CIRM Grants Administration Policy
for Academic and Non-Profit Institutions

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Preface

This grants administration policy, serves as the terms and conditions of research grants and contracts awarded by the California Institute for Regenerative Medicine (CIRM). In addition, it provides guidance to applicants, Grantees and Recipients on their responsibilities as CIRM Grantees. 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 grants. Applicants Grantees and Recipients may be required to document compliance with any and all provisions set forth in this policy.

This policy applies to all CIRM applicants, Grantees and Recipients who receive CIRM funding through an Award to an academic or non-profit institution. By accepting CIRM funding, the Grantee and Recipients 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 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 grants 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, those rights may be enforced by the State of California.

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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 will support 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

PD – Program Director

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 Facilities or Equipment. An Application shall contain all information upon which approval for funding is based.
Approved Budget	The financial expenditure plan for the funded project or activity, including revisions approved by CIRM and permissible revisions made by the PI or Grantee.
Authorized Executive Official (AEO)	The individual, named by the applicant organization, who has the authority, or who has been delegated the authority, to commit organizational funds and resources.
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 awards, Grant, loan, or contract that is based on an approved Application and budget or Progress and Financial Reports.
Budget Period	The intervals of time (usually 12 months) into which a Project Period is divided for budgetary, funding and reporting purposes.
CIRM-funded Project or Activity	Those activities specified or described in an Application that are approved by the ICOC for funding and for which CIRM has issued an NGA, regardless of whether CIRM funding constitutes all or only a portion of the financial support necessary to carry them out.
Clinical Research	Patient-oriented research; that is, research conducted with Human Subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) in which an investigator (or colleague) directly interacts with Human Subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Included in this definition are: (1)(a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research.
Consultant	An individual who provides professional advice or services related to the proposed project in exchange for a fee.

Co-Principal Investigator (Co-PI)	An individual designated by the Grantee to direct a specific portion of the CIRM-funded Project or activity. He or she is responsible and accountable to the Grantee and CIRM for the proper conduct of the project or activity.
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 a Grantee'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 Grantee for financial management purposes or $5,000.
Facility or Facilities	Buildings, building leases, or capital equipment eligible for funding under Proposition 71.
Financial Report	A Grantee's periodic report to CIRM detailing expenditures against CIRM funds during the Budget Period specified in the NGA (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 providing money and/or property to an eligible entity to assist the Recipient in carrying out an approved project or activity.
Grant Close-out	The final stage in the life-cycle of an Award, whether in the form of a grant, loan or contract. During this phase, CIRM ensures that all applicable administrative actions and required work have been completed by the PI and Grantee. CIRM also reconciles and makes any final fiscal adjustments to the Grantee's account.
Grantee	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 Grantee is the entire legal entity even if a particular component is designated in the NGA. Campuses of the University of California shall be considered as separate and individual Grantees

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 a Grantee incurred for common or joint objectives, which cannot be readily and specifically identified with a particular project.
Key Personnel	The PI and other individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not they receive salaries or compensation from the CIRM-funded Project or Activity.
Milestone	A quantifiable, reliable and time-delineated measure of outcomes critical to the success of the CIRM-Funded Project. A Milestone is useful in assessing whether a large and/or complex project is on track to achieve its ultimate objective(s). CIRM and the Grantee agree to a Milestone(s) in advance for inclusion in the Notice of Grant Award.
Non-profit and Not-for-profit	Means or refers to either: (a) a governmental entity of the state of California: or (b) 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 Grantee and others that an Award has been made, contains or references all terms and conditions of the Award as well as the Grantee's and PI's agreement to those terms and conditions, and documents the commitment of CIRM funds.
Operation and Maintenance Expenses	The general operating costs of a Grantee's facilities include 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 B, part 3).

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 Grantee to direct the CIRM-funded Project or activity. He or she is responsible and accountable to the Grantee and CIRM for the proper conduct of the project or activity. For training programs or similarly structured programs, the PD is the same as the PI.
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")	Similar to a Request for Applications, but used for funding opportunities that accept applications on an ongoing basis, rather than a fixed deadline.
Progress Report	A Grantee'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 Period	The total amount of time as stated in an 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 completed to date.
Proposition 71	The California Stem Cell Research and Cures Act passed on November 2, 2004, which added Article XXXV to the California Constitution and Chapter 3 (sections 125290.10 *et seq.*) to Part 5, Division 106 of the Health and Safety Code.
Recipient	The Grantee, PI or PD, trainee, Subcontractor, Consultant or any other person or entity that receives CIRM funding pursuant to an Award.
Request for Applications ("RFA")	An official solicitation for Applications directed to a particular funding opportunity. Each RFA will specify the objectives and requirements that apply, and the review criteria that will be used to evaluate the merits of responsive Applications
Research Patient Care Costs	The same definition as found in the National Institutes of Health Grants Policy Statement, Part II.B.19 "Research Patient Care Costs," effective August 8, 2014, and incorporated herein. Such costs include but are not limited to, routine and ancillary services provided by hospitals to individuals participating in research programs. As set forth in Part II.B.19, Research Patient Care Costs do not include: (1) the otherwise allowable items of

	personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of individuals, including inpatients, outpatients, subjects, volunteers, and donors, (2) costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned laboratory) or laboratory tests performed at a medical school/university not associated with a hospital routine or ancillary service , (3) recruitment or retention fees or (4) the data management or statistical analysis of clinical research results.
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. Proposition 71 establishes two other working groups that make recommendations to the ICOC on medical and ethical standards, and on the merit of facilities grant applications.
Stipend	A payment made to an individual under a fellowship or training grant in accordance with pre-established levels (see chapter VI, section C, part 1, *Stipend Levels*) to provide for the individual's living expenses during the period of training. A Stipend is not considered compensation for the services expected of an employee.
~~Subaward~~	~~An award of financial assistance in the form of money, or property in lieu of money, made under a Grant by a Grantee to an eligible Subrecipient.~~
Subcontract (Subaward)	A contract between the Grantee and a third party to perform a portion of research proposed in the Application.
~~Subrecipient~~	~~The legal entity to which a Subaward is made and which is accountable to the Grantee for the use of the funds provided. All provisions of CIRM regulations shall apply to Subrecipients.~~
Tuition and Fees	Costs charged by the Grantee 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.
Working Budget	The funds available in any given Budget Period for use under a CIRM Award. This includes funds budgeted per the NGA plus any funds carried forward from a previous budget period.

