

# **CIRM Grants Administration Policy for Discovery, Translation, and Education Projects**

Adopted September 2016

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## **Preface**

This grants administration policy serves as the terms and conditions for Discovery, Translation, and Education Projects funded by the California Institute for Regenerative Medicine (CIRM). In addition, it provides guidance to applicants and Awardees regarding their responsibilities as CIRM Awardees. Principal investigators, program directors, and organizational officials with grants management responsibilities are urged to read this document carefully and to refer to relevant sections for answers to questions that arise concerning the administration of CIRM Awards. Applicants and Awardees may be required to document compliance with any and all provisions set forth in this policy.

By accepting CIRM funding, the Awardees agree to comply with the provisions set forth in this policy.

This policy may be amended or revised periodically. Any new or amended regulations adopted by the Independent Citizens' Oversight Committee (ICOC), the governing board of CIRM, will be applied to currently active awards funded under Discovery, Translation and Education Projects on the start date of the next Budget Period, except as provided in the relevant CIRM Intellectual Property Regulations. CIRM will notify principal investigators, program directors and organizational officials with active CIRM Awards of amendments to or revisions of this policy as they are released. Amendments or revisions will be posted on the CIRM website (<http://www.cirm.ca.gov>).

CIRM's right to enforce this policy shall survive the end of the term of the Project Period, and should CIRM no longer exist, the State of California may exercise that right.

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## **I. GENERAL INFORMATION**

### **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 percent of California voters on November 2, 2004. Proposition 71 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, loans and contracts for the purpose of conducting stem cell research and constructing research facilities in the State of California.

CIRM funding supports stem cell research and other vital research opportunities for the development of life-saving regenerative medical 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 Proposition 71, CIRM is prohibited from funding research on human reproductive cloning.

CIRM is governed by the Independent Citizens' 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. 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. Abbreviations**

CFR – Code of Federal Regulations

CIRM – California Institute for Regenerative Medicine

DHHS – U.S. Department of Health and Human Services

FDA – U.S. Food and Drug Administration

FWA – Federal-Wide Assurance

GMO – Grants Management Office

IACUC – Institutional Animal Care and Use Committee

ICOC – Independent Citizens' Oversight Committee

IDE – Investigational Device Exception

IND – Investigational New Drug

IRB – Institutional Review Board

NGA – Notice of Grant Award

NIH – U. S. National Institutes of Health

OHRP – Office for Human Research Protections, DHHS

PHS – Public Health Service, DHHS

PI – Principal Investigator

RFA – Request for Applications

SCRO – Stem Cell Research Oversight Committee

GWG – Scientific and Medical Research Funding Working Group

SPO – Scientific Program Officer

SRO – Scientific Review Officer

### C. Defined Terms

Application	A request for CIRM funding to conduct research; provide services; or construct, lease, or acquire Equipment. An Application shall contain all information upon which approval for funding is based.
Approved Budget	The financial expenditure plan for the CIRM-Funded Project or Activity, including revisions approved by CIRM and permissible revisions made by the PI or Awardee.
Authorized Organizational Official (AOO)	The individual, named by the applicant organization, who is authorized to act for the applicant organization and to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to Applications and Awards.
Award	CIRM funding in the form of a Grant, Loan, or contract that is based on an approved Application and budget.
Award Close-out	The final stage in the life-cycle of an Award. During this phase, CIRM ensures that all applicable administrative actions and required work have been completed by the PI and Awardee. CIRM also reconciles and makes any final fiscal adjustments to the Awardee's Award.
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 Grant Award. Campuses of the University of California shall be considered as separate and individual Awardees.
Budget Period	The intervals of time (usually 12 months) into which a Project Period is divided for budgetary, funding and reporting purposes. For Awards with Operational Milestones, the Budget Period represents the time between achievement of each Operational Milestone.
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 a Notice of Grant Award, regardless of whether CIRM funding constitutes all or only a portion of the financial support necessary to carry them out.
Consultant	An individual who provides professional advice or services related to the proposed project in exchange for a fee.

Covered Stem Cell Line	A culture-derived, human pluripotent stem cell population that is capable of: (1) sustained propagation in culture; and (2) self-renewal to produce daughter cells with equivalent developmental potential. This definition includes both embryonic and non-embryonic human stem cell lines regardless of the tissue of origin. “Pluripotent” means capable of differentiation into mesoderm, ectoderm, and endoderm.
Direct Research Funding Costs	The sum of project costs and facilities costs of a CIRM Award. “Project costs” are those costs that can be specifically identified with a particular CIRM-Funded Project or Activity. “Facilities costs” are the operating costs of an Awardee’s facilities attributable to housing all elements of the CIRM-Funded Project or Activity.
Equipment	Non-expendable, free-standing, tangible personal property with a normal life expectancy of one year or more and an acquisition cost which equals or exceeds the lesser of the capitalization level established by the Awardee for financial management purposes or \$5,000.
Financial Authorized Organizational Official (FAOO)	An individual, named by the Awardee organization, who is authorized by that organization to submit required Financial Reports to CIRM.
Financial Report	An Awardee’s periodic report to CIRM detailing expenditures against CIRM funds as specified in the Notice of Grant Award (see chapter V, section H, part 1).
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. Such organizations also are referred to as “commercial organizations”.
Grant	A funding mechanism pursuant to which CIRM provides money and/or property to an Awardee on terms set forth in a Notice of Grant Award, in order to assist the Awardee in carrying out approved CIRM-Funded Project or Activity.
Human Embryonic Stem Cells	Human embryonic stem cells are immature (i.e., undifferentiated) cells that are derived from a human early stage, preimplantation embryo. Human embryonic stem cells can be cultured in vitro where they self-renew indefinitely and have the potential to develop into any cell type of the body (i.e., they are pluripotent).
Human Subject	A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of Human Subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as Human Subjects and to graphic, written, or recorded



	information derived from such individuals.
Indirect Costs	Administrative costs of an Awardee incurred for common or joint objectives, which cannot be readily and specifically identified with a particular project.
Key Personnel	(1) the principal investigator or program director; or (2) any other person, including an independent consultant or an employee of a Subcontractor or Partner, who is expected to contribute to the scientific development or execution of the project in a substantive, measurable way and who is expected to: (a) receive or has been promised income, or anything else of value, of \$10,000 or more per year for his or her contribution to the project or (b) contribute one percent (1%) or more effort to the proposed project. “Key Personnel” does not include a person who is expected to be involved in the proposed project but who does not satisfy conditions (1) or (2).
Loan	A funding mechanism pursuant to which CIRM loans money and/or property to an Awardee, in exchange for a promise to prepay CIRM pursuant to terms set forth in a Notice of Grant Award, in order to assist the Awardee in carrying out a CIRM-Funded Project or Activity.
Non-Profit and Not-for-Profit	(1) a governmental entity of the state of California; or (2) a legal entity that is tax exempt under Internal Revenue Code section 501(c)(3) and California Revenue and Taxation Code section 23701d.
Notice of Grant Award (NGA)	The document that notifies the Awardee that a Grant has been made, contains or references all terms and conditions of the Award as well as the Awardee’s and PI’s agreement to those terms and conditions, and documents the commitment of CIRM funds.
Operation and Maintenance Expenses	The general operating costs of an Awardee’s facilities, including expenses normally incurred for such items as janitorial and utility services; repairs and ordinary or normal alterations of buildings, furniture and Equipment; care of grounds; maintenance and operation of buildings and other plant facilities; security; earthquake and disaster preparedness; environmental safety; hazardous waste disposal; property, liability and all other insurance relating to property; space and capital leasing; facility planning and management; and central receiving that are necessary for carrying out the CIRM-Funded Project or Activity (see chapter V, section F).
Operational Milestone	An objective event that is indicative of project progress occurring as proposed in the application. The successful achievement of an Operational Milestone may trigger the disbursement of additional funds under the award as scheduled in the NGA. The intervals between Operational Milestones are used to divide a Project Period for budgetary, funding and reporting purposes.

Organization	A generic term used to refer to a Non-Profit, Not-for-Profit or For-Profit Organization or other legal entity which applies for or receives CIRM funding.
Other Support	Includes all financial resources – whether federal, non-federal, commercial, or organizational – available in direct support of an investigator’s research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other Support does not include training awards, prizes, or gifts.
Principal Investigator (PI) or/Program Director (PD)	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.
Prior Approval	Prior written approval from CIRM that is required for specified post-award changes in the Approved Budget or project. Such approval must be obtained before undertaking or spending CIRM funds for the proposed activity.
Program Announcement (“PA”)	The mechanism for funding opportunities that accept applications on an ongoing basis, rather than a fixed deadline.
Progress Report	An Awardee’s periodic report to CIRM detailing scientific activities and findings in the research project identified in the NGA (see chapter V, section H, part 2).
Project Milestone	An objective event established by CIRM in which the failure to meet the event grants CIRM the right, at its sole discretion, to suspend payment and/or terminate the project.
Project Period	The total amount of time as stated in the NGA for which CIRM intends to fund a project or activity and authorizes a PI to conduct the work in the approved Application. For reporting purposes, the Project Period includes all Budget Periods and/or Operational Milestones.
Recipient	The Awardee, PI or PD, trainee, Subcontractor, Consultant or any other person or entity that receives CIRM funding pursuant to an Award.
Scientific and Medical Research Funding Working Group (GWG)	The advisory body responsible for reviewing the scientific and programmatic content of Applications for research funding and for making funding recommendations to the ICOC.
Subcontract/Subaw	A contract between the Awardee and a third party to perform a portion of

ard	research proposed in the Application.
Tuition and Fees	Costs charged by the Awardee for the enrollment and instruction of a student. It does not include costs of health insurance for a trainee, which is an allowable cost addressed separately.

