

CIRM Loan Administration Policy **(Rev. 9/2011)**

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~~ supplemented 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.

Purpose

Proposition 71 requires CIRM to balance the benefit of receiving revenues for the state of California from inventions made in whole or in part from CIRM funding with the need to ensure that essential research is not unreasonably hindered by CIRM regulations. The LAP regulations strike that balance by ensuring that our awardees and future investors are allowed and incentivized to determine how best to exploit new technologies, while simultaneously ensuring that CIRM receives a fair return on its investment. This balance is based on two important principles: 1) The greatest economic return to the state's general fund and its citizens will result from the discovery and successful commercialization of therapies and cures; and 2) The involvement of the private sector is an essential element in developing a therapy or cure. In reaching this balance CIRM recognizes that it is critical to the success of its mission that CIRM accept significant risk both scientifically and financially. Accordingly, this may result in funding companies that would not likely qualify for a commercially available loan and/or funding cutting-edge science with unknown prospects for success.

Payments to CIRM based on loans which result in commercially successful products would recirculate back to CIRM and thereby provide an opportunity for CIRM to provide

continued funding of stem cell research in the future. However, given the risky nature and long time horizon for development of new therapeutics, such benefits will likely be many years in the future. Hence, in recognition of the principles set forth above, the loan regulations are intended to provide a reasonable basis for a return should commercially successful products result from CIRM-funded research, without creating economic or structural disincentives for the clinical development and successful commercialization of new stem cell therapies and cures.

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 ~~as described herein~~. 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. Capitalized terms that are not defined have the meanings set forth in the Non-Profit GAP and Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees.

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-success (or lack of

	success) 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 Amount	The total amount of the Loan Award as set forth in the Notice of Loan Award.
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.
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.
Net Commercial Revenue	Income from the sale or transfer of a Drug, product(s), service(s), CIRM-Funded Inventions or CIRM-Funded Technologies employing or resulting in whole or in part from a CIRM-Funded Project. Net Commercial Revenue excludes the following (as they pertain to the making, using or selling of products resulting from a CIRM-Funded Project): <ol style="list-style-type: none"> (1) import, export, excise and sales taxes, and customs duties; (2) costs of insurance, packing, and transportation from the place of manufacture to the customer’s premises; (3) credit for returns, allowances or trades; and (4) payments received upon entering into an agreement for the development of a Drug or product resulting in whole or in part from CIRM-Funded Research and payments received pursuant to such agreement as a result of the satisfaction of a pre-commercial development milestone.
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 - <u>success</u> of the CIRM-funded project <u>as defined in Section VII.B.</u>
Product Revenue	<u>Defined below in Section VII.E.2.d.</u>

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~~-Intellectual Property and Industry 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~~Loan.
2. ~~The ICOC~~-The RFA will specify whether ~~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~~-may 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 may 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~~ [Loan](#) 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~~ [Loan](#).

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 [where the CIRM-Funded Project is managed and/or performed in California](#) ~~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~~ [Notice of 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 Loan~~ and ~~Award Loan~~ Transfer

A Loan Recipient may at any time relinquish ~~an Award~~ [a Loan](#) by submitting a relinquishing statement that includes a) a statement of reasons for relinquishing the ~~award~~ [Loan](#); 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~~ [a Loan](#) transfer [approved by CIRM's President, such funds shall be](#) 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~~ [Loan](#).

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; [or](#)
- 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 to~~ the original Loan Recipient. The request must be submitted at least 90 days before the proposed effective date of ~~award~~ [Loan](#) transfer, [unless the President of CIRM waives this requirement](#). If the initial request to transfer the ~~award~~ [Loan](#) 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 organization must meet the eligibility requirements for the RFA under which the Loan was made. The transferee Loan Recipient must submit to CIRM a letter that states its intention to assume responsibility for the ~~Award-Loan~~ 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-Loan~~ 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-Loan~~ 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-Loan~~ of a CIRM-funded program is not approved, CIRM may provide written notification of termination of the ~~Award-Loan~~. 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.**

In the event that Loan Recipient is acquired by merger, purchase or otherwise after completion of the research described in the Notice of Loan Award, the successor in

~~interest shall have the same obligations as the Loan Recipient under the Loan Administration Policy.~~

~~The assignee of any CIRM Funded Invention shall have the same obligations as the Loan Recipient under the Loan Administration Policy.~~

~~Any such assignment or transfer to a successor in interest shall be subject to CIRM's prior written approval which shall not be unreasonably withheld.~~

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~~ [Notice of Loan 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-Loan](#) 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 [Change in Control](#) ~~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~~ [Loans](#) 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 [the CIRM-F funded researchProject](#). (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.

