Intellectual Property Policy
for
CIRM Awards

Introduction

The California Institute for Regenerative Medicine ("Institute" or "CIRM") was established in early 2005 with the passage of Proposition 71, the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides $3 billion in funding for stem cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004, called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

Proposition 71 requires the agency to:

> *"… establish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements."*

This policy serves as the terms and conditions for CIRM awards with respect to intellectual property, except as may be provided otherwise in CIRM regulations. Applicants and Awardees should familiarize themselves with the provisions set forth in this policy, and may be required to document compliance with any and all of its provisions.

Except as noted in section XII below, revisions to this policy will only apply to awards made after the effective date of any new policy or amendments, unless the Awardee and CIRM agree to apply the new policy or amendments to existing awards.

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I. Defined Terms

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.

Award. CIRM funding in the form of an Award, Grant, Loan, or contract that is based on an approved application and budget.

Awardee. An organization that is the Recipient of an Award and that is legally responsible and accountable for the use of the funds provided and for the performance of the CIRM-funded Project or Activity. The Awardee is the entire legal entity even if a particular component is designated in the Notice of Award. Campuses of the University of California shall be considered as separate and individual Awardees.

CIRM-Funded Invention. An Invention, whether patentable or not, which arises from CIRM-Funded Research and is either:

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

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

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 NOA, regardless of whether CIRM funding constitutes all or only a portion of the financial support necessary to carry them out.

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.

CIRM-Funded Technology. Data, materials, research results or know-how whether patentable or not, that arises from CIRM-Funded Research.

Collaborator. Any person or entity other than a Awardee and Awardee Personnel who obtains any ownership rights to a CIRM-Funded Invention or CIRM-Funded Technology.

Commercializing Entity. Any (1) entity that sells, offers for sale or transfers a Drug: (a) resulting in whole or in part from Regulatory Use; or (b) that consists, in whole or in part, of a CIRM-Funded Invention; or (2) Awardee, Collaborator, or Exclusive Licensee who commercializes a non-Drug product or service resulting in whole or in part from CIRM-Funded Research.

Data. Scientific, clinical or technical recorded information derived during the Project Period of an Award, 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).

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.

Exclusive License. A License Agreement that conveys to an individual or entity the sole right to make, use, sell, offer for sale and/or import a CIRM-Funded Invention or CIRM-Funded Technology in any field of use or territory, or an agreement that precludes conveyance of the right to make, use, sell, offer for sale and/or import, in any field of use or territory, a CIRM-Funded Invention or CIRM-Funded Technology to another.

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

First Commercial Sale. The date upon which revenue is derived from the sale or transfer, but not the licensing or assignment, of a Drug, product or service.

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.

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

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

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

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

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.

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

Net Commercial Revenue. Gross amounts invoiced for the sale in any country or transfer (but not licensing or assignment) of a Drug, product(s) or service(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, such as upfront and milestone payments.

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.

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.

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.

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

Principal Investigator. The Principal Investigator ("PI") is an individual designated by the Awardee to direct CIRM-Funded Research. He or she is responsible and accountable to the Awardee and CIRM for the proper conduct of the project or activity. References herein to "Principal Investigator" include Co-Principal Investigators as well.

Project Period. The amount of time over which CIRM funds a specific Award.

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.

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 Awardee, Awardee Personnel, Licensee or a Collaborator, as determined by CIRM pursuant to Title 17, California Code of Regulations section 100604, subdivision (e).

Regulatory Use. The use of any CIRM-Funded Research in a Food and Drug Administration (or equivalent foreign regulatory body) submission or filing. Regulatory Use does not include a reference or citation to a publicly available publication that describes or references CIRM-Funded Research.

II. Invention and Licensing Reporting Requirements

Prior to an NOA and continuing 12 months after the close of a Award, a Awardee must have written agreements with Awardee Personnel and Collaborators requiring prompt disclosure to the Awardee of any CIRM-Funded Invention.