## **D. Types of Support**

This Grants Administration Policy will support a number of different CIRM funding opportunities, each with its own defined objective. The objective of translation stage program is to create a highly competitive opportunity for promising stem cell-based projects that accelerate completion of translational stage activities necessary for advancement to clinical study or broad end use. The objective of the discovery stage program is to support exploratory research leading to the discovery of novel stem cell technologies to improve patient care. The objective of the Conference Grants program is to create a highly competitive opportunity for CIRM to support valuable mission-specific scientific conferences. The objective of the education program is to create the next generation of stem cell scientists and a trained workforce for California, ensuring that the state has young scientists ready to continue the search for cures.

## **E. Roles and Responsibilities**

### **1. Awardee Organization Staff:**

#### **a. Authorized Organizational Official (AOO)**

The AOO is the designated representative of the Awardee organization for matters related to the Award and administration of CIRM funding. This individual's signature on the Application certifies that, should the ICOC approve the Application for funding and should CIRM issue an Award, the Organization will be accountable both for the appropriate use of funds and for the performance of the CIRM-Funded Project or Activity. This individual also certifies to CIRM that the PI and Awardee comply with applicable federal and state laws and regulations, including required certifications and assurances (e.g., IRB, SCRO, IACUC), and CIRM policies, including the terms and conditions of the Award.

A designated AOO must have the legal authority to commit the Awardee to indemnify CIRM as provided in Chapter III, Section B, Liability, and an Awardee's designation of an AOO confers apparent authority to commit the Awardee to such indemnification of CIRM.

#### **b. Principal Investigator (PI) or Program Director (PD)**

The PI is the individual, designated by the Awardee, responsible for the scientific or technical aspects of the CIRM-Funded Project or Activity and for its management. The PI and the Awardee are both responsible for

ensuring compliance with the financial and administrative aspects of the Award. The PI must work closely with other Awardee 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.

## **II. GRANT APPLICATION AND REVIEW PROCESS**

### **A. Eligibility**

#### **1.PI and PD Eligibility**

The PI/PD will be subject to a background check to ensure this individual has not been convicted of fraud or other misuse of funds, nor subject to disbarment of federal funds. There are no citizenship requirements for PIs.

#### **2. Organizational Eligibility**

An applicant organization must be a legal entity that is accountable for both the performance of the approved project or activity and the appropriate expenditure of funds. In general, Non-profit and For-profit research organizations located and conducting research in California are eligible to apply for and to receive CIRM research funding. Under certain programs, CIRM may limit eligibility to meet the specific goals of the program. The determination of eligibility includes verification of the applicant's ability to carry out the proposed project and responsibly manage and account for State funds in the organization's accounting systems, and verification of corporate status.

CIRM allows California and Non-California Organizations (for-profit and non-profit) to apply to CIRM. The allowable project costs vary between the two types of organizations and will be stated in the program announcement. To qualify as a California organization, the organization must employ and pay more than 50% of its employees in California. Non-California organizations are those that employ and pay 50% or less of its employees in California.

### **3. Other Requirements**

Because eligibility may vary, applicants should carefully review CIRM announcements. An applicant may be required to provide proof of eligibility, such as organizational eligibility, PI or PD eligibility.

#### **B. Application Submission**

CIRM funding opportunities will be announced on the CIRM website (<http://www.cirm.ca.gov>). Programs will specify the objectives and requirements that apply, and the elements that will be used to evaluate the merits of Applications submitted in response to the announcement. Information regarding Application forms and instructions for completion and submission of Application materials will be available as part of the funding opportunity announcement. CIRM may require submission of a Letter of Intent (LOI) and/or Communication Plan prior to or as a condition of submission of a full Application.

#### **C. Legal Effect of Signed/Submitted Application**

In signing the Application, the AOO warrants to CIRM that the information contained in the application is true and complete and that all eligibility requirements have been satisfied and AOO agrees that should an Award be issued, the organization will abide by the terms and conditions of the Award, all applicable CIRM regulations, all applicable public policy requirements, and will perform the activities included in the submitted Application as approved by the ICOC (unless Prior Approval is sought and obtained).

#### **D. Application Review**

In accordance with Proposition 71, the Scientific and Medical Research Funding Working Group (Grants Working Group or GWG) makes funding recommendations to the Application Review Subcommittee of the ICOC. The role of the GWG includes consideration of the scientific merit of Applications to support research Facilities. The membership of the GWG consists of seven patient advocate members of the ICOC, 15 scientists from institutions outside of California, and the chairperson of the ICOC (ex officio).

The GWG conducts its review of Applications in accordance with procedures recommended by the GWG and adopted by the ICOC. For each Application, a recommendation on funding is made by the full GWG and submitted to the Application Review Subcommittee of the ICOC, which makes all funding decisions. The GWG will designate each reviewed Application as either recommended for

funding or not recommended for funding.

## **E. Criteria for Review of Research Grant Applications**

Pursuant to Proposition 71 (Health and Safety Code section 125290.60), the ICOC has established criteria for the evaluation of Applications by the GWG, each of which may be weighted differently depending on the purpose and goals of a particular PA. The ICOC may also adopt additional or revised review criteria, when appropriate to meet the objectives set forth in a particular program.

## **F. Appeals of Scientific Review**

An appeal of scientific review is limited to demonstrable conflicts of interest as defined in CIRM's Conflict of Interest Policy for Scientific Members of the GWG. Any such appeal shall be filed pursuant to this section.

An applicant may lodge a formal appeal of the review only if the applicant can show that a demonstrable financial, professional, or personal conflict of interest, as defined in the GWG Conflict of Interest Policy, had a negative impact on the review process and resulted in a flawed review. Differences of scientific opinion between or among PIs and reviewers are not grounds for appeal.

To lodge an appeal, the applicant must submit an appeal request in writing to CIRM within 10 days of CIRM's making the review report available to the applicant. The CIRM team will then assess whether the applicant has established facts constituting a conflict of interest and whether the conflict of interest had a negative impact on the review process and resulted in a flawed review and present a recommendation to the president of CIRM. If the president concludes that the applicant has established facts constituting a conflict of interest and that the conflict of interest had a negative impact on the review process and resulted in a flawed review, the application will be submitted to the GWG for a new review.

## **G. Approval for Funding**

The GWG is responsible for making recommendations to the ICOC on funding of Applications based on scientific merit and programmatic relevance. The Application Review Subcommittee of the ICOC makes all final funding decisions. In deciding which Applications to fund, the Application Review Subcommittee may consider: (i) programmatic issues, with a focus on portfolio balance, relevance to unmet health need, urgency of timeline, alignment with focus of Proposition 71, alignment with the

goals and priorities of the Program Announcement, budget adjustments if necessary, and other stipulations; (ii) recommendations made by CIRM's scientific team based on their review of the Grants Working Group's recommendations; and (iii) public comment.

## **H. Policy on Collection and Use of Personal Information**

CIRM values and respects an individual's right to keep personal information private. Likewise, CIRM recognizes the need to collect and use personal information that will enable CIRM to effectively perform the responsibilities for which it was created. All personal information collected about individuals will be kept confidential and in a secure environment. However, information that is not protected from disclosure under the California Public Records Act may be subject to disclosure upon request.

In addition, individuals must seek a Principal Investigator's permission before they publicly communicate about unpublished data.

## **I. Public Access to Public Records**

In the California Public Records Act (Government Code section 6250 *et seq.*), the California Legislature declared that access to information concerning the conduct of the people's business is a fundamental and necessary right of every person in this state. The California Public Records Act requires that public records be generally available to the public upon request (Government Code section 6253(a)) but also contains numerous exceptions.

Proposition 71 (Health and Safety Code section 125290.30(e)) provides that the California Public Records Act shall apply to all records of CIRM but does not require disclosure of the following:

1. Personnel, medical or similar files, the disclosure of which would constitute an unwarranted invasion of privacy;
2. Records containing or reflecting confidential intellectual property or work product, whether patentable or not, including, but not limited to, any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information, which is not patented, which is known only to certain individuals who are using it to fabricate, produce, or compound an article of trade or a service having commercial value and which gives issuer an opportunity to obtain a business advantage over competitors who do not know it or use it; or
3. Pre-publication scientific working papers or research data.



