~~Adopt~~ Amend Chapter 4, 17 Cal. Code of Regs. section ~~100300~~100400 to read:

~~§ 100300.~~Chapter 4 - Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit ~~Organizations~~ Grantees

§ 100400. Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit ~~Organizations~~Grantees - Scope.

The regulations of this chapter apply to all ~~CIRM grant awards issued~~California Institute for Regenerative Medicine ("CIRM") Grants ~~issued~~awarded to Non-Profit and For-Profit ~~Organizations~~Grantees on or after the effective date of these regulations. By accepting a CIRM ~~grant award~~Grant, the ~~grantee~~Grantee agrees to comply with ~~the provisions of~~ these regulations. Any new or amended regulations subsequently adopted by the Independent ~~Citizen's~~Citizens Oversight Committee ("ICOC") will ~~be applied to currently active grants~~apply to Currently Active Grants on the start date of the next non-competitive renewal period after the effective date of the regulations~~. A currently active grant is a grant that is still in the Project Period or a grant for which CIRM funds are still being expended. New or amended regulations under this chapter adopted after the expiration of the Project Period of a grant and after all CIRM funds for the grant have been expended will apply on January 1 following the effective date of the new or amended regulation, unless specified otherwise in the regulation. Principal investigators, program directors and organizational officials with active CIRM grants will receive notification of revised grant terms and conditions or revised editions of the CIRM Grants Administration Policy as they are released. In addition, all revisions to these~~, except amendments to Title 17, California Code of Regulations, sections 100406, 100407 and 100408, ~~which~~ shall only apply to ~~grants~~Grants awarded after adoption of the new or amended regulations. ~~CIRM will notify a Grantee's Principal Investigator and Authorized Organizational Official of the adoption of new~~

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~~or amended regulations. In addition, all~~ All revisions to CIRM regulations will be posted on the CIRM website at www.cirm.ca.gov~~. Failure by a principal investigator or other person affiliated with the grantee to have notification of new or amended regulations, revised grant terms and conditions, or revised editions of the Grants Administration Policy,~~of actual, which shall serve as notice to athe Grantee~~'s Principal Investigator or Authorized Organizational Official~~ shall not excuse non-compliance as long as the~~with any regulation if~~ CIRM has notified the grantee.~~Grantee of the changes.~~ or Authorized Organization Official of such revisions.

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

~~Adopt~~

Amend 17 Cal. Code of Regs. section ~~100301~~100401 to read:

§ ~~100301.~~100401. 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~~organizationGrantee, who is authorized to execute agreements that legally bind the ~~applicant institution~~institutionGrantee to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to ~~grant~~Grant applications or ~~grant~~Grant awards.

~~(b) "Award." The provision of funds by CIRM, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.~~

~~(c) "Bayh-Dole Act." Section 6(a) of the federal Patent and Trademark Law Amendments Act as amended (35 U.S.C. §§ 200-212).~~

~~(d) "Biomedical Materials." Entities of biomedical relevance first produced as a consequence of CIRM-funded scientific 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. 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.~~

~~(b) CIRM-funded Patented Invention. An invention that has been patented under Title 35 of the United States Code, and that resulted wholly or in part from CIRM-funded Research, except in the event the patent has expired, been abandoned or found to be invalid or otherwise unenforceable (unless noted otherwise in these regulations).~~

Decision: Bracketed language below – use "and" or use "or"? See also subdivisions (d) and (m).

(b) CIRM-Funded Invention. An Invention, whether patentable or not, arising from CIRM-Funded Research, conceived [and/or] first reduced to practice during the performance of a Currently Active Grant by a Grantee and/or its Collaborator(s).

(c) CIRM-~~funded Research. Research that has been funded in whole or in part by a CIRM Grant~~Funded Research.
All aspects of work conducted on a Currently Active Grant by a Grantee [and/or] its Collaborators(s) that is paid for, in whole or in part, with CIRM funds.

Decision: Same as subdivision (b).

(d) CIRM-Funded Technology. Data, materials, research results or know-how whether patentable or not, that is conceived {and/or} first reduced to practice in the performance of a Currently Active Grant~~,~~ and paid for in whole or in part with CIRM-funds.

(e) Collaborator. Any person or entity, other than a Grantee, who conducts research and/or related work described in a Grant application, including but not limited to Principal Investigators, researchers and "Key Personnel" identified in the Grant application.

(f) Currently Active Grant. A Grant: (i) that is still in the Project Period~~, or~~; (ii) that is outside the Project Period but CIRM Grant funds are still being spent on the project~~,~~; or (iii) for which the repayment of CIRM grant funds remains unsatisfied.

(~~e) "Data." The recorded factual material commonly accepted in the scientific community as necessary to validate research findings~~g) Data. Recorded information, regardless of form or the media on which it may be recorded, including, but not limited to, recorded information of a scientific or technical nature, 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. ~~This "recorded" material~~ "Data" excludes physical objects (e.g., laboratory samples).

