# CIRM Award Management Policy

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Adopted September 2016
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**Preface**¶
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This grants administration policy serves as the terms and conditions for Discovery, Translation, and Education Projects funded by the



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## Applicability

Except where provided for otherwise in a CIRM Program Announcement, Request for Applications, or Notice of Award, the terms and conditions set forth in this Policy shall govern projects funded by CIRM. In addition, this Policy provides guidance to Applicants and Awardees regarding their responsibilities as CIRM Awardees. Principal Investigators, Program Directors, and Authorized Organizational Officials with Award management responsibilities are urged to read this document carefully and to refer to relevant sections for answers to questions that arise concerning the administration of CIRM Awards. Applicants and Awardees may be required to document compliance with any and all provisions set forth in this policy. CIRM, or any other appropriate state governmental agency, may audit the Awardee for compliance with the terms governing the CIRM Award. The Awardee will maintain and provide access to all records that establish compliance with the terms governing a CIRM Award. Failure to comply with any term set forth in this Policy, or any other term applicable to a CIRM Award, will subject the Awardee and Key Personnel under an Award to any and all available remedies, including those identified in Chapter V, Section R, *Failure of Compliance and Award Termination.*

By Accepting CIRM funding, the Awardee agree to comply with the provisions set forth in this Policy.

This Policy may be amended or revised periodically. Any new or amended regulations adopted by the Independent Citizens' Oversight Committee, the governing board of CIRM, will be applied to currently active Awards on the start date of the next Budget or Operational Milestone Period, except as provided in the applicable CIRM Intellectual Property Regulations. CIRM will notify Principal Investigators, Program Directors, and organizational officials with active CIRM Awards of amendments to or revisions of this Policy as they are released. Amendments or revisions will be posted on the CIRM website (http://www.cirm.ca.gov).

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



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# I. GENERAL INFORMATION

## A. Abbreviations

AAWG – Treatment and Cures Accessibility and Affordability Working Group

ARS – Application Review Subcommittee

AMP – Award Management Policy

CFR – Code of Federal Regulations

CIRM – California Institute for Regenerative Medicine

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

DSMP – Data Sharing and Management Plan

DUL – Data Use Limitation

FDA – U.S. Food and Drug Administration

FWA – Federal-Wide Assurance

FWG – Facilities Working Group

GWG – Grants Working Group

IACUC – Institutional Animal Care and Use Committee

ICOC – Independent Citizens' Oversight Committee

IDE – Investigational Device Exception

IND – Investigational New Drug

IRB – Institutional Review Board

NCE – No-Cost Extension

NOA – Notice of Award

NIH – U.S. National Institutes of Health

OHRP – Office for Human Research Protections, DHHS

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The California Institute for Regenerative Medicine (CIRM) is a state agency that was established with the passage of Proposition 71, the California Stem Cell Research and Cures Act, a state ballot initiative approved by 59 percent of California voters on November 2, 2004. Proposition 71 authorizes CIRM to disburse up to $3 billion in state bond funds over a period of 10 years or more in the form of grants, loans and contracts for the purpose of conducting stem cell research and constructing research facilities in the State of California.¶
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CIRM funding supports stem cell research and other vital research opportunities for the development of life-saving regenerative medical treatments and therapies. All research proposals will be peer-reviewed so that the most promising scientific proposals are funded.¶
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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.¶
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CIRM is governed by the Independent Citizens' Oversight Committee (ICOC), a 29- member board composed of executive officers from California universities and research institutions, representatives of patient advocacy groups, and experts in the development of medical therapies from the life sciences community. ICOC members are public officials appointed because of their experience in California's leading public universities, non-profit academic and research institutions, patient advocacy groups, and the biotechnology industry.¶
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PA – Program Announcement

PAR – Prior Approval Request

PHS – Public Health Service, DHHS

PI – Principal Investigator

RFA – Request for Applications

RFP – Request for Proposals

SCRO – Stem Cell Research Oversight Committee

## B. Defined Terms

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| Applicant | An organization that requests CIRM funding by submitting an Application in response to a PA/RFA and is responsible for administering the Award if approved. An Applicant must be a legal entity that is accountable for both the performance of the approved project or activity and the appropriate expenditure of funds. |
| Application | A request for CIRM funding to conduct research; provide services; or construct, lease, or acquire Equipment. An Application shall contain all information upon which approval for funding is based. |
| Application Review Subcommittee (ARS) | A subcommittee of the ICOC that reviews application recommendations from the GWG and FWG and makes funding decisions. |
| Approved Budget | The financial expenditure plan for the CIRM-Funded Project or Activity, including revisions approved by CIRM and permissible revisions made by the PI or Awardee. |
| Authorized Organizational Official (AOO) | The individual, named by the Applicant, who is authorized to act for the Applicant and to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to Applications and Awards. |
| Award | CIRM funding in the form of a Grant, Loan, or contract that is based on an approved Application and budget. |

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SPO – Scientific Program Officer¶
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SRO – Scientific Review Officer¶
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| Award Close-Out | The final stage in the life cycle of an Award. During this phase, CIRM ensures that all applicable administrative actions and required work have been completed by the PI and Awardee. CIRM also reconciles and makes any final fiscal adjustments to the Award. |
| Awardee | An organization that is the Recipient of an Award and that is legally responsible and accountable for the use of the funds provided and for the performance of the CIRM-Funded Project or Activity. The Awardee is the entire legal entity even if a particular component is designated in the NOA. Campuses of the University of California shall be considered as separate and individual Awardees. |
| Budget Period | The intervals of time (usually 12 months) into which a Project Period is divided for budgetary, funding, and reporting purposes. For Awards with Operational Milestones, the Budget Period represents the time between achievement of each Operational Milestone. |
| California Organization | A "California Organization" is a For-Profit or Non-Profit Organization or is a California-domiciled wholly owned subsidiary of a non-California organization (defined as any entity that does not qualify as a California Organization) that meets all of the following criteria:<br><br>a) Employment and Payroll:<br>(i) Employs at least one W-2 employee; and<br>(ii) More than 50% of its W-2 employees, whether part-time or full-time, who are paid in any manner (e.g., wage, salary, commission, equity), must be domiciled full-time in California and be required to file California state income taxes due to their employment with the organization.<br>b) Management of Award Activities: The Principal Investigator (PI) must be physically located in California while overseeing all project activities.<br>c) Intellectual Property Rights: In the case of a California-domiciled wholly owned subsidiary of a non-California organization, the subsidiary must retain exclusive rights to any intellectual property arising out of the CIRM-Funded Project as well as any pre-existing IP rights held by the parent organization. |
| CIRM-Funded Project or Activity | Those activities specified or described in an Application that are approved by the ICOC for funding and for which CIRM has issued an NOA, regardless of whether CIRM funding constitutes all or only a portion of the financial support necessary to carry them out. |

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| Co-Funding | A portion of the Allowable Project Costs approved in the CIRM-Funded Project. Co-Funding may come from any non-CIRM funding source arranged by the Applicant but may not include "in-kind" or similar types of support. The minimum percentage of Co-Funding is required to be maintained at each Operational Milestone achievement, when applicable. |
| Contingency Expenditures | Expenditures incurred above the cumulative CIRM milestone disbursement and required Co-Funding prior to achievement of an Operational Milestone that are the sole responsibility of the Awardee.<br><br>Cash contributions from a non-CIRM funding source not previously anticipated or budgeted. Contingency Expenditures may be needed to sustain a project in the event a project does not achieve an Operational Milestone and CIRM reduces or suspends payments. |
| Clinical Research | Patient-oriented research; that is, research conducted with Human Subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which an investigator (or colleague) directly interacts with Human Subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Included in this definition are: (1)(a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research. |
| Consultant | An individual who provides professional advice or services related to the proposed project in exchange for a fee. |
| Covered Stem Cell Line | A culture-derived, human pluripotent stem cell population that is capable of: (1) sustained propagation in culture; and (2) self-renewal to produce daughter cells with equivalent developmental potential. This definition includes both embryonic and non-embryonic human stem cell lines regardless of the tissue of origin. "Pluripotent" means capable of differentiation into mesoderm, ectoderm, and endoderm. |
| Critical Role | A subset of Key Personnel who have a minimum effort requirement as described in the specific PA/RFA, and whose absence could cause serious disruption to the project and its operations. This definition includes personnel who are vital to the project's success and who may be responsible for driving strategic objectives, ensuring operational continuity, and making impactful decisions. |
| Direct Research Funding Costs | The sum of project costs and facilities costs of a CIRM Award. "Project costs" are those costs that can be specifically identified with a particular CIRM-Funded Project or Activity. "Facilities costs" are the operating costs of an Awardee's facilities attributable to housing all elements of the CIRM- |

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| | Funded Project or Activity. |
| Data Safety Monitoring Plan | A Data Safety Monitoring Plan is a detailed plan that outlines how a study will be monitored to ensure the safety of participants and the validity of the data. |
| Data Sharing and Management Plan (DSMP) | A framework for data management that captures information (metadata) about the biological samples used for data generation, the data types generated, the methods and data analysis pipelines used during CIRM-funded studies, the Data Use Limitations (DULs) that apply to the data, and the databases where data has been deposited for access to other researchers. Adherence to CIRM's data sharing requirements for Awardees includes the development and execution of the CIRM DSMP. The purpose of the DSMP is to facilitate data sharing and reuse in alignment with FAIR (Findable, Accessible, Interoperable, and Reusable) data principles. |
| Equipment | Non-expendable, free-standing, tangible personal property with a normal life expectancy of one year or more and an acquisition cost which equals or exceeds the lesser of the capitalization level established by the Awardee for financial management purposes or $5,000. |
| Facility | Building, building lease, or capital equipment eligible for funding under Proposition 14. |
| Facilities Working Group (FWG) | The Facilities Working Group is responsible for reviewing and making recommendations on Applications related to infrastructure and capital projects. This includes facilities and equipment intended to support CIRM's mission. The FWG provides its recommendations directly to the ARS or full ICOC, depending on the nature of the proposal. |
| Financial Authorized Organizational Official (FAOO) | An individual, named by the Awardee, who is authorized by that organization to submit required Financial Reports to CIRM. |
| Financial Report | An Awardee's periodic report to CIRM detailing expenditures against CIRM funds as specified in the NOA (see Chapter V, Section P, Part 1, *Financial Report*). |
| For-Profit Organization | A sole-proprietorship, partnership, limited liability company, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders, limited partners, members, or other owners. Such organizations are also referred to as "commercial organizations." |