Although Proposition 71 also provides that the California Public Records Act shall not apply to CIRM working groups, including the GWG (Health and Safety Code section 125290.50(f)), the ICOC has decided that the public shall also have access to the records of the working groups except for, among other things: (i) Applications for research, training, and facilities grants, loans, and contracts; (ii) evaluations of such Applications; and (iii) exceptions provided for in the California Public Records Act itself and Health and Safety Code section 125290.30. Subsection (e) of section 125290.30 exempts from public access records containing or reflecting confidential intellectual property and work product, such as that found in invention disclosures to CIRM.

For further information, please see the California Public Records Act and Proposition 71. For details on how CIRM responds to Public Records Act requests, see the CIRM guidelines available at (<http://www.cirm.ca.gov/general/pdf/guidelines.pdf>).

### **III. PRE-AWARD AND AWARD**

#### **A. Pre-Funding Administrative Review (PFAR)**

After the approval of funding by the Application Review Subcommittee or ICOC, applications are then reviewed by the CIRM to ensure that they meet all applicable CIRM funding requirements, including the submission of required public policy assurances. CIRM reviews the Application budget to ensure that all proposed costs are allowable, reasonable and appropriate for the work being performed and as specified in this Grants Administration Policy and the pertinent Program Announcement. During the administrative review, CIRM reserves the right to revise individual budget items as appropriate.

Issues that arise during administrative review generally must be resolved before CIRM will issue an NGA. CIRM may, however approve an Application for funding contingent upon the acceptance (by the PI and AOO) of a condition.

The funding opportunity will specify when an approved awardee must initiate work on the funded project, but is generally within 3 months of approval and authorization for funding by the Application Review Subcommittee of CIRM's governing board for Translation programs, and within 4 months of approval and authorization for Discovery programs.

## **B. Liability**

CIRM is not responsible for the conduct of CIRM-funded research or for the acts or omissions of Recipients of CIRM funding, because such conduct is under the direction and control of the Awardee and subject to its organizational policies. Further, Awardee organization personnel compensated in whole or in part with CIRM funds are not considered employees of CIRM.

Awardees shall indemnify or insure and hold CIRM harmless against any and all losses, claims, damages, expenses, or liabilities, including attorneys' fees, arising from research conducted by the Awardee pursuant to the award, and/or, in the alternative, Awardees shall name CIRM as an additional insured and submit proof of such insurance. (Health and Safety Code section 125290.45, subd. (a)(2).). If the Awardee chooses only to insure, such insurance must provide coverage in amounts appropriate and proportional to cover the risks described in the previous sentence. Awardees that fail to provide evidence of such insurance prior to issuance of the NGA will be deemed to have agreed to indemnify and hold CIRM harmless.

In all cases, the Awardee will maintain, or cause to be maintained, in full force and effect, insurance or a self-insurance program that provides for general liability coverage that is (a) applicable to the CIRM-Funded Project or Activity, (b) in an amount not less than \$1 million per occurrence, \$3 million aggregate and (c) that is comparable to coverage held by institutions of similar size and nature. Upon request, the Awardee shall provide CIRM with certificates of insurance evidencing such coverage.

## **C. Public Policy Requirements**

Organizations and individuals that receive support from CIRM shall comply with, and where applicable provide evidence of compliance with, the following public policies. Initial funding or continued funding of any CIRM-Funded Project or Activity is contingent upon compliance with these requirements. Documentation that certifies or verifies compliance generally may be required to be submitted before CIRM will issue a Notice of Grant Award. In cases where research requiring public policy assurances will be conducted at a later phase of the funded research, CIRM may issue a Notice of Grant Award imposing a condition or restriction on the use of funds until documentation of required assurances is submitted.

The Awardee shall retain records and supporting documentation that demonstrate compliance with public policy requirements for a minimum five years from the date of submission of the final expenditure report for the Award. If related audit findings

have not been resolved, documentation must be maintained for longer than five years, until such findings are resolved. Records and supporting documentation may be audited by CIRM or other appropriate state agencies, including the Office of the Attorney General of California.

## **1. Conduct of Research**

- a.** “Research misconduct” means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. “Fabrication” means making up data or results and recording or reporting them. “Falsification” means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. “Plagiarism” means the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.
- b.** Awardees and Recipients must conduct all research in accordance with the highest medical and ethical standards for scientific research and all applicable laws. The Awardee bears the ultimate responsibility for preventing, detecting and imposing sanctions for research misconduct. Awardees must adopt, maintain and ensure compliance with written policies and procedures for inquiry, investigation, and adjudication of allegations of research misconduct. An acceptable standard for such policies and procedures, for example, is found in the *Public Health Service Policies on Research Misconduct* (42 CFR Part 93)(effective May 17, 2005).
- c.** Within 30 days of concluding an investigation of research misconduct, Awardees shall notify CIRM in writing of any finding of research misconduct against a Recipient of CIRM funding and of any related proposed corrective actions.
- d.** The administrative actions imposed by CIRM for research misconduct may include, but are not limited to, the following: correction of the scientific literature; special plan of supervision to ensure integrity of the scientific research; certification of the accuracy of the scientific data; certification of the accuracy of sources and contributions for scientific ideas and writings; disqualification of the Awardee or Recipient from eligibility for CIRM funds; termination of the Award, and/or return of CIRM funds. The duration of these actions will depend on the nature and seriousness of the misconduct. Additional actions that CIRM may take are described in chapter V, section J,

*Failure of Compliance and Award Termination.*

## **2. Conflict of Interest**

Awardees must establish safeguards to prevent employees, Consultants, contractors, collaborators, and members of governing bodies who may be involved in the CIRM-Funded Project or Activities from participating in or in any way attempting to use their position to influence those activities in which they know or have reason to know they have a financial interest. The Awardee must promptly notify CIRM if and when it takes any action against the PI or another Recipient of CIRM funding relating to a financial conflict of interest.

Awardees must enforce within their institutions all such applicable safeguards. If the Awardee uses contractors or collaborators to conduct CIRM-funded research, the Awardee must take reasonable steps to ensure that such contractors or collaborators comply with the Awardee's safeguards. An acceptable standard for such a policy, for example, may be found in 42 CFR Part 50, Subpart F (*Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought*)(effective October 1, 2000).

## **3. Administrative Actions**

The Awardee promptly shall promptly notify CIRM of the results of any investigation and any administrative, civil, or other action taken by any funding agency, the Office of Research Integrity, the Office of Laboratory Animal Welfare, the Office for Human Research Protections (OHRP), the Awardee itself, any other institution, or any law enforcement agency concerning a charge of research misconduct made against an Awardee concerning the Awardee's research activities.

## **4. Use of Human Stem Cell Lines**

Awardees shall abide by the CIRM Medical and Ethical Standards (commencing with Title 17, California Code of Regulations, section 100010) developed by the CIRM Scientific and Medical Accountability Standards Working Group (Standards Working Group or SWG) and adopted by the ICOC for the use of "Covered Stem Cell Lines" or use of human oocytes or embryos. This requirement includes use and derivation of Human Embryonic Stem Cells. Consequences of failure to comply with CIRM regulations governing medical and ethical standards are described in chapter V, section Q, *Failure of Compliance and Award Termination*. All CIRM-funded research

involving “Covered Stem Cell Lines” must comply with CIRM regulations relating to SCRO committee review or notification as described in Title 17, California Code of Regulations, section 100070. CIRM will not issue an NGA or continue payment on active Awards without current certification of compliance with section 100070 as required or without imposing limiting conditions. In addition to the certification of compliance, CIRM may request documentation of the approval or notification required by section 100070. The documentation must include the name of the organization hosting the SCRO, the name of the committee, the name of the PI, the name of the Awardee, the CIRM Application number, the specific Covered Stem Cell Lines approved, the project title, and the period for which approval has been granted or expiration date of the approval. (*see chapter III, section D, Just-in-Time Policy*).

## **5. Use of Human Fetal Tissue**

When using human fetal tissue in research, CIRM Awardees shall abide by Title 17, California Code of Regulations, section 100085. Unless otherwise required by CIRM, the certifying statement required pursuant to Section 100085 (c) shall be provided just-in-time for approved Applications prior to issuance of the NGA (see Chapter III, Section D, *Just-in-Time Policy*). Consequences of failure to comply with the CIRM regulations are described in chapter V, section Q, *Failure of Compliance and Award Termination*.

## **6. Research Involving Human Subjects**

- a.** An organization is engaged in research involving Human Subjects when its employees or agents (1) intervene or interact with living individuals to obtain data for research purposes, or (2) obtain individually identifiable private information for research purposes.
- b.** Awardee organizations must apply California Health and Safety Code 24170-24179.5 to all CIRM-funded human biomedical or clinical subjects research. Compliance with this requirement may be demonstrated through written institutional policies or through provisions or full accreditation through the Association for the Accreditation of Human Research Protection Programs. In addition, the Awardee and any collaborating organizations (within the United States) must be covered by a Federal-Wide Assurance (FWA) approved by the OHRP, or an IND or IDE approved by the U.S. Food and Drug Administration (FDA).
- c.** The Awardee must appoint and maintain an Institutional Review Board

(IRB) to provide oversight of research involving human subjects.

