

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

**INITIAL STATEMENT OF REASONS FOR THE
PROPOSED AMENDMENT OF THE CIRM GRANTS ADMINISTRATION POLICY FOR ACADEMIC
AND NON-PROFIT INSTITUTIONS**

HEARING DATE: None scheduled.

CLOSE OF PUBLIC COMMENT: April 2, 2012

SUBJECT MATTER OF PROPOSED REGULATIONS: CIRM Grants Administration Policy for Academic and Non-Profit Institutions

SECTIONS AFFECTED: The proposed amendment is to the document incorporated by reference into Chapter 5 and Section 100500 of Title 17 of the California Code of Regulations and is reflected in the reference to that document in subdivision (a) of Section 100500.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH AMENDMENT:

SECTION 100500 – GRANTS ADMINISTRATION POLICY:

Purpose:

The purpose of Section 100500 is to describe the terms and conditions that govern grant awards from the California Institute for Regenerative Medicine (“CIRM”) to academic and non-profit institutions. The amendments are to the document incorporated by reference through subdivision (a) of Section 100500: CIRM’s Grants Administration Policy for Academic and Non-Profit Institutions. The only amendment to Section 100500 itself is to correct the reference to the document incorporated by reference through subdivision (a).

Rationale:

Title 1 of California Code of Regulations, Section 20, permits agencies to incorporate by reference documents under certain conditions. Subdivision (c)(1) of that regulation allows such incorporation when to do otherwise be “cumbersome, unduly expensive, or otherwise impractical” to publish the document in regulatory form. In light of the size and magnitude of the policy and given the burdens associated with translating each of the document’s separate provisions into specific regulations, incorporation by reference serves the needs of both efficient use of resources, avoids the cumbersome task of rewriting an entire manual, and avoids the risk of inadvertent disagreement between the regulations and the policies being implemented.

DOCUMENT INCORPORATED BY REFERENCE:

**CIRM GRANTS ADMINISTRATION POLICY FOR ACADEMIC
AND NON-PROFIT INSTITUTIONS**

VERSION: with a footer that dates the document as “Non-Profit and Academic Institution Grants Administration Policy (Rev. April 28th, 2009)”.

SECTION I. GENERAL INFORMATION:

Section I.C. Glossary of Defined Terms:

Purpose:

Amended to define “Co-Principal Investigator (Co-PI)” and “Financial Report.” The definitions of “indirect Costs” and “Key Personnel” have been amended. Finally, the term “Working Budget” has been added.

Rationale:

These amendments make specific the language and terminology used in these regulations. Some of the amendments are new definitions, some are non-substantive changes and others clarify existing definitions that are ambiguous. All of the amendments are important to ensure consistent interpretation of the defined terms throughout the CIRM regulations.

Section I.D. Types of Support; and I.E. Roles and Responsibilities

Purpose:

Amended to correct typographical errors, improve grammatical clarity and other non-substantive amendments.

Rationale:

These amendments provide are intended to provide clarity by eliminating vague or erroneous words/grammar.

Section I.F. Sources of Information

Purpose:

This section is deleted.

Rationale:

ISR 02/12

This section is removed because it is no longer serving a necessary function. The CIRM website was not a robust tool during the original GAP, but has since grown and is now a proper resource and excellent source of information for Applicants and Grantees. The website is updated with real-time information and is a preferable location to provide links to other websites both for ease of use and ensuring use of current and accurate information.

SECTION III. PRE-AWARD AND AWARD.

Purpose:

Subpart A. Administrative Review: The amendment changes the title to “Pre-Funding Administrative Review (PFAR)” and deletes the sentence stating unallowable costs are not to be expended.

Rationale:

The amendments clarify language to align with the common terminology used by CIRM and removes a redundant statement. These amendments provide clarity and remove unnecessary provisions.

