

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

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

4 **§ 100600. Intellectual Property and Revenue Sharing Requirements for Non-Profit and**
5 **For-Profit Grantees - Scope.**

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

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

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

2 **§ 100601. Intellectual Property Regulations - Definitions.**

3 The following definitions apply to the regulations in this chapter:

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

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

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

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

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

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

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

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

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

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

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

(j) 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 the licensee the sole right

1 to make, use, sell, offer for sale and/or import in one or more fields of use or territories, as to a
2 CIRM-Funded Invention or CIRM-Funded Technology, that is not available to be licensed to
3 other entities or persons.

4 (l~~k~~) Exclusive Licensee. Any individual or entity receiving by license all rights to make,
5 use, sell, offer for sale and/or import in one or more fields of use or territories a CIRM-Funded
6 Technology or a CIRM-Funded Invention.

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

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

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

16 (p~~n~~) Grantee. The Non-Profit Organization or For-Profit Organization awarded a Grant
17 by CIRM that is legally responsible and accountable for the use of the CIRM funds provided for
18 the performance of the grant-supported project or activity. The Grantee is the entire legal entity,
19 including Affiliates, even if only a particular division is designated in the Notice of Grant Award
20 (“NGA”). An entity is an Affiliate of a Grantee if both entities share substantial common
21 direction or control (either directly or indirectly), or if either entity owns (directly or through one
22 or more entities) at least a 25% capital or profits interest in the other. All University of
23 California Grantee campuses shall be considered as separate and individual Grantees.

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

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

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

(tr) License Agreement. An agreement by which an owner of a CIRM-Funded Invention or CIRM-Funded Technology conveys the right to make, use, develop, sell, offer to sell, and/or import a CIRM-Funded Invention or CIRM-Funded Technology in exchange for consideration.

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

(vt) Licensing Revenue. The consideration received from the license of a CIRM-Funded Invention or CIRM-Funded Technology (provided however that with respect to a For-Profit Grantee or For-Profit Collaborator, Licensing Revenue does not include pre-commercial revenues such as development milestones and upfront payments). Licensing revenue excludes any additional grants, loans and other forms of research funding obtained to support the Project.

Calculation: Revenue is calculated by subtracting a proportion of expenses reasonably incurred in prosecuting, defending and enforcing related patent rights equal to CIRM's percentage of support for development of such CIRM-Funded Invention and/or CIRM-Funded Technology from total consideration rendered, except to the extent that such expenses are recoverable from a third party as provided in Section 100605(c) or otherwise. In the case of non-profit Grantees and non-profit Collaborators Licensing Revenue is calculated by subtracting

1 amounts due to the Inventor pursuant to existing institutional policies from total consideration
2 rendered.

3 ~~rendered to an owner or Collaborator of a CIRM-Funded Invention or CIRM-Funded~~
4 ~~Technology pursuant to a License Agreement, but excludes subsequent research funding. In the~~
5 ~~case of Non-Profit Grantees only, Licensing Revenue is calculated by subtracting amounts due to~~
6 ~~the Inventor pursuant to existing institutional policies from total consideration rendered. For all~~
7 ~~owners of a CIRM-Funded Invention or CIRM-Funded Technology, Licensing Revenue is~~
8 ~~calculated by subtracting a proportion of expenses reasonably incurred in prosecuting, defending~~
9 ~~and enforcing related patent rights equal to CIRM's percentage of support for development of~~
10 ~~such Invention and Technology from total consideration rendered except to the extent that such~~
11 ~~expenses are recoverable from a third party as provided in Section 100605(e) or otherwise.~~

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

16 (xv) Net Commercial Revenue. Income from the sale in any country or transfer (but not
17 licensing or assignment) of a Drug, ~~or~~ product(s) or services resulting in whole or in part from
18 CIRM-Funded Research. Net Commercial Revenue excludes the following (as they pertain to
19 the making, using or selling of products resulting from CIRM-Funded Research):

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

21 (2) costs of insurance, packing, and transportation from the place of manufacture to the
22 customer's premises;

23 (3) credit for returns, allowances or trades; and

1 (4) pre-commercial revenues received in connection with research and development
2 and/or clinical activities, such as upfront and milestone payments.

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

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

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

13 (b~~bz~~) Notice of Grant Award (“NGA”). The document that notifies the Grantee and
14 others that an award has been made, contains or references all terms and conditions of the award
15 as well as the Grantee’s and Principal Investigator’s agreement to those terms and conditions,
16 and documents the commitment of CIRM funds.

