2/10/06 ICOC Meeting
Agenda Item # 8

Working draft:

CIRM Intellectual Property Policy for Non-Profit Organizations

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CIRM Intellectual Property Policy for Non-Profit Organizations

Preface

This intellectual property policy for non-profit organizations (IPPNPO) serves not only as a statement of policy relating to intellectual property created under grant awards issued by the California Institute for Regenerative Medicine (CIRM) to non-profit research organizations, but also includes the terms and conditions for such awards. This policy serves as an accompaniment to the CIRM Grants Administration Policy (GAP)[*insert link or reference*]. In addition, it provides guidance to recipients on their responsibilities as CIRM grantees. Specifically, general information is provided in Section I, the intellectual property policy is detailed in Section III, and terms and conditions of award are detailed in Section II. Principal investigators, program directors and organizational officials with grants management and technology transfer responsibilities are urged to read this document carefully and to refer to relevant sections for answers to questions that arise concerning the administration of intellectual property that is made under CIRM funding. In general, CIRM terms and conditions are consistent with federal obligations for intellectual property mandated by the Bayh-Dole Act. The regulations that ensue from this policy carry the force and effect of law. CIRM may refer alleged violations of terms and conditions to the Office of the Attorney General of California for investigation and enforcement.

The CIRM IPPNPO applies to all CIRM grant awards issued on or after [*insert effective date*]. By accepting a CIRM grant award, the grantee agrees to comply with the terms and conditions in this policy.

The CIRM IPPNPO will be updated periodically by CIRM. Any new or amended regulations adopted by the Independent Citizen's Oversight Committee (ICOC), the governing board of the CIRM, will be applied to currently active grants on the start date of the next non-competitive renewal period. Principal investigators, program directors and organizational officials with active CIRM grants will receive notification of revised grant terms and conditions or revised editions of the CIRM Grants Administration Policy as they are released. All revisions will be posted on the CIRM website at http://www.cirm.ca.gov/.

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I. GENERAL INFORMATION

Section I provides general information about CIRM, the CIRM Intellectual Property Policy for Non-Profit Organizations, abbreviations and glossary for terms used throughout this document, roles and responsibilities of staff and sources of information used in the development of the policy and the terms and conditions found herein.

A. CIRM Background and Mission

The California Institute for Regenerative Medicine (CIRM) is a state agency that was established with the passage of Proposition 71, the California Stem Cell Research and Cures Act, a state ballot initiative approved by 59% of California voters on November 2, 2004. The California Stem Cell Research and Cures Act authorizes CIRM to disburse up to $3 billion in state bond funds over a period of 10 years or more in the form of grants and loans to investigators at California universities and institutions for the purpose of conducting stem cell research and constructing research facilities.

CIRM funding will support stem cell research and other vital research opportunities for the development of regenerative medical diagnostics, treatments and therapies. All research proposals will be peer-reviewed so that the most promising scientific proposals are funded.

Priority for research grant funding is given to stem cell research that meets the criteria established by CIRM and is unlikely to receive federal funding. Under the California Stem Cell Research and Cures Act, CIRM is prohibited from funding research on human reproductive cloning.

CIRM is governed by an Independent Citizen's Oversight Committee (ICOC), a 29-member board composed of executive officers from California universities and research institutions, representatives of patient advocacy groups, and experts in the development of medical therapies from the life sciences community. The ICOC members are public officials appointed because of their experience in California's leading public universities, non-profit academic and research institutions, patient advocacy groups, and the biotechnology industry.

B. CIRM Intellectual Property Policy for Non-Profit Organizations (IPPNPO)

The CIRM IPPNPO is the first of two CIRM intellectual property policies; a second CIRM intellectual property policy will be written to regulate intellectual property that may arise from CIRM funding of for-profit organizations. The IPPNPO is intended to meet the dual goals of academic openness and the need to bring scientific advances to the public via commercialization. A primary objective of the CIRM IPPNPO is to promote sharing of all types of intellectual property created as a consequence of CIRM funding for use in research conducted by both academic and commercial research and development organizations. Through the sharing of CIRM-funded data, knowledge, biomedical materials and patented inventions, CIRM strives to promote the general advancement of stem cell research and regenerative medicine. Another objective of the IPPNPO is to facilitate the commercialization of CIRM-funded discoveries without impeding the progress of stem cell research. To facilitate the translation of scientific discoveries to medical therapies, the CIRM IPPNPO recognizes the importance of transferring research results in the public interest through effective communication and collaboration with commercial entities with appropriate expertise, resources and capacity. Finally, the CIRM IPPNPO aims to provide a financial benefit to the State of California through revenue sharing in the event that CIRM-funded discoveries lead to valuable diagnostics and/or medical therapies.

C. Abbreviations

CELR - CIRM Electronic Library Repository

CIRM – California Institute for Regenerative Medicine

GAP - CIRM Grants Administration Policy

ICOC – Independent Citizen's Oversight Committee

IPPNPO – Intellectual Property Policy for Non-Profit Organizations

MTA – Materials Transfer Agreement

NAS – National Academy of Sciences

NGA – Notice of Grant Award

NIH – National Institutes of Health

OTT – Office of Technology Transfer

PD – Program Director

PI – Principal Investigator

SPO – Scientific Program Officer

USPTO – United States Patent and Trademark Office

D. Glossary

Authorized organizational official - The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to grant applications or grant awards. (See section on *Roles and Responsibilities* below)

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

Bayh-Dole Act – Section 6(a) of the federal Patent and Trademark Law Amendments Act (96 P.L.517,1980) as amended (35 U.S.C. §§200-212). Generally speaking, this law gives federal grantees the right to retain title to inventions created as a consequence of federal funding in exchange for an agreement to attempt to commercialize them.

Biomedical materials- Entities of biomedical relevance produced as a consequence of scientific 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. 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 intellectual property such as computer programs.

CIRM Electronic Library Repository – An internet-accessible library of documents authored by CIRM-funded researchers. The Library will include abstracts written for the general public that highlight CIRM-funded scientific achievements reported in scientific journals.

Data - The recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples).

Database – A compilation of data, typically generated from research, sometimes from one source, but often combined from many sources.

Final manuscript – A manuscript accepted for publication in a peer-reviewed scientific journal as changed as a consequence of the peer-review process.

For-profit organization - An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners.

Grant - A financial assistance mechanism providing money and/or property, or a loan or guarantee, to an eligible entity to assist the recipient in carrying out an approved project or activity.

