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: August 10, 2015

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

SECTIONS AFFECTED: The proposed action adds section 100503 to Chapter 5 of Title 17 of the California Code of Regulations, and incorporates by reference the Grants Administration Policy for Clinical Stage Projects.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH AMENDMENT:

SECTION 100503 – GRANTS ADMINISTRATION POLICY for CLINICAL STAGE PROJECTS:

Purpose:

The purpose of Section 100503 is to describe the terms and conditions by which institutions who are California Institute for Regenerative Medicine ("CIRM") award recipients must abide during the term of the award.

Subdivision (a): This subdivision describes the scope of the regulation, indicating the regulation reaches all recipients of a grant, loan or guarantee from the California Institute for Regenerative Medicine ("CIRM") for Clinical Stage Projects (pursuant to Program Announcements PA 15-01, PA 15-02, and PA 15-03), who thereby agree to be bound by the terms and conditions of the CIRM Grants Administration Policy for Clinical Stage Projects. The subdivision incorporates by reference the CIRM's Grants Administration Policy for Clinical Stage Projects, which is anticipating final approval 2015.

Subdivision (b): This subdivision identifies which provisions of the policy are being incorporated by reference. The CIRM Grants Administration Policy for Clinical Stage Projects is incorporated by reference herein in its entirety as to Sections "II" through and including "VI". As to Section "I," only parts "I.B.," ("Abbreviations"), "I.C.," ("Defined Terms"), "I.D" ("Types of Support") and "I.E." ("Roles and Responsibilities") are incorporated by reference.

Subdivision (c): This subdivision indicates when amendments to the policy (effectuated by amendment to this regulation) are effective as to grants already funded and active. Amendments to this regulation and the policy incorporated herein will be applied to already active grants on the start date of the next budget period after the effective date of this regulation's amendment.

Subdivision (d): This subdivision indicates the term of enforcement of the policy and informs awardees that should the CIRM cease to exist the provisions of the regulation remain enforceable by the State of California.

Rationale:

Subdivision (a) is necessary to provide clarity in the scope of the policy – recipients of awards for Clinical Stage projects. Pursuant to the definition already provided in Proposition 71, the regulation reaches all grants, loans or guarantees from the CIRM. The subdivision establishes the rule that all covered recipients are bound by the terms and conditions of the policy.

Title 1 of the 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.

Subdivision (b): This section clarifies the specific sections of the policy which are being incorporated by reference, as permitted by Title 1 of the California Code of Regulations, section 20, subdivision (c)(5). Because the unincorporated parts of Section "I" of the policy are informational or background material only, they are not incorporated in the regulation.

Subdivision (c): This subdivision is necessary to address what will be a common-place circumstance, wherein active grants that may span several years will become subject from time to time to amendments to the policy. Once those amendments are effective (through amendment of the policy and the regulation incorporating it), the regulation clarifies that the amended policy will become effective as to existing grants at the start of the next budget period.

Subdivision (d): The rationale for this subdivision is to ensure that awardees are aware that the terms and conditions of the grant awards survive even in the event the CIRM should no longer exist.

DOCUMENT INCORPORATED BY REFERENCE:

CIRM GRANTS ADMINISTRATION POLICY FOR CLINICAL STAGE PROJECTS
VERSION: with a footer that dates the document as "Grants Administration Policy for Clinical Stage Projects - 2015".

SECTION I. GENERAL INFORMATION:

Purpose:
The incorporated sections set out a key to the abbreviations used throughout the document and contain a glossary of the terms. In addition, the roles and responsibilities of awardee organization staff are described.

Section I.B. Abbreviations: The purpose is to provide a key of commonly used acronyms.

Section I.C. Glossary: The definitions contained in this section shall apply to their respective terms used in the policy. Definitions of the following terms are set forth: Application, Approved Budget, Authorized Organizational Official, Award, Award Close-out, Awardee, CIRM-Funded Project or Activity, Clinical Research, Consultant, Covered Stem Cell Line, Direct Research Funding Costs, Equipment, Financial Report, For-Profit Organization, Grant, Human Embryonic Stem Cells, Human Subject, Indirect Costs, Key Personnel, Loan, Non-Profit and Not-for-Profit, Notice of Award, Operation and Maintenance Expenses, Operational Milestone, Organization, Other Support, Principal Investigator or Program Director, Prior Approval, Program Announcement, Progress Report, Project Period, Recipient Research Patient Care Costs, Scientific and Medical Research Funding Working Group, Subcontract/Subaward, Suspension Event and Tuition and Fees.

