CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Memorandum

To: Members of ICOC

From: Jennifer Lewis, Vice President, Operations; Rafael Aguirre-Sacasa, General Counsel

Re: New Award Management Policy

Date: June 26, 2025

The mission of CIRM is to accelerate world-class science and deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and World. In 2020, Californians approved Proposition 14 providing $5.5 billion to continue this mission which expanded the Agency's ability to address diseases with high unmet medical needs while fostering a vibrant biotech ecosystem. As we continue to enact this mission through the Strategic Allocation Framework by introducing new concept plans to the ICOC and revamping our review processes, we must also make changes to our existing Grants Administration Policies (GAPs) to govern these awards in this new era of CIRM. We have attached a redlined version of the original GAP for Discovery, Translation, and Education Projects to this memorandum to document the proposed changes. The new comprehensive Policy will be called the Award Management Policy (AMP).

I. Background

CIRM's set of regulations that govern the management of awards was previously referred to as the Grants Administration Policy (GAP). CIRM currently has two Grants Administration Policies: 1) GAP for Clinical Stage Projects and 2) GAP for Discovery, Translation, and Education Projects. The GAP is generally modeled on the National Institute of Health's Grants Policy Statement with key differences that reflect CIRM's distinct role, accelerated operations and mission.

The first GAP was adopted by the ICOC in December 2006. On five subsequent occasions, the ICOC adopted amendments intended to further clarify certain provisions, simplify some requirements, and incorporate several modifications based on experience with the GAP. The two current active GAPs were adopted by the ICOC in 2016. Additionally, in March 2008, the ICOC adopted a third GAP for Facilities & Equipment Grants to govern awards under the Shared Labs and Major Facilities programs.

The CIRM team regards the newly proposed AMP as a unified all-encompassing policy that combines previous distinctions by program, organization type or facilities components to ensure consistency and adaptability as the Strategic Allocation Framework (SAF) is operationalized.

II. CIRM Award Management Policy Components

The proposed AMP follows the same basic template of the existing GAPs. This policy is organized chronologically to follow the life of a CIRM award, governing the award-making process, addressing the primary areas of the application and review process, the pre-award and award requirements, and the rules governing payment and use of funds as the award is managed. In

creating this new unified AMP, the CIRM team reviewed each aspect of the existing GAPs through the lens of CIRM's new/amended programs and changes outlined in Proposition 14. The result is a policy designed to be user friendly, clear, and enforceable across all currently planned and future program offerings and to provide more efficient administration and oversight of projects. In addition, this new AMP eliminates references to policies that are applicable under other state or federal laws and other CIRM regulations.

An overarching change to this policy is in the Applicability section which now specifies that failure to comply with any term set form in the AMP or term applicable to a CIRM award will be subject to the remedies described in the Failure of Compliance section. Previously these consequences were addressed separately within each individual policy section. For clarity and consistency, the proposed AMP defines the applicability of the terms at the onset. (p. 2)

A. Part I. General Information (p. 6-15)

This section contains introductory information that includes a glossary of abbreviations, defined terms, and generally describes the roles and responsibilities of key individuals in the Awardee organization. There are several additions to the Defined Terms that were previously referred to but never clearly defined in the previous GAP. These are California Organization, Co-funding, Contingency Expenditures, Facility, Matching Funds, Project Manager, Research Misconduct, Serious Adverse Event, and Unobligated Funds.

One new term is introduced, Critical Role. (p. 9) This role was created to be a subset of Key Personnel who have a minimum effort requirement as described in the specific Program Announcement (PA) or Request for Application (RFA), and whose absence could cause serious disruption to the project and its operations. The rationale for this new term is to capture personnel who are vital to the project's success, reviewed by the Grants Working Group as a required role, and approved by the ICOC. By creating this term, the PA or RFA would specify the required percent effort, and this AMP states prior approval is required from CIRM for a change in status and/or effort requirements on the project. An example of a Critical Role is the required Project Manager role found in the CLIN2 and PDEV programs.

Additionally, under the section for Roles and Responsibilities, Clinical Advisory Panel has been renamed to CIRM Experts. To align with the SAF, this role will serve as strategic advisors to CIRM staff on an ad-hoc basis to guide project direction and ensure alignment with program goals. This new title encompasses all programs and can be deployed by the PA/RFA, such as in the PDEV and CLIN2 concepts. (p. 15)

A. Part II. Application and Review Process (p. 16-19)

This section removes the process of Budget Review, which is program specific and not applicable for all awardees prior to ICOC approval. The removal of the Budget Review requirement allows CIRM staff to make enhancements to that process with board direction based on the program scope and funding commitment and to outline the specifics in the individual PAs. The AMP has also been streamlined with respect to Application Review (p. 17) by eliminating specific scoring criteria for individual programs which are already defined in the Grants Working Group (GWG) Bylaws or Concept Plans and approved by the ICOC.