- d.** The Awardee bears ultimate responsibility for protecting Human Subjects involved in CIRM-funded research, including Human Subjects at all participating and collaborating sites. PIs and Awardees engaged in CIRM-funded research involving Human Subjects must certify that the research has been reviewed and approved by an IRB and will be subject to continuing review by the IRB. At CIRM's request, the prospective Awardee must provide the following documentation regarding itself and each collaborating site to CIRM:
  - i.** Documentation of IRB review and approval specifying the name of the PI, the name of the Awardee and any collaborating organization or site, the CIRM Application number, the project title, and inclusive dates for which IRB approval has been granted;
  - ii.** Sample human subject (patient) information and informed consent documents;
  - iii.** Documentation of human research subject education of Key Personnel;
  - iv.** For clinical trials, a data safety monitoring plan;
  - v.** Institutional assurance that the research is conducted in accordance with relevant national, state, and local laws; and
  - vi.** A copy of the FDA-IND or IDE letter, where applicable when a clinical investigation involves the use of any drugs or devices.

Prior to the issuance of an NGA and during annual Progress Reports (see chapter V, section O, *Reporting Requirements*), an Awardee shall certify to CIRM that any IRB approval required to conduct the CIRM-Funded Project or Activity is obtained or will be obtained before CIRM funding is spent on such activities. (see section Chapter III, section D, *Just-in-Time Policy*). CIRM will not authorize continued funding of active Awards without current certification for Human Subjects research.

- e.** Serious Adverse Event Reporting. In the case of an adverse event occurring during a CIRM-funded clinical trial or program that is both serious and unexpected, the PI must notify CIRM of such an event at the same time that the IRB and Awardee are notified. Prior to issuance of a NGA the Awardee shall agree to a Communication Plan that addresses the process and timelines for notifying CIRM in the event of a Serious Adverse Event or other crisis issue or occurrence that may impact the conduct of a trial.

- f. Consequences of failure to comply with required Human Subjects research assurance are described in chapter V, section Q, *Failure of Compliance and Award Termination*. The AOO shall promptly inform CIRM of any investigation or administrative action by OHRP or by the Awardee concerning Recipients of CIRM funding and their use of Human Subjects in research.
- g. Women and members of minority groups must be included in all CIRM-funded Clinical Research, unless a clear and compelling rationale and justification establishes to the satisfaction of CIRM that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. This policy applies to research subjects regardless of age in all CIRM-funded Clinical Research studies.
  - i. Since a primary aim of research is to provide scientific evidence leading to a change in health policy or standard of care, it is imperative to determine whether the intervention or therapy being studied affects women or men or members of minority groups and their subpopulations differently. This requirement ensures that all CIRM-funded clinical research will be carried out in a manner sufficient to elicit information about individuals of both sexes/genders and diverse racial and ethnic groups and, particularly in clinical trials, to examine differential effects on such groups.
  - ii. PIs must include in their annual Progress Report the cumulative subject accrual and progress in conducting analyses for sex/gender and race/ethnicity differences (see chapter V, section O, Reporting Requirements).

## **7. Animal Subjects**

The PI, Awardee and any collaborating sites are responsible for the humane care and treatment of animals involved in research activities and must establish appropriate policies and procedures that are based on the standards set forth in the *Guide for the Care and Use of Laboratory Animals* prepared by the National Academy of Sciences and released January 2, 1996.

The PI, Awardee and any collaborating sites conducting CIRM-funded research that involves the use of vertebrate animals shall comply with all

applicable federal, state, and local laws. Sites where CIRM-funded animal research is conducted must be accredited or seeking accreditation by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

The Awardee must appoint and maintain an Institutional Animal Care and Use Committee (IACUC) to provide oversight of research involving vertebrate animals.

The prospective Awardee must provide certification of IACUC review and approval of research involving the use of live vertebrate animal subjects. Prior to the issuance of an NGA, a prospective Awardee shall certify to CIRM that any IACUC approval required to conduct the CIRM-Funded Project or Activity will be obtained before CIRM funding is spent on such activities. CIRM may request documentation of IACUC approval at any time upon request. The documentation must include the name of the PI, the name of the Awardee, the name of the organization hosting the committee, the CIRM Application number, the project title and inclusive dates for which approval has been granted. (see Chapter III, section D, *Just-in-Time Policy*).

Certification of updated IACUC approvals must be submitted with the annual Progress Report (see chapter V, section O, *Reporting Requirements*). CIRM will not authorize continued funding of active Awards without current certification of such approval.

Consequences of failure to comply with required animal subjects research assurance are described in chapter V, section Q, *Failure of Compliance and Award Termination*.

## **8. Biosafety**

The Awardee must ensure that any approval required by the Awardee and/or federal or state law for the proposed use of biohazardous materials, radioisotopes, and/or controlled substances is current and in effect. The applicant must also ensure all research personnel will obtain appropriate training and authorization for the use of biohazardous materials, radioisotopes, and/or controlled substances prior to their commencing work on the proposed project or activity. A prospective Awardee shall provide documentation that verifies such organizational approvals upon request. Awardees are also responsible for meeting applicable federal, state, and local health and safety standards, and for establishing and implementing necessary measures to



minimize their employees' risk of injury or illness in conducting CIRM-funded research.

## **9. Preference for California Suppliers**

It is a goal of Proposition 71 that more than 50 percent of the goods and services used in CIRM-supported research is purchased from California Suppliers (Health and Safety Code section 125290.30, subpart (i); Title 17, California Code of Regulations section 100502). To achieve this goal, CIRM expects the Awardee to purchase from California Suppliers, to the extent reasonably possible, the goods and services it uses in its CIRM-supported research. The PI and Awardee must provide a clear and compelling explanation in the Progress Report for not purchasing more than 50 percent of its goods and services from California Suppliers. Please see chapter V, section H, part 2, *Progress Report*.

## **D. Just-in-Time Policy**

Just-in-time procedures allow CIRM to defer review of certain required information until after an Application is approved for funding by the ICOC and prior to issuance of an NGA. When the required information is requested of the prospective Awardee, the information is to be submitted to CIRM. Just-in-time information includes, but is not limited to the following:

### **1. Certification**

CIRM requires certification from the Awardee that the Awardee has or will obtain appropriate IRB, SCRO and/or IACUC approval or notification for CIRM-funded Activity requiring such approvals before CIRM funding is spent on such activities.

### **2. Other Support**

As part of the just-in-time procedures, the PI and Awardee shall provide information on all other active and pending support. Before a NGA is issued, CIRM will review this information to ensure the following:

PIs, PDs (and other Key Personnel when requested) are not committed beyond a total effort of 100% for all active and other approved but not yet funded projects, whether or not salary support is requested in the Application and that the PI and PD are committed the required minimum effort to the project as required by the appropriate Program Announcement.

There is no scientific or budgetary overlap. Scientific overlap occurs when substantially the same research, or a specific research aim, proposed in the approved Application is funded over any part of the Project Period by another source. Budgetary overlap occurs when funds from more than one source are used to cover the same item or the same part of a budgetary item (e.g., Equipment, salaries) and may be evident when duplicate or equivalent budgetary items are requested in an Application but are already funded by another source.

### **3. For-Profit Applicants – Certification and Verification.**

The PI, CEO and CFO of a For-Profit Applicant will certify at the time of application that none of these individuals have been convicted of a felony involving fraud or the misappropriation of funds, and that no such charges are pending. In addition, these individuals will certify that none have ever been barred by any federal or state agency from applying for a grant or other funding. In the event the application is awarded funding by the ICOC, the applicant may be required to engage a third party to conduct the necessary background evaluation to verify this information.

For-Profit applicants will also undergo a financial stability assessment to assess the risk of insolvency due to, for example, bankruptcy or risk of litigation.

### **E. Award Notice**

Once CIRM funding requirements are fully met, a NGA will be sent to the AOO designated in the Application. The NGA specifies the Project Period (start and end dates of the project or program) as well as the monetary allocations (itemized Direct Research Funding Costs (including Facilities costs) and an amount allocated for Indirect Costs). The NGA also incorporates this Grants Administration Policy and all other applicable CIRM regulations by reference and specifies any special terms and conditions of the Award. During the active award period, the NGA may be amended in response to Prior Approval Requests, failure to meet milestones, or other circumstances warranting amendment.

## **IV. AWARD ACCEPTANCE AND TERMS**

### **A. Award Acceptance**

An Award is accepted when a NGA is signed by the PI and AOO, and returned to and received by CIRM. In accepting an Award, the PI and Awardee assure CIRM that any funds expended under the Award will be for the purposes set forth in the

approved Application. Further, the PI and Awardee agree to comply with terms and conditions of all applicable CIRM regulations, including this Grants Administration Policy. The NGA must be signed and returned to CIRM within 30 days (or more, if extended in writing by CIRM) of issuance. Payment will not be issued until then Award is accepted. If the PI or Awardee cannot accept the Award, including the legal obligation to perform in accordance with its provisions, they shall so notify CIRM in writing immediately upon receipt of the NGA.

