ee. The Non-Profit Organization or For-Profit Organization awarded a Grant~~Award by CIRM that is legally responsible and accountable for the use of the CIRM funds provided for the performance of the grant~~award~~ supported project or activity. The Grant~~Award~~ee is the entire legal entity, including Affiliates, even if only a particular division is designated in the Notice of Grant~~Award Award ("NGA"). An entity is an Affiliate of a Grant~~Award~~ee 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 Grant~~Award~~ee campuses shall be considered as separate and individual Grant~~Award~~ees.~~

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

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

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

(t) License Agreement. An agreement by which the holder of 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 or which precludes the holder of such rights from enforcing those rights against such other individual or entity.

(u) 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.

~~(v) Licensing Revenue. The consideration received for the grant of rights (including license rights), 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, 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(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 non-profit Grantees' or non-profit Collaborators' policies from total consideration rendered, in addition to the deduction of expenses per the previous sentence.~~

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

(x) Net Commercial Revenue. Gross amounts invoiced for the sale in any country or transfer (but not licensing or assignment) of a Drug, product(s) or service(s) 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.

(y) 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.

(z) 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.

(aa) 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.

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

(cc) Principal Investigator. The Principal Investigator ("PI") is an individual designated by the ~~Grant~~Awardee to direct CIRM-Funded Research. He or she is responsible and accountable to the ~~Grant~~Awardee and CIRM for the proper conduct of the project or activity. References herein to "Principal Investigator" include Co-Principal Investigators as well.

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

(ee) 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.

(ff) 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 ~~Grant~~Awardee, ~~Grant~~Awardee Personnel, Licensee or a Collaborator, as determined by CIRM pursuant to Title 17, California Code of Regulations section 100604, subdivision (e).

(gg) Regulatory Use. The use of any CIRM-Funded Research in a Food and Drug Administration (or equivalent foreign regulatory body) submission or filing. Regulatory Use does not include a reference or citation to a publicly available publication that describes or references CIRM-Funded Research.

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~~NOA and continuing 12 months after the close of a ~~Grant~~Award, a ~~Grant~~Awardee must have written agreements with ~~Grant~~Awardee Personnel and Collaborators requiring prompt disclosure to the ~~Grant~~Awardee of any CIRM-Funded Invention.

(b) Within 60 calendar days after a CIRM-Funded Invention has been disclosed to a ~~Grant~~Awardee, the ~~Grant~~Awardee 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~~disclosure shall identify the ~~Grant~~Award under which the CIRM-Funded Invention was made, the Inventor(s) and the Principal~~le~~ Investigator. The d~~D~~isclosure 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 d~~D~~isclosure 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 90 calendar days a~~After an ~~Grant~~Awardee executes a License Agreement (exclusive or non-exclusive) conveying rights in CIRM-Funded Inventions or CIRM-Funded Technology, ~~a~~ the ~~Grant~~Awardee shall notify CIRM in the next Utilization Report of the execution of such agreement(s) and submit to CIRM a copy of ~~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 disclosures made pursuant to this subdivision by a ~~Grant~~Awardee may be made without identifying the licensee, and shall be marked

"Confidential" in accordance with Health and Safety Code section 125290.30, subdivision (g)(2)(B). In lieu of the disclosure process described in this subdivision, CIRM and a ~~Grant~~Awardee may agree to an alternative method of conveying the information described in this subdivision.

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

(1) ~~Grant~~Awardees 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) ~~Grant~~Awardees 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 ~~Grant~~Awardee 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), an ~~Grantee~~ Awardee must report such revenue or consideration received during the preceding 12 month period or since the last Utilization R~~r~~eport, whichever is longer.

(6) A ~~Grant~~Awardee 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) ~~Grant~~Awardee shall have written agreements with its ~~Grant~~Awardee Personnel, Collaborators, licensees and transferees requiring such third parties to report to the ~~Grant~~Awardee information described in ~~this~~ subdivision (d~~e~~) of this section.

