

Interim CIRM Loan Administration Policy

Preface

The California Institute for Regenerative Medicine (CIRM) issues Requests for Applications for research grants, inviting applications from non-profit and for-profit organizations. Beginning in early 2009, CIRM intends to supplement its grant funding by offering research loans to for-profit organizations. This policy covers the procedures that will apply to research loans.

The Independent Citizen’s Oversight Committee (ICOC), CIRM’s governing board, has adopted the CIRM Grants Administration Policy for Academic and Non-Profit Institutions (Non-Profit GAP). The Non-Profit GAP applies generally to grant funding of scientific and medical research. The ICOC has also adopted the CIRM Grants Administration Policy for For-Profit Organizations (For-Profit GAP), which is applicable to for-profit organizations that apply for or receive CIRM funding through grants. The For-Profit GAP largely incorporates the Non-Profit GAP. Where differences between for-profit and non-profit organizations warrant different treatment, the For-Profit GAP provides the modified policies that apply to for-profit applicants and grant recipients.

This Loan Administration Policy (LAP) takes a similar approach, working from the Non-Profit GAP and setting out the modified policies that apply to CIRM loan funding of for-profit organizations. Note that this LAP does not incorporate the For-Profit GAP, which continues to apply to for-profit organizations to the extent that CIRM funds them through grants.

I. INCORPORATION BY REFERENCE

The Non-Profit GAP and all appendices, as they may be amended from time to time, are hereby made applicable to for-profit organizations that apply for or receive CIRM loans, to the extent that they do not conflict with the policies stated herein. Where differences between grants and loans warrant different treatment, this LAP provides the modified sections that apply to loans. All other provisions of the Non-Profit GAP apply to loans. When Non-Profit GAP provisions are applied to loans, “Loan” replaces “Grant” and “Loan Recipient” replaces “Grantee.”

The Non-Profit GAP and this loan administration policy statement may be updated periodically by CIRM. Any new or amended regulations adopted by the ICOC will be applied to currently active loans on the start date of the next budget period. Principal investigators, program directors and organizational officials with active CIRM loans will receive notification of revised loan terms and conditions or revised editions of the Non-Profit GAP and LAP as they are released. All revisions will be posted on the CIRM website (<http://www.cirm.ca.gov>).

CIRM’s right to enforce the provisions of this LAP shall survive the end of the term of the loan, and should CIRM no longer exist, those rights may be enforced by the State of California.

C. Defined terms

The following definitions supplement the definitions provided in the Non-Profit GAP.

Accrued Interest	Interest owed on the Loan.
Debtor	A For-Profit Organization that is responsible for repayment of a Loan. The Debtor may or may not be the Loan Recipient.
Earned Interest	Interest that a Loan Recipient earns on unspent funds that it has received from CIRM.
Loan	A funding mechanism with repayment provisions providing money and/or property to an eligible entity to assist the Loan Recipient in carrying out an approved project or activity. Loans may be Recourse or Non-Recourse.
Loan Balance	Amount determined by adding (1) the amount CIRM has distributed to the Loan Recipient pursuant to the Loan, and (2) Accrued Interest to date, and subtracting (3) any prepayment of the Loan Balance.
Loan Period	The time between the date of CIRM’s first release of funds pursuant to the Loan Award and the date when the loan must be repaid. This repayment deadline is different from the end of the research project – see “Project Period.”
Loan Recipient	An Organization that is the Recipient of an Award and that is legally responsible and accountable for the use of the funds provided and for the performance of the CIRM-funded Project or Activity. The Loan Recipient is the entire legal entity even if a particular component is designated in the NLA. The Loan Recipient may or may not be the Debtor.
Non-Recourse Loan	A Loan which the Loan Recipient organization is obligated to repay, subject to suspension or forgiveness of all or part of the loan based on the status of the CIRM-funded project.
Notice of Loan Award (NLA)	The document that notifies the Loan Recipient and others that an Award has been made, contains or references all terms and conditions of the Award as well as the Loan Recipient’s and PI’s agreement to those terms and conditions, and documents the commitment of CIRM funds.
Recourse Loan	A loan which the Loan Recipient organization is obligated to repay, notwithstanding the status of the CIRM-funded project.