Grantee/grantee organization - The individual or organization awarded a grant by CIRM that is legally responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activity. The grantee is the entire legal entity even if a particular component is designated in the NGA. All University of California grantee institutions shall be considered as separate and individual grantee institutions.

Grantee organization's share – The revenues received by a grantee organization under a commercial license of a CIRM-funded patented invention remaining after deducting the inventor's share of those revenues.

Invention – As used in the Bayh-Dole Act, i.e., a discovery that is or may be patentable (novel, useful and non-obvious) or otherwise protectable under Title 35 of the United States Code.

Invention disclosure - A description of an invention that triggers a patent bar under U.S. Patent Law.

Invention Disclosure Form – A written notification to CIRM that a CIRM-funded patentable invention has been made.

Invention Utilization Report – Applicable to grantee organizations that have previously filed an Invention Disclosure Form, this annual report is a written description of efforts made by authorized organizational officials to commercialize CIRM-funded patentable inventions. This report will include information about the status of development, date of first commercial sale or use and any licensing fees and/or gross royalties received by the grantee organization relating to CIRM-funded patented inventions.

Inventor - A person who thinks of, finds, discovers, or creates an invention during the project period of a CIRM grant and using CIRM funds as determined under U.S. Patent Law.

License agreement - An agreement by which a patent owner allows another party to make, use and/or sell an invention protected by a patent.

Licensing activities –Actions taken by authorized organizational officials, the desired outcome of which is a contractual agreement under which the grantee organization grants permission to another party to use intellectual property under specific conditions.

Licensing fee – A one-time cost payable by a licensee to the patent owner typically associated with execution of a license agreement.

Materials Transfer Agreement – A document which governs the exchange of a substance, element or item (material) to another party for the purposes of research. It typically limits the commercial exploitation of the material without the permission of the provider party.

No-cost license – An agreement to practice an invention protected by a patent where no licensing fee, royalty or any other payment is required of the licensee.

Non-profit organization – A university or other institution of higher education or an organization of the type described in 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501 (c) and exempt from taxation under 501 (a) of the Internal Revenue

Code (25 U.S.C. 501 (a)) or any non-profit scientific or educational organization qualified under a state non-profit organization statute.

Notice of Grant Award - The document that notifies the grantee and others that an award has been made, contains or references all terms and conditions of the award, and documents the obligation of CIRM funds.

Office of Technology Transfer- The office at a grantee institution that is responsible for evaluating, protecting, monitoring and managing an invention portfolio for the public good through overseeing invention disclosures, patent filings, patent prosecution, and negotiating and monitoring licensing agreements.

Organization - A generic term used to refer to a non-profit or for-profit organization or other entity.

Patent – The privilege that a government confers upon the inventor(s) of an invention the right to exclude others from making, using, and selling that invention for a set period of time.

Patent application – A document submitted to a government patent office (e.g. USPTO) requesting that a patent be issued. It typically includes an Abstract of Disclosure, patent drawings, specification, claims, oath or declaration, and a filing fee payment.

Patentable invention – A novel, useful and non-obvious invention that typically advances science and enables new useful applications including therapeutics or diagnostic tools, as determined under relevant patent law.

Principal investigator/program director - The principal investigator (PI) or program director (PD) is an individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and CIRM for the proper conduct of the project or activity. For training programs or similarly structured programs, the PD is the same as the PI. (See section on *Roles and Responsibilities* below).

Progress report - Periodic, usually annual, report submitted by the grantee and used by CIRM to assess progress and, except for the final progress report of a project period, to determine whether to provide funding for the budget period subsequent to that covered by the report.

Project period - The total amount of time for which CIRM promises to fund a grant and authorizes a grantee to conduct the approved work of the project described in the application.

Proposition 71 - The California Stem Cell Research and Cures Act passed on November 2, 2004, which added Article XXXV to the California Constitution and Chapter 3 (sections 125290.10 *et seq.*) to Part 5, Division 106 of the Health and Safety Code.

Publication-related biomedical materials – biomedical materials (see definition above) described in a scientific article.

Recipient - The organization or individual receiving a grant or other type of support from CIRM. This term is generally used interchangeably with grantee (see "grantee").

Requestor – One who makes a request for publication-related biomedical materials, or one who has received publication-related biomedical materials.

Research exemption - The ability to use patented inventions for research purposes free from the threat of patent infringement or costs of licensing fees, royalties or any other payments.

Research tool – A composition or method that broadly facilitates subsequent research.

Royalty - The compensation that is paid to the owner of a patented invention based on income earned by the invention's user, typically a percentage of net sales (gross sales minus costs, including but not limited to taxes, freight and insurance).

Royalty-free license –A license agreement that lacks a royalty obligation.

Scientific article - A publication in a scientific journal containing data and interpretation, applicable to both research and review articles.

Technology transfer – Process by which technology developed in one organization is made available for use in another organization. Common mechanisms include publication of scientific information and/or licensing of intellectual or tangible property.

Unique research resources – See "biomedical materials".

United States Code – The compilation of the general and permanent law of the United States.

U.S. Patent Laws - Title 35 of the United States Code which contains the section of the United States Code that contains the United States Patent Act, the federal statutes governing patent law in the United States.

E. Roles and Responsibilities

a. CIRM Staff:

i. President of CIRM

The President of CIRM is the chief executive of the Institute and oversees the implementation and operating requirements of the California Stem Cell Research and Cures Act (Proposition 71). CIRM NGAs will be signed by the President or by a staff member designated by the President.

ii. Communications Officer

The CIRM Communications Officer oversees the planning, management and implementation of the CIRM public relations and information outreach efforts. The Communications Officer is the primary contact for issues related to press releases and media advisories.

iii. Scientific Program Officer (SPO)

The SPO is responsible for the programmatic, scientific, and technical aspects of applications and grants. The SPO's responsibilities include, but are not limited to, developing research and research training programs to support the CIRM mission; providing consultation and assistance to applicants and grantees in scientific and programmatic areas, including interpretation of CIRM grants policies and procedures; and performing post-award administration such as review of progress reports, coordinating site visits and closing out grants. The name of the SPO and his/her contact information is provided with the NGA.

b. Grantee Organization Staff:

i. Authorized Organizational Official

The authorized organizational official is the designated representative of the grantee organization for matters related to the award and administration of CIRM grants. This individual's signature on the grant application certifies that, should the application be awarded, the organization will be accountable both for the appropriate use of funds and for the performance of the grant-supported project or activity resulting from the application. This individual also certifies that the organization complies with applicable federal and state laws and regulations, including required certifications and assurances (e.g., human subjects), and CIRM policies, including the terms and conditions of award.

ii. Principal Investigator (PI) or Program Director (PD)

The PI is the individual, designated by the grantee organization, responsible for the scientific or technical aspects of the grant and for management of the project or activity. The PI also is responsible for ensuring compliance with the financial and administrative aspects of the award. The PI must work closely with other grantee officials to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge CIRM support of research findings in publications, announcements, news programs, and other media; and ensure compliance with CIRM, federal, state, and organizational requirements. The PI must have a formal written agreement with the grantee organization that specifies an official relationship between the two parties even if the relationship does not involve a salary or other form of remuneration. For training programs or similarly structured programs, the PI is designated as the PD.