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| Grant | A funding mechanism pursuant to which CIRM provides money and/or property to an Awardee on terms set forth in an NOA, in order to assist the Awardee in carrying out an approved CIRM-Funded Project or Activity. |
| Grants Working Group (GWG) | The advisory body responsible for reviewing the scientific content of Applications for research funding and for making funding recommendations to the ARS of the ICOC. This body is referred to in Proposition 14 as the "Scientific and Medical Research Funding Working Group." |
| Human Embryonic Stem Cells | Human Embryonic Stem Cells are immature (i.e., undifferentiated) cells that are derived from a human early stage, preimplantation embryo. Human Embryonic Stem Cells can be cultured in vitro where they self- renew indefinitely and have the potential to develop into any cell type of the body (i.e., they are pluripotent). |
| Human Subject | A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of Human Subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as Human Subjects and to graphic, written, or recorded information derived from such individuals. |
| Indirect Costs | Administrative costs of an Awardee incurred for common or joint objectives, which cannot be readily and specifically identified with a particular project. |
| Key Personnel | (1) the Principal Investigator or Program Director; or<br>(2) any other person, including an independent Consultant or an employee of a Subcontractor or Partner, who is expected to contribute to the scientific development or execution of the project in a substantive, measurable way and who is expected to:<br>(a) receive or has been promised income, or anything else of value, of $10,000 or more per year for his or her contribution to the project or<br>(b) contribute one percent (1%) or more effort to the proposed project.<br><br>"Key Personnel" does not include a person who is expected to be involved in the proposed project but who does not satisfy conditions (1) or (2). |
| Loan | A funding mechanism pursuant to which CIRM loans money and/or property to an Awardee, in exchange for a promise to prepay CIRM pursuant to terms set forth in an NOA, in order to assist the Awardee in carrying out a CIRM-Funded Project or Activity. |
| Matching Funds | Cash or in-kind (non-cash) contributions, as approved by CIRM, provided by the Awardee or their contractor that are directly beneficial, specifically identifiable, and necessary for performance of the CIRM-Funded Project during the Project Period. |

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| Non-Profit Organization | 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) or California Revenue and Taxation Code section 23701d. |
| Notice of Award (NOA) | The document that notifies the Awardee that an Award has been made. The NOA contains or references all terms and conditions of the Award as well as the Awardee's and PI's agreement to those terms and conditions, and documents the commitment of CIRM funds. |
| Operation and Maintenance Expenses | The general operating costs of an Awardee's facilities include expenses normally incurred for such items as janitorial and utility services; repairs and ordinary or normal alterations of buildings, furniture and Equipment; care of grounds; maintenance and operation of buildings and other plant facilities; security; earthquake and disaster preparedness; environmental safety; hazardous waste disposal; property, liability and all other insurance relating to property; space and capital leasing; facility planning and management; and central receiving that are necessary for carrying out the CIRM-Funded Project or Activity. |
| Operational Milestone | An objective event that is indicative of project progress occurring as proposed in the Application. The successful achievement of an Operational Milestone may trigger the disbursement of additional funds under the Award as schedule in the NOA. The intervals between Operational Milestones are used to divide a Project Period for budgetary, funding, and reporting purposes. |
| Other Support | Includes all financial resources – whether federal, non-federal, commercial, or organizational – available in direct support of an investigator's research endeavors. This includes, but is not limited to, research Grants, cooperative agreements, contracts, or organizational awards. Other Support does not include training awards, prizes, or gifts. |
| Principal Investigator (PI) or Program Director (PD) | An individual designated by the Awardee to direct the CIRM-Funded Project or Activity. They are responsible and accountable to the Awardee and CIRM for the proper conduct of the Project or Activity. |
| Prior Approval | Prior written approval from CIRM that is required for specified post-award changes in the Approved Budget or project. Such approval must be obtained before undertaking or spending CIRM funds for the proposed activity. |
| Program Announcement (PA) | An official solicitation issued by CIRM to inform prospective Applicants about a funding opportunity that is offered recurrently with application deadlines occurring once or multiple times per year. Each PA will describe the objectives, project scope, award amount, submission timelines, review process, and other requirements that apply. |

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| Progress Report | An Awardee's periodic report to CIRM detailing scientific activities and findings in the research project identified in the NOA (see Chapter V, Section P, Part 2, *Progress Report*). |
| Project Manager | A professional who organizes and executes a CIRM Project under the direction of the Principal Investigator or lead Program Manager. Project Managers are expected to shepherd the project through to its completion by developing and executing project plans, communicating with cross-functional stakeholders, and mitigating project risks to achieve project goals within the defined budgets and timelines. They operate within the parameters of a given Award's requirements, as specified in the relevant Program Announcement, Request for Application, and NOA. All Project Managers proposed by Awardees will be subject to approval by CIRM on an Award-specific basis. |
| Project Milestone | An objective event established by CIRM in which the failure to meet the event grants CIRM the right, at its sole discretion, to suspend payment and/or terminate the project. |
| Project Period | The total amount of time as stated in the NOA for which CIRM intends to fund a project or activity and authorizes a PI to conduct the work in the approved Application. For reporting purposes, the Project Period includes all Budget Periods and/or Operational Milestones. |
| Recipient | The Awardee, PI/PD, trainee, Subcontractor, Consultant or any other person or entity that receives CIRM funding pursuant to an Award. |
| Request for Application (RFA) | An official solicitation issued by CIRM to inform prospective Applicants about a funding opportunity that is available temporarily and offered only once or infrequently. Each RFA will describe the objectives, project scope, Award amount, submission timelines, review process, and other requirements that apply. |
| Research Misconduct | Fabrication, falsification or plagiarism in proposing, performing or reviewing research, or in reporting research results and does not include honest error or differences of opinion. |
| Research Patient Care Costs | These costs include, but are not limited to, routine and ancillary services provided by hospitals to individuals participating in research programs. The costs of these services normally are assigned to specific research projects through the development and application of research patient care rates or amounts. Research Patient Care Costs do not include:<br>(1) the otherwise allowable items of personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of individuals, including inpatients, outpatients, subjects, volunteers, and donors,<br>(2) costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned |

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| | laboratory) or laboratory tests performed at a medical school/university not associated with a hospital routine or ancillary service,<br>(3) recruitment or retention fees, or<br>(4) the data management or statistical analysis of Clinical Research results. |
| Serious Adverse Event | A Serious Adverse Event (SAE) refers to any expected or unexpected adverse event, related or unrelated to the therapy being studied, occurring at any agent dose, any phase of product, or procedure testing, that results in any of the following outcomes: death, a life-threatening adverse event, requires inpatient hospitalization (not required as part of the treatment) or prolongation of existing hospitalization, a persistent or significant disability or incapacity, or cancer, or a congenital anomaly or birth defect.<br><br>Important medical events that may not result in the listed outcomes may be considered as serious when, based upon appropriate medical judgment, they represent significant hazards or potentially serious harm to the research subject or others and may require medical intervention to prevent one of the outcomes listed in this definition. |
| Subcontract/Subaward | A contract between the Awardee and a third party to perform a portion of research proposed in the Application. |
| Suspension Event | A pre-defined condition that triggers a hold of CIRM funding until the Suspension Event has been resolved, if resolvable. |
| Treatments and Cures Accessibility and Affordability Working Group (AAWG) | The Treatments and Cures Accessibility and Affordability Working Group (AAWG), also established by Proposition 14, provides strategic input on access and reimbursement models to support the accessibility and affordability of CIRM-funded treatments. Recommendations from the AAWG may inform program design and, where applicable, criteria used in the review and evaluation of Applications, particularly in late-stage clinical programs. |
| Tuition and Fees | Costs charged by the Awardee for the enrollment and instruction of a student. It does not include costs of health insurance for a trainee, which is an allowable cost addressed separately. |
| Unobligated Funds | The amount of funds authorized under the NOA that has not expended or obligated. |

## C. Roles and Responsibilities

### 1. Awardee Organizational Staff

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

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

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

A designated AOO must have the legal authority to commit the Awardee to indemnify CIRM as provided in Chapter IV, Section C, Part 1, *Limitation of CIRM Liability*. An Awardee's designation of an AOO confers apparent authority to commit the Awardee to such indemnification of CIRM.

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

The PI/PD is the individual, designated by the Awardee, responsible for the scientific or technical aspects of the CIRM-Funded Project or Activity and for its management. The PI/PD and the Awardee are both responsible for ensuring compliance with the financial and administrative aspects of the Award. The PI/PD must work closely with other Awardee officials to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge CIRM support of research findings in publications, announcements, news programs, and other media; and ensure compliance with CIRM, federal, state, and organizational requirements.

**c. CIRM Experts**

CIRM Experts, or similar informal bodies, are expert advisory panels created and appointed by CIRM's President to support CIRM staff in overseeing funded projects. These Experts serve as strategic advisors to CIRM staff and may be engaged on an ad-hoc basis to help guide project direction and ensure alignment with program goals. While they may attend select meetings with project teams, their primary role is to advise CIRM. Awardees are expected to identify and fund their own scientific and development advisors through their Award. Project teams will be required to submit any requested documents to CIRM in advance of meetings where CIRM Experts are present.

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## II. APPLICATION AND REVIEW PROCESS

### A. Eligibility

#### 1. PI and PD Eligibility

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

#### 2. Organizational Eligibility

An Applicant must be a legal entity that is accountable for both the performance of the approved project or activity and the appropriate expenditure of funds. In general, Non-Profit and For-Profit Organizations located and conducting research in California are eligible to apply for and to receive CIRM research funding. Under certain programs, CIRM may limit eligibility to meet the specific goals of a PA/RFA. The determination of eligibility includes verification of the Applicant's ability to carry out the proposed project and responsibly manage and account for State funds in their accounting systems, and verification of corporate status. Should the ICOC approve the Application for funding and should CIRM issue an Award, the Awardee shall maintain an accounting system and supporting fiscal records to ensure that CIRM funds awarded are used solely for the purpose outlined in the approved Application and for allowable costs and activities.

CIRM allows California Organizations and, in some cases, non-California organizations (For-Profit and Non-Profit) to apply to CIRM. The allowable project costs vary between the different types of organizations and will be stated in the PA/RFA.

#### 3. Other Requirements

Because eligibility may vary, Applicants should carefully review the PA/RFA for specific eligibility requirements. An Applicant may be required to provide proof of organizational, PI, PD, or any other eligibility requirements.

### B. Application Submission

CIRM funding opportunities will be announced via a PA/RFA on the CIRM website (http://www.cirm.ca.gov). Information regarding Application forms and instructions for completion and submission of Application materials will be available as part of the funding opportunity announcement. CIRM may require submission of a Letter of Intent (LOI) and/or other presubmission form prior to or as a condition of submission of a full Application. The Application will

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provide an opportunity to declare and exclude up to three individuals and/or For-Profit Organizations the Applicant believes could not provide an impartial review of the proposal.

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

In signing the Application, the AOO warrants to CIRM that the information contained in the Application is true and complete and that all eligibility requirements have been satisfied. In signing the Application, the AOO agrees that should an Award be issued, the Applicant/Awardee will abide by the terms and conditions of the Award, all applicable CIRM regulations, all applicable public policy requirements, and will perform the activities included in the submitted Application as approved by the ICOC.

