CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INITIAL STATEMENT OF REASONS FOR THE
PROPOSED ADOPTION OF THE CIRM INTELLECTUAL PROPERTY POLICY
FOR
CIRM AWARDS

HEARING DATE: None scheduled.

CLOSE OF PUBLIC COMMENT: July 16, 2018

SUBJECT MATTER OF PROPOSED REGULATIONS: CIRM IP Rules

SECTIONS AFFECTED: The proposed action adds section 100650 to Chapter 6 of Title 17 of the California Code of Regulations and incorporates by reference the Intellectual Property Policy for CIRM Awards.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH AMENDMENT:

SECTION 100650 – Intellectual Property and Revenue Sharing Requirements for CIRM Awards:

Purpose:

The purpose of Section 100650 is to describe the terms and conditions by which institutions who are California Institute for Regenerative Medicine ("CIRM") award recipients must abide during the term of the award.

Subdivision (a): This subdivision describes the scope of the regulation, indicating the regulation reaches all recipients of an award from the California Institute for Regenerative Medicine ("CIRM") agree to be bound by the terms and conditions of the CIRM Intellectual Property Policy for CIRM Awards incorporated herein by reference as identified below.

Subdivision (b): This subdivision identifies which provisions of the policy are being incorporated by reference. The 2018 CIRM Intellectual Property Policy for CIRM Awards is incorporated by reference herein in its entirety as to Sections "I" through and including "XII".

Subdivision (c): This subdivision indicates when amendments to the policy (effectuated by amendment to this regulation) are effective as to grants already funded. This regulation shall only apply to awards approved after the adoption of this regulation unless the parties agree that this regulation, including any amendments, apply to Awards funded

in whole or in part prior to the effective date of these regulations, or as provided in section XII of the policy incorporated herein, if applicable.

Subdivision (d): This subdivision indicates the term of enforcement of the policy and informs awardees that should the CIRM cease to exist the provisions of the regulation remain enforceable by the State of California.

Rationale:

Subdivision (a) is necessary to provide clarity in the scope of the policy – recipients of CIRM awards. The subdivision establishes the rule that all covered recipients are bound by the terms and conditions of the policy.

Title 1 of the California Code of Regulations, section 20, permits agencies to incorporate by reference documents under certain conditions. Subdivision (c)(1) of that regulation allows such incorporation when to do otherwise be "cumbersome, unduly expensive, or otherwise impractical" to publish the document in regulatory form. In light of the size and magnitude of the policy and given the burdens associated with translating each of the document's separate provisions into specific regulations, incorporation by reference serves the needs of both efficient use of resources, avoids the cumbersome task of rewriting an entire manual, and avoids the risk of inadvertent disagreement between the regulations and the policies being implemented.

Subdivision (b): This section clarifies the specific sections of the policy which are being incorporated by reference, as permitted by Title 1 of the California Code of Regulations, section 20, subdivision (c)(5).

Subdivision (c): This subdivision is necessary to address what will be a common-place circumstance, wherein active grants that may span several years may wish to become subject from time to time to amendments to the policy, or make take subsequent awards to further develop existing CIRM technologies that otherwise might be subject to two different IP policies. Once those amendments are effective (through amendment of the policy and the regulation incorporating it), the regulation clarifies that the new policy applies only to new grants unless the parties agree to apply them retroactively, or if the rules of section XII apply.

Subdivision (d): The rationale for this subdivision is to ensure that awardees are aware that the terms and conditions of the grant awards survive even in the event CIRM should no longer exists.

DOCUMENT INCORPORATED BY REFERENCE:

INTELLECTUAL PROPERTY POLICY
FOR
CIRM AWARDS

VERSION: with a footer that dates the document as "September 2017".

This policy is largely derived from existing California Code of regulations, Title 17 sections 100600 through 100611 and mirrors the subject of each section found in the 100600 series. Specifically, each Section of this policy corresponds directly to its 100600 counterpart. For instance, section 100601 "Definitions" is addressed in "Section 1 – Definitions" of this policy. Section 100604 – "Publication-Related Biomedical Materials Requirements" is addressed in "Section 4 – Publication-Related Biomedical Materials Requirements" of this policy.