D. Types of support

1. CIRM may offer support in the form of Grants or Loans. In an RFA for which the ICOC has budgeted less than \$3 million per award, CIRM will only offer Grants. For RFAs targeting larger awards, eligibility for each type of funding will be decided by the ICOC when it authorizes CIRM to prepare and issue the RFA. The ICOC may direct that an RFA offer only Grants, only Loans, or some combination, subject to the following guidelines.
2. The ICOC may provide that For-Profit Applicants are only eligible for Loans, or that they can choose between Grants and Loans. When a For-Profit Organization receives a Loan, that organization is both the Loan Recipient and the Debtor.
3. The ICOC may permit Non-Profit Applicants to apply for Loans, but only if the Application includes a Co-PI from a For-Profit Organization that agrees to be the Debtor. The Non-Profit Applicant would be the Loan Recipient.
4. The ICOC may require Loan funding for awards given to a Non-Profit Applicant with at least one Co-PI from a For-Profit Organization, if more than 40% of Direct Research Funding Costs (exclusive of the costs of Equipment, Tuition and Fees, and Consultant fees or Subcontract amounts in excess of \$25,000) is to go to For-Profit Co-PI Organizations. The ICOC may adjust the 40% threshold for a particular RFA.

This section supplements Section I.D. of the Non-Profit GAP.

E. Roles and Responsibilities

3. Financial Services Provider:

CIRM will engage the services of external financial services providers to perform specified functions related to the evaluation and administration of loans.

II. LOAN APPLICATION AND REVIEW PROCESS

A. Eligibility

1. PI and PD Eligibility

Principal Investigators (“PI”) or Program Directors (“PD”) from For-Profit applicants and Loan Recipients must be employed primarily by the For-Profit organization (i.e., at least 50% time) at the time of award and during the entire project period.

This requirement supplements the requirements of section II.A.1. of the Non-Profit GAP.

III. PRE-AWARD AND AWARD

C. Public Policy Requirements

9. Sharing of Publication-Related Biomedical Materials

CIRM Loan Recipients shall share biomedical materials first created with CIRM funding and described in published scientific articles for research purposes in California as specified in CIRM's Intellectual Property and Revenue Sharing regulations. Annual reporting requirements pertaining to CIRM-funded patented inventions and projects, which may extend 15 years beyond the project period, are also specified in CIRM's Intellectual Property and Revenue Sharing regulations.

This section supersedes Section III.C.9. of the Non-Profit GAP.

V. PAYMENT AND USE OF FUNDS

B. Costs and Activities

1. Allowable Project Costs and Activities

Allowable travel-related expenses include costs for transportation, lodging, subsistence, and related items incurred by key personnel on project-related business. Reimbursement for transportation expenses shall be based on the most economical mode of transportation (e.g., coach fare) and the most commonly traveled route consistent with the authorized purpose of the trip. Reimbursed lodging and subsistence expenses must be ordinary and necessary to accomplish the official business purpose of the trip. Excluding travel for clinical research or regulatory affairs, travel-related expenses shall be limited to an annual allowance of \$5,000 per person per CIRM award.

This section supersedes paragraph 3, section V.B.1. of the Non-Profit GAP.

3. Facilities Costs

Facilities costs cover general operating costs of the Loan Recipient's facilities that will house all elements of the funded project or activity. A fixed rate for facilities costs to for-profits organizations will be specified on a per-RFA basis. The fixed facilities cost rate shall be no higher than the average of the Category A and B facilities costs reported per fiscal year for Academic and Non-Profit Organizations.

This section supersedes section V.B.3. of the Non-Profit GAP.

5. Indirect Costs

Indirect costs will be up to 25 percent of allowable direct research funding costs awarded by CIRM (i.e., project costs and facilities costs), exclusive of the costs of equipment, consulting and subcontract amounts in excess of \$25,000, and will be specified on a per-RFA basis.

This section supersedes section V.B.5. of the Non-Profit GAP.

6. Interest Earned on CIRM Funds

Loan Recipients with Recourse Loans are not required to account to CIRM for interest earned on funds that CIRM advanced pursuant to the Loan award. Loan Recipients with Non-Recourse Loans must reinvest and account for interest earned as provided in the Non-Profit GAP. Interest earned on CIRM funds does not increase or decrease the amount required to be repaid.

D. Prior Approval Requirements

5. Relinquishment of Award and Award Transfer

A Loan Recipient may at any time relinquish an Award by submitting a relinquishing statement that includes a) a statement of reasons for relinquishing the award; b) an estimate of the unexpended balance of any funds paid to the Loan Recipient; c) and an assurance that all unexpended funds will either be returned to CIRM, or in the case of an Award transfer, transferred to a new Loan Recipient within 90 days of the date of relinquishment. In the case of a transfer, the relinquishing Loan Recipient may be required to transfer CIRM-funded equipment purchased with the Award.