B. Part III. Pre-Award (p. 20-21)

This section has been streamlined by moving several provisions that are applicable to the terms & conditions of a Notice of Award to the Award Acceptance & Terms section. These are: Public Policy Requirements; Research Misconduct; Conflict of Interest; Administrative Actions; Use of Human Stem Cell Lines, Oocytes, or Embryos; Use of Human Fetal Tissue; Research Involving Human Subjects; Animal Subjects; and Biosafety policies (p. 23-29).

C. PART IV: Award Acceptance and Terms (p. 22-34)

As a state agency, CIRM relies on grantees to acknowledge CIRM support through press releases, publications, conference presentations, and other similar types of communication. To bolster this compliance and have greater reach, a new term has been added to require all Awardees to acknowledge CIRM in any public communications. Non-compliance by the Awardee will result in an administrative action set forth in Failure of Compliance section. (p. 31)

The Limitation of CIRM Liability section has been updated to clarify CIRM's limited liability for Awardee's actions, research, etc. The section further emphasizes that the Awardee must comply with all applicable federal, state, and local laws, regulations, institutional requirements, and recognized ethical standards. (p. 22-23)

As referenced in the 22-23 Performance Audit by Moss Adams[1], CIRM's Loan Election policy, located within the GAP for Clinical Stage Projects, contains references to outdated information that would impact the terms of a potential loan. Therefore, the Award Conversion section has been updated to replace LIBOR with the Secured Overnight Financing Rate (SOFR). In addition, the interest rate chart for the award conversion has been edited in two significant ways. The first major change is the removal of the Cell Therapy only column since Proposition 14 differs from Proposition 71 by expanding the scope of regenerative medicine funded by the agency. Therefore, the rationale to provide favorable economics solely for cell therapies has been removed.

The second major change relates to the selection of the prior Non-Cell Based category as the basis going forward for interest rates and increases of interest rates in certain categories. When the award conversion option was included in the 2016 version of the Clinical GAP, the economic environment was significantly different, with much lower interest rates than present and a more active venture capital life sciences market. The starting higher rates under the Non-Cell Based category was chosen due to the market changes and certain interest rates were adjusted so that there was no category where an awardee could pay off a loan conversion at less than or equal to the received award amount. (p. 31-34)

[1] https://www.cirm.ca.gov/wp-content/uploads/2024/01/14.-CIRM-2023-Performance-Audit-FINAL-1.pdf

D. PART V: Payment and Use of Funds (p. 35-49)

This section has been reorganized to ensure that critical information is highlighted and definitions are clear. In addition, a clear Unobligated Funds policy has been added that includes the requirement on Awardees to return all unused funds to CIRM no later than 30 days after the final report deadline due to the urgency of receiving refunds and accounting for all research dollars. (p. 35)

The Pre-Award Cost spending provision defines the allowable period during which an Awardee may incur costs at its own risk prior to full execution of a Notice of Award, with such expenditures subsequently chargeable to the Award. The allowable period is measured from the date of ARS approval to the date of executed NOA. While the substance of the Policy remains unchanged, specific references to individual programs with different allowable start periods such as the 45 day period for CLIN2 awards, have been removed. This revision aligns with the broader changes to remove duplicative provisions and ensure clarity across all programs, as specific time periods are listed in the relevant Program Announcement. (p. 36)

The previous Policy also addresses the allowable maximum salary for personnel. Under the previous version, the maximum was based on a specific dollar amount calculated annually using the California Consumer Price Index for All Urban Consumers set in 2010. The revised Policy removes specific dollar figures and instead aligns with University of California Office of the President (UCOP) Health Sciences Compensation Plan. This comparator provides better alignment with Proposition 14's focus on UCOP contracting practices and builds on the ICOC approval of salary range changes for predoctoral and postdoctoral students on September 28, 2023.[2] (p. 37)

The Allowable Cost provision has been updated to include two new items: Patient-Qualified Costs and Non-California costs. Patient-Qualified Costs support the Proposition 14 mandate of Access and Affordability in reimbursing patient expenses for research participants and caregivers that include, but are not limited to, medical expenses, lodging, meals, and travel. The addition of Patient-Qualified Costs specifies that Award funding can be used for participation in CIRM-funded clinical trials, including necessary and reasonable donor, patient, or caregiver costs directly incurred as a result of screening, donation, or participation in research activities. Allowable costs may include but are not limited to costs associated with travel, housing, childcare, and medical care. (p. 37-38)

The second addition is Allowable Costs for Non-California Awardees. This provision has been added to formalize the criteria for clinical trial stage awards that allows Non-California applicants to receive an Award only to support those activities occurring within California. These activities are delineated as:

[2] https://www.cirm.ca.gov/wp-content/uploads/2023/09/15-EDUC4-Cover-Memo_FINAL-Posted.pdf

- 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; and

- 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; and

- Costs of manufacturing conducted in California for a subsequent clinical trial when the applicant adequately justifies conducting such activities during the proposed clinical trial. (p. 38)

Similarly, there are changes to the Unallowable Project Costs policy, including the inclusion of:

- 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;

