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: September 22, 2014

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. November 2012)".

SECTION I. GENERAL INFORMATION:

Section I.C. Glossary of Defined Terms:

Purpose:

Amended to define "Patient Care Costs," merge the existing definitions of "Subcontract" and "Subaward," and delete "Subrecipient."

"Research Patient Care Costs" is defined as the same definition as found in the National Institutes of Health Grants Policy Statement, Part II.B.19 "Research Patient Care Costs," effective August 8, 2014, and incorporated therein. Such costs include but are not limited to, routine and ancillary services provided by hospitals to individuals participating in research programs. As set forth in Part II.B.19, Research Patient Care Costs do not include: (1) the otherwise allowable items of personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of individuals, including inpatients, outpatients, subjects, volunteers, and donors, (2) costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned laboratory) or laboratory tests performed at a medical school/university not associated with a hospital routine or ancillary service , (3) recruitment or retention fees or (4) the data management or statistical analysis of clinical research results.

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.

With regard to "Research Patient Care Costs," it is necessary in late-stage research projects that involve clinical trial expenditures to ensure that a proper accounting of costs is rendered against the permissible activities within the grant. By using the same definition as the federal government via the NIH policy, CIRM will use the standards already applicable to grantees that use federal funds, which will ensure a consistent application of rules and increase the likelihood of compliance.

Section I.D. Types of Support; and **I.F. Appeals of Scientific Review**

Purpose:

Amended to expand the grounds of appeals of scientific review as follows:

Outside of ICOC Programmatic Review, any challenges to a funding recommendation by the Grants Working Group (GWG) shall be filed pursuant to this section.

Under this policy, applicants for CIRM funding may appeal a GWG funding recommendation on the basis of 1) a financial or scientific conflict of interest with a reviewer; 2) a "material dispute of fact," or, 3) with respect to Translational Applications also seek reconsideration of a GWG funding recommendation based on "material new information," as set forth below. This policy does not apply to pre-applications or applications for conference grants or patent assistance funds.

Before filing an appeal or request for reconsideration, the PI/PD should carefully examine the GWG review report provided by CIRM. Any questions or concerns about the conduct of the review or appeals process must first be raised with the CIRM Review Office ("RO"). After the PI/PD has conferred with the RO, CIRM may then accept an appeal or request for reconsideration. Failure to confer with the RO before filing an appeal or request for reconsideration may result in an appeal or request for reconsideration being denied.

All appeals and requests for reconsideration shall be made in writing and shall be filed with the CIRM RO no later than ten (10) days after the review report was provided in writing to the PI/PD. An untimely appeal or request for reconsideration may be denied. Appeals and requests for reconsideration shall be limited to no more than a three (3) page narrative explaining the grounds for the appeal or request for reconsideration, exclusive of supporting documents, exhibits, or attachments.

1. ***Conflict of Interest.*** An applicant may lodge a formal appeal of the review if the applicant can show that a demonstrable financial or scientific conflict of interest had a negative impact on the review process and resulted in a flawed review. Differences of scientific opinion between or among PIs and reviewers are not grounds for appeal.

To lodge an appeal, the applicant must submit an appeal request in writing to the SRO or to the Director of Scientific Activities within 10 days of CIRM's making the review report available to the applicant. CIRM staff will then assess the merit of the request in consultation with the chair of the GWG and present a recommendation to the President of CIRM. If the chair of the GWG has a financial or scientific conflict of interest with the application that is the subject of the appeal, as determined by ICOC policy adopted pursuant to Health and Safety Code section 125290.50(e), a different scientific member of the GWG who has no financial or scientific conflict of interest will be consulted. The President of CIRM will then make the final decision on the merit of the appeal.

If an appeal is meritorious, the application will receive a new review by the GWG. A recommendation based on the new review will then be presented to the ICOC, which will

make the final decision on funding the application in question.

2. *Material Dispute of Fact.*

a. **Grounds for Appeal**. Grounds for an appeal (other than for a conflict of interest) are strictly limited to a "material dispute of fact." In order to demonstrate a material dispute of fact, the PI/PD must clearly and succinctly state facts establishing all of the following criteria: (1) the dispute involves the accuracy of a statement in the review summary; and (2) the dispute pertains to an objectively verifiable fact, rather than a matter of scientific judgment or opinion; and (3) the dispute was not resolved prior to or during the GWG meeting. A "material dispute of fact" does not include disagreements over interpretation or analysis of facts by the GWG or specialist reviewers.

b. **Review of Appeal**.