D. Types of Support

CIRM's scientific program offers funding for projects, programs, and activities that will most effectively realize the goals set by Proposition 71. The initial phase of the scientific program may include funding for comprehensive training programs, innovative research, and facilities infrastructure. Future mechanisms that are appropriate to foster the advancement of the stem cell biology field may include support for independent laboratory projects, collaborative program projects, clinical trials, scientific resource centers, and development of specialized research centers.

E. Roles and Responsibilities

1. CIRM Staff:

a. President of CIRM

The President of CIRM is the chief executive of the Institute and oversees the implementation and operating requirements of Proposition 71. CIRM Notices of Grant Award (NGA) will be signed by the President of CIRM or the President's delegee.

b. Scientific Program Officer (SPO)

The SPO is responsible for the programmatic, scientific, and technical aspects of Applications and Awards. The SPO's responsibilities include, but are not limited to, developing research and research training programs to support the CIRM mission; providing consultation and assistance to applicants and PIs in scientific and programmatic areas, including guidance on CIRM policies and procedures, and performing post-award administration such as reviewing Progress Reports, conducting site visits and closing out Grants. The SPO works with the SRO in pre-award administration, and with the GMO in post-award activities. The name of the assigned SPO and his/her contact information is provided in the NGA.

c. Scientific Review Officer (SRO)

The SRO is responsible primarily for coordinating and conducting the scientific review of Applications by organizing and overseeing the activities of the Scientific and Medical Research Funding Working Group (GWG). In fulfilling this function, the SRO is responsible for pre-review activities including receipt and assignment of Applications for review to appropriate reviewers based on scientific and technical expertise, and determination of the recusal of reviewers based on each reviewer's conflicts of interest. The SRO's responsibilities also include post-review administration including writing and distribution of review reports, and coordination of the ICOC's review of Applications. The SRO's activities are complementary to those of the SPO and the GMO; all three work as a team in many of these activities.

d. Grants Management Office (GMO)
The GMO is responsible for the business management and other non-programmatic aspects of the Application and Award. These activities include, but are not limited to, evaluating Applications for administrative content and compliance with statutes, regulations, and guidelines; providing consultation and technical assistance to Applicants and Grantees with budgetary and non-programmatic areas (including CIRM's grants administration policies and procedures); and administration of Close-out. The GMO works closely with the SPOs. The GMO is the focal point for receiving required reports and acting on requests for CIRM's Prior Approval. The name of the GMO staffer responsible for each award and his/her contact information is provided in the NGA.

2. Grantee Organization Staff:

a. Authorized Executive Official (AEO)
CIRM generally requires the identification of an AEO in connection with capital grants.

b. Authorized Organizational Official (AOO)
The AOO is the designated representative of the Grantee 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 Grantee 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 or AEO must have the legal authority to commit the Grantee to indemnify CIRM as provided in Chapter III, Section B, *Liability,* and a Grantee's designation of an AOO or AEO confers apparent authority to commit the Grantee to such indemnification of CIRM.

c. Principal Investigator (PI) or Program Director (PD)
The PI is the individual, designated by the Grantee, responsible for the scientific or technical aspects of the CIRM-funded Project or Activity and for its management. The PI and the Grantee are both responsible for ensuring compliance with the financial and administrative aspects of the Award. The PI must work closely with other Grantee officials to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge CIRM support of research findings in publications, announcements, news programs, and other media; and ensure compliance with CIRM, federal, state, and organizational requirements. The PI must have a formal written agreement with the Grantee that specifies an official relationship between

the two parties even if the relationship does not involve a salary or other form of remuneration. For training programs or similarly structured programs, the PI is designated as the Program Director (PD).

II. GRANT APPLICATION AND REVIEW PROCESS

A. Eligibility

1. PI and PD Eligibility

To be eligible to serve as a PI or PD, the individual must at a minimum possess an M.D., Ph.D., or equivalent degree, unless otherwise noted in an RFA. There are no citizenship requirements for PIs.

2. Organizational Eligibility

CIRM-funded research must be conducted in California. 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 an RFA. 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.

3. Other Requirements

Because eligibility may vary, applicants should carefully review the funding opportunity announcements, such as an RFA or Program Announcement, for specific eligibility requirements. An applicant may be required to provide proof of eligibility, such as organizational eligibility, PI or PD eligibility, trainee or fellow eligibility.

B. Application Submission

CIRM funding opportunities will be announced via official solicitations, such as a Request for Applications (RFA) or Program Announcement, on the CIRM website (http://www.cirm.ca.gov). Each solicitation will specify the objectives and requirements that apply, and the review criteria 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 Candidate Nomination Form (Version 4/2009) (CNF) or Letter of Intent (LOI) 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 or AEO warrants to CIRM that all eligibility requirements have been satisfied and 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 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. ~~In general, CIRM will use a two-stage review process. The first stage is a peer review process in which the scientist members of the GWG evaluate and score Applications for scientific merit. In the second stage, the full membership of the GWG assesses Applications that are scientifically meritorious for programmatic value to the CIRM mission.~~ For each Application, a recommendation on funding is ~~then~~ made by the full GWG and submitted to the *Application Review Subcommittee of the* ICOC, which makes all funding decisions. The GWG may designate each reviewed Application as one of the following:

1. ***Recommended for Funding*** (Tier 1)– For highly meritorious Applications that are recommended for funding to the ICOC.
2. ***Provisionally Recommended for Funding*** (Tier 2)– For ~~meritorious Applications that require further consideration by the ICOC. The GWG may change the designation as needed to reflect the appropriate communication to the ICOC regarding the merit of the Applications in Tier 2.~~ *meritorious Applications that require further consideration by the ICOC. The GWG may change the designation as needed to reflect the appropriate communication to the ICOC regarding the merit of the Applications in Tier 2.*
3. ***Not Recommended for Funding*** (Tier 3)– For applications that are not recommended for funding at this time.

