

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

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

3 **Organizations**

4 **§ 100400. Intellectual Property and Revenue Sharing Requirements for For-Profit**

5 **Organizations - Scope.**

6 The regulations of this chapter apply to all CIRM grant awards issued on or after the
7 effective date of these regulations. By accepting a CIRM grant award, the awardee agrees to
8 comply with the provisions of these regulations. Any new or amended regulations adopted by
9 the Independent Citizen’s Oversight Committee (“ICOC”) will be applied to currently active
10 grants, loans or contracts on the start date of the next non-competitive renewal period after the
11 effective date of the regulations. A currently active grant, loan or contract is one that is still in
12 the Project Period or one for which CIRM funds are still being expended or the repayment of
13 which is still unsatisfied. New or amended regulations adopted after the expiration of the Project
14 Period of a grant, loan or contract and after all CIRM funds for the grant, loan or contract have
15 been expended will apply on January 1 following the effective date of the new or amended
16 regulation, unless specified otherwise in the regulation. Principal investigators, program
17 directors and organizational officials with active CIRM grants, loans or contracts will receive
18 notification of revised terms and conditions or revised editions of the CIRM Grants
19 Administration Policy as they are released. In addition, all revisions to these regulations will be
20 posted on the CIRM website at www.cirm.ca.gov. Failure by a principal investigator or other
21 person affiliated with the awardee to have notification shall not excuse non-compliance as long
22 as the CIRM has notified the awardee.

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

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

2 **§ 100401. Intellectual Property Regulations - Definitions.**

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

6 (b) Awardee/Awardee Organization. The entity awarded a grant by CIRM that is legally
7 responsible and accountable for the use of the funds provided and for the performance of the
8 grant-supported project or activity. The awardee is the entire legal entity even if a particular
9 component is designated in the Notice of Grant Award.

10 (c) Awardee Organization's Share. The revenues received by an awardee organization
11 under a commercial license of a CIRM-funded patented invention remaining after deducting the
12 direct costs associated with patents and patent applications claiming inventions made under
13 CIRM funding and the inventor's share of those revenues.

14 (d) Biomedical Materials. Entities of biomedical relevance first produced as a
15 consequence of CIRM-funded scientific research including but not limited to unique research
16 resources such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned
17 DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and
18 spectroscopic data. Specific examples include specialized and/or genetically defined cells,
19 including normal and diseased human cells, monoclonal antibodies, hybridoma cell lines,
20 microbial cells and products, viruses and viral products, recombinant nucleic acid molecules,
21 DNA probes, nucleic acid and protein sequences, certain types of animals including transgenic
22 mice and other property such as computer programs.

1 (e) Exclusive License. Any License Agreement for a CIRM-funded patented invention
2 that permits the licensee to exclusively exercise any commercial right within the state of
3 California or the United States, or within any field of use, or for any licensed product or licensed
4 purpose.

5 (f). For-Profit Organization. An institution, corporation, or other legal entity, which is
6 organized for the profit or benefit of its shareholders or other owners

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

9 (h) License Agreement. An agreement by which a patent owner allows another party to
10 make, use, sell, offer to sell, and/or import an invention protected by a patent.

11 (i) Licensing Activities. Actions taken by authorized organizational officials, the desired
12 outcome of which is a contractual agreement under which the awardee organization grants
13 permission to another party to use intellectual property under specific conditions.

14 (j) Materials Transfer Agreement. A document (“MTA”) which governs the exchange of
15 a substance, element or item (material) to another party for the purposes of research. It limits the
16 commercial exploitation of the material without the permission of the provider party.

17 (k) Principal Investigator/Program Director. The principal investigator (“PI”) or program
18 director (“PD”) is an individual designated by the awardee to direct the project or activity being
19 supported by the grant, loan or contract. He or she is responsible and accountable to the awardee
20 and CIRM for the proper conduct of the project or activity. For training programs or similarly
21 structured programs, the PD is the same as the PI.

1 (l) Project period. The total amount of time for which CIRM promises to fund a grant,
2 loan or contract and authorizes an awardee to conduct the approved work of the project
3 described in the application.

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.