### D. Application Review

In accordance with Proposition 14, the Scientific and Medical Research Funding Working Group (GWG), the Scientific and Medical Research Facilities Working Group (FWG), and the Access and Affordability Working Group (AAWG) make funding recommendations to the ICOC for their respective areas of authority. The membership, authority, functions, and general procedures of these Working Groups are described in the respective bylaws adopted for each Working Group. The Working Groups conduct reviews following procedures adopted by the ICOC, including scoring methodologies defined in the group's bylaws and the relevant PAs or RFAs.

### E. Criteria for Review of Applications

Consistent with Proposition 14, the 15 scientist members of the GWG shall score Applications for scientific merit, while the FWG evaluates infrastructure-related Applications. Both groups base their reviews on the criteria specified in the relevant PA/RFA.

### F. Appeals of Application Review

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

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

To lodge an appeal, the Applicant must submit an appeal request in writing to

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The GWG conducts its review of Applications in accordance with

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CIRM within 10 days of CIRM's making the review report available to the Applicant. The CIRM team will then assess whether the Applicant has established facts constituting a conflict of interest and whether the conflict of interest had a negative impact on the review process and resulted in a flawed review and present a recommendation to the President of CIRM. If the President concludes that the Applicant has established facts constituting a conflict of interest and that the conflict of interest had a negative impact on the review process and resulted in a flawed review, the Application will be submitted to the Working Group for a new review.

**G. Approval for Funding**

The Working Groups are responsible for making recommendations to the ICOC on funding of Applications based on scientific merit. The ARS of the ICOC makes all final funding decisions for funding recommendations from the GWG and FWG. The ICOC makes all final funding decisions for funding recommendations from the AAWG.

**H. Policy of 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 pursuant to the Act.

**I. Public Access to Public Records**

Proposition 14 (Health and Safety Code section 125290.30(g)) provides that the California Public Records Act shall apply to all records of CIRM.

Public Records:

(1) The California Public Records Act, Article 1 (commencing with Section 6250) of Chapter 3.5 of Division 7 of Title 1 of the Government Code, shall apply to all records of the institute, except as otherwise provided in this section.

(2) Nothing in this section shall be construed to require disclosure of any records that are any of the following:

(b) Personnel, medical, or similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy.

(c) Records containing or reflecting confidential intellectual property or

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

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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.

(d) Prepublication scientific working papers or research data, including but not limited to applications and progress reports [JH1]

[JH1] Public Records Act Exemption: Clarifies that Public Records Act exemption includes applications and progress reports. Working Group Records as described in Health and Safety Codes section 125290.50, subdivision (f).

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Although Proposition 71 also provides that the California Public Records Act shall not apply to CIRM working groups, including the GWG (Health and Safety Code section 125290.50(f)), the ICOC has decided that the public shall also have access to the records of the working groups except for, among other things: (i) Applications for research, training, and facilities grants, loans, and contracts; (ii) evaluations of such Applications; and (iii) exceptions provided for in the California Public Records Act itself and Health and Safety Code section 125290.30. Subsection (e) of section 125290.30 exempts from public access records containing or reflecting confidential intellectual property and work product, such as that found in invention disclosures to CIRM.¶
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For further information, please see the California Public Records Act and Proposition¶
71. For details on how CIRM responds to Public Records Act requests, see the CIRM¶
guidelines available at
(http://www.cirm.ca.gov/general/pdf/guidelines.pdf).¶

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## III. PRE-AWARD

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

After the approval of funding by the ARS, CIRM will perform an administrative review of all approved Applications to ensure that they meet all applicable CIRM funding requirements. CIRM reviews the Application budget to ensure that all proposed costs are allowable, reasonable, and appropriate for the work being performed and as specified in this AMP and the pertinent PA/RFA. During the administrative review, CIRM reserves the right to revise individual budget items as appropriate.

Issues that arise during administrative review must be resolved to CIRM's satisfaction before an NOA will be issued. CIRM may issue an NOA contingent upon the acceptance (by the PI and AOO) of conditions and/or restriction on the use of funds until the Applicant submits the required documentation. The PA/RFA will specify when an approved Awardee must initiate work on the funded project.

The PFAR process includes a review of key compliance requirements and budget (including Co-Funding and Contingency), and the establishment of Operational or Project Milestones to measure progress and goal achievement. The PFAR also includes the establishment of Project Milestones and success criteria that will be used to assess Award progress. In setting these Milestones, CIRM staff retains full discretion to define, modify, and finalize Milestones and success criteria. CIRM may work directly with the PI, AOO, and external Consultants as needed to ensure that project objectives are clearly articulated, and operational requirements are met.

### B. Just-in-Time Policy

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

#### 1. Certification

The Awardee will be required to certify compliance with all the terms and conditions set forth in the relevant PA/RFA. CIRM may, in its sole and absolute discretion, request supporting documentation for verification.

#### 2. Other Support

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As part of the Just-in-Time procedures, the PI/PD and Awardee shall provide information on all other current and pending support. Before an NOA is issued, CIRM will review this information to ensure the following:

(1) PIs, PDs, and other Key Personnel are not committed beyond a total effort of 100 percent for all active and other approved but not yet funded projects, whether or not salary support is requested in the Application.

(2) That the PI/PD are committed the required minimum effort to the project as required by the appropriate PA/RFA.

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

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### 3. Good Standing

Applicants (and any other entities identified by CIRM) will be required to make certain disclosures regarding the "good standing" of the Applicant (and any other entities identified by CIRM). Based on these disclosures, if any, CIRM will determine whether or not to disqualify an Application.

The Awardee shall notify CIRM in writing no later than five business days of any material changes to the disclosures required by CIRM. For-Profit Applicants will also undergo a financial stability assessment to assess the risk of insolvency due to, for example, bankruptcy or risk of litigation.

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## IV. AWARD ACCEPTANCE AND TERMS

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### A. Notice of Award (NOA)

Once CIRM funding requirements are fully met, an NOA will be sent to the AOO and the PI designated in the Application. The NOA specifies the Project Period as well as the monetary allocations for Direct Costs, Facilities Costs, and Indirect Costs. The NOA also incorporates this AMP and all other applicable CIRM regulations by reference and specifies any special terms and conditions of the Award. During the active Award period, the NOA may be amended in response to a PAR, delay or failure to meet milestones, or other circumstances warranting an amendment of the NOA.

### B. Award Acceptance

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An Award is accepted and effective when an NOA is signed by the PI and AOO, and the fully executed document is received by CIRM. In accepting an Award, the PI/PD and Awardee assure CIRM that any funds expended under the Award will be used for the purposes set forth in the approved Application. Further, the PI/PD and Awardee agree to comply with terms and conditions of all applicable NOA and CIRM regulations, including this AMP. The NOA must be signed and received by CIRM within 30 days (or more, if extended in writing by CIRM) of issuance. Payment will not be issued until the NOA is accepted by CIRM.

Urgency is one of the driving values of CIRM's mission. Therefore, a prospective CIRM Awardee is required to certify that they can initiate work on the funded project within the timeline specified in the PA/RFA. This provision can be waived in writing by the President.

### C. Terms and Conditions

#### 1. Limitation of CIRM Liability

Awardee acknowledges and agrees that CIRM shall have no responsibility or liability whatsoever for the design, conduct, outcomes, or conclusions of any research or related activities undertaken by Awardee and funded by CIRM. Awardee further acknowledges and agrees that CIRM makes no representations or warranties, express or implied, as to the accuracy, validity, efficacy, safety, or commercial potential of any data, results, products, services, or processes developed or derived, in whole or in part, from research activities funded by CIRM.

Awardee shall be solely and exclusively responsible for all such activities and outcomes, including ensuring compliance with all applicable federal, state, and local laws, regulations, institutional requirements, and recognized ethical standards.

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To the fullest extent permitted by law, Awardee agrees to indemnify, defend, and hold harmless CIRM and its officers, employees, agents, and representatives from and against any and all claims, demands, damages, losses, liabilities, costs, and expenses (including reasonable attorneys' fees and costs of investigation) arising out of or relating to: (a) Awardee's research activities under this Agreement; (b) the use or application of any data, results, materials, or inventions resulting therefrom; or (c) any breach by Awardee of its obligations under this Agreement.

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

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

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

**2. Public Policy Requirements**

All CIRM Awardees must comply with the following provision and, upon request from CIRM, provide evidence of compliance with such provision. Initial funding or continued funding of any CIRM-Funded Project or Activity is contingent upon compliance with these requirements. Documentation that certifies or verifies compliance generally shall be required to be submitted before CIRM will issue an NOA. In cases where research requiring public policy assurances will be conducted at a later phase of the funded research, CIRM may issue an NOA imposing a condition or restriction on the use of funds until documentation of required assurances is submitted.

The Awardee shall retain records and supporting documentation that demonstrate compliance with public policy requirements for a minimum of

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five years from the date of submission of the final expenditure report for the applicable Award. If related audit findings have not been resolved, documentation must be maintained until such findings are resolved. Records and supporting documentation may be audited by CIRM or other appropriate state agencies, including the Office of the Attorney General of California.

**a. Research Misconduct**

Awardees and Recipients must conduct all research in accordance with the highest medical and ethical standards for scientific research and all applicable laws. The Awardee bears the ultimate responsibility for preventing, detecting and imposing sanctions for Research Misconduct. Awardees must adopt, maintain and ensure compliance with written policies and procedures for inquiry, investigation, and adjudication of allegations of Research Misconduct. An acceptable standard for such policies and procedures, for example, is found in the *Public Health Service Policies on Research Misconduct* (42 CFR Part 93) (Sept. 17, 2024).

In the event of an investigation of Research Misconduct, Awardees must notify CIRM in writing of any finding of Research Misconduct against a Recipient of CIRM funding and of any related proposed corrective actions.

The administrative actions imposed by CIRM for Research Misconduct may include, but are not limited to, the following: correction of the scientific literature; special plan of supervision to ensure integrity of the scientific research; certification of the accuracy of the scientific data; certification of the accuracy of sources and contributions for scientific ideas and writings; disqualification of the Awardee or Recipient from eligibility for CIRM funds; termination of the Award, and/or return of CIRM funds. The duration of these actions will depend on the nature and seriousness of the misconduct. Additional actions that CIRM may take are described in Chapter V, Section R, *Failure of Compliance and Award Termination.*

**b. Conflict of Interest**

Awardees must establish safeguards to prevent employees, Consultants, contractors, collaborators, and members of governing bodies who may be involved in the CIRM-Funded Project or Activities from participating in or in any way attempting to use their position to influence those activities in which they know or have reason to know they have a financial interest.

The Awardee must promptly notify CIRM in writing if and when an Awardee determines that a PI/PD or another Recipient of CIRM funding has violated any laws, regulations, or policies relating to a financial conflict of interest relating to or arising from a CIRM-

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Awardees must enforce within their institutions all such applicable safeguards.