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 RFA.

The ICOC may also adopt additional or revised review criteria, when appropriate to meet the objectives set forth in a particular RFA.

Consistent with Proposition 71, the 15 scientist members of the GWG shall score Applications for scientific merit in three separate classifications – research, therapy development, and clinical trials (Health and Safety Code section 125290.60, subsection (c)), and base their evaluation on the following standard criteria:

1. ***Impact and Significance***. Whether and to what extent the proposed research addresses an important problem; significantly moves the field forward, either scientifically or medically; moves the research closer to therapy; and changes the thinking or experimental or medical practice in the field.

2. ***Quality of the Research Plan***. Whether and to what extent the proposed research is planned carefully to give a meaningful result; acknowledges the possible difficulties and provides for alternative plans should the proposed strategy fail; proposes a timetable that allows for achieving significant research or clinical results and uses appropriate Milestones to assess progress towards the aims and goals of the proposal.

3. ***Innovation***. Whether and to what extent the research approach is original, breaks new ground, and brings novel ideas, technologies or strategies to bear on an important problem.

4. ***Feasibility***. Whether and to what extent the aims of the research can be reasonably achieved and the investigator has access to appropriate technology to perform the research.

5. ***Investigators***. Whether and to what extent the investigators have the training and experience to carry out the proposed project, including the investigators' record of achievement in the areas of pluripotent stem cell and progenitor cell biology, unless the research proposal is determined to be a vital research opportunity.

6. ***Collaboration.*** Whether and to what extent the proposal supports collaborative efforts that would enhance the quality or potential of the research.

7. ***Responsiveness to RFA.*** Whether and to what extent the proposed research project or activity adequately and appropriately addresses the goals and objectives of the RFA.

8. ***Eligibility for Federal Funding***. Whether and to what extent the research is ineligible or unlikely to receive federal funding. If not, whether and to what extent the research is sufficiently compelling in that it presents "a vital research opportunity" that will materially aid the objectives of CIRM.

In deciding which Applications to recommend for funding, the GWG will consider the following criteria when assessing the entire portfolio of Applications under review for programmatic value:

1. An appropriate balance between innovation and feasibility.

2. An appropriate balance between fundamental research, therapy development and clinical work. The balance that is appropriate may vary with the requirements or goals of a particular RFA, and according to the progress of stem cell research over time.

3. Where relevant, that an appropriate range of diseases are addressed.

4. Other considerations from the perspective of patient advocates.

F. Appeals of Scientific Review

~~Outside of ICOC Programmatic Review, any challenges~~ *Any challenge* to a funding recommendation by the Grants Working Group (GWG) shall be filed pursuant to this section.

Under this policy, applicants for CIRM funding may appeal a GWG funding recommendation on the basis of 1) a financial or scientific conflict of interest with a reviewer; 2) a "material dispute of fact," or, 3) with respect to Translational Applications also seek reconsideration of a GWG funding recommendation based on "material new information," as set forth below. This policy does not apply to pre-applications or applications for conference grants or patent assistance funds.

~~The applicant should carefully examine the review report provided by CIRM. Any questions about the conduct of the review must first be raised with the SRO responsible for the review meeting in question.~~

Before filing an appeal or request for reconsideration, the PI/PD should carefully examine the GWG review report provided by CIRM. Any questions or concerns about the conduct of the review or appeals process must first be raised with the CIRM Review Office ("RO"). After the PI/PD has conferred with the RO, CIRM may then accept an appeal or request for reconsideration. Failure to confer with the RO before filing an appeal or request for reconsideration may result in an appeal or request for reconsideration being denied.

All appeals and requests for reconsideration shall be made in writing and shall be filed with the CIRM RO no later than ten (10) days after the review report was provided in writing to the PI/PD. An untimely appeal or request for reconsideration may be denied. Appeals and requests for reconsideration shall be limited to no more than a three (3) page narrative explaining the grounds for the appeal or request for reconsideration, exclusive of supporting documents, exhibits, or attachments.

1. *Conflict of Interest.* An applicant may ~~then~~ lodge a formal appeal of the review ~~only~~ if the applicant can show that a demonstrable financial or scientific conflict of interest had a negative impact on the review process and resulted in a flawed review. ~~This shall be the only ground for appeal.~~ 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 the SRO or to the Director of Scientific Activities within ~~30~~ 10 days of CIRM's making the review report available to the applicant. CIRM staff will then assess the merit of the request in consultation with the chair of the GWG and present a recommendation to the President of CIRM. If the chair of the GWG has a financial or scientific conflict of interest with the application that is the subject of the appeal, ~~as determined by ICOC policy adopted pursuant to Health and Safety Code section 125290.50(e),~~ a different scientific member of the GWG who has no ~~financial or scientific~~ conflict of interest will be consulted. The President of CIRM will then make the final decision on the merit of the appeal.

If an appeal is meritorious, the application will receive a new review by the GWG *as described below in subpart F.2.c*. A recommendation based on the new review will then be presented to the ICOC, which will make the final decision on funding the application in question.