(i) CIRM staff will first determine whether the applicant has set forth clear grounds for an appeal pursuant to paragraph F.2.a., i.e., whether the PI/PD has set forth facts that demonstrate the occurrence of a material dispute of fact. If the PI/PD has NOT set forth clear grounds for an appeal, the appeal will be terminated, the applicant will be so informed in writing, and the GWG's recommendation will be presented to the ICOC without any further scientific review. If staff determines that the PI/PD has set forth clear grounds for an appeal, staff will initiate an investigation and ICOC consideration of the application will be deferred until a resolution is reached.

(ii). If staff determines that the PI/PD has set forth clear grounds for an appeal, staff will next assess whether or not the disputed fact was significant in the scoring of the application and could have affected the outcome of the GWG recommendation. In making this assessment, CIRM staff may consult with the review chair of the GWG and GWG scientists involved with the initial review of the application at issue, and/or may consult with additional scientific experts as needed. Based on that assessment, CIRM staff will present a recommendation to the CIRM President. CIRM's President will then make the final decision whether to grant an appeal based on the following factors: (1) whether the claims are substantiated; and (2) whether the disputed fact may have significantly affected the scoring of the application and may have affected the outcome of the GWG recommendation.

c. **Further Scientific Review**. If the President grants an appeal, the application will be referred to a GWG subcommittee consisting of not less than three scientific members of the GWG, including the GWG review chair, and not less than one patient advocate member of the GWG, for further scientific review. If the review chair has a conflict of interest with the application, a new review chair will be appointed by CIRM. Further scientific review shall be limited to an assessment by the scientific members of the subcommittee whether the disputed fact, if it had previously been correctly determined, would have changed or changes the GWG's funding recommendation. The recommendation of the scientific members of the

subcommittee, based on this assessment, will then be presented to the ICOC, which will make the final decision on funding the application in question.

3. ***Request for Reconsideration Based on Material New Information –Translational Applications ONLY***.

a. **Grounds for Reconsideration**. Grounds for reconsideration are strictly limited to "material new information" in connection with a Translational Application. A "Translational Application" means an application where the goal is to achieve a Development Candidate, an IND filing, or to complete a clinical trial. Requests for reconsideration based on material new information will not be entertained in connection with other applications for funding. In order to demonstrate the existence of material new information in connection with a Translational Application, the PI/PD must clearly and succinctly state facts establishing criteria (a) through (c), as follows: (a) the new information consists of one of the following: (i) approval by a regulatory body, such as the Food and Drug Administration, to initiate or continue a clinical trial; or (ii) a documented, enforceable agreement between the applicant and a commercial partner; or (iii) a final court decision or administrative action; or (iv) documentation confirming the availability of critical material(s) necessary to carry out the proposed project; (v) a manuscript containing relevant new scientific data that has been peer reviewed and published or peer reviewed and accepted for publication in final form; (vi) a filed patent application containing relevant new scientific data; or (vii) confidential data in the possession of a for-profit applicant that is unpublished but that the applicant is willing to make available for consideration of the application and (b) the new information became available to the applicant after the GWG review meeting at which the application was considered; and (c) the new information responds directly to a specific criticism or question addressed in the review summary.

b. **Review of Request for Reconsideration**.

(i) CIRM staff will first determine whether the application has set forth clear grounds for reconsideration pursuant to paragraph F.3.a., i.e., whether the PI/PD has stated facts that demonstrate the existence of "material new information" in connection with a Translational Application. If the PI/PD has NOT set forth clear grounds for reconsideration, the request will be terminated, the applicant will be so informed, and the GWG's recommendation will be presented to the ICOC without any further scientific review. If staff determines that the PI/PD has set forth clear grounds for reconsideration, staff will initiate an investigation and ICOC consideration of the application will be deferred until a resolution is reached.

(ii) If staff determines that the PI/PD has set forth clear grounds for reconsideration, staff will next assess whether or not the criticism or question addressed by the new information was likely significant in the scoring of the application and could have affected the outcome of the GWG recommendation had it been available at the time of the review. In making this assessment, CIRM staff may consult with the review chair of the GWG and GWG scientists involved with the initial review of

the application at issue, and/or may also consult with additional scientific experts as needed to evaluate the merit of the request. Based on that assessment, CIRM staff will present a recommendation to the CIRM President. CIRM's President will then make the final decision whether to grant a request for reconsideration based on the following factors: (1) whether the claims are substantiated; and (2) whether the new information addresses a criticism or question that may have significantly affected the scoring of the application and may have affected the outcome of the GWG recommendation had it been available at the time of the review.

c. **Further Scientific Review**. If the President grants a request for reconsideration, the application will be referred to a GWG subcommittee consisting of not less than three scientific members of the GWG, including the GWG review chair, and not less than one patient advocate members of the GWG, for further scientific review. If the review chair has a conflict of interest with the application a new review chair will be appointed by CIRM. Further scientific review shall be limited to an assessment by the scientific members of the subcommittee whether the new information, if it had been available previously, would have changed or changes the GWG's funding recommendation. The recommendation of the scientific members of the subcommittee, based on this assessment, will then be presented to the ICOC, which will make the final decision on funding the application in question.