Urgency is one of the component values of CIRM's mission. Therefore, a prospective Translation Awardee is required to certify that they are able to initiate work on the funded project within 90 days of ICOC approval, while a prospective Discovery Awardee is required to certify that they are able to initiate work on the funded project within 120 days of ICOC approval, unless this provision is waived in writing by the president.

## **B. Terms**

- 1. Meetings:** CIRM has the right to attend key FDA meetings regarding the funded project, including but not limited to pre-pre-IND meetings, pre-submission meetings or pre-IND meetings (FDA Meetings). To facilitate CIRM's participation in such meetings, Awardee shall notify CIRM as soon as practicable after it has scheduled an FDA meeting and provide to CIRM any data package(s) or other information, including confidential and/or proprietary information, prior to submission to the FDA as well as any FDA Meeting minutes. CIRM reserves the right to share such information with CIRM's confidential advisers.
- 2. Operational Milestone:** Some programs will require awards to be assigned Operational Milestones (generally Translational Stage programs). In such cases, CIRM will disburse funds based on achievement of specific Operational Milestones as established by CIRM. An "Operational Milestone" is an objective event that is indicative of project progress occurring as proposed in the application. CIRM establishes Operational Milestones for inclusion in the NGA based upon information provided in the Application. Upon issuance of the award, funds budgeted to achieve the initial Operational Milestone will be disbursed. Upon the successful completion of the initial Operational Milestone and each successive milestone, additional funds will be disbursed. A final Operational Milestone will be identified to define the award end date for the project. If funds allocated to a specific Operational Milestone (including both CIRM funds and the required applicant co-funds) are exhausted prior to achievement of that milestone, the Awardee will be responsible for covering

any remaining costs. CIRM expects that the applicant's contingency plan will identify the project timeline and budget risks and will provide details for covering such costs, including the source of funding. CIRM reserves the right to make adjustments to the timeline for inclusion in the NGA to ensure that funds are appropriately dispersed across Operational Milestones.

If CIRM determines, in its sole discretion, that Awardee has not satisfied an Operational Milestone as set forth in Appendix A to the NGA, CIRM may suspend disbursements until such time as Awardee satisfies the Operational Milestone. Upon suspending disbursements, CIRM may permanently cease disbursements if Awardee does not satisfy the Operational Milestone within six months of the date that the Operational Milestone was scheduled to have been satisfied, or if the delay is not addressed to CIRM's satisfaction, as determined by CIRM in its sole discretion.

3. If the Award is terminated for any reason, or upon submission of the final financial report, the Awardee shall return unused funds to CIRM within 30 days of the final report deadline.

### **C. Award Conversion**

Refer to the Grants Administration Policy for Clinical Stage Projects for the terms of a Award Conversion, section IV.C. via the Loan Election Policy which also apply to awards for a therapeutic translational stage project.

## **V. PAYMENT AND USE OF FUNDS**

### **A. Payment**

For awards subject to Operational Milestones, the schedule of payments will be based on Operational Milestones established by CIRM prior to issuance of a NGA. Once CIRM has a fully-executed NGA, it may initiate payment for activities leading up to the first Operational Milestone. Payments for each subsequent Operational Milestone are contingent on the receipt and acceptance by CIRM of documentation demonstrating achievement of the prior Operational Milestone as well as submission of the financial and progress reports due. Costs resulting from the delay or failure to meet an Operational Milestone will be the sole responsibility of the Awardee to be covered by the Awardee's financial contingency plan.

For awards not subject to Operational Milestones, payments can be made on an annual or semi-annual basis based on the negotiated, annualized budget. The 1<sup>st</sup> payment will

be made upon execution of the NGA for the 1<sup>st</sup> 6 or 12 month period and thereafter as long as reports are being submitted on time and the award remains in good standing.

The timing of the distribution of funds pursuant to this Grant shall be contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the State Treasury, as determined by CIRM in its sole discretion.

If CIRM terminates the award for any reason, the Awardee shall return unused funds to CIRM at CIRM's direction but not later than 120 days of the date of termination of the award.

An Awardee may accrue interest on the balance of CIRM funds paid, but such funds may only be used to pay for expenses incurred on the CIRM-funded project.

### **B. Costs and Activities**

During the Project Period, CIRM funds shall only be used for allowable project costs and activities. Specific allowable or unallowable costs may be described by CIRM. In accordance with Proposition 71, Direct Research Funding Costs include scientific and medical funding for an approved research project and the general operating costs of Facilities for conducting the approved project.

### **C. Pre-Award Costs**

An Awardee may, at its own risk and without Prior Approval, incur obligations and expenditures to cover costs up to a maximum of 90 days for Translation programs, and 120 days for Discovery programs, prior to the negotiated award start date, but not to proceed the date of the ICOC or Application Review Subcommittee's approval, if such costs are necessary to conduct the project and are allowable CIRM costs and activities. If specific expenditures or activities would otherwise require Prior Approval, the Awardee must obtain CIRM approval before incurring the cost. An Awardee's decision to incur pre-award costs in anticipation of an Award imposes no obligation on CIRM either to make the Award or to increase the amount of the Approved Budget if an Award is made for less than the amount anticipated and is inadequate to cover pre-award costs incurred. Awardees are on notice that a decision to incur pre-award costs is a decision to borrow against future support and that such borrowing must not impair the Awardee's ability to accomplish the project objectives or in any way adversely affect the conduct of the CIRM-Funded Project.

#### **D. Allowable Project Costs and Activities**

Project costs are those costs that can be specifically identified with a CIRM-Funded Project or Activity. Unless otherwise specified by CIRM, allowable project costs can include but are not limited to salary for personnel (detailed below), fringe benefits, itemized supplies, Tuition and Fees, research animal costs, Consultants, itemized clinical study costs (including Research Patient Care Costs), travel-related expenses (detailed below), itemized project-related Equipment (as approved), publication costs, service contracts, Subcontracts, and specific, identifiable administrative costs where required to carry out the approved project. When not otherwise specified by CIRM regulations, CIRM applies the Office of Management and Budget cost allocation principles of reasonableness, allocability, consistency, and allowability in determining whether costs under specific scenarios are allowable as a direct charge to a CIRM research grant.

Salaries for all personnel shall not exceed an annual rate of \$230,000. CIRM will adjust this limitation biennially beginning July 1, 2014 as follows: (a) the base dollar amount of \$230,000 shall be increased or decreased by the cumulative percentage change in the annual average California Consumer Price Index for All Urban Consumers from 2010 to the end of the calendar year immediately preceding the year in which the adjustment will take effect and (b) the dollar amount obtained by Application of the calculation set forth in subdivision (a) shall be rounded to the nearest \$1,000. The resulting figure shall be the adjusted maximum annual salary in effect until June 30 of the next even-numbered year. Biennial adjustments will be posted at [www.cirm.ca.gov](http://www.cirm.ca.gov).

Allowable travel-related expenses for both domestic and international travel include costs for transportation, lodging, subsistence, and related items incurred by all personnel on project-related business. Reimbursement for transportation expenses shall be based on the most economical mode of transportation (e.g., coach fare) and the most commonly traveled route consistent with the authorized purpose of the trip. Reimbursed lodging and subsistence expenses must be ordinary and necessary to accomplish the official business purpose of the trip.

#### **E. Unallowable Project Costs and Activities**

Unallowable project costs and activities cannot be charged to CIRM funding nor accounted for as part of the Awardee's co-funding requirement and include but are not limited to visa expenses for foreign nationals, malpractice insurance, furniture, telephone equipment, personnel recruitment, receptions, gifts, lobbying expenses, equity compensation, fines or penalties not related to

costs incurred to comply with the terms of the award, cost of food or meals unrelated to allowable travel expenses, construction or renovation of physical infrastructure and attorneys' fees related to litigation and patent defense, including any administrative action either prior or subsequent to the grant of a patent, such as oppositions, interferences, re-examinations and other similar administrative actions, that are outside of the scope of normal patent prosecution for that jurisdiction.

#### **F. Allowable Facilities Costs**

Facilities costs cover general operating costs of the Awardee's facilities attributable to housing all elements of the CIRM-Funded Project or Activity. Non-profit Awardees may request two categories of facilities costs: (a) costs based on the Awardee's current, federally negotiated rates for Operation and Maintenance Expenses, and for Library Expenses; and (b)(1) costs based on the Awardee's current, federally negotiated rates for depreciation or use allowances on buildings, capital improvements, and Equipment, and for interest on capital debt, as a proxy for a market lease rate of reimbursement (Health and Safety Code section 125292.10, subdivision (u)); or (b)(2) the actual out-of-pocket lease cost incurred by a Awardee if the Awardee leases space to conduct approved research; this cost must be reported in the Annual Financial Report (see chapter V, section H, part 1, Annual Financial Report). Non-profit Awardees may request their federally negotiated rates or provisionally approved rates in effect at the time of application for both categories (a) and (b) as allowable facilities costs. If provisionally approved facilities rates are used in an application that is funded, CIRM shall be notified immediately once the provisional rates have been finalized in order to reduce the award budget to reflect the federally approved rates. If the final facilities rates are higher than the provisionally approved rates, CIRM will not increase the award above the amount originally approved by the ICOC. Facilities costs for for-profit Awardees or any non-profit Awardees without a federally-negotiated Facilities & Administrative Rate agreement are limited to 35% of direct project costs and must be consistent with facilities rates applied to similar research awards at the organization. Total facilities rates shall be applied to the total allowable project costs exclusive of costs of Equipment, Tuition and Fees, Research Patient Care Costs, and the total cost of each service contract, Subcontract and Consultant agreement in excess of \$25,000.