2. *Material Dispute of Fact.*

a. **Grounds for Appeal**. Grounds for an appeal (other than for a conflict of interest) are strictly limited to a "material dispute of fact." In order to demonstrate a material dispute of fact, the PI/PD must clearly and succinctly state facts establishing all of the following criteria: (1) the dispute involves the accuracy of a statement in the review summary; and (2) the dispute pertains to an objectively verifiable fact, rather than a matter of scientific judgment or opinion; and (3) the dispute was not resolved prior to or during the GWG meeting. A "material dispute of fact" does not include disagreements over interpretation or analysis of facts by the GWG or specialist reviewers.

b. **Review of Appeal**.

(i) CIRM staff will first determine whether the applicant has set forth clear grounds for an appeal pursuant to paragraph F.2.a., i.e., whether the PI/PD has set forth facts that demonstrate the occurrence of a material dispute of fact. If the PI/PD has NOT set forth clear grounds for an appeal, the appeal will be terminated, the applicant will be so informed in writing, and the GWG's recommendation will be presented to the ICOC without any further scientific review. If staff determines that the PI/PD has set forth clear grounds for an appeal, staff will initiate an investigation and ICOC consideration of the application will be deferred until a resolution is reached.

(ii). If staff determines that the PI/PD has set forth clear grounds for an appeal, staff will next assess whether or not the disputed fact was significant in the scoring of the application and could have affected the outcome of the GWG recommendation. In making this assessment, CIRM staff may consult with the review chair of the GWG and GWG scientists involved with the initial review of the application at issue, and/or may consult with additional scientific experts as needed. Based on that assessment, CIRM staff will present a recommendation to the CIRM President. CIRM's President will then make the final decision whether to grant an appeal based on the following factors: (1) whether the claims are substantiated; and (2) whether the disputed fact may have significantly affected the scoring of the application and may have affected the outcome of the GWG recommendation.

c. **Further Scientific Review**. If the President grants an appeal, the application will be referred to a GWG subcommittee consisting of not less than three scientific members of the GWG, including the GWG review chair, and not less than one patient advocate member of the GWG, for further scientific review. If the review chair has a conflict of interest with the application, a new review chair will be appointed by CIRM. Further scientific review shall be limited to an assessment by the scientific members of the subcommittee whether the disputed fact, if it had previously been correctly determined, would have changed or changes the GWG's funding recommendation. The recommendation of the scientific members of the subcommittee, based on this assessment, will then be presented to the ICOC, which will make the final decision on funding the application in question.

3. *Request for Reconsideration Based on Material New Information – Translational Applications ONLY*.

a. **Grounds for Reconsideration**. Grounds for reconsideration are strictly limited to "material new information" in connection with a Translational Application. A "Translational Application" means an application where the goal is to achieve a Development Candidate, an IND filing, or to complete a clinical trial. Requests for reconsideration based on material new information will not be entertained in connection with other applications for funding. In order to demonstrate the existence of material new information in connection with a Translational Application, the PI/PD must clearly and succinctly state facts establishing criteria (a) through (c), as follows: (a) the new information consists of one of the following: (i) approval by a regulatory body, such as the Food and Drug Administration, to initiate or continue a clinical trial; or (ii) a documented, enforceable agreement between the applicant and a commercial partner; or (iii) a final court decision or administrative action; or (iv) documentation confirming the availability of critical material(s) necessary to carry out the proposed

project; (v) a manuscript containing relevant new scientific data that has been peer reviewed and published or peer reviewed and accepted for publication in final form; (vi) a filed patent application containing relevant new scientific data; or (vii) confidential data in the possession of a for-profit applicant that is unpublished but that the applicant is willing to make available for consideration of the application and (b) the new information became available to the applicant after the GWG review meeting at which the application was considered; and (c) the new information responds directly to a specific criticism or question addressed in the review summary.

b. **Review of Request for Reconsideration**.

(i) CIRM staff will first determine whether the application has set forth clear grounds for reconsideration pursuant to paragraph F.3.a., i.e., whether the PI/PD has stated facts that demonstrate the existence of "material new information" in connection with a Translational Application. If the PI/PD has NOT set forth clear grounds for reconsideration, the request will be terminated, the applicant will be so informed, and the GWG's recommendation will be presented to the ICOC without any further scientific review. If staff determines that the PI/PD has set forth clear grounds for reconsideration, staff will initiate an investigation and ICOC consideration of the application will be deferred until a resolution is reached.

(ii) If staff determines that the PI/PD has set forth clear grounds for reconsideration, staff will next assess whether or not the criticism or question addressed by the new information was likely significant in the scoring of the application and could have affected the outcome of the GWG recommendation had it been available at the time of the review. In making this assessment, CIRM staff may consult with the review chair of the GWG and GWG scientists involved with the initial review of the application at issue, and/or may also consult with additional scientific experts as needed to evaluate the merit of the request. Based on that assessment, CIRM staff will present a recommendation to the CIRM President. CIRM's President will then make the final decision whether to grant a request for reconsideration based on the following factors: (1) whether the claims are substantiated; and (2) whether the new information addresses a criticism or question that may have significantly affected the scoring of the application and may have affected the outcome of the GWG recommendation had it been available at the time of the review.

c. **Further Scientific Review**. If the President grants a request for reconsideration, the application will be referred to a GWG subcommittee consisting of not less than three scientific members of the GWG, including the GWG review chair, and not less than one patient advocate members of the GWG, for further scientific review. If the review chair has a conflict of

interest with the application a new review chair will be appointed by CIRM. Further scientific review shall be limited to an assessment by the scientific members of the subcommittee whether the new information, if it had been available previously, would have changed or changes the GWG's funding recommendation. The recommendation of the scientific members of the subcommittee, based on this assessment, will then be presented to the ICOC, which will make the final decision on funding the application in question.

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 ICOC makes all final funding decisions.