Purpose:

Subpart C. Public Policy Requirements: The amendments to this subpart clarify the deadlines for submitting documentation of public policy assurances, and permit CIRM to issue a NGA subject to a condition subsequent. In subpart C.6.b, the amendment clarifies that compliance with California Health and Safety Code sections 24170-24179.5 is required for all CIRM-funded human subjects research and describes how compliance may be demonstrated. The amendments delete reference to federal requirements regarding human subjects research. In subpart C.8, term “Key Personnel is changed to all research personnel.

Rationale:

The amendments regarding human subjects research are consistent with the intent of the ICOC’s Standards Working Group, to apply the substantive and procedural protections of the Common Rule to all CIRM-funded human subjects research. Specifically, those aspects of the Common Rule that advance voluntary informed consent, which are embodied in the Health and Safety Code sections identified in the amendments. These amendments harmonize the GAP with ICOC policy and state policy on this subject.

The amendments to part C.8, Biosafety, clarify that all research personnel funded under a CIRM award need to have the described training and certification.

Purpose:

Subpart E. Award Notice: The amendments to subpart E state that during the active award

period, the NGA may be amended in response to Prior Approval Requests or documentation of GMO implementation of the GAP regulations.

Rationale:

The amendments are updated to reflect CIRM practice. Amendments to awards allow Grantees to track approved changes clearly and consistently.

SECTION V. PAYMENT AND USE OF FUNDS.

Purpose:

Subpart B. Costs and Activities: The amendments relocate the section on “Pre-Award Costs” becoming subpart B.1. Subpart 1 becomes subpart 2, and variously changes to identified personnel, costs and types of allowed costs and activities, including provision for prior approval to exceed annual allowance for travel costs. Subpart 5, “Indirect Costs,” is amended to state that the specific percentage allowable for an RFA will be stipulated in the RFA and clarifies, per Proposition 71, the amounts subject to the limit. The amendments also delete subpart 6., “Interest Earned on CIRM Funds.”

Rationale:

The amendment moving the “Pre-Award Costs” is non-substantive.

The amendments to include “personnel,” “specific identifiable administrative costs,” and other changes therein are nonsubstantive and clarify the scope of the provision. The amendments also implement the stated policy of adjusting salary caps biennially and make those appropriate calculations. The amendments allowing for approval to exceed travel cost caps provide for an exception and reflect the reality that as CIRM funds larger projects such as international collaborations, Grantees may have concomitantly higher travel costs under these programs.

The clarification to the subpart concerning “Indirect Costs,” is a clarification at the request of CIRM Grantees for informational purposes. The ICOC sets the Indirect Cost Rate on a per RFA basis. To date, the range has been 10-20%, depending on the type of RFA. The amendments do not reflect a change in policy but instead provide greater level of information to the Grantee.

The amendments delete an unnecessary provision regarding tracking of interest on CIRM funds. The deletion is aligned with CIRM’s practice of issuing frequent, small payments (quarterly instead of annual at the start of each budget period). Also, CIRM now monitors cash balances and withholds disbursements if significant cash balance is indicated. Thus, interest earnings potential for Grantees at CIRM’s expense is reduced to a negligible amount.

Purpose:

Subpart C. Budgetary Overlap: (Non-substantive amendment relocating provision for “Pre-Award Costs.”)

Purpose:

Subpart D. Prior Approval Requirements: This section outlines the requirements and responsibilities of PIs and Grantees for prior approval from CIRM for pre- and post-award changes to the research proposal. The amendments make clarifying technical changes and substantive process changes to reflect actual Grantee/PI and CIRM practices. The amendments pertain to changes in scope, the carrying forward of funds, no-cost extensions, rebudgeting, relinquishment of award and award transfer, change in PI or Co-PI status or percent effort, and submission of prior approval requests.

Rationale:

The amendments to subpart D.1 specify that CIRM's written approval comes in the form of a formal contract amendment, to make clear how the contract will be amended. The amendments to the Change in Scope provide grammatical clarity and include references to changes in milestones, which are a new concept to CIRM and thus have not been included in previous versions of the GAP. In light of the significance of milestones to the overall research goals that are funded by CIRM, changes to milestones are the proper subject for prior approval.