(~~f) "Exclusive License." Any License Agreement for a CIRM-funded patented invention that permits the licensee to exclusively exercise any commercial right within the state of California or the United States, or within any field of use, or for any licensed product or licensed purpose.~~ h) 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 man or other 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, cells, and cell therapies.

(~~f~~i) Exclusive License. ~~A License Agreement~~ An agreement for ~~a CIRM-funded Patented~~CIRM-Funded Technology or a CIRM-Funded Invention that ~~authorizes~~transfers, or that conveys to the licensee ~~to~~, the exclusive exercise of, the right to make, use, sell, offer for sale and/or import in one or more ~~of the rights (or a portion of the rights) belonging to the patent holder under the patent.~~fields of use or territories.

(j) Exclusive Licensee. Any individual or entity receiving all rights 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, whether by assignment, license, or other mechanism.

(~~g~~j) For-Profit Organization. A legal entity that is organized for the profit or benefit of its shareholders or owners.

(~~h~~k) Grant. CIRM funding, other than a loan, in the form of a payment to conduct research and/or related work.

(~~g) "Grantee/Grantee Organization." The non-profit organization awarded a grant by~~i) Grantee. ~~A~~The Non-Profit Organization or For-Profit Organization ~~that receives~~awarded a Grant ~~and~~by CIRM that is legally responsible and accountable for the use of the funds provided and for the performance of ~~CIRM-funded Research.~~ the grant-supported project or activity. The ~~grantee~~Grantee is the entire legal entity, including Affiliates, even if only a particular ~~component~~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~~Grantee campuses shall be considered as separate and individual ~~Grantee Organizations.~~ Grantees.

~~(h) "Grantee Organization's Share." The revenues received by a Grantee Organization under a commercial license of a CIRM-funded patented invention remaining after deducting the direct costs associated with patents and patent applications claiming inventions made under CIRM funding and the inventor's share of those revenues.~~

~~(i) "Invention." A discovery that is or may be patentable (novel, useful and non-obvious) or otherwise protectable under Title 35 of the United States Code.~~

~~(j) "Invention Disclosure." A description of an invention that, if made public, would trigger a patent bar under U.S. Patent Law.~~

~~(k) "Invention Disclosure Form." A written notification to CIRM that a CIRM-funded patentable invention has been made.~~

~~(l) "Invention Utilization Report." Applicable to Grantee Organizations that have previously filed an Invention Disclosure Form, this annual report is a written description of efforts made by authorized organizational officials to commercialize CIRM-funded patentable inventions. This report will include information about the status of development, date of first commercial sale or~~

~~use and any licensing fees and/or gross royalties received by the Grantee Organization relating to CIRM-funded patented inventions.~~

Decision: Same as subdivision (b):

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

~~(m) "Inventor." A person who thinks of, finds, discovers, or creates an invention during the project period of a CIRM grant and using CIRM funds as determined under U.S. Patent Law.~~

~~(n) "License Agreement." An agreement by which a patent owner allows another party to make, use,~~ (n) Inventor. A person who contributes to the conception of an Invention.

(~~j~~o) License Agreement. An agreement by which ~~the~~an owner of a CIRM-~~funded Patented~~Funded Invention ~~allows a licensee to commercially use or develop the CIRM-funded Patented Invention~~or CIRM-Funded Technology conveys the right to make, use, develop, sell, offer to sell, and/or import ~~an invention protected by a patent~~a CIRM-Funded Invention or CIRM-Funded Technology in exchange for ~~financial or other~~ consideration.

~~(o) "Licensing Activities." Actions taken by authorized organizational officials, the desired outcome of which is a contractual agreement under which the Grantee Organization grants permission to another party to use intellectual property under specific conditions.~~

~~(p) "Licensing Fee." A one-time cost payable by a licensee to the patent owner typically associated with execution of a license agreement.~~

~~(q) "Materials Transfer Agreement." A document ("MTA") which governs the exchange of a substance, element or item (material) to another party for the purposes of research. It limits the commercial exploitation of the material without the permission of the provider party.~~

~~(r) "No-Cost License." An agreement to practice an invention protected by a patent where no licensing fee, royalty or any other payment is required of the licensee.~~

(~~k~~p) Licensing Activities. Efforts of ~~a Grantee to~~an owner or licensee of a CIRM-Funded Invention or CIRM-Funded Technology to negotiate, execute or enforce a License Agreement.

(~~l~~) q) Licensing Revenue. The consideration rendered to an owner or licensee of a CIRM-Funded Invention or CIRM-Funded Technology pursuant to a License Agreement. In the case of Non-Profit Grantee only, Licensing Revenue does not include amounts due to the Inventor pursuant to existing institutional policies.