1 Adopt 17 Cal. Code of Regs. section 100402 to read:

2 **§ 100402. Invention Reporting Requirements.**

3 Awardee organizations must submit annual progress reports including scientific and
4 financial statements during and after the period of the grant award, regarding CIRM-funded
5 inventions and research as follows:

6 (a) Awardee organizations shall report filings of patent applications, including the
7 application serial number, that claim inventions. All disclosures to the CIRM of such inventions
8 shall detail the invention and be marked confidential in accordance with Health and Safety Code
9 section 125290.30, subdivision (e)(2)(B).

10 (b) Awardee organizations must notify CIRM regarding the issuance or nonissuance of
11 patent applications, including the patent number and date of issuance, that claim inventions.

12 (c) Awardee organization must notify CIRM regarding execution of any licensing
13 agreements of patented inventions made in the performance of CIRM-funded research.

14 (d) In the event of revenue streams created as a consequence of CIRM-funded patented
15 inventions (whether from license agreements or self-commercialization activities), awardee
16 organizations shall keep accurate records and accounts, and submit to CIRM a statement
17 describing financial information relating to the CIRM-funded invention-related revenue stream
18 for the preceding 12 month period. This information shall be marked confidential in accordance
19 with Health and Safety Code 125290.30, subdivision (e)(2)(B).

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

1 Adopt 17 Cal. Code of Regs. section 100403 to read:

2 **§ 100403. Publication Requirements.**

3 (a) Within 60 days of the publication of CIRM-supported research results in a scientific
4 journal, Principal Investigators must submit to CIRM a 500-word abstract written for the general
5 public that highlights the findings of the published body of work. In addition, Principal
6 Investigators must submit a biographical sketch to accompany the abstract. The abstract and the
7 biographical sketch will be deposited into the publicly-accessible CIRM Electronic Library
8 Repository, to be accessed via the CIRM website.

9 (b) One copy of each publication resulting from work performed under a CIRM grant
10 must accompany the mandatory annual progress report submitted to CIRM pursuant to Title 17,
11 California Code of Regulations section 100402.

12 (c) In the final manuscript, authors must include the URL of a website where the CIRM
13 MTA (or similar document) can be accessed to facilitate requests for publication-related
14 materials.

15 (d) CIRM awardees must acknowledge CIRM support of research findings in
16 publications, announcements, presentations, and press releases by the awardees. An example of
17 an acknowledgement is:

18 “The research was made possible by a grant from the California Institute for
19 Regenerative Medicine (Grant Number _____). The contents of this publication are solely the
20 responsibility of the authors and do not necessarily represent the official views of CIRM or any
21 other agency of the State of California.”

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

1 Adopt 17 Cal. Code of Regs. section 100404 to read:

2 **§ 100404. Publication-Related Biomedical Materials Requirements.**

3 Unless a special case is made to CIRM that doing so would endanger the competitive
4 position of the company, an awardee shall share biomedical materials described in published
5 scientific articles for research purposes in California within 60 days of receipt of a request and
6 without bias as to the affiliation of the requestor unless legally precluded. Under special
7 circumstances, exceptions to the above are possible with approval by CIRM; if requests to the
8 awardee become onerous or are in direct conflict with the business of the awardee, awardees can
9 appeal to CIRM for alternative arrangements. Alternatively, authors may provide requestors with
10 information on how to reconstruct or obtain the material. Materials are to be shared without cost
11 or at cost.

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.

1 Adopt 17 Cal. Code of Regs. section 100405 to read:

2 **§ 100405. Patent Applications.**

3 Awardee organizations shall bear responsibility for costs associated with patents and
4 patent applications claiming their CIRM-funded inventions.

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

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

2 **§ 100406. Licensing CIRM-Funded Patented Inventions.**

3 (a) Awardee organizations shall assume responsibility for licensing activities including
4 identification of potential licensees, negotiation of license agreements and documentation of
5 development progress for licenses relating to CIRM-funded patented inventions. Awardee
6 organizations are required to submit a licensing activities report relevant to CIRM-funded
7 patented inventions on an annual basis.

