

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

3 § 100600. Intellectual Property and Revenue Sharing Requirements for Non-Profit and

4 For-Profit Grantees - Scope.

5 The regulations of this chapter apply to all California Institute for Regenerative Medicine
6 (“CIRM”) Grants awarded to Non-Profit and For-Profit Grantees on or after the effective date of
7 these regulations. By accepting a CIRM Grant, the Grantee agrees to comply with these
8 regulations. Any new or amended regulations of this Chapter subsequently adopted by the
9 Independent Citizens Oversight Committee (“ICOC”) will apply to CIRM-Funded Project(s) or
10 Activities on the start date of the next Budget Period after the effective date of the regulations.

11 Notwithstanding the foregoing sentence, amendments to Title 17, California Code of
12 Regulations, sections 100606, 100607 and 100608, shall only apply to Grants awarded after
13 adoption of the new or amended regulations unless the parties agree the amendments shall apply
14 to existing Grants. All revisions to CIRM regulations will be posted on the CIRM website at
15 www.cirm.ca.gov, which shall serve as notice to the Grantee or Authorized Organization Official
16 of such revisions.

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

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1 **§ 100601. Intellectual Property Regulations - Definitions.**

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

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

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

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

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

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

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

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

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

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

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

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

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

23 (k) Exclusive License. A License Agreement that conveys to an individual or entity the

1 sole right to make, use, sell, offer for sale and/or import a CIRM-Funded Invention or CIRM-
2 Funded Technology in any field of use or territory, or an agreement that precludes conveyance of
3 the right to make, use, sell, offer for sale and/or import, in any field of use or territory, a CIRM-
4 Funded Invention or CIRM-Funded Technology to another.

5 (l) Exclusive Licensee. Any individual or entity receiving the sole right to make, use,
6 sell, offer for sale and/or import a CIRM-Funded Technology or a CIRM-Funded Invention in
7 any field of use or territory.

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

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

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

17 (p) Grantee. The Non-Profit Organization or For-Profit Organization awarded a Grant by
18 CIRM that is legally responsible and accountable for the use of the CIRM funds provided for the
19 performance of the grant-supported project or activity. The Grantee is the entire legal entity,
20 including Affiliates, even if only a particular division is designated in the Notice of Grant Award
21 (“NGA”). An entity is an Affiliate of a Grantee if both entities share substantial common
22 direction or control (either directly or indirectly), or if either entity owns (directly or through one

1 or more entities) at least a 25% capital or profits interest in the other. All University of
2 California Grantee campuses shall be considered as separate and individual Grantees.

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

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

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

10 (t) License Agreement. An agreement by which the holder of rights in a CIRM-Funded
11 Invention or CIRM-Funded Technology conveys to another individual or entity the right to
12 make, use, develop, sell, offer to sell, and/or import a CIRM-Funded Invention or CIRM-Funded
13 Technology or which precludes the holder of such rights from enforcing those rights against such
14 other individual or entity.

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

17 (v) Licensing Revenue. The consideration received for the grant of rights (including
18 license rights), or an agreement to not enforce rights, to make, use, develop, sell, offer to sell,
19 and/or import a CIRM-Funded Invention or CIRM-Funded Technology, excluding the following:
20 (1) any additional grants, loans and other forms of research funding obtained to support the
21 Project; (2) consideration received prior to commercialization of the CIRM-Funded Invention or
22 CIRM-Funded Technology, such as development milestones and upfront payments, by For-Profit
23 Grantees and/or For-Profit Collaborators who have expended, or are expending, their own funds

1 on developing the CIRM-Funded Invention or CIRM-Funded Technology; and (3) consideration
2 derived from Net Commercial Revenue upon which CIRM has received payment from a
3 Commercializing Entity pursuant to section 100608(b).

4 Calculation: Revenue is calculated by subtracting a proportion of expenses reasonably
5 incurred in prosecuting, defending and enforcing related patent rights equal to CIRM's
6 percentage of support for development of such CIRM-Funded Invention and/or CIRM-Funded
7 Technology from total consideration rendered, except to the extent that such expenses are
8 recoverable from a third party as provided in section 100605(c), or otherwise. In the case of
9 non-profit Grantees and non-profit Collaborators, Licensing Revenue is calculated by subtracting
10 amounts due to the Inventor pursuant to existing non-profit Grantees' or non-profit
11 Collaborators' policies from total consideration rendered, in addition to the deduction of
12 expenses per the previous sentence.