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.

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 its

user 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)

Applications approved for funding by the ICOC are then reviewed by the GMO and SPO 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, as specified in this Grants Administration Policy and the pertinent RFA. 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 or AEO) of a condition.

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 Grantee and subject to its organizational policies. Further, Grantee organization personnel compensated in whole or in part with CIRM funds are not considered employees of CIRM.

Grantees 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 Grantee pursuant to the award, and/or, in the alternative, Grantees 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 Grantee chooses only to insure, such insurance must provide coverage in amounts appropriate and proportional to cover the risks described in the previous sentence. Grantees that fail to provide evidence of such insurance prior to issuance of the NGA will on execution of the NGA be deemed to have agreed to indemnify and hold CIRM harmless.

In all cases, the Grantee 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 research, (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 Grantee 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 must be submitted before CIRM will issue an NGA. In

cases where research requiring public policy assurances will be conducted at a later phase of the funded research. CIRM may issue an NGA imposing a condition or restriction on the use of funds until documentation of required assurances is submitted.

The Grantee 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. **Research Conduct**

   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. Grantees and Recipients must conduct all research in accordance with the highest medical and ethical standards for scientific research and all applicable laws. The Grantee bears the ultimate responsibility for preventing, detecting and imposing sanctions for research misconduct. Grantees 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, Grantees 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 Grantee or Recipient from eligibility for CIRM funds; 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.*

2. **Conflict of Interest**
   Grantees must establish safeguards to prevent employees, Consultants, contractors, collaborators, and members of governing bodies who may be involved in CIRM-funded 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.

   Grantees must enforce within their institutions all such applicable safeguards. If the Grantee uses contractors or collaborators to conduct CIRM-funded research, the Grantee must take reasonable steps to ensure that such contractors or collaborators comply with the Grantee's safeguards. An acceptable standard for such a policy, for example, may be found in 42 CFR Part 50, Subpart F (R*esponsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought*)(effective October 1, 2000). The Grantee must promptly notify CIRM if and when it takes a suspension or separation action involving a financial conflict of interest against a PI or other Recipient of CIRM Funding.

3. **Administrative Actions**
   The Grantee promptly shall 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 Grantee itself, any other institution, or any law enforcement agency concerning a charge of research misconduct made against a Recipient of CIRM-funding concerning the Recipient's research activities.

4. **Use of Human Stem Cell Lines**
   Grantees 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 J, *Failure of Compliance*. 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 documentation of approval or notification as required or without imposing limiting conditions. 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 Grantee, 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. Unless otherwise required by CIRM, this information shall be provided just-in-time for approved Applications prior to issuance of an NGA (see chapter III, section D, *Just-in-Time Procedures*).

5. Use of Human Fetal Tissue

When using human fetal tissue in research, CIRM Grantees 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 Procedures*). Consequences of failure to comply with the CIRM regulations are described in chapter V, section J, *Failure of Compliance*.

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. PIs and Grantees 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. In addition, the Grantee 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). Grantee 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.

c. The Grantee bears ultimate responsibility for protecting Human Subjects involved in CIRM-funded research, including Human Subjects at all participating and collaborating sites. At CIRM's request the prospective Grantee must provide the following documentation regarding itself and each collaborating site to the GMO:

i. Documentation of IRB review and approval specifying the name of the PI, the name of the Grantee 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.

CIRM will not issue an NGA or authorize continued funding without current and complete documentation for Human Subjects research. Unless otherwise required by CIRM, this information (where applicable) shall be provided just-in-time for approved Applications prior to issuance of an NGA (see section D, *Just-in-Time Procedures*).

d. Evidence of updated IRB approvals and related documents must be submitted with the annual Progress Report (see chapter V, section H, *Reporting Requirements*). CIRM will not authorize continued funding of active Awards without current and complete documentation 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 Grantee are notified.

f. Consequences of failure to comply with required Human Subjects research assurance are described in chapter V, section J, *Failure of Compliance*. The AOO shall promptly inform CIRM of any investigation or administrative action by OHRP or by the Grantee 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.

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.

h. 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 H, *Reporting Requirements*).

7. Animal Subjects

a. The PI. Grantee 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.

b. The PI, Grantee 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).

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

d. The prospective Grantee must provide evidence of IACUC review and approval of research involving the use of live vertebrate animal subjects. The documentation must include the name of the PI, the name of the Grantee, the name of the organization hosting the committee, the CIRM Application number, the project title and inclusive dates for which approval has been granted. CIRM will not issue an NGA without current documentation of such approval or without imposing limiting conditions. Unless otherwise required by CIRM, this information shall be provided just-in-time for approved Applications prior to issuance of an NGA (see section D, *Just-in-Time Procedure*s).

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

f. Consequences of failure to comply with required animal subjects research assurance are described in chapter V, section J, *Failure of Compliance*.

8. Biosafety

Prior to the issuance of an NGA, a prospective Grantee shall certify to CIRM that any approval required by the Grantee and/or federal or state law for the proposed use of biohazardous materials, radioisotopes, and/or controlled substances is current and in effect. Where applicable, the applicant shall additionally certify that 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 Grantee shall provide documentation that verifies such organizational approvals upon request. Grantees 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. **Sharing of Intellectual Property: Publications, Biomedical Materials, Patented Inventions**
   PIs and Grantees shall share intellectual property generated by CIRM-funded research including research results in scientific articles, publication-related biomedical materials, and patented inventions for research use in California as required by CIRM regulations duly adopted by the ICOC.

