# CIRM Grants Administration Policy for Academic and Non-Profit Institutions

## Preface

This grants administration policy ~~statement, which includes all appendices,~~ serves as the terms and conditions of research grants and contracts ~~awards issu~~awarded by the California Institute for Regenerative Medicine (CIRM). In addition, it provides guidance to applicants, Grantees and ~~recipient~~Recipients on their responsibilities. ~~as CIRM grantee~~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. ~~The regulations that ensue from this policy statement carry the force and effect of law.~~ Applicants, ~~and grantee~~Grantees and Recipients may be required to document compliance with any and all provisions set forth in this policy ~~statement~~.

This ~~grants administration~~ policy ~~statement~~ applies to all CIRM applicants, ~~and grantee~~Grantees and Recipients who receive CIRM funding through an Award to an~~from~~ academic or~~and~~ non-profit institution~~s~~. By accepting ~~a~~ CIRM funding~~grant award~~, the ~~grantee~~Grantee and Recipients agree~~s~~ to comply with the provisions set forth in this policy ~~statement for the entire project period~~Project Period ~~of the grant~~Grant.

This ~~grants administration~~ policy ~~statement~~ may be amended or revised ~~updated~~ periodically. ~~by CIRM.~~ Any new or amended regulations adopted by the Independent Citizen~~'~~s Oversight Committee (ICOC), the governing board of CIRM, will be applied to currently active awards~~grants~~ on the start date of the next ~~budget period~~Budget Period, except as provided in the relevant CIRM Intellectual Property Regulations, title 17 California Code of Regulations sections 100300 et seq. and 100400 et seq. CIRM will notify p~~P~~rincipal investigators, program directors and organizational officials with active CIRM grants ~~will receive notification~~ of amendments to or revisions of~~revised grant terms and conditions or revised editions of the CIRM Grants Administration~~ this ~~P~~policy as they are released. A~~ll~~ mendments or revisions will be posted on the CIRM website (http://www.cirm.ca.gov).

CIRM's right to enforce ~~the provisions of~~ this policy ~~and all of its appendices~~ shall survive the end of the term of the ~~grant~~~~Grant~~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, ~~and~~ loans and contracts ~~to investigators at California universities and institutions~~ 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. Proposals seeking funds of $100,000 or less for scientific conferences, workshops, symposia, or education programming may be reviewed by the President ~~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 Citizen~~'~~s Oversight Committee (ICOC), a 29-member board composed of executive officers from California universities and research institutions, representatives of patient advocacy groups, and experts in the development of medical therapies from the life sciences community. ~~The~~ ICOC members are public officials appointed because of their experience in California's leading public universities, non-profit academic and research institutions, patient advocacy groups, and the biotechnology industry.

## B. Abbreviations

CFR – Code of Federal Regulations

CIRM – California Institute for Regenerative Medicine

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

~~ESCRO – Embryonic Stem Cell Research Oversight~~

FDA – U.S. Food and Drug Administration

FWA – Federal-Wide Assurance

GMO – Grants Management Office~~r~~

IACUC – Institutional Animal Care and Use Committee

ICOC – Independent Citizen~~'~~s 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

G~~S~~MRF~~F~~WG – Scientific and Medical Research Funding Working Group

SPO – Scientific Program Officer

SRO – Scientific Review Officer

## C. Defined Terms~~Glossary~~

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| Application | A request for CIRM funding~~financial support~~ to conduct research; provide services; or construct, lease, or acquire F~~f~~acilities or ~~equipment~~Equipment. An A~~a~~pplication shall contain all information upon which approval for funding is based. |
| Approved B~~b~~udget | The financial expenditure plan for the funded~~grant supported~~ project or activity, including revisions approved by CIRM and permissible revisions made by the PI or G~~g~~rantee. |
| 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 O~~o~~rganizational O~~o~~fficial (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 ~~grant~~Grant ~~applications~~ Applications and~~or grant award~~Awards. |
| Award | CIRM funding in the form of a ~~grant~~Grant, loan or contract that is~~The provision of funds by CIRM,~~ based on an approved ~~application~~Application and budget or ~~progress report~~Progress Reports~~, to an organizational entity or an individual to carry out a project or activity.~~ |
| Budget P~~p~~eriod | The intervals of time (usually 12 months ~~each~~) into which a P~~p~~roject P~~p~~eriod is divided for budgetary and funding 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 R~~r~~esearch | ~~Clinical research refers to p~~Patient-oriented research; that is, research conducted with ~~human subject~~Human Subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) in~~for~~ which an investigator (or colleague) directly interacts with ~~human subject~~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. |
| Covered S~~s~~tem C~~e~~ell L~~l~~ine | A culture-derived, human pluripotent stem cell population that is capable of: (1) sustained propagation in culture; and (2) self- |

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| | 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 Rresearch Ffunding Ceosts | ~~"Direct research funding costs" is t~~The sum of ~~the~~ project costs and facilities costs of a CIRM Awardgrant~~.~~ "Project costs" are those costs that can be specifically identified with a particular CIRM-funded Pproject or Aactivity ~~under a CIRM grant~~Grant. "Facilities costs" are the~~cover general~~ operating costs of a~~the~~ Ggrantee's facilities attributable to ~~that will~~ housinge all elements of the CIRM-funded Pproject or Aactivity. |
| 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 Ggrantee ~~institution~~ for financial management purposes or $5,000. |
| Facility or Facilities | Buildings, building leases, or capital equipment eligible for funding under Proposition 71. |
| For-profit Oorganization | A ~~n organization, institution~~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". |
| ~~Full-time appointment~~ | ~~The number of days per week and months per year representing full-time effort at the applicant/grantee~~Grantee ~~organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.~~ |
| Grant | A ~~grant is a~~ fundinginancial assistance mechanism providing money and/or property to an eligible entity to assist the ~~recipient~~Recipient in carrying out an approved project or activity. |
| Grant Celose-out | The final stage in the life-cycle of an Award ~~grant~~, whether in the form of a grant, loan or contract. During this phase, CIRM ensures that all applicable administrative actions and required work ~~of a grant~~ have been completed by the PI and the Ggrantee. CIRM also reconciles and makes any final fiscal adjustments to the Ggrantee's account. |
| ~~Grant-supported project or activity~~ | ~~Those activities specified or described in a grant application or in a subsequent submission that are approved by the ICOC for funding, regardless of whether CIRM funding constitutes all or only a portion of the financial support necessary to carry them out.~~ |
| Grantee | ~~The organization or individual~~ An Organization that is the Recipient of an Aaward~~ed a grant by CIRM~~ and that is legally responsible and accountable for the use of the funds provided |

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| | and for the performance of the CIRM~~grant~~-funded~~supported~~ P~~p~~roject or A~~a~~ctivity. The G~~g~~rantee is the entire legal entity even if a particular component is designated in the NGA. C~~All~~ ampuses of the University of California ~~grantee campuses~~ shall be considered as separate and individual G~~g~~rantees ~~institutions~~. |
| Human E~~e~~mbryonic S~~s~~tem C~~e~~ells | Human embryonic stem cells are immature (i.e., undifferentiated) cells that are derived from a human early stage, pre-implantation 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 S~~s~~ubject | 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~~ Human ~~subjects~~ Subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as ~~human~~ Human ~~subjects~~ Subjects and to graphic, written, or recorded information derived from such individuals. |
| Indirect C~~e~~osts | Administrative costs of ~~an~~ a Grantee~~organization~~ incurred for common or joint objectives, which cannot be readily and specifically identified with a particular ~~grant~~Grant project. Indirect costs may not exceed ~~will be limited to~~ a maximum of 25 percent of D~~d~~irect R~~r~~esearch F~~f~~unding C~~e~~osts exclusive of the costs of ~~equipment~~Equipment, ~~tuition and fees~~Tuition and Fees, and consultant fees or subcontract amounts in excess of $25,000. |
| Key P~~p~~ersonnel | 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~~under the grant~~Grant. A minimum of one percent effort is required for K~~k~~ey P~~p~~ersonnel. "Zero percent" effort or "as needed" is not an acceptable level of involvement for K~~k~~ey P~~p~~ersonnel. |
| ~~Library expense~~Library ~~expense~~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~~Grantee and others that an ~~award~~Award has been made, contains or references all terms and conditions of the ~~award~~Award as well as the Grantee's and PI's agreement to those terms and conditions, and documents the commitment~~obligation~~ of CIRM funds. |
| Operation and Maintenance Expenses~~ng costs~~ | The general operating costs of a G~~g~~rantee's facilities include expenses normally incurred for such items as janitorial and utility services; repairs and ordinary or normal alterations of |