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

17 (x) Net Commercial Revenue. Gross amounts invoiced for the sale in any country or
18 transfer (but not licensing or assignment) of a Drug, product(s) or service(s) resulting in whole or
19 in part from CIRM-Funded Research. Net Commercial Revenue excludes the following (as they
20 pertain to the making, using or selling of products resulting from CIRM-Funded Research):

21 (1) import, export, excise and sales taxes, and customs duties;
22 (2) costs of insurance, packing, and transportation from the place of manufacture to the
23 customer's premises;

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

(4) pre-commercial revenues received in connection with research and development

and/or clinical activities, such as upfront and milestone payments.

(y) Non-Exclusive License. A License Agreement under which the rights transferred or

conveyed in a CIRM-Funded Technology or a CIRM-Funded Invention to the licensee remain

available to be licensed to one or more entities.

(z) Non-Exclusive Licensee. Any individual or entity that obtains the right to make, use,

sell, offer for sale and/or import in a specific field of use or territory, CIRM-Funded Technology

or a CIRM-Funded Invention, through a Non-Exclusive License.

(aa) Non-Profit Organization. A university or other institution of higher education or

another organization of the type described in 501(c)(3) of the Internal Revenue Code of 1986, as

12 amended (26 U.S.C. 501 (c)(3)) and is exempt from taxation under 501 (a) of the Internal

13 Revenue Code (26 U.S.C. 501 (a)) and California Revenue and Taxation Code section 23701d.

(bb) Notice of Grant Award (“NGA”). The document that notifies the Grantee and others

15 that an award has been made, contains or references all terms and conditions of the award as well

16 as the Grantee's and Principal Investigator's agreement to those terms and conditions, and

17 documents the commitment of CIRM funds.

(cc) Principal Investigator. The Principal Investigator ("PI") is an individual designated

19 by the Grantee to direct CIRM-Funded Research. He or she is responsible and accountable to

20 the Grantee and CIRM for the proper conduct of the project or activity. References herein to

21 “Principal Investigator” include Co-Principal Investigators as well.

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

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

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

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

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1 **§ 100602. Invention and Licensing Reporting Requirements.**

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

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

16 (c) Within 90 calendar days after a Grantee executes a License Agreement (exclusive or
17 non-exclusive) conveying rights in CIRM-Funded Inventions or CIRM-Funded Technology, a
18 Grantee shall notify CIRM of the execution of such agreement(s) and submit to CIRM a copy of
19 those parts of the agreement that address license revenue, including but not limited to upfront
20 and milestone payments, royalties, income and equity. The notification and disclosures made
21 pursuant to this subdivision by a Grantee may be made without identifying the licensee, and shall
22 be marked “Confidential” in accordance with Health and Safety Code section 125290.30,
23 subdivision (g)(2)(B). In lieu of the disclosure process described in this subdivision, CIRM and

1 a Grantee may agree to an alternative method of conveying the information described in this
2 subdivision.

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

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

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

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

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

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

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

- 3 (A) Initiation of clinical testing;
4 (B) Initiation of pivotal studies; and
5 (C) Application for marketing approval.

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

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

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

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

18

§ 100603. Publication Requirements.

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

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

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

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

1 publication abstract nor the statement of public benefit submitted as part of the application
2 satisfy this requirement.

3 (f) A Grantee must ensure that the final abstract or manuscript includes the URL
4 of a website where a Materials Transfer Agreement (or similar document) can be accessed to
5 facilitate requests for Publication-related Biomedical Materials.

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

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

14

1 **§ 100604. Publication-Related Biomedical Materials Requirements.**

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

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

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

9 (1) the number of sharing requests has become financially onerous for the Grantee;
10 (2) the material or its transfer could pose a public health risk; or
11 (3) the request is otherwise inappropriate, as determined by CIRM.

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

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

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

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

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

9

1 **§ 100605. Patents.**

2 (a) Nothing in these Regulations grants CIRM an ownership interest in CIRM-Funded
3 Inventions, CIRM-Funded Research or CIRM-Funded Technology.

4 (b) Grantees may retain or transfer all or a portion of any of Grantee's right, title or
5 interest to any CIRM-Funded Invention or CIRM-Funded Technology or CIRM-Funded
6 Research and to any patent or patent application relating thereto.