10. **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 Grantee to purchase from California Suppliers, to the extent reasonably possible, the goods and services it uses in its CIRM-supported research. The PI and Grantee 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 Grantee, the information is to be submitted to the GMO. Just-in-time information includes, but is not limited to the following:

1. **Certification**
   CIRM requires documentation from the Grantee organization that:
   - **a.** verifies IACUC review and approval of the project's proposed use of live vertebrate animals; or
   - **b.** certifies SCRO committee (or equivalent) notification or review and approval of the project's proposed use of Covered Stem Cell Lines as specified in Title 17, California Code of Regulations, section 100070; or
   - **c.** certifies IRB review and approval (including applicable documents outlined in the chapter III, section C, part 6, *Research Involving Human Subjects*) of the project's proposed use of Human Subjects.

~~c.~~

2. **Other Support**
As part of the just-in-time procedures, the PI, Co-PI and Grantee shall provide information on all other active and pending support. Before an NGA is issued, the SPO and GMO will review this information to ensure the following:

a. PIs, Co-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.

b. 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.

E. Award Notice

Once CIRM funding requirements are fully met, an NGA will be sent to the AOO or AEO 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) for each Budget Period. 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 or documentation of GMO implementation of the GAP regulations.

IV. AWARD ACCEPTANCE

An Award is accepted when an NGA is signed by the PI and AOO or AEO, and returned to and received by CIRM. In accepting an Award, the PI and Grantee assure CIRM that any funds expended under the Award will be for the purposes set forth in the approved Application. Further, the PI and Grantee 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 45 days (or more, if extended in writing by CIRM) of issuance. Payment will not be issued until the Award is accepted. If the PI or Grantee 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, CIRM requires that all NGAs have a start date no later than six (6) months after the date the ICOC approves an Application for funding, unless this provision is waived in writing by the President.

V. PAYMENT AND USE OF FUNDS

A. Payment

Once CIRM has a fully-executed NGA, it may initiate payments for the first Budget Period. For Grantees from any University of California campus, payments may be made on a prospective or reimbursement basis. The schedule of payments will be negotiated by CIRM and the Grantee prior to issuance of an NGA. Payments for each subsequent Budget Period are contingent on the receipt and acceptance by CIRM of the financial, progress, and other reports due for the prior Budget Period; applicable public policy assurance documents (e.g., SCRO, IRB, and IACUC); and any requests for budget changes applicable to the new Budget Period.

B. Costs and Activities

CIRM funds shall only be used for expenditures necessary to carry out the approved Application. Specific allowable or unallowable costs may be described in the RFA or the NGA. 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.

1. **Pre-Award Costs**
   After the ICOC approves an Application for funding, a Grantee may, at its own risk and without Prior Approval, incur obligations and expenditures to cover costs up to 90 days prior to the effective date of Award if such costs are necessary to conduct the project and would be allowable if the Application were funded. If specific expenditures or activities would otherwise require Prior Approval, the Grantee must obtain CIRM approval before incurring the cost. A Grantee'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. Grantees 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 Grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the CIRM-funded Project.

2. **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 in an RFA or NGA, allowable project costs include salary for personnel (detailed below), fringe benefits, itemized supplies, Stipends and Tuition and Fees (as defined in chapter VI, section C, *Allowable Costs and Activities for Training Grants*), 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. CIRM applies the OMB Circulars A-21 and A-133 cost allocation principles of reasonableness, allocability, consistency, and allowablity in determining whether cost under specific scenarios are allowable as a direct charge to a CIRM research grant. (For specific allowable costs related to training grants see chapter VI, section C, *Allowable Costs and Activities for Training Grants.*)

Subcontracts or consulting agreements with individuals or organizations located outside the State of California must be justified and are limited to $15,000 per agreement per Budget Period and $25,000 per Budget Period in aggregate unless Prior Approval is sought and obtained during administrative review.

Salaries for all personnel shall not exceed an annual rate of $~~213~~230,000. CIRM will adjust this limitation biennially beginning July 1, ~~2012~~ 2014 as follows: (a) the base dollar amount of $~~213~~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.

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. Travel-related expenses shall not exceed an annual allowance of $5,000 per person per CIRM Award unless otherwise approved via Prior Approval Request to CIRM or as specified in an RFA.

3. **Unallowable Project Costs and Activities**
   Unallowable project costs and activities cannot be charged to CIRM funding and include but are not limited to visa expenses for foreign nationals, malpractice insurance, membership dues, furniture, telephone equipment, personnel recruitment, receptions, and cost of food or meals unrelated to allowable travel expenses.

4. **Allowable Facilities Costs**

Facilities costs cover general operating costs of the Grantee's facilities attributable to housing all elements of the CIRM-funded Project or Activity. Grantees may request two categories of facilities costs: (a) costs based on the Grantee's current, federally negotiated rates for Operation and Maintenance Expenses, and for Library Expenses; and (b)(1) costs based on the grantee'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 Grantee if the Grantee 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*). Grantees may request both categories (a) and (b) as allowable facilities costs. Rates from both categories 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,~~s~~ *Subcontract and Consultant agreement* in excess of $25,000 ~~per Budget Period and the total cost of Subcontract and Consultant Fees in excess of $25,000 per Budget Period~~. *(The amendments to this subsection shall apply only to Grants awarded after the effective date of this amended policy.)*

5. Unallowable Facilities Costs (Major Facilities)

A facility constructed with funds awarded in a CIRM Major Facilities Grant (i.e., a facility Grant subject to 17 Cal. Code Regs. § 100701) shall be used only for stem cell research and stem cell-related research. Each such "Major Facility" will house stem cell and related research funded by CIRM and other sources. An institution that receives a CIRM Major Facilities Grant shall locate CIRM-funded research activities in the Major Facility as described in the NGA for the CIRM Major Facilities Grant.

Beginning on the date of occupancy projected in the NGA for a CIRM Major Facilities Grant, on a going-forward basis, CIRM will not fund the facilities costs for category (b) ("Facilities Part B") noted in paragraph 3 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.