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Funded Project.

If the Awardee uses contractors or collaborators to conduct CIRM-funded research, the Awardee must take reasonable steps to ensure that such contractors or collaborators comply with the Awardee's safeguards. An acceptable standard for such a policy, for example, may be found in 42 CFR Part 50, Subpart F (*Responsibility of Applicants for Promoting Objectivity in Research*) (effective August 25, 2011).

**c. Administrative Actions**

The Awardee shall notify CIRM in writing no later than five business days of receiving 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, the Awardee itself, any other institution, or any law enforcement agency concerning a charge of Research Misconduct made against an Awardee relating to or arising from the Awardee's research activities.

**d. Use of Human Stem Cell Lines, Oocytes, or Embryos**

Awardees shall abide by the CIRM Medical and Ethical Standards (commencing with Title 17, California Code of Regulations, section 100010 et Seq.) developed by the CIRM Scientific and Medical Accountability Standards Working Group (Standards Working Group) and adopted by the ICOC for the use of "Covered Stem Cell Lines" or use of human oocytes or embryos. This requirement includes use and derivation of Human Embryonic Stem Cells. Consequences of failure to comply with CIRM regulations governing medical and ethical standards are described in Chapter V, Section R, *Failure of Compliance and Award Termination*. All CIRM-funded research involving "Covered Stem Cell Lines" must comply with CIRM regulations relating to SCRO committee review or notification as described in Title 17, California Code of Regulations, section 100070. CIRM will not issue an NOA or continue payment on active Awards without current certification of compliance with section 100070 as required or without imposing limiting conditions. In addition to the certification of compliance, CIRM may request documentation of the approval or notification required by section 100070.

The documentation must include the name of the organization hosting the SCRO, the name of the committee, the name of the PI, the name of the Awardee, the CIRM Application number, the specific Covered Stem Cell Lines approved, the project title, and the period for which approval has been granted or expiration date of the approval. (see

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Chapter III, Section B, *Just-in-Time Policy*).

**e. Use of Human Fetal Tissue**

When using human fetal tissue in research, CIRM Awardees shall abide by Title 17, California Code of Regulations, section 100085. Unless otherwise required by CIRM, the certifying statement required pursuant to Section 100085 (c) shall be provided during the Just-in-Time process for approved Applications prior to issuance of the NOA (see Chapter III, Section B, *Just-in-Time Policy*).

**f. Research Involving Human Subjects**

An organization is engaged in research involving Human Subjects when its employees or agents (1) intervene or interact with living individuals to obtain data for research purposes, or (2) obtain individually identifiable private information for research purposes.

Awardees must apply California Health and Safety Code 24170- 24179.5 to all CIRM-funded human biomedical or clinical subjects research. Compliance with this requirement may be demonstrated through written institutional policies or full accreditation through the Association for the Accreditation of Human Research Protection Programs. In addition, the Awardee and any collaborating organizations (within the United States) must be covered by a Federal-Wide Assurance (FWA) approved by the OHRP, or an IND or IDE approved by the U.S. Food and Drug Administration (FDA).

The Awardee must appoint and maintain an Institutional Review Board (IRB) to provide oversight of research involving Human Subjects.

The Awardee bears ultimate responsibility for protecting Human Subjects involved in CIRM-funded research, including Human Subjects at all participating and collaborating sites. PIs and Awardees engaged in CIRM-funded research involving Human Subjects must certify that the research has been reviewed and approved by an IRB and will be subject to continuing review by the IRB. At CIRM's request, the prospective Awardee must provide the following documentation regarding itself and each collaborating site to CIRM:

(1) Documentation of IRB review and approval specifying the name of the PI, the name of the Awardee and any collaborating organization or site, the CIRM Application number, the project title, and inclusive dates for which IRB approval has been granted.

(2) Sample Human Subject (patient) information and informed consent documents.

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(3) Documentation of human research subject education of Key Personnel;

(4) For clinical trials, a Data Safety Monitoring Plan

(5) Institutional assurance that the research is conducted in accordance with relevant national, state, and local laws;

(6) A copy of the FDA-IND or IDE letter, where applicable, when a clinical investigation involves the use of any drugs or devices.

Prior to the issuance of an NOA and during annual Progress Reports (see Chapter V, Section P, Part 2, *Progress Report*), an Awardee shall certify to CIRM that any IRB approval required to conduct the CIRM-Funded Project or Activity is obtained or will be obtained before CIRM funding is spent on such activities. (see Chapter III, Section B, *Just-in-Time Policy*). CIRM will not authorize continued funding of active Awards without current certification for Human Subjects research.

For clinical trials, the Awardee shall report Serious Adverse Events to CIRM and agree to a communication plan outlined in the NOA.

Consequences of failure to comply with required Human Subjects research assurance are described in Chapter V, Section R, *Failure of Compliance and Award Termination*. The Awardee shall inform CIRM in writing of any investigation or administrative action by OHRP or by the Awardee concerning Recipients of CIRM funding and their use of Human Subjects in research no later than five business days from the commencement of such investigation or administrative action by OHRP.

CIRM Awardees shall comply with the California State Law including Health Research Fairness Act, California Health and Safety Code, sections 439.900-439.906.

**g. Animal Subjects**

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

The PI, Awardee and any collaborating sites conducting CIRM-funded research that involves the use of vertebrate animals shall comply with all applicable federal, state, and local laws. Sites where CIRM-funded animal research is conducted must be accredited or seeking accreditation by the Association for the Assessment and Accreditation of Laboratory

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Serious Adverse Event Reporting. In the case of an adverse event occurring during a CIRM-funded clinical trial or program that is both serious and unexpected, the PI must notify CIRM of such an event at the same time that the IRB and Awardee are notified. Prior to issuance of a NGA the Awardee shall agree to a Communication Plan that addresses the process and timelines for notifying CIRM in the event of a Serious Adverse Event or other crisis issue or occurrence that may impact the conduct of a trial. ¶
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Women and members of minority groups must be included in all CIRM- funded Clinical Research, unless a clear and compelling rationale and justification establishes to the satisfaction of CIRM that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. This policy applies to research subjects regardless of age in all CIRM-funded Clinical Research studies.¶
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Since a primary aim of research is to provide scientific evidence leading to a change in health policy or standard of care, it is imperative to determine whether the intervention or therapy being studied affects women or men or members of minority groups and their subpopulations differently. This requirement ensures that all CIRM-funded clinical research will be carried out in a manner sufficient to elicit information about individuals of both sexes/genders and diverse racial and ethnic groups and, particularly in clinical trials, to examine differential effects on such groups.¶
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***<object>***PIs must include in their annual Progress Report the cumulative subject accrual and progress in conducting analyses for sex/gender and race/ethnicity differences (see chapter V, section O, Reporting Requirements).¶
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Animal Care International (AAALAC).

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

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

IACUC approval must be certified in the annual Progress Report (see Chapter V, Section P, Part 2, *Progress Report*). CIRM will not authorize continued funding of active Awards without current certification of such approval.

**h. Biosafety**

Awardee represents, warrants, and covenants that, prior to commencing any work or performing any services under this Agreement, it shall obtain and thereafter maintain in full force and effect all licenses, permits, consents, certifications, approvals, and other authorizations required by applicable federal, state, and local laws, regulations, and ordinances (collectively, the "Approvals") for the proposed use, handling, storage and disposal of biohazardous materials, radioisotopes, and/or controlled substances.

Awardee shall remain in continuous compliance with all such Approvals and shall, upon CIRM's request, provide prompt written evidence of such compliance. Awardee shall also provide CIRM with written notice of any suspension, revocation, non-renewal, or other material change in the status of any Approval within five business days of becoming aware of such change.

Awardee must also ensure all research personnel will obtain appropriate training and authorization for the use of biohazardous materials, radioisotopes, and/or controlled substances prior to their

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commencing work on the proposed project or activity. A prospective Awardee shall provide documentation that verifies such organizational approvals upon request. Awardees are also responsible for meeting applicable federal, state, and local health and safety standards, and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in conducting CIRM-funded research.

### i. Sharing of Intellectual Property

PIs and Awardees shall comply with any obligations to share the results of CIRM-funded research, as required by regulations adopted by the ICOC. For further information, PIs and Awardees should consult Title 17, California Code of Regulations section 100650.

### j. Preference for California Suppliers

It is a goal of Proposition 14 that more than 50 percent of the goods and services used in CIRM-supported research is purchased from California Suppliers (Health and Safety Code section 125290.30, subpart (i); Title 17, California Code of Regulations section 100502). To achieve this goal, CIRM expects the Awardee to purchase the goods and services it uses in its CIRM-supported research from California Suppliers to the extent reasonably possible. The PI and Awardee must provide a clear and compelling explanation in the Progress Report for not purchasing more than 50 percent of its goods and services from California Suppliers. Please see Chapter V, Section P, Part 2, *Progress Report*.

### k. Meetings

CIRM has the right to attend any FDA meetings regarding CIRM-Funded Projects, including but not limited to INTERACT meetings, pre-IND meetings, end-of-phase meetings, type C meetings, and pre-BLA meetings. The Awardee shall notify CIRM within 48 hours after it has scheduled an FDA meeting and provide to CIRM any data package(s) or other information, including confidential and/or proprietary information, prior to submission to the FDA as well as any FDA Meeting minutes. CIRM reserves the right to share such information with CIRM's confidential advisers.

### l. Data Sharing and Management

CIRM requires Awardees to manage and preserve raw data, processed data, and metadata, and make applicable data and metadata available to the broader scientific community by deposit into data repositories and in accordance with FAIR data principles.





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**Deleted:** <#>certification from the Awardee that the Awardee has or will obtain appropriate IRB, SCRO and/or IACUC approval or notification for CIRM-funded Activity requiring such approvals before CIRM funding is spent on such activities.¶ ¶ ***<object>*** Other Support
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**Moved up [5]:** <#>¶ There is no scientific or budgetary overlap. Scientific overlap occurs when substantially the same research, or a specific research aim, proposed in the approved Application is funded over any part of the Project Period by another source. Budgetary overlap occurs when funds from more than one source are used to cover the same item or the same part of a budgetary item (e.g.,
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**Deleted:** <#>just-in-time procedures, the PI and Awardee shall provide¶ ... [5]
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CIRM requires that Awardees develop and execute a detailed Data Sharing and Management Plan (DSMP). The data repositories selected and other information about deposited data must be reported to CIRM during and after the Project Period. CIRM may publicly share information about CIRM-funded data, including what types of data were generated and where data are deposited.