SECTION I – DEFINITIONS

Purpose:

The following definitions shall apply to language contained in the policy:

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

C. 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.

D. CIRM-Funded Invention. An Invention, whether patentable or not, which arises from specific results directly generated by funding under an Award and is either:

(1) reduced to practice by a Awardee, Awardee Personnel and/or its Collaborator(s) during an Award; 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.

E. 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.

F. CIRM-Funded Technology. Data, materials, research results or know-how whether patentable or not, that is generated under an Award.

G. Collaborator. Any person or entity other than an Awardee and Awardee Personnel who obtains any ownership rights to a CIRM-Funded Invention or CIRM-Funded Technology and (a) receives CIRM funding directly or indirectly under the Award; or (b) knowingly participates in the Awardee's CIRM-Funded Project.

H. 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 is covered by, in whole or in part, 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 an Award.

I. 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).

J. 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.

K. 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.

L. 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.

M. 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.

N. 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.

O. 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.

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 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.

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. 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.

U. 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 an Award. Net Commercial Revenue excludes the following (as they pertain to the making, using or selling of products resulting from an Award):

(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.

V. 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.

W. 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.

X. 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.

Y. 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.

Z. Principal Investigator. The Principal Investigator ("PI") is an individual designated by the Awardee to direct the CIRM-Funded Project or Activity. 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.

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

BB. 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.

CC. Publication-Related Biomedical Materials. Tangible research material of biomedical relevance first produced in the course of an Award 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 Part III of this Policy. 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.

DD. Regulatory Use. The use of any CIRM-Funded Technology 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 Technology.

EE. Target CIRM-Funded Technology. For non-DISC awards, the CIRM Funded Technology specifically identified as "Target CIRM-Funded Technology" in the Notice of Award (or executed amendment thereto) and subject to the obligations in Part VI, subpart (B) of this policy.

Rationale:

To make specific the language and terminology used in formulating this policy. These definitions are largely duplicated from the definitions set forth in existing Section 100601, which are used as well in this policy. However, the following definitions were changed, as described below.

For Definition CC **Publication-Related Biomedical Materials**, the last sentence was deleted since it's a restatement of the concept in Section IV that the Awardee can tell a requestor where to obtain materials, especially if commercially available.

In addition, a new definition EE was added for **Target CIRM-Funded Technology** which would allow the Awardees, especially academic ones to understand what would need to be tracked by their Technology Licensing Departments

Award/Awardee. In updating CIRM's terms to describe recipients of CIRM funding, which can come in the form of a grant or loan, CIRM has dropped the terms "Grant" and "Grantee" in favor of the more global term, "Awardee." This definition is consistent with the definition CIRM uses in its Grants Administration Policy of "Award" and "Awardee," which restates Proposition 71's requirement that campuses of the University of California shall be considered as separate legal entities. As a result, the terms "**Grant"/"Grantee**" from Section 100601 have been deleted and replaced with "Award"/"Awardee."

Award Personnel. This term's title is modified from "Grantee Personnel" in Section 100601, to reflect the replacement of the terms "Grant/Grantee" with "Award/Awardee." The substance of the definition is unchanged.

CIRM-Funded Research from Section 100601 was deemed confusing and redundant. It was therefore deleted. The term was used in various other definitions and was subsequently replaced by "an Award" or "CIRM-Funded Technology/Activity" where appropriate.

Commercializing Entity. This term no longer excludes non-profit awardees. This change focuses on commercial revenue sharing and applies to all awardees, which reflects the following goals: By eliminating licensing revenue and focusing on commercial successes, CIRM seeks to optimize CIRM's remaining resources which will

allow the team to focus on CIRM's strategic mission. By simplifying the revenue sharing rules, CIRM will make them easier to understand, explain and administer. As a result, potential applicants will be able to more accurately predict the cost of CIRM money and thus, likely make CIRM's programs more attractive to follow-on investment and commercialization. All entities will be able to keep licensing revenue instead of diverting such resources away from further development of the technology.

