

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

ADDENDUM TO THE

**INITIAL STATEMENT OF REASONS FOR THE
PROPOSED ADOPTION OF THE CIRM AWARD MANAGEMENT POLICY**

June 9, 2026

CIRM provides this addendum to the Initial Statement of Reasons to include the following information regarding the Specific Purpose and Necessity for the document incorporated by reference by proposed Section 100505. The additional information is indicated by underlined text.

DOCUMENT INCORPORATED BY REFERENCE:

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 forth 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.

Part I. General Information

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. 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.

Additional changes to terms are as follows:

The term "Application" carries forward the same definition except the second sentence is now deleted to remove regulatory language that is more appropriately carried in the body of the AMP. Thus, in the third comment period, the sentence regarding what an Application should contain is deleted.

The term "Application Review Subcommittee" is added to identify a name used throughout the AMP to identify its full name.

"California Organization" brings forward a definition from the prior Clinical Stage GAP and supplements the term to include a requirement of management of award activities and IP rights. These additional criteria ensure that the Proposition's assurance that CIRM will fund research conducted in California by Californians is not circumvented. By managing activities in California and retaining rights in California, foreign entities will not be tempted to create shell entities for the sole purpose of gaining CIRM funding.

"Co-Funding" and "Contingency Expenditures" are new terms used in the AMP but which were previously defined in PA/RFAs.

"Data Safety Monitoring Plan" and "Data Sharing and Management Plan" are included to identify a new section in this AMP. The use of these terms is found under "Payment and Use of Funds" in the AMP and identify new requirements surrounding the collection and use of data generated by CIRM-funded research.

The term "Equipment" is carried over from prior GAP policies, except that the \$5,000 threshold is raised to \$10,000. This matches and aligns with federal OMB Uniform Guidance and ensures awardee institutions that have both CIRM and federal awards are operating under the same definitions.

Definitions of the "Facilities Working Group" and "Grants Working Group" are provided to identify the names of the two grant-review working groups that make funding recommendations to CIRM and its board, the ICOC.

The term "Prior Approval" is carried over from prior GAP policies, but the second sentence was deleted during the third comment round to remove reference to the requirement that such approval must be obtained prior to use of CIRM funds – in order to remove regulatory language from the definition itself. That requirement is stated elsewhere in the AMP.

“Program Announcement” is also carried over from prior GAP policies, but is expanded to provide specifics regarding what is in such a solicitation and their frequency. The term “Request for Application” is provided to identify funding opportunities that are provided less frequently than a “Program Announcement,” and identify the similar specifics that are in such a solicitation.

“Serious Adverse Event” is a term used in the existing Clinical Stage GAP but which is contained in the body of that document. The definition is moved here to the terms section and tracks the definition used by the National Institutes of Health for research involving human subjects. This ensures alignment with federal definition of a key term.

Finally, under the defined terms section, definitions are provided to identify the new Accessibility and Affordability Working Group created by Proposition 14 (which is now referenced in the AMP), and provides a definition for “Unobligated Funds,” to identify those funds authorized under the NOA that has not been expended or obligated. This is an incorporation of regular accounting terminology into the AMP to address a commonly used term.

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.

Part II. Application and Review Process

Section A.1 – Eligibility is carried over from existing GAP policies. This section is amended in the third comment round to clarify the scope as “Leadership Eligibility” in light of revisions to the draft policy made in the third comment round. The revisions expand on the circumstances and conditions under which a background check of certain applicant leadership will be subject to. CIRM does not require background checks on non-profit organizations that have been in existence longer than five years because based on experience it is reasonable to rely on more established non-profit organizations to have internal hiring checks in place for these leadership roles. We place more frequent oversight on for-profit organizations due to the smaller-resourced nature of these industry partners, and so will continue to perform these checks every 24 months to ensure greater safeguards on state funds.

Part II.B Application Submission incorporated existing GAP language and is updated to reflect the new PA/RFA terms. This section also describes the new use of a Letter of Intent that may be used from time to time as a pre-submission step. This section is further clarified in the third public comment period to indicate that the use of a LOI will be applied to all applicants for the given funding round – and not selectively. CIRM may use a LOI as a tool to gain insight into the state of the field and to help focus areas of funding pursuant to CIRM strategic goals.

Part II.I.(2)(c) – pertaining to Prepublication of scientific working papers and its exception to “Public Access to Public Records” – extraneous non-regulatory language is deleted. This language appears to have been a background comment that sources the exception provided in the

AMP to Health and Safety Code section 125290.50, subdivision (f). Because this background commentary is unnecessary, it is being deleted.

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 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.

Part III. Pre-Award

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.