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| | buildings, furniture and ~~equipment~~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~~such as library, janitorial, utility, and maintenance~~ that are necessary for carrying out ~~the ICOC approved~~a CIRM-funded ~~project~~ Project or Activity (see chapter V, section B, part 3). |
| Organization | A generic term used to refer to a N~~n~~on-profit, Not-for-profit or ~~for-profit organization~~For-profit Organization or other legal entity which applies for or receives ~~a~~ CIRM funding~~grant~~. |
| Other S~~s~~upport | Includes all financial resources – whether federal, non-federal, commercial, or organizational – available in direct support of an investigator's~~ndividual's~~ research endeavors, including, but not limited to, research grants, cooperative agreements, contracts~~,~~ or organizational ~~award~~awards. Other support does not include training ~~award~~awards, prizes~~,~~ or gifts. |
| Principal I~~i~~nvestigator (PI) or ~~/~~P~~p~~rogram D~~d~~irector (PD) | ~~The principal investigator (PI) or program director (PD) is a~~An individual designated by the ~~grantee~~ Grantee to direct the CIRM-funded P~~p~~roject or A~~a~~ctivity ~~being supported by the grant~~. He or she is responsible and accountable to the G~~g~~rantee 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 A~~a~~pproval | Prior w~~W~~ritten approval from CIRM that is required for specified post-award changes in the A~~a~~pproved Budget or project ~~or budget~~. Such approval must be obtained before undertaking or spending CIRM funds for the proposed activity. |
| ~~Progress report~~ | ~~Periodic, usually annual, report submitted by the grantee and used by CIRM to assess progress and, except for the final progress report~~Progress Report ~~of a project period, to determine whether to provide funding for the budget period~~Budget Period ~~subsequent to that covered by the report. The progress report~~Progress Report ~~includes the financial, programmatic, and other reports described in chapter V, section H, *Reporting Requirements* and chapter VI, section E, *Reporting Requirements for Training Grants*.~~ |
| Project P~~p~~eriod | The total amount of time for which CIRM intends to fund a ~~grant~~Grantproject or activity and authorizes a PI~~grantee~~ to conduct the work in the approved ~~work of the project described in the~~ A~~a~~pplication. For reporting purposes, the ~~project period~~Project Period includes all B~~b~~udget P~~p~~eriods 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 |

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| | 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 ~~RFA is an~~ official solicitation ~~by CIRM~~ for A~~a~~pplications 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 ~~application~~Applications ~~submitted in response to the announcement~~. |
| 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 ~~g~~Ggrant applications. |
| ~~Recipient~~ | ~~The organization or individual receiving a grant or other type of support from CIRM. This term is generally used interchangeably with grantee (see "grantee").~~ |
| 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~~Stipend is not considered compensation for the services expected of an employee. |
| Subcontract | A contract between the Grantee and a third party to perform a portion of research proposed in the Application. |
| Tuition and F~~f~~ees | ~~"Tuition and fees" means c~~Costs charged by the G~~g~~rantee ~~organization~~ for the enrollment and instruction of a student. I~~t~~~~This definition~~ does not include costs of health insurance for a trainee, which is an allowable cost addressed separately. |
| ~~Scientific and Medical Research Funding Working Group~~ | ~~In accordance with Proposition 71, the Scientific and Medical Research Funding Working Group (SMRFWG; "Working Group") is the body responsible for reviewing the scientific and programmatic content of grant applications and for making recommendations for funding 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.~~ |

## D. Types of Support

~~The~~ CIRM's scientific program will offer fundings~~support~~ 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 ~~I~~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~~by a staff member designated by the president~~.

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#### b. ~~Director of Scientific Activities~~

~~The Director of Scientific Activities oversees the planning, management and implementation of the institute's scientific endeavors. Other responsibilities include participation in strategic planning in order to help CIRM meet its mission and goals, oversight of activities to track and analyze the portfolio of funded grants, and the development of reporting capabilities. In particular, the Director of Scientific Activities is responsible for all personnel and efforts involved in scientific, programmatic, review and grants management activities. The Director of Scientific Activities ensures that CIRM issues initiatives such as Requests for Applications (RFAs), accepts and reviews applications, and implements the funding of grants and contracts in full compliance with requirements defined by Proposition 71.~~

#### c. Scientific Program Officer (SPO)

The SPO is responsible for the programmatic, scientific, and technical aspects of ~~application~~Applications and Awards~~grants~~. The SPO's responsibilities include, but are not limited to, developing research and research training programs to support the CIRM mission; providing consultation and assistance to applicants and PIs~~grantee~~~~Grantees~~ in scientific and programmatic areas, including guidance on CIRM ~~grants~~ policies and procedures, and performing post-award administration such as reviewing ~~progress report~~Progress Reports, coordinating 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 with the NGA.

**d. Scientific Review Officer (SRO)**

The SRO is responsible primarily for coordinating and conducting the scientific review of ~~application~~Applications by organizing and overseeing the activities of the Scientific and Medical Research Funding Working Group (G~~SMRF~~WG). In fulfilling this function, the SRO is responsible for pre-review activities including receipt and assignment of ~~application~~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 ~~application~~Applications~~, and determination of recusal from participation and voting by ICOC members based on their conflicts of interest with each application~~. 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.

**e. Grants Management Office~~r~~ (GMO)**

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

**2. Grantee ~~Organization~~ Staff:**

**a. 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. CIRM generally requires the identification of an AEO in connection with capital grants.

**b. Authorized Organizational Official (AOO)**

The AOO~~authorized organizational official~~ is the designated representative of the Ggrantee ~~organization~~ for matters related to the

aawardAward and administration of CIRM fundinggrants. This individual's signature on the grant Aapplication certifies that, should the ICOC approve the applicationApplication for funding and should CIRM issue an Award be awarded, the Oorganization will be accountable both for the appropriate use of funds and for the performance of the grantGrant supportedCIRM-funded P project or Aactivity resulting from the application. This individual also certifies to CIRM that the PI and Granteeorganization complyies 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 awardAward.

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.

b.c. **Principal Investigator (PI) or Program Director (PD)**
The PI is the individual, designated by the Ggrantee organization, responsible for the scientific or technical aspects of the CIRM-funded Project or Activitygrant and for its management of the project or activity. The PI and the Ggrantee organization aare both responsible for ensuring compliance with the financial and administrative aspects of the awardAward. The PI must work closely with other Ggrantee 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 Ggrantee organization that specifies an official relationship between the two parties even if the relationship does not involve a salary or other form of remuneration. For training programs or similarly structured programs, the PI is designated as the Program Director (PD).

## F. Sources of Information

There are a number of information sources (i.e., websites) that provide helpful information about the administration of CIRM-supported grants or that are relevant to CIRM-supported grants. The following is a listing of websites containing information of interest to applicants for and recipientRecipients of CIRM fundinggrants:

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| CIRM | http://www.cirm.ca.gov/ |
| National Academy of Sciences | http://www.nas.edu/ |
| National Institutes of Health | http://www.nih.gov/ |

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| Office for Human Research Protections, DHHS | http://www.hhs.gov/ohrp/ |
| Office of Laboratory Animal Welfare, NIH | http://grants1.nih.gov/grants/olaw/olaw.htm |
| Office of Research Integrity, DHHS | http://www.ori.dhhs.gov/ |
| U.S. Food and Drug Administration | http://www.fda.gov/ |

## II. GRANT APPLICATION AND REVIEW PROCESS

### A. Eligibility

#### 1. PI and PD Eligibility

To be eligible to serve as a PI or PD ~~on a CIRM grant-supported project or activity~~, 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

~~All~~ CIRM-funded ~~supported~~ research must be conducted in California. An applicant organization must be a legal ~~n~~ entity that is accountable for both the performance of the approved project or activity and the appropriate expenditure of funds. In general, N~~n~~on-profit and F~~f~~or-profit research organizations located and conducting research in California are eligible to apply for and to receive CIRM research funding~~grants~~. 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~~handle~~ and account for State funds.

#### 3. Other Requirements

Because eligibility may vary ~~based on the type of grant support~~, 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 ~~grant~~ 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 ~~announcement or~~ solicitation will specify the objectives and requirements that apply, and the review criteria that will be used to evaluate the merits of ~~application~~Applications submitted in response to the announcement. Information regarding ~~application~~ Application forms and instructions for completion and submission of ~~application~~ Application materials will be available as part of the funding opportunity announcement. CIRM may require submission of a~~A~~ Candidate Nomination Form (CNF) or Letter of Intent (LOI) ~~may be required~~ prior to or as a condition of ~~-~~submission of a full ~~application~~Application.