Licensing Revenue from section 100601 was deleted because the concept of licensing revenue for all awardees was eliminated. The policy focuses instead on the "commercial revenue" concept currently applicable only to for-profit awardees. By eliminating licensing revenue and focusing on commercial successes, we believe we can optimize CIRM's remaining resources which will allow the team to focus on CIRM's strategic mission. By simplifying our revenue sharing rules, we will make them easier to understand, explain and administer. As a result, potential applicants will be able to more accurately predict the cost of CIRM money and thus, likely make CIRM's programs more attractive to follow-on investment and commercialization.

Notice of Grant Award from Section 100601 is amended, consistent with the changes described above with reference to "Grant/Grantee," to be **Notice of Award**, eliminating the word "grant" from the title. This is necessary because CIRM no longer issues grants but awards, instead. The substance of the definition is unchanged.

Regulatory Use is a new definition that is used to describe entities ("Commercializing Entity") that are subject to the revenue sharing formula described in Part VIII of the policy. Because the policy no longer relies on a license of a CIRM-funded technology to reach a commercializing entity, the policy reaches instead any entity that makes regulatory use of such technology.

SECTION II. Invention and Licensing Reporting Requirements

Purpose:

To ensure efficient use of CIRM-funded inventions, grantees are required annually to notify the CIRM of certain progress invention-related activities. This section identifies the information pertinent to such activities that must be reported in addition to any other information required by the CIRM under other regulations.

This section states that 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) An 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's technology licensing office (or similar entity), upon learning of such unlicensed use, shall notify CIRM within 10 days. In the case of non-profit academic Institutions, the obligations only extend to the technology licensing office (or similar entity) becoming aware of such an unlicensed usage or suspected or potential unlicensed usage.

Rationale:

This is essentially a restatement of existing CIRM regulation (Section 100602), and mandates that results and accomplishments of the activities it funds be made available to the public. Moreover, the CIRM is charged with ensuring that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State to benefit from the patents, royalties and licenses that result from the research funded by the CIRM. (Health & Safety Code § 125290.30, subd. (h).) To fulfill this role, the CIRM must monitor the work of grantees and ensure that inventions are pursued and exploited wherever possible. Therefore, this section is necessary to ensure that the CIRM is kept apprised whenever inventions are made and the steps taken or not taken regarding patents of those inventions. In addition, the reporting of licensing agreements ensures that the CIRM is able to determine whether CIRM-funded inventions are being used appropriately in the search for therapies and cures.

The existing requirement (section 100602(c)) of a notification within 90 days of the execution of a License Agreement involving CIRM-funded intellectual property has been dropped – and instead the notification can be made in the normal course of submitting the next Utilization Report, a report already required under the current regulations. CIRM found that the 90-day requirement was infrequently observed and that the information would still be timely if made in the utilization report.

Also, the existing requirement (section 100602(d)(3)) to report total funding from all sources that contributed to the CIRM-funded IP has been deleted. Because this information is relevant only in the context of the sharing of licensing revenue (which share can be diluted if the IP is co-funded by sources other than CIRM) and because licensing revenue sharing is no longer required under the proposed rule, this reporting requirement is no longer necessary.

Finally, the requirement that the Awardee notify CIRM upon learning of unlicensed use of the Awardee's technology is designed to ensure the State is aware of any potential income that is due from Regulatory Use about which the state may likely be unaware. The Awardee is often in the best position to be aware of how the Awardee's technology is being exploited.

SECTION III. Publication Requirements

Purpose:

This section identifies the procedures and content for publication of CIRM-supported research results. This section requires submission of copies of the publication to the CIRM, identification of where the MTA or similar document may be found, and a sample acknowledgment of CIRM funding.

It requires that 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 _____)."