The amendments to subpart D.2 alter the trigger for prior approval to carry forward unspent funds. CIRM project size increases make a higher adjustment sensible, as the additional threshold is necessary to ensure good fiscal management of awards. In the case of larger projects, CIRM may decide to hold payment if the carry forward exceeds \$200,000, which may be far less than 25%. CIRM retains the ability to reschedule or postpone payments.

The amendments to subpart D.4 improve and clarify the requirements for prior approval for rebudgeting. After analyzing average budgets for the categories pertaining to Personnel and Supplies, CIRM determined that the \$5,000 threshold doesn't actually serve a useful purpose. Also, CIRM learned that the dual threshold was very confusing for Grantees. The 25% or \$100,000 threshold is responsive to Grantee comments, provides clear, consistent requirement and ensures that PARs are submitted for substantive changes, reducing the administrative burden on Grantees. In the "Consultants and Subcontracts" subpart, an analysis of average budgets revealed that the \$1,500 threshold was too low and PARs for very small changes were creating additional administrative burden for Grantees with little to no positive improvement of staff's ability to manage grants effectively. Amendments to "Equipment" reflect analysis that determined that the \$1,500 threshold creates needless administrative burden on Grantees. Revised threshold ensures CIRM ability to adequately manage changes to equipment budget. The deletion of the language regarding corresponding reductions in the next budget period is to allow for rebudgeting within total approved budget to ensure Grantee budget changes are motivated by research project needs and not about the impact of changes on Facilities or Indirect cost allocations.

The amendments to subpart D.5 add clarifying language to include the circumstance of transfer prior to issuance of the NGA. In addition, for purposes of CIRM accounting, it is important to have all Grant payments come directly from CIRM – the transfer of funds between institutions does not meet that requirement.

The amendments to subpart D.6 are clarifying changes to include reference to a Co-PI, and the amendment to subpart D.7 clarifies the information necessary to fully consider a PAR.

Purpose:

Subpart H. Reporting Requirements: The amendments to subpart H.2 specify the items that must be included in Progress Reports and states that CIRM will not issue payment for any subsequent budget period until it has received a Progress Report.

Rationale:

The changes to subpart H alert Grantees to applicable Reporting Requirements. The deletion of the language pertaining to payment for the subsequent Budget Period is redundant in light of language included in "Overdue Reports." Progress report timelines are changed in order to have a more robust progress report, the date for which is now pushed to include the full 12 month period instead of only 10 months. The publication list is deleted in light of the fact that the information is now gathered real-time via CIRM's online publication reporting module. The same applies to information gathered directly from the Technology Transfer Office.

Purpose:

Subpart I. Grant Close-Out: The amendments to this subpart clarify that CIRM will close out an Award after conclusion of the Project Period end date or the end date of any authorized extension after the PI and Grantee have submitted all required reports.

Rationale:

Final financial reports are due 90 days after close of the final budget period. Thus, the close-out takes place at a point after that 90 day period. The changes ensure GAP language accurately reflects CIRM process and practice.

SECTION VI. SPECIAL POLICIES FOR TRAINING GRANTS

Purpose:

Subpart B. Trainee Policy: The amendments to this subpart state that trainees appointed under a CIRM Training Program must be supervised by a faculty mentor or scientist of equivalent rank 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, a mentor may not be appointed to supervise more than two concurrent trainees from any CIRM training program at any one time. Prior to making a trainee appointment, Program Directors should consider the availability of the mentor to supervise a new trainee, including any possible overlaps with existing trainees that might result in exceeding this mentorship limit.

The amendments also indicate the parameters for Grantee institutions' policies for leave.

Rationale:

The amendment provides language to address concerns with Mentor over-commitment and provides clear guidelines for all participants. Consistent with federal approach and institutional practice, trainees may take parental leave and sick leave, following the Grantee institution rules. Other leaves of absence must be approved by CIRM and may require termination and reappointment.