#### **G. Unallowable Facilities Costs (Major Facilities)**

Beginning on the date of occupancy projected in the NGA for a CIRM Major Facilities Grant (i.e., a facility Grant subject to 17 Cal. Code Regs. § 100701), on a going-forward basis, CIRM will not fund the facilities costs for category (b) ("Facilities Part B") noted above for any currently active or subsequently funded CIRM research Grant

located in a CIRM Major Facility. CIRM will calculate on an annual basis the cumulative amount of the Facilities Part B reductions for all research grants to an institution or members of a consortium or facilities collaboration. Once this cumulative reduction equals the amount funded under the CIRM Major Facilities Grant (adjusted for the annual cost of funds) to an institution, consortium or facilities collaboration, Facilities Part B funding will be restored to all CIRM funded research grants to those institutions.

## **H. Indirect Costs**

The specific, allowable indirect cost percentage will be stipulated by CIRM but are generally limited to a maximum of 20 percent of allowable Direct Research Funding Costs for non-profit Awardees, exclusive of the costs of Equipment, Tuition and Fees, Research Patient Care Costs, and the total cost of each service contract, Subcontract and Consultant agreement in excess of \$25,000. CIRM will not provide indirect costs to for-profit Awardees.

## **I. Post-Project Allowable Costs**

For any Translation or Discovery Projects, if the Awardee has remaining CIRM funds following the completion of the CIRM-Funded Project or Activity, those funds may be used to either (1) reduce co-funding to an amount no lower than originally required by the Award; (2) fund project(s) at the Awardee organization that further CIRM's mission, subject to CIRM regulations and audit; or (3) return to CIRM within 30 days of the deadline for submission of the final financial report. The Awardee will be required to obtain CIRM's Prior Approval of its intentions for use of the funds and certification that those funds will be appropriately accounted for.

## **J. Budgetary Overlap**

CIRM funds cannot be combined with the operating budgets of the Awardees and may not be used for any fiscal year-end expenditures or deficits not directly related to the Award. Budgetary overlap, defined as using funds from more than one source to cover the same item or the same part of a budgetary item (e.g., salary, Equipment), is prohibited.

## **K. Prior Approval Requirements**

PIs and Awardees must perform project activities as described in the approved Application. A PI and Awardee must request and obtain prior written approval for pre-award or post-award changes described below by submitting such requests in writing together with appropriate justification for the proposed change. Such approval will be



granted in the form of an amendment to the NGA and must be obtained before expending CIRM funds for the proposed activity. The following changes require CIRM Prior Approval:

### **1. Change in Research Plan:**

The PI and Awardee must obtain Prior Approval in writing via an amendment to the NGA for any change that constitutes a significant deviation from the aims, objectives, experimental design, or purposes of the approved Application (hereafter “change in scope”). When considering such a change, the PI should consult with CIRM. Examples of actions likely to be considered a change in scope requiring Prior Approval include but are not limited to:

- a. Any change in the specific aims in the approved Application.
- b. Any change that impacts activities described in the Milestones in the Notice of Award.
- c. Any change in the use of animals or Human Subjects from that described in the approved Application and as approved by the IRB or IACUC.
- d. A removal or addition of substantive activities described in the Application; any savings due to the elimination of activities will result in a reduction to the Award unless CIRM approves use of those funds for the additional activities.
- e. Transfer of the performance of substantive funded activities to a third part not previously identified in the approved Application.
- f. A change in disease indication or shift in the research emphasis from one disease area or technological approach to another.

If the president determines that a requested change in scope would materially affect the purpose for which the award was made or the expected outcome, the president may deny the request, terminate the award and provide up to 120 days for wind down activities, and invite the Awardee to submit a new application, subject to GWG review and approval by Application Review Subcommittee.

### **2. No-Cost Extensions**

When the program announcement allows, a Grantees may request a one-time, no-cost extension (NCE) of the Project Period end date. The program announcement will specify the length of the extension that is allowed. A request and justification

for a no-cost extension must be submitted to the GMO in writing at least 30 days prior to the original Project Period end date.

### **3. Relinquishment of Award and Award Transfer**

An Awardee may at any time relinquish an Award or Application approved for funding by the ICOC by submitting a relinquishing statement that includes a) a statement of reasons for relinquishing the award; b) an estimate of the unexpended balance of any funds paid to the Awardee; c) and an assurance that all unexpended balance of any funds will be returned to CIRM within 120 days of the date of relinquishment. In the case of a transfer, the relinquishing Awardee may be required to transfer CIRM-funded equipment purchased with the Award.

With Prior Approval, an Award may be transferred to another eligible organization when a PI transfers from an Awardee to that organization. CIRM approval will be contingent upon the Awardee relinquishing rights to the Award among other considerations.

The transferee Awardee must submit to CIRM a letter that states its intention to assume responsibility for the Award based on the approved Application, and that encloses the following items:

- a. A new Application with original signatures;
- b. Description of how the PI will ensure the project will be able to accomplish its goals, potential length of delays in project progress due to the transition and mitigation plans to minimize project delays.
- c. Detailed budget(s) for the remaining Project Period (including the estimated unexpended balance from the relinquishing Awardee). The originally approved budget prevails when an award is transferred. CIRM does not have authority to increase the award amount without approval by the Application Review Subcommittee;
- d. Biographical sketches for new Key Personnel;
- e. Description of facilities and resources; and
- f. Certification to public policy assurances (e.g., Human Subjects, animal, biohazard), where applicable.

If the president determines that the proposed transferee Awardee is eligible and can fulfill the responsibilities of the relinquishing Awardee, CIRM will approve the transfer by cancelling the original NGA and issuing a new NGA to the transferee Awardee. Transfer of the Award will be effective when CIRM receives the new NGA executed by the PI and the AOO of the transferee

Awardee. Payment will not be issued until the Award transfer is effective.

#### **4. Change in PI or Project Manager Status or Percent Effort**

Prior Approval is required for the PI or Project Manager to decrease his/her percent effort on the approved project below the level required by the program.

In addition, Awardees must notify CIRM immediately if any of the following changes in PI or Project Manager status occur:

- a. The PI's status at the Awardee organization changes (e.g., from full-time to part-time appointment, from paid to an unpaid position or from employee to a non-employee position).
- b. The PI or Project Manager withdraws from the project, takes a leave of absence, or is expected not to be involved in the day-to-day conduct of the approved project for a continuous period exceeding 90 days. This includes requests for sabbaticals.
- c. The PI or Project Manager is no longer eligible (under either the standards of the Awardee or the criteria in the program) to serve as a PI or Project Manager.

If CIRM determines that a PI's change in status will adversely impact the conduct of the CIRM-funded Project as described in the approved Application, CIRM will so notify the Awardee. The Awardee may respond to such notification by seeking approval to substitute an eligible PI that is satisfactory to CIRM. CIRM may terminate the Award if no request is made or if the proposed substitute PI is not satisfactory. The Awardee shall return to CIRM all unexpended funds within 120 days of termination of the Award.

#### **5. Progression Events Report and Award proposal**

The "Partnering Opportunity for Discovery Stage Research Projects: The Quest Awards" provides a funding mechanism for those Quest Grant Awardees who have achieved a Progression Event within one year of the project end date. If such Awardees are interested in a Progression Award, they must submit a Progression Event Report and Progression Award proposal to be reviewed and approved by CIRM.

#### **6. Submitting Prior Approval Requests**

Prior Approval requests must be submitted in writing to CIRM and must be signed by the PI and the AOO. All such requests shall identify the proposed

action requiring CIRM Prior Approval and include a justification. Approval by CIRM shall not be effective unless in writing and signed by the president of CIRM, or his/her delegee.

#### **L. Equipment Management**

The Awardee must have a property management system for Equipment that includes the following:

1. Records that adequately identify items of Equipment purchased with CIRM funds;
2. Control procedures and safeguards to prevent loss, damage, and theft;
3. Adequate maintenance procedures to keep the Equipment in good condition; and
4. Proper procedures to dispose of, sell, or transfer Equipment purchased with CIRM funds when authorized by CIRM.

#### **M. Accounting Records, Documentation, Access to Records and Audits**

##### **1. Accounting Records**

The Awardee shall maintain an accounting system and supporting fiscal records to assure that CIRM funds awarded are used solely for the purpose outlined in the approved Application and for allowable costs and activities.