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

In signing the ~~application~~Application, the AOO~~authorized organizational official~~ or AEO warrants to CIRM that all eligibility requirements have been satisfied and agrees that should an A~~a~~ward be issued, the organization will abide by the terms and conditions of the A~~a~~ward, all applicable CIRM regulations, all~~including~~ applicable public policy requirements, and will perform the activities included in the submitted ~~application~~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~~"SMRFWG"~~) ~~is responsible for reviewing the scientific and programmatic content of grant applications and~~ mak~~es~~ing funding recommendations ~~for funding~~ to the ICOC. The role of the GWG~~SMRFWG~~ includes consideration of the scientific merit of ~~application~~Applications to support research F~~f~~acilities. The membership of the GWG~~SMRFWG~~ consists of seven~~7~~ patient advocate members of the ICOC, 15 scientists from institutions outside of California, and the C~~c~~hairperson of the ICOC (ex officio).

The G~~SMRF~~WG conducts its review of ~~application~~Applications in accordance with procedures recommended by the G~~SMRF~~WG and adopted~~ratified~~ by the ICOC. In general, CIRM will use a two-stage review process. The first stage is a peer review process in which~~where~~ the scientist members of the G~~SMRF~~WG evaluate and score ~~application~~Applications for scientific merit. In the second stage, the full membership of the GWG assesses ~~application~~Applications that are scientifically meritorious ~~are assessed by the full SMRFWG~~ for programmatic value~~relevance~~ to the CIRM mission. For each ~~application~~Application, a recommendation on funding is then made by the full G~~SMRF~~WG and submitted ~~presented~~ to the ICOC, which makes all funding decisions ~~for their approval~~. The G~~SMRF~~WG may designate~~s~~ each reviewed ~~application~~Application as one of the following:

~~3.~~***Recommended for Funding*** (Tier 1) – For highly meritorious ~~grant and loan application~~Applications that are recommended for funding to the ICOC.

1. ~~***Recommended for Funding Pending Available Funds*** – For meritorious grant and loan applications that~~
2. ***Provisionally Recommended for Funding*** (Tier 2) – For meritorious grant and loan 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.~~are recommended to the ICOC for funding pending available funds.~~
3. ***Not Recommended for Funding*** (Tier 3) – For ~~grant or loan application~~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 ~~research grant~~ Aapplications by the G~~SMRF~~WG, each of which may be weighted differently depending on the purpose and goals of a particular~~each~~ RFA. The ICOC may also adopt additional or revised review criteria ~~for review,~~ when appropriate to meet the objectives set forth in a particular~~specific~~ RFA.
~~Applicants should refer to a specific RFA to determine how criteria are considered for that RFA.~~

Consistent with Proposition 71, the 15 scientist members of the G~~SMRF~~WG shall score ~~grant application~~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 ~~are acknowledged, with~~ and provides for alternative plans should the proposed strategy fail; proposes a~~and the~~ timetable that allows for achieving significant research or clinical results; and uses ~~. Whether~~ appropriate milestones ~~are used~~ 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 ~~presented in~~ 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 ~~grant application~~Applications to recommend for funding, the G~~SMRF~~WG will consider the following criteria when assessing the entire portfolio of ~~grant application~~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 ~~according to~~ the ~~specific~~ requirements or goals of a particular~~the~~ 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**

A~~The a~~pplicants 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. If an applicant's concern cannot be informally resolved in consultation with the SRO, CIRM will accept a formal appeal.

Grounds for~~An applicant may then lodge a formal~~ a formal appeal of the review are strictly limited to circumstances in which ~~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 a written ~~n appeal~~ request ~~in writing~~ to the SRO or to the Director of Scientific Activities. The deadline for submission is ~~within~~ 30 days from the date that ~~of~~ CIRM ~~'s making~~ makes the review report ~~available~~ available to the applicant. CIRM staff in consultation with the Chair of the GWG will then assess the merit of the appeal ~~request in consultation with the chair of the SMRFWG~~ and present a written recommendation to the President of CIRM. If the C~~c~~hair of the G~~SMRF~~WG has a financial, professional or personal ~~or scientific~~ conflict of interest with the ~~application~~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 GSMRFWG who has no financial, professional -or personalscientific conflict of interest will be consulted. The President of CIRM will consider the appeal and the recommendation and will then issue a make the final written decision on the merits of the appeal.

If the President determines that an appeal is meritorious, then the applicationApplication will be reevaluated for scientific merit by two scientist members of receive a new review by the GSMRFWG. The resulting new review and recommendationA recommendation based on the new review will then be submitted presented to the ICOC, which will make the final decision on funding the applicationApplication in question.

**G. Approval for Funding**

The GSMRFWG is responsible for making recommendations to the ICOC on funding of applicationApplications based on scientific merit and programmatic relevance. The ICOC makes all the final funding decisions regarding the specific proposals that shall be funded by CIRM.

## 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 GSMRFWG (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) applicationApplications for research, training, and facilities grants, loans, and contracts; (ii) evaluations of such applicationApplications; and (iii) exceptions provided for in the California Public Records Act itself and Health and Safety Code section 125290.30. SubsectionParagraph (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~~on the CIRM website (~~ http://www.cirm.ca.gov/general/pdf/guidelines.pdf~~)~~.

## III. PRE-AWARD AND AWARD

### A. Administrative Review

A~~ll a~~pplications approved for funding by the ICOC ~~for funding~~ are then reviewed by the GMO and SPO~~CIRM~~ to ensure that~~determine if~~ they meet all applicable CIRM funding requirements, including the submission of required public policy assurances. CIRM reviews the ~~application~~Application budget to ensure that all proposed costs are allowable, as specified in this Grants Administration Policy and the pertinent RFA~~, for the proposed project or activity~~. ~~CIRM may require that the applicant submit an amended budget that removes costs determined to be unallowable.~~ CIRM reserves the right to revise individual budget items as appropriate. ~~Even if an amended budget is not required by CIRM or submitted by the applicant, the~~ U~~u~~nallowable costs are not to be expended ~~under the award~~. ~~CIRM reserves the right to renegotiate individual budget items as appropriate.~~

Issues that arise during administrative review generally must be resolved before CIRM will issue an NGA. CIRM~~The ICOC~~ may, however, approve an ~~application~~Application for funding ~~that is~~ contingent upon the acceptance (by the PI and AOO or AEO~~authorized organizational official~~) of a condition~~reduced project period~~Project Period ~~or narrowed scope of work from that proposed in the application. In such cases, the award will be made only after submission to the GMO of an official addendum to the application that specifies the revised scope of work or award duration with a revised budget, signed by both the PI and the authorized organizational official~~.

~~Issues that arise during the administrative review must be resolved by CIRM and the authorized organizational official before the award is made but no later than the initial payment.~~

### B. Liability

CIRM is not ~~does not assume~~ responsib~~i~~le~~ity~~ for the conduct of CIRM-funded research~~activities that the grant~~Grant ~~supports~~ or for the acts or omissions of ~~recipient~~Recipients of CIRM funding, because such conduct is ~~the grantee as both are~~ under the direction and control of the Ggrantee ~~organization~~ and subject to its organizational policies. Further, Ggrantee organization personnel compensated in whole or in part with CIRM funds are not considered employees of CIRM.

G~~CIRM g~~rantees 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 Ggrantee pursuant to the Awardgrant, and/or, in the alternative, Ggrantees shall name CIRMthe institute as an additional insured and submit proof of such insurance during administrative review of the Application approved for funding. (Health and Safety Code section 125290.45, subd. (a)(2).) If the Ggrantee 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 Ggrantee organization 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 and, $3 million aggregate, and (c) that is comparable to coverage held by institutions of similar size and nature. Upon request by CIRM, the Ggrantee organization shallwill 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 offor compliance with, the following public policies. Initial funding or continued funding of any CIRM-funded Project or Activity grantGrant is contingent upon the prospective or current grantee meetingcompliance with these requirements. DAlthough documentation that certifies or verifies compliance generally may not be required at the time of submission of an application, such documentation (where applicable) is required must be submitted before prior to CIRM will issue 's issuing an NGA. In cases where research requiring public policy assurances will be conducted as 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 Ggrantee shall retain records and supporting documentation that demonstrate compliance with public policy requirements for a minimum of five years from the date of submission of the final expenditure report for the Awardgrant. If related audit findings have not been resolved, such dDocumentation must be maintained for longer than five years, until such findings are resolved.beyond this time period if related audit findings have not been 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.** ~~CIRM~~ Ggrantees and ~~recipient~~Recipients must conduct all research in accordance with the highest medical and ethical standards for scientific research and all applicable laws. The Ggrantee ~~organization~~ bears the ultimate responsibility for ~~detecting and~~ preventing, detecting and imposing sanctions for research misconduct ~~associated with its own institution~~. Grantees ~~organizations~~ must adopt, maintain and insure compliance~~y~~ 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, Ggrantees ~~organizations~~ shall notify CIRM in writing of any finding of research misconduct against~~by~~ a ~~recipient~~Recipient of CIRM funding ~~supported researcher~~ 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 ~~ebarment~~of the Grantee or Recipient ~~from~~ eligibility for ~~receipt of~~ 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~~grant~~-funded~~supported~~ Aactivities 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 Ggrantee uses contractors or collaborators to conduct~~carries out~~ CIRM-funded research ~~through contractors or collaborators~~, the Ggrantee ~~institution~~ must take reasonable steps to ensure that such contractors or collaborators~~investigators working for such entities~~ comply with ~~established~~

