NOTICE OF PROPOSED REGULATION ADOPTION

California Code of Regulations
Title 17. - Public Health
Division 4 - California Institute for Regenerative Medicine
Chapter 5, Section 100505

Date: September 5, 2025
Deadline for Submission of Written Comment: October 21, 2025 -5:00 p.m.
Public Hearing Date: None Scheduled

Subject Matter of Proposed Amendments:
CIRM Award Management Policy

Submittal of Comments:

Any interested party may present comments in writing about the proposed amendments to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on October 21, 2025. Comments regarding this proposed action may also be transmitted via e-mail to ampcomments@cirm.ca.gov or via US Mail to the address listed below under "Agency Contact".

Public Hearing:
At this time, no public hearing has been scheduled concerning the proposed regulations. However, CIRM will hold a hearing if it receives a written request for a public hearing from any interested person, or their authorized representative, no later than 15 days before the close of the written comment period.

Sections Affected: The proposed regulatory action adds Section 100505 to Chapter 5 of Title 17 of the California Code of Regulations, and the document incorporated by reference into section 100505.

Authority: Article XXXV of the California Constitution and Health and Safety Code Section 125290.40, subdivision l).

Reference: Sections 125290.30, 125290.40, 125290.50, 125290.60 and 125292.10, Health and Safety Code.

Informative Digest/Policy Statement Overview:
The California Institute for Regenerative Medicine ("Institute" or "CIRM") was established in 2005 after the passage in 2004 of Proposition 71and allocated additional funds in 2020 with passage of Proposition 14 (the "Act") in November of that year. These ballot measures established a new state agency to make grants and provide loans for stem cell research, gene therapy research, research facilities and other vital research opportunities. The Independent Citizens' Oversight Committee ("ICOC") is the 35-member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry. The Act charges the ICOC with developing standards and criteria to make awards and to

develop standards and criteria for proper oversight of awards. (§ 125290.50.) To that end, CIRM adopted the CIRM Award Management Policy ("AMP"), an update to existing regulations governing oversight and management of CIRM awards (see CIRM Regulations 100503 and 100504 (“Grants Administration Policy for Clinical Stage Projects” and “Grants Administration Policy for Discovery, Translation, and Education Projects,” respectively), and the Grants Administration Policy for Facilities and Equipment Grants (Regulation 100700)).

Proposed section 100505 incorporates by reference the AMP and indicates that recipients of awards will be subject to this particular AMP. This section indicates that amendments to the policy will be applied to current active awards at the next budget or milestone period after the effective date of any amendments.

The policy incorporated by reference by section 100505 serves as the terms and conditions for all CIRM awards. In addition, it provides guidance to applicants and Awardees regarding their responsibilities. Principal investigators, program directors, and organizational officials with grants management responsibilities are urged to read this document carefully and to refer to relevant sections for answers to questions that arise concerning the administration of CIRM awards. Applicants and Awardees may be required to document compliance with any and all provisions set forth in this policy.

By accepting CIRM funding, Awardees agree to comply with the provisions set forth in this policy.

This policy may be amended or revised periodically. Any new or amended regulations adopted by the Independent Citizens' Oversight Committee (ICOC), the governing board of CIRM, will be applied to currently active awards on the start date of the next Operational Milestone, except as provided in the relevant 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 CIRM Award, and should CIRM no longer exist, that right may be exercised by the State of California.

As with prior CIRM grants administration policies, this AMP will describe the grant application and review process, which details the application submission, budget review and application review processes, criteria for the review of applications, appeals of scientific review, the process for approval for funding and delineate certain policies regarding access to public records and use of personal information.

The AMP also addresses the elements of the pre-award process, which governs the pre-funding administrative review, conditions of liability, public policy requirements (such as rules governing use of human stem cell lines, for example), documents and certifications required during the "just-in-time" period prior to award execution, and the elements of the award notice.

Principal Investigators and institutions will also find terms governing award acceptance and rules governing election to treat an award as a loan.

Finally, consistent with prior CIRM grants administration policies, the AMP details the rules governing the payment and use of CIRM funds, identifying and describing allowable costs and activities that may be funded with CIRM funds, allowable and unallowable facilities costs, prior approval requirements, accounting and documentation requirements (which are subject to access and audit requirements by CIRM or its agents), consequences for misuse of CIRM funds, the reporting requirements necessary to monitor progress, and finally rules regarding termination and consequences for failure of compliance.

Anticipated Benefits of the Proposed Regulation:
To the extent the regulation facilitates use of the funds and encourages development of intellectual property and return to the state as required by law, and to the extent California institutions apply for and receive research funds, such requirements are indirectly attributable to increased economic activity spurred by the investment research funds in the state and resultant positive business and employment development. Also, to the extent the regulation makes it possible for the expenditure of research funds in the state, and to the extent that research results in medical treatments and cures for chronic disease and injury, the regulation indirectly benefits the health and welfare of California residents who will benefit from such treatments and cures.