Within 60 calendar days after a CIRM-Funded Invention has been disclosed to a Awardee, the Awardee must notify CIRM of the CIRM-Funded Invention , which will be received in confidence by CIRM. The disclosure shall identify the Award under which the CIRM-Funded Invention was made, the Inventor(s) and the Principal Investigator. The disclosure shall be sufficiently complete in technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose, operation, and physical, chemical, biological or electrical characteristics of the CIRM-Funded Invention. If the CIRM-Funded Invention has been submitted for publication or presentation, then the disclosure shall identify the publication, the date of the abstract or manuscript or presentation, the submission date and if relevant any publication dates, including publication via the internet.

After an Awardee executes a License Agreement (exclusive or non-exclusive) conveying rights in CIRM-Funded Inventions or CIRM-Funded Technology, the Awardee shall notify CIRM in the next Utilization Report of the execution of such agreement(s) and submit to CIRM a copy of the agreement. The notification and disclosures made pursuant to this subdivision by a Awardee may be made without identifying the licensee, and shall be marked “Confidential” in accordance with Health and Safety Code section 125290.30, subdivision (g)(2)(B). In lieu of the disclosure process described in this subdivision, CIRM and a Awardee may agree to an alternative method of conveying the information described in this subdivision.

An Awardee must submit annually to CIRM during, and for 15 years after, the Project Period of the Award, a Utilization Report containing the following information:

(1) Awardees 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) Awardees 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) An Awardee must report to CIRM the execution of all Material Transfer Agreements or Collaborative Agreements conveying rights in CIRM-Funded Inventions or CIRM-Funded Technology; and

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

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

(A) Initiation of clinical testing;

(B) Initiation of pivotal studies; and

(C) Application for marketing approval.

(6) Awardee shall have written agreements with its Awardee Personnel, Collaborators, licensees and transferees requiring such third parties to report to the Awardee information described in Part II.D.

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

CIRM reserves the right to itself and its agents to conduct an audit of the Awardee and Collaborators to ensure compliance with this policy. Awardee and Collaborators must maintain and provide such documentation as is necessary to establish compliance. Further, Awardee must ensure that its Collaborators, Awardee Personnel and all Licensees maintain such documentation as is necessary to establish compliance.

In the event there is unlicensed Regulatory Use by a third party, the Awardee, upon learning of such unlicensed use, shall notify CIRM immediately.

III. Publication Requirements

An Awardee must provide for public access to any publication of a CIRM Funded Invention or CIRM-Funded Technology, as provided in this section.

For any manuscript that is peer-reviewed and accepted for publication in a scientific journal, the Awardee 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 Awardee 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 Awardee is unable to submit the manuscript to PubMed Central, the Awardee 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 Awardee may submit the final published article.

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

Awardees are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Regulation.

Within 60 calendar days of the publication, Awardees shall notify CIRM of the Award Number, Awardee Institution, Principal Investigator and the PubMed Central identification number for the manuscript. In addition, Awardees shall provide CIRM with a short paragraph, written for the general public, describing both the importance of the discovery that is the subject of the publication and the approach or methodology employed. Neither the publication abstract nor the statement of public benefit submitted as part of the application satisfy this requirement.

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

Any written or oral publication reporting a CIRM-Funded Invention or CIRM-Funded Technology must acknowledge CIRM funding. An example of an acknowledgement is: "This research was made possible by an award from the California Institute for Regenerative Medicine (Award Number _____)."

IV. Publication-Related Biomedical Materials Requirements.

An Awardee shall share Publication-related Biomedical Material, for bona fide purposes of research in California. Such materials are to be shared without cost to the requestor or at the actual cost of providing the materials without an allocation of costs for overhead, research, discovery or other non-direct costs of providing the materials.

An Awardee must share such materials within 60 calendar days of receipt of a written request, without bias as to the affiliation of the requestor, unless otherwise prohibited by law.

CIRM may approve alternatives to this sharing requirement on a showing that:

(1) the number of sharing requests has become financially onerous for the Awardee;

(2) the material or its transfer could pose a public health risk; or

(3) the request is otherwise inappropriate, as determined by CIRM.

In lieu of sharing as provided herein, an Awardee may provide requestors with the information necessary to reconstruct or obtain identical material.

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

Prior to transferring any Publication-related Biomedical Material, an Awardee may require the requestor to execute an industry-standard or university-standard Material Transfer Agreement restricting the use and dissemination of such materials and its derivatives.