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

~~(m) Net Licensing Revenue. Gross revenue derived from a License Agreement minus the direct costs incurred in the prosecution and protection of a CIRM-funded Patented Invention.~~

~~(n)~~s) Net Commercial Revenue. Income from ~~commercial sales of~~the sale or transfer, but not licensing or assignment, of a Drug or product(s) resulting in whole or in part from CIRM-~~funded~~Funded Research. Net Commercial Revenue excludes the following (as they pertain to the making, using or selling of products resulting from CIRM-~~funded~~Funded Research):

(1) import, export, excise and sales taxes, and customs duties;

(~~s) "Non-Profit Organization." A (1)~~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.

(t) Non-Exclusive License. An agreement that transfers, or that conveys to more than one viable licensee, the right to make, use, sell, offer for sale and/or import in a specified field of

use or territory, CIRM-Funded Technology or a CIRM-Funded Invention, including co-exclusive or semi-exclusive arrangements.(x) Non-Exclusive Licensee. Any individual or entity that shares with another individual or entity the right to make, use, sell, offer for sale and/or import in s specific field of use or territory, CIRM-Funded Technology or a CIRM-Funded Invention, through a Non-Exclusive License.

(u) 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)),; or (2) any other non-profit scientific or educational organization qualified under a state non-profit organization statute whose organizational charter provides that (A) the organization is not organized or operated for the private gain of any person, (B) no part of the organization's net income or assets shall inure to the benefit of any person, and (C) the organization's net assets upon dissolution shall be distributed to a non-profit fund, foundation or corporation which is organized and operated exclusively for charitable purposes.

(tv). " Notice of Grant Award." ("NGA"). The CIRM document that notifies the grantee and othersGrantee that an award has been made, contains or references all terms and conditions of the award, and documents the obligation of CIRM funds. obligations of the Grantee.

(u) "Patentable Invention." A novel, useful and non-obvious invention that advances science and enables new useful applications including therapeutics or diagnostic tools, as determined under relevant patent law.

(v) "Person." A "person" means an individual, proprietorship, firm, partnership, joint venture, syndicate, business trust, company, corporation, limited liability company, association, or any other organization or group of persons acting in concert.

(wow) " Principal Investigator/Program Director." The principal investigator ("PI") or program director ("PD. The Principal Investigator ("PI") is an individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible

~~and~~~~individual~~one or more individuals designated by the Grantee to direct CIRM-~~funded~~Funded Research and who is accountable to the ~~grantee~~Grantee and to CIRM for the proper conduct of ~~the project or activity. For training programs or similarly structured programs, the PD is the same as the PI.~~that research.

(~~x) "Project period." The total amount of time for which CIRM promises to fund a grant and authorizes a grantee to conduct the approved work of the project described in the application.~~px) Project Period. The amount of time over which CIRM funds research through a Grant.

(~~q~~y) 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.

(~~r~~z) Publication-related Biomedical Materials. Tangible research material of biomedical relevance first produced ~~by a Grantee~~ in the course of CIRM-~~funded~~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 100403. 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 ~~therapeutic products or diagnostic products~~tangible research material of biomedical relevance that is commercially available, as determined by CIRM pursuant to Title 17, California Code of Regulations section 100404, 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.

~~Adopt~~

Amend 17 Cal. Code of Regs. section ~~100302~~100402 to read:

§ ~~100302.~~100402. Invention and Licensing Reporting Requirements.

~~A Grantee must annually report to CIRM all patenting and Licensing Activities relating to CIRM-funded Research during and for 15 years after the Project Period of the Grant as follows:~~

(a) A Grantee ~~organizations are required to~~must have written agreements with ~~researchers~~Collaborators requiring prompt disclosure ~~of inventions made in the performance of CIRM-funded research.~~ to the Grantee of any CIRM-Funded Invention or CIRM-Funded Technology.

(b) Within 60 ~~days after an inventor discloses a CIRM-funded invention to a grantee organization, the grantee organization~~calendar days after a CIRM-Funded Invention or CIRM-Funded Technology has been disclosed to a Grantee, the Grantee must notify CIRM of the ~~invention~~CIRM-Funded Invention or CIRM-Funded Technology 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~~Grant under which the ~~invention~~CIRM-Funded Invention or CIRM-Funded Technology was made and the ~~inventor(s). It~~Inventor(s) and the Principle Investigator. The Notification 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 ~~invention. The disclosure shall also identify whether a manuscript describing the invention~~CIRM-Funded Invention or CIRM-Funded Technology. If the description has been submitted for publication~~. If so, the disclosure~~ or presentation, then the Notification shall identify the publication ~~to which the manuscript has been submitted and the submission date.~~

~~(c) Grantee organizations must notify CIRM on an annual basis regarding the filing of patent applications that claim inventions made in the performance of CIRM-funded research.~~