K. Termination of CIRM Funded Project and Loan Agreement

I. General: The Loan Agreement entered into by the Loan Recipient and CIRM will provide terms under which CIRM may terminate the Notice of Loan Award. In addition as provided in Section V.D.5, the Loan Recipient may desire to terminate the Notice of Loan Award and Loan Agreement. In the event either

CIRM or the Loan Recipient seeks to terminate the Notice of Loan Award and Loan Agreement the following obligations apply:

- a. All unexpended funds as of 30 days after the date of Loan termination must be returned to CIRM within 60 days after termination of the Loan.
- b. All warrants owing to CIRM must be delivered by Loan Recipient and are not subject to return by CIRM.

VII. LOAN TERMS

A. General Provisions:

The following are guidelines for loan terms. Specific terms will be determined in each RFA by the Intellectual Property and Industry Subcommittee of the ICOC, based on the recommendation of the President, as appropriate for each RFA. If the Intellectual Property and Industry Subcommittee does not modify these guidelines for a specific RFA, the terms set forth herein shall apply to the RFA. However, the loan terms may be modified in a loan agreement provided that the Loan Recipient agrees to the modifications and the Intellectual Property and Industry Subcommittee approves them.

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~~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 (unless accelerated), 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. “Success” means that the Loan Recipient has obtained Net Commercial Revenue arising in whole or in part from the CIRM-Funded Project. To the extent that a Loan Recipient has obtained Net Commercial Revenue arising in whole or in part from the CIRM-Funded Project in an amount less than the loan amount Loan Balance, the Loan Recipient shall be required to repay CIRM the ~~principal and interest on the loan~~ Loan Balance up to the amount of revenue generated. The Loan Recipient may deduct from the amount of revenue generated, reasonable costs (up to a maximum of 50% of such costs) incurred in seeking to bring and CIRM-Funded Inventions or CIRM-Funded Technology to practical use as required by Title 17, California Code of Regulations section 100606.-

~~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. However, the loan terms may be modified in a loan agreement provided that the Loan Recipient agrees to the modifications and the Finance Subcommittee approves them.~~

~~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.~~

CB. Interest Rate

Unless otherwise provided in the RFA,

- i. The interest rate for a 5 year loan term shall be a per annum rate equal to the London Inter-Bank Offered Rate (“LIBOR”) for a one-year deposit in U.S. dollars, as published by the Wall Street Journal (or if the Wall Street Journal is not available, a comparable source) on the date of the first disbursement, plus two percent (2%). On the date of each subsequent disbursement, the applicable interest rate shall be a per annum rate equal to LIBOR for a one-year deposit in U.S. dollars, as published by the Wall Street Journal (or comparable source) on such date, plus two percent (2%). The rate established for each disbursement shall apply only to that disbursement and not to the amount outstanding before such disbursement. Interest shall be compounded annually on the principal amount disbursed by CIRM from the date of the applicable disbursement to Loan Recipient~~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 from the base rate by 1% in year 6; 2% in year 7; 3% in year 8; 4% in year 9; and 5% in year 10. Put another way, the rate shall increase 1% over the previous year, for each year the term is extended.
- 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.

DC. Warrants

1. Requirement

a. Company-Backed Loans: Except as provided in subpart “D” of this regulation, 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.~~ i. 10% of the amount of the Loan Amount ~~Loan disbursed~~ if the Loan Recipient shows a profit for previous 2 ____ years; or
- ~~v.~~ ii. 25% of the amount of the Loan disbursed ~~Loan Amount~~ if the Loan Recipient has **BOTH:** (a) raised in prior financings since its inception three times -the total amount of the loan; **AND-OR** (b) has entered into a contractual arrangement (still in effect) with a biotechnology or pharmaceutical company which requires the payment of ~~licensing revenues~~ royalties or milestone payments predicated on the success of a funded project (e.g., a development agreement), ~~(regardless of whether it is at the CIRM Funded Project)~~ is the subject matter of such agreement; or-
- iii. 50% of the ~~Loan Amount~~ amount of the Loan disbursed if the Loan Recipient has not met ~~only one of the two~~ either of the requirements set forth above in section C.1(a)(ii). ~~(v)~~
- ~~vi.~~ i.v. Such warrants in aggregate will never exceed 20% of Loan Recipient’s fully diluted shares at each warrant issuance.
- ~~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 amount of CIRM’s contribution as a percentage of the total funds required to complete conduct the CIRM-Funded Project as set forth in the Notice of Loan Award during the period covered by the applicable CIRM disbursement. This allocation will be determined at the time of each loan disbursement, e.g., if CIRM’s funds represent 60% of the total project costs for the period covered by the first disbursement, the loan recipient would be required to provide CIRM with warrant coverage equal to 60% of the project costs CIRM disbursement -during the period covered by the first disbursement; if CIRM funds represent 30% of the total project costs during the period covered by the second disbursement, then CIRM would be entitled to

warrant coverage equal to 30% of the total project costs CIRM disbursement for that period.