F. Sources of Information

There are many sources that provide helpful information about the administration of CIRM-supported grants or that are relevant to the CIRM IPPNPO. Below is a compendium of websites that contains information of interest to applicants for and recipients of CIRM grants as well as useful reports relating to intellectual property, data and materials sharing, and licensing trends. Some components of the CIRM IPPNPO were developed using guidelines and regulations contained in these documents:

a. General Interest Sites:

CIRM – http://www.cirm.ca.gov/

NAS – http://www.nas.edu/
NIH – http://www.nih.gov

b. Reports:

Data and biomedical materials sharing:

- 1999 Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources

  http://ott.od.nih.gov/pdfs/64FR72090.pdf

- 2003 Sharing Publication-Related Data and Materials

  http://www.nap.edu/catalog/10613.html

- 2004 A Patent System for the 21st Century

  http://www.nap.edu/catalog/10976.html

- 2005 Considerations in Developing an Intellectual Property Model for Research Grants Awarded by the California Institute for Regenerative Medicine

- 2005 Policy Framework for Intellectual Property Derived from Stem Cell Research in California

  http://www.ccst.us/ccst/pubs/IP/IP%20Interim.pdf

- 2005 Implementation of Proposition 71: Options for Handling Intellectual Property Associated with Stem Cell Research Grants

  http://democrats.sen.ca.gov/articlefiles/455110.31.05%20IP%20hearing%20transcript.doc

- 2005 Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation and Public Health

  http://www.nap.edu/catalog/11487.html

- 2006 Policy Framework for Intellectual Property Derived from State Funded Research

  http://www.ccst/us/ccst/pubs/ip/ipfinal.pdf

General patent information:

- http://web.mit.edu/tlo/www/patentbars.html
- http://www.uspto.gov/

Licensing trends:

- 2002 Association for University Technology Managers: Licensing Survey

  http://www.autm.net/events/File/Surveys/02_Abridged_Survey.p df
- 2003 Association for University Technology Managers: Annual Report

  http://www.autm.net/events/File/Surveys/03_Abridged_Survey.pdf

Alternative intellectual property models:

- 2003 Independent Evaluation of the International AIDS Vaccine Initiative

  http://www.iavi.org/file.cfm?fid=416
- 2004 International AIDS Vaccine Initiative Annual Report

  http://www.iavi.org/viewpage.cfm?aid=48

Biotechnology

- 2004 California's Biomedical Industry

  http://chi.org/brandomatic/othermedia/chi/biomed.pdf

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II. Intellectual Property Terms and Conditions

This section contains proposed terms and conditions with which grantee organizations and grantees must comply. Once finalized, these terms and conditions will comprise formal regulations that will be adopted by the ICOC pursuant to the Administrative Procedure Act. As with all regulations, these regulations will be binding on grantee organizations with the force and effect of law.

G. Invention Reporting Requirements

1. Grantee organizations are required to have written agreements with researchers requiring prompt disclosure of inventions made in the performance of CIRM-funded research.

2. Within 60 days after an inventor discloses a CIRM-funded invention to a grantee organization, the grantee organization must notify CIRM of the invention through the use of the CIRM Invention Disclosure Form [*insert link/reference here*], which will be received in confidence by CIRM. The Invention Disclosure Form shall identify the grant under which the invention was made and the inventor(s). It 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 invention. The disclosure shall also identify whether a manuscript describing the invention has been submitted for publication. If so, the disclosure shall identify the publication to which the manuscript has been submitted and the submission date.

3. Grantee organizations must notify CIRM on an annual basis regarding the filing of patent applications that claim inventions developed in the performance of CIRM-funded research.

4. Grantee organization must notify CIRM on an annual basis regarding execution of any licensing agreements of inventions developed in the performance of CIRM-funded research.

5. If relevant, grantee organizations must submit annually the Invention Utilization Report [*insert link/reference here*] that lists all CIRM-funded inventions, patents claiming such inventions and a statement of efforts made to utilize CIRM-funded inventions. Such reports shall include information about the status of development, date of first commercial sale or use and all licensing fees and/or gross royalties

received by the grantee organization under licenses of CIRM-funded patented inventions.

H. Sharing of CIRM-Funded Intellectual Property:

a. Publication requirements

1. Within 60 days of the publication of CIRM-supported research results in a scientific journal, PIs must submit to CIRM a 500 word abstract written for the general public that highlights the findings of the published body of work. In addition, PIs must submit a biographical sketch to accompany the abstract. The abstract and the biographical sketch will be deposited into the publicly-accessible CELR, to be accessed via the CIRM website.

2. One copy of each publication resulting from work performed under a CIRM grant must accompany the mandatory annual progress report submitted to CIRM.

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

4. CIRM grantees must acknowledge CIRM support of research findings in publications, announcements, presentations, and press releases by the grantees. An acknowledgement should be to the effect that:

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

b. Publication-related biomedical materials requirements

1. Grantees shall share biomedical materials described in published scientific articles for research purposes within 60 days of receipt of a request and without bias as to the affiliation of the requestor. Under special circumstances, extensions beyond 60 days may be possible with approval of the SPO. Alternatively, authors may provide requestors with information on how to reconstruct or obtain the material. Materials are to be shared without cost. Under such

circumstances where significant expenses are required to generate the materials, the grantee may recover those expenses (and only those) from the requestor after approval by the SPO.

c. Patent applications requirements

1. Grantee organizations shall bear responsibility for costs associated with patents and patent applications claiming their CIRM-funded inventions.