the Grantee's safeguards. An acceptable standard for such a policy, for example, may be found in 42 CFR Part 50, Subpart F (*Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought*) (effective October 1, 2000). The Ggrantee ~~organization~~ must promptly notify CIRM if and when it~~the grantee organization~~ takes a suspension or separation action involving a financial conflict of interest against a PI or other Recipient of CIRM funding~~investigator on the CIRM grant~~.

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

4. **Use of Human Stem Cell Lines**
G~~CIRM g~~rantees 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~~ratified~~ by the ICOC for the use of ~~"covered stem cell line~~Covered Stem Cell Lines~~"~~ or use of human oocytes ~~-~~or embryos. This requirement includes use and derivation of ~~human embryonic stem cell~~Human Embryonic Stem Cells. Consequences of failure to comply with ~~the~~ CIRM regulations governing medical and ethical standards are described in chapter V, section J, *Failure of Compliance*. All CIRM-funded ~~proposed~~ research involving~~on~~ ~~"covered stem cell line~~Covered Stem Cell Lines~~"~~ ~~supported by CIRM~~ must comply with CIRM regulations~~policies~~ 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 ~~award~~Awards without current documentation of approval or notification as required, or without imposing limiting conditions~~applicable~~. 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 name of the organization~~, the CIRM Application number, the specific Covered Stem Cell Lines approved, the project title~~,~~ and ~~where applicable,~~ 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 ~~application~~Applications prior to issuance of an NGA (see chapter III, section D, *Just-in-Time Procedures*).

5. **Use of Human Fetal Tissue**

Adult stem cells are derived from various differentiated tissues, including human fetal tissue. When using human fetal tissue in research, CIRM ~~grantee~~Grantees shall abide by any regulations developed by the ~~CIRM Scientific and Medical Accountability~~ Standards Working Group and adopted~~ratified~~ by the ICOC (see Title 17, California Code of Regulations, sections 100010 et seq.). 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 subject~~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~~ organizations~~ engaged in CIRM-funded research involving ~~human subject~~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 Ggrantee ~~organization~~ and any collaborating organizations~~sites~~ (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). In the FWA, the Ggrantee ~~organization~~ must agree to apply the federal regulations, 45 CFR Part 46 and all of its subparts (A,B,C,D) or 21 CFR Parts 50 and 56, to all its ~~human subject~~Human Subjects research regardless of source of support.

**c.** The Ggrantee ~~organization~~ bears ultimate responsibility for protecting ~~human subject~~Human Subjects involved in CIRM-funded research~~under the award~~, including ~~human subject~~Human Subjects at all participating and collaborating sites. At CIRM's request, t~~T~~he prospective Ggrantee ~~organization must~~ must provide the following documentation regarding itself and each collaborating site to the GMO:

**i.** Documentation of IRB review and approval (~~i.e., must indicat~~specifying~~e~~ 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);

~~i. Sample human subject (patient) information and informed consent documents;~~

~~i. Documentation of human research subject education of key personnel;~~

~~iv.~~**ii.** For clinical trials, a data safety monitoring plan;

~~v.~~**iii.** Institutional assurance that the research is conducted in accordance with relevant national, state, and local laws; and

~~vi.~~**iv.** A c~~C~~opy 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 subject~~Human Subjects research. Unless otherwise required by CIRM, this information (where applicable) shall be provided just-in-time for approved ~~application~~Applications prior to issuance of an NGA (see section D, *Just-in-Time Procedure~~ss~~*).

**d**. Evidence of updated IRB approvals and related documents must be submitted with the annual ~~programmatic report~~Progress Report (see chapter V, section H, *Reporting Requirements*). CIRM will not authorize continued funding ~~continue payment on~~of active ~~award~~Awards without current and complete documentation for ~~human subject~~Human Subjects research. ~~At any time, if human subject~~Human Subjects ~~are no longer part of the project or activity, the PI must submit a letter (co-signed by the authorized organizational official) verifying termination of the original protocols and seeking approval for a change of scope, as necessary.~~

**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 subject~~Human Subjects research assurance are described in chapter V, section J, *Failure of Compliance*. The AOO~~authorized organizational official~~ shall promptly~~also~~ inform CIRM of any investigation or administrative action by OHRP or by the Ggrantee ~~organization itself~~ concerning Recipients of CIRM funding and their ~~involving the~~ use of ~~human subject~~Human Subjects in research ~~by PIs receiving CIRM funds~~.

**g~~f~~.** Women and members of minority groups must be included in all CIRM-funded ~~clinical research~~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-fundedsupported ~~clinical research~~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~~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.

**hg.** PIInvestigators must includereport in their annual programmatic reportProgress 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, Ggrantee organization 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, Ggrantee organization and any collaborating sites conducting CIRM-fundedsupported research that involves the use of vertebrate animals shall comply with all applicable federal, state, and local laws. Sites where CIRM-fundedsupported 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 Ggrantee organization must appoint and maintain an Institutional Animal Care and Use Committee (IACUC) to provide oversight of research involving vertebrate animals.

**d.** The prospective Ggrantee organization must provide to CIRM evidence of IACUC review and approval of research involving the use of animal subjects. The documentation must includedicate 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 applicationApplications prior to issuance of an NGA (see section D, *Just-in-Time Procedures*).

**e.** Evidence of updated IACUC approvals must be submitted with the annual programmatic reportProgress Report (see chapter V, section H, *Reporting Requirements*). CIRM will not authorize continued funding of continue payment on an active Awardsaward without current documentation of such approval.
At any time, if animal subjects are no longer part of the project or activity, the PI should report this change to CIRM in the next programmatic report. If a change in scope is necessary, the PI must submit a letter (co-signed by the

~~authorized organizational official) verifying termination of the original protocols and requesting approval for such a change.~~

f. ~~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~~n applicant~~ shall certify to CIRM that any approval required by the Ggrantee ~~organization~~ 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 ~~key personnel~~Key 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 ~~n applicant or g~~Grantee shall provide documentation that verifies such organizational approvals upon request ~~by CIRM~~. Grantees ~~organizations~~ 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 ~~activities related to CIRM~~ CIRM-funded research~~grants~~.

**9. Sharing of Intellectual Property: Publications, Biomedical Materials, Patented Inventions**

PIs and ~~CIRM grantee~~Grantees shall share intellectual property generated by CIRM-funded research~~under a CIRM grant~~Grant including research results in scientific articles, publication-related biomedical materials, and patented inventions for research use in California as required by Title 17, California Code of Regulations section 100300, et seq. and section 100400, et seq., as applicable.~~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)). To achieve this goal, CIRM expects the ~~grantee~~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~~Grantee must provide a clear and compelling explanation in the~~its annual~~ Pprogram~~matic~~ R~~r~~eport for not purchasing more than 50 percent of its goods and services from California suppliers. Please see chapter V, section H, part 2, *Programmatic Report*.

[A definition for the term "California Supplier" is being separately considered as an interim regulation and will be added to this document for additional notice and comment consistent with that interim regulation.]

## D. Just-in-Time Policy

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

1. **Certification**
   CIRM requires documentation from the Ggrantee ~~organization~~ that:

   **a.** verifies IACUC review and approval of the project's proposed use of live vertebrate animals; or
   **b.** certifies SCRO~~, ESCRO~~ committee (or equivalent) notification or review and approval of the project's proposed use of ~~"covered stem cell line~~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 subject~~Human Subjects.

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

   **a.** ~~Key personnel~~ PIs~~rincipal Investigators~~, 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 ~~pending~~ projects, whether or not salary support is requested in the ~~application~~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 A~~a~~pplication is funded over any part of the ~~project period~~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~~Equipment, salaries) and may be evident when duplicate or equivalent budgetary items are requested in an ~~application~~Application but are already funded by another source.