##### **2. Document Retention**

The Awardee shall retain accounting records and supporting documentation for five years from the date of submission of the final expenditure report for the entire Project Period. All records must be maintained in excess of this minimum time period if audit findings have not been resolved.

##### **3. Access to Records**

The Awardee shall allow CIRM and the Bureau of State Audits access to its accounting records and supporting documentation the California State Controller, or any other appropriate state agency with reasonable notice.

##### **4. Audits**

Accounting records and supporting documentation may be audited at the direction of appropriate state agencies, including the Bureau of State

Audits, the State Controller's Office and CIRM. In addition, CIRM may require an Awardee to commission an independent audit of Award accounting records at the Awardee's expense as a condition of further funding eligibility

#### **N. Misuse of Funds**

Misuse of funds means fraud or abuse of public funds. Fraud means an intentional deception or misrepresentation made by a person who knows or should have known that the deception could result in some unauthorized benefit to that person or some other person. It includes any act that constitutes fraud under applicable state or federal statutes. Abuse means any Awardee practice that is inconsistent with sound fiscal, business or research practices or that results in an unnecessary cost to CIRM.

Awardees shall report to CIRM cases of real or apparent fraud, or abuse of CIRM funding immediately upon knowledge thereof. Examples of fraud, and abuse that must be reported include, but are not limited to: embezzlement of CIRM funds, misuse or misappropriation of CIRM funds or property; and false statements regarding the use of CIRM funds, whether by organizations or individuals. This includes personal use of CIRM funds; using funds for non-approved purposes; theft of CIRM-funded property or property acquired or leased with CIRM funds; charging CIRM for services of "ghost" individuals; submitting false financial reports; and submitting false financial data in bids submitted to the Awardee (for eventual payment by CIRM).

Fraud, or abuse can result in any of the administrative and other actions described in section Q, *Failure of Compliance and Award Termination*. In addition, any PI, Awardee or Recipient of CIRM funds suspected of misuse of funds may be referred for investigation to state and/or local law enforcement authorities.

#### **O. Reporting Requirements**

Awardees must report financial and scientific progress to CIRM quarterly and upon achievement of an Operational Milestone.

The requested information is required for effective grant management by CIRM and for meeting specific reporting requirements of the California State Legislature. CIRM also is responsible for disseminating the outcomes of funded research to interested constituencies, as well as to the general public.

## **1. Financial Report**

Financial Reports shall be submitted to the GMO within 30 days after each quarterly or semi-annual period and within 60 days after each Operational Milestone or Budget Period, unless CIRM requires more or less frequent reports as specified in the NGA. The financial report must include all cumulative actual costs incurred against CIRM funds and any co-funding.

## **2. Progress Report**

Progress Reports shall be submitted to the GMO within 30 days after each quarterly or semi-annual period and upon achievement of each Operational Milestone, or on each Budget Period anniversary, unless CIRM requires more or less frequent reports as specified in the NGA.

Quarterly or Semi-Annual Progress Reports shall include a summary of scientific and operational progress. Operational Milestone Report or Annual Progress Reports shall include the same items as quarterly Progress Reports as well as an updated budget, budget narrative and Gantt chart; award outcomes; updated list of personnel who participated in the project; an updated list of Other Support for the PI; and a statement of the percentage of goods and services purchased with CIRM funds from California suppliers; and certification of applicable public policy assurances (e.g., ESCRO, IRB, IACUC). An Operational Milestone Report or Annual Progress Report may substitute for a quarterly Progress Report when submitted within 45 days of the next quarterly Progress Report due date. A Final Progress Report shall include a public summary of progress.

## **3. Other Reports**

PIs and Awardees are also required to report to CIRM publications, inventions, patent applications, licensing and invention utilization activities that result from CIRM-funded research. Specific reporting requirements related to these areas may be found in regulations adopted by the ICOC governing intellectual property.

## **4. Overdue Reports**

Failure to submit complete financial, progress, or other required reports in a timely fashion may result in reduction, delay or suspension of payments. Further, if a report is delinquent for more than 30 days, CIRM may take action

as described in section *Q, Failure of Compliance and Award Termination*.

#### **P. Grant Close-Out**

CIRM will close out an Award after conclusion of the authorized Project Period end date after the PI and Awardee have submitted all required reports, and reconciliation of amounts due the Awardee or CIRM. CIRM may withhold funds for future or concurrent Awards if an Awardee is delinquent in submitting reports.

Close-out of an Award does not extinguish requirements for property accountability, record retention, financial accountability, or requirements associated with regulation of medical and ethical standards or intellectual property. Following close-out, CIRM may recover amounts based on the results of an audit covering any part of the funding period.

#### **Q. Failure Compliance and Award Termination**

CIRM, in its sole discretion, may take one or more of the actions specified below if: (1) the Awardee or PI violates one or more terms and conditions of the Award, including this policy and any applicable CIRM regulations; (2) the Awardee or PI engages in research misconduct; or (3) the failure to achieve an Operational Milestone within six months of the target date or which CIRM determines, in its sole discretion, cannot be cured.

CIRM will afford the Awardee an opportunity to correct any deficiency before taking action unless public health or welfare concerns require immediate action or prompt action is necessary to protect CIRM's interests. (See also chapter III, section C, part 1, *Conduct of Research*.)

Depending on the nature of the deficiency, CIRM actions may include, but are not limited to the following:

1. Temporary withholding of payment;
2. Placing special conditions on Awards;
3. Conversion to a reimbursement payment method;
4. Termination of the Award
5. Disqualifying the Awardee (or PI as appropriate) from eligibility for future Awards for a specified period;
6. Disqualifying the Awardee (or PI as appropriate) from receipt of further CIRM funds;
7. Recovery of previously awarded funds;

8. Civil action and/or referral to the Office of the Attorney General of California for criminal investigation and enforcement;
9. Consideration of past performance by Awardee (or PI as appropriate) during review of subsequent applications for CIRM funding;
10. Other available legal remedies.

## **VI. SPECIAL POLICIES FOR TRAINING GRANTS**

This chapter supplements the general policies described in Chapters I through V and provides information on policies and requirements that apply specifically to CIRM training grants including the SPARK and Creativity Programs.

### **A. Criteria for Review of Training Grant Applications**

Training grant Applications are evaluated by criteria established by the ICOC, which may include but are not limited to the following factors:

1. Overall quality of the (proposed) training program
2. Qualifications of the program leadership
3. Research and training strength of the proposed mentors
4. Quality and diversity of existing training programs
5. Strength of the stem cell research at the institution

### **B. Trainee Policy**

#### **1. Appointment**

The PD should appoint trainees, giving appropriate consideration to the level of training, academic qualifications, and the inclusion of women and minorities. The NGA specifies the maximum number and type of trainees that may be appointed and supported by the CIRM training grant. Trainees appointed under a CIRM Training Program must be supervised by a faculty mentor or faculty level scientist who is accountable for the conduct of the research and operations of the laboratory or facility where the trainee research is performed. To ensure appropriate supervision and commitment to each trainee, a mentor may not be appointed to supervise more than two concurrent trainees from any CIRM training program at any one time. Prior to making a trainee appointment, Program Directors should consider the availability of the mentor to supervise a new trainee, including any possible overlaps with existing trainees that might result in exceeding this mentorship limit. The PD must complete and sign a Trainee Appointment Form for each trainee and



submit the form to CIRM at the time of appointment (see section E, *Reporting Requirements for Training Grants*).

**2. Degree Requirements**

To qualify for appointment, a trainee must have acquired the necessary academic preparation and degree(s) that are appropriate for the level of proposed training as described by CIRM.

**3. Training Period**

The duration of the training period for any individual trainee will be as specified in the program. An awarded trainee position cannot be shared among multiple individuals. CIRM trainees must devote full-time to training activities, which, in addition to their research, may include relevant coursework, workshops, and scientific conferences. Clinical trainees should confine clinical duties to those that are an integral part of their training experience. Clinical trainees may not expend more than 25 percent of their appointment time on clinical duties that are unrelated to or independent of the CIRM training program. Awardee institutions may apply their own policies to CIRM trainees requesting parental leave or sick leave during the training period. Other leaves of absence must be approved by the Program Director and CIRM and may require termination and reappointment of a trainee.

**C. Allowable Costs and Activities for Training Grants**

CIRM supports direct project costs for the training program that are specifically associated with trainee support (i.e., parts 1-4 below) and program administration (i.e., part 5), including administrative support salaries. Indirect Costs, which cannot be specifically associated with the training grant program, are limited to 10 percent of the direct project costs.

A trainee may not be concurrently supported with another fellowship or similar Award that provides a Stipend or otherwise duplicates provisions of the training grant Award; however, CIRM trainees may accept supplemental funding from other sources to increase funds available to the individual trainee.

**1. Stipend Levels**

Annual trainee Stipend levels should be commensurate with the individual's experience and the level of training as specified in the program. CIRM encourages the Grantee to supplement trainee Stipends when necessary to

meet institutional requirements and maintain equity among trainees, provided that the supplementation is without obligation to the trainee.