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

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

(g) In the event there is unlicensed Regulatory Use by a third party, the Awardee, upon learning of such unlicensed use, shall notify CIRM immediately.

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

§ 100603. Publication Requirements.

(a) A ~~Grant~~Awardee must provide for public access to any publication of a CIRM Funded Invention or CIRM-Funded Technology, as provided in this section.

(b) For any manuscript that is peer-reviewed and accepted for publication in a scientific journal, the ~~Grant~~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 months after the official date of publication. The ~~Grant~~Awardee shall make reasonable efforts to comply with this requirement through submission to PubMed Central, including notifying CIRM of the PubMed Central identification number. If the ~~Grant~~Awardee is unable to submit the manuscript to PubMed Central, the ~~Grant~~Awardee may comply by providing the manuscript to CIRM, no later than 12 months after the official date of publication. In lieu of the final peer-reviewed manuscript, the ~~Grant~~Awardee may submit the final published article.

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

(d) ~~Grant~~Awardees are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Regulation.

(e) Within 60 calendar days of the publication, ~~Grant~~Awardees shall notify CIRM of the ~~Grant~~Award Number, ~~Grant~~Awardee Institution, Principal Investigator and the PubMed Central identification number for the manuscript. In addition, ~~Grant~~Awardees shall provide CIRM with a short paragraph, written for the general public, describing both the importance of

the discovery that is the subject of the publication and the approach or methodology employed. Neither the publication abstract nor the statement of public benefit submitted as part of the application satisfy this requirement.

(f) A ~~Grant~~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 accessed to facilitate requests for Publication-related Biomedical Materials.

(g) Any written or oral publication reporting a CIRM-Funded Invention or CIRM-Funded Technology must acknowledge CIRM funding. An example of an acknowledgement is: "This research was made possible by a ~~grant~~award from the California Institute for Regenerative Medicine (~~Grant~~Award Number _____). ~~The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of CIRM or any other agency of the State of California.~~"

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 100604 to read:

§ 100604. Publication-Related Biomedical Materials Requirements.

(a) A ~~Grant~~Awardee shall share Publication-related Biomedical Material, for bona fide purposes of research in California. Such materials are to be shared without cost to the requestor or at the actual cost of providing the materials without an allocation of costs for overhead, research, discovery or other non-direct costs of providing the materials.

(b) A ~~Grant~~Awardee must share such materials within 60 calendar days of receipt of a written request, without bias as to the affiliation of the requestor, unless otherwise prohibited by law.

(c) CIRM may approve alternatives to this sharing requirement on a showing that:

(1) the number of sharing requests has become financially onerous for the ~~Grant~~Awardee;

(2) the material or its transfer could pose a public health risk; or

(3) the request is otherwise inappropriate, as determined by CIRM.

(d) In lieu of sharing as provided herein, a ~~Grant~~Awardee may provide requestors with the information necessary to reconstruct or obtain identical material.

(e) With prior approval from CIRM, a ~~Grant~~Awardee's obligations under this regulation may cease when the materials are made broadly commercially available. CIRM's review in response to a request for such approval shall include a determination of whether ~~Grant~~Awardee's terms for access are unreasonably onerous so as to create an unreasonable barrier to access to the materials.

(f) Prior to transferring any Publication-related Biomedical Material, a ~~Grant~~Awardee may require the requestor to execute an industry-standard or university-standard Material Transfer Agreement restricting the use and dissemination of such materials and its derivatives.

(g) A ~~Grant~~Awardee has no obligation under these regulations to share third party materials described in publications, patents, patent applications or presentations of CIRM-Funded Research or CIRM-Funded Technology or CIRM-Funded Inventions such as raw materials purchased by the ~~Grant~~Awardee to develop or synthesize the Publication-related Biomedical Material or other materials covered by third party intellectual property rights, or if the ~~Grant~~Awardee is legally prohibited from doing so.

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 100605 to read:

§ 100605. Patents.