Rationale:

To make specific the language and terminology used in formulating these regulations.

Purpose:

Section I.D. Types of Support: The objective of clinical stage programs is to create a highly competitive partnering opportunity for promising stem cell-based projects to accelerate the completion of preclinical activities necessary to attain an active IND with the FDA, to initiate start-up activities of the proposed clinical trial, to accelerate the completion of a clinical trial, and support new activities on active projects that will significantly accelerate development of the proposed therapy or increase the likelihood of success.

Rationale: This section is intended to broadly describe the types of support and activities that comprise the focus of the clinical stage projects that are governed by this GAP.

Purpose:

Section I.E.1. Roles and Responsibilities – Awardee Organization Staff:
This section describes who on the awardee organization staff is an "authorized organizational official" and who is a principal investigator or program director. The section indicates the authorized official is a designated representative of the awardee whose signature of on the grant application certifies the accountability of the organization for appropriate use of funds and performance, as well as compliance with applicable state and federal laws governing the covered activity. The Principal Investigator ("PI") or Program Director ("PD") is the official charged with ensuring compliance with the financial and administrative aspects of the award. The PI must have a formal written agreement with the awardee organization identifying the official relationship between the two.

Rationale:
Roles and responsibilities of awardee organization staff are commonplace and addressed in similar policies of the National Institutes of Health ("NIH") and Special Research Programs at UCOP ("SRP"). In order to ensure proper oversight of CIRM grants, appropriate individuals within awardee institutions must be identified and charged with assuming responsibility for compliance with pertinent rules.

Purpose:

Section I.E.1. Roles and Responsibilities – Clinical Advisory Panel:
This section describes the Clinical Advisory Panel employed by CIRM. The Clinical Advisory Panels ("CAPs") are expert advisory panels created and appointed by CIRM's President to work closely with each CIRM-funded clinical and pre-clinical project to accelerate the successful development of therapies for patients with unmet medical needs. The CAPs will meet regularly with CIRM awardees to provide scientific, medical, and drug development advice, recommend real-time course correction if warranted, and facilitate a seamless transition from one stage of development to the next. Project teams will be required to submit all requested documents to CIRM in advance of the CAP meeting.

Rationale:
CAPs are an integral tool CIRM will use to develop and accelerate existing CIRM awards to ensure the best possible outcomes in the shortest time possible. By meeting regularly to address scientific, medical and drug development issues, the CIRM awards will be leveraged by outside expertise to resolve problems and identify opportunities for efficiency and success.

SECTION II. GRANT APPLICATION AND REVIEW PROCESS.

Purpose:

Subpart A. Eligibility: Eligibility requirements for applicants for CIRM funding must meet the described criteria. In addition, the subpart describes the educational requirements for service as a PI or PD. Any additional requirements specific to a given grant will be contained in grant announcements.

Subpart B. Application Submission: Identifies how grant funding opportunities will be announced by the CIRM, through the use of Requests for Applications ("RFA's"). The section

also indicates that a Letter of Intent may be required under specific RFA's prior to submission of a full application.

Subpart C. Legal Effect of Signed/Submitted Application: This subpart states that an authorized organizational official's signature on an application warrants that all eligibility requirements are met and that terms and conditions of an award will be followed.

Subdivision D. Budget Review: This section describes the process for evaluation of an applicant's proposed budget. When CIRM determines that a proposed budget differs significantly from market rates, adjustments to the budget will be required by CIRM prior to further review of the application. Applicants will be notified of the specific discrepancies and applications will not be forwarded for scientific review until an amended budget has been submitted and approved by CIRM. Additionally, project budgets may be subject to further adjustments prior to issuance of an award based upon assessments of the GWG, the CIRM team or by the Application Review Subcommittee of the ICOC.

Subpart E. Application Review: This section describes for applicants how applications are reviewed by the Scientific and Medical Research Funding Working Group ("SMRFWG").