Rationale:

This is a restatement of existing CIRM regulations (Section 100603), which mandates that results and accomplishments of the activities it funds be made available to the public. Moreover, the CIRM is charged with ensuring that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State to benefit from the patents, royalties and licenses that result from the research funded by CIRM. (§ 125290.30, subd. (h).) The CIRM also supports broad sharing of intellectual property of all kinds and encourages the timely publication of scientific articles in open-access journals that provide immediate access to scientific accomplishments by the scientific community and general public. It is CIRM's intention to create a database for tracking CIRM-funded inventions, patent applications and license agreements that involve CIRM-funded patented inventions based on information received from grantee organizations. Non-confidential information about CIRM-funded intellectual property may be shared with the public through a CIRM annual report. As a result, this section is necessary to ensure CIRM is aware of CIRM-supported research results that the grantee deems worthy of publishing. The advance press release requirement also ensures the CIRM is kept abreast of and can report important progress of CIRM-supported research.

This section also ensures that CIRM can support sharing of research findings with the scientific community and the general public as a whole through the creation of a repository for such findings. This resource is intended to allow access by the scientific community and the general public to summaries of published scientific articles resulting from CIRM-funded projects. The regulation supports this disclosure by requiring abstracts to be written by the authors of scientific articles specifically for the general public and submitted to the CIRM within 60 days of the publication of the corresponding scientific articles.

The existing language in section 100603(g) that requires a disclaimer regarding the responsibility of the contents of a publication is eliminated from the proposed rule. CIRM has found historically this last provision was rarely included in disclosures, but

that the failure to do so did not result in any confusion in the general public about such responsibility. As a result, the requirement is eliminated as unnecessary.

SECTION IV. Publication-Related Biomedical Materials Requirements

Purpose:

This section requires grantees to share biomedical materials described in published scientific articles for research purposes within a certain time after a receipt of a request unless legally prohibited from doing so. The section provides for CIRM-approved deviation in some circumstances and provides that authors may provide requestors with information on how to reconstruct or obtain the material. The section requires materials to be shared without cost or at cost.

Specifically, the section states that 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.

Rationale:

This is a restatement of existing CIRM regulations (Section 100604). It is expected that intellectual property of all types will be created as a consequence of CIRM grants to both for- and non-profit institutions and the policies in these two areas should be in harmony. The policy is intended to provide recipients of CIRM funding with guidance concerning appropriate terms for disseminating and acquiring unique research resources developed with CIRM funds and is designed to assist recipients in complying with their obligations under the Bayh-Dole Act and CIRM funding policy. In order to achieve maximum public benefit, data and biomedical materials (including research tools) should be as freely available as possible in the public domain.

That said, in order to ensure vital industries are not unduly burdened by sharing requirements that directly conflict with their business models, and that a balance is struck between sharing of materials and cooperation in the advancement of cures and therapies, the regulation describes circumstances under which CIRM may allow relief from the sharing obligations. By requiring CIRM prior approval, the agency is able to ensure the exceptions are utilized in good faith and allows the CIRM to monitor and control exemptions from the policy's requirements.

SECTION V. Patents

Purpose:

This section states that 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.

Rationale:

This is a restatement of existing CIRM regulations (Section 100605). It is not a policy of the CIRM to fund costs associate with patent applications, though specific programs may make an exception. This regulation is necessary to ensure grantees are

aware of conditions of their award. This section emphasizes Grantee ownership of IP and to describe the responsibility Grantees have to ensure third parties are aware of their obligations under the regulations.

The language "Unless provided otherwise by CIRM…" reflects the fact that some non-profit institutions may be a recipient of a specific CIRM award designed to cover or assist in covering costs associated with patent prosecution of CIRM-funded technology.

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

Purpose:

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. For non-DISC Awards, the obligations to negotiate Licenses shall only apply to the Target CIRM-Funded Technology from such Awards.

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.

Rationale:

This is largely a restatement of existing the existing CIRM regulation on point (Section 100606). Due to the importance of effective patent licensing to the development and availability of new products arising from CIRM-funded inventions, the CIRM licensing policy includes several important elements such as appropriate use of non-exclusive and exclusive licenses, diligent efforts to commercialize CIRM-funded inventions and plans for access to resultant therapies and diagnostics for qualified patients in California.