Grantees must re-budget within the total amount already awarded to accommodate any variation in Stipend levels. CIRM will not provide additional funds for this purpose. (See section D, *Prior Approval Requirements for Training Grants*.)

Trainee Stipends and allowances are not provided as a condition of employment with CIRM, the state government, or the Grantee. Accordingly, Grantees may not seek funds, or charge training grant Awards, for costs that normally would be associated with employee benefits (e.g., FICA, workman's compensation, and unemployment insurance). This limitation does not include health insurance for trainees, which is described under part 3 of this section.

## **2. Tuition and Fees**

"Tuition and Fees" means costs charged by the Grantee for the enrollment and instruction of a student and may include costs of health insurance for the student. Tuition and Fees may only be claimed for trainees who are enrolled in an accredited certificate, undergraduate, or graduate program. Grantees may request for each trainee up to 100 percent of the first \$3,000 incurred for Tuition and Fees and 60 percent of expenses in this category incurred thereafter up to a maximum of \$16,000. CIRM does not cover Tuition and Fees that are otherwise subsidized by the Grantee.

Tuition and Fees at the postdoctoral or clinical trainee levels are not allowed.

## **3. Health Insurance for Postdoctoral and Clinical Trainees**

If the postdoctoral or clinical trainee's health insurance is not otherwise covered by the Grantee institution, the Grantee may request up to 100 percent of basic health insurance costs for the trainee and immediate family (if applicable). Health insurance may include coverage for costs such as vision and/or dental care if consistent with organizational policy.

## **4. Trainee-Related Research and Travel Funds**

Grantees may request an annual allowance for trainees for research training-related expenses such as books and laboratory supplies and for trainee travel to scientific conferences or workshops.

Grant funds may be used to cover the costs of a trainee's travel to attend a scientific meeting that would benefit the trainee's research experience. Funds

may not be expended to cover the costs of travel between the trainee's place of residence and the training institution or to the training institution for the purpose of recruitment.

Generally, research training experiences away from the Grantee must be justified on the basis of the type of opportunities for training available, the opportunities offered that are different from those at the Grantee, and the relationship of the proposed experience to the trainee's career stage and career goals. Expenditure of CIRM funds for this type of research training requires Prior Approval by CIRM.

Textbooks required for coursework, specialty volumes that will enhance training, laboratory and technical manuals are appropriate for purchase. Professional journal subscriptions are not allowable costs.

#### **5. Program Administration Funds**

Grantees may request funds for administrative costs as part of direct project costs. Unless otherwise specified by CIRM, allowable program administrative direct project costs include administrative support salaries, seminar speakers, outside speakers for courses, audio-visual equipment or supplies, and costs of developing or delivering new courses.

The cost of advertising the training program to all prospective candidates may be allocated to program administration costs.

The cost of food and meals served at a seminar or meeting is not an allowable cost.

### **D. Prior Approval Requirements for Training Grants**

Grantees must perform project activities as described in the approved Application. A Grantee must request Prior Approval for any post-award changes by submitting to the GMO such requests in writing together with appropriate justification for the proposed change (see chapter V, section K, part 4, *Submitting Prior Approval Requests*). The request must be signed by the PD and the AOO. Such approval must be obtained in writing before expending CIRM funds for the proposed activity. Notwithstanding Chapter V, Section K, *Prior Approval Requirements*; the following are post-award changes for training grants that require approval:

- 1. Stipends** – Rebudgeting funds out of the Stipend category; however, funds may be re-budgeted into Stipends without Prior Approval. Trainee stipends

cannot exceed the current published CIRM Stipend Caps using CIRM funds.

2. **Training Period for Clinical Trainees** – Appointing a clinical trainee for a period that is less than 12 consecutive months.
3. **Trainee-Related Funds/Program Administration Funds/Indirect Costs** – Rebudgeting between 1) trainee-related funds (Stipends, Tuition and Fees, Health Insurance or Research and Travel ) and 2) Program Administration funds, or 3) Indirect Costs.
4. **Carry Forward of Funds** – Carry-forward of unobligated trainee funds from one Budget Period to the next. Carry-forward of obligated funds from one Budget Period to the next does not require CIRM’s prior approval.
5. **Extensions** – Extending the Project Period beyond the scheduled end date. A one-time no-cost extension for up to one year beyond the scheduled Project Period end date is allowed with Prior Approval. The written request for Prior Approval shall be submitted to CIRM at least 30 days in advance of the scheduled Project Period end date.
6. **Change in Program Director** –Appointing a new PD for the training grant program.
7. **Change in Sponsor, Mentor, or Collaborating Institution** –Appointing a new trainee sponsor or mentor. Any mentor changes approved by CIRM shall be reported in the annual Progress Report (see section E, *Reporting Requirements for Training Grants*).
8. **Addition to Number of Approved Trainees-** CIRM will not provide additional funds for increasing the number of approved trainee positions but will consider use of carry-forward funds for this purpose.

#### **E. Reporting Requirements for Training Grants**

Notwithstanding Chapter V, Section O, *Reporting Requirements*, the PD must submit financial and Progress Reports as described in this section to CIRM on an annual basis. The Progress Report is due each anniversary of the Project Period start date stated in the NGA. In addition, the PD must submit an annual financial report within 90 days after each anniversary of the Project Period start date.

### **1. Annual Financial Report**

The Grantee shall submit to the GMO an annual financial report, within 90 days after each anniversary of the Project Period start date stated in the NGA. The annual financial report must include all actual costs incurred during the expired Budget Period and any carry-forward amounts.

Upon initial appointment of a trainee and on each subsequent annual reappointment, costs for Stipend, Tuition and Fees, health insurance, and research and travel that cover an entire 12 months should be charged to the current Budget Period. The full amount not yet expended at the end of the Budget Period should be reported as a cost incurred but not yet paid.

### **2. Annual Progress Report**

The Grantee shall submit an annual report detailing progress and activities of the training program during the Budget Period. This report is due each anniversary of the Budget Period start date indicated in the NGA. The Progress Report for training grants includes two components: a description of the training program and an account of the appointed trainees.

#### **a. Training Program Report**

A programmatic description of progress made since the initiation of the Award is required. The training program report requests information such as:

- i.** Trainee selection process
- ii.** Current number and type of trainees in the program
- iii.** Program activities (e.g., seminars, workshops, retreats)
- iv.** Course developments or changes
- v.** Changes in the administration of the program
- vi.** Plans for the upcoming year
- vii.** Anticipated budget changes in future Budget Periods

### **3. Appointment**

#### **Trainee Appointment Form**

- a.** A Trainee Appointment Form must be completed online for each trainee and submitted at the time of appointment. Award disbursements to cover a trainee's costs will not be released until an acceptable Trainee Appointment Form has been submitted. The form requests information about the appointment such as the name of trainee, name of mentor, anticipated period of training, level

of Stipend support, and anticipated program of training. By submitting the form, the mentor, trainee, and PD agree to comply with the proposed training program, period of support, Stipend level, and the terms and conditions specified in this Grants Administration Policy. The complete submitted form is the official document for establishing the Stipend, which should be reflected in annual financial reports.

**b. Trainee Completion Form**

A Trainee Completion Form must be completed online for each trainee and submitted to CIRM at the time of termination of the trainee appointment due to the expiration of the appointment period or early termination prior to the pre-determined appointment period. The form requests information about the appointment term, such as the final term of appointment, a summary of the training received during the appointment period, the Stipend support received during the appointment period, post award activities (if known) of the trainee, and trainee contact information after completing CIRM support. The PD must complete this form.

**4. Other Reports**

Grantees are also required to report to CIRM publications, inventions, patent applications, licensing and invention utilization activities that result from CIRM-funded Activities. Specific reporting requirements may be found in regulations adopted by the ICOC governing intellectual property.

**5. Overdue Reports**

Failure to timely submit financial, progress, or other reports may result in action reducing, delaying or suspending payment until required materials are received. Further, if a report is delinquent for more than 60 days, CIRM may take action as described in chapter V, section Q, *Failure of Compliance*.

**6. Ethical Research Practices**

Appointed trainees (and their faculty mentors, where applicable) must conduct research in accordance with the highest medical and ethical standards, including compliance with institutional requirements, and regulations set forth and approved by the ICOC. See Title 17 California Code of Regulations section 100010, et seq. Trainees may not initiate or engage in research activities without documented institutional approvals where required by CIRM or the Grantee. The Grantee must submit to CIRM, with the Annual Progress Report, documentation that certifies that each appointed trainee has current institutional approval (where appropriate) to conduct research involving 1) the use of the live vertebrate animals, 2) use of Covered Stem Cells Lines (as

specified in Title 17, California Code of Regulations, section 100070), or 3) use of Human Subjects; Certification must be given by the Grantee's official institutional approval committee. The documentation must include for each trainee, the period for which approval has been granted, the name of the PI, and the approval number or identifier.