(a) Nothing in these Regulations ~~grant~~awards CIRM an ownership interest in CIRM-Funded Inventions, CIRM-Funded Research or CIRM-Funded Technology.

(b) ~~Grant~~Awardees may retain or transfer all or a portion of any of ~~Grant~~Awardee's right, title or interest to any CIRM-Funded Invention or CIRM-Funded Technology or CIRM-Funded Research and to any patent or patent application relating thereto.

(c) ~~Grant~~Awardees shall bear the costs associated with any patent application disclosing or claiming any one or more CIRM-Funded Inventions, any patent itself, and all costs of pursuing, maintaining and protecting such applications patents. However, these Regulations shall not restrict the rights of ~~Grant~~Awardees to recover these costs through license fees or other consideration.

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 100606 to read:

§ 100606. Licensing and Assignment of CIRM-Funded Inventions and Technology.

(a) Subject to the provisions of Title 17, California Code of Regulations, section 100610, a ~~Grant~~Awardee shall make reasonable efforts to develop, commercialize or otherwise bring to practical application CIRM-Funded Technology or CIRM-Funded Inventions.

(b) If an ~~Grant~~Awardee elects not to develop, commercialize or otherwise bring to practical application a CIRM-Funded Invention or CIRM-Funded Technology itself, then it shall make reasonable efforts to negotiate ~~Non-Exclusive~~ Licenses for third party development of such CIRM-Funded Invention~~s~~ or CIRM-Funded Technology, unless (1) doing so would put the ~~Grant~~Awardee at a competitive disadvantage with a competitor, or (2) in the case of a CIRM DISC (or successor program) Award, the ~~Grant~~Awardee through reasonable means shares or otherwise makes publicly available the CIRM-Funded Invention~~s~~ or Technology.

(c) An ~~Grant~~Awardee may negotiate an Exclusive License for a CIRM-Funded Invention or CIRM-Funded Technology if exclusivity is reasonably believed by the ~~Grant~~Awardee to be an economic incentive necessary to achieve commercial development and availability of the invention.

~~(1) A Grant~~ The Awardee must document the development and commercialization capabilities of any intended exclusive licensee prior to entering ~~into~~ an Exclusive License.

~~(2) A Grant~~ The Awardee must include in any Exclusive License terms addressing all reasonably anticipated therapeutic and diagnostic uses for the CIRM Funded Invention or CIRM-Funded Technology that the licensee is prepared to diligently develop and commercialize. Such terms shall include the following:

(1A) a commercial development plan to bring the invention to practical application, including milestones and benchmarks, so that the Exclusive Licensee's progress of development can be assessed and monitored;

(2B) explicit remedies for failure to develop, including modification or termination of an Exclusive License in the event thatif a licensee is unable to fully develop the rights grantawarded; and

(3C) explicit grounds for modification or termination, such as failure to use commercially reasonable efforts to meet agreed-upon milestones or benchmarks, failure to negotiate in good faith alternative milestones or benchmarks, and failure to abide by subdivision (f) of this regulation.

(ed) A GrantAwardee may negotiate a License Agreementn Exclusive License[ST1] for a CIRM- Funded Invention or CIRM-Funded Technology that is required for commercialization of a Drug, as defined in Title 17, California Code of Regulations, section 100601, subdivision (i), only if the licensee agrees in writing to abide by the provisions of Title 17, California Code of Regulations, sections 100607 and 100608. The License Agreement shall include language stating the following: "The California Institute for Regenerative Medicine and the State of California are intended beneficiaries of this agreement".