## E. Award Notice

Once CIRM funding requirements are fully met, an NGA will beis sent to the PI or PD. A copy is also sent and to the AOO or AEOauthorized organizational official designated in the applicationApplication. The NGA specifies the projectProject Period (start and end dates of the project or program) as well as the monetary allocations (itemized direct research funding costsDirect Research Funding Costs (including Facilities costs) and an amount allocated for indirect costIndirect Costs) for each budget periodBudget Period. The NGA also incorporates this Ggrants Aadministration Ppolicy and all other applicable CIRM regulations statement by reference and specifies any special terms and conditions of the awardAward.

## IV. AWARD ACCEPTANCE

An Aaward is accepted when an NGA is ~~is~~ signed by the ~~grantee~~PI and AOO or AEO, and returned to and received by CIRM. In accepting an Award ~~CIRM grant~~Grant, the PI and Ggrantee assure~~s~~ CIRM that any funds expended under the ~~award~~Award will be for the purposes set forth in the approved Aapplication. Further, the PI and Ggrantee agree~~s~~ to comply with terms and conditions of all applicable CIRM regulations, including this Grants Administration Policy. ~~Grant recipients shall comply with all applicable CIRM regulations, including research standards adopted by the ICOC. To accept officially the CIRM grant, the PI and authorized organizational official must sign the~~ The NGA must be signed and returned ~~and return it~~ to CIRM within 4530 days (or more, if extended in writing by CIRM) of issuance. Payment will not be issued until the Aaward is accepted. If the PI or Ggrantee cannot accept the Aaward, including the legal obligation to perform in accordance with its provisions, they~~it~~ shall~~ould~~ so notify CIRM in writing immediately upon receipt of the NGA.

Urgency is one of the component values of ~~that~~ 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.

~~This grants administration policy statement may be updated periodically by CIRM. Any new or amended regulations adopted by the ICOC will be applied to currently active grants on the start date of the next budget period~~Budget Period~~. A new NGA will be issued that reflects the new or amended regulations.~~

## V. PAYMENT AND USE OF FUNDS

### A. Payment

Once CIRM has a fully-executed NGA, it will ~~The~~ initiate~~l~~ payment for the first Budget Period~~an approved application is made after award acceptance~~. Payment for each subsequent~~future budget period~~Budget Period is contingent on the receipt and acceptance by CIRM of the financial, programmatic, and other reports due for the prior ~~budget period~~Budget Period; applicable public policy assurance documents (e.g., ~~E~~SCRO, IRB, and IACUC); and any requests for budget changes applicable to the new ~~budget period~~Budget Period.

### B. Costs and Activities

CIRM ~~grant~~ funds shall only be used for expenditures necessary to carry out the approved Application~~project and activities~~. Specific allowable or unallowable costs may be described in the RFA or the NGA. In accordance with Proposition 71, ~~direct research funding costs~~Direct Research Funding Costs include scientific and medical

funding for an approved research project and the general operating costs of ~~f~~Facilities for conducting the approved project.

1. **Allowable Project Costs and Activities**
   Project costs are those costs that can be specifically identified with a CIRM-funded ~~particular project~~ Project or ~~a~~Activity ~~under a CIRM grant~~. Unless otherwise specified in an RFA or NGA, allowable project costs include salary for investigators (detailed below), fringe benefits, itemized supplies, S~~s~~tipends and ~~tuition and fees~~Tuition and Fees (as defined in chapter VI, section C, *Allowable Costs and Activities for Training Grants*), research animal costs, C~~c~~onsultants, itemized clinical study costs, travel-related expenses (detailed below), itemized project-related ~~equipment~~Equipment (as approved), publication costs, service contracts, subcontracts, and administrative costs where required to carry out the approved project. 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 Budget Period and $25,000 per Budget Period in aggregate, unless Prior Approval is sought and obtained during administrative review.

   ~~Investigator s~~Salaries for PIs, PDs and Key Personnel shall not exceed~~be limited to~~ an annual rate of $2070~~0~~,000 ~~per investigator~~. CIRM will adjust this ~~This~~ limitation ~~shall be adjusted~~ biennially ~~by CIRM~~ beginning July~~anuary~~ 2, 20~~0~~10~~8~~ as follows: (a) the base dollar amount of $2070~~0~~,000 shall be increased or decreased by the cumulative percentage change in the annual average California Consumer Price Index for All Urban Consumers from 2008~~6~~ 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~~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 ~~rate limitation~~ in effect until June~~anuary~~ 1 of the next even-numbered year. Biennial adjustments will be posted at www.cirm.ca.gov.

   Allowable travel-related expenses include costs for transportation, lodging, subsistence, and related items incurred by ~~key personnel~~Key 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~~be limited to~~ an annual allowance of $5,000 per person per CIRM ~~award~~Award.

2. **Unallowable Project Costs and Activities**
Unallowable project costs and activities ~~are costs that~~ cannot be charged to ~~a~~ CIRM fundinggrant 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.

3. **Allowable Facilities Costs**
Facilities costs cover general operating costs of the Ggrantee's facilities attributable to housing ~~that will house~~ all elements of the CIRM-funded ~~project~~ Project or ~~activity~~Activity. Grantees may request two categories of facilities costs: (a) costs based on the Ggrantee's current, federally negotiated rates for operation and maintenance expenses, and for ~~library expense~~Library Eexpenses; and (b)(1) costs based on the grantee's current, federally negotiated rates for depreciation or use allowances on buildings, capital improvements, and ~~equipment~~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~~Grantee if the ~~grantee~~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*). ~~Grantee~~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~~Equipment, ~~tuition and fees~~Tuition and Fees, and subcontract amounts in excess of $25,000.

4. **Unallowable Facilities Costs**
Costs already provided for by a CIRM facilities or infrastructure ~~grant~~Grant, or by another research g~~grant~~Grant (from any source), are not allowable facilities costs in a CIRM Award~~research grant~~.

A Grant awarded under CIRM Major Facilities Program RFA 07-03 is a facilities grant as used in this section. CIRM-funded research facilities shall be used only for stem cell research and research directly related to moving this technology forward. CIRM-funded facilities will house stem cell and related research funded by CIRM and other sources. An institution that receives a facilities grant shall locate CIRM-funded research activities in the facility as described in the Application submitted in response to RFA 07-03.

Beginning on the date of occupancy projected in the Application for a 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-funded 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 RFA 07-03 (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.

**5. Indirect Costs**

~~Indirect cost~~Indirect Costs will be limited to a maximum of 25 percent of allowable ~~direct research funding costs~~Direct Research Funding Costs ~~awarded by CIRM (i.e., project costs and facilities costs)~~, exclusive of the costs of ~~equipment~~Equipment, ~~tuition and fees~~Tuition and Fees, and subcontracts or consultant fees~~amounts~~ in excess of $25,000.

**6. Interest Earned on CIRM Funds**

Interest earned on CIRM funds must be reinvested in the program that the funds support. Carry forward reported on a financial report must include any interest earned during the expired budget period. Interest on CIRM funds may be determined according to the Grantee's own interest cycle but, at a minimum, must be calculated at a monthly rate. Grantees are required to include a copy of the interest calculations in their financial report.

~~C.~~**Budgetary Overlap**

**C.**

CIRM ~~grant~~ funds shall only be used for expenditures directly related to the approved Application~~project and activities~~. CIRM ~~grant~~ funds cannot be combined with the operating budgets of the Grantee~~recipient~~s and may not be used for any fiscal year-end expenditures or deficits not directly related to the ~~award~~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~~Equipment), is not permitted.

**Pre-award Costs**: 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.

**C.Prior Approval Requirements**
**D.**

PIs and CIRM gGrantees must perform project activities as described in the approved Aapplication. A PI and Ggrantee must request and obtain prior written approval for pre-award or post- award changes described below by submitting to CIRM such requests in writing together with appropriate justification for the proposed change. Such approval must be obtained in writing before expending CIRM funds for the proposed activity. The following are examples of post-award changes that require CIRM pre-approval. (see chapter VI, section D, *Prior Approval Requirements for Training Grants* for additional prior approvalPrior Approvals that apply specifically to training grants):

1. **Change in Scope**
   The PI and Ggrantee must obtain prior approvalPrior Approval from CIRM for any change that constitutes a significant deviation from the aims, objectives, experimental design, or purposes of the approved Applicationproject or activity (hereafter "change in scope"). When considering such a change, the PIgrantee should consult with the GMO and SPO. Examples of actions likely to be considered a change in scope and therefore requiring CIRM prior approvalPrior Approval include but are not limited to:
   **a.** Any cChange in the specific aims in the approved Applicationat the time of award;
   **b.** Any change in the use of animals or human subjectHuman Subjects from that described in the ICOC approved Applicationproposal and as approved by the IRB or IACUC;
   **c.** Shift in of the research emphasis from one disease area to another; or
   **d.** Transfer of the performance of substantive funded activities to a third party not previously identified in the approved Aapplication.