Consistency and Compatibility with Existing State Regulations:
CIRM has conducted an evaluation for any other regulations on this area and has concluded that this is the only regulation concerning administration of CIRM-funded awards for late-stage research projects. Therefore, the proposed regulation is neither inconsistent nor incompatible with any other existing state regulations.

Incorporated by Reference Documents: California Institute for Regenerative Medicine Award Management Policy (AMP) dated (regulation effective date).

DISCLOSURES REGARDING THE PROPOSED AMENDMENTS:
CIRM has made the following initial determinations:

Mandate on local agencies and school districts: None.

Effect on Small Business:
CIRM has determined that the proposed action will have no impact on small businesses. The regulation implements conditions on awarding and administering awards for stem cell and gene therapy research. This research is conducted almost exclusively by large public and private nonprofit institutions. As such, the regulation is not expected to adversely impact small business as defined in Government Code Section 11342.610.

Impact on Local Agencies or School Districts:
CIRM has determined that the proposed action does not impose a mandate on local agencies or school districts, nor do they require reimbursement by the state pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code because the

amendments do not constitute a "new program or higher level of service of an existing program" within the meaning of Section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed amendments.

Costs or Savings to State Agencies:
CIRM has determined that no savings or increased costs to any agency will result from the proposed regulation.

Effect on Federal Funding to the State:
CIRM has determined that no costs or savings in federal funding to the state will result from the proposed regulation.

Effect on Housing Costs:
CIRM has determined that the proposed regulation will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:
CIRM has made an initial determination that the proposed regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:
CIRM has made an initial determination that the adoption of this regulation will not have a significant cost impact on representative private persons or businesses. CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed regulation.

Business Reporting Requirement:
CIRM finds that it is necessary for the health, safety, or welfare of the people of this state that the document incorporated by reference by the proposed regulation, which requires a report, apply to business.

Results of Economic Impact Analysis:
The above analysis is based on that fact that the proposed regulation does not impose new requirements on existing business operations or functions of other agencies or individuals, but implements standards for seeking and using state grant funds for scientific research. In most cases, such grants include funds to cover overhead and other indirect costs of the research, including most compliance activities. CIRM has made an initial determination that it is unlikely the proposed action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California, nor directly impact the health and welfare of California residents, worker safety, and the state's environment. However, applicants and awardees of CIRM funds would have a clear understanding of their responsibilities in accepting and using state funds for stem cell and gene therapy research, which ultimately benefits the citizenry of California. In addition, to the extent the regulation facilitates use of the funds and encourages invention and return to the state as required by law, and to the extent California institutions apply for and receive research, infrastructure, workforce development and other funds, such requirements are indirectly attributable to increased economic activity spurred by the investment funds in the state and resultant positive business and employment development. Also, to the extent the regulation makes it possible for the expenditure of funds in the state, and to the extent that research results in medical treatments and cures for chronic disease and injury, the regulation indirectly benefits the health and welfare of California residents who will benefit

from such treatments and cures.

Consideration of Alternatives:
In accordance with Government Code Section 11346.5, subdivision (a)(l3), CIRM must determine that no reasonable alternative it considered, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of the law than the proposal described in this Notice. CIRM invites interested persons to present statements or arguments with respect to alternatives to the proposed amendments at the scheduled hearing or during the written comment period.

Availability of Statement of Reasons, Text of Proposed Regulations, and Rulemaking File:
CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed regulation and the policy incorporated by reference, all of the information upon which the regulation and policy are based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation and policy may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:
After holding the hearing and considering all timely and relevant comments, CIRM may adopt the proposed amendments substantially as described in this notice. If CIRM makes modifications that are sufficiently related to the originally proposed text of the amendments, it will make the modified text (with the changes clearly indicated) available to the pubic for at least 15 days before it adopts the regulations as amended. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Availability of Documents on the Internet:
Copies of this Notice, the proposed text of the regulation, and the Initial Statement of Reasons may be accessed on CIRM's website at www.cirm.ca.gov .

Agency Contact:
Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the amendments; and inquiries regarding the rulemaking file may be directed to:

C. Scott Tocher
Associate Vice President, Board Governance
California Institute for Regenerative Medicine
601 Gateway Boulevard, Suite 400
South San Francisco, CA 94080
(510) 340-9101

Questions on the substance of the proposed regulatory action may be directed to:

Ione Hughes, Project Manager - Operations
California Institute for Regenerative Medicine
(510)-424-4694

Availability of Final Statement of Reasons:
Following its preparation, a copy of the Final Statement of Reasons may be obtained from the contact person named above.

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