### m. Co-Funding Requirement

Upon completion of an Operational Milestone, the Awardee will demonstrate to CIRM's reasonable but sole satisfaction that the Awardee has expended non-CIRM funds in an amount that is equal to the total Co-Funding requirement set forth in Appendix A for that Operational Milestone. Only funds expensed to cover Allowable Project Costs shall count towards the Awardee's Co-Funding requirement. Provision by the Awardee of "in-kind" or similar types of support shall not be counted toward the Co-Funding requirement. Only funds spent concurrently with CIRM funds (no sooner than ARS approval and no later than the final Operational Milestone) will qualify toward the Co-Funding requirement.

### n. Operational Milestone

CIRM will disburse funds based on achievement of specific Operational Milestones established by CIRM. CIRM establishes Operational Milestones for inclusion in the NOA based upon information provided in the Application. Upon issuance of the Award, funds budgeted to achieve the initial Operational Milestone will be disbursed. Upon the successful completion of the initial Operational Milestone and each successive Milestone, additional funds will be disbursed. A final Operational Milestone will be identified to define the Award end date for the project. If funds allocated to a specific Operational Milestone (including both CIRM funds and the required Applicant co-funds) are exhausted prior to achievement of that Milestone, the Awardee will be responsible for covering any remaining costs. CIRM expects that the Applicant's Contingency plan will identify the project timeline and budget risks and will provide details for covering such costs, including the source of funding. CIRM reserves the right to adjust the timeline for inclusion in the NOA to ensure that funds are appropriately dispersed across Operational Milestones.

If CIRM determines in its sole discretion that the Awardee has not satisfied an Operational Milestone as set forth in Appendix A to the NOA, CIRM may suspend disbursements until such time as the Awardee satisfies the Operational Milestone. CIRM may permanently cease disbursements if the Awardee does not satisfy the Operational Milestone within the grace period

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stated in the PA/RFA, or if CIRM determines in its sole and absolute discretion that the Awardee has failed to meet the Operational Milestone.

The Awardee shall have 30 days from the date of CIRM's notice of a Suspension Event to submit a remediation plan to cure the cause of the Suspension Event. The Awardee may continue to use CIRM funds for project-related allowable costs during this 30-day period until CIRM has determined whether the Suspension Event can be cured by the Awardee's proposed remediation plan. If CIRM determines in its sole and absolute discretion that the Suspension Event cannot be cured or will not be cured by the Awardee's proposed remediation plan, CIRM may terminate the Award.

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

**o. Use of the CIRM Logo by Third Parties**

CIRM-funded Awardees must acknowledge CIRM in any public communications, including press releases, publications, conference presentations, or other similar types of communications (collectively, "Communications") as noted in Articles III and IX of Section 100650 (Cal. Code Regs. tit. 17, § 100650). The Remedies in Chapter V, Section R, *Failure of Compliance and Award Termination* shall apply for failure to acknowledge CIRM in such Communications.

An Awardee carrying out a project that is being funded, either entirely or in part, by CIRM may use the CIRM logo in connection with that project because the funding has been approved by the governing board, the ICOC.

The CIRM logo may not be used by a company, institution, or researcher if the project is not funded by CIRM, even if that project is being conducted in a CIRM Alpha Stem Cell Clinic.

## D. Award Conversion

### 3. Loan Election, Repayment Rates, and Interest

After completing the research specified in the NOA and after the Award period end date, an Awardee who has received an Award pursuant to PDEV (includes TRAN1 and CLIN1) or CLIN2 and any preclinical and clinical equivalents may elect to treat its Award as a Loan on the terms specified below by sending CIRM written notice of its election. Unless CIRM and the Awardee agree to a different repayment period and terms, an Awardee that elects to treat its Award as a Loan shall repay CIRM at the rate specified in paragraph (2) within 10 business days of making the election.

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(a) The rate of repayment shall vary depending upon the type of Award, the stage of the research (preclinical, Phase I, II, or III), and the stage of development at which time the election is made. The table below sets forth the repayment rate based on these variables:

| | | | **Percent of Loan to be Repaid** |
|---|---|---|---|
| **Type of Award** | **Stage of Research** | **Election Point** | **Therapeutic Candidate** |
| PDEV | Preclinical | Prior to First-on-human clinical trial | 100% |
| PDEV | Preclinical | First-in-human clinical trial | 100% + 10% APR + SOFR |
| PDEV | Preclinical | Subsequent clinical trial | 100% + 15% APR + SOFR |
| PDEV | Preclinical | Registration | 100% + 20% APR + SOFR |
| CLIN | First-in-human clinical trial | Prior to subsequent clinical trial | 100% + 10% APR + SOFR |
| CLIN | First-in-human clinical trial | Subsequent clinical trial | 100% + 15% APR + SOFR |
| CLIN | First-in-human clinical trial | Registration | 100% + 25% APR + SOFR |
| CLIN | Subsequent clinical trial | Prior to Registration | 100% + 20% APR + SOFR |
| CLIN | Subsequent clinical trial | Registration | 100% + 30% APR + SOFR |

(b) For purposes of this Section:

(i) When an election is made during a first-in-human clinical trial or subsequent clinical trial, the term "election point" refers to a point in time near the commencement of the clinical trial, namely the first dosing of the first patient (or equivalent). Any election prior to such dosing shall result in placement in the "Prior to" category. For a CLIN Award funding a subsequent clinical trial, any election point prior to Registration as defined in (ii) below, will be

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categorized in the "Prior to Registration" category.

(ii) When an election is made at Registration, the term "election point" refers to, whichever is first applicable, a point in time (a) completion of a pre-BLA, pre-NDA meeting with the FDA (or equivalent), (b) the first dosing of a first patient (or equivalent) in a pivotal trial, or (c) submission of any part of an application for marketing authorization to the FDA (i.e., BLA, NDA) or foreign equivalent. The end of the election period is ten business days after the FDA notifies the Awardee that it has accepted its application for marketing authorization.

(c) If an Awardee is required to pay interest under this Section, interest shall accrue at the Secured Overnight Financing Rate (SOFR) as published by the Federal Reserve Bank of New York, plus three percent (3%). If SOFR is no longer published or available, the interest rate shall accrue at the most comparable alternative reference rate as determined by CIRM in its sole discretion, plus three percent (3%). Interest shall be compounded annually on the principal amount disbursed by CIRM from the date of each disbursement and shall include interest for any partial year on the same terms.

(i) An Award shall be considered to be a Loan only upon the Awardee's satisfaction of all of the terms specified in this Section, including any terms negotiated by the Parties pursuant to Paragraph (1).

(ii) An Awardee that elects to treat its Award as a Loan shall be subject to Articles I, II (except D(4), III, IV, V, VI, VII, IX, X, XI, and XII in CIRM regulation 100650 (Cal. Code Regs. tit. 17, § 100650).

(iii) If an Awardee does not make the election specified in Paragraph (1) within ten years of the date of the Award, the Award shall be considered a Grant.

(iv) CIRM reserves the right to modify this Section, but the modifications shall apply prospectively to Awards made after the modification takes effect and shall have no application to Awards made before the

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effective date of the modification.

**4. Eligible Programs**

This Section shall apply to all Awards issued under TRAN1, PDEV, CLIN1, CLIN2, and any preclinical and clinical equivalents awarded under the effective date of this Section.

**5. Survival of Rights; Waiver of Bankruptcy Discharge**

Notwithstanding any bankruptcy, insolvency, dissolution, or other proceeding involving the Awardee, CIRM's rights to repayment, enforcement, and any other remedies under this Policy shall survive and shall not be discharged, impaired, avoided, or otherwise affected by such proceedings. Awardee expressly waives any defense, discharge, or stay that might otherwise be available to it under Title 11 of the United States Code (Bankruptcy Code) or other applicable insolvency laws to the maximum extent permitted by law. Awardee further acknowledges and agrees that, as an agency of the State of California, CIRM retains all rights and protections afforded by sovereign immunity doctrines.



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## V. PAYMENT AND USE OF FUNDS

### A. Payment

The timing of the distribution of Award funds shall be contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the State Treasury, as determined by CIRM in its sole discretion. Awardees shall deposit CIRM funds into an interest-bearing account and track interested accrued on payments. Interest earned from the account shall be used only for eligible Award-related expenses or returned to CIRM.

For Awards subject to Operational Milestones, an initial disbursement will be made upon execution of the NOA to fund the work needed to reach the first OM. Payments for each subsequent OM are contingent on the receipt and acceptance by CIRM of the associated Operational Milestone Progress Report. The Awardee shall be responsible for all Costs in excess of those provided by CIRM ("Contingency Funds") in the NOA milestone disbursement schedule. In the final Operational Milestone period, CIRM-funded costs incurred can include milestone disbursement and the final hold-back payment.

For Awards not subject to Operational Milestones, an initial disbursement will be made upon execution of the NOA, and subsequent payments will be disbursed per the payment schedule in the NOA provided the Awardee submits all required reports on time and the Award remains in compliance with all CIRM regulations. All CIRM payments to an Awardee can be placed on hold for non-compliance. See Chapter V, Section R, *Failure of Compliance and Award Termination*.

### B. Unobligated Funds

Upon Award Close-Out, including termination by CIRM, the Awardee shall return all Unobligated Funds to CIRM no later than 30 days after the final report deadline.

### C. Misuse of Funds

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

Awardees shall report to CIRM all cases of real or apparent fraud, or abuse or apparent abuse of CIRM funding immediately upon knowledge thereof. Examples

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¶
For awards not subject to Operational Milestones, payments can be made on an annual or semi-annual basis based on the negotiated, annualized budget. The 1st payment will be made upon execution of the NGA for the 1st 6 or 12 month period and thereafter as long as reports are being submitted on time and the award remains in good standing.¶
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of fraud and abuse that must be reported include but are not limited to: embezzlement of CIRM funds; misuse or misappropriation of CIRM funds or property; and false statements regarding the use of CIRM funds, whether by organizations or individuals. This includes personal use of CIRM funds; using funds for non-approved purposes; theft of CIRM-funded property or property acquired or leased with CIRM funds; charging CIRM for services of "ghost" individuals; submitting false financial reports; and submitting false financial data in bids submitted to the Awardee (for eventual payment by CIRM).

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

## D. Pre-Award Costs

In the event an Awardee incurs costs between the ARS approval date and the Award start date without CIRM Prior Approval, it does so at its own risk. If specific expenditures or activities would otherwise require Prior Approval, the Awardee must obtain CIRM approval before incurring the cost. An Awardee's decision to incur pre-award costs in anticipation of an Award imposes no obligation on CIRM either to make the Award or to increase the amount of the Approved Budget if an Award is made for less than the amount anticipated and is inadequate to cover pre-award costs incurred. An Awardee's decision to incur pre-award costs is a decision to borrow against future support and that such borrowing must not impair the Awardee's ability to accomplish the project objectives or in any way adversely affect the conduct of the CIRM-Funded Project. The pre-award period may be adjusted with a later start date at CIRM's discretion and with approval by the President.