Subpart F. Criteria for Review. Health and Safety Code section 125290.60, subdivision (c), requires evaluation of grant applications based on criteria established by the ICOC. The section identifies the eight standard criteria and identifies additional criteria in evaluating the entire portfolio of grant applications under review by the SMRFWG.

Subpart G. Appeals of Scientific Review: This subpart describes the process for applicants to appeal the review conducted by the SMRFWG.

Subpart H. Approval for Funding: This clarifies that it is the ICOC that makes all decisions regarding whether to fund a grant application.

Subpart I. Policy on Collection and Use of Personal Information: This section describes the CIRM's policy to respect the privacy of individuals. The section makes clear that the California Public Records Act may yet require the CIRM to disclose certain information.

Subpart J. Public Access to Public Records. This section clarifies CIRM's responsibilities for compliance with the California Public Records Act ("PRA") and describes specific provisions in Proposition 71 governing applicability of the PRA to the CIRM and the SMRFWG.

Rationale:

These subdivisions are necessary to meet statutory requirements of the CIRM and its working groups governing the retention and maintenance of records regarding CIRM-funded research, as well as to comply with the establishment and application of standards governing the criteria for evaluating grant applications. The description of the review process ensures awardees are aware of the expectations placed on them during the grant process and what can be expected of the CIRM during the evaluation of the applications.

SECTION III. PRE-AWARD AND AWARD.

Subpart A. Administrative Review.
Purpose: This aspect of the policy advises awardees of the nature and scope of administrative review of applications approved by the ICOC for funding. The reviews address the budget to ensure proposed costs are allowable and ensure all funding requirements are or can be met. Amended budgets to removed unallowable costs may be required. This section states that the ICOC may render conditional approvals of applications contingent upon awardee acceptance of a reduced project period or narrowed scope of work from that proposed in the application.

Rationale: Administrative review terms are specified in NIH policies and those of the SRP, for instance. These provisions ensure flexibility for both applicant and the ICOC in funding necessary research.

Subpart B. Liability.
Purpose: This section indicates, pursuant to Health and Safety Code section 125290.45, subdivision (a)(2), respective indemnity and liability rules applicable to CIRM awardees. The section identifies minimum insurance requirements to ensure compliance with the Health and Safety Code.

Rationale: CIRM does not assume responsibility for the conduct of activities that the grant supports or for the acts of the awardee. Accordingly, and as required by Proposition 71, awardees are required to assume liability responsibilities as outlined in this subpart.

Subpart C. Public Policy Requirements.
Purpose: This subpart identifies public policies governing certain activities upon which CIRM funding is contingent. This subpart requires conduct of research be compliant with existing federal and state requirements governing research misconduct, conflicts of interest, use of human stem cell lines, use of human fetal tissue, research involving human subjects, animal subjects, use of biohazardous materials, the sharing of intellectual property and the Proposition 71-mandated preference for California suppliers.

Rationale: These provisions are necessary to ensure adequate compliance with federal and state laws governing certain types of research. As part of its oversight function, the CIRM must identify those areas in which awardees are expected to give assurance of compliance so that CIRM is assured that funded research follows applicable rules.

Research misconduct and possible administrative remedies for misconduct are analogous to policies followed by the NIH, the American Cancer Society ("ACS"), Florida Department of Health and the Susan B. Komen Breast Cancer Foundation. Existing federal policy as embodied in Title 42, Code of Federal Regulations, Part 93, contain similar standards for such policies.

Requirements for research involving human subjects are based on Title 45, Code of Federal Regulations part 46, and policies of the NIH, the American Heart Association ("AHA"), the ACS and Department of Health and Human Services ("DHHS").

Subpart D. Just-in-Time Policy
Purpose:
Just-in-time procedures allow CIRM to defer review of certain required information until after an Application is approved for funding by the ICOC and prior to issuance of an NOA. When the required information is requested of the prospective Awardee, the information is to be submitted to CIRM.

Rationale: The just-in-time policy provisions allow for deferral of certain required information after approval of funding but before issuance of a Notice of Grant Award. These provisions are similar to those already in existence at the NIH and are familiar to institutions that accept federal funding for research.