(fe) Subject to the provisions of Title 17, California Code of Regulations, section 100610, a GrantAwardee bears responsibility for Licensing Activities including identification of potential licensees, negotiation of License Agreements, and documentation of the progress and execution of development under a License Agreement for all CIRM-Funded Inventions or CIRM-Funded Technology. A GrantAwardee must submit an annual Invention Utilization Report describing,

~~among other things, these licensing and/or assignment activities as described in Title 17, California Code of Regulations, section 100602.~~

(~~g~~f) In licensing CIRM-Funded Inventions or CIRM-Funded Technology Exclusively or Non-Exclusively, Non-Profit ~~Grant~~Awardees shall retain the right to practice the use of its CIRM-Funded Inventions or CIRM-Funded Technology and to utilize the same for its non-commercial purposes. Except for clinical data, a~~A~~ Non-Profit ~~Grant~~Awardee agrees to make its CIRM-Funded Inventions or CIRM-Funded Technology readily accessible on reasonable terms, directly or through a licensee or licensees or other suitable means, to other Non-Profit ~~Grant~~Awardees for non-commercial purposes, upon request from a Non-Profit ~~Grant~~Awardee.

~~(g) A Grantee must monitor and annually report to CIRM in its Invention Utilization Report the performance of an Exclusive Licensee to ensure that said Licensee performs according to the milestones and benchmarks as described in section 100602, subdivision (c).~~

(i~~h~~) A ~~Grant~~Awardee must take reasonable action to enforce the terms of an Exclusive License and must promptly report any material breach affecting any of the obligations under these regulations of an Exclusive License in writing to CIRM.

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 100607 to read:

§ 100607. Access Requirements for Products Developed by ~~Grant~~Awardees.

(a) A ~~Grant~~Awardee, ~~a Collaborator or an Exclusive Licensee that is commercializing a Drug, as defined in Title 17, California Code of Regulations, section 100601, subdivision (i), that resulted in whole or in part from CIRM-Funded Research~~Commercializing Entity must submit a plan to afford access to ~~such a~~a Drug to Californians who have no other means to purchase the Drug. As used in this section, "no other means" means Californians who are not covered by a prescription drug benefit provided by any third-party payer (private or public) covering the particular Drug, and whose family incomes are below 300 percent of the federal poverty level. The access plan must be consistent with industry standards at the time of commercialization accounting for the size of the market for the Drug and the resources of the ~~Grant~~Awardee, ~~the Collaborator or its Exclusive Licensee~~Commercializing Entity. ~~Grant~~Awardees, ~~Collaborators and/or their Exclusive Licensees~~Commercializing entities shall have the burden of establishing that the proposed access plan satisfies the requirements of this Section.

(b) A ~~Grant~~Awardee, ~~a Collaborator or an Exclusive Licensee that commercializes a Drug~~Commercializing Entity must submit the access plan described in subdivision (a) of this regulation to CIRM within 10 business days following final approval of the Drug by the federal Food and Drug Administration, unless, within that timeframe, the ~~Grant~~Awardee, ~~Collaborator or Exclusive Licensee~~Commercializing Entity seeks an extension from CIRM. If CIRM grants an extension, the access plan must be submitted no later than 30 business days following final approval of the Drug by the federal Food and Drug Administration.

(c) The access plan shall be subject to the approval of CIRM after a public hearing conducted by CIRM that provides for receipt of public comment. CIRM may adopt appropriate procedures to protect proprietary information submitted by ~~Grant~~Award~~Awardees, Collaborators and Exclusive Licensees~~ Commercializing Entities in connection with said public hearing. Approval shall not be unreasonably withheld. Overall, CIRM shall not require that proposed Access plans exceed industry standards for such plans at the time of commercialization in California.

(d) Access plans approved hereunder shall make ~~Grant~~Awardees~~, Collaborators and Exclusive Licensees that commercialize a Drug~~ a Commercializing Entity responsible only for providing the Drug itself. Nothing herein shall require the ~~Grant~~Award~~ee, Collaborator or Exclusive Licensee~~Commercializing Entity to be responsible for any costs of administering the Drug nor for any associate costs of medical procedures or protocols for the Drug therapy, nor for any costs for attendant care.