For inventions with potential preventive, diagnostic, or therapeutic uses, where some type of exclusivity (and therefore patent protection) is necessary for product development, licensing of the patent rights is the primary vehicle for transferring the technology to commercial partners.

Awardee organizations are responsible for licensing activities including identification of potential licensees, negotiation of license agreements and documentation of development progress. Awardee organizations are required elsewhere to submit a licensing activities report for CIRM-funded patentable inventions on an annual basis.

CIRM seeks to ensure development of each invention for the broadest possible applications, optimizing the number of products developed from CIRM-funded

inventions. This is accomplished first and foremost through diligent assertion of inventorship rights to inventions in accordance with current patent law. In addition, CIRM policy is for awardees to retain those ownership rights for transfer to the private sector through licensing instead of assignment. In the due diligence phase of licensing activities, awardee organizations are required to document the development and commercialization capabilities of the intended licensee, and include terms in the license agreement that address all relevant therapeutic and diagnostic indications for which the invention is applicable. This strategy allows CIRM awardees to engage in licensing negotiations which ensure the broadest and most expeditious development of new products.

CIRM encourages the use of non-exclusive licenses and recognizes that exclusive licenses may be required to enable development of therapies. Awardee organizations shall grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies only to organizations with plans to provide access to resultant therapies and diagnostics for uninsured California patients. In addition, such licensees will agree to provide to patients whose therapies will be purchased in California by public funds the therapies at a discounted price. These access plans may be made available by CIRM for review by the ICOC and the general public on an annual basis.

CIRM seeks to ensure that licensees of CIRM-funded patented inventions obtain the appropriate scope of rights necessary for them to develop potential applications of the invention while optimizing public good through the widespread use of the invention.

The implementation of the Target CIRM-Funded Technology is in the last sentence of VI.B: “For non-DISC Awards, the obligations to negotiate Licenses shall only apply to the Target CIRM-Funded Technology from such Awards.” This allows the Awardees to have a defined subject matter for their Office of Technology Licensing to track for licensing purposes. The Target CIRM-Funded Technology can also be amended by CIRM/Awardee in the Notice of Award if the research takes an unexpected direction. The distinction between non-DISC versus DISC awards takes into account the fact that non-DISC awards have more complicated IP postures that can be more easily focused in the targeted technology.

The requirement that “The California Institute for Regenerative Medicine and the State of California are intended beneficiaries of this agreement” be included in a license is intended to alert the potential downstream partner of its obligations to the State and ensure the State has standing to assert its rights in the event the State must enforce this policy against a downstream partner.

The existing requirement in 100606(g) to report on licensee milestones and benchmarks has been eliminated since the proposed rule no longer has revenue tied to licensee achievements and licensee-derived revenue.

SECTION VII. Access Requirements for Products Developed by Awardees

Purpose:

This section states that 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.

Rationale:

This is a restatement of current CIRM regulation on point (Section 100607). As a consequence of expenditure of the "first dollar" of CIRM funding, the for-profit awardee organization agrees to provide a plan (at the time of commercialization) to provide to uninsured California residents access to resultant therapies. The access plan shall be consistent with industry standards extant at the time of commercialization. This will ensure that Californians without insurance are able nonetheless to have improved access to therapies developed with the financial assistance of California's taxpayers.

In addition, the awardees will provide the therapies at a discount price to residents whose therapies are purchased in California by public funds. For drugs generated as a consequence of CIRM funding, awardees agree to provide drugs at benchmarks described in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500, et seq.) to eligible Californians under that program. Awardees also agree to provide discount pricing for therapies in addition to drugs that result from CIRM funding.

Section VIII. Revenue Sharing

Purpose:

This section states that 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) The royalty obligations under this section shall not apply to the resale of any Drug, product or service but upon the initial sale or transfer of such Drug, product or service as a treatment or prevention or for other similar end uses and not for uses in an intermediary step of commercialization.

(4) 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.

Rationale:

Commercialization of stem cell research discoveries for public benefit is an expected outcome from CIRM funding. Current data suggest that discovery and development of a therapy can cost in excess of $800 million. Although CIRM is not expected to completely fund the discovery and development of a stem cell-related therapy from start to finish, state funding may contribute in substantial ways to the commercialization of a product.

