

Agenda Item # 3 LAP REDLINE
1/21/09 Finance Subcommittee

Redline comparing 1/20/09 draft to 11/17/08 draft

Interim CIRM Loan Administration Policy for For-Profit Organizations

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.

Author
Deleted: science
Author
Deleted: grant funding of program costs.

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.”

Author
Deleted: a

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>).

**Agenda Item # 3 LAP REDLINE
1/21/09 Finance Subcommittee**

Redline comparing 1/20/09 draft to 11/17/08 draft

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.

Author
Deleted: and all of its appendices

C. Defined terms

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

Accrued Interest	Interest owed on the Loan.
Earned Interest	Interest that a Loan Recipient earns on <u>unspent</u> 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 Recipient in carrying out an approved project or activity. Loans may be Recourse or Non-Recourse.
Loan Period	The time between the start of the CIRM funded project 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.
Non-Recourse Loan	A loan which the Loan Recipient organization is obligated to repay, subject to <u>suspension</u> of all or part of the loan based on the <u>status</u> 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 <u>status</u> of the CIRM-funded project.

Author
Deleted: forgiveness

Author
Deleted: outcome

Author
Deleted: outcome

D. Types of support

CIRM will provide funding to Non-Profit applicants in the form of Grants. In an RFA for which the ICOC has budgeted less than \$3 million per award, CIRM will fund For-Profit applicants through Grants. RFAs with budgets at or above \$3 million per award will state whether For-Profit applicants may apply only for Loan funding, only for Grant funding, or for either.

Author
Deleted: offer Loans to For-Profit applicants, and Grants to

Author
Deleted: ,

Author
Deleted: those RFAs that include preclinical development and or clinical investigation. Other RFAs will continue to offer only grant funding to For-Profit and Non-Profit applicants.

**Agenda Item # 3 LAP REDLINE
1/21/09 Finance Subcommittee**

Redline comparing 1/20/09 draft to 11/17/08 draft

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

Author

Deleted:

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., greater than 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

Author

Deleted: <#>Organizational Eligibility -

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](#).

Author

Deleted: the CIRM

Author

Deleted: Requirements for For-Profit Organizations (Appendix B).

Author

Deleted: Appendix B

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

**Agenda Item # 3 LAP REDLINE
1/21/09 Finance Subcommittee**

Redline comparing 1/20/09 draft to 11/17/08 draft

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

**Agenda Item # 3 LAP REDLINE
1/21/09 Finance Subcommittee**

Redline comparing 1/20/09 draft to 11/17/08 draft

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:

Author
Deleted: another

- a. a PI transfers organizations
- b. a program is sold to another organization
- c. a 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.

Author
Deleted: no less than 90 days before the effective date of award transfer

Author
Deleted:

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 provisions of this Loan Administration Policy for For-Profit Organizations and CIRM's Intellectual Property and Revenue Sharing regulations, and the following items:

Author
Deleted: the CIRM

Author
Deleted: Requirements for For-Profit Organizations

- 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

**Agenda Item # 3 LAP REDLINE
1/21/09 Finance Subcommittee**

Redline comparing 1/20/09 draft to 11/17/08 draft

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 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 60 days of 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.

Author
Deleted: the CIRM
Author
Deleted: Requirements for For-Profit Organizations

Author
Deleted: the CIRM Intellectual Property Policy for For-Profit Organizations (Appendix B)

Author
Deleted: the CIRM
Author
Deleted: Requirements for For-Profit Organizations

**Agenda Item # 3 LAP REDLINE
1/21/09 Finance Subcommittee**

Redline comparing 1/20/09 draft to 11/17/08 draft

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

5. Repayment Acceleration Triggers.

In addition to other reporting requirements, Loan Recipients must notify CIRM of any event that would trigger accelerated Loan repayment, including initial public offerings and follow-on financing.

I. Project Close-Out

Close-out marks the end of the CIRM-funded research project. Project close-out has no effect on repayment dates or obligations. 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.

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 when calculating the amount of Loan repayment, but the Loan Recipient must pay interest that accrued on those funds before they were returned to CIRM. Recovery of funds for failure of compliance does not affect CIRM's interest in the warrants issued when those funds were released.

Author
Deleted: (see Appendix B, CIRM)

Author
Deleted: Requirements for For-Profit Organizations).

**Agenda Item # 3 LAP REDLINE
1/21/09 Finance Subcommittee**

Redline comparing 1/20/09 draft to 11/17/08 draft

Funds returned for failure of compliance are deducted from the Loan balance for purposes of calculating Loan repayment.

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

Loan Recipients are required to issue stock warrants to CIRM. Warrants must be provided whenever CIRM disburses a portion of the total Loan amount. Recipients of Recourse Loans must provide warrants with a value equivalent to ten percent (10%) of the amount disbursed. Recipients of Non-Recourse Loans must provide warrants with a value equivalent to the full amount disbursed. CIRM will not require or accept warrants for more than 20% of the Loan Recipient's shares, on a fully diluted basis.