Rationale:

These amendments provide are intended to provide clarity to the existing ground of appeal (conflicts of interest of reviewers) and expand the grounds on which to appeal.

Under this policy, appeals based on "material disputes of fact" and requests for "reconsideration based on material new information" are presented to CIRM staff, who determine whether the applicant has set forth clear grounds establishing the occurrence of a material dispute of fact or the existence of material new information, both as defined in the new policy. If staff determines that the applicant has made this showing, the President determines whether additional scientific review is warranted. If so, a subset of the Grants Working Group consisting of at least three scientific members and one Patient Advocate participates in the review and the scientific members determine whether or not the resolution of the material dispute of fact or the new information, would have, in their view, changed the Grants Working Group's recommendation. This new recommendation is then presented to the Board for its consideration. This process will provide efficiency by ensuring that grounds for dispute of scientific reviews are first presented to staff instead of initially at the meetings of the Board, where careful and thorough consideration is challenging.

SECTION V. PAYMENT AND USE OF FUNDS.

Purpose:

Subpart B. 2. Allowable Project Costs and Activities:

The amendments clarify the existing description of allowable project costs and activities to state that project costs are those costs that can be specifically identified with a CIRM-funded Project or Activity. Unless otherwise specified in an RFA or NGA, allowable project costs include salary for personnel (detailed below), fringe benefits, itemized supplies, Stipends and Tuition and Fees (as defined in chapter VI, section C, Allowable Costs and Activities for Training Grants), research animal costs, Consultants, itemized clinical study costs (including Research Patient Care Costs), travel-related expenses (detailed below), itemized project-related Equipment (as approved), publication costs, service contracts, Subcontracts, and specific, identifiable administrative costs where required to carry out the approved project. CIRM applies the OMB Circulars A-21 and A-133 cost allocation principles of reasonableness, allocability, consistency, and allowablity in determining whether cost under specific scenarios are allowable as a direct charge to a CIRM research grant. (For specific allowable costs related to training grants see chapter VI, section C, Allowable Costs and Activities for Training Grants.)

The amendments also implement the biennial adjustment to salaries as provided in the GAP.

Rationale:

The amendments clarify that Research Patient Care costs are now considered "allowable" project costs that may be charged to a grant. In addition, the amendments make clear that costs should be allocated in accordance with cost principles set forth in the federal Office of Management and Budget Circular A-21 (Cost Principles for Educational Institutions) and A-133 (Audits of States, Local Governments and Non-Profit Organizations). Relying on the federal cost principles is consistent with federal grants and lead to more efficient administration.

The amendments adjusting the salary caps are necessary to implement the biennial adjustment for inflation to reflect economic conditions presently.

Purpose:

Subpart B.4. Allowable Facilities Costs; and B.6. Indirect Costs.

Section B.4. is amended to define allowable facilities costs as those that cover general operating costs of the Grantee's facilities attributable to housing all elements of the CIRM-funded Project or Activity. Grantees may request two categories of facilities costs: (a) costs based on the Grantee's current, federally negotiated rates for Operation and Maintenance Expenses, and for Library Expenses; and (b)(1) costs based on the grantee's current, federally negotiated rates for depreciation or use allowances on buildings, capital improvements, and Equipment, and for interest on capital debt, as a proxy for a market lease rate of reimbursement (Health and Safety Code section 125292.10, subdivision (u)); or (b)(2) the actual out-of-pocket lease cost incurred by a Grantee if the Grantee leases space to conduct approved research; this cost must be reported in the Annual Financial Report (see chapter V, section H, part 1, Annual Financial Report). Grantees may request both categories (a) and (b) as allowable facilities costs. Rates from both categories shall be applied to the total allowable project costs exclusive of costs of Equipment, Tuition and Fees, Research Patient Care Costs, the total cost of service contracts in excess of $25,000 per Budget Period and the total cost of Subcontract and Consultant Fees in excess of $25,000 per Budget Period.

Conforming amendments are made to section B.6. to state that the specific percentage allowable for indirect costs for an RFA will be stipulated in the RFA. Per Proposition 71, Indirect Costs are limited to a maximum of 25 percent of allowable Direct Research Funding Costs, exclusive of the costs of Equipment, Tuition and Fees, Research Patient Care Costs, service contracts in excess of $25,000 per Budget Period and combined cost of Subcontract amounts and Consultant Fees in excess of $25,000 per Budget Period.