(e) The Independent Citizens Oversight Committee ("ICOC") may waive the requirement in subdivision (a) of this section if the ICOC determines, after a public hearing, that in the absence of the waiver, development and broad delivery of the Drug will be unreasonably hindered or that the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to subdivision (a) of this section. To invoke this waiver provision, a ~~Grant~~Award~~ee, Collaborator or Exclusive Licensee~~Commercializing Entity must deliver a written request to the Chair of the ICOC within 10 business days following final approval of the Drug by the federal Food and Drug Administration, unless the Chair of the ICOC agrees to an extension. The request must be accompanied by materials describing how

development and broad delivery of the Drug will be unreasonably hindered by compliance with subdivision (a) of this section, and/or how the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to subdivision (a) of this section. The request shall be posted on CIRM's website no fewer than ten (10) business days prior to the ICOC's consideration. The ICOC may meet in closed session to review confidential or proprietary material, or other material as allowed by Health and Safety Code section 125290.30, subdivision (d).

(f) A ~~GrantAwardee, Collaborator, or an Exclusive Licensee that is commercializing the Drug~~ Commercializing Entity must provide ~~a~~ the Drug~~, that resulted in whole or in part from CIRM-Funded Research, at a price as provided in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500) (or a successor statewide prescription drug discount program) to eligible Californians under said program.~~in accordance with any applicable statewide discount prescription drug program.

(g) A ~~GrantAwardee, Collaborator or its Exclusive Licensee that is commercializing the Drug~~ Commercializing Entity must sell a Drug, ~~that~~ which resulted in whole or in part from CIRM-Funded Research, and which is purchased in California with Public Funds (as defined in Title 17, California Code of Regulations, section 100601, subdivision (cc)) at any benchmark price described in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500) or a successor statewide prescription drug discount program.

(h) This regulation is not intended, and this regulation shall not be construed, to preempt or prevent any other requirement under state or federal law or regulation, or agreement or contract, that would result in selling a Drug at a lower price than provided hereunder.

Note: Authority cited: Article XXXV, California Constitution; and Section 125290.40(j), Health and Safety Code.
Reference: Sections 125290.30 and 125290.80, Health and Safety Code.

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

§ 100608. Revenue Sharing.

~~(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:~~

~~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.~~

~~(~~(a~~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 as follows:

(1) A royalty on Net Commercial Revenue at a rate of 0.1% per $1 million of CIRM ~~Grant~~Award utilized (s) for the earlier of Ten (10) years from the date of First Commercial Sale of the applicable Drug, product or service, or until such ~~royalty~~ payments equals nine times the amount of the ~~Grant~~Award(s). (By way of example, ~~Grant~~Awards 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~~Award or ~~Grant~~Awards were made in support of such CIRM-Funded Research, CIRM-Funded Technology or CIRM-Funded Inventions.

~~(3) For purposes of subdivision (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, effective January 27, 2014.~~

(4) Royalty payments owed pursuant to this section shall be paid within 60 days following the end of each calendar quarter and shall be paid to the California State Treasurer's Office, Division of Cash Management.

~~(bc) Grant~~Awardees 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.~~

~~(cd) 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.

Amend 17 Cal. Code of Regs. section 100609 to read:

§ 100609. Press Release Requirements.

~~Grant~~Awardees and Collaborators must notify CIRM's communications officer at least one calendar day before issuing any press release that refers to CIRM-Funded Research.

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 100610 to read:

§ 100610. March-In Rights.

(a) CIRM may request that a ~~Grant~~Awardee, Collaborator, Commercializing Entity or an Exclusive Licensee enter into a nonexclusive, partially exclusive, or Exclusive License Agreement with respect to a CIRM-Funded Invention or CIRM-Funded Technology, in any field of use or territory with a responsible applicant or applicants, upon terms that are reasonable under the circumstances.