With prior approval, and at the request of the Loan Recipient organization, the continuation of CIRM loan activities may be transferred to a different eligible organization in California in the event that:

- a. the PI transfers organizations
- b. the program is sold to another organization
- c. the CIRM Loan Recipient is acquired by another organization

The CIRM Loan Recipient must submit to CIRM a written request and justification that the prospective transferee organization has the intent and means to continue the proposed research – including access to intellectual property rights available at the original Loan Recipient. The request must be submitted at least 90 days before the proposed effective date of award transfer. If the initial request to transfer the award is approved, final approval will be contingent upon the current Loan Recipient relinquishing rights to the Loan. Furthermore, the Loan Recipient may be required to transfer to the new organization any equipment purchased under the Loan.

Before the transfer can take place, the original Loan Recipient must submit to CIRM a relinquishing statement that includes an estimate of the unexpended balance of any funds paid to the Loan Recipient and an assurance that all unexpended funds will be transferred to the new Loan Recipient or returned to CIRM within 90 days of the relinquishing date.

The transferee Loan Recipient must submit to CIRM a letter that states its intention to assume responsibility for the Award based on the approved application, including all applicable provisions of this Loan Administration Policy for For-Profit Organizations and CIRM's Intellectual Property and Revenue Sharing regulations, and the following items:

- a. New application face page with original signatures
- b. Detailed budget(s) for the remaining project period (including the estimated unexpended balance from the original Loan Recipient)
- c. Biographical sketches for new key personnel
- d. Other support for new key personnel
- e. Facilities and resources
- f. Public policy assurances (e.g., human subjects, animal, biohazard), where applicable.

The transferee Loan Recipient will be subject to the same financial and business evaluation as new Loan applicants. CIRM will not approve transfer of a Loan to an organization that does not meet CIRM underwriting standards.

CIRM will issue a new NLA to the PI and the transferee Loan Recipient when all required documents have been received and the transfer has been approved by CIRM. Transfer of the Award is effective when the NLA is signed by the PI and the Authorized Organizational Official of the transferee Loan Recipient and returned to and received by CIRM. Payment will not be issued until the Award transfer is effective.

As part of the new NLA, the transferee Loan Recipient assumes all loan repayment obligations of the relinquishing Loan Recipient. If the request to transfer the Award of a CIRM-funded program is not approved, CIRM may provide written notification of termination of the Award. The Loan Recipient will be required to submit a final report on the project and a final financial report within 90 days of the effective date of Award termination. All unexpended funds as of 30 days of the date of Award termination must be returned to CIRM within 120 days of termination of the Award. Further, the Loan Recipient shall continue to be responsible for all ongoing obligations of the award under CIRM's Intellectual Property and Revenue Sharing regulations.

This section supersedes section V.D.5. of the Non-Profit GAP.

H. Reporting Requirements

3. Other Reports

During the Loan Period and for 15 years after the end of the Loan Period, Loan Recipients must provide written notification to CIRM within 30 days of the occurrence of any of the post-Award changes described below:

- a.** Loan Recipients shall report to CIRM publications, inventions, patent applications, licensing and invention utilization activities that result from CIRM-funded research. Specific reporting requirements are detailed in CIRM's Intellectual Property and Revenue Sharing regulations.
- b.** Termination of a program that is currently funded by CIRM. The Loan Recipient organization will be required to submit a final report on the project and a final financial report within 90 days after the effective date of award termination. All unexpended funds as of 30 days after the date of award termination must be returned to CIRM within 60 days after termination of the award. Further, the Loan Recipient organization shall continue to be responsible for all ongoing obligations of the award under CIRM's Intellectual Property and Revenue Sharing regulations.

This section supersedes section V.H.3. of the Non-Profit GAP.

5. Reporting Related to Loan Terms

In addition to other reporting requirements, Loan Recipients and Debtors must notify CIRM of any event that would trigger accelerated Loan repayment pursuant to section VII.F, including initial public offerings and follow-on financing. Loan Recipients and Debtors must also provide any reports required by the terms of plans and terms agreed to pursuant to sections VII.G.2 and VII.H.

I. Project Close-Out

Close-out marks the end of the CIRM-funded research project. Project close-out has no effect on the date when Loan repayment is due. CIRM will close out a project as soon as possible after the project period end date or the end date of any authorized extension. Close-out includes timely submission of all required reports and reconciling amounts due the Loan Recipient or CIRM. CIRM may withhold funds from the Loan Recipient for future or concurrent Awards if a project close-out is pending the submission of overdue reports.