~~(d) Grantee organization must notify CIRM on an annual basis regarding execution of any licensing agreements of inventions made in the performance of CIRM-funded research. (e) Grantee organizations must submit annually an Invention Utilization Report that lists all CIRM-funded inventions, patents claiming such inventions and a statement of efforts made to utilize CIRM-funded inventions. Such reports shall include information about the status of development, date of first commercial sale or use and all licensing fees and/or gross royalties received by the grantee organization under licenses of CIRM-funded patented inventions.~~, the date of the abstract or manuscript or presentation, the submission date and if relevant any publication dates including publication via the internet. (c) A Grantee must submit annually to CIRM during, and for 15 years after, the Project Period of the Grant, an Invention Utilization Report that lists all CIRM-Funded Inventions, CIRM-Funded Technology, patents and patent applications disclosing or claiming such CIRM-Funded Inventions or CIRM-Funded Technology and all Licensing Activities, assignments, Exclusive Licenses, Non-Exclusive Licenses and Material Transfer Agreements relating to CIRM-Funded Inventions or CIRM-Funded Technology, including but not limited to, the following:

~~(a) A Grantee~~i) Grantees must report all patent applications filed ~~with respect to any inventions arising out of CIRM-funded Research~~disclosing and/or claiming any CIRM-Funded Inventions, including the countries in which application(s) were filed, application serial number(s), status and detailed description(s) of the ~~invention(s). These reports shall be marked confidential in accordance with Health and Safety Code section 125290.30, subdivision (e)(2)(B).~~ CIRM-Funded Invention(s).

~~(b) A Grantee~~ii) Grantees must report the issuance or ~~nonissuance~~abandonment of any patent applied for ~~with respect to inventions arising out of CIRM-funded Research~~that discloses

or claims a 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.

~~(c) At the time of filing of a patent application, a Grantee~~(iii) Grantees must report the ~~percentage of support provided by CIRM and by all other~~total funding from all sources ~~of funding~~ that directly contributed ~~in whole or in part to the discovery of the CIRM-funded invention~~to a CFI or CFT disclosed or claimed in the patent application. CIRM may audit all such co-funding reports. ~~This information shall be marked confidential in accordance with Health and Safety Code section 125290.30, subdivision (e)(2)(B).~~ CIRM may audit all such co-funding reports.

(~~d~~iv) A Grantee must report to CIRM the execution of ~~any Licensing Agreement pertaining to CIRM-funded Patented Inventions. This information shall be marked confidential in accordance with Health and Safety Code section 125290.30, subdivision (e)(2)(B). (e~~all Exclusive License Agreements, Non-Exclusive License Agreements, Material Transfer Agreements or Collaborative Agreements relating to CIRM-Funded Inventions or CIRM-Funded Technology. (v) In the event that a CIRM-~~funded Patented~~ Funded Invention or CIRM-Funded Technology generates revenue (whether from a License Agreement or otherwise), a Grantee must report such revenue received during the preceding 12 month period or since the last report, whichever is longer. ~~This information~~

(d) These Invention Utilization Reports shall be marked "confidential" in accordance with Health and Safety Code section 125290.30, subdivision (e)(2)(B).

(~~f~~e) CIRM reserves the right to itself and its agents to conduct an audit of the Grantee, Collaborator or an Exclusive Licensee or Non-Exclusive Licensee to ensure compliance with ~~this section~~these Regulations and the Grantee agrees to maintain and provide such documentation as 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.

~~Adopt~~

Amend 17 Cal. Code of Regs. section ~~100303~~100403 to read:

§ ~~100303.~~100403. Publication Requirements.

(a) Within 60 calendar days of the publication ~~of CIRM-funded research results~~ in a scientific journal~~, PIs of CIRM-funded Research, the PI~~, or the publication of an abstract in connection with a scientific meeting, of a CIRM-Funded Invention or CIRM-Funded Technology, the Grantee must submit to CIRM a 500 -word abstract written for the general public that highlights the findings of the ~~published body of work. In addition, PIs must submit a biographical sketch to accompany the abstract.~~publication, as well as a brief statement of the Principal Investigator's biographical credentials. The ~~abstract and the~~ biographical ~~sketch~~statement will be deposited into the publicly-accessible ~~CELR~~CIRM electronic library repository, to be accessed via the CIRM website.

(b) One copy of each publication ~~resulting from work performed under a CIRM grant~~of ~~CIRM-funded Research~~or abstract must accompany the ~~mandatory annual progress report~~~~report~~Invention Utilization Report submitted to CIRM~~.~~ pursuant to Title 17, California Code of Regulations, section 100402.

(c) ~~In~~ A Grantee must ensure that the final abstract or manuscript~~, authors must include of any publication of CIRM-funded Research~~ includes the URL of a website where ~~the CIRM~~an MTA (or similar document) can be accessed to facilitate requests for ~~publication~~Publication-related ~~materials~~Biomedical Materials.