Purpose:

Subpart C. Allowable Costs and Activities for Training Grants: The amendments to this subpart clarify the direct costs and indirect costs allowable for Training Grants. The amendments state that a trainee may not be concurrently supported with another fellowship or similar Award that provides a Stipend or otherwise duplicates provisions of the training grant Award; however CIRM trainees may accept supplemental funding from other sources to increase funds available to the individual trainee. The amendments also delete language regarding textbook costs and specify that limitations on uses of funds for the PD's salary will be specified in the RFA.

Rationale:

The amendment contains non-substantive technical changes and relocates language to a more logical placement within the policy. Because textbook access has changed, the language pertaining to text books is no longer necessary. The amendment regarding PD salary is the type of detailed program requirement best dealt with in the specific RFA.

Purpose:

Subpart D. Prior Approval Requirements for Training Grants: The amendments clarify the permitted use of stipends and state they cannot exceed the current published CIRM Stipend Caps using CIRM funds. The amendments delete unnecessary language regarding the carry forward of funds.

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Rationale:

The amendments provide clarify of existing practice to address Grantee concerns about uncertainty in these areas. The changes are consistent with the changes in the Financial Report section discussed above.

Purpose:

Subpart E. Reporting Requirements for Training Grants: The amendments delete language regarding the time for a Progress Report and statement about CIRM delay in subsequent Budget Period expenditures for failure to file reports.

Rationale:

The amendments align GAP with CIRM practice and reflect that CIRM no longer requires the CV for each trainee in the Annual Progress Report.

SPECIFIC PURPOSE OF REGULATION AND FACTUAL BASIS FOR AMENDMENTS TO REGULATION:

The Grants Administration Policy for Academic and Non-Profit Institutions (Non-Profit GAP) is required for effective grants management by CIRM. Further, the Non-Profit GAP is necessary for meeting the specific reporting requirements of the California State Legislature and also for disseminating the outcomes of funded research to interested constituencies and the general public. The Non-Profit GAP outlines statutory requirements applicable to CIRM and its working groups and those governing CIRM-funded research. The Policy also serves to guide Academic and Non-profit Grant recipients on their responsibilities as CIRM Grantees. Principal investigators, Program Directors, and Organizational Officials with grants management responsibilities may refer to pertinent sections for answers to questions that arise concerning the administration of the awards and compliance protocols. The amendments to the Non-Profit GAP are necessary to achieve the requirements and purposes discussed above.

CIRM formulated the amendments to the Non-Profit GAP over time in response to requests for clarification from Grantees and after experience administering funding pursuant to the Policy. Changes were also made so that the Policy will continue to reflect current practices both at CIRM and at analogous agencies including the U.S. Food and Drug Administration and National Institutes of Health. The amendments remove unnecessary reports or activities and streamline the administration of CIRM grant funds.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS:

CIRM did not rely upon any specific technical, theoretical or empirical studies, reports or documents in proposing the amendments to these regulations.

MANDATE FOR SPECIFIC TECHNOLOGIES OR EQUIPMENT:

The proposed amendments do not mandate the use of specific technologies or equipment.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES:

In view of information currently possessed, no reasonable alternative considered would be more effective in carrying out the purposes for which the amendments are proposed, or would be as effective as the amendments proposed.

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.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THAT WOULD LESSON ANY ADVERSE IMPACT ON SMALL BUSINESS:

CIRM has made the initial determination that the proposed amendments will not have an adverse impact on small business. The Non-Profit GAP applies to CIRM Grantees who are Academic Institutions and Non-Profit Institutions and who do not meet the definition of small business as defined in Government Code Section 11342.610.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS:

CIRM has made the initial determination that the proposed amendments will not have a statewide adverse economic impact.

ECONOMIC IMPACT ANALYSIS REQUIRED BY GOVERNMENT CODE SECTION 11346.3, SUBDIVISION (b)

CIRM has prepared the economic impact analysis required by Government Code section 11346.3, subdivision (b)(1).

TECHNICAL, THEORETICAL, and/or EMPIRICAL STUDY, REPORTS, OR DOCUMENTS RELIED UPON:

"Economic Impact Analysis"

Copies of the documents referenced above are available at the offices of CIRM located at 210 King Street, San Francisco, California, 94107.

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