- the prohibition of the purchase of Alcohol, and

- all legal fees and attorney's fees that are outside of the scope of normal reasonable patent prosecution for that jurisdiction. (p. 38-39)

The Allowable Facilities Costs section has been revised to remove references to federally negotiated rates and to delegate authority for establishing facilities rates to the ICOC. This change promoted a consistent approach, while allowing CIRM to be responsive to evolving environments. (p. 39). In addition, the term Post-Project Allowable Costs has been updated to include three clarifications: 1) it applies only to awards with Operational Milestones, 2) it is allowable only upon the successful completion of the project, and 3) awardees may reduce co-funding and/or contingency funding. (p. 40)

The requirement necessitating prior approval for a Change in Status of PI has also been expanded to include a Change in Status of Critical Role as defined in the RFA or PA. This change requires the Awardee to notify CIRM and obtain approval of any changes in a Critical Role as part of the Strategic Allocation Framework, such as Data Project Manager or Co-Investigators in DISC4. (p. 41-42)

The Equipment Management provision has added language to strengthen award management and align with the Strategic Allocation Framework that CIRM-funded equipment must be leveraged across any future CIRM Applications or Awards, ensuring responsible use of Proposition 14 funding. (p. 44)

A key priority of the Strategic Allocation Framework is to promote data sharing, which has led to the addition of a new section requiring a Data Sharing Management Plan (DSMP). The DSMP has been incorporated into the required Progress Reporting obligations and is subject to the same submission requirements and conditions outlined in the Notice of Award, including potential penalties such as the withholding of future disbursements for noncompliance. The DSMPs must

comply with CIRM's data sharing and management requirements. In addition, CIRM may require that the DSMP be fully executed by Award close and that data be shared in accordance with FAIR (Findable, Accessible, Interoperable, and Reusable) principles. (p. 46)

The Award Close-Out provision has been revised to include new deadlines intended to promote the responsible use of funding and enhance administrative efficiency. First, there is new language specifying that for awards that have been terminated, the Awardee relinquishes any claim to the unobligated balance owed from CIRM. For all awards that are closed, CIRM will not consider revisions to the submitted financial report more than 6 months after the Award end date. After this 6-month period time, CIRM may accept revised Final Financial Reports but will not issue payments for any additional expenditures reported after the 6-month deadline. The Awardee remains obligated to return any unobligated CIRM funds resulting from refunds, corrections, or other post-close transactions, and CIRM retains the right to recover amounts based on the results of an audit covering any part of the award period. (p. 47-48)

E. PART VI: Training Program Awards (p. 50-55)

This section removes Criteria for Review of Training Grant Applications as these criteria are established in other governing documents of CIRM, as these criteria are established in other CIRM governing documents and eliminates references to general requirements that apply across all Awards.

It also removes specific criteria for mentor to trainee ratios, instead allowing the PA and RFA to specify appropriate limits based on the trainee's stage and type of program. (p. 50)

Similarly, the Tuition & Fees section has eliminated detailed limits and calculations instead allowing the relevant PA or RFA. to set program-specific limits which will consider comparable funding institutions to determine the allowable maximum. (p. 51-52)

The Research Related Activities section has been revised to include additional requirements for partnering laboratory institutions where internships are occurring to recover indirect costs rates at a rate of 10%. (p. 52)

Trainee Travel has been updated to specify that the funds are for annual travel allowable for the annual CIRM-sponsored Trainee Conference or SPARK meeting and that any remaining funds may be used to cover other trainee travel related to the program. (p. 52)

The Prior Approval Requirements for the Training Awards section (p. 53-54) has been updated to provide clearer administrative processes and oversight while ensuring that programs can utilize funds fully to support the trainees. The updates fall into three areas:

1) Require CIRM's prior approval only when rebudgeting funds from Trainee-Related funds to Program Administration funds. Awardees may rebudget amongst Trainee-Related cost categories without prior approval. The policy also clarifies that trainee stipends may not exceed CIRM's published stipend maximums when using Award funds.

2) CIRM will approve no-cost extensions of up to 12 months only where necessary to allow a trainee to complete the training term.

3) Change in Sponsor, Mentor or Host Institution:

- Changes in a trainee's Sponsor or Mentor no longer require prior approval, as such changes are now incorporated into the Trainee Appointment process.
- Changes in the Host Institution, however, still require prior approval to ensure host sites have the appropriate personnel, resources and structure to support the trainees in a successful program.

F. PART VII: Facilities Awards (p. 56-57)

This section incorporates what was previously referred to as the CIRM GAP for Facilities and Equipment Grants. The provision has been refined to eliminate references to programs that were offered under Proposition 71 and refer to the Proposition 14 programs that will adhere to this section of the AMP – Shared Labs and Community Care Centers of Excellence.

III. Recommendation

The CIRM Team requests the ICOC approve the draft Award Management Policy to initiate the rulemaking process to adopt this regulation.

Exhibits to Memo:

1. New Award Management Policy (AMP)
2. Redlined Version of GAP for Discovery, Translation, and Education Projects