An Awardee has no obligation under this policy to share third party materials described in publications, patents, patent applications or presentations of CIRM-Funded Research or CIRM-Funded Technology or CIRM-Funded Inventions such as raw materials purchased by the Awardee to develop or synthesize the Publication-related Biomedical Material or other materials covered by third party intellectual property rights, or if the Awardee is legally prohibited from doing so.

V. Patents

Nothing in this policy awards CIRM an ownership interest in CIRM-Funded Inventions, CIRM-Funded Research or CIRM-Funded Technology.

Awardees may retain or transfer all or a portion of any of Awardee's right, title or interest to any CIRM-Funded Invention or CIRM-Funded Technology or CIRM-Funded Research and to any patent or patent application relating thereto.

Unless provided otherwise by CIRM, Awardees shall bear the costs associated with any patent application disclosing or claiming any one or more CIRM-Funded Inventions, any patent itself, and all costs of pursuing, maintaining and protecting such applications patents. However, these Regulations shall not restrict the rights of Awardees to recover these costs through license fees or other consideration.

VI. Licensing and Assignment of CIRM-Funded Inventions and Technology

Subject to the provisions of section X of this policy, an Awardee shall make reasonable efforts to develop, commercialize or otherwise bring to practical application CIRM-Funded Technology or CIRM-Funded Inventions.

If an Awardee 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 Licenses for third party development of such CIRM-Funded Invention or CIRM-Funded Technology, unless (1) doing so would put the Awardee at a competitive disadvantage with a competitor, or (2) in the case of a CIRM DISC (or successor program) Award, the Awardee through reasonable means shares or otherwise makes publicly available the CIRM-Funded Invention or Technology.

An Awardee may negotiate an Exclusive License for a CIRM-Funded Invention or CIRM-Funded Technology if exclusivity is reasonably believed by the Awardee to be an economic incentive necessary to achieve commercial development and availability of the invention. The Awardee must document the development and commercialization capabilities of any intended exclusive licensee prior to entering an Exclusive License. The Awardee 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:

(1) 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;

(2) explicit remedies for failure to develop, including modification or termination of an Exclusive License if a licensee is unable to fully develop the rights awarded; and

(3) 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.

An Awardee may negotiate a License Agreement for a CIRM- Funded Invention or CIRM-Funded Technology for commercialization of a Drug only if the licensee agrees in writing to abide by the provisions of sections VII and VIII of this policy. The License Agreement shall include language stating the following: "The California Institute for Regenerative Medicine and the State of California are intended beneficiaries of this agreement".

In licensing CIRM-Funded Inventions or CIRM-Funded Technology Exclusively or Non-Exclusively, Non-Profit Awardees 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. Except for clinical data, a Non-Profit Awardee 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 Awardees for non-commercial purposes, upon request from a Non-Profit Awardee.

An Awardee must take reasonable action to enforce the terms of an Exclusive License and must promptly report any material breach affecting any of the obligations under this policy of an Exclusive License in writing to CIRM.

VII. Access Requirements for Products Developed by Awardees

A Commercializing Entity must submit a plan to afford access to a Drug to Californians who have no other means to purchase the Drug. As used in this section, "no other means" means Californians who are not covered by a prescription drug benefit provided by any third-party payer (private or public) covering the particular Drug, and whose family incomes are below 300 percent of the federal poverty level. The access plan must be consistent with industry standards at the time of commercialization accounting for the size of the market for the Drug and the resources of the Commercializing Entity. Commercializing entities shall have the burden of establishing that the proposed access plan satisfies the requirements of this Section.

A Commercializing Entity must submit the access plan described above to CIRM within 10 business days following final approval of the Drug by the federal Food and Drug Administration, unless, within that timeframe, the Commercializing Entity seeks an extension from CIRM. If CIRM grants an extension, the access plan must be submitted no later than 30 business days following final approval of the Drug by the federal Food and Drug Administration.

The access plan shall be subject to the approval of CIRM after a public hearing conducted by CIRM that provides for receipt of public comment. CIRM may adopt appropriate procedures to protect proprietary information submitted by Commercializing Entities in connection with said public hearing. Approval shall not be unreasonably withheld. Overall, CIRM shall not require that proposed Access plans exceed industry standards for such plans at the time of commercialization in California.

