

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 loan administration policy statement may be updated periodically by CIRM. Any new or amended regulations adopted by the ICOC will be applied only to loans awarded after the amendments are adopted, unless CIRM and the Loan Recipient agree otherwise. All revisions to the LAP 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.
Change of Control	In the event of a sale, merger, transfer, exchange or other disposition (whether of assets, stock or otherwise) of a majority or controlling ownership position.
Borrower	A For-Profit Organization that is responsible for repayment of a Loan. The Borrower may or may not be the Loan Recipient.
CIRM-funded Project	The research project described in the Notice of Loan Award
Company-Backed Loan	A loan which the Loan Recipient organization is obligated to repay, notwithstanding the status of the CIRM-funded project.
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 Company-Backed or Product-Backed.
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 Borrower.
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.
Product-Backed 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.

D. Types of support

1. CIRM may offer support in the form of Grants or Loans. Eligibility for each type of funding will be decided on a case-by-case basis prior to issuance of the Request for Applications (“RFA”). Unless otherwise determined by the Finance Subcommittee of the ICOC, based on the recommendation of the President, CIRM will not offer loans in connection with RFAs for which the ICOC has budgeted less than \$3 million per award.
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 Borrower.
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 Borrower. The Non-Profit Applicant would be the Loan Recipient.
4. An RFA may place other restrictions or conditions on eligibility, such as requiring the Investigational New Drug application (“IND”) holder of a CIRM Funded Project to be the Loan Recipient.

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. Unless otherwise provided in an RFA, the Loan Recipient shall be required to cover certain or all costs incurred on CIRM’s behalf by the Financial Services Provider.

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.

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 4, 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 Company-Backed Loans are not required to account to CIRM for interest earned on funds that CIRM advanced pursuant to the Loan award. Loan Recipients with Product-Backed 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.

This section supersedes section V.B.6. of the Non-Profit GAP.

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 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.

CIRM will issue a new Notice of Loan Award ("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 regulations.

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

H. Reporting Requirements

3. Other Reports

During 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:

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 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 Borrowers must notify CIRM of any event that would trigger accelerated Loan repayment pursuant to section VII.F. Loan Recipients and Borrowers shall also report initial public offerings and follow-on financing.

I. Project Close-Out

Close-out marks the end of the CIRM-funded Project. Project close-out has no effect on the date when Loan repayment is due. CIRM will close out a CIRM-funded 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 Product-Backed Loan, the Loan Recipient and Borrower 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 reasonable 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 Company-Backed or Product-Backed.

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. Company-Backed and Product-Backed Loans

CIRM will offer two types of Loans: Product-Backed Loans and Company-Backed Loans. Company-Backed Loans must be repaid to CIRM, with accrued interest, at the end of the Loan Period, regardless of whether the CIRM-Funded Project results in any revenues. Repayment of a Product-Backed Loan is predicated upon the success of the product being developed.

The following are guidelines for Loan Terms. Specific terms will be determined in each RFA by the the Finance Subcommittee of the ICOC, based on the recommendation of the President, as appropriate for each RFA. If the Finance Subcommittee does not modify these guidelines for a specific RFA, the terms set forth herein shall apply to the RFA.

Funding of the loan will occur at intervals set forth in the Notice of Loan Award and only upon satisfaction of conditions set forth in the Notice of Loan Award. A delay in meeting timelines will not automatically result in acceleration or termination of the loan, but it could result in a delay or suspension in the disbursement of additional funds.

B. Interest Rate

Unless otherwise provided in the RFA,

- i. The interest rate for a 5 year loan term shall be LIBOR plus 2%.
- ii. For each additional year of the Loan Term beyond the 5th year, the interest rate of the Loan shall increase by: 1% in year 6; 2% in year 7; 3% in year 8; 4% in year 9; and 5% in year 10.
- iii. The interest rate shall not exceed the maximum interest rate permitted by law.

Interest **shall be** compounded annually, from the date on which CIRM disburses funds to the Loan Recipient.

C. Warrants

1. Requirement

a. Company-Backed Loans: A Loan Recipient that is awarded a Company-Backed Loan shall provide warrants to CIRM equal to the lesser of 20% of Loan Recipient's shares, fully diluted and

- iv. 10% of the Loan Amount if Loan Recipient shows a profit for previous 2 years
- v. 25% of the Loan Amount -if Loan Recipient has BOTH: (a) raised in prior financings since its inception three times the total amount of the loan; AND (b) has entered into a contractual arrangement (still in effect) with a biotechnology or pharmaceutical company which requires the payment of licensing revenues or milestone payments predicated on the success of a funded project (regardless of whether it is a CIRM Funded Project).
- vi. 50% of the Loan Amount if Loan Recipient has met only one of the two requirements set forth above in section C.1(a)(v)
- vii. 75% of the Loan Amount if none of the criteria set forth above in Section C.1(a)(v) are satisfied

b. Product-Backed Loans: A Loan Recipient that is awarded a Product-Backed Loan shall provide warrants to CIRM equal to the lesser of 20% of Loan Recipient's shares, fully diluted and