8 (b) Awardee organizations shall negotiate non-exclusive licenses of CIRMfunded
9 inventions to third parties whenever possible. Nevertheless, awardee organizations may negotiate
10 and award exclusive licenses for CIRM-funded inventions if such licenses are necessary to
11 provide economic incentives required to enable commercial development and availability of the
12 inventions. In due diligence relating to such exclusive licenses, awardee organizations shall
13 document development and commercialization capabilities of the intended licensee, and include
14 terms in the license agreement addressing all relevant therapeutic and diagnostic uses for which
15 the invention is applicable.

16 (c) In exclusive license agreements, awardee organizations shall include terms for
17 commercial development plans to bring the invention to practical application. Such provisions
18 shall include commercial development milestones and benchmarks so that development can be
19 assessed and monitored.

20 (d) Awardee organizations shall grant exclusive licenses involving CIRM-funded
21 patented inventions relevant to therapies only to organizations with plans to provide access at the
22 time of commercialization to resultant therapies for uninsured California patients. In addition,
23 such licensees will agree to provide to patients whose therapies will be purchased in California

1 by public funds the therapies at a discount price. The CIRM may make access plans available for
2 review by the ICOC.

3 (e) Awardee organizations shall monitor the performance of exclusive licensees of
4 CIRM-funded patented inventions to ensure that the licensed invention is developed in a timely
5 fashion. Remedies for failure to develop may include modification or termination of a license in
6 the event that a licensee is unable to fully develop the rights granted.

7 (f) Awardee organizations shall negotiate relevant and specific grounds for modification
8 or termination of the license. Examples would include failure to meet agreed-upon
9 commercialization benchmarks, and failure to reasonably meet the agreed-upon plan for access
10 to resultant therapies as described above in subdivision (d).

11 (g) Awardee organizations shall monitor the commercial development activities of the
12 licensees to determine compliance with the terms of the license agreement and include reports of
13 monitoring activities annually.

14 (h) Awardee organizations shall take administrative action to modify or terminate license
15 rights where necessary and report such action to the CIRM Scientific Program Officer.

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

18 Reference: Section 125290.30, Health and Safety Code.

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

2 **§ 100407. Access Requirements for Products Developed by For-Profit Awardees.**

3 (a) The awardee organization will provide (at time of commercialization) to CIRM a plan
4 to provide access to resultant therapies for uninsured Californians for therapies developed with
5 CIRM funds. The access plan shall be consistent with industry standards extant at the time of
6 commercialization. The CIRM may make access plans available for review by the ICOC and the
7 public.

8 (b) Awardees agree to provide therapies resulting from CIRM funding purchased in
9 California by public funds at a discount price. For drugs generated as a consequence of CIRM
10 funding, awardees agree to provide drugs purchased in California by public funds at any
11 benchmark price described in the California Discount Prescription Drug Program (commencing
12 with California Health and Safety Code section 30500, et seq.).

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

15 Reference: Section 125290.30, Health and Safety Code.

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

2 **§ 100408. Revenue Sharing.**

3 (a) In the event of the creation of revenue streams from CIRM-funded patented
4 inventions licensed to third parties, the following requirements pertain:

5 (1) Awardee organizations shall share a fraction of any net revenues received in excess of
6 \$500,000 under a license agreement that involves CIRM-funded patented inventions. Net
7 revenues are defined as gross revenues minus direct costs incurred in the generation and
8 protection of the patents from which the revenues are received. The rate of payment of the
9 return to the State shall be negotiated between the awardee and the CIRM, but in no event shall
10 be less than two (2) percent nor more than five (5) percent of the annual revenue from the
11 invention.

12 (2) The awardee organization may retain a threshold amount of its share of any revenues
13 received under a license agreement or agreements of any CIRM-funded patented invention(s).
14 The awardee organization shall pay 17 percent of its share of such revenues to the State of
15 California for deposit into the State's General Fund unless such action violates any federal law.
16 The threshold amount is \$500,000 (in the aggregate) multiplied by a fraction, the denominator of
17 which is the Consumer Price Index, All Urban Consumers, All Items (San Francisco-Oakland-
18 San Jose; 1982-84=100) as prepared by the Bureau of Labor Statistics of the United States
19 Department of Labor and published for the month of October 2007, and the numerator of which
20 is such Index published for the month in which the grant award is accepted by the awardee.