6. Indirect Costs

The specific percentage allowable for an RFA will be stipulated in the RFA. Per Proposition 71, Indirect Costs are limited to a maximum of 25 percent of allowable Direct Research Funding Costs, exclusive of the costs of Equipment, Tuition and ~~Fees, Research Patient Care Costs, service contracts in excess of $25,000 per Budget Period and combined cost of Subcontract amounts and Consultant Fees in excess of $25,000 per Budget Period.~~ *Fees, Research Patient Care Costs, and the total cost of each service contract, Subcontract and Consultant agreement in excess of $25,000. . (The amendments to this subsection shall apply only to Grants awarded after the effective date of this amended policy.)*

C. Budgetary Overlap

CIRM funds shall only be used for expenditures directly related to the approved Application. CIRM funds cannot be combined with the operating budgets of the Grantees 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 not permitted.

D. Prior Approval Requirements

PIs and Grantees must perform project activities as described in the approved Application. A PI and Grantee 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 (see chapter VI, section D, *Prior Approval Requirements for Training Grants* for additional Prior Approvals that apply specifically to Training Grants):

1. **Change in Scope**
   The PI and Grantee 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 the GMO and SPO. Examples of actions likely to be considered a change in scope requiring Prior Approval include but are not limited to:

   a. The addition, deletion, or modification of the Specific Aims or Milestones in the approved Application, NGA, or any amendments to the NGA;
   b. Any change that introduces the use of live vertebrate animals, Human Subjects, or covered stem cells that was not previously proposed or approved under the award;
   c. Shift in the research emphasis from one disease area to another;
   d. Transfer of the performance of substantive funded activities to a third party not previously identified in the approved Application, NGA, or any amendments to the NGA; or
   e. Amendments to Milestones and success criteria set out in the NGA or any amendments to the NGA.

2. **Carry Forward of Funds**
   PIs and Grantees must obtain Prior Approval to carry forward from one Budget Period to the next unexpended funds exceeding the lesser of $200,000 or 25 percent of the working budget for the expiring Budget Period. This threshold applies to the working budget for each PI and Co-PI budget. Absent

Prior Approval, any amount that exceeds this limit will be deducted from payment of funds for the next Budget Period. If the carry-forward amount is greater than $200,000 CIRM may elect to postpone the next scheduled payment of funds. At the end of a Project Period, any unexpended funds must be returned to CIRM within 120 days of the Project Period end date.

3. **No-Cost Extension**
PIs and Grantees may ~~request~~ be granted a one-time, no-cost extension of the Project Period end date of up to one year. CIRM will consider a request for a no-cost extension beyond 12 months for awards that fund clinical trials and pivotal IND-enabling activities, subject to approval of the ICOC based on a recommendation from the President. 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.

4. **Rebudgeting**
Recipients must spend CIRM funds in conformance with the budget stated in the NGA and any amendments to the NGA. Except as provided below, Prior Approval is required for any changes in the Approved Budget.

   a. **Personnel or Supplies** –Prior Approval is required only if rebudgeting would change (i.e., increase or decrease) the total budget of either category by the lesser of $100,000 or 25 percent of the working budget for that category, which includes any carry-forward amounts.

   b. **Travel** –Prior Approval is required only if rebudgeting would change (i.e., increase or decrease) the total budget of this category by more than $~~2,000~~5,000, ~~**and** the change exceeds 25 percent~~ of the working budget for this category, which includes any carry-forward amounts.

   c. **Consultants and Subcontracts** –Prior Approval is required only if rebudgeting would change (i.e., increase or decrease) the total budget of the category by the lesser of $100,000 or 25 percent of the working budget for that category, which includes any carry-forward amounts.

   d. **Equipment** – Prior Approval is required to purchase items of Equipment that are not listed in ~~of~~ the approved NGA or any amendment to the NGA. Prior Approval is required if the budget for Equipment has increased by the lesser of $100,000 or 25 percent of the working budget for that category, ~~-~~ which ~~-~~includes any carry-forward amounts.

A request for rebudgeting may be submitted to the GMO at any time after the ICOC approves an Application for funding and before the end of the Project Period. Requests must specify the budget categories affected by any proposed change and the reason for the change.

When a budget change would trigger an increase in the calculation of Facilities and Indirect Costs, CIRM will not fund any increase in the calculation of Facilities and Indirect Costs.

5. Relinquishment of Award and Award Transfer

A Grantee 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 unexpected balance of any funds paid to the Grantee; c) and an assurance that all unexpended balance of any funds will be returned to CIRM within 90 days of the date of relinquishment. In the case of a transfer, the relinquishing Grantee 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 a Grantee to that organization. CIRM approval will be contingent upon the Grantee relinquishing rights to the Award among other considerations.

The transferee Grantee 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. Detailed budget(s) for the remaining Project Period (including the estimated unexpended balance from the relinquishing Grantee). The originally approved budget prevails when an award is transferred. CIRM does not have authority to increase the award amount without ICOC approval;
c. Biographical sketches for new Key Personnel;
d. Description of facilities and resources; and
e. Public policy assurances (e.g., Human Subjects, animal, biohazard), where applicable.

If the President determines that the proposed transferee Grantee is eligible and can fulfill the responsibilities of the relinquishing Grantee, CIRM will approve the transfer by cancelling the original NGA and issuing a new NGA to the transferee Grantee. Transfer of the Award will be effective when CIRM receives the new NGA executed by the PI and the AOO or AEO of the transferee Grantee. Payment will not be issued until the Award transfer is effective.

6. Change in PI or Co-PI Status or Percent Effort

Prior Approval is required for the PI or Co-PI to decrease his/her percent effort on the approved project by 25 percent or more (e.g., from 40 percent to 30 percent or less) of the level specified in the approved Application.