As part of close-out of a project funded by a Non-Recourse Loan, the Loan Recipient and Debtor must submit a plan for continued development of the project. CIRM approval of

the plan is necessary to complete close-out, and will be based on whether the plan, in the judgment of the President of CIRM, appropriately balances the considerations specified in Section 125290.30, subdivision (h), of the Health and Safety Code.

Close-out of a project does not cancel any requirements for property accountability, record retention, reporting or financial accountability. Following close-out, the Loan Recipient remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and CIRM may recover amounts based on the results of an audit covering any part of the funding period. In addition, the Loan Recipient is obligated to report to CIRM after project close-out any patents filed, patents issued, licenses granted, or income received that resulted from CIRM-funded research. (See CIRM's Intellectual Property and Revenue Sharing regulations.)

This section supersedes section V.I. of the Non-Profit GAP.

J. Failure of Compliance

If the Loan Recipient or PI fails to comply with the terms and conditions of a Loan Award, CIRM may take any of the actions that it could take for failure of compliance with a Grant Award, as described in section V.J. of the Non-Profit GAP. If CIRM determines that the failure justifies recovery of previously awarded funds, the Loan Recipient is fully liable for that obligation, without regard to whether the Loan is Recourse or Non-Recourse.

If a Loan Recipient is required to return funds due to failure of compliance, the returned funds will be deducted from the Loan Balance. Interest that accrued on those funds before they were returned to CIRM will not be deducted from the Loan Balance. Recovery of funds for failure of compliance does not affect CIRM's interest in the warrants issued when those funds were released.

This section supplements section V.J. of the Non-Profit GAP.

VII. LOAN TERMS

A. Recourse and Non-Recourse Loans

CIRM will offer two types of Loans: Recourse Loans and Non-Recourse Loans. Recourse Loans must be repaid to CIRM, with accrued interest, at the end of the Loan Period. For Non-Recourse Loans, repayment obligations are conditional, as described below. Evaluation of applications for Recourse Loans will consider the ability of the applicant organization to repay the loan.

B. Interest Rate

Each RFA that offers Loans will state the applicable interest rate, determined by the Finance Subcommittee of the ICOC. Interest is calculated as simple interest, from the date on which CIRM disburses funds to the Loan Recipient.

C. Warrants

1. Requirement

Debtors are required to issue stock warrants to CIRM. Warrants must be provided whenever CIRM disburses a portion of the total Loan amount. Debtors on Recourse Loans must provide warrants with a value equivalent to ten percent (10%) of the amount disbursed. Debtors on Non-Recourse Loans must provide warrants with a value equivalent to the lesser of (1) the full amount disbursed or (2) 20% of the Debtor's shares, on a fully diluted basis.

2. Warrant terms

If the Debtor is publicly held, the warrant strike price will be the closing price of the Debtor's common stock reported for the business day immediately before CIRM disburses funds. For privately held Debtors, the warrant strike price will be set at the share price from the most recent round of equity financing prior to ICOC approval of the Loan. If there has been no previous round, the warrants will be floated until the next round. The warrants are transferrable, may be exercised at any time, and expire 10 years from the date on which they are issued.

D. Loan Period

Debtors may elect a Loan Period of six years or ten years at the time of Application. The Finance Subcommittee may authorize CIRM to offer different Loan Periods in a particular RFA.

E. Repayment at End of Loan Period

Unless the repayment obligation has been accelerated, suspended or forgiven, the Loan Balance is due and payable to CIRM on the last day of the Loan Period. A Debtor may prepay the full amount of the Loan Balance, with accumulated interest, at any time, without penalty.

F. Loan Acceleration

A Loan will become due before the end of the Loan Period, upon the occurrence of certain events which trigger an obligation to repay to repay the Loan.

1. Change of Control

If there is a change of control of the Debtor, including a merger with a public or private company, and if the combined enterprise value exceeds

\$100 million, the Loan Balance becomes due and payable to CIRM 30 days after the effective date of the change of control.

2. Follow-on Financing

If the Debtor secures follow-on financing that exceeds \$60 million or 20 times amount of the Loan authorized by the ICOC, whichever is less, the Loan Balance becomes due and payable to CIRM 30 days after the close of financing.

3. Relinquishment or Termination

If the Loan Recipient relinquishes the Loan, or if CIRM terminates the Loan for any of the reasons stated in chapter V of the Non-Profit GAP and the LAP, the Loan Balance becomes due and payable to CIRM 90 days after the effective date of the relinquishment or termination.

