

1 Adopt 17 Cal. Code of Regs. section 100301 to read:

2 **§ 100301. Intellectual Property Regulations - Definitions.**

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

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

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

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

21 (e) “Data.” The recorded factual material commonly accepted in the scientific
22 community as necessary to validate research findings, but not any of the following: preliminary

1 analyses, drafts of scientific papers, plans for future research, peer reviews, or communications
2 with colleagues. This “recorded” material excludes physical objects (e.g., laboratory samples).

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

7 (g) “Grantee/Grantee Organization.” The non-profit organization awarded a grant by
8 CIRM that is legally responsible and accountable for the use of the funds provided and for the
9 performance of the grant-supported project or activity. The grantee is the entire legal entity even
10 if a particular component is designated in the Notice of Grant Award (“NGA”). All University
11 of California grantee campuses shall be considered as separate and individual Grantee
12 Organizations.

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

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

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

21 (k) “Invention Disclosure Form.” A written notification to CIRM that a CIRM-funded
22 patentable invention has been made.

1 (l) “Invention Utilization Report.” Applicable to Grantee Organizations that have
2 previously filed an Invention Disclosure Form, this annual report is a written description of
3 efforts made by authorized organizational officials to commercialize CIRM-funded patentable
4 inventions. This report will include information about the status of development, date of first
5 commercial sale or use and any licensing fees and/or gross royalties received by the Grantee
6 Organization relating to CIRM-funded patented inventions.

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

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

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

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

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

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

21 (s) “Non-Profit Organization.” A (1) university or other institution of higher education or
22 another organization of the type described in 501(c)(3) of the Internal Revenue Code of 1986, as
23 amended (26 U.S.C. 501 (c)(3)) and is exempt from taxation under 501 (a) of the Internal

1 Revenue Code (26 U.S.C. 501 (a)), or (2) any other non-profit scientific or educational
2 organization qualified under a state non-profit organization statute whose organizational charter
3 provides that (A) the organization is not organized or operated for the private gain of any person,
4 (B) no part of the organization’s net income or assets shall inure to the benefit of any person, and
5 (C) the organization’s net assets upon dissolution shall be distributed to a non-profit fund,
6 foundation or corporation which is organized and operated exclusively for charitable purposes.

7 (t). “Notice of Grant Award.” (“NGA”) The document that notifies the grantee and
8 others that an award has been made, contains or references all terms and conditions of the award,
9 and documents the obligation of CIRM funds.

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

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

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

21 (x) “Project period.” The total amount of time for which CIRM promises to fund a grant
22 and authorizes a grantee to conduct the approved work of the project described in the
23 application.

- 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.