## E. Budgetary Overlap

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

## F. Allowable Project Costs

Allowable Project Costs are those costs that can be specifically identified with a CIRM-Funded Project or Activity. Unless otherwise specified by CIRM in the PA/RFA, Allowable Project Costs can include but are not limited to salary for

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An Awardee may accrue interest on the balance of CIRM funds paid, but such funds may only be used to pay for expenses incurred on the CIRM-funded project.¶
¶
**Costs and Activities**¶
During the Project Period, CIRM funds shall only be used for allowable project costs and activities. Specific allowable or unallowable costs may be described by CIRM. In accordance with Proposition 71, Direct Research Funding Costs include scientific and medical funding for an approved research project and the general operating costs of Facilities for conducting the approved project.¶

**Deleted:** An Awardee may, at its own risk and without Prior Approval, incur obligations and expenditures to cover costs up to a maximum of 90 days for Translation programs, and 120 days for Discovery programs, prior to the negotiated award start date, but not to proceed the date of the ICOC or Application Review Subcommittee's approval, if such costs are necessary to conduct the project and are allowable CIRM costs and activities.

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personnel (detailed below), fringe benefits, itemized supplies, Tuition and Fees, research animal costs, Consultants, itemized clinical study costs (including Research Patient Care Costs), travel-related expenses (detailed below), patient-qualified costs (detailed below), itemized project-related Equipment (as approved), publication costs, service contracts, Subcontracts, and specific, identifiable administrative costs where required to carry out the approved project.

**1. Salary for Personnel**

Base salaries for all personnel shall not exceed an annual rate that is posted on the CIRM public website. CIRM will adjust this limitation annually upon the effective date of this Policy, based on the posted UCOP Health Sciences Compensation Plan for general scale 4, step 9 or provide another rate scale specified in the relevant PA/RFA.

**2. Travel-Related Expenses**

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

The cost of food and meals served at a seminar, conference, workshop, or business meeting is not an allowable cost for CIRM Awards (see CIRM's Business Meeting Expenditure Policy). However, participants traveling together shall be eligible for reimbursement of shared meals under the following circumstances:

a. All participants must be traveling to an event on CIRM business (such as a CIRM-required auxiliary meeting). Travel between the participants' place of residence and their place of employment (for Training Awards, this includes their host institution) will not be eligible for reimbursement, including shared meals; and

b. Must adhere to CIRM's published per diem rates.

**3. Patient-Qualified Costs**

Allowable Costs for participation in CIRM-funded clinical trials include necessary and reasonable donor, patient, or caregiver costs directly incurred as a result of screening, donation, or participation in research activities. Allowable

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

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costs may include but are not limited to costs associated with travel, housing, childcare, and medical care.

**4. Allowable Costs for Non-California Awardees**

a. The per-subject share of the costs of Clinical and non-Clinical Research activities, whether conducted in California or outside of California, that are directly attributable to the treatment of California subjects enrolled in the proposed clinical trial

b. Costs of manufacturing conducted in California for the proposed clinical trial for subjects enrolled, provided such costs are deducted before calculating the per subject share of costs

c. Costs of manufacturing conducted in California for a subsequent clinical trial when the Applicant adequately justifies conducting such activities during the proposed clinical trial

## G. Unallowable Project Costs and Activities

Unallowable project costs and activities cannot be charged to CIRM funding nor accounted for as part of the Awardee's Co-Funding requirement, and include but are not limited to:

a. Visa expenses for foreign nationals
b. Malpractice insurance
c. Furniture
d. Telephone equipment
e. Personnel recruitment
f. Receptions
g. Gifts
h. Lobbying expenses
i. Equity compensation
j. Fines or penalties not related to costs incurred to comply with the terms of the Award
k. Cost of food or meals unrelated to allowable travel expenses
l. Alcohol
m. Construction or renovation of physical infrastructure
n. Payments to potential or enrolled research participants in excess of necessary and reasonable expenses incurred as a result of screening, donation, or participation in CIRM-funded research
o. All legal fees outside of the scope of reasonable patent prosecution for that jurisdiction

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Costs of activities performed or expenses incurred by a separate out-of-state organization that retains intellectual property or independent publication rights in any intellectual property (e.g., invention, technology, data) arising out of the CIRM-Funded Project are unallowable.

## H. Allowable Facilities Costs

In accordance with Proposition 14, Direct Research Funding Costs include scientific and medical funding for an approved research project and the general operating costs of Facilities for conducting the approved project. Facilities costs cover general operating costs of the Awardee's Facilities attributable to housing all elements of the CIRM-Funded Project or Activity. The ICOC will determine the allowable Facilities costs based on analysis of federal, state, and/or comparative funder overhead rates.

Awardees may request two categories of Facilities costs:

(a) Costs associated with Operation and Maintenance Expenses, and for library expenses; and

(b) One of the following:

(1) costs associated with depreciation or use allowances on buildings, capital improvements, and Equipment, and for interest on capital debt, as a proxy for a market lease rate of reimbursement (Health and Safety Code section 125292.10, subdivision (w)); or,

(2) the actual out-of-pocket lease cost incurred by an Awardee if the Awardee leases space to conduct approved research; this cost must be reported in the Annual Financial Report (see Chapter V, Section P, Part 1, *Financial Report*).

Total Facilities rates shall be applied to the total Allowable Project Costs exclusive of costs of Equipment, Tuition and Fees, Research Patient Care Costs, and the total cost of each service contract, Subcontract and Consultant agreement in excess of $25,000.

## I. Unallowable Facilities Costs for Major Facilities

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

CIRM will calculate on an annual basis the cumulative amount of the Facilities Part B reductions for all research Awards to an institution or members of a consortium or

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facilities collaboration. Once this cumulative reduction equals the amount funded under the CIRM Major Facilities Award (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 Awards to those institutions.

## J. Indirect Costs

The specific, allowable indirect cost percentage will be stipulated by CIRM in the PA/RFA.

Non-Profit Awardees are generally limited to a maximum of 20 percent of allowable Direct Research Funding Costs, exclusive of the costs of Equipment, Tuition and Fees, Research Patient Care Costs, and the total cost of each service contract, Subcontract and Consultant agreement in excess of $25,000.

For-Profit Awardees will not be provided Indirect Costs on CIRM-funded Awards.

## K. Post-Project Allowable Costs

For Operational Milestone-based Awards only, if the Awardee has remaining CIRM funds following the successful completion of the CIRM-Funded Project or Activity, those funds may be used to:

a. Reduce Co-Funding to an amount no lower than originally required by the Award, including Awardee Contingency Expenditures

b. Fund project(s) at the Awardee organization that further CIRM's mission, subject to this AMP and all other CIRM regulations

c. Return to CIRM within 30 days of the deadline for submission of the final Financial Report

The Awardee will be required to obtain CIRM's Prior Approval of its intentions for use of the funds and certification that those funds will be appropriately accounted for.

## L. Prior Approval Requirements

PIs/PDs and Awardees must perform project activities as described in the approved Application. A PI/PD and AOO must request and obtain Prior Approval for pre-award or post-award changes described below by submitting such requests to CIRM with appropriate justification for the proposed change. If approved by CIRM, an amendment to the NOA will be issued and must be executed by all parties before expending CIRM funds for the proposed activity. The following changes require CIRM Prior Approval:

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

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1. **Change in Scope**

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

a. Any change in the specific aims in the approved Application.

b. Any change that impacts activities described in the Milestones in the NOA

c. Any change in the use of animals or Human Subjects from that described in the approved Application and as approved by the IRB or IACUC.

d. A removal or addition of substantive activities described in the Application; any savings due to the elimination of activities will result in a reduction to the Award unless CIRM approves use of those funds for the additional activities.

e. Transfer of the performance of substantive funded activities to a third party not previously identified in the approved Application.

f. A change in disease indication or shift in the research emphasis from one disease area or technological approach to another.

If CIRM determines that a requested change in scope would materially affect the purpose for which the Award was made or the expected outcome, CIRM may deny the request and may terminate the Award.

2. **Change in Status or Percent Effort of Critical Role(s)**

Prior Approval is required for any Critical Role to decrease their percent effort on an approved project below the level required by the PA/RFA.

In addition, Awardees must notify CIRM immediately if any of the following changes in status of any Critical Role(s) occur:

a. The status of an individual filling a Critical Role at the Awardee organization changes (e.g., from full-time to part-time appointment, from a paid to an unpaid position, or from an employee to a non-employee position)

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b. Any individual filling a Critical Role withdraws from the project, takes a leave of absence, or alters their expected involvement in the project from that originally proposed in the Application for a continuous period exceeding 90 days, including requests for sabbaticals

c. Any individual filling a Critical Role is no longer eligible (under either the standards of the Awardee or the criteria in the PA/RFA) to serve that role

CIRM will notify the Awardee if it is determined that a change in status for any Critical Role(s) will adversely impact the CIRM-Funded Project as described in the approved Application. The Awardee may propose a substitute to fill the Critical Role, subject to CIRM's approval. If no appropriate substitute is proposed, CIRM may terminate the Award. The Awardee must return all unexpended funds to CIRM within 30 days of termination of the Award.

### 3. Post-Project Allowable Costs

Prior Approval is required to utilize unobligated CIRM funds at the conclusion of a successful project to fund additional project(s) at the Awardee organization that further CIRM's mission. A Prior Approval Request for Post-Project Allowable Costs shall include the following components:

a. A description of the new activities proposed using remaining CIRM funds and how the proposed project furthers CIRM's mission

b. The estimated CIRM funding available for the new activities, a description of why those funds were not needed in the original Award, and a budget and budget narrative describing the planned use of the funds by budget category

c. The duration of the new activities requested (# of months)

d. The PI/PD's effort for the proposed activities, PI/PD's Other Support document, and a list of other personnel proposed

### 4. Relinquishment of Award and Award Transfer

An Awardee may at any time relinquish an Award or Application approved for funding by the ICOC by submitting a statement that includes:

a. The date of relinquishment

b. Reasons for relinquishing the Award

c. An estimate of the unobligated balance of any funds paid to the Awardee

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d. An assurance that all unobligated balance of any funds will be returned to CIRM within 30 days of the date of relinquishment

With Prior Approval, an Award may be transferred to another eligible organization when a PI/PD transfers from an Awardee to that organization. CIRM approval will be contingent upon the Awardee relinquishing rights to the Award, among other considerations. In the case of a transfer, the relinquishing Awardee may be required to transfer CIRM-funded Equipment purchased with the Award.

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

a. A new Application with original signatures

b. A description of how the PI/PD will ensure the project will be able to accomplish its goals, potential length of delays in project progress due to the transition and mitigation plans to minimize project delays

c. A detailed budget(s) for the remaining Project Period (including the estimated unexpended balance from the relinquishing Awardee). The original Approved Budget prevails when an Award is transferred. CIRM does not have authority to increase the Award amount without approval by the ARS

d. Biographical sketches for new Key Personnel

e. Description of facilities and resources

f. Certification to public policy assurances (e.g., Human Subjects, animal, biohazard), where applicable

g. A term sheet or agreement between the Awardee and transferee Awardee for any CIRM Technology/Inventions or other pre-existing data or background intellectual property related to the Award. An agreement must be in place prior to receipt of any CIRM funding

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

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effective.