4. Pivotal Trial

If the Loan Recipient, Debtor or a licensee begins a pivotal trial based on the CIRM-funded research, the Loan Balance becomes due and payable to CIRM six months after the start of the trial, but this acceleration trigger does not apply to Loans with a Loan Period shorter than 10 years.

G. Suspension and Forgiveness of Non-Recourse Loans

1. Project Abandonment

At any time prior to the end of the Loan Period, the Debtor may apply for suspension of all or part of the Loan, based on a showing that it has abandoned the project funded by CIRM. A project will be considered abandoned if, during the Project Period, CIRM has terminated the project or discontinued funding at a Go/No-Go decision point specified in the RFA and/or NLA. At or after the end of the Project Period, a project will be considered abandoned if the Debtor has determined that it is not commercially feasible to continue development of the product.

2. Suspension of Repayment

To apply for suspension of repayment, the Debtor must show that it has complied with all CIRM reporting requirements and audit requests. The Debtor must also submit a plan for access to and exploitation of any CIRM-Funded Invention* or CIRM-Funded Technology* arising from the Loan-funded project. Suspension of repayment will not be granted unless, in the judgment of the President of CIRM, the plan appropriately balances the considerations specified in Section 125290.30, subdivision (h), of the Health and Safety Code.

* Term defined in CIRM's Intellectual Property and Revenue Sharing Regulations

The Debtor must also agree to terms for full or partial repayment of the Loan Balance if the Debtor resumes development of the project or otherwise derives revenue from CIRM-Funded Invention* or CIRM-Funded Technology* arising from the Loan-funded project. Suspension of repayment will not be granted unless the terms for resumption of repayment are approved by the Finance Subcommittee of the ICOC, which will determine whether the proposed terms, under the circumstances of the project, appropriately balance the considerations specified in Section 125290.30, subdivision (h), of the Health and Safety Code. If further activity results in a repayment obligation under the agreed-upon terms, the Debtor must promptly notify CIRM and make whatever payments are owed under those terms.

3. Loan Forgiveness

Any Loan Balance which has not become due and payable 15 years after the end of the Project Period will be forgiven.

H. Extension of Loan Period for Non-Recourse Loans

The Debtor may apply to extend the Loan Period, and delay repayment, based on a showing that there has been a delay in the further development of the project. A project is delayed if technical or financial obstacles have impeded development of the project, and the Debtor organization has a viable plan to move development forward. The application for suspension must be submitted to CIRM no later than 30 days before the end of the Loan Period. It must explain the current development plan, and demonstrate complete compliance with all CIRM reporting requirements. The application may be granted if, in the judgment of the President of CIRM, the application demonstrates that the extension is necessary to allow a viable development plan to proceed.

If the Loan extension application is granted, the Loan Period will be extended by up to two years to accommodate the new development plan. A Debtor organization may apply for an additional two-year extension at the end of an extended loan term. There is no fixed limit on the number of extensions available. Extended loans continue to accrue interest.

I. Loan Application Process

1. CIRM Loan Application Form

By the application deadline for an RFA that offers Loan funding, a Loan applicant must submit a Loan application form. The applicant must indicate its preference among available Loan terms for that RFA, e.g., Recourse, Non-Recourse, Loan Term, etc. If an Application seeks Recourse Loan funding for a project with scientific merit, the ICOC may deny the Application if the applicant does not meet the credit standards for Recourse Loans. Accordingly, applicants that prefer Recourse Loans must indicate whether they would accept Non-Recourse Loan funding as an

alternative. Applicants must also indicate on the application whether they seek a Loan Period of six or ten years (or other Loan Period that the Finance Subcommittee has authorized for the RFA). If a Loan applicant is a Non-Profit Organization, the loan application form must be submitted by the proposed Debtor.

2. Financial Feasibility Review

CIRM will assign each Loan applicant (or Debtor) to a Financial Services Provider. Each applicant or Debtor will work directly with a Financial Services Provider to provide the financial and business information that the Financial Services Provider needs to evaluate the applicant's ability to manage and repay CIRM funds. The Financial Services Provider will collect from the applicant a processing fee to offset the cost of financial feasibility review.

J. Loan Administration Fee

During the Loan Period, CIRM may charge each Debtor a loan administration fee to offset the cost of loan administration by a Financial Services Provider.

K. Intellectual Property and Revenue Sharing Regulations

Except as provided in section VII.E.1.b. (regarding suspension of Non-Recourse Loans), Loan Recipients are not subject to the revenue sharing provisions of CIRM's Intellectual Property and Revenue Sharing regulations. In all other respects, Loan Recipients are subject to the same intellectual property regulations as Grantees.