17 (c~~caa~~) Principal Investigator. The Principal Investigator (“PI”) is an individual
18 designated by the Grantee to direct CIRM-Funded Research. He or she is responsible and
19 accountable to the Grantee and CIRM for the proper conduct of the project or activity.
20 References herein to “Principal Investigator” include Co-Principal Investigators as well.

21 (d~~ddb~~) Project Period. The amount of time over which CIRM funds a a specific Grant.

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

(~~ffdd~~) Publication-Related Biomedical Materials. Tangible research material of biomedical relevance first produced in the course of CIRM-Funded Research including but not limited to unique research resources (such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data), as described in a published scientific paper as provided by Title 17, California Code of Regulations, section 100603. Specific examples include specialized and/or genetically defined cells, including normal and diseased human cells, monoclonal antibodies, hybridoma cell lines, microbial cells and products, viruses and viral products, recombinant nucleic acid molecules, DNA probes, nucleic acid and protein sequences, certain types of animals including transgenic mice and other property such as computer programs. This term does not include tangible research material of biomedical relevance that is made commercially available by a Grantee, Grantee Personnel, Licensee or a Collaborator, as determined by CIRM pursuant to Title 17, California Code of Regulations section 100604, subdivision (e).

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

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

2 **§ 100602. Invention and Licensing Reporting Requirements.**

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

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

17 (c) Within 60 calendar days after a Grantee executes an exclusive license agreement,
18 non-exclusive license agreement, material transfer agreement, research collaboration agreement,
19 or any other agreement conveying rights in CIRM-Funded Inventions or CIRM-Funded
20 Technology, a Grantee shall notify CIRM of the execution of such agreement(s) and submit to
21 CIRM a copy of the executed agreement. The notification and agreement(s) shall be marked
22 “Confidential” in accordance with Health and Safety Code section 125290.30, subdivision
23 (e)(2)(B).

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

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

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

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

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

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

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

1 (A) Initiation of clinical testing;

2 (B) Initiation of pivotal studies; and

3 (C) Application for marketing approval.

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

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

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

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

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

§ 100608. Revenue Sharing.

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

(1) ~~InSubject to subdivision (a)(2) of this regulation and to adjustments made in accordance with the~~ event that CIRM funds at least one half of the total cost of the CIRM-Funded Project resulting in the licensed or transferred CIRM-Funded Invention, CIRM-Funded Technology or results of CIRM-Funded Research. then provisions hereof, the amount owed is 25 percent of Licensing Revenue received in excess of \$500,000 and shall be payable to the State of California for deposit into the State's General Fund (such payments to be used by the State of California in a manner consistent with Title 35 United States Code, Section 202, subdivision (c)(7)). The threshold amount of \$500,000 (in the aggregate) shall be adjusted annually by a multiple of a fraction, the denominator of which is the Consumer Price Index, All Urban Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the Bureau of Labor Statistics of the United States Department of Labor and published for the month of October 2009, and the numerator of which is such Index published for the month in which the Grantee accepts the Grant. In the event that CIRM funds less than one half of the total cost of the CIRM-Funded Project resulting in the licensed or transferred CIRM Funded Invention, CIRM Funded Technology or results of CIRM-Funded Research then the amount owed is 15 percent of Licensing Revenue in excess of the threshold amount described above.

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

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

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

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

1 CIRM Grant(s) for the earlier of Ten (10) years~~three (3) percent of the annual Net Commercial~~
2 ~~Revenue~~ from the date of First Commercial Sale; or nine times the ~~product.~~

3 ~~(2) In addition, if Net Commercial Revenue from a product commercialized by the~~
4 ~~Grantee, or Collaborators and which resulted from its CIRM-Funded Research exceeds the~~
5 ~~milestone of \$250 million in any calendar year, a one-time payment of three times the total~~
6 ~~amount of the Grant(s); (By way of example, Grants totaling \$15 million) awarded shall be paid~~
7 ~~to the State of California. In addition, if Net Commercial Revenue exceeds the milestone of~~
8 ~~\$500 million in any calendar year, an additional one-time payment of three times the total~~
9 ~~amount of the Grant(s) awarded shall be paid to the State of California.~~

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

20 (2) In addition, upon satisfaction of the obligation in subsection (b)(1) above, a
21 1% royalty shall be owed on Net Commercial Revenues in excess of \$500 million per
22 year, until the last to expire patent covering a CIRM Funded Invention, if any, that
23 generates, or plays a role in the generation of, in whole or in part said Net Commercial

1 Revenue; provided at least \$5 million in CIRM Grant or Grants were made in support of
2 such CIRM-Funded Research, CIRM Funded Technology or CIRM Funded Inventions

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

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

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

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

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