2. Grantee organizations shall report on an annual basis filings of such patent applications that claim inventions developed in the performance of CIRM-funded research.

d. Requirements for licensing of CIRM-funded patented inventions

1. Grantee organizations shall assume responsibility for licensing activities including identification of potential licensees, negotiation of license agreements and documentation of development progress for licenses relating to CIRM-funded patented inventions. Grantee organizations are required to submit a licensing activities report relevant to CIRM-funded patented inventions on an annual basis.

2. Grantee organizations shall negotiate non-exclusive licenses of CIRM-funded inventions whenever possible. Nevertheless, grantee organizations may negotiate and award exclusive licenses for CIRM-funded inventions relevant to therapies and diagnostics if such licenses are necessary to provide economic incentives required to enable commercial development and availability of the inventions. In due diligence relating to such licenses, grantee organizations shall document development and commercialization capabilities of the intended licensee, and include terms in the license agreement addressing all relevant therapeutic and diagnostic uses for which the invention is applicable.

3. In exclusive license agreements, grantee organizations shall include terms for commercial development plans to bring the invention to practical application. Such provisions shall include commercial development milestones and benchmarks so that development can be assessed and monitored.

4. Grantee organizations shall grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies and diagnostics to organizations with plans to provide access to resultant therapies 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 cost not to exceed the lowest available commercial U.S. price. The CIRM may make access plans available for review by the ICOC on an annual basis.

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

I. Grantee organizations shall negotiate relevant and specific grounds for modification or termination of the license. Examples would include failure to meet agreed-upon commercialization benchmarks, failure to keep the licensed invention reasonably accessible to the public for research purposes, and failure to reasonably meet the agreed-upon plan for access to resultant therapies as described in H(d)4.
II. Grantee organizations shall monitor the commercial development activities of the licensees to determine compliance with the terms of the license agreement and include reports of monitoring activities annually *[insert link here]*.
III. Grantee organizations shall take administrative action to modify or terminate license rights where necessary and report such action to the SPO.

e. Requirements to enable research exemption for CIRM-funded patented inventions

1. Grantee organizations agree that California research institutions may use their CIRM-funded patented inventions for research purposes at no cost. Grantee organizations shall require the same agreement of each of their licensees of CIRM-funded patented inventions.

f. Revenue sharing requirements

In the event of the creation of revenue streams from CIRM-funded patented inventions:

1. Grantee organizations shall share a fraction of any royalty revenues with the inventor(s) in accordance with their established policies.
2. The grantee organization may retain a threshold amount of its share of any revenues received under a license agreement of any CIRM-funded patented invention(s). Thereafter, the grantee organization shall pay 25% of its share of such revenues to the State of California for deposit into the State's General Fund unless such action violates any federal law. The threshold amount is $500,000 (in the aggregate) multiplied by a fraction, the denominator of which is the Consumer Price Index, All Urban Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the Bureau of Labor Statistics of the United States Department of Labor and published for the month of February, 2006, and the numerator of which is such Index published for the month in which the grant award is accepted by the grantee.
3. If funding sources in addition to CIRM were used in the creation of a CIRM-funded patented invention, the return to the State of California of any resultant revenues shall be proportionate to the support provided by CIRM for the discovery of the invention.
4. Grantees shall apply the grantee organization's share of any royalties earned as a result of CIRM-funded patented inventions to the support of scientific research or education.

g. Press release requirements

CIRM grantees must notify CIRM prior to any press releases that refer to research findings, collaborations, inventions, patents or licensing activities that arise as a consequence of CIRM funding by contacting the CIRM Communications Officer and the SPO. In the event that the CIRM wishes to participate in a joint press release, the grantee will coordinate with the CIRM Communications Officer.

I. March-in Rights requirements

With regard to CIRM-funded patented inventions, CIRM shall have the right to require the grantee organization, or exclusive licensee of a CIRM-funded invention, to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are

reasonable under the circumstances, and if the grantee organization, non-exclusive licensee, or exclusive licensee refuses such request, to grant such a license itself, if the CIRM determines that such an action is required:

1. Because the grantee organization or the licensee has not made responsible efforts in a reasonable time to achieve practical application of a CIRM-funded patented invention
2. Because the licensee has failed to adhere to the agreed-upon plan for access to resultant therapies as described in H(d)4.
3. To meet requirements for public use and the requirements have not been satisfied by the grantee organization or its licensee
4. To alleviate public health and safety needs which are not reasonably satisfied by the grantee organization or its licensee and which needs constitute a public health emergency

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

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III. Intellectual Property Policy

Unlike Section II of this document which contains proposed terms and conditions ultimately destined to be regulations, the following discussion provides an intellectual property primer and sets forth the policies (regulatory and aspirational) behind the terms and conditions of Section II. As such, the following section is for education and discussion purposes to provide context to the regulatory language that will ultimately be adopted.

J. Types of Intellectual Property

(Background material in Section J is based in part on *Policy Framework for Intellectual Property Derived from Stem Cell Research and California* by the California Council for Science and Technology Intellectual Property Study Group.)

Intellectual property exists in several forms. CIRM-funding is expected to generate many types of intellectual property including but not limited to data, databases, biomedical materials, patents, scientific articles, research tools and software. Intellectual property is protected by different instruments such as patents, copyrights and trade secrets.

Patents provide exclusive protections for patentable inventions for a limited time period. From twenty years from the patent application filing date, a patent holder may exclude others from making, using or selling the patented invention. To obtain a patent, an inventor must file an application with the United States Patent and Trademark Office (USPTO), which will determine whether the invention meets the patentability requirements and if so, will issue a patent. New, useful, and non-obvious machines, manufactures, compositions of matter, and processes qualify for patentability. In return for full disclosure of the invention in the body of a patent, the inventor obtains the right to exclude others from practicing the invention.

Patents are commonly used to protect biological, biotechnological and pharmaceutical tools and products, including living materials such as cell lines and engineered organisms. Further, the methods by which such cell lines are isolated may be protected through patenting.

Another form of intellectual property protection is a trade secret, which is defined as a formula, process, device, or item of information that has economic value because it is not generally known or easily discovered by observation or examination and for which reasonable efforts to maintain secrecy have been made. Intellectual property acquires trade secret status after reasonable efforts have been made to keep the

information secret, such as marking all relevant materials "confidential", keeping the intellectual property in a secure location and restricting access. Unlike patents, trade secrets exist as long as the information remains secret.