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

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

13

1 **§ 100606. Licensing and Assignment of CIRM-Funded Inventions and Technology.**

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

5 (b) If a Grantee elects not to develop, commercialize or otherwise bring to practical
6 application a CIRM-Funded Invention or CIRM-Funded Technology itself, then it shall make
7 reasonable efforts to negotiate Non-Exclusive Licenses for third party development of such
8 CIRM-Funded Inventions or CIRM-Funded Technology, unless (1) doing so would put the
9 Grantee at a competitive disadvantage with a competitor, or (2) the Grantee through reasonable
10 means shares or otherwise makes publicly available the CIRM-Funded Inventions or
11 Technology.

12 (c) A Grantee may negotiate an Exclusive License for a CIRM-Funded Invention or
13 CIRM-Funded Technology if exclusivity is reasonably believed by the Grantee to be an
14 economic incentive necessary to achieve commercial development and availability of the
15 invention.

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

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

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

(B) 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

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

11 (d) A Grantee may negotiate an Exclusive License for a CIRM- Funded Invention or
12 CIRM-Funded Technology that is required for commercialization of a Drug, as defined in Title
13 17, California Code of Regulations, section 100601, subdivision (i), only if the licensee agrees in
14 writing to abide by the provisions of Title 17, California Code of Regulations, section 100607.

22 (f) In licensing CIRM-Funded Inventions or CIRM-Funded Technology Exclusively or
23 Non-Exclusively, Non-Profit Grantees shall retain the right to practice the use of its CIRM-

1 Funded Inventions or CIRM-Funded Technology and to utilize the same for its non-commercial
2 purposes. A Non-Profit Grantee agrees to make its CIRM-Funded Inventions or CIRM-Funded
3 Technology readily accessible on reasonable terms, directly or through a licensee or licensees or
4 other suitable means, to other Non-Profit Grantees for non-commercial purposes, upon request
5 from a Non-Profit Grantee.

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

9 (h) A Grantee must take reasonable action to enforce the terms of an Exclusive License
10 and must promptly report any material breach affecting any of the obligations under these
11 regulations of an Exclusive License in writing to CIRM.

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

14

1 **§ 100607. Access Requirements for Products Developed by Grantees.**

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

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

19 (c) The access plan shall be subject to the approval of CIRM after a public hearing
20 conducted by CIRM that provides for receipt of public comment. CIRM may adopt appropriate
21 procedures to protect proprietary information submitted by Grantees, Collaborators and
22 Exclusive Licensees in connection with said public hearing. Approval shall not be unreasonably

1 withheld. Overall, CIRM shall not require that proposed Access plans exceed industry standards
2 for such plans at the time of commercialization in California.

3 (d) Access plans approved hereunder shall make Grantees, Collaborators and Exclusive
4 Licensees that commercialize a Drug responsible only for providing the Drug itself. Nothing
5 herein shall require the Grantee, Collaborator or Exclusive Licensee to be responsible for any
6 costs of administering the Drug nor for any associate costs of medical procedures or protocols
7 for the Drug therapy, nor for any costs for attendant care.

8 (e) The Independent Citizens Oversight Committee (“ICOC”) may waive the requirement
9 in subdivision (a) of this section if the ICOC determines, after a public hearing, that in the
10 absence of the waiver, development and broad delivery of the Drug will be unreasonably
11 hindered or that the waiver will provide significant benefits that equal or exceed the benefits that
12 would otherwise flow to the state pursuant to subdivision (a) of this section. To invoke this
13 waiver provision, a Grantee, Collaborator or Exclusive Licensee must deliver a written request to
14 the Chair of the ICOC within 10 business days following final approval of the Drug by the
15 federal Food and Drug Administration, unless the Chair of the ICOC agrees to an extension. The
16 request must be accompanied by materials describing how development and broad delivery of
17 the Drug will be unreasonably hindered by compliance with subdivision (a) of this section,
18 and/or how the waiver will provide significant benefits that equal or exceed the benefits that
19 would otherwise flow to the state pursuant to subdivision (a) of this section. The request shall be
20 posted on CIRM’s website no fewer than ten (10) business days prior to the ICOC’s
21 consideration. The ICOC may meet in closed session to review confidential or proprietary
22 material, or other material as allowed by Health and Safety Code section 125290.30, subdivision
23 (d).