Subpart E. Award Notice
Purpose: Once CIRM funding requirements are fully met, an NOA will be sent to the AOO designated in the Application. The NOA specifies the Project Period (start and end dates of the project or program) as well as the monetary allocations (itemized Direct Research Funding Costs (including Facilities costs) and an amount allocated for Indirect Costs). The NOA also incorporates this Grants Administration Policy and all other applicable CIRM regulations by reference and specifies any special terms and conditions of the Award. During the active award period, the NOA may be amended in response to Prior Approval Requests, failure to meet Operational Milestones, and/or occurrence of Suspension Events.

Rationale: The description of the process of the award notice ensures that applicants are aware of the procedural requirements of accepting an award and the conditions appurtenant thereto.

SECTION IV. AWARD ACCEPTANCE AND TERMS.

Subsection A. Award Acceptance:
Purpose:

This section states that an Award is accepted when an NOA is signed by the PI and AOO, and returned to and received by CIRM. In accepting an Award, the PI and Awardee assure CIRM that any funds expended under the Award will be for the purposes set forth in the approved Application. Further, the PI and Awardee agree to comply with terms and conditions of all applicable CIRM regulations, including this Grants Administration Policy. The NOA must be signed and returned to CIRM within 45 days (or more, if extended in writing by CIRM) of issuance. Payment will not be issued until the Awardee executes the NOA. If the PI or Awardee cannot accept the Award, including the legal obligation to perform in accordance with its provisions, they shall so notify CIRM in writing immediately upon receipt of the NGA/NLA.

Urgency is one of the component values of CIRM's mission. Therefore, the prospective Awardee is required to certify that they are able to initiate work on the funded project within 45 days of approval by the Application Review Subcommittee of the ICOC, unless this provision is waived in writing by the President.

Rationale:

This section is necessary to set forth the procedures for accepting a grant award and indicating the point at which an applicant becomes bound by the terms of this policy. The provisions regarding amendment of the policy are necessary to apprise awardees of the timing for application of amendments to the grants administration policy. The requirement of projects to be funded within 45 days ensures that successful applicants will be ready to go one the funding decision is made.

Subsection B. Terms:

Purpose:
This section describes the general requirements regarding the terms of the award related to cooperation with CIRM for meetings with the FDA, necessary co-funding requirements that are particular to a given Program Announcement, and describes the purposes and effect of operational milestones and suspension events. Finally, the section describes the process for returning unspent CIRM award funds at the end of the award.

Rationale:

By utilizing suspension events and operational milestones, CIRM is able to incentivize progress on CIRM awards and ensure risk for unanticipated events is places squarely on the Awardee.

Subsection C. Award Election

Purpose:
Under this section, recipients of CIRM's Clinical Stage Program awards have the option to treat their awards as loans within the earlier of the submission of an application for marketing approval by the Food and Drug Administration or seven years from the effective date of the award. Unless the parties agreed to different terms, the awardee would be required to repay the loan balance within ten days of making the loan election at a rate that would escalate based on the date of repayment. The loan election would become final only after the awardee has satisfied the terms of the election. If an awardee does not make this election, its award would be treated as a grant.

Rationale:
This program would advance CIRM's mission to accelerate the delivery of stem cell therapies to patients with unmet medical needs in three ways. First, it is designed to encourage industry involvement in the commercialization of CIRM-funded inventions by offering an alternative to the traditional grant and loan options. Second, it would create an incentive for awardees to repay CIRM early, so that the agency could use the proceeds to make new research awards. Finally, it would increase efficiency by eliminating the complexity of the loan program and reducing the administrative burden of negotiating a loan agreement with each loan recipient and maintaining and enforcing a separate administrative policy to cover loans.

SECTION V. PAYMENT AND USE OF FUNDS.

The purpose of this section is to describe the procedures that will guide how and when payments of grants will be made and the rules applicable in the expenditure by awardees of those funds.

CIRM funds shall only be used for expenditures necessary to carry out the approved project and activities. The section identifies specific allowable and unallowable costs that can be charged by awardees to the grant funds.

The section also describes the prohibition against budgetary overlap and prohibits the commingling of grant funds with an organization's other fund sources.

This section also describes the circumstances under which a CIRM awardee must seek prior approval from CIRM for departure from project activities described in the approved application. Prior approval is required for changes in scope of the research, for the carrying forward of funds from one grant year to the next, extensions of the project completion date, rebudgeting of funds from one section of the approved budget to another, the transfer of awards when the PI transfers to a new organization, the change in status of a PI and the procedures for submitting prior approval requests.