A copyright is a legal right granted for an original work of authorship, such as a scientific article. Protection begins at the first tangible expression of the author's work and lasts for the life of the author plus seventy additional years thereafter.

Recent significant developments in biology such as gene expression profiling illustrate how patents, trade secrets and copyrights converge to protect particular aspects of new technologies. Similarly, CIRM-funded inventions are likely to benefit from combinations of protection mechanisms.

CIRM policy mandates that results and accomplishments of the activities it funds be made available to the public. Therefore PIs and grantee organizations are expected to make the results and accomplishments of their activities available to the research community and the public at large, and to effect their timely transfer to industry for commercialization. If research findings result in inventions, grantee organizations have the right to ownership of these inventions so long as the right is consistent with the provisions of the Bayh-Dole Act for the utilization, commercialization and public availability of the invention. The Bayh-Dole Act encourages grantee organizations to utilize patent and licensing processes to transfer grant-supported inventions to industry for development. Alternatively, when an invention is useful as a research tool, technology transfer in the form of journal articles or other publications or through the dissemination of research products or resources may be a more appropriate means of promoting utilization, commercialization or public availability of an invention.

K. Core Principles of the CIRM Intellectual Property Policy for Non-Profit Organizations:

1. **Ownership**: CIRM grantee non-profit organizations will own intellectual property that arises from CIRM-funded research activities.

2. **Broad Sharing**: Intellectual property, including but not limited to data, knowledge, scientific articles, biomedical materials and patented inventions, that are made in the performance of CIRM-funded research will be shared broadly and promptly with the scientific community. This CIRM sharing policy is structured to extend the sharing of CIRM-funded intellectual property beyond practices commonly in use by the scientific community in 2005.

3. **Research Exemption**: Patented inventions that are made in the performance of CIRM-funded research are to be made freely available for research purposes in California research institutions.

4. **Licensing**: For patented inventions that are made in the performance of CIRM-funded research, grantee organizations are expected to negotiate non-exclusive licensing agreements where possible except in those circumstances when exclusivity is required to encourage the successful commercial development of the invention into products and services that can benefit the public. In addition, CIRM has established licensing policies regarding access to resultant therapies and revenue-sharing which are described in detail in **Licensing Policy Elements** (pg. 34).

5. **March-in rights**: Like other funding agencies, CIRM maintains a licensing provision referred to as march-in rights, the purpose of which is to prevent the underutilization of CIRM-funded inventions. Details regarding CIRM's march-in rights are described in **N. March-in Rights** (pg. 37).

L. Rights in Ownership

Intellectual property, including but not limited to data, inventions, discoveries or improvements that arises from CIRM funding during the project period, is the property of the grantee organization. Decisions about whether to publish, whether to patent, how to identify appropriate licensees and how to allocate resultant revenues to inventors and other appropriate grantee organization programs are the responsibilities of the grantee organization.

Inventors must report inventions to the grantee organization prior to publication or presentation at any open meeting since failure to do so may result in the loss of rights to the grantee organization or inventor. The grantee organization must report inventions, patent applications, patents and licensing activities involving CIRM-funded inventions to CIRM as outlined in Section II,G.

The grantee is not required to notify CIRM when publications, data or other copyrightable works are developed under or in the course of work supported by a CIRM grant. Copyrighted or copyrightable works also include materials developed by students, fellows or trainees supported by awards whose primary purpose is education or training of such individuals. CIRM requires that grantee organizations allow CIRM (without charge of any fees) to reproduce, publish or otherwise use the

copyrighted material for public benefit so long as such use is not in violation of any copyright held by another party.

PIs may arrange for publication of initial reports of original research, supported in whole or in part by CIRM funds, in primary scientific journals and for copyright by the journal unless the journal's copyright policy would preclude individuals from making or having made a copy of any such scientific article for their own use. PIs are encouraged to assert copyright in research articles based on data produced under the grant where this is necessary to effect publication in academic, technical or professional journals, symposia, proceedings or similar works.

a. Publications/Acknowledgement of Support

i. CIRM 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. To encourage the use of open-access media by CIRM-funded researchers, CIRM will support publication costs associated with publication of scientific articles in open-access journals through the use of budget supplements.

ii. To support the sharing of research findings with the scientific community and the general public as a whole, CIRM will create a CIRM Electronic Library Repository (CELR), accessible through the CIRM website. 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. Such abstracts will be written by the authors of scientific articles specifically for the general public and submitted to CIRM within 60 days of the publication of the corresponding scientific articles. Principal investigators will also submit a biographical sketch to accompany abstracts.

iii. To extend access to CIRM-funded research findings to the public, a copy of the final manuscripts of all scientific articles supported in whole or in part by CIRM may be deposited into PubMed Central *[insert link here]* to be made freely available within twelve months of the journal publisher's official date of final publication unless prohibited by the copyright policy of the publisher.

iv. A copy of each publication shall be submitted to CIRM along with the mandatory annual progress report.

v. In all publications, announcements, presentations, and press releases by grantee organizations, grantee organizations shall acknowledge CIRM support and identify the number of the CIRM grant that enabled the work.

See Section II,H(a) for publication requirements.

b. Press releases

CIRM grantees must notify CIRM in advance of any press releases that refer to research findings, scientific articles, collaborations, inventions, patents or licensing activities that arise as a consequence of CIRM funding. In the event that the grantee wishes to participate in a joint press release, the grantee should coordinate with the CIRM Communications Officer.

See Section II,H(g) for press release requirements.

c. Invention Reporting

CIRM will 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. In brief, grantee organizations are required to report to CIRM information about:

i. inventions made under CIRM funding
ii. patent applications claiming CIRM-funded inventions
iii. licenses of CIRM-funded patented inventions
iv. efforts made to license and develop CIRM-funded patented inventions

See Sections II,G for requirements for invention, patent application and licensing activities reporting.

M. Core Principles of the CIRM Sharing Policy Are:

1. Protect academic freedom and promote publication

2. Minimize impediments to stem cell research

3. Allow grantees to conform to Bayh-Dole obligations with respect to inventions that result from research funded by both CIRM and federal funds

4. Encourage broad dissemination of CIRM-funded intellectual property of all types beyond practices commonly used in 2005 to promote scientific progress

5. Facilitate the translation of CIRM-funded discoveries to medical therapies

6. Ensure broad access for California research institutions to patented inventions made under CIRM funding for research purposes through a research exemption

The free exchange and dissemination of scientific information and the pursuit of basic scientific research has led to remarkable advances in the understanding of biology. This scientific progress, combined with the protections and information dissemination possibilities afforded by a vigorous patent system has resulted in the development of numerous products that can be used to diagnose, treat and cure a variety of diseases and injuries. Critically important to furthering scientific progress and enhancing human health are provisions that allow the open dissemination of and access to scientific discoveries while protecting the rights of inventors and commercial entities invested in the development of medical therapies.