## M. No-Cost Extensions

When the PA/RFA allows, an Awardee may request a **one**-time, No-Cost Extension **of the** Project Period **end date.** The PA/RFA will specify the length of the extension that is allowed. A request and justification for an NCE must be submitted to CIRM at least 30 days prior to the original Project Period end date. Operational Milestone-based Awards do not require Prior Approval for an NCE.

## N. Equipment Management

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

1. Records that adequately identify items of Equipment purchased with CIRM funds, subject to audit by CIRM
2. Control procedures and safeguards to prevent loss, damage, and theft
3. Adequate maintenance procedures to keep the Equipment in good condition
4. Written policies on Equipment and supplies purchased with CIRM funds, including procedures to dispose of, sell or transfer Equipment
5. Procedures to leverage CIRM-funded Equipment on any future CIRM Applications and Awards

## O. Award Documentation, Access to Records, and Audits

### 1. Document Retention

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

### 2. Access to Record and Audits

The Awardee shall allow access to accounting records and supporting documentation which may be audited at the direction of CIRM and appropriate state agencies, including the Bureau of State Audits, the State Controller's Office, and Office of the Attorney General. In addition,

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In addition, Awardees must notify CIRM immediately if any of the following changes in PI or Project Manager status occur:¶
The PI's status at the Awardee organization changes (e.g., from full-time to part-time appointment, from paid to

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The PI or Project Manager withdraws from the project, takes a leave of absence, or is expected not to be involved in the day-to-day conduct of the approved project for a continuous period exceeding 90 days. This includes requests for sabbaticals.¶
The PI or Project Manager is no longer eligible (under either the standards of the Awardee or the criteria in the program) to serve as a PI or Project Manager.¶
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If CIRM determines that a PI's change in status will adversely impact the conduct of the CIRM-funded Project as described in the approved Application, CIRM will so notify the Awardee. The

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CIRM may require an Awardee to commission an independent audit of Award accounting records at the Awardee's expense as a condition of further funding eligibility.

## P. Reporting Requirements

Awardees must report financial and scientific progress to CIRM on a predetermined schedule and/or immediately upon achievement of an Operational Milestone.

### 1. Financial Report

Financial Reports shall be submitted to CIRM on a schedule detailed in the NOA. The Financial Report must include all cumulative costs incurred against CIRM funds, required Co-Funding, and Contingency.

If the Awardee has required Co-Funding based on the program type, the percentage of Co-Funding is required to be maintained at each Operational Milestone. If upon completion of an Operational Milestone the Co-Funding is any less than the required minimum in proportion to the CIRM funds disbursed for that Operational Milestone, CIRM will reduce the next payment by the amount the Co-Funding was short the requirement. CIRM will also check to ensure the Awardee has access to the Co-Funding necessary to get to each subsequent Operational Milestone. The failure to provide evidence of access to the Co-Funding required for each subsequent Operational Milestone will result in a Suspension Event.

Expenditures incurred above the cumulative CIRM milestone disbursement and required Co-Funding prior to achievement of an Operational Milestone are the sole responsibility of the Recipient and permanently recognized as Contingency Expenditures in financial reporting.

Some Financial Reports require reporting of Facilities and Indirect Costs based on allowable rates approved in the NOA.

For Operational Milestone-based Financial Reports, CIRM requests the Awardee estimate the date at which current project funds will be exhausted. If the sufficient funds date precedes the estimated achievement date of the next Operational Milestone, a Contingency funding plan is required.

### 2. Progress Report

Progress Reports shall be submitted to CIRM on the schedule specified in the NOA. The Awardee is required to file Quarterly, Semi-Annual, and Operational Milestone Progress Reports, which shall include a summary of scientific and operational progress.

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**Misuse of Funds**¶

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**Moved up [12]:** Fraud means an intentional deception or misrepresentation made by a person who knows or should have known that the deception could result in some unauthorized benefit to that person or some other person. It includes any act that constitutes fraud under applicable state or federal statutes. Abuse means any Awardee practice that is inconsistent with sound fiscal, business

**Moved up [13]:** misuse or misappropriation of CIRM funds or property; and false statements regarding the use of CIRM funds, whether by organizations or individuals. This includes personal use of CIRM funds; using funds for non-approved purposes; theft of CIRM-funded property or property acquired or leased with CIRM funds; charging CIRM for services of "ghost" individuals; submitting false financial reports; and submitting false financial data in bids submitted to the Awardee (for eventual payment by CIRM).¶
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Awardees shall report to CIRM cases of real or apparent fraud, or abuse of CIRM funding immediately upon knowledge thereof. Examples of fraud, and abuse that must be reported include, but are not limited to: embezzlement of CIRM funds,

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

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Quarterly Progress Reports for Operational Milestone-based Awards shall also include: a list of the names of all organizations and institutions that have received funding through this project, either directly or through their personnel; when applicable, the Co-Funding needed and available for the next Operational Milestone and certification of CA or non-CA status; and clinical trial enrollment data.

Annual Progress Reports and the Final Operational Milestone Progress Report may include the same items as quarterly Progress Reports as well as a summary of any budget changes; an updated list of Other Support for the PI/PD; a statement of the percentage of goods and services purchased with CIRM funds from California suppliers; an updated list of personnel who participated in the project; certification of applicable public policy assurances (e.g., ESCRO, IRB, IACUC); IP Disclosure reporting; and Outcomes Survey. A Final Progress Report shall also include a Progression Plan and Public Summary of Scientific Progress.

**3. Data Sharing Management Plan (DSMP)**

DSMPs shall be updated and submitted to CIRM per the reporting requirements in the NOA. DSMPs shall include progress on data sharing and management following CIRM's data sharing and management requirements in the PA/RFA. CIRM may require the DSMP to be fully executed by Award close, including sharing of data in accordance with FAIR principles. If CIRM determines that an Awardee is not in compliance with its approved Data Sharing and Management Plan (DSMP), CIRM may issue a written notice requiring the Awardee to take corrective action within a specified period, not to exceed 30 days.

**4. Suspension Event Reporting**

The Awardee shall promptly inform CIRM in writing of the occurrence of any Suspension Event, as detailed in the NOA by submitting a Suspension Event Report and Plan to CIRM. Awardees can use CIRM funds for Allowable Project Costs up to 30 days following the occurrence of a Suspension Event, after which the Awardee must use its own Contingency funding for the project. The Awardee must report to CIRM a plan to resolve the issues associated with the Suspension Event within 30 days and then show evidence that the Suspension Event has been resolved in order to re-initiate the use of CIRM funds. In the event the Awardee is able to resolve a Suspension Event, the Awardee shall report the details of such in the Suspension Event Resolution Report which needs to be submitted to CIRM no later than 30 days after the resolution of the Suspension Event.

**5. Other Reports**

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PIs and Awardees are also required to report activities that result from CIRM-funded research; including but not limited to:

a. Publications

b. Data deposition in data repositories

c. Inventions

d. Patent applications

e. Licensing

f. Invention utilization activities that result from CIRM-funded research.

Specific reporting requirements related to these areas may be found in regulations adopted by the ICOC governing intellectual property.

**6. Overdue Reports**

Failure to submit complete and accurate Financial Reports, Progress Reports, or other required reports in a timely fashion may result in reduction, delay or suspension of payments. Further, if a report is delinquent for more than 30 days, CIRM may take action as described in Chapter V, Section R, *Failure of Compliance and Award Termination.*

**Q. Award Close-Out**

CIRM will close-out an Award after conclusion of the Project Period and after the PI/PD and AOO have submitted all required reports, including a reconciliation by CIRM of the remaining funds due to the Awardee or CIRM. CIRM may withhold funds for future or concurrent Awards if an Awardee is delinquent in submitting reports.

If an Awardee does not submit final financial reporting on a terminated Award after 120 days from the termination date, the Awardee relinquishes the unobligated balance owed from CIRM, if any.

Following close-out, CIRM will accept revisions to any Financial Report up to six months after the Award end date. After this time, CIRM will continue to accept revisions to the Final Financial Report but will not issue payments for any additional expenditures reported after the six-month timeframe. The Awardee remains obligated to return any unobligated CIRM 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 period of funding support.

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The close-out of an Award does not extinguish requirements for property accountability, record retention, financial accountability, or requirements associated with regulation of medical and ethical standards or intellectual property. Pursuant to the Intellectual Property Regulations, a utilization report on any CIRM-Funded Inventions and CIRM-Funded Technology shall be reported to CIRM for 15 years after Award close.

**R. Failure of Compliance and Award Termination**

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

CIRM will afford the Awardee an opportunity to correct any deficiency before taking action unless public health or welfare concerns require immediate action or prompt action is necessary to protect CIRM's interests. (See also Chapter IV, Section C, Part 2*a.*, *Research Misconduct*).

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

1. Temporary withholding of payment
2. Reduction of Total Award Amount
3. Placing special conditions on Awards
4. Conversion to a reimbursement payment method
5. Termination of the Award
6. Removal of the personnel from the Award
7. Disqualifying the Awardee (or PI/PD as appropriate) from eligibility for future Awards for a specified period
8. Disqualifying the Awardee (or PI/PD as appropriate) from receipt of further CIRM funds
9. Recovery of previously awarded funds
10. Civil action and/or referral to the appropriate authorities for criminal investigation and enforcement
11. Consideration of past performance by Awardee (or PI/PD as appropriate)

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during review of subsequent Applications for CIRM funding.

12. Other available legal remedies.

If CIRM decides to terminate an Award and the Awardee still has Unobligated Funds, the Awardee must return to CIRM all unexpended funds as specified in the wind down plan provided by CIRM, but not later than 120 days of termination of the Award.

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

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

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

¶

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

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## VI. TRAINING PROGRAM AWARDS

Proposition 14 authorizes CIRM to establish training and fellowship programs (Health & Safety Code § 125290.73). This Chapter VI addresses the procedures unique to the administration of these programs under CIRM's Education pillar that focus on education and workforce activities. The provisions in other sections of this AMP apply to these Awards, except where those provisions conflict with Chapter VI, in which case the provisions of this chapter control.

### A. Trainee Policy

#### 1. Appointment

The NOA specifies the funded number and type of trainees that may be appointed and supported by the CIRM applicable training Award. Unless otherwise specified in the PA/RFA, trainees appointed under a CIRM training program Award must be supervised by a faculty mentor or faculty level scientist who is accountable for the conduct of the research and operations of the laboratory or facility where the trainee research is performed. To ensure appropriate supervision and commitment to each trainee, mentor qualifications and allowable CIRM trainee to mentor ratios are addressed on a program basis and outlined in the PA/RFA. The PD must complete and sign a Trainee Appointment Form for each trainee and submit verification to CIRM at the time of appointment (see Chapter VI, Section D, *Reporting Requirements for Training Awards*).