Part III.A. Pref-Funding Administrative Review is carried over from existing GAP policies and streamlined with the use of the new terms used in the AMP. In addition, this section provides more detail and clarifications regarding CIRM's PFAR process. Specifically, this section indicates, among other things, that CIRM will review key compliance requirements and budget, and establishment of milestones. The section identifies CIRM's role in reviewing milestones and success criteria. This additional clarity on the PFAR process is necessary to ensure awardees are aware of the elements of the PFAR process and CIRM's role in ensuring project objectives are clearly identified prior to award start so that progress can be adequately monitored.

Part III.B.1 – Certification is added as a new distinct subpart, drawn from disparate provisions of existing GAP policies. This provision alerts an awardee that it will have to certify compliance with all terms and conditions described in the PA/RFA, and that CIRM may, pursuant to its inherent audit function, request supporting documentation for verification. In this way CIRM will be able to ensure proper use of state funds.

Part III.B.3 – Good Standing – is a now-deleted section. Related provisions are elsewhere located in CIRM PA/RFA provisions, and accordingly it is repetitive here and risks confusion if language becomes unaligned with a PA/RFA.

PART IV: Award Acceptance and Terms

Part A., Notice of Award (NOA) is largely carried over from existing GAP policies. During the third comment period clarifying language was included to give greater description of the types of circumstances where a NOA might need to be amended. This non-exhaustive list is considered exemplary of the many types of changes that lead to NOA amendments.

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.

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, and ensure the Awardee's subcontractors and subrecipients agree to indemnify CIRM as well. In addition, pursuant to public comment, this section clarifies how self-insured Awardees shall comply with the duty to include CIRM as an additional covered party under such a self-insurance program.

Part IV.C.2 – Public Policy Requirements carries forward existing GAP policy requirements regarding compliance with stated public policy provisions that govern some aspects of biomedical research – such as research misconduct, conflicts of interest, use of human tissue and humans in research. This section clarifies which public policy compliance assurances will be required prior to issuance of an NOA. This reflects the importance of those topics by requiring the certification under the stated circumstances.

Subpart (a) of the section above has also been modified from the current GAP policies to delete reference to 42 CFR Part 93 regarding Research Misconduct. In CIRM's experience, institutions already have suitable research misconduct standards in place and CIRM has never had an awardee attempt to propound rules from the stated CFR. To avoid unnecessary confusion or administrative burden on awardees, the reference is deleted.

Subpart (b) pertaining to "Conflict of Interest" also is a restatement of existing policy reflected in current GAP policies. The grammar is streamlined and the method of notification to CIRM of a COI infraction is clarified to indicate such notification must be in writing. This method will assist CIRM in assuring compliance with this section and help prevent conflicts of interest in CIRM-funded research.

Subpart (c) pertaining to administrative actions is updated to provide clear and specific timelines for awardee clarification. Accordingly, the notice to CIRM must be in writing no later than five business days of receiving the results of any investigation for the reasons stated therein.

Subpart (f) Research Involving Human Subjects is also carried over from existing GAP policies. In addition to non-substantive changes to conform to new terminology, the section has been clarified to require notification to CIRM "in writing" for any investigation or administrative action concerning a violation of this section "no later than five business days" from the commencement of the investigation or administrative action. This detail is added to the pre-existing requirement to provide clear means of notification and specific timelines for compliance.

Subpart (g) Vertebrate Animals – reflects updated terminology in the title and is a restatement of existing GAP policy. The prior requirement that sites conducting research on such animals have policies and procedures based on the described National Academy of Sciences standards are deleted as unnecessary and largely redundant in light of the subsequent existing provisions of this section concerning compliance with applicable federal state and local laws. CIRM believes

these safeguards are adequately addressed in the remaining requirements and accreditation by the AAALAC.

Subpart (h) Biosafety is also imported from existing GAP policy. The section is further clarified to indicate the method of ensuring the compliance with existing laws pertaining to handling, storage and disposal of biohazardous materials. This section provides clarity and specifics for awardees regarding the type of documentation of compliance that must be maintained and the conditions for when CIRM must be notified of any changes. By ensuring CIRM receives written notice of the specified changes in the status of any identified Approvals, CIRM can ensure proper processes are followed in CIRM-funded research. The five-business-day timeline for notification to CIRM is a reasonable timeframe and is consistent with other notification deadlines within the AMP.

Part IV.C.3 Terms is carried over from existing provisions of GAP policies except as noted herein.

Subpart (a) Sharing of Intellectual Property is a new section intended to alert awardees of possible obligations under existing regulations adopted by the ICOC governing intellectual property. Accordingly, this section refers awardees to consult section 100650 for further review.