CIRM strongly endorses the broad sharing of all types of intellectual property (such as data, information, scientific articles and biomedical materials) created under CIRM funding as recommended by the National Research Council in its 2005 report *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* and its 2003 report *Sharing Publication-Related Data and Materials:*

> *Community standards for sharing publication-related data and materials should flow from the general principle that the publication of scientific information is intended to move science forward. More specifically, the act of publishing is a quid pro quo in which authors receive credit and acknowledgement in exchange for disclosure of their scientific findings. An author's obligation is not only to release data and materials to enable others to verify or replicate published findings but also to provide them in*

> *a form on which other scientists can build with further research. All members of the scientific community – whether working in academia, government, or a commercial enterprise – have equal responsibility for upholding community standards as participants in the publication system, and all should be equally able to derive benefits from it* (NRC, 2003, p.4).
>
> *The principles and standards of scientific publication are also consistent with society's interest in the applications of scientific knowledge and their economic and other benefits. An author who publishes a paper is expected to share materials related to that publication to other scientists for research purposes, but that does not prevent an author from seeking intellectual property rights protection in order to realize the commercial value of those materials. To encourage the disclosure of scientific information, the patent system bestows inventors of a novel, non-obvious, and useful innovation with the right, for a limited time, to prevent others from making or using that innovation, unless licensed to do so. Scientific publication provides no such incentive, but to the contrary, encourages other scientists to use and integrate into new research those things described in a scientific publication. An author who publishes a scientific paper describing a patented process, for example, may have a legal right to prevent others from using it, but the scientific community holds the expectation that an author will make available a license to use that process for research. From a social perspective, the two systems are complementary: patenting fosters the commercialization of ideas; scientific publication communicates the ideas that build the edifice of science. Scientific publications also influence the issuance of patent rights by defining the landscape of the "prior art" and "obviousness" criteria used in assessing the novelty of putative patent claims.* (NRC, 2003, p. 31-32).

CIRM encourages the broad sharing of both unpatented and patented intellectual property. Under the sharing policy for CIRM-funded intellectual property, grantees are expected to share their data, biomedical materials, and copyrighted materials (as well as patented intellectual property through the CIRM research exemption), and do so in a manner that does not preclude patenting CIRM-funded inventions in foreign countries.

1) Protect academic freedom and promote publication

Research organizations that receive CIRM funding through grants or contracts are obliged to preserve research freedom, safeguard appropriate authorship and ensure timely disclosure of their scientists' research findings through publications and presentations at scientific meetings. Recipients are expected to avoid signing agreements that unduly limit the freedom of the investigators to collaborate and publish or that automatically grant co-authorship or copyright to another party, such as the provider of a material.

Reasonable restrictions on collaboration by academic researchers involved in sponsored research agreements with a commercial partner that avoid conflicting obligations to other commercial partners are acceptable. Similarly, brief delays in publication may be appropriate to permit the filing of patent applications and to ensure that confidential information obtained from a sponsor or the provider of a research tool is not inadvertently disclosed. However, excessive publication delays or requirements for editorial control, approval of publications or withholding of data are unacceptable.

2) Minimize impediments to stem cell research

CIRM recognizes that multiple iterations of license agreements or materials transfer agreements (MTAs) during negotiation periods can significantly delay the implementation of the scientific discovery for the public good. Recipients should take every reasonable step to streamline the process of transferring research tools freely to other research institutions using the CIRM MTA (or similar document), a cover letter, or no formal agreement.

3) Allow grantee organizations to conform to Bayh-Dole obligations

CIRM recognizes the obligations imposed on researchers in California as a consequence of the Bayh-Dole Act in the event that researchers co-mingle federal funds with CIRM funding and produce patentable inventions. CIRM policies have been developed so as to allow CIRM grantee organizations to conform to those obligations.

4) Ensure broad dissemination (beyond 2005 practices) of CIRM-funded intellectual property of all types to promote scientific progress

Publication-related biomedical materials sharing

It is expected that intellectual property of all types will be created as a consequence of CIRM grants and contracts. This IPPNPO 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.

Unique research resources include synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. 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 intellectual property such as computer programs. Under certain circumstances, computer-related products such as databases and software may also be regarded as copyrighted materials.

Timely publication of research findings is a researcher's obligation and a valued technology transfer mechanism to share data and biomedical materials with the scientific community.

Prospective authors should be aware that publishing implies an obligation to share intellectual property described in the publication, whether protected by patent or copyright or not. Materials described in a publication must be shared promptly (within 60 days of receipt of a request unless otherwise arranged with the SPO) and in a manner that permits other researchers to replicate and extend the work described. Authors must provide publication-related materials to requestors regardless of whether the author and requestor are from the academic, public, private non-profit, or for-profit (commercial) sector. Authors must make published materials available to all requestors on similar, if not identical, terms (see Section II,H(b) for requirements relating to the sharing of publication-related biomedical materials).

CIRM encourages authors to provide publication-related materials to the scientific community at no cost. However, some requested materials are costly to produce and distribute. Under these circumstances, authors may charge a fee that covers costs of production and distribution of the requested materials with prior approval by the SPO. Alternatively, authors may provide requestors with information on

how to reconstruct or obtain the material. Occasionally, the frequency of production and/or distribution of requested publication-related materials presents a burden to the author. Under such conditions, the SPO may work with the author's grantee organization to identify or establish a supplier or distributor to promote the dissemination of CIRM-funded discoveries to the scientific community. In such cases, the grantee organization should contact the SPO with a description of the publication-related material, relevant production procedures, history of requests and details related to the special nature of the case.

In their publications, authors must include the URL of a website where the CIRM MTA (or similar document) can be accessed to facilitate requests for publication-related materials. If the material described in the publication is patented, the provider of the material must make the material for research use. If a license is used to make the material available, the licenses will be at no-cost, royalty-free, non-exclusive and for purposes of research at California research institutions.