2. **Carry Forward of Funds**
   PIs/The gGrantees must obtain prior approvalPrior Approval from CIRM to carry forward from one Budget Period to the next unexpended funds exceeding 25 percent of the annual project costs for the expiring Budget Period from one budget period to the next that exceed 25 percent of the annual project costs for the expiring budget period. Absent Prior Approval, any amount that exceeds this limit will be deducted from the next budget periodBudget Period unless approval to carry the amount forward is granted. If the carry forward amount is greater than 50 percent of the expiring budget periodBudget Period's project costs, CIRM may elect to postpone payment of funds for the next budget periodBudget Period may be postponed. At the

~~conclusion or termination of an award,~~ U~~u~~nexpended funds must be returned to CIRM within 120 days of the ~~project period~~Project Period end date.

3. **Extensions**
PIs/Grantees may request a one-time, no-cost extension of the Project Period end date of~~or~~ up to one year ~~beyond the scheduled project period end date~~. 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 ~~award project period~~Project Period end date.

4. **Rebudgeting**
~~Recipient~~Recipients must spend CIRM~~expend~~ funds ~~as~~ in conformance with ~~described in~~ the ~~CIRM approved~~ budget stated in the NGA. Except as provided below, ~~prior approval~~Prior Approval ~~by CIRM~~ is required for any changes in the ~~approved budget~~Approved Budget.

   a. **Personnel or~~/~~ Supplies** – ~~Prior approval~~Prior Approval is required only if rebudgeting would change (i.e., increase or decrease) the total budget of either category by more than $5,000, **and** the change exceeds 25 percent of the previously approved total for that category. The budget total includes any carry-forward amounts.

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

   c. **Consultants or~~/~~ Subcontracts** – ~~Prior approval~~Prior Approval is required only if rebudgeting would change (i.e., increase or decrease) the total budget of either category by more than $1,500, **and** the change exceeds 25 percent of the previously approved total for that category. The budget total includes any carry-forward amounts.

   d. **Equipment** – ~~Prior approval~~Prior Approval is required to purchase items of ~~equipment~~Equipment that are not part of the approved ~~award~~Award budget. ~~Prior approval~~Prior Approval is not required if the cost of ~~approved equipment~~Equipment has not increased by more than $1,500 **and** the change does not exceed 25 percent of the ~~previously approved budget~~Approved Budget~~ed amount~~ shown in the NGA. The budget total 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 ~~during the project period~~Project Period. Requests must specify the budget categories affected by any proposed change and the reason for the change.

~~Even~~ When ~~if~~ a budget change would trigger ~~results in~~ an increase in the calculation~~amount~~ of ~~indirect cost~~Facilities and Indirect Costs, CIRM will not fund ~~provide additional funds~~ any increase in the calculation of ~~indirect cost~~Facilities and Indirect Costs~~for this purpose~~. ~~Unexpended funds from the direct research funding costs categories, however, may be used at the end of the budget period~~Budget Period ~~to cover any deficit in indirect costs resulting from the rebudgeting actions.~~If a budget change triggers a decrease in the calculation of Facilities and Indirect Costs, CIRM will reduce the payment of Facilities and Indirect Costs in the next Budget Period by a corresponding amount.

## 5. Relinquishment of Award and Award Transfer

~~5.Award Transfer~~

A Grantee may at any time relinquish an Award by submitting a relinquishing statement that includes a) a statement of reasons for relinquishing the reward; b) an estimate of the unexpended balance of any funds paid to the Grantee; c) and an assurance that all unexpended funds will either be returned to CIRM, or in the case of an Award transfer, transferred to a new Grantee 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~~Prior Approval, an Award ~~CIRM grant~~ may be transferred to another eligible organization ~~in California~~ when~~if~~ a PI transfers from a Grantee to that organization. CIRM a~~A~~pproval will be contingent upon the ~~current g~~Grantee ~~organization~~ relinquishing rights to the Award~~grant~~, among other considerations. ~~Furthermore, the grantee organization may be required to transfer to the new organization any equipment purchased under the grant.~~

~~Before the transfer can take place, the original grantee organization must submit to CIRM a relinquishing statement that includes an estimate of the unexpended balance of any funds paid to the grantee and an assurance that all unexpended funds will be transferred to the new grantee organization or returned to CIRM within 90 days of the relinquishing date.~~

T~~T~~he transferee~~new~~ G~~g~~rantee ~~organization~~ must submit to CIRM a letter that states its~~their~~ intention to assume responsibility for the ~~award~~Award based on the approved Application, and that encloses the following items:

**a.** A n~~N~~ew ~~application~~Application face page with original signatures

**b.** Detailed budget(s) for the remaining ~~project period~~Project Period (including the estimated unexpended balance from the relinquishing ~~original g~~Grantee)

**c.** Biographical sketches for new ~~key personnel~~Key Personnel

~~**e.**Other support for new key personnel~~Key Personnel

~~**e.**~~**d.**Description of f~~F~~acilities and resources

~~**f.**~~**e.** Public policy assurances (e.g., ~~human subject~~Human Subjects, animal, biohazard), where applicable.

If the President~~CIRM~~ determines that the proposed transferee Grantee is eligible and can fulfill the responsibilities of the relinquishing Grantee, CIRM will approve the transfer by ~~will~~ cancelling the original NGA and issuing~~e~~ a new NGA to the ~~PI and the~~ transferee~~new g~~ Grantee ~~organization when all required documents have been received and the transfer has been approved by CIRM~~. Transfer of the ~~award~~Award will be~~is~~ effective when CIRM receives the new NGA ~~is~~ executed~~signed~~ by the PI and the AOO or AEO ~~authorized organizational official~~ of the transferee~~new~~ Ggrantee ~~organization and returned to and received by CIRM~~. Payment will not be issued until the A~~a~~ward transfer is effective.

6

**6. Change in PI Status or Percent Effort**
~~**6. or Percent Effort**~~

~~Prior approval~~Prior Approval is required for the 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~~award~~.

In addition, Grantees must notify CIRM immediately if any of the following changes in PI status occur.

**a.** The PI's status ~~appointment~~ 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 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~~operations~~ for a continuous period exceeding 90 days.
**c.** The PI is no longer eligible (under either the standards of the Grantee or the criteria in the RFA) to serve as a ~~PI~~ PI ~~at the grantee organization.~~

~~CIRM will notify the grantee organization i~~If CIRM determines that a PI's change in status will adversely impact the conduct of ~~prevent~~ the CIRM-funded ~~p~~Project ~~from being conducted~~ as described in the approved Application~~award~~, CIRM will so notify the Grantee. ~~Under such circumstances, t~~The G~~g~~rantee ~~organization~~ may respond to such notification by seeking~~request~~ approval to substitute~~continue the project with~~ an eligible PI that is satisfactory to CIRM. CIRM may~~will~~ terminate the ~~award~~Award if no request is made or if the proposed substitute PI is not satisfactory. The Grantee shall return to CIRM a~~A~~ll unexpended funds ~~will be returned to CIRM~~ within 120 days of termination of the ~~award~~Award. In general, CIRM will not approve a substitution~~change~~ of PI or decrease in percent effort exceeding 25 percent ~~will not be approved~~ during the first 180 days of the ~~project period~~Project Period.

**7. Submitting Prior Approval Requests**

~~Prior approval~~Prior Approval requests must be submitted in writing to the GMO and must be signed by the PI and the AOO or AEO~~authorized organizational official~~. All such requests sh~~ould explain the nature of the~~all identify the proposed action requiring CIRM ~~prior approval~~Prior Approval and ~~must~~ include a justification, an estimate of the expected duration of the change, and any budgetary modifications that would result if the request were granted~~from the request~~. Approval by CIRM shall not be effective unless in writing and signed by the P~~p~~resident of CIRM, or his/her de~~legee~~~~signated authority~~.