#### 2. Degree Requirements

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

#### 3. Training Period

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

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leave during the training period. Other leaves of absence must be pre-approved by the Program Director and CIRM and may require termination and reappointment of a trainee.

### B. Allowable Costs and Activities for Training Awards

CIRM supports direct project costs for the training program that are specifically associated with trainee support and program administration, including administrative support salaries. Indirect Costs, which cannot be specifically associated with the training Award, are limited to 10 percent of the direct project costs exclusive of Tuition and Fees.

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

#### 1. Stipend Levels

Annual trainee stipend levels should be commensurate with the individual's experience and the level of training as specified in the program. CIRM encourages the Awardee to supplement trainee stipends when necessary to meet institutional requirements and maintain equity among trainees, provided that the supplementation is without obligation to the trainee. Awardees must re-budget within the total amount already awarded to accommodate any variation in stipend levels. CIRM will not provide additional funds for any re-budgeting purposes. (See Chapter VI, Section C, *Prior Approval Requirements for Training Awards.*)

Trainee stipends and allowances are not provided as a condition of employment with CIRM, the state government, or the Awardee. Accordingly, Awardees may not seek funds, or charge training Awards, for costs that normally would be associated with employee benefits (e.g., FICA, workman's compensation, and unemployment insurance). This limitation does not include health insurance for trainees.

#### 2. Tuition and Fees

Tuition and Fees may only be claimed for trainees who are enrolled in an accredited certificate, undergraduate, or graduate program. CIRM limits the amount of Tuition and Fees that Awardees can charge to CIRM funds for trainees or graduate students working on CIRM research Awards. Please reference CIRM's public website and the relevant PA/RFA for specific Tuition and Fees limits. CIRM funds cannot be used to cover Tuition and Fees that are

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otherwise subsidized by the Awardee.

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

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

If the postdoctoral or clinical trainee's health insurance is not otherwise covered by the Awardee, the Awardee 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. Research Related Activities**

Awardees may request an annual allowance for trainees for research training-related expenses such as books and laboratory supplies. For internships taking place outside of the Awardee institution, the partnering (host) laboratory institution will recover overhead on these costs at a rate of 10 percent. Textbooks required for coursework, specialty volumes that will enhance training, and laboratory and technical manuals are allowable costs.

**5. Trainee Travel**

Awardees may request an annual travel allowance to cover costs for trainees to attend a CIRM trainee conference or SPARK Annual Meeting. Excess funds may be used to cover other program-related travel for the trainee.

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

Generally, research training experiences away from the Awardee institution must be justified on the basis of the type of opportunities for training available, the opportunities offered that are different from those at the Awardee institution, and the relationship of the proposed experience to the trainee's career stage and career goals.

**6. Program Administration**

Awardees may request funds for administrative costs as part of direct project costs. Unless otherwise specified by CIRM, allowable program administrative direct project costs include:

a. Administrative support salaries

b. Seminar speakers

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c. Outside speakers for courses

d. Audio-visual equipment or supplies

e. Costs of developing or delivering new courses

f. Cost of advertising the training program to all prospective candidates

See Chapter V for more information about Allowable and Unallowable Costs for CIRM Awards.

## C. Prior Approval Requirements for Training Awards

Awardees must perform project activities as described in the approved Application. An Awardee must request Prior Approval for any post-award changes by submitting a request to CIRM. The following are post-award changes for training Awards that require Prior Approval:

### 1. Training Period for Clinical Trainees

Appointing a clinical trainee for a period that is less than 12 consecutive months.

### 2. Funds for Trainee-Related/Program Administration/Indirect Costs

Rebudgeting from (1) trainee-related funds (Stipends, Tuition and Fees, Health Insurance or Research and Travel) into (2) Program Administration funds, and/or (3) Indirect Costs. Trainee stipends cannot exceed the current published CIRM Stipend Caps using CIRM funds.

### 3. Carry Forward of Unobligated Funds

Upon initial appointment of a trainee and on each subsequent annual reappointment, costs for Stipend, Tuition and Fees, Health Insurance, or Research and Travel that cover an entire 12 months should be obligated to the current Budget Period. The full amount not yet expended at the end of the Budget Period should be reported as obligated trainee funds. Carry forward of obligated trainee funds and unobligated Program Administration funds from one Budget Period to the next does not require Prior Approval. However, carry forward of unobligated trainee funds from one Budget Period to the next requires Prior Approval from CIRM. CIRM will not provide additional funds for increasing the number of approved trainee positions but will consider use of carry forward funds for this purpose.

### 4. Extensions

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A No-Cost Extension (NCE) extends the Project Period beyond the scheduled end date without providing additional CIRM funds. NCEs are only permitted where an extension would facilitate the completion of a trainee's normal training term. A one-time NCE for up to one year beyond the scheduled Project Period end date is allowed with Prior Approval. The written request for Prior Approval shall be submitted to CIRM at least 30 days in advance of the scheduled Project Period end date.

**5. Change in Program Director**

Appointing a new PD for the training program.

**6. Change in Host Institution**

Before adding new internship host sites or laboratories to a program, the PD must verify that the research, mentorship, and financial resources are adequate to support interns for the duration of their training.

## D. Reporting Requirements for Training Awards

Please see Chapter V, Section P, *Reporting Requirements*, for general reporting requirements. Requirements specific to CIRM's Training Programs are below.

**1. Training Program Report**

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

a. Trainee Alumni Tracking
b. Public Summary of Progress
c. Trainee Detailed Progress Summary
d. Personnel Overview
e. Changes in Interns, Mentors, or Personnel
f. Program Activities and Outreach
g. Trainee Assurances (see Ethical Research Practices below)

**2. 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 Awardee. The Awardee must certify to CIRM, in the Annual Progress Report, that all appointed trainees have current institutional approval (where appropriate) to conduct research

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**Deleted:** 90 days after each anniversary of the Project Period start date.¶ ¶ **1. Annual Financial Report**¶ The Grantee shall submit to the GMO an annual financial report, within 90 days after each anniversary of the Project Period start date stated in the NGA. The annual financial report must include all actual costs incurred during the expired Budget Period and any carry-forward amounts.¶
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involving 1) the use of the 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.

### 3. Trainee Appointment Form

A Trainee Appointment Form must be completed online for each trainee and submitted at the time of appointment. For programs where trainees are supported for more than one year, the form must also be completed at the time of reappointment. The form requests information about the appointment such as the name of the trainee, the name of the mentor, the anticipated period of training, and the anticipated program of training. By submitting the form, the mentor, trainee, and PD agree to comply with the proposed training program, period of support, stipend level, and the terms and conditions specified in this AMP.

### 4. Trainee Completion Form

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

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**iv.**→Course developments or changes¶
**v.**→Changes in the administration of the program¶
**vi.**→Plans for the upcoming year¶
**vii.**→Anticipated budget changes in future Budget Periods¶
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Grantees are also required to report to CIRM publications, inventions, patent¶
applications, licensing and invention utilization activities that result from CIRM-funded Activities. Specific reporting requirements may be found in regulations adopted by the ICOC governing intellectual property.¶
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5. **Overdue Reports**¶
Failure to timely submit financial, progress, or other reports may result in¶
action reducing, delaying or suspending payment until required materials are received. Further, if a report is delinquent for more than 60 days, CIRM may take action as described in chapter V, section Q, *Failure of Compliance*.¶
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6. **Ethical Research Practices**

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research in accordance with the highest medical and ethical standards, including compliance with institutional requirements, and regulations set forth and approved by the ICOC.

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## VII. FACILITIES AWARDS

CIRM is authorized to make both Grants and Loans for buildings, building leases, and capital Equipment. (Health & Safety Code § 125290.65, subd. (b)(1).) This Chapter VII addresses the procedures unique to the administration of facilities Awards. The provisions in other sections of this AMP apply to these Awards, except where those provisions conflict with Chapter VII, in which case the provisions of this chapter control.

### A. Application Requirements

#### 1. Renovation and Construction

Health and Safety Code § 125290.65, subd, (b)(1)(B) specifies that the criteria, requirements, and standards for awarding facilities Grants shall include "Priority for Applicants that provide for facilities that will be available for research no more than two years after the grant award." (Health & Safety Code § 125290.65, subd, (b)(1)(B).) Therefore, Applicants are encouraged to consider all opportunities for expediting renovations or construction so that research activities may commence quickly, including the use of interim space while renovations are underway. Facilities Applications may include a funding plan that will allocate a portion of the Award to pay for interim measures, such as leasing of space, in order to accommodate research activities prior to completion of the main Facility funded by the Award.

### B. Construction/Procurement Process

#### 1. Prevailing Rate of Per Diem Wages on Construction

The criteria, requirements, and standards for awarding facilities Grants shall include the requirement that all workers employed on projects funded by a CIRM facilities Grant receive the prevailing wage. (Health & Safety Code § 125290.65, subd. (b)(1)(E).) This requirement applies generally to California state agencies. Non-Profit Organizations that are facilities Award Recipients will be required to certify compliance with prevailing wage requirements for work undertaken using CIRM funds.

#### 2. Cost Standards (Buildings, Leases, Other)

The criteria, requirements, and standards for awarding facilities Grants shall include the requirement that Awardees comply with reimbursable building cost standards, competitive building leasing standards, capital Equipment cost standards, and reimbursement standards and terms recommended by the Facilities Working Group and adopted by the ICOC. (Health & Safety Code § 125290.65, subd. (b)(1)(D).) The cost of specific items of Equipment should be within the range of costs that are generally available within the market for a particular item of Equipment. Where the cost of Equipment items appear to be outside the usual

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and customary range to accommodate convenience, customization or sole source acquisitions, the Application will receive a lower score.

## C. Equipment Purchases

For Equipment to be purchased with CIRM funds and Matching Funds, Applicants may propose cost sharing of Equipment based on shared use with other programs within the host institution, provided this cost sharing maintains the "NIH-free" conditions that CIRM is seeking under this program.

## D. Oversight and Payment Procedures

### 1. Equipment Reimbursement

CIRM will reimburse Applicants for the cost of Equipment based on actual costs after payment has been made. Applicants may request reimbursement for items of Equipment on a phased basis as items are procured.

### 2. Site Audits

CIRM staff may periodically visit the site of CIRM-funded facilities projects to review progress. Awardees shall provide access to CIRM or its designated representative as requested by CIRM.

### 3. Notice of Completion

On completion of a CIRM-funded Facility, a Notice of Completion filed pursuant to California Civil Code section 3093 shall be delivered to CIRM indicating that the contracted work has been completed. The Notice of Completion may be preceded by a Notice of Beneficial Occupancy that grants access to the Facility under renovation pending final resolution of any remaining contract performance issues.



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