(b) If a ~~Grant~~Awardee, Collaborator, Commercializing Entity or an Exclusive Licensee refuses CIRM's request to enter into a License Agreement to a CIRM-Funded Invention or CIRM-Funded Technology as provided by this regulation, CIRM shall have the right to enter into such a license with an applicant on behalf of the ~~Grant~~Awardee or its Exclusive Licensee (march-in) if :

(1) the ~~Grant~~Awardee, Collaborator, Commercializing Entity or an Exclusive Licensee has not made reasonable efforts to achieve practical application of a CIRM- Funded Invention and/or CIRM- Funded Technology, as applicable;

(2) the ~~Grant~~Awardee, Collaborator, Commercializing Entity or an Exclusive Licensee have failed to provide or comply with a plan for access to a Drug in accordance with Title 17, California Code of Regulations, section 100607;

(3) the ~~Grant~~Awardee, Collaborator, Commercializing Entity or Exclusive Licensee has unreasonably failed to use a CIRM- Funded Invention or CIRM- Funded Technology to alleviate public health and safety needs that constitute a public health emergency as declared by the Governor.

(c) One consideration in taking the action described in subdivision (b) of this regulation will be whether doing so will impinge on the ~~Grant~~Awardee's, Collaborator's, Commercializing Entity's or Exclusive Licensee's academic freedoms.

(d) CIRM will promptly notify a ~~Grant~~Awardee, Collaborator, Commercializing Entity or an Exclusive Licensee of any adverse determination under this provision and the basis therefore, as well as its intention to exercise march-in rights ("March-In Notice").

(e) CIRM will not exercise its march-in rights if the ~~Grant~~Awardee, Collaborator, Commercializing Entity or an Exclusive Licensee promptly takes action to cure the deficiency and such deficiency is cured sooner than one year from the date of the March-In Notice ~~-~~(or longer period by mutual agreement). With respect to a deficiency described in subdivision (b)(3) of this regulation, however, CIRM may exercise such right at any time in the event of a public health or safety emergency declared by the Governor and where CIRM finds that exercise of march-in rights is likely to alleviate the circumstances or conditions that give rise to the emergency declaration.

(f) Within thirty (30) days of the date CIRM issues a March-In Notice, the subject ~~Grant~~Awardee, Collaborator, Commercializing Entity or Exclusive Licensee may appeal CIRM's decision to the ICOC by notifying the President of CIRM in writing ~~-~~of its intent to appeal CIRM's decision. Within sixty (60) days of the March –In Notice date, the subject ~~Grantee~~appellant must submit a written statement of the reasons for the appeal and any supporting materials it wishes to have considered by the ICOC. Absent extraordinary circumstances, the ICOC shall render a final determination on the appeal within one hundred twenty (120) days of the March-In Notice. In cases where an appeal is filed, CIRM shall not effect a march-in unless and until the ICOC renders a final determination on the appeal. The

ICOC may reverse the decision of the CIRM to exercise march-in rights under this regulation for any reason.

(g) Unless provided otherwise by CIRM, any applicant to receive a License or Assignment pursuant to this regulation will be bound by this Chapter as if it were an original ~~Grant~~Awardee recipient of the funding that resulted in the applicable CIRM-Funded Invention or CIRM-Funded Technology.

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 100611 to read:

§ 100611. Assurance of Third-Party Compliance.

Any party that becomes a successor in interest by merger, purchase**,** assignment or any other means, of a ~~Grant~~Awardee, Collaborator, Commercializing Entity or Exclusive Licensee with regard to a CIRM-Funded Invention, CIRM-Funded Technology or CIRM-Funded Research, assumes all obligations of the ~~Grant~~Awardee, Collaborator, Commercializing Entity or Exclusive Licensee, as applicable, described in this Chapter.

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

Adopt 17 Cal. Code of Regs. section 100612 to read:

§ 100612. Application of Amended Regulations to Prior CIRM Awards.

In the event that an Awardee has a pre-existing CIRM Award(s) and subsequently receives an Award that is subject to this Chapter, this Chapter shall apply to all prior CIRM Award(s) made to that Awardee provided that the new award utilizes a CIRM-Funded Technology or CIRM-Funded Invention arising out of the prior CIRM Award(s).

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