The California Stem Cell Research and Cures Act anticipates a return to the State of California:

> *The ICOC shall 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.*

Therefore, CIRM requires that in the event of the creation of a revenue stream from commercialization of a CIRM-funded program, awardees will share a portion of such revenues with the State of California for deposit into the General Fund.

In 2010, CIRM's revenue sharing regulations were codified by the Legislature (see Ch. 637, Stats 2010 (SB 1064-Alquist)).

The new policy eliminates license revenue sharing and focuses instead on commercial revenue sharing, applied to all awardees.) By eliminating licensing revenue and focusing on commercial successes, we believe we can optimize CIRM's remaining resources which will allow the team to focus on CIRM's strategic mission. By simplifying the revenue sharing rules, CIRM will make them easier to understand, explain and administer. As a result, potential applicants will be able to more accurately predict the cost of CIRM money and thus, likely make CIRM's programs more attractive to follow-on investment and commercialization.

Section VIII.A.(3) clarifies that the royalty obligations under this section do not apply to resales. Rather, the intent of the rule is not to compound royalty payments at various stages of commercialization but instead reach the initial sale of the Drug. This is consistent with commercial practices.

Section IX. Press Release Requirements

Purpose:

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.

Rationale: This is a restatement of existing CIRM regulation on point (100609). This regulation is necessary to the CIRM is apprised of current significant developments regarding CIRM-funded research and ensure proper attribution to the CIRM and the State of California for the CIRM-funded activity.

Section X. March-In Rights

Purpose:

This section states that 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.

Rationale:

This is a restatement of CIRM regulation on point (Section 100610). CIRM maintains a mandatory licensing provision commonly referred to as the march-in authority, the purpose of which is to prevent the underutilization of CIRM-funded inventions. March-in would apply only to those research tools that could be defined as patentable inventions. Prior to exercising march-in rights, CIRM must determine that such action is necessary because of the failure of the awardee organization or its licensees to take effective steps to achieve practical application of the inventions in a particular field of use, to satisfy health or safety needs, or to meet requirements for public use. Unlike the research exemption license retained by CIRM, the march-in provision is not limited to use for research purposes. CIRM march-in rights may be exercised in the event of (but are not limited to) failure to license CIRM-funded patentable inventions, failure to meet plans outlined in license agreements, or failure to provide adequate availability of resultant products for the public use.

CIRM will give to the awardee or licensee notice of such determination and the basis on which it was made. CIRM will not exercise its rights described above if the awardee or licensee takes diligent action promptly to cure the deficiency and such deficiency is cured not more than one year from receipt of notice (or longer period if agreed to by CIRM). CIRM may exercise such right at any time in the event of a public health or safety emergency. This is an appropriate tool in emergencies and is consistent with federal march-in provisions for federally-funded research.

Section XI. Assurance of Third-Party Compliance

Purpose:

This section states 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.

Rationale:

The proposed section is a restatement of existing policy, intended to ensure that Grantees have in place the mechanisms necessary to establish compliance of third parties with the requirements of CIRM's policy. This section enables the CIRM to track Grantee performance and the performance of third parties with obligations under the regulations.

Section XII. Application of Amended Regulations to Prior CIRM Awards

Purpose:

If an Awardee has a pre-existing CIRM Award(s) and subsequently receives an Award that is subject to this Chapter, the Awardee can choose to have this Chapter 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).

Rationale:

It may often be the case that CIRM will fund more than one stage of development of a given technology, and a team may apply for and receive more than one award as the development of the project proceeds. An earlier award may be subject initially to a given set of rules, and a subsequent award may be subject to a different set. Therefore the policy provides an option which can be chosen by the Awardee.

SPECIFIC PURPOSE OF REGULATION AND FACTUAL BASIS:

The IP Policy is required for effective grants management by CIRM. Further, this IP is necessary for meeting the specific reporting requirements of the Proposition to balance the opportunity to share in the success of CIRM-funded IP while not hindering development of the research. The IP policy is necessary to achieve the requirements and purposes discussed above.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS:

A. Documents or Laws:

None.