In addition, Grantees must notify CIRM immediately if any of the following changes in PI or Co-PI status occur:

a. The PI or Co-PI's status at the Grantee 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 Co-PI 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 Co-PI is no longer eligible (under either the standards of the Grantee or the criteria in the RFA) to serve as a PI.

If CIRM determines that a PI or Co-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 Grantee. The Grantee 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 or Co-PI is not satisfactory. The Grantee shall return to CIRM all unexpended funds within 120 days of termination of the Award. In general, CIRM will not approve a substitution of PI or Co-PI or decrease in percent effort exceeding 25 percent during the first 180 days of the Project Period.

7. Submitting Prior Approval Requests

Prior Approval requests must be submitted in writing to the GMO and must be signed by the PI and the AOO or AEO and Co-PI when appropriate. All such requests shall identify the proposed action requiring CIRM Prior Approval and include a justification, an estimate of the expected duration of the change, the budget period(s) impacted by the change, and any budgetary modifications that would result if the request were granted. Approval by CIRM shall not be effective unless in writing and signed by the President of CIRM, or his/her delegee.

E. Equipment Management

The Grantee 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.

F. Accounting Records, Documentation, Access to Records and Audits

1. Accounting Records

The Grantee 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 in accordance with Approved Budget in the NGA.

2. **Document Retention**
   The Grantee 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 Grantee shall allow CIRM, 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 a Grantee to commission an independent audit of Award accounting records at the Grantee's expense as a condition of further funding eligibility.

G. 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 Grantee practice that is inconsistent with sound fiscal, business or research practices or that results in an unnecessary cost to CIRM.

Grantees shall report to the GMO 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 Grantee (for eventual payment by CIRM).

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

H. Reporting Requirements

Grantees must report financial and scientific progress to CIRM annually at minimum.

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.

Please see chapter VI, section E, *Reporting Requirements for Training Grants,* for reporting requirements specific to training grants.

1. **Financial Report**
   The Grantee shall submit to the GMO an annual financial report within 90 days after each anniversary of the Award start date stated in the NGA, unless CIRM requires more frequent reports. The financial report must include all actual costs incurred against CIRM funds during the expired Budget Period and any carry forward amounts. Grantees claiming facilities costs for leased research space as described in chapter V, section B, part 3, *Allowable Facilities Costs*, shall report the actual out-of-pocket lease cost incurred by the Grantee.

2. **Progress Report**
   The Grantee shall submit to CIRM an annual Progress Report detailing scientific progress, outcomes and activities during the expired Budget Period, unless CIRM requires more frequent reports. This report is dueeach anniversary of the Award start date stated in the NGA.

   The Progress Report shall include a summary of scientific progress; a listing of personnel who participated in the project and their level of effort; an updated list of Other Support for the PI;~~;~~ cumulative subject accrual and progress in conducting analyses for sex/gender and race/ethnicity differences in clinical trials; applicable public policy assurances (e.g., ESCRO, IRB, IACUC); and a statement of the percentage of goods and services purchased with CIRM funds from California suppliers~~;~~ . The Progress Report must also include an overview of any major unexpected expenditures or unspent funds (actual or anticipated) for the expiring Budget Period and any changes anticipated for future Budget Periods.

3. **Other Reports**
   PIs and Grantees 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 timely submit complete financial, progress, or other required reports may result in reduction, delay or suspension of payments. Further, if a report is delinquent for more than 60 days, CIRM may take action as described in section J, *Failure of Compliance*.

I. Grant Close-Out

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

Close-out of an Award does not extinguish requirements for property accountability, record retention, or financial accountability, or requirements associated with regulation of medical and ethical standards of intellectual property. Following close-out, the Grantee remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and CIRM may recover amounts based on the results of an audit covering any part of the funding period.

J. Failure of Compliance

If a Grantee or PI fails to comply with the terms and conditions of an Award, CIRM may take one or more actions, depending on the severity and duration of the non-compliance. Failure of compliance includes confirmed instances of research misconduct, violations of medical or ethical standards as provided in Title 17, California Code of Regulations, section 100010 et seq, or violations of intellectual property regulations duly adopted by the ICOC. CIRM will afford the Grantee 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, *Research Conduct.*)

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. Disqualifying the Grantee (or PI as appropriate) from eligibility for future Awards for a specified period;
5. Disqualifying the Grantee (or PI as appropriate) from receipt of further CIRM funds;
6. Recovery of previously awarded funds;
7. Civil action and/or referral to the Office of the Attorney General of California for criminal investigation and enforcement;
8. 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.

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 set forth in the RFA.

3. **Training Period**
   The duration of the training period for any individual trainee will be as specified in the RFA. 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. Grantee 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 RFA. 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. This general rule, however, may vary by RFA.

   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 in the RFA, 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. Limitations on use of funds in this category for the PD's salary will be specified in the RFA.

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 D, part 7, *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 D, *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 funds from one Budget Period to the next that exceed 25 percent of project costs for the expiring Budget Period.

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 H, *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

   b. **Trainee Report**
      In addition to the training program description, the annual Progress Report must include data for all trainees who were or are supported by the training grant. The trainee report requests information such as:
      - **i.** Mentor and trainee assignments

ii. Description of proposed trainee research and progress

~~iii.~~ [1] ~~List of relevant publications~~

3. Appointment

Trainee Appointment Form

a. A Trainee Appointment Form (Rev 4/2008) must be completed for each trainee and submitted at the time of appointment. 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. The mentor, trainee, and PD must sign the form and in so doing all parties 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 completed and signed form is the official document for establishing the Stipend, which should be reflected in annual financial reports.

b. **Trainee Termination Form**
A Trainee Termination Form (Version6/2008) must be completed 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 trainee and the PD must sign the 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 J, *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.

APPENDIX:

Candidate Nomination Form (Version 4/2009)
Trainee Appointment Form (Rev 4/2008)
Trainee Termination Form (Version 6/2008)