Subpart (c) Meetings is updated to provide details around the kinds of FDA meetings CIRM may attend and provides a timeline for notifying CIRM after the identified meeting has been scheduled. The clarifications specify that CIRM must be notified about FDA INTERACT, type C and Pre-BLA meetings. With this specificity, awardees will be certain of the types of FDA meetings that are subject to this section. These meetings are considered critical FDA meetings involving the progress of a CIRM-funded program and ensures CIRM has visibility into the progress of CIRM-funded projects.

Subpart (d) Data Sharing and Management. 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 as indicated in the Definitions section of Part I..

Subpart (f) Operational Milestone is updated to reflect new terminology and to include a provision from the Clinical stage GAP that the grace period to rectify an unsatisfied operational milestone, if not otherwise stated in the NOA, will be four months. Historically this timeframe has proven appropriate for programs to make arrangements to address milestone failures while preventing programs from becoming stale for failure to progress.

Subpart (g) Acknowledgement of Funder is a new section intended to alert awardees to existing obligations under Section 100650 – CIRM's Intellectual Property Regulations. Rather than

restate the requirements of that section, CIRM points awardees to review that section to ensure funder acknowledgment is assured. Failure to acknowledge CIRM in such communications may result in any remedies identified in the failure of compliance section of the AMP. Ensuring CIRM receives due credit for its funded achievements ensures California taxpayers receive the credit for funding successful work and ensures CIRM can track possible intellectual property development.

Part IV.D. Award Conversion:

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.

Subpart (D)(3) Survival of Rights; Waiver of Bankruptcy Discharge is a new provision that CIRM's right to repayment, enforcement and any other remedies under the AMP shall survive and not be discharged by any bankruptcy proceeding to the extent permitted by law. This section also reserves CIRM's rights and protections afforded by sovereign immunity doctrines. This section is necessary to ensure California taxpayers are not victimized by bankruptcy proceedings intended to thwart CIRM from repayment or other remedies.

Part V. PAYMENT AND USE OF FUNDS

This section has been reorganized to ensure that critical information is highlighted and definitions are clear.

Subpart A. Payment provides that awardees shall deposit CIRM funds into an interest-bearing account and track interest accrued on payments. Interest earned from the account shall be used only for eligible Award-related expenses or returned to CIRM. This provision is a preexisting requirement found in current GAP policies.

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. Operational Milestone provisions are part of existing GAP policy requirements, including the requirement that awardees must cover excess costs with contingency funds.

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*. This new section is necessary to address those awards without Operational Milestones and describes how payments will be disbursed. CIRM will condition disbursement on compliance with the terms of the NOA to ensure the terms are followed and the awardee is in compliance with its obligations.

Subpart B. Unobligated Funds

In addition, a clear Unobligated Funds policy 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. This is a preexisting provision found in current GAP policies.

Subpart D. Pre-Award Costs

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.

Subpart F. Allowable Project Costs

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.

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.

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:

- 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.

A new provision has been added that states that 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. This provision is necessary to ensure that such organizations conducting research out of state by out of state entities do not get CIRM funding for those activities. This will ensure CIRM is able to focus funds on California recipients and/or California patients.

Subpart H. Allowable Facilities Costs

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. 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. These provisions address a common occurrence at the end of CIRM-funded projects where funds may be left over and the awardee requests to use the funds.

These rules ensure such funds are only used in circumstances where milestone-based project has been completed successfully, which serves the interest of encouraging and rewarding successful projects.

Finally, the Facilities rates cap was raised from \$25,000 to \$50,000 in keeping with federal OMB updates to this figure. Alignment with the OMB rate makes administration of facilities grants easier to manage for awardees.

Subpart J. Indirect Costs

This provision is largely carried over from existing GAP policies. It has been updated to raise the indirect costs cap for contracts from \$25,000 to \$50,000 for the same reasons as in Subpart H. In addition, CIRM will allow awardees operating und the existing cap of \$25,000 to apply the new formula once the AMP is applicable to that award, allowing awardees to benefit from the change mid-award.

Subpart L. Prior Approval Requirements

These provisions are carried over from existing GAP policies with the following differences.

First, CIRM has updated the policy to provide that except as provided further in the policy, if CIRM determines that a requested change would have an adverse material impact on the outcome of the original evaluation and funding decision (considering scope of activities, eligibility criteria, project duration, budgetary limitations, key personnel, or the overall value proposition of the proposed change), CIRM will deny the request. This standard provides clarity on how CIRM will exercise its discretion to approve a requested change in the circumstances that are enumerated in Subpart L. These elements ensure that awardees are aware of the standard that will be applied to such requests, and that the discretion is exercised such that the program goals and funding decision are served well by the change.

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. This ensures incorporation of the new term “Critical Role” is encompassed in the existing requirements regarding change of status for key personnel.

