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

**Chapter 4 - Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations**

**§ 100400. Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations - Scope.**

The regulations of this chapter apply to all CIRM Grants issued to For-Profit Organizations 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 subsequently adopted by the Independent Citizens Oversight Committee ("ICOC") will apply to Currently Active Grants on the start date of the next non-competitive renewal period after the effective date of the regulations, except amendments to Title 17, California Code of Regulations sections 100406, 100407 and 100408, which shall only apply to 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 or amended regulations. In addition, all revisions to CIRM regulations will be posted on the CIRM website at www.cirm.ca.gov. Failure of actual notice to a Grantee shall not excuse non-compliance with any regulation if CIRM has notified the Grantee of the changes.

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

Adopt 17 Cal. Code of Regs. section 100401 to read:

**§ 100401. Intellectual Property Regulations - Definitions.**

(a) Authorized Organizational Official. The individual, named by the applicant organization, who is authorized to execute agreements that legally bind the applicant institution to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to Grant applications or Grant awards.

(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).

(c) CIRM-funded Research. Research that has been funded in whole or in part by a CIRM Grant.

(d) Currently Active Grant. A Grant that is still in the Project Period, or that is outside the Project Period but CIRM funds are still being spent on the project, or the repayment of CIRM grant funds remains unsatisfied.

(e) 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) Exclusive License. A License Agreement for a CIRM-funded Patented Invention that authorizes the licensee to the exclusive exercise of one or more of the rights (or a portion of the rights) belonging to the patent holder under the patent.

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

(h) Grant. CIRM funding in the form of a payment to conduct research.

(i) Grantee. A For-Profit Organization that receives a Grant and that is legally accountable for the funds and for the performance of CIRM-funded Research.

(j) License Agreement. An agreement by which the owner of a CIRM-funded Patented Invention allows a licensee to commercially use or develop the CIRM-funded Patented Invention in exchange for financial or other consideration.

(k) Licensing Activities. Efforts of a Grantee to execute or enforce a License Agreement.

(l) Material Transfer Agreement. An agreement that governs the transfer of tangible research material between organizations and defines the rights of the providor and 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) Net Commercial Revenue. Income from commercial sales of a product(s) resulting 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.

(n) Principal Investigator. The Principal Investigator ("PI") is an individual designated by the Grantee to direct CIRM-funded Research and who is accountable to the Grantee and to CIRM for the proper conduct of that research.

(o) Project Period. The amount of time over which CIRM funds research through a Grant.

(p) 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.

(s) Publication-related Biomedical Materials. Tangible research material of biomedical relevance first produced by a Grantee in 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 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.

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 100402 to read:

**§ 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 must report all patent applications filed with respect to any inventions arising out of CIRM-funded Research, including the application serial number(s), 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).

(b) A Grantee must report the issuance or nonissuance of any patent applied for with respect to inventions arising out of CIRM-funded Research, including the patent number and date of issuance.

(c) At the time of filing of a patent application, a Grantee must report the percentage of support provided by CIRM and by all other sources of funding that contributed in whole or in part to the discovery of the CIRM-funded invention. 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).

(d) 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) In the event that a CIRM-funded Patented Invention 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 shall be

marked confidential in accordance with Health and Safety Code 125290.30, subdivision (e)(2)(B).

(f) CIRM reserves the right to itself and its agents to conduct an audit of the Grantee to ensure compliance with this section 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 17 Cal. Code of Regs. section 100403 to read:

**§ 100403. Publication Requirements.**

(a) Within 60 days of the publication in a scientific journal of CIRM-funded Research, the PI must submit to CIRM a 500-word abstract written for the general public that highlights the findings of the publication, as well as a brief statement of the Principal Investigator's biographical credentials. The abstract and the biographical statement will be deposited into the publicly-accessible CIRM Electronic Library Repository, to be accessed via the CIRM website.

(b) One copy of each publication of CIRM-funded Research must accompany the annual progress report submitted to CIRM pursuant to Title 17, California Code of Regulations section 100402.

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

(d) A Grantee must acknowledge CIRM funding of research in publications, announcements, presentations, and press releases. An example of an acknowledgement is:

"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 17 Cal. Code of Regs. section 100404 to read:

**§ 100404. Publication-Related Biomedical Materials Requirements.**

(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 materials without an allocation of costs for overhead, research, discovery or other non-direct costs of providing the materials.

(b) A Grantee must share such materials within 60 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.

(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 may require the requestor to execute an industry-standard Material Transfer Agreement restricting the use and dissemination of such materials.

**Option:** (g) A Grantee has no obligation under these regulations to share third party materials described in publications of CIRM-funded Research 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 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 17 Cal. Code of Regs. section 100405 to read:

**§ 100405. Patents.**

A Grantee shall bear the costs associated with any patent application claiming any one or more inventions arising out of CIRM-funded Research, any patent itself, and all costs of protecting such patents.