(d) ~~CIRM grantees~~A Grantee Any written or oral publication reporting a CIRM-Funded Invention or CIRM-Funded Technology must acknowledge CIRM ~~support~~funding ~~of research findings in publications, announcements, presentations, and press releases by the grantees~~. An example of an acknowledgement is:

"~~The~~This research was made possible by a grant from the California Institute for Regenerative Medicine (Grant 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.

~~Adopt~~

Amend 17 Cal. Code of Regs. section ~~100304~~100404 to read:

§ ~~100304.~~100404. Publication-Related Biomedical Materials Requirements.

~~Grantees shall share biomedical materials first created under CIRM funding and described in published scientific articles for research purposes in California within 60 days of receipt of a request and without bias as to the affiliation of the requestor unless legally precluded. Under special circumstances, exceptions to the above are possible with approval by CIRM. Alternatively, authors may provide requestors with information on how to reconstruct or obtain the material.~~(a) A Grantee shall share Publication-related Biomedical Material ~~that results from CIRM-funded Research~~, 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 ~~material~~materials without an allocation of costs for overhead, research, discovery or other non-direct costs of providing the ~~material~~materials.

(b) A Grantee 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 Grantee;

~~(2) a sharing request is in direct conflict with the business of the Grantee;~~ (3) the material or its transfer could pose a public health risk; or

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

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

(e) With prior approval from CIRM, a Grantee's obligations under this regulation may cease when the materials are made broadly commercially available.

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

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

~~Adopt~~

Amend 17 Cal. Code of Regs. section ~~100305~~100405 to read:

~~§ 100305. Patent Applications.~~
§ 100405. Patents.

(a) Except as provided in Title 17, California Code of Regulations, section 100410, nothing in these Regulations grants CIRM an ownership interest in CIRM-Funded Research or CIRM-Funded Technology.

(b) Grantees may retain and transfer all or a portion of any of Grantee's right, title or interest to any patent application or patent that discloses or claims a CIRM-Funded Invention or CIRM-Funded Technology.

~~(a)~~ A ~~Grantee organizations~~(c) Grantees shall bear ~~responsibility for costs associated with patents and patent applications claiming their CIRM-funded inventions. This requirement~~the costs associated with any patent application disclosing or claiming any one or more ~~inventions arising out of CIRM-funded Research~~CIRM-Funded Inventions, any patent itself, and all costs of pursuing, maintaining and protecting such applications patents.

(d) These Regulations shall not restrict the rights of ~~Grantee Organizations~~Grantees to recover these costs through license fees or ~~otherwise.~~ other consideration.

~~(b) Grantee organizations shall report pursuant to Code of California Regulations, Title 17, section 100302, on an annual basis filings of such patent applications that claim inventions made in the performance of CIRM-funded research.~~

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

~~Adopt~~

Amend 17 Cal. Code of Regs. section ~~100306~~100406 to read:

§ ~~100306.~~100406. Licensing and Assignment of CIRM-Funded ~~Patented~~ Inventions and Technology.

~~(a) A Grantee Organization shall assume~~bears ~~responsibility for licensing activities~~Licensing Activities ~~including identification of potential licensees, negotiation of license agreements, and documentation of development progress for licenses relating to CIRM-funded patented inventions. In licensing CIRM-funded patented inventions, a Grantee Organizations agrees that it shall retain the right to practice the use of its CIRM-funded patented inventions for its non-commercial purposes. A Grantee Organization agrees to make its CIRM-funded patented inventions readily accessible on reasonable terms, directly or through a licensee or licensees, to other Grantee Organizations for non-commercial purposes, upon request from a Grantee Organization. Grantee organizations are required to submit an Invention Utilization Report relevant to CIRM-funded patented inventions on an annual basis.the progress and execution of development under a License Agreement of a CIRM-funded Patented Invention. A Grantee must submit an annual report of these Licensing Activities as described in Title 17, California Code of Regulations, section 100402.~~

(a) Subject to the provisions of Title 17, California Code of Regulations, section 100410, a Grantee shall make reasonable efforts to commercialize the development of CIRM-Funded Technology or CIRM-Funded Inventions.

(b) If a Grantee elects not to develop a CIRM-~~funded Patented~~Funded Invention or CIRM-Funded Technology itself, then it shall make ~~commercially~~ reasonable efforts to negotiate ~~non-exclusive licenses~~Non-Exclusive Licenses for third party development of such ~~inventions~~CIRM-Funded Inventions or CIRM-Funded Technology, unless doing so would put the Grantee at a competitive disadvantage with a competitor.

(c) CIRM reserves the right to itself and its agents to conduct an audit of the Grantee or the Non-Exclusive Licensees to confirm that Non-Exclusive Licensees are making reasonable efforts to commercialize the development of such inventions or technology.

(~~b~~e) A Grantee ~~organizations shall negotiate non-exclusive licenses of CIRM-funded inventions whenever possible. Nevertheless, grantee organizations may negotiate and award exclusive licenses for CIRM-funded inventions if such licenses are necessary to provide economic incentives required to enable~~may negotiate an Exclusive License for CIRM-Funded Invention or CIRM-Funded Technology if exclusivity is reasonably believed by the Grantee to be an economic incentive necessary to achieve commercial development and availability of the ~~inventions. In due diligence relating to such exclusive licenses, grantee organizations shall~~invention.

