Adopt 17 Cal. Code of Regs. section 100601 to read:

§ 100601. Intellectual Property Regulations - Definitions.

The following definitions apply to the regulations in this chapter:

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

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

(c) CIRM-Funded Invention. An Invention, whether patentable or not, which arises from CIRM-Funded Research and either (1) is conceived in the performance of a CIRM-Funded Project or Activity by a Grantee, Grantee Personnel and/or its Collaborator(s), and reduced to practice in the performance of a CIRM-Funded Project or Activity, or within 12 months of the close of the Grant, or (2) is reduced to practice by a Grantee, Grantee Personnel or its Collaborator in the performance of a CIRM-Funded Project or Activity or within 12 months of the close of the Grant.

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

(e) CIRM-Funded Research. All aspects of work conducted on a CIRM-Funded Project 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) 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).

(i) 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.

(j) Exclusive License. A License Agreement that conveys to the licensee the sole right to make, use, sell, offer for sale and/or import in one or more fields of use or territories, as to a CIRM-Funded Invention or CIRM-Funded Technology, that is not available to be licensed to other entities or persons.

Decision 1. Option A:

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

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Or Option B:

[(k) Exclusive Licensee. Any individual or entity receiving all rights to make, use, sell, offer for sale and/or import in one or more fields of use or territories a CIRM-Funded Technology or a CIRM-Funded Invention whether by assignment, license, or other mechanism.**]**

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

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

(n) Grantee. The Non-Profit Organization or For-Profit Organization awarded a Grant by CIRM that is legally responsible and accountable for the use of the CIRM funds provided for the performance of the grant-supported project or activity. The Grantee is the entire legal entity,

including Affiliates, even if only a particular division is designated in the Notice of Grant Award ("NGA"). An entity is an Affiliate of a Grantee if both entities share substantial common direction or control (either directly or indirectly), or if either entity owns (directly or through one or more entities) at least a 25% capital or profits interest in the other. All University of California Grantee campuses shall be considered as separate and individual Grantees.

(o) 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.

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

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

(r) 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.

(s) 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.

(t) Licensing Revenue. The consideration rendered to an owner or Collaborator of a CIRM-Funded Invention or CIRM-Funded Technology pursuant to a License Agreement, but excludes subsequent research funding. In the case of Non-Profit Grantees only, Licensing Revenue is calculated by subtracting amounts due to the Inventor pursuant to existing

institutional policies from total consideration rendered. For all owners of a CIRM-Funded Invention or CIRM-Funded Technology, Licensing 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 Invention and 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.

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

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

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

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

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

(4) pre-commercial revenues received in connection with research and development and/or clinical activities.

Decision 2: Option A

[(w) 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.**]**

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or Option B:

[(w) 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 other entities.**]**

(x) 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.

(y) 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 amended (26 U.S.C. 501 (c)(3)) and is exempt from taxation under 501 (a) of the Internal Revenue Code (26 U.S.C. 501 (a)) and California Revenue and Taxation Code section 23701d.

(z) Notice of Grant Award ("NGA"). The document that notifies the Grantee and others that an award has been made, contains or references all terms and conditions of the award as well as the Grantee's and Principal Investigator's agreement to those terms and conditions, and documents the commitment of CIRM funds.

(aa) Principal Investigator. The Principal Investigator ("PI") is an individual designated by the Grantee to direct CIRM-Funded Research. He or she is responsible and accountable to

the Grantee and CIRM for the proper conduct of the project or activity. References herein to "Principal Investigator" include Co-Principal Investigators as well.

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

(cc) 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.

(dd) 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.

Adopt 17 Cal. Code of Regs. section 100606 to read:

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

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

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

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

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

(2) A Grantee must include in any Exclusive License terms addressing all reasonably anticipated therapeutic and diagnostic uses for the CIRM Funded Invention or CIRM-Funded

Technology that the licensee is prepared to diligently develop and 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.

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

(e) Subject to the provisions of Title 17, California Code of Regulations, section 100610, a Grantee bears responsibility for Licensing Activities including identification of potential licensees, negotiation of License Agreements, and documentation of the progress and execution of development under a License Agreement for all CIRM-Funded Inventions or CIRM-Funded Technology. A Grantee must submit an annual Invention Utilization Report describing, among

other things, these licensing and/or assignment activities as described in Title 17, California Code of Regulations, section 100602.

(f) In licensing CIRM-Funded Inventions or CIRM-Funded Technology Exclusively or Non-Exclusively, Non-Profit Grantees shall retain the right to practice the use of its CIRM-Funded Inventions or CIRM-Funded Technology and to utilize the same for its non-commercial purposes. A Non-Profit Grantee agrees to make its CIRM-Funded Inventions or CIRM-Funded Technology readily accessible on reasonable terms, directly or through a licensee or licensees or other suitable means, to other Non-Profit Grantees for non-commercial purposes, upon request from a Non-Profit Grantee.

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

(h) A Grantee must take reasonable action to enforce the terms of an Exclusive License and must promptly report any material breach **[Decision 3:** affecting any of the obligations under these regulations**]** of an Exclusive License in writing to CIRM.

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

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100611 to read:

§ 100611. Assurance of Third-Party Compliance.

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

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