Access plans approved hereunder shall make a Commercializing Entity responsible only for providing the Drug itself. Nothing herein shall require the Commercializing Entity to be responsible for any costs of administering the Drug nor for any associate costs of medical procedures or protocols for the Drug therapy, nor for any costs for attendant care.

The Independent Citizens Oversight Committee ("ICOC") may waive the requirement to submit an access plan if the ICOC determines, after a public hearing, that in the absence of the waiver, development and broad delivery of the Drug will be unreasonably hindered or that the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to an access plan. To invoke this waiver provision, a Commercializing Entity must deliver a written request to the Chair of the ICOC within 10 business days following final approval of the Drug by the federal Food and Drug Administration, unless the Chair of the ICOC agrees to an extension. The request must be accompanied by materials describing how development and broad delivery of the Drug will be unreasonably hindered by compliance with this section, and/or how the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to an access plan. The request shall be posted on CIRM's website no fewer than ten (10) business days prior to the ICOC's consideration. The ICOC may meet in closed session to review confidential or proprietary

material, or other material as allowed by Health and Safety Code section 125290.30, subdivision (d).

A Commercializing Entity must provide the Drug in accordance with any applicable statewide discount prescription drug program.

A Commercializing Entity must sell a Drug, which resulted in whole or in part from CIRM-Funded Research, and which is purchased in California with Public Funds at any benchmark price described in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500) or a successor statewide prescription drug discount program.

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

VIII. Revenue Sharing

A Commercializing Entity must share with the State of California for deposit in the State's General Fund a fraction of Net Commercial Revenue as follows:

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

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

(3) Royalty payments owed pursuant to this section shall be paid within 60 days following the end of each calendar quarter and shall be paid to the California State Treasurer's Office, Division of Cash Management.

IX. Press Release Requirements

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

X. March-In Rights

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

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

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

(2) the Awardee, Collaborator, Commercializing Entity or an Exclusive Licensee have failed to provide or comply with a plan for access to a Drug in accordance with section VII of this policy;

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

One consideration in forcing a license will be whether doing so will impinge on the Awardee's, Collaborator's, Commercializing Entity's or Exclusive Licensee's academic freedoms.

CIRM will promptly notify an Awardee, Collaborator, Commercializing Entity or an Exclusive Licensee of any adverse determination under this provision and the basis therefore, as well as its intention to exercise march-in rights ("March-In Notice").

CIRM will not exercise its march-in rights if the Awardee, Collaborator, Commercializing Entity or an Exclusive Licensee promptly acts to cure the deficiency and such deficiency is cured sooner than one year from the date of the March-In Notice (or longer period by agreement). With respect to public health emergency as declared by the governor, however, CIRM may exercise such right at any time in the event of a public health or safety emergency declared by the Governor and where CIRM finds that exercise of march-in rights is likely to alleviate the circumstances or conditions that give rise to the emergency declaration.

Within thirty (30) days of the date CIRM issues a March-In Notice, the subject Awardee, Collaborator, Commercializing Entity or Exclusive Licensee may appeal CIRM's decision to the ICOC by notifying the President of CIRM in writing of its intent to appeal CIRM's decision. Within sixty (60) days of the March –In Notice date, the subject appellant must submit a written statement of the reasons for the appeal and any supporting materials it wishes to have considered by the ICOC. Absent extraordinary circumstances, the ICOC shall render a final determination

on the appeal within one hundred twenty (120) days of the March-In Notice. In cases where an appeal is filed, CIRM shall not effect a march-in unless and until the ICOC renders a final determination on the appeal. The ICOC may reverse the decision of the CIRM to exercise march-in rights under this regulation for any reason.

Unless provided otherwise by CIRM, any applicant to receive a License or Assignment pursuant to this regulation will be bound by this policy as if it were an original Awardee recipient of the funding that resulted in the applicable CIRM-Funded Invention or CIRM-Funded Technology.

XI. Assurance of Third-Party Compliance

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

XII. Application of Amended Regulations to Prior CIRM Awards

If an Awardee has a pre-existing CIRM Award(s) and subsequently receives an Award that is subject to this Chapter, this Chapter shall apply to all prior CIRM Award(s) made to that Awardee if the new award utilizes a CIRM-Funded Technology or CIRM-Funded Invention arising out of the prior CIRM Award(s).