~~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.~~

ii) 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, unless CIRM agrees in writing to a revised budget and amount.

~~iv) —~~

2. Calculation:

i. The term “fully diluted” means the sum of basic shares outstanding; all preferred stock on an as-converted basis; all in-the-money convertible debt on an as-converted basis; and all options and warrants calculated using the treasury method.

ii. Multiple Loans: The limit on total warrants owed to CIRM (e.g., 20% of Loan Recipient’s shares, fully diluted) applies to each Loan such that if the Loan Recipient has two loans, CIRM may hold warrants up to 40% of the Loan Recipient’s shares on a fully diluted basis.

32. 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, ~~dependent depending 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~~ will be of either common or preferred stock, as ~~determined by CIRM in its sole discretion~~ elected by Borrower. Warrants due or provided to CIRM pursuant to this Subpart remain CIRM's property regardless of the final disposition of the Loan, success of the Project or acquisition of the Loan Recipient.

D. Risk Premium Alternative to Warrants

Subject to the Sunset Provision in section VII.E.3 below, in lieu of providing warrants pursuant to Subpart C of this regulation, Loan Recipients may elect to pay CIRM, as a risk premium, a multiple of the principal amount of their loan. The risk premium payment owed is based on the achievement of certain revenue thresholds.

1. **Definitions:** The following definitions shall apply to terms in this Subpart ~~DE~~. Capitalized terms which are undefined have the same meaning set forth in CIRM's Loan Administration Policy.

~~a. **Advisory Letter and Term Sheet** means correspondence issued by CIRM to the Loan Recipient identifying the sources of revenue streams that will be included in the definition of Product Revenue for Product Backed Loans and Company Backed Loans.~~

b. **Risk Premium Payment** means a payment due pursuant to Subparts "2.b" and "2.c" of this Subpart ~~DE~~.

c.b. **Product Revenue:** see Subpart "2.d" of this Subpart ~~DE~~.

2. Risk Premium Payment

a. **Election of Risk Premium Payment in Lieu of Warrants:** A Loan Recipient may elect to pay CIRM the Risk Premium Payments set forth in this Subpart ~~DE~~ in lieu of providing the warrants set forth in the Loan Administration Policy.

b. **Company-Backed Loans:** Subject to the conditions set forth in Subpart "2.e~~5~~" of this Subpart ~~DE~~, the Loan Recipient of a Company-Backed Loan shall, in addition to any other obligations it has under any CIRM loan agreement or under CIRM's Loan Administration Policy (excluding the requirement to provide warrants), pay up to three hundred percent (300%) of the principal loan amount, payable upon the achievement of certain revenue thresholds as follows:

i. Upon generation of \$300 million of Product Revenue cumulatively, Loan Recipient shall pay to CIRM an amount equal to one

hundred percent (100%) of the amount of the principal of the Company Backed Loan.

ii. Upon generation of \$600 million of Product Revenue cumulatively, Loan Recipient shall pay to CIRM an amount equal to two hundred percent (200%) of the amount of the principal of the Company Backed Loan.

c. **Product-Backed Loans:** Subject to the conditions set forth in Subpart “2.e” of this Subpart “DE”, the Loan Recipient of a Product-Backed Loan shall, in addition to any other obligations it has under any CIRM loan agreement or under CIRM’s Loan Administration Policy (excluding the requirement to provide warrants), pay up to five hundred percent (500%) of the principal loan amount, payable upon the achievement of certain revenue thresholds as follows:

i. Upon generation of \$1050 million of Product Revenue in a fiscal year, Loan Recipient shall pay to CIRM an amount equal to one hundred percent (100%) of the amount of the principal of the Product-Backed Loan.

ii. Upon generation of \$300 million of Product Revenue cumulatively, Loan Recipient shall pay to CIRM an amount equal to two hundred percent (200%) of the amount of the