## E. Equipment Management

The Ggrantee ~~organization~~ must have a property management system for ~~equipment~~Equipment that includes the following:

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

~~For equipment costing more than $10,000, title may vest in the grantee organization only with CIRM approval. For equipment costing $10,000 or less, title to equipment vests in the organization upon acquisition. If title vests in the grantee organization, the organization shall upon request by CIRM transfer title to equipment purchased with CIRM grant~~Grant ~~funds to a third party (e.g., when transferring a grant award to a new grantee). Equipment purchased with CIRM grant funds must stay within the State of California for the duration of the grant project period.~~

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

1. **Accounting Records**
   The Ggrantee shall maintain an accounting system and supporting fiscal records to assure that CIRM funds awarded are used solely for the purposes outlined in the approved Application~~NGA~~ and in accordance with ~~approved budget~~Approved Budget in the NGA~~at document~~.
2. **Document~~ation~~ Retention**
   The Ggrantee 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 years covered by the grant~~. All records ~~Documentation~~ must be maintained in excess of this minimum ~~beyond this~~ time period if ~~related~~ audit findings have not been resolved.
3. **Access to Records**
   The Ggrantee shall allow CIRM, the Bureau of State Audits, the California State Controller, or any other appropriate state agency access to its accounting records and supporting ddocumentation ~~by state audit personnel and by grants management officials of CIRM~~ with reasonable notice.
4. **Audits**
   Accounting records and supporting documentation may be audited at the direction of ~~by~~ 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 Ggrantee practice that is inconsistent with sound fiscal, business or research practices or that result in an unnecessary cost to CIRM~~the grant program~~.

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

Fraud, ~~waste,~~ or abuse can result in any of the administrative and other actions described in section J, *Failure of Compliance*. In addition, any PI, Ggrantee or ~~recipient~~Recipient of CIRM funds suspected of misuse of funds~~fraud~~ 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 ~~on an~~ annually at minimum ~~basis~~. ~~The annual programmatic report is due 60 days prior to each anniversary of the award start date indicated in the NGA. The subsequent budget period's funding will not be awarded until this report has been received, reviewed, and approved by CIRM. In addition, the grantee must submit an annual financial report within 90 days after each anniversary of the award start date.~~

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. ~~Annual~~ Financial Report

The Ggrantee shall submit to the GMO an annual financial report within 90 days after each anniversary of the Aaward start date stated~~indicated~~ in the NGA, unless CIRM requires more frequent reports. The ~~annual~~ financial

report must include all actual costs incurred against CIRM funds ~~under the CIRM grant~~ during the expired ~~budget period~~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~~Grantee.

2. ~~Annual~~ **Progress~~sammatic~~ Report**
The G~~g~~rantee shall submit to CIRM an annual ~~programmatic report~~Progress Report detailing scientific progress and activities, unless CIRM requires more frequent reports ~~under the CIRM grant~~. This report is due 60 days prior to each anniversary of the A~~a~~ward start date stated~~indicated~~ in the NGA.

The ~~programmatic report~~Progress Report shall include~~s~~ a summary of scientific progress; a listing of personnel who participated in the project and their level of effort; an updated list~~ing~~ of other support for the PI ~~and other key personnel~~; a list of publications ~~(including submitted or in press)~~ resulting from the CIRM-funded~~supported~~ ~~project~~ Project or ~~activity~~Activity; 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); a statement of the percentage of~~n estimate of~~ goods and services purchased with CIRM funds from California suppliers; and a listing of inventions disclosed, patents filed, or licenses granted for the ~~project period~~Project Period (see part 3, *Other Reports*). The ~~programmatic report~~Progress Report must also include an overview of any major unexpected expenditures or unspent funds (actual or anticipated) for the expiring ~~budget period~~Budget Period and any ~~anticipated~~ changes anticipated for~~in~~ future ~~budget period~~Budget Periods.

CIRM will not issue payment for the subsequent Budget Period until it has received, reviewed and approved this report.

3. **Other Reports**
PIs and Grantees are~~may~~ also ~~be~~ required to report to CIRM publications, inventions, patent applications, licensing and invention utilization activities that result from CIRM-~~-~~funded research~~ing~~. Specific reporting requirements related to these areas may be found in regulations adopted by the ICOC governing intellectual property ~~for non-profit organizations~~. See Title 17 California Code of Regulations section 100300 et seq., section 100400 et seq.

4. **Overdue Reports**
Failure to timely submit~~provide~~ financial, progress, or other required reports ~~on time~~ may result in reduction, delay or suspension of payments~~a CIRM award until required materials are received~~. Further, if a report is delinquent for more than 6~~9~~0 days ~~beyond its established due date~~, CIRM may take action as described in section J, *Failure of Compliance*.

## I. Grant Close-Out

CIRM will close out an Award ~~grant~~ within 60 days ~~as soon as possible~~ after the ~~project period~~Project Period end date or the end date of any authorized extension. Close-out requires~~includes~~ a PI and Grantee to timely submit~~ssion~~ of all required reports and reconciliation of ~~ng~~ amounts due the Ggrantee or CIRM. CIRM may withhold funds ~~from a PI~~ for future or concurrent ~~award~~Awards if a Grantee is delinquent in submitting ~~grant close-out is pending the submission of overdue~~ reports.

Close-out of an Award ~~grant~~ does not extinguish~~cancel any~~ requirements for property accountability, record retention, or financial accountability, or requirements associated with regulation of medical and ethical standards or intellectual property. Following close-out, the Ggrantee 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 ~~of grant support~~.

~~In addition, the grantee is obligated to report to CIRM after grant close-out any inventions disclosed, patents filed, or licenses granted that resulted from CIRM-funded research as required by regulations duly adopted by the ICOC governing intellectual property for non-profit organizations.~~

## ~~J.~~J. Failure of Compliance

If a Ggrantee or PI fails to comply with the terms and conditions of an Aaward, CIRM ~~mm~~may take one or more actions, depending on the severity and duration of the non-compliance. F~~or instance, f~~ailure of compliance includes confirmed instances of research misconduct, violations of medical or ethical standards as provided ~~defined~~ in Title 17, California Code of Regulations, ~~commencing with~~ section 100010 et seq., or violations of intellectual property regulations, as provided in Title 17, California Code of Regulations, section 100300 et seq. ~~duly adopted by the ICOC.~~ CIRM will afford the Ggrantee an opportunity to correct any~~the~~ deficiency~~ies~~ before taking action unless public health or welfare concerns require immediate action, or prompt action is necessary ~~. Even if a grantee is taking corrective action, CIRM may take action~~ 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 Aawards;
3. Conversion to a reimbursement payment method;
4. Disqualifying ~~Precluding~~ the Ggrantee (or PI ~~or grantee organization~~ as appropriate) from eligibility for ~~obtaining~~ future ~~award~~Awards for a specified period;

5. Disqualifying the Grantee (or PI as appropriate)~~ebarment~~ from receipt of further CIRM funds;
6. Recovery of previously awarded funds;
7. Civil or criminal action, including referring the matter to the Office of the Attorney General of California for 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 ~~application~~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~~program director~~ 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 ~~(e.g., pre-doctoral, post-doctoral, clinical fellow)~~ of trainees that may be appointed and supported by the CIRM training grant. Each trainee must be sponsored by an eligible faculty mentor who will supervise the training and research experience. The PD~~program director~~ 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*).

#### ~~1.~~Degree Requirements

2.

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. ~~Specifically, a graduate student~~

~~must have received a bachelor's degree and must be enrolled in a degree-awarding graduate program. A pre-doctoral student must be enrolled in a doctoral degree program in a basic science program or medically-related professional program such as medicine, dentistry, or veterinary medicine. Post-doctoral fellows must have earned a Ph.D., M.D., or equivalent degree. Clinical fellows must have received a professional doctoral degree in a medically-related field and should be training in a residency or immediate post-residency program.~~

**3. Training Period**

The training period for any individual trainee will be as specified in the RFA~~is limited to 36 months and should not be less than 12 consecutive months (clinical trainees may request prior approval for a shorter training period, but only with written justification)~~. 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.

~~Program directors of CIRM training grants are encouraged to appoint individuals who are committed to a career in research, particularly stem cell research and related areas, and plan to remain in the CIRM training program for a minimum of 2 years. The CIRM training grant is not intended to provide opportunities to participate in short-term research assignments during the summer or other "off-quarter" periods.~~

## 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 cost~~Indirect Costs, which cannot be specifically associated with the training grant program, are limited to 10 percent of the direct project costs.

**1. Stipend Levels**
**~~Stipend Levels~~**

Annual t~~T~~rainee ~~stipend~~Stipend levels should be commensurate with the individual's experience and the level of training, as specified in the RFA. ~~Unless otherwise specified in the RFA, grantees may request support for: pre-doctoral students with a maximum annual stipend of $25,000; postdoctoral fellows at a range of $36,000 to $52,000 per year, depending on years of experience; and clinical fellows at a range of $65,000 to a maximum of $75,000 per year, depending on experience.~~ CIRM encourages the Ggrantee

~~organization~~ to supplement trainee ~~stipend~~Stipends when necessary to meet institutional requirements and maintain equity among trainees, provided that the supplementation is without obligation to the trainee~~. The maximum stipend limitations shall be adjusted biennially by CIRM beginning January 2, 2008 to reflect changes in the annual average California Consumer Price Index for All Urban Consumers~~.