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

(2) A Grantee must include in any Exclusive License terms ~~in the license agreement~~ addressing all ~~relevant~~reasonably anticipated therapeutic and diagnostic uses for ~~which~~ the ~~invention is applicable and the licensee agrees to diligently develop.~~ CIRM Funded Invention or CIRM-Funded Technology.

(~~c) In exclusive license agreements, grantee organizations shall include terms for~~3) A Grantee must include in any Exclusive License terms including:

(A) a commercial development ~~plans~~plan to bring the invention to practical application~~. Such provisions shall include commercial development~~, including milestones and benchmarks, so that the progress of development can be assessed and monitored~~.~~;

(~~d) Grantee organizations shall grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies and diagnostics only to persons that agree to have a plan in place at the time of commercialization to provide access to resultant therapies and diagnostics for uninsured California patients. In addition, such licensees will agree to provide drugs at prices negotiated pursuant to the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500, et seq.) to eligible Californians under that program. This regulation is not intended, and this regulation shall not be construed, to preempt any other requirement under state or federal law or regulation that would otherwise require provision of drugs at a lower price than provided hereunder. The CIRM may make access plans available for review by the ICOC on an annual basis. (e) Grantee organizations shall monitor the performance of exclusive licensees of CIRM-funded patented inventions to ensure that the licensed invention is developed in a timely fashion. Remedies for failure to develop may include~~B) explicit remedies for failure to develop, including modification or termination of ~~a license by the grantee~~an Exclusive License in the event that a licensee is unable to fully develop the rights granted~~. (f) Grantee organizations shall negotiate relevant and specific~~; and

(C) explicit grounds for modification or termination ~~of the license. Examples would include failure to meet agreed-upon commercialization benchmarks, failure to keep the licensed invention reasonably accessible to the public for research purposes, and failure to reasonably meet the agreed-upon plan for access to resultant therapies as described in subdivision (d) of this regulation.~~, 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 ~~provide access as provided in~~abide by subdivision ~~(e)~~(5). f) of this regulation.

~~(g) Grantee organizations shall monitor the commercial development activities of the licensees to determine compliance with the terms of the license agreement and include reports of monitoring activities annually to the CIRM.~~

(4f) A Grantee may negotiate an Exclusive License for a CIRM-~~funded Patented~~ Funded Invention or CIRM-Funded Technology that is required for commercialization of a Drug, as defined in Title 17, California Code of Regulations, section 100401, subdivision (~~e~~h), only if the licensee agrees to abide by the provisions of Title 17, California Code of Regulations, section 100407.

(~~5)~~ g) Subject to the provisions of Title 17, California Code of Regulations, section 100410, a Grantee 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 Grantee 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 100402.

Decision: Maintain the following subdivision?

(h) In licensing CIRM-Funded Inventions or CIRM-Funded Technology Exclusively or Non-Exclusively, Non-Profit Grantees shall retain the right to practice the use of its CIRM-Funded Inventions or CIRM-Funded Technology and to utilize the same developed during the course of CIRM-Funded Research, for its non-commercial purposes. A Non-Profit Grantee agrees to make its CIRM-Funded Inventions or CIRM-Funded Technology readily accessible on reasonable terms, directly or through a licensee or licensees, to other Non-Profit Grantees for non-commercial purposes, upon request from a Non-Profit Grantee.

(i) A Grantee must monitor and annually report to CIRM in its Annual Utilization Report the performance of an ~~exclusive licensee~~Non-Exclusive License or Exclusive Licensee to ensure

that the ~~licensee~~Licensee develops the invention according to the milestones and benchmarks of the commercial development plan.

(~~h~~6j) A Grantee ~~organizations shall take administrative action to modify or terminate license rights where necessary and report such action~~must take ~~commercially~~ reasonable action to enforce the terms of an Exclusive License and must promptly report any material breach of an Exclusive License to the CIRM scientific program officer.

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

Reference: Section 125290.30, Health and Safety Code.

~~Adopt~~

Amend 17 Cal. Code of Regs. section ~~100308~~100407 to read:

§ ~~100308.~~**100407. Access Requirements for Products Developed by ~~For-Profit~~ Grantees.**

(a) A Grantee ~~(or, by terms of~~, a Collaborator or an Exclusive ~~License, its exclusive licensee)~~Licensee must submit a plan to afford uninsured Californians access to a Drug, as defined in Title 17, California Code of Regulations, section 100401, subdivision (e), ~~the development of~~ which ~~was~~resulted in whole or in part ~~the result of~~from CIRM-~~funded~~Funded Research.