Prospective authors are responsible for understanding the risks and consequences of public disclosures, including but not limited to publications in scientific journals and presentations at scientific conferences, as they relate to any anticipated patenting activities. A useful reference for more information about the risks of public disclosure to patenting activities can be found here:

http://web.mit.edu/tlo/www/patentbars.html

CIRM expects grantee organizations to promote the dissemination of data, information, methods, biomedical materials, patented inventions and other intellectual property through appropriate administrative procedures and oversight.

MTAs for the transfer of publication-related materials

CIRM expects grantee organizations to provide appropriate support to their researchers in activities that promote broad sharing, such as those that require the use and approval of an MTA. Transfers of materials between institutions are typically accompanied by MTAs. An MTA typically defines the rights of the requestor to the use of a material and may define how any intellectual property resulting from use of the material will be apportioned between the material provider and the requestor.

Grantee organizations should make use of CIRM MTA (or similar) forms when sharing publication-related materials and promptly process (within 60 days of

receipt of a request or otherwise arranged due to production requirements) forms during sharing transactions.

CIRM supports and recommends the following terms for MTAs because they are consistent with the spirit of sharing publication-related materials and acknowledge the provider's contribution:

a) A general description of the research for which the requestor intends to use the material (to eliminate frivolous or irresponsible requests rather than to approve the research plan)

b) A requirement that the provider be acknowledged as a source of the material in any publication by the requestor

c) An acknowledgement that the transfer of material does not affect the legal title to it.

d) A requirement that the requestor not disseminate the material to others outside the laboratory without the provider's permission.

e) A requirement that the material be used only for research purposes; that is, where the primary intention of the research is the fundamental increase in knowledge. This excludes its manufacture for sale, licensing to others, or contract research undertaken for a commercial concern.

f) A prohibition against the use of the material for work with human subjects, including diagnostic testing, if the material has not been previously approved for use with human subjects.

g) A provision that disclaims any warranties on the material and excludes the provider from any liability for damages that arise from the use, storage, transport, or disposal of the material by the requestor, including liability related to the requestor's infringement of any third party intellectual property rights.

CIRM discourages the following terms in any MTA involving CIRM-funded materials:

i. Requirements for periodic reporting of research findings related to the use of the material.

ii. Ownership by the provider of the requestor's data or other research results.
iii. Limitations on the requestor's ability to publish research results.
iv. Limitations on the requestor's ability to discuss research results with his or her laboratory members before publication.
v. Automatic co-authorship rights for the provider.
vi. Requirement for an exclusive license to commercialize a new substance that the requestor makes with the material

CIRM encourages CIRM-funded researchers to report to the SPO any non-compliance with publication-related material requests.

Disclosure and patenting of inventions

The Intellectual Property Clause of the United States Constitution grants Congress power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." CIRM recognizes that patenting entails making public a complete description and fully enabling disclosure of a novel invention and in so doing, provides public access to information that may otherwise be kept as a trade secret while granting exclusive ownership of the invention to the inventor. Patent exclusivity is limited in duration and provides a means of protecting inventions without secrecy. The law exclusive rights under intellectual property law rests on the assumption that exclusive rights create the ability to attract investments to fund the research and development required to bring a novel product to market.

CIRM recognizes the value of patents when follow-on private investment adds social value by bringing products and services to market. Consequently, CIRM encourages the filing of patent applications for CIRM-funded inventions. It is expected that grantee organizations will work with researchers to identify inventions that may have therapeutic or diagnostic value, file patent applications, maintain patent portfolios, and engage in efforts to commercialize CIRM-funded discoveries through diligent technology transfer practices. However, grantee organizations are expected to refrain from patenting hypothetical proteins, random single nucleotide polymorphisms and haplotypes as well as proteins that have only research, as opposed to therapeutic, diagnostic, or preventive, functions. CIRM discourages the patenting of upstream inventions/research tools.

Grantee organizations are responsible for the education of researchers regarding public disclosures as they relate to patenting activities.

Grantee organizations are responsible for all decisions relating to and costs of the filing of provisional patent applications, non-provisional patent applications claiming priority to provisional applications and Patent Cooperation Treaty (PCT) applications (which preserve foreign rights). Similarly, grantee organizations are responsible for the identification of potential licensees and negotiation of license agreements with potential licensees.

For CIRM-funded patented inventions, grantee organizations are expected to allow scientific research institutions in the State of California to use the inventions for research purposes at no cost.

5) Facilitate the transfer of CIRM-funded discoveries to medical therapies

Technology transfer and licensing activities

Technology transfer is fundamental to the translation of scientific discoveries to eventual medical diagnostics and therapies. Technology transfer is process by which technology developed in one organization is applied in another organization. The Federal Technology Transfer Act of 1986 requires federal laboratories to actively seek opportunities to transfer technology to industry, universities, and state and local governments. This mandate underscores the role of technology transfer in creating public benefit.

A primary mechanism for technology transfer in the biomedical field is the sharing of scientific information and materials through publications and presentations. Another major mechanism for technology transfer is enabled by licensing activities which facilitate the transfer of technology embodied in patented inventions for society's use and public benefit. License agreements are the intended output of licensing activities, and license agreements can exist in various forms including exclusive, non-exclusive, royalty-free, no-cost and those that have costs associated with them. Through the execution of license agreements, patented inventions are made available for use by others.

Partnerships between academic laboratories and private industry already have extended and accelerated research, research training and the dissemination of information in diverse and creative ways. As researchers confront ever more complex biomedical challenges, strategic partnerships between private industry

and nonprofit organizations will become increasingly central to realizing potential of early scientific discoveries.

Private industry complements academic institutions through the provision of expertise, resources and capacity that are typically absent from universities and other non-profit research institutions. Public-private partnerships through licensing agreements provide opportunities for grantee organizations to translate scientific discoveries into products for the public good by commercial entities with appropriate resources and capacity. Private partners can offer the significant financial and technical investments required to bring a product through the discovery and optimization phases, preclinical testing, and clinical trials required to gain market approval.

As research institutions build and develop their OTTs, licensing activities have played a major role in bringing early stage discoveries to public use. Almost all research universities in the United States have had technology licensing operations since before 1998. A license agreement grants a licensee access to (not ownership of) a patented invention in exchange for the licensee's commitment to further develop and commercialize the invention. The provisions of the license define the rights and responsibilities of each party. In a typical license agreement, the licensee is granted access to an early stage invention that is protected by a patent owned by the research institution. In exchange, the licensee agrees to perform functions necessary to commercialize the invention, pay any upfront fees required by the research institution, reimburse the institution for expenses incurred for patenting activities and pay royalty payments when products reach the marketplace.