2. Warrant terms

If the Loan Recipient is publicly held, the warrant strike price will be the closing price of the Loan Recipient common stock reported for the business day immediately before CIRM disburses funds. For privately held Loan Recipients, 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

Author
Deleted: Applicant Organization
Author
Deleted: if the CIRM-funded project does not succeed

Author
Deleted:

Author
Deleted: do not

**Agenda Item # 3 LAP REDLINE
1/21/09 Finance Subcommittee**

Redline comparing 1/20/09 draft to 11/17/08 draft

Loan Recipients 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. Loan Repayment

1. End of Loan Period

a. Recourse Loans

Within 30 days after the end of the Loan Period, the Loan Recipient must repay to CIRM the full amount of the outstanding Loan, along with all Accrued Interest.

b. Non-Recourse Loans: Project Abandonment

Within 30 days after the end of the Loan Period, the Loan Recipient is expected to repay to CIRM the full amount of the outstanding loan, along with all Accrued Interest. However the Loan Recipient 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 is abandoned if the Loan Recipient organization has no plan for further development of the project. The application for suspension must be submitted to CIRM no later than 30 days before the end of the Loan Period, and must demonstrate complete compliance with all CIRM reporting requirements. The application will be granted if, in the judgment of the President of CIRM, the Loan Recipient organization has complied with all terms of the Loan and with CIRM regulations.

Author
Deleted: the
Author
Deleted: loan has failed. Each RFA will define project failure for Awards under that RFA.

If the Loan suspension application is granted, the repayment obligation is suspended. To the extent that the CIRM-funded project produces revenue in the future, the Loan Recipient must comply with the revenue sharing provisions of CIRM's Intellectual Property and Revenue Sharing regulations. Payments to CIRM under that Policy will constitute repayment of the Loan, Suspended loans continue to accrue interest.

Author
Deleted: Revenue Sharing
Author
Deleted: Requirements for Non-Profit and For-Profit Grantees.

c. Non-Recourse Loans: Project Delay

Within 30 days after the end of the Loan Period, the Loan Recipient is expected to repay to CIRM the full amount of the outstanding loan, along with all Accrued Interest. However the Loan Recipient may apply for extension of all or part of the Loan, based on a showing that there has been a delay in the project funded by CIRM. A project is delayed if technical or financial obstacles have impeded development of the project, and the Loan Recipient 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

Author
Deleted: , and will be capped at the amount of the outstanding Loan, plus interest that had accrued at the end of the Loan Period

**Agenda Item # 3 LAP REDLINE
1/21/09 Finance Subcommittee**

Redline comparing 1/20/09 draft to 11/17/08 draft

compliance with all CIRM reporting requirements. The application will 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 Loan Recipient 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.

2. Payment acceleration triggers

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 CIRM the full amount of the outstanding loan, along with all accrued interest.

a. Change of Control

If there is a change of control of the Loan Recipient, including a merger with public or private company, and if the combined enterprise value exceeds \$100 million, the Loan becomes due 30 days after the effective date of the change of control.

b. Follow-on Financing

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

Author
Deleted: Initial Public Offering

Author
Deleted: makes an initial public offering in excess of \$20

Author
Deleted: ,

Author
Deleted: IPO

c. 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 becomes due 90 days after the effective date of the change of relinquishment or termination.

d. Additional Triggers for Ten Year Loans

i. The Loan becomes due 90 days after the Loan Recipient submits to the FDA Investigation Device Exemption application based on the CIRM-funded research.

Author
Deleted: i. If the Loan Recipient secures follow-on financing in an amount at least 20 times amount of the Loan authorized by the ICOC, the Loan becomes due 30 days after the close of financ[... [1]

ii. The Loan becomes due six months after the Loan Recipient begins the first pivotal trial based on the CIRM-funded research.

Author
Deleted: i

Author
Deleted: a

Author
Deleted: or files an IND application

3. Prepayment

**Agenda Item # 3 LAP REDLINE
1/21/09 Finance Subcommittee**

Redline comparing 1/20/09 draft to 11/17/08 draft

Loan Recipients may prepay the full amount of the Loan, with accumulated interest, at any time, without penalty.

F. Loan Application Process

1. CIRM Application Form

On the form that all applicants complete in response to an RFA that offers Loan funding, Applicants must indicate a preference for Recourse or Non-Recourse Loans. 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).

2. Financial Feasibility Review

CIRM will assign each Loan applicant to a Financial Services Provider. Each applicant 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.

Author
Deleted: Applicant

G. Loan Administration Fee

CIRM may charge each loan recipient a loan administration fee to offset the cost of loan administration by a financial services provider.

H. 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 for-profit Grantees.

Author
Deleted: regulation.

Author
Deleted: APPENDIX A. CIRM MEDICAL AND ETHICAL STANDARDS .