(~~1~~b) A Grantee, a Collaborator or an Exclusive Licensee must submit this access plan to CIRM ~~at~~no fewer than 90 calendar days prior to the time the Drug is commercialized~~.~~ in California, unless the agency agrees to shortened time.

(~~2~~c) 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 Grantee or its exclusive licensee.

~~(3) CIRM will review the access plan and may make it available for review by the ICOC and the public.~~

(d) The plan shall be subject to the approval of CIRM after a public hearing conducted by CIRM that provides for receipt of public comment.

(~~4~~e) The Grantee ~~or its exclusive licensee~~, Collaborator or an Exclusive Licensee is responsible only for providing the Drug itself, not any costs of administering the Drug or other attendant care.

(~~b~~f) A Grantee ~~(or its exclusive licensee)~~, Collaborator, or an Exclusive Licensee must provide a Drug, the development of which was in whole or in part the result of CIRM-~~funded~~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 this program.

(~~e~~g) A Grantee or its ~~exclusive licensee~~Exclusive Licensee must sell a Drug, the development of which is in whole or in part the result of CIRM-~~funded~~Funded Research, and which is purchased in California with Public Funds (as defined in Title 17, California Code of Regulations, section 100401, subdivision (q)) at any benchmark price described in the California Discount Prescription Drug Program or a successor statewide prescription drug discount program.

(~~d~~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; Section 125290.40(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

~~Adopt~~

Amend 17 Cal. Code of Regs. section 100408 to read:

§ 100408. Revenue Sharing.

(a) ~~Grantee organizations shall share a fraction of any net revenues with the inventor(s) in accordance with their established policies. Net revenues are defined as gross revenues minus the direct costs incurred in the generation and protection of the patents from which the revenues are received.~~ A Grantee must share with the State of California a fraction of ~~any Net~~ Licensing Revenue ~~it~~the Grantee receives under a License Agreement for a CIRM-~~funded Patented~~Funded Invention or CIRM-Funded Technology as follows:

(~~b) The grantee organization may retain a threshold amount of its share (after payments to inventors) of any net revenues received under a license agreement or agreements of any CIRM-funded patented invention(s). Thereafter, the grantee organization shall pay 25% of its share after payments to inventors of such net revenues~~1) Subject to subdivision (a)(2) of this regulation, a Grantee must pay 25 percent of ~~Net~~ Licensing Revenue in excess of $500,000 to the State of California for deposit into the State's General Fund ~~unless such action violates any federal law~~. The threshold amount ~~is~~of $500,000 (in the aggregate) ~~multiplied by~~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 ~~February, 2006,~~~~December 2007,~~June 2008, and the numerator of which is such Index published for the month in which the ~~grant award is accepted by the grantee~~Grantee accepts the Grant.

(~~c) If funding sources in addition to CIRM were used in the creation of a CIRM-funded patented invention,~~2) If funding sources other than CIRM (including those of the Grantee)

directly contributed to the development of a CIRM-~~funded Patented~~ Funded Invention or CIRM-Funded Technology, then the return to the State of California ~~of any resultant revenues~~on ~~Net~~ 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 ~~for the discovery of the invention.~~ , as follows: The amount of CIRM funding of the ~~patented invention~~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 ~~Net~~ Licensing Revenue.

~~(d) Grantees shall apply the grantee organization's share of any revenues earned as a result of CIRM-funded patented inventions to the support of scientific research or education.~~

(b) A Grantee must share with the State of California a fraction of any Net Commercial Revenue it receives from a self-commercialized product resulting from its CIRM-~~funded~~Funded Research (regardless of whether a CIRM-~~funded Patented~~ Funded Invention or CIRM-Funded Technology is involved) as follows:

(1) A Grantee 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. The precise rate of payback in the form of a royalty shall be negotiated between the Grantee and CIRM, but in no event shall be less than two (2) percent nor more than five (5) percent of the annual Net Commercial Revenue from the invention, unless the product achieves blockbuster status, as provided in subdivisions (b)(2) and (b)(3) below. **Decision:** Should the range of rate of payback be eliminated in favor of a rate fixed in the regulation?(2) If Net Commercial Revenue from a

self-commercialized product resulting from its CIRM-Funded Research exceeds the milestone of $250 million per year ~~from a self-commercialized CIRM-funded Patented Invention~~, and then if Net Commercial Revenue exceeds the milestone of $500 million per year from a self-commercialized ~~CIRM-funded Patented Invention~~product resulting from its CIRM-Funded Research, then upon the first occurrence of each of these milestones the Grantee will pay to the State of California a one-time blockbuster payment of three times the total amount of the Grant.

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

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

~~Adopt~~

Amend 17 Cal. Code of Regs. section ~~100309~~100409 to read:

§ ~~100309.~~100409. Press Release Requirements.