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

Adopt 17 Cal. Code of Regs. section 100406 to read:

**§ 100406. Licensing CIRM-Funded Patented Inventions.**

(a) 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 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.

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

(c)A Grantee may negotiate an Exclusive License if exclusivity is reasonably believed by Grantee to be an economic incentive necessary to achieve commercial development and availability of the invention.

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

(2) A Grantee must include in any Exclusive License terms addressing all reasonably anticipated therapeutic and diagnostic uses for the invention .

(3) A Grantee must include in any Exclusive License terms including:

(i) a commercial development plan to bring the invention to practical application, including milestones and benchmarks, so that the progress of development can be assessed and monitored;

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

(iii) 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 provide access as provided in subdivision (c)(5).

(4) A Grantee may negotiate an Exclusive License for a CIRM-funded Patented Invention that is required for commercialization of a Drug, as defined in Title 2, California Code of Regulations section 100401, subdivision (d), only if the licensee agrees to abide by the provisions of Title 17, California Code of Regulations, section 100407.

(5) A Grantee must monitor and annually report to CIRM the performance of an exclusive licensee to ensure that the licensee develops the invention according to the milestones and benchmarks of the commercial development plan.

(6) A Grantee 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: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100407 to read:

**§ 100407. Access Requirements for Products Developed by For-Profit Awardees.**

(a) A Grantee (or, by terms of an Exclusive License, its exclusive 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 (d), the development of which was in whole or in part the result of CIRM-funded Research.

(1) A Grantee must submit this access plan to CIRM at the time the Drug is commercialized.

(2) 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.

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

(b) A Grantee (or its exclusive licensee) must provide a Drug, the development of which was in whole or in part the result of CIRM-funded Research, at a price as provided in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500, et seq.) (or a successor statewide prescription drug discount program) to eligible Californians under this program.

(c) A Grantee or its exclusive licensee must sell a Drug, the development of which is in whole or in part the result of CIRM-funded Research, and which is purchased in California with public funds (as defined in Title 17, California Code of Regulations, section 100401, subdivision

(p)) at any benchmark price described in the California Discount Prescription Drug Program or a successor statewide prescription drug discount program.

(d) 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: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

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

**§ 100408. Revenue Sharing.**

(a) A Grantee must share with the State of California a fraction of any Net Licensing Revenue it receives under a License Agreement for a CIRM-funded Patented Invention as follows:

(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. 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 December 2007, and the numerator of which is such Index published for the month in which the Grantee accepts the Grant.

(2) If funding sources other than CIRM (including those of the Grantee) contributed to the development of a CIRM-funded Patented Invention, then the return to the State of California on Net Licensing Revenue in excess of the amount described in subdivision (a)(1) of this regulation shall be proportionate to the support provided by CIRM, as follows: The amount of CIRM funding of the patented invention 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.

(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 CIRM-funded Research (regardless of whether a CIRM-funded patented invention 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 shall 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 below.

(2) If Net Commercial Revenue exceeds $250 million per year and then exceeds $500 million per year from a self-commercialized CIRM-funded Patented Invention, then at 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 Invention(s) 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 Research that contributed to the creation of Net Commercial Revenue, the Grantee will pay the State of California one percent 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 17 Cal. Code of Regs. section 100409 to read:

**§ 100409. Press Release Requirements.**

A Grantee must notify CIRM's Communications Officer at least one day in advance of 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.

Adopt 17 Cal. Code of Regs. section 100410 to read:

**§ 100410. March-In Rights.**

(a) CIRM may request that a Grantee or its exclusive licensee to enter into a nonexclusive, partially exclusive, or exclusive License Agreement with respect to a CIRM-funded Patented Invention and/or data generated in CIRM-funded Research, in any field of use with a responsible applicant or applicants, upon terms that are reasonable under the circumstances.

(b) If a Grantee or its exclusive licensee refuses CIRM's request to enter into a License Agreement to a CIRM-funded Patented Invention 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) the Grantee or its exclusive licensee has not made commercially reasonable efforts to achieve practical application of a CIRM-funded Patented Invention and/or CIRM-funded Research data, as applicable;

(2) the Grantee or its exclusive licensee has failed to provide or comply with a plan for access to a Drug in accordance with Title 17, California Code of Regulations, section 100407;

(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) the Grantee or its exclusive licensee has unreasonably failed to use a CIRM-funded Patented Invention or CIRM-funded Research data to alleviate public health and safety needs that constitute a public health emergency as declared by the Governor.

(c) CIRM will promptly notify a Grantee or its exclusive licensee of any adverse determination under this provision and the basis therefore, as well as its intention to exercise march-in rights.

(d) CIRM will not exercise its march-in rights if the Grantee or its excusive licensee promptly takes action to cure the deficiency and such deficiency is cured sooner than one year from the date of notice (or longer period by mutual agreement). With respect to a deficiency described in subdivision (a)(4) 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 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 applicant to receive a license 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 Invention.

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