B. Public Input:

None.

Any information upon which the proposed regulation is based will be made available at the offices of CIRM located at 1999 Harrison Street, Suite 1650, Oakland, CA. Alternatively, transcripts and agendas for public meetings identified above are available on CIRM's website, www.cirm.ca.gov.

MANDATE FOR SPECIFIC TECHONOLOGIES OR EQUIPMENT:

The proposed regulation does not mandate the use of specific technologies or equipment.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES:

In view of information currently possessed, no reasonable alternative considered would be more effective in carrying out the purposes for which the regulation is proposed, or would be as effective as the regulation.

CIRM invites interested persons to present statements or arguments with respect to alternatives to the proposed action during the written comment period.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THAT WOULD LESSON ANY ADVERSE IMPACT ON SMALL BUSINESS:

CIRM has made the initial determination that the proposed action will not have an adverse impact on small business. The IP rules apply to CIRM Awardees who receive funds from CIRM to perform research. As such, no private conduct or commercial activity by a business of any size is being regulated.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS:

CIRM has made the initial determination that the proposed action will not have a statewide adverse economic impact. This action is not expected to have a direct impact on the creation or elimination of jobs, nor the creation of new businesses or elimination of existing businesses, nor the expansion of business currently doing business within the State of California because the amendments affect only administrative requirements regarding use of grant funds. The use of grant funds is required neither by law nor these regulations. To the extent the regulation facilitates use of the funds and encourage development of intellectual property and return to the state as required by law, and to the extent California institutions apply for and receive research funds, such requirements are indirectly attributable to increased economic activity spurred by the investment research funds in the state and resultant positive business and employment development. Also, to the extent the policy makes it possible for the expenditure of research funds in the state, and to the extent that research results in medical treatments and cures for chronic disease and injury, the policy indirectly benefit the health and welfare of California residents who will benefit from such treatments and cures.

ECONOMIC IMPACT ANALYSIS REQUIRED BY GOVERNMENT CODE SECTION 11346.3, SUBDIVISION (b)

Economic Impact Assessment Per Government Code Section 11346.3, subdivision (b):

For adoption of CIRM Intellectual Property and Revenue Sharing Requirements for CIRM Awards

Action: The regulatory action modifies existing Intellectual Property rules that govern CIRM awards. The new regulation states the requirements attendant to expending CIRM

research funds. The action does not regulate a commercial or private activity of any individual or institution but attaches conditions on the use of CIRM research funds.

Impact:

Under section 3 of the "California Stem Cell Research and Cures Act," which established the California Institute for Regenerative Medicine, funds for this agency are continuously appropriated without regard to fiscal year and not subject to budgetary control. By statute, this agency requires strict fiscal and public accountability through mandatory independent audits.

CIRM has determined that that proposed regulatory action has no impact on small businesses. The regulation implements conditions on awards for stem cell research. This research will be conducted almost exclusively by large public and private non-profit institutions, as well as large for-profit institutions. As such, and the regulations are not expected to adversely impact small business as defined in Government Code section 11343.610. Application for award funds is voluntary and awards are required by Proposition 71 to include provisions governing intellectual property created with CIRM funding.

This action is not expected to have a direct impact on the creation or elimination of jobs, nor the creation of new businesses or elimination of existing businesses, nor the expansion of business currently doing business within the State of California because the regulation affects only conditions regarding use of award funds. The use of award funds is required neither by law nor these regulations. To the extent the regulations facilitate use of the funds and encourage development of intellectual property and return to the state as required by law, and to the extent California institutions apply for and receive research funds, such requirements are indirectly attributable to increased economic activity spurred by the investment research funds in the state and resultant positive business and employment development. Also, to the extent the regulation makes it possible for the expenditure of research funds in the state, and to the extent that research results in medical treatments and cures for chronic disease and injury, the regulation indirectly benefits the health and welfare of California residents who will benefit from such treatments and cures.

************END************