~~CIRM grantees must notify CIRM prior to any press releases that refer to research findings, collaborations, inventions, patents or licensing activities that arise as a consequence of CIRM funding by contacting the CIRM Communications Officer and the Scientific Program Officer. In the event that the CIRM wishes to participate in a joint press release, the grantee will coordinate with the CIRM Communications Officer.~~

A Grantee must notify CIRM's communications officer at least one calendar day in advance of issuing any press release that refers to CIRM-~~funded~~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.

~~Adopt~~

Amend 17 Cal. Code of Regs. section ~~100310~~100410 to read:

§ ~~100310.~~100410. March-In Rights.

(a) ~~With regard to CIRM-funded patented inventions, CIRM shall have the right to require the grantee organization, or exclusive licensee of a CIRM-funded invention, to grant~~CIRM may request that a Grantee or its ~~exclusive licensee to~~Exclusive Licensee enter into a nonexclusive, partially exclusive, or ~~exclusive license~~~~exclusive~~Exclusive License Agreement with respect to a CIRM-~~funded Patented~~Funded Invention ~~and/~~or ~~data generated in CIRM-funded Research~~CIRM-Funded Technology, in any field of use ~~to~~or territory with a responsible applicant or applicants, upon terms that are reasonable under the circumstances~~, and if the grantee organization,~~.

(b) If a Grantee or its ~~exclusive licensee refuses such request, to grant such a license itself, if the CIRM determines that such an action is required~~~~licensee~~Exclusive Licensee refuses CIRM's request to enter into a License Agreement to a CIRM-~~funded Patented~~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 Grantee or its exclusive licensee (march in) if :

(1) ~~Because the grantee organization or the licensee~~the Grantee or its ~~exclusive licensee~~Exclusive Licensee has not made ~~responsible efforts in a~~~~commercially~~ reasonable ~~time~~efforts to achieve practical application of a CIRM-~~funded patented invention~~~~Patented~~ Funded Invention and/or CIRM-~~funded Research data~~ Funded Technology, as applicable;

(2) ~~Because the licensee~~the Grantee or its ~~exclusive licensee~~Exclusive Licensee has failed to ~~adhere to the agreed-upon~~provide or comply with a plan for access to ~~resultant therapies as~~

~~described in subdivision (d) of Code of~~a Drug in accordance with Title 17, California Code of Regulations, ~~Title 17,~~ section ~~100306~~100407;

~~(3) To meet requirements for public use and the requirements have not been satisfied by the grantee organization or its licensee;~~

Decision: Should the following subdivision be eliminated?

(3) the Grantee or its exclusive licensee has failed to satisfy requirements for public use, including broad availability in California (for reasons other than price) in accordance with Title 17, California Code of Regulations, section 100407;

(4) ~~To~~~~the Grantee or its exclusive licensee~~Exclusive Licensee has unreasonably failed to use a CIRM-~~funded Patented~~ Funded Invention or CIRM-~~funded Research data~~ Funded Technology to alleviate public health and safety needs ~~which are not reasonably satisfied by the grantee organization or its licensee and which needs~~that constitute a public health emergency as declared by the Governor.

(~~b) CIRM will give to the grantee or licensee notice of such~~c) CIRM will promptly notify a Grantee or its ~~exclusive licensee~~Exclusive Licensee of any adverse determination under this provision and the basis ~~on which it was made.~~therefore, as well as its intention to exercise march-in rights.

(d) CIRM will not exercise its ~~rights described above if the grantee or licensee takes diligent action promptly~~march-in rights if the Grantee or its ~~exclusive licensee~~Exclusive Licensee promptly takes action to cure the deficiency and such deficiency is cured sooner than one year from ~~receipt~~the date of notice (or longer period by mutual agreement). With respect to a deficiency described in subdivision (~~a~~b)(~~4~~43) 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.

(e) At any time within one year of the date CIRM issues a notice of determination and intent to exercise march-in rights, a Grantee may appeal CIRM's decision to the ICOC by notifying the President of CIRM in writing within 30 calendar days of the next regularly scheduled meeting of the ICOC of its intent to appeal CIRM's decision. The ICOC may reverse the decision of the CIRM to exercise march-in rights under this regulation for any reason.

(f) ~~Any~~ Unless provided otherwise by CIRM, any applicant to receive a ~~license~~License or Assignment pursuant to this regulation will be bound by this Chapter as if it were an original Grantee recipient of the funding that resulted in the applicable CIRM-~~funded Patented~~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.

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Document 2	interwovenSite://OHSPRDMS01/SVCA/237924/1
Rendering set	standard

Legend:	
Insertion	
~~Deletion~~	
~~Moved from~~	
Moved to	
Style change	
Format change	
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Total changes	424

Document comparison done by Workshare DeltaView on Friday, November 14, 2008 1:48:20 PM

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Document 2	interwovenSite://OHSPRDMS01/SVCA/237931/1
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Moved to	
Style change	
Format change	
~~Moved deletion~~	
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Moved cell	
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Padding cell	

Statistics:	
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