

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

**INITIAL STATEMENT OF REASONS FOR THE
PROPOSED AMENDMENTS OF THE LOAN ADMINISTRATION POLICY INCORPORATED BY
REFERENCE BY SECTION 100800, AND SECTION 100800**

HEARING DATE: None scheduled.

CLOSE OF PUBLIC COMMENT: April 27, 2015

SUBJECT MATTER OF PROPOSED AMENDMENTS: Loan Administration Policy

SECTIONS AFFECTED: The proposed amendments apply to Chapter 8 and section 100800 of Title 17 of the California Code of Regulations, and specifically the document incorporated by reference therein.

AMENDMENT OF SECTION 100800:

The proposed nonsubstantive amendment to the text of section 100800 merely identifies the effective date of the substantive amendments to the policy incorporated by reference, which is the subject of this regulatory action.

DOCUMENT INCORPORATED BY REFERENCE BY SECTION 100800:

CIRM LOAN ADMINISTRATION POLICY

VII. LOAN TERMS

I. Forgiveness and Reinstatement of Product-Backed Loans

Purpose: The amendments add the following language to allow a CIRM loan recipient to convert its Loan to a Grant, as follows:

(3) In the event that CIRM has forgiven a Loan pursuant to subpart (1), above, the Loan Recipient may elect to convert its Loan to a Grant by notifying CIRM in writing of its election within one year of CIRM's forgiveness of the Loan, or for loans forgiven prior to the effective date of this provision, one year from the effective date. Upon CIRM's receipt of such notice, Loan Recipient's obligations under this section shall be extinguished and Loan Recipient's award shall be treated as a Grant subject to CIRM regulations governing Grants, including Chapter 6 (Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees), sections 100600, et seq.

Rationale:

In the event that the CIRM-funded project is not a successful, a Product-Backed Loan is automatically forgiven if, among other things, the loan recipient complies with reporting

requirements and abandons the project. Under these circumstances the loan recipient's obligation to repay the loan is extinguished. However, a loan that has been forgiven will automatically be reinstated in the event that the loan recipient obtains revenue arising in whole or in part from the CIRM-Funded Project. If the Loan Recipient's obligation to repay has been forgiven and if further activity results in a repayment obligation, the Product Backed Loan will automatically be reinstated under terms that the Intellectual Property and Industry Subcommittee approves. Because of this springing obligation, a loan recipient whose loan has been forgiven may be required to continue to carry the loan as a liability on its books indefinitely.

To provide clarity regarding future obligations, CIRM proposes giving existing loan recipients whose loan has been forgiven by CIRM the option to convert their loan to a grant and forego reinstatement of a forgiven loan. In this way, loan recipients will be automatically governed by the revenue sharing (and other) principles of the agency's intellectual property regulations in the event future revenue streams are realized. This will be particularly important in the event future revenues are realized after CIRM has exhausted its funding.

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

To provide clarity regarding future obligations, CIRM proposes giving existing loan recipients whose loan has been forgiven by CIRM the option to convert their loan to a grant and forego reinstatement of a forgiven loan. In this way, loan recipients will be automatically governed by the revenue sharing (and other) principles of the agency's intellectual property regulations in the event future revenue streams are realized. This will be particularly important in the event future revenues are realized after CIRM has exhausted its funding. In addition, Loan Recipients will not have to carry, possibly in perpetuity, a forgive loan on its books.

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

A. Documents or Laws:

None.

B. Public Input:

None.

Copies of the documents referenced above are available at the offices of CIRM located at 1999 Harrison Street, Oakland California, 94612. Alternatively, transcripts and agendas for public meetings are available on CIRM's website, www.cirm.ca.gov.

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. This regulation large academic and well-capitalized biotechnology institutions. As such, no private conduct or commercial activity by a business of any size is being regulated. Moreover, the amendments provide a voluntary option for Loan Recipients, and thus requires no action on the part of CIRM Loan Recipients.

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 internal operations. 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 GOVERNMENT CODE SECTION 11346.3, SUBDIVISION (b)

Action: The regulatory action amends the existing loan administration policy regulation (and the policy incorporated thereby) (section 100800). The amendments provide a CIRM research loan recipient with the option to extinguish it's obligations under the Loan Policy, and instead treat the loan as a Grant under the conditions identified. The action does not regulate a commercial or

private activity of any individual or institution but provides flexibility to CIRM loan recipients with flexibility in how it chooses to book its loan obligations.

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. The Act requires CIRM adopt rules to apply to Grants and Loans made by the agency.

CIRM has determined that that proposed regulatory action has no direct impact on small businesses. Virtually all applicants for CIRM funding are either large academic nonprofit institutions or well-capitalized biotechnology ventures. As such, the regulation is 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 loan and grant funds. The use of loan 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 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. Finally, to the extent that a loan recipient with a forgiven loan is able to convert that potential liability to a grant and remove the debt from its accounting, that will help loan recipients improve their financial standing.