The requirement for pre-approval regarding us of Post-Project Allowable Costs is a preexisting requirement found in the current GAP. CIRM has added a description of four elements that the awardee must describe in its request, to wit: 1) A description of the new activities proposed using remaining CIRM funds and how the proposed project furthers CIRM’s mission; 2) 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; 3) The duration of the new activities requested (# of months); and 4) The PI/PD’s effort for the proposed activities, PI/PD’s Other Support document, and a list of other personnel proposed. These elements provide specificity regarding the type of information to be submitted for a PAR in order for CIRM to exercise the discretion identified at the beginning of Subpart L.

Subpart N. Equipment Management

The Equipment Management provision is imported from existing GAP policies, and 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.

Subpart P.1. Financial Report

This section is imported from existing GAP policies. This section updates the schedule of reporting to reflect milestone schedules set forth in the NOA and includes reporting any costs that may come out of a Contingency fund. In addition, an awardee must develop a Contingency funding plan in the event the awardee estimates the project funds will be exhausted prior to the achievement of the next Milestone. This reporting and development of a Contingency plan is necessary to ensure CIRM has visibility on financial solvency of the project and that an awardee has a plan to achieve milestone success in the event all CIRM funds allocated for the milestone are spent.

Subpart P.2. Progress Report is a preexisting section imported from current GAP policies. It is updated to include description of a new Quarterly Progress Report for milestone-based awards. Such a report shall include a list of names of organizations that have received funding through this project, certification of California status and clinical trial enrollment data in addition to requirements pertaining to Co-Funding needs. This section ensures CIRM is able to carefully monitor pace and content of expenditure of CIRM award funds.

Subpart P.3. Data Sharing Management Plan

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) and reporting on the plan as required in the NOA. 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.

Subpart Q. Award Close-Out

The Award Close-Out provision is imported from existing GAP policies and 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. This six-month deadline reflects CIRM's experience that this is a sufficient period of time for an

awardee to conclude work on a project and issue back any unobligated funds that belong to CIRM.

Part R. Failure of Compliance and Award Termination

This section is a restatement of existing GAP policies regarding failure of compliance. The section is updated to address the fact that grace periods are determined in the PA/RFA. Therefore, that period governs and, if not specified there, the default period of four months will pertain. CIRM has found that four months is sufficient to address deficiencies in achieving Milestones.

CIRM has added two forms of remedies: Reduction of Total Award Amount, and Removal of personnel from the award. Reduction of the award amount accounts for options short of termination, and ensures that where certain planned and funded activities do not occur, then associated costs are recovered by a reduction in the award amount. Removal of personnel may be apt when there is misconduct committed by a member of the research team.

PART VI: Training Program Awards. This section is part of the existing GAP for Discovery, Translation and Education.

A new introductory paragraph states that 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. This section is necessary to explain the purpose of the section and clarifies that this section controls over other chapters as to this program.

Subpart A.3. Training Period is identical to the DTE GAP except that “personal time off” is expressly called out as a permissible type of leave that an institution may provide for. This expansion reflects real-world contexts and addresses a need of awardee institutions.

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. This ensures program flexibility to meet unique needs of specific types of PA/RFAs.

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. The indirect cost limit of 10 percent now states the calculation is “exclusive of Tuition and Fees.” This overhead exclusion follows and aligns with the same calculation earlier in the AMP pertaining to overhead calculations for another non-research award program – Facilities awards.

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%, thus ensuring consistent application of the cap across the different facilitators of the internships.

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. This ensures CIRM conferences are prioritized with CIRM funds over competing travel needs.

The Prior Approval Requirements for the Training Awards section 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.

This section also imports the same standard from the AMP's other "prior approval" section and indicates the basis for exercising CIRM's discretion on whether to approve the identified prior approval circumstances. This ensures consistency and clarity of how and when CIRM's discretion to grant a prior approval request will be exercised.

Subpart C.3. is updated to allow carry forward of unobligated trainee funds without Prior Approval for the purpose of increasing the number of approved trainee positions in the next Budget Period. Submitting the PAR is administratively burdensome to Awardees and this enables program expansion to reach even more trainees.

Subpart C.4. Extensions is updated to indicate that no-cost extensions are only permitted where an extension would facilitate the completion of a trainee's normal training term. This provides a standard for approval of a no-cost extension, establishing a common-sense application of necessity to complete the training program.

Subpart D.1. Training Program Report is imported from the existing DTE GAP but adds Trainee Alumni Tracking in order to measure the impact and success of the training program. This will be used to determine the value of the program to Californians.

Subparts D.3. and D.4. are updates to the current information collected by CIRM regarding trainee appointments and training completion of the program. The detailed information collected is necessary to track key demographic impact and visibility into the reach of the program into the various sectors of Californians that are being recruited into the program.

PART VII: Facilities Awards

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.