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

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

A ~~CIRM~~ trainee may not be concurrently supported with another fellowship or similar ~~award~~Award that provides a ~~stipend~~Stipend or otherwise duplicates provisions of the ~~CIRM~~ training grant ~~award~~Award.

**2. Tuition and Fees for Student Trainees**

"Tuition and fees" means costs charged by the ~~g~~Grantee ~~organization~~ for the enrollment and instruction of a student~~. This definition does not~~ and may include costs of health insurance for ~~a~~the student. ~~trainee, which is an allowable cost addressed separately in part 3, *Health Insurance*, of this section. Tuition and fees are allowable CIRM training grant costs only if such charges are applied consistently to all individuals in a similar training status at the G~~grantee organization, without regard to the source of support. 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~~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~~Tuition and Fees that are otherwise subsidized by the G~~g~~rantee ~~organization~~.

~~Tuition and fees~~Tuition and Fees at the postdoctoral or clinical trainee levels are not allowed~~able only for costs related to specific courses in support of the approved CIRM training program~~.

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

If the postdoctoral or clinical trainee's health insurance is not otherwise covered by the Ggrantee institution, the Ggrantee 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, rResearch training experiences away from the Ggrantee organization must be justified on the basis of the type of opportunities for training available, the opportunities offered that are different from those at the Ggrantee organization, and the relationship of the proposed experience to the trainee's career stage and career goals. Expenditure of CIRM grant funds for this type of research training requires prior approvalPrior 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 provided they are not available in the Ggrantee organization's library or at the training institution. Professional journal subscriptions covering the period of the appointment are not allowable costs to the CIRM training grant.

If personal computers are purchased under the CIRM training grant, they are to remain at the grantee institution for the benefit of all trainees in the CIRM training grantGrant program. ]

5. **Program Administration Funds**
Grantees may request funds for administrative costs as part of for the program with an annual direct project costs allowance. Unless otherwise specified in the RFA, Aallowable 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. Up to 25% of the amount awarded in this category (i.e., program administration funds) may be used for the PDprogram director's salary.

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

The cost of food and meals served at a seminar or meeting is not an allowable cost~~may not be charged to the CIRM training grant~~.

### D. Prior Approval Requirements for Training Grants

GCIRM grantees must perform project activities as described in the approved Aapplication. A Ggrantee must request approvalPrior 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 PDgrant program director and the AOOauthorized organizational official. 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 examples of post-award changes for training grants that require approval:

1. **Stipends** – Rebudgeting funds out of the stipendStipend category.

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 SupportFunds/Indirect Costs** – Rebudgeting between 1) trainee-related funds (i.e., Stipends, Tuition and Fees, health insurance, or research and travel), 2) program administration funds, and 3) Indirect Costs any of these categories; however, funds may be re-budgeted into the trainee-related funds category for use as stipendStipends category without prior approvalPrior Approval.

4. **Carry Forward of Funds** –Carrying forward of unexpended funds from one budget periodBudget Period to the next that exceed 25 percent of the annual project project costs –for the expiring budget periodBudget Period. If the carry forward amount is greater than 50 percent of the expiring budget periodBudget Period's project costs, payment of funds for the next budget periodBudget Period may be postponed.

5. **Extensions** – Extending the project periodProject Period beyond the scheduled end date. A one-time no-cost extension for up to one year beyond the scheduled project periodProject Period end date is allowed with prior approvalPrior Approval. The written request for prior approvalPrior Approval shallould be submitted to CIRM at least 30 days in advance of the scheduled award project periodProject Period end date.

6. **Change in Program Director** –Appointing a new PDprogram director for the training grant program.

7. **Change in Sponsor, or Mentor, or Collaborating Institution** –Appointing a new trainee sponsor or mentor. Any mentor changes approved by CIRM

shallould be reported in the annual programmatic reportProgress 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 or interest earned on CIRM funds for this purpose.

Additions to the total number of approved trainee positions or to any one type of trainee position are not permitted. The grantee organization must submit a competitive application for a supplement to request an increase in the number of approved trainees.

## E.E. Reporting Requirements for Training Grants

Notwithstanding chapter V, section H, *Reporting Requirements*, the PDprogram director of a CIRM training grant must submitreport financial and Pprogrammatic Reportsprogress as described in this section to CIRM on an annual basis. The programmatic reportProgress Report is due 60 days prior to each anniversary of the project periodProject Periodaward start date statedindicated in the NGA. Funding for tThe subsequent budget periodBudget Periodyear's funding will not be paidawarded until CIRM has this report has been received, reviewed, and approved this reportby CIRM. In addition, the PDprogram director must submit an annual financial report within 90 days after each anniversary of the project periodProject Periodaward start date.

1. **Annual Financial Report**
   The Ggrantee shall submit to the GMO an annual financial report, within 960 days after each anniversary of the project periodProject Periodaward start date statedindicated in the NGA. The annual financial report must include all actual costs incurred under the CIRM grant during the expired budget periodBudget Period and any carry forward amounts.

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

2. **Annual Programmatic Report**
   The gGrantee shall submit to CIRM an annual report detailing progress and activities of the training program during the project periodBudgetProject Period. This report is due 60 days prior to each anniversary of the project

~~period~~Budget Period~~award~~ start date indicated in the NGA. The ~~programmatic report~~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~~Award is required. The training program report requests information such as~~must provide the following information~~:

- **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

~~**iv.**Course roster, syllabus, and evaluations~~

- ~~**vi.**~~**v.** Changes in the administration of the program
- ~~**vii.**~~**vi.** Plans for the upcoming year
- ~~**viii.**~~**vii.** Anticipated budget changes in future ~~budget period~~Budget Periods

**b. Trainee Report**

In addition to the training program description, the annual ~~programmatic report~~Progress Report must include data for all trainees who were or are supported by the training grant. The trainee report requests information such as~~must include the following information~~:

- **i.** Mentor and trainee assignments
- **ii.** Description of proposed trainee research and progress
- **iii.** Curriculum vitae of each trainee
- **iv.** List of relevant publications

~~**iv.**For trainees who have completed the program, a list of their current position, affiliation, and contact information.~~

**3. Appointment**

**a. Trainee Appointment Form**

A Trainee Appointment Form ~~(Rev. 6/2006)~~ must be completed for each trainee and submitted ~~to CIRM~~ 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~~Stipend support, and anticipated program of training ~~(e.g., proposed research project)~~. The mentor (if required), trainee, and PD~~program director~~ must sign the form and in so doing all parties agree to comply with the proposed training program, period of support, ~~stipend~~Stipend level, and the terms and conditions specified in this G~~g~~rants A~~a~~dministration P~~p~~olicy ~~statement~~. To amend or update any individual trainee information, Grantees must complete and submit a revised Trainee Appointment form to CIRM. The completed and signed form is the official document for establishing the ~~stipend~~Stipend, which should be reflected in ~~the~~ annual financial reports.

**b. Trainee Termination Form**

~~.~~A Trainee Termination Form must completed for each trainee and submitted to CIRM at the time of termination of the trainee appointment due to expiration of the appointment period or early termination prior to he 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~~may~~ also be required to report to CIRM publications, inventions, patent applications, licensing and invention utilization activities that result from CIRM-~~-~~funded Activities~~ing~~. Specific reporting requirements ~~related to these areas~~ may be found in regulations adopted by the ICOC governing intellectual property, Title 17 California Code of Regulations, section 100300 et seq., and section 100400 et seq ~~for non-profit organizations~~.

**5. Overdue Reports**

Failure to timely submit~~provide~~ financial, progress, or other reports ~~on time~~ may~~will~~ result in action~~CIRM's~~ reducing, delaying or suspending payment~~a CIRM award~~ until required materials are received. Further, if a report is delinquent for more than 690 days ~~beyond its established due date~~, 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 live vertebrate animals, 2) use of Covered Stem Cell 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. ~~Upon appointment of a trainee, the program director must submit to CIRM documentation (where appropriate) pertaining to the trainee's research project that:~~

~~a. verifies IACUC review and approval of the project's proposed use of live vertebrate animals; or~~
~~b. certifies SCRO, ESCRO committee (or equivalent) notification or review and approval of the project's proposed use of "covered stem cell line~~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 subject~~Human Subjects~~.~~