This section requires awardees to have property management systems for equipment and sets forth the circumstances when title to CIRM funded equipment vests in the awardee organization or the CIRM.

This section further provides that the awardee is responsible for keeping appropriate records documenting compliance with the terms and conditions of the award and providing for access by the CIRM other agencies for audit purposes.

This section states the prohibition against intentional deception or misrepresentation and requires awardees to report cases of fraud, waste or abuse under a CIRM grant. This section defines what constitutes fraud and abuse, as well.

Subpart H details the financial and programmatic reporting requirements. Awardees must report financial and scientific progress to CIRM on an annual basis. The annual programmatic report is due 60 days prior to each anniversary of the award start date indicated in the NGA. The subsequent budget period's funding will not be awarded until this report has been received, reviewed, and approved by the CIRM. In addition, the awardee must submit an annual financial report within 90 days after each anniversary of the award start date. Failure to provide reports may lead to a cessation of funding.

This section also addresses the procedures and expectations for close-out of a grant after the project period end date. Awardees remain obligated to return funds due as a result of refunds, corrections or other transactions.

Subpart J identifies the range of consequences for failure of compliance.

Rationale:

The requested information for reporting is required for effective grant management by the CIRM and for meeting specific reporting requirements of the California State Legislature. The CIRM is also responsible for disseminating the outcomes of funded research to interested constituencies, as well as to the general public.

Cost allocation formulae are necessary to ensure awardees and the public are aware of costs that are allowable and that can be assessed against the grant funds, ensuring proper expenditure of taxpayer-funded research. Prior approval requirements, which are similar to those of the NIH, AHA, SRP and JDRF, ensure that flexibility in the research process is balanced with proper oversight. Similarly, equipment management provisions, similar to those of the NIH, AHA, SRP, and ACS, ensure that awardees are aware of the consequences of expenditures for equipment and are able to plan accordingly.

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

The Grants Administration Policy for Clinical Stage Projects is required for effective grants management by CIRM. Further, this 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 GAP outlines statutory requirements applicable to CIRM and its working groups and those governing CIRM-funded research. The Policy also serves to guide award recipients on their responsibilities as CIRM Awardees. Principal investigators, Program Directors, and Organizational Officials with award management responsibilities may refer to pertinent sections for answers to questions that arise concerning the administration of the awards and compliance protocols. The GAP is necessary to achieve the requirements and purposes discussed above.

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

A. Documents or Laws:

1) "Economic Impact Analysis"

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 regulation does 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 regulation is proposed, or would be as effective as the regulation.

CIRM invites interested persons to present statements or arguments with respect to alternatives to the proposed action 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 action will not have an adverse impact on small business. The GAP applies to CIRM Awardees 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 action 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 regulation facilitates 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 policy 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 policy indirectly benefit the health and welfare of California residents who will benefit from such treatments and cures.

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

Economic Impact Assessment Per Government Code Section 11346.3, subdivision (b):

<u>For adoption of CIRM Grants Administration Policy for Clinical Stage Programs</u>

<u>Action:</u> The regulatory action enacts the CIRM grants administration policy that is applicable to Clinical Stage Programs (section 100503 and document incorporated thereby). The regulation states the requirements attendant to applying for, receiving and expending CIRM research funds. The action does not regulate a commercial or private activity of any individual or institution but reaches only administrative functions of institutions in connection with the use of CIRM research funds.

Impact:

Under section 3 of the "California Stem Cell Research and Cures Act," which established the California Institute for Regenerative Medicine, funds for this agency are continuously appropriated without regard to fiscal year and not subject to budgetary control. By statute, this agency requires strict fiscal and public accountability through mandatory independent audits.

CIRM has determined that that proposed regulatory action has no impact on small businesses. The regulation implements conditions on awarding grants for stem cell research. This research will be conducted almost exclusively by large public and private non-profit institutions, as well as large for-profit institutions. As such, and the regulations are not expected to adversely impact small business as defined in Government Code section 11343.610. Application for grant funds is voluntary and grant awards are required by Proposition 71 to include a prescribed additional amount to cover any costs associated with administration of the grant by grant recipients.

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 regulation 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 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 benefit the health and welfare of California residents who will benefit from such treatments and cures.

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.