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

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

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

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

17 Reference: Sections 125290.30 and 125290.80, Health and Safety Code.

18

1 **§ 100608. Revenue Sharing.**

2 (a) Licensing Revenue. A Grantee and Collaborator must share with the State of
3 California a fraction of Licensing Revenue arising in whole or in part from a CIRM-Funded
4 Invention, CIRM-Funded Technology, or results of CIRM-Funded Research, as follows:

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

20 (b) Net Commercial Revenue. A Commercializing Entity must share with the State of
21 California for deposit in the State's General Fund a fraction of Net Commercial Revenue as
22 follows:

1 (1) A royalty on Net Commercial Revenue at a rate of 0.1% per \$1 million of CIRM
2 Grant(s) for the earlier of Ten (10) years from the date of First Commercial Sale of the
3 applicable Drug, product or service, or until such royalty equals nine times the amount of the
4 Grant(s). (By way of example, Grants totaling \$15 million will result in royalty payments of
5 1.5% of Net Commercial Revenues.)

6 (2) In addition, upon satisfaction of the obligation in subsection (b)(1) above, a 1%
7 royalty shall be owed on Net Commercial Revenues in excess of \$500 million per year until the
8 last-to-expire patent covering a CIRM-Funded Invention, if any, that generates or plays a role in
9 the generation of, in whole or in part, said Net Commercial Revenue; provided at least \$5 million
10 in CIRM Grant or Grants were made in support of such CIRM-Funded Research, CIRM-Funded
11 Technology or CIRM-Funded Inventions.

12 (3) For purposes of subdivision (b) of this section, the royalty rate calculation shall apply
13 only to Grants made to For-Profit Grantees and which were awarded subsequent to the effective
14 date of this section, as amended, effective _____ [OAL to insert effective date].

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

17 (c) Grantees and Collaborators shall include provisions within any license of a CIRM-
18 Funded Technology or CIRM-Funded Invention ensuring that a Commercializing Entity,
19 whether a licensee or sub-licensee, directly owes payments to the state pursuant to subdivision
20 (b) of this section, where applicable.

21 (d) Revenues due the state according to this section shall be paid to the California State
22 Treasurer's Office, Division of Cash Management.

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

3

1 **§ 100609. Press Release Requirements.**

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

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

6

1 **§ 100610. March-In Rights.**

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

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

10 (1) the Grantee, Collaborator or an Exclusive Licensee has not made reasonable
11 efforts to achieve practical application of a CIRM- Funded Invention and/or CIRM-
12 Funded Technology, as applicable;

13 (2) the Grantee, Collaborator or an Exclusive Licensee have failed to provide or
14 comply with a plan for access to a Drug in accordance with Title 17, California Code of
15 Regulations, section 100607;

16 (3) the Grantee, Collaborator or Exclusive Licensee has unreasonably failed to use
17 a CIRM- Funded Invention or CIRM- Funded Technology to alleviate public health and
18 safety needs that constitute a public health emergency as declared by the Governor.

19 (c) One consideration in taking the action described in subdivision (b) of this regulation
20 will be whether doing so will impinge on the Grantee's, Collaborator's or Exclusive Licensee's
21 academic freedoms.

1 (d) CIRM will promptly notify a Grantee, Collaborator or an Exclusive Licensee of any
2 adverse determination under this provision and the basis therefore, as well as its intention to
3 exercise march-in rights (“March-In Notice”).

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

11 (f) Within thirty (30) days of the date CIRM issues a March-In Notice, the subject
12 Grantee may appeal CIRM’s decision to the ICOC by notifying the President of CIRM in writing
13 of its intent to appeal CIRM’s decision. Within sixty (60) days of the March –In Notice date, the
14 subject Grantee must submit a written statement of the reasons for the appeal and any supporting
15 materials it wishes to have considered by the ICOC. Absent extraordinary circumstances, the
16 ICOC shall render a final determination on the appeal within one hundred twenty (120) days of
17 the March-In Notice. In cases where an appeal is filed, CIRM shall not effect a march-in unless
18 and until the ICOC renders a final determination on the appeal. The ICOC may reverse the
19 decision of the CIRM to exercise march-in rights under this regulation for any reason.

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

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

3

1 **§ 100611. Assurance of Third-Party Compliance.**

2 Any party that becomes a successor in interest by merger, purchase, assignment or any
3 other means, of a Grantee, Collaborator or Exclusive Licensee with regard to a CIRM-Funded
4 Invention, CIRM-Funded Technology or CIRM-Funded Research, assumes all obligations of the
5 Grantee, Collaborator or Exclusive Licensee, as applicable, described in this Chapter.

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