Rationale:

CIRM proposes to align itself with NIH policy and exclude the indirect cost bump when CIRM funds research patient care costs directly. When CIRM funds a grant, the amount of the grant is determined primarily by two sets of costs: direct and indirect. Generally speaking, direct costs are those for activities or services that benefit a specific project, e.g., salaries for project staff and laboratory supplies required for a particular grant project. Because these costs are easily traced to specific grant activities, they are charged to projects on an item-by-item basis and form the primary basis for a given budget. In contrast, indirect costs are those for activities or services that benefit more than one project. Their precise benefits to a specific project may be difficult or impossible to trace, such as the services of the accounting staff and research administrators. Indirect costs are applied as a percentage of the direct costs, and together with the direct project costs form the total budget of the grant.

There are some circumstances, however, where a given category of direct project cost is not subject to the additional indirect cost funding calculation – such as equipment or tuition costs that CIRM may pay for in a given grant. In the context of research patient care costs, NIH policy is to exclude these direct costs from indirect cost calculations. Thus, even where NIH pays for such activities directly in a grant, the NIH does not include the extra indirect funds on top. Currently, the GAP is silent on how to treat indirect funds to patient care costs.

CIRM proposes excluding or otherwise capping the amount of facilities and indirect costs allowed on service contracts. CIRM is funding more research projects that budget for expensive service contracts for which a Grantee can incur full facilities and indirect cost. These services happen largely outside the Grantee organization and do not require administrative costs in proportion to the size of the service contract, so excluding or otherwise capping the amount of facilities and indirect costs, similar to how we treat research subcontracts, is a more equitable calculation.

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.

Subpart 2 "Carry Forward of Funds" is amended to clarify that the threshold budget limits applies to the working budget for each PI and Co-PI budget.

Subpart 3 "No-Cost Extension" states that PIs and Grantees may be granted a one-time, no-cost extension of the Project Period end date of up to one year. CIRM will consider a request for a no-cost extension beyond 12 months for awards that fund clinical trials and pivotal IND-enabling activities, subject to approval of the ICOC based on a recommendation from the President. A request and justification for a no-cost extension must be submitted to the GMO in writing at least 30 days prior to the original Project Period end date.

Subpart 4 "Rebudgeting" is amended in the "Travel" subsection to increase the threshold amount for prior approval to $5,000 and delete the percentage threshold.

Subpart 6 "Change in PI or Co-PI Status or Percent Effort" is amended to state explicitly that leave's of absence requiring prior approval include requests for sabbaticals.

Rationale:

Currently the GAP allows a one-time no-cost extension of the Project Period end date of up to one year, upon a request and justification submitted at least 30 days prior to the end date. CIRM proposes allowing a no-cost extension greater than 12 months for awards that fund clinical trials and pivotal IND-enabling activities in extraordinary circumstances and subject to additional review including Presidential and Board approval. This additional layer will ensure visibility is maintained in high-dollar projects whose completion is time-sensitive.

The amendments to carry-forward are necessary to ensure uniform application of budget rules to both the PI and Co-PI.

The amendment to the Travel Rebudgeting item is intended to ensure only significant travel budgeting requests are subject to additional review.

The amendment regarding sabbaticals is important because the policy reflects the critical role that the Grantee institution and PI maintains on the grant and affirms CIRM's ability to ensure the ability of the team to fulfill the grant's objectives. While the GAP currently speaks to "leaves of absence" from an institution, CIRM proposes making explicit the interpretation of that language to include sabbaticals, which will require prior approval from CIRM to continue the award.

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 langue included in "Overdue Reports." Progress report timelines are changed in order to have a more robust progress report, the date for wish 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 ensures 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~~ies~~ 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.

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.

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

A. Documents or Laws:

1) "Economic Impact Analysis"; 2) "National Institutes of Health Grants Policy Statement, Part II.B.19 "Research Patient Care Costs"; 3) OMB Circular A-21: Cost Principles for Educational Institutions.

B. Public Input:

None.

Copies of the documents referenced above are available at the offices of CIRM located at 210 King Street, San Francisco, California, 94107. Alternatively, transcripts and agendas for public meetings identified above are available on CIRM's website, www.cirm.ca.gov.

MANDATE FOR SPECIFIC TECHONOLOGIES 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 receive funds from CIRM to perform research. As such, no private conduct or commercial activity by a business of any size is being regulated.

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. This action is not expected to have a direct impact on the creation or elimination of jobs, nor the creation of new businesses or elimination of existing businesses, nor the expansion of business currently doing business within the State of California because the amendments affect only administrative requirements regarding use of grant funds. The use of grant funds is required neither by law nor these regulations. To the extent the regulations facilitate use of the funds and encourage 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 amendments 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 amendments indirectly benefit the health and welfare of California residents who will benefit from such treatments and cures.

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

CIRM has prepared the economic impact analysis required by Government Code section 11346.3, subdivision (b)(1), a copy of which is available via the address indicated at the bottom of this document.

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.