21 (3) If funding sources in addition to CIRM were used in the creation of a CIRM-funded
22 patented invention, the return to the State of California of any resultant revenues shall be
23 proportionate to the support provided by CIRM for the discovery of the invention. Awardees

1 must submit, at the time of reporting to the CIRM the filing of a patent application pursuant to
2 Title 17, California Code of Regulations section 100402, calculations detailing CIRM's
3 contribution to the invention. CIRM reserves the right to commission an audit of any expenditure
4 funds provided by CIRM and all co-funding calculations. This information shall be marked
5 confidential in accordance with Health and Safety Code section 125290.30, subdivision
6 (e)(2)(B).

7 (b) In the event of the creation of revenue streams from self-commercialized products
8 that result from CIRM-funded patented inventions, the following requirements pertain:

9 (1) Awardee organizations shall share revenues with the State of California (to be
10 deposited into the State's General Fund) in the form of royalties capped at three times the total
11 awarded money, for revenue exceeding the threshold amount described in subdivision (a)(2) of
12 this regulation, and at the rate described in subdivision (a)(1) of this regulation.

13 (2) Awardee organizations must submit calculations detailing CIRM's contribution to
14 commercialization of the resultant product. CIRM reserves the right to commission an audit of
15 any CIRM expenditure and all co-funding calculations.

16 (c) In the event that revenues from CIRM-funded projects achieve blockbuster status as
17 defined below, the following requirements pertain:

18 (1) For grants that lead to very successful commercial products, a one-time blockbuster
19 payment equal to three times the total awarded money is expected when revenues exceed \$250
20 million per year and when revenues exceed \$500 million per year.

21 (2) In the event that CIRM invested more than \$5 million (in aggregate) in the research
22 project and a CIRM-funded patented invention was involved in the achievement of blockbuster

- 1 revenues equivalent to or greater than \$500 million per year, CIRM requires the payment of 1
- 2 percent of revenues in excess of \$500 million for the life of the patent(s).
- 3 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
- 4 Safety Code. Reference: Section 125290.30, Health and Safety Code.

1 Adopt 17 Cal. Code of Regs. section 100409 to read:

2 **§ 100409. Press Release Requirements.**

3 CIRM awardees must notify CIRM prior to any press releases that refer to events that
4 arise as a consequence of CIRM funding by contacting the CIRM Communications Officer.

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

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

2 **§ 100410. March-In Rights.**

3 (a) With regard to CIRM-funded patented inventions or CIRM-funded research projects,
4 CIRM shall have the right to require the awardee organization, or exclusive licensee of a CIRM-
5 funded invention, to grant a nonexclusive, partially exclusive, or exclusive license in any field of
6 use to a responsible applicant or applicants, upon terms that are reasonable under the
7 circumstances, and if the awardee organization, or exclusive licensee refuses such request, to
8 grant such a license itself, if the CIRM determines that such an action is required:

9 (1) Because the awardee organization or the licensee has not made responsible efforts in
10 a reasonable time to achieve practical application of a CIRM-funded patented invention;

11 (2) Because the awardee or licensee has failed to adhere to the agreed-upon plan for
12 access to resultant therapies;

13 (3) To meet requirements for public use including broad availability in California (for
14 reasons other than price), and the requirements have not been satisfied by the awardee
15 organization or its licensee;

16 (4) To alleviate public health and safety needs which are not reasonably satisfied by the
17 awardee organization or its licensee and which needs constitute a public health emergency.

18 (b) CIRM will give notice of such determination and the basis on which it was made to
19 the awardee or licensee. CIRM will not exercise its rights described above if the awardee or
20 licensee takes diligent action promptly to cure the deficiency and such deficiency is cured sooner
21 than one year from receipt of notice (or longer period by mutual agreement). With respect to a
22 deficiency described in subdivision (a)(4) of this regulation, CIRM may exercise such right at
23 any time in the event of a public health or safety emergency declared by the Governor.

- 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.