- i) 50% of the Loan Amount if the Loan Amount is less than 50% of the total funds required to complete the CIRM-funded Project as set forth in the Notice of Loan Award.
- ii) 60% of the Loan Amount if the Loan Amount is less than 75% of the total funds required to complete the CIRM-Funded Project as set forth in the Notice of Loan Award.
- iii) 100% of the Loan Amount if the Loan Amount represents more than 75% of the total funds required to complete the CIRM-Funded Project as set forth in the Notice of Loan Award.
- iv) For the purposes of Section C.1(b)(i), (ii) and (iii), the "total funds required to complete the CIRM-funded Project" shall be determined as of the date of the execution of the Notice of Loan Award and shall be

calculated using the indirect cost reimbursement rate specified in the Grants Administration Policy.

2. Warrant terms

If the Borrower is publicly held, the warrant strike price will be the closing price of the Borrower's common or preferred stock reported for the business day immediately before each CIRM disbursement of funds, depended upon whether CIRM selects common or preferred stock warrants. For privately held Borrowers, the warrant strike price will be set at the share price from the most recent round of equity financing before each disbursement of CIRM funds. 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. Warrants may be of either common or preferred stock, as determined by CIRM in its sole discretion.

D. Loan Period

The term of CIRM loans shall be 5 years, subject to modification on an RFA by RFA basis by the Finance Subcommittee, based on the recommendation of the President. The Loan Recipient may extend the term of the loan up to a maximum term of 10 years, provided that it agrees to be bound by the provisions set forth below in Section H. A term of more than ten years shall require the approval of the Finance Subcommittee, based upon the recommendation of the President.

E. Prepayment and 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 Borrower may prepay the full amount of the Loan Balance, with accumulated interest, at any time, without penalty.

F. Loan Acceleration

In the event of any change of control, CIRM shall have the right but not the obligation to accelerate repayment of the Loan. This decision shall be made by the Finance Subcommittee, based on the recommendation of the President. If the proposed change of control is not a matter of public knowledge, the Finance Subcommittee shall consider the matter in closed session to protect the confidentiality of the proposal.

G. Suspension and Forgiveness of Product-Backed Loans

1. Project Abandonment

At any time prior to the end of the Loan Period, the Borrower 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 Borrower 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 Borrower must show that it has complied with all CIRM reporting requirements and audit requests. The Borrower 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.

The Borrower must also agree to terms for repayment of the Loan Balance if the Borrower 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 and amount 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 Borrower 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. Conditions and Notice for Extension of Loan

A Loan Recipient may extend the term of its five-year loan according to the conditions of this Section. The Loan Recipient must provide notice of its intent to extend the loan term at least 90 days prior to end of the Loan Term. The term may be extended on a year by year basis up to 10 years in the sole discretion of Loan Recipient, subject to satisfaction of scientific and financial milestones, the absence of an event of acceleration,

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

and compliance with terms of Notice of Loan Award. Payment of interest Accrued for a Five (5)-year Loan will occur as follows:

- A. Years 1 -5: interest accrues, no payment due
- B. Year 6: Recipient owes 25% of unpaid, accrued interest paid out over the 6th year in 4 equal quarterly payments; remaining interest is accrued
- C. Year 7: Recipient owes 25% of unpaid, accrued interest paid out over the 7th year in 4 equal quarterly payments; remaining interest is accrued
- D. Year 8: Recipient owes 25% of unpaid, accrued interest paid out over the 8th year in 4 equal quarterly payments; remaining interest is accrued
- E. Year 9: Recipient owes 25% of unpaid, accrued interest paid out over the 9th year in 4 equal payments; remaining interest is accrued.
- F. Year 10: Recipient owes 25% of unpaid, accrued interest paid out over the first 3 quarters in 3 equal payments; principal and remaining unpaid accrued interest are due at end of year 10.

I. Subordination

In the case of a Product-Backed Loan, unless additional debt is used to support the CIRM-Funded Project, CIRM will not subordinate to company-wide debt without the consent of the Finance Subcommittee, based on the recommendation of the President. Such consent may not be unreasonably withheld.

J. 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., Product-Backed or Company-Backed, etc. If an Application seeks a Company-Backed Loan for a project with scientific merit, the ICOC may deny the Application if the applicant does not meet the credit standards for such Loans. Accordingly, applicants that prefer Company-Backed Loans must indicate whether they would accept Product-Backed Loan funding as an alternative. If a Loan applicant is a Non-Profit Organization, the loan application form must be submitted by the proposed Borrower.

2. Financial Feasibility Review

CIRM will assign each Loan applicant (or Borrower) to a Financial Services Provider. Each applicant or Borrower 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.