The transfer of technology is a complicated process that involves many stages and variables and has been most successful when it has involved one-on-one negotiations between the owner of the patented invention and the licensee. Consequently, CIRM regards technology transfer as best approached on a case-by-case basis where specifics relevant to the invention, the market potential of the application of the invention and the parties involved can be appropriately considered.

CIRM recognizes the necessity of private industry involvement to bring stem cell research discoveries to the marketplace. Consequently, grantee organizations are expected to actively support efforts to license and commercialize CIRM-funded patented discoveries and report those efforts to CIRM on an annual basis.

A license is an agreement between two parties whereby one party is granted by the other the right to make use of the second party's property.

An *exclusive license* gives a licensee sole rights to commercialize the invention. In some cases, licensing agreements may be signed with more than one party, especially in cases where research tools are involved or where a market can be divided into exclusive parts, and are termed *non-exclusive* licenses.

A typical licensing agreement has several components which include:

Licensing fee – a one-time cost paid after execution of the license.

Patent expenses - reflect costs that are incurred for filing and protecting the invention.

Development period – time period defined in an agreement to allow an invention to be developed. A development plan, which can include milestone achievement goals, is included in the licensing agreement. Regular reports provide documentation that active development is under way and provide a basis for monitoring progress.

Royalties – fees paid by the licensee to the patent holder upon sales of a resultant product, typically a percentage-of-sales annual fee or fee-per-unit payment structure.

Minimum royalty –an annual royalty payment that is independent of sales.

A *no-cost license* is one where the licensee gains access to patented inventions without having to pay any fees to do so. A *royalty-free license* is one where terms of the agreement do not specify a requirement for fees to be paid to the patent holder as a consequence of revenues generated by a marketed product enabled by the licensed invention.

Licensing Policy Elements

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 for qualified patients in California.

CIRM does not encourage patent protection for "upstream inventions", those that require significant further research and development efforts to realize the commercial application of the invention. For example, CIRM does not encourage patent protection for research tools, such as transgenic mice, receptors, or cell lines for research use (as opposed to therapeutic or diagnostic uses). For such research tools, the public interest is served primarily by ensuring that the research tool is widely available to both academic and commercial scientists to advance further scientific discovery.

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.

Grantee organizations are responsible for licensing activities including identification of potential licensees, negotiation of license agreements and documentation of development progress. Grantee organizations are required to submit a licensing activities report for CIRM-funded patentable inventions on an annual basis (see Section II,G for details).

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 grantees to retain those ownership rights for transfer to the private sector through licensing instead of assignment. In the due diligence phase of licensing activities, grantee 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 grantee organizations 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 and diagnostics. In the event that such licenses are granted, grantee organizations are required to grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies and diagnostics to organizations with plans to provide access to resultant therapies to uninsured patients in California. In addition, such licensees will agree to provide to patients whose therapies will be purchased in California by

public funds therapies at a cost not to exceed the lowest available commercial U.S. 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.

Revenue sharing

CIRM seeks to obtain a financial return on the public's research investment through the recovery of 25% of revenues from the grantee organization's (not the inventor's) share of revenues from licenses for CIRM-funded patented inventions. Consistent with their Bayh-Dole obligations, grantee organizations must share a fraction of any royalty revenues with the inventor(s). The CIRM-mandated 25% fee will go to the General Fund of the State of California unless such action violates any federal law. CIRM expects the balance of remaining revenues earned by the grantee organization to be applied for the support of research or education.

CIRM recognizes that administrative costs associated with filing patent applications, maintaining patent portfolios and carrying out licensing activities are a major financial burden for grantee organizations whether or not an invention is successfully licensed and results in any licensing revenues. Consequently, CIRM will recover funds from a grantee organization only when revenues from a license of CIRM-funded patented invention(s) exceed $500,000 in the aggregate (see Section II,H(f) for specific information).

CIRM also recognizes that funds from multiple sources may be used in the creation of intellectual property in the course of scientific research. In the event that CIRM partially funds research that leads to a licensed patented invention with revenues in excess of $500,000, the return to the State of California will be proportionate to the CIRM financial support for the research that resulted in the invention.

6) Establish a research exemption to promote broad access for California research institutions to patented inventions made under CIRM funding

Research exemption: a mechanism for access to patented inventions

Research is a critical element of technological and medical progress. However, research activities may have unintended intellectual property implications. Under the Patent Act of 1952, any individual who makes, uses, sells, offers to sell or imports into the United States a patented invention without the authorization of the patent owner faces liability for infringement. The Patent Act of 1952 does not authorize a generally applicable research exemption. To the extent that researchers use another's patented invention without authorization, they may face liability for patent infringement. A research exemption (also known as "research use exemption" or "experimental use exemption") is the ability to experiment with patented inventions free from the threat of patent infringement or costs of licensing fees or royalties.

To promote the advancement of research and medical therapies through broad use of patented inventions developed under CIRM funding, CIRM grantee organizations agree that California research institutions may use their CIRM-funded patented inventions for research purposes at no cost. This policy will allow researchers to experiment with state-of-the-art technology generated as a consequence of CIRM funding without constraints which might otherwise apply under patent law (see Section II,H(e) for research exemption requirements).

N. March-in Rights

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 grantee 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.

In observance of the march-in provision, CIRM grantee organizations may not assign to a third party all rights to an invention, although exclusive licensing is permitted under the CIRM IPPNPO.

CIRM retains march-in rights that may be exercised:

1. Because the grantee organization or the licensee has not made responsible efforts in a reasonable time to achieve practical application of a CIRM-funded patented invention
2. Because the licensee has not made acceptable efforts to adhere to the agreed-upon plan for access to resultant therapies as described in Section II, H(d)4
3. To meet requirements for public use and the requirements have not been satisfied by the grantee organization or its licensee
4. To alleviate public health and safety needs which are not reasonably satisfied by the grantee organization or its licensee and which needs constitute a public health emergency

CIRM will give to the grantee or licensee notice of such determination and the basis on which it was made. CIRM will not exercise its rights described above if the grantee 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). With respect to a deficiency described in item 4, CIRM may exercise such right at any time in the event of a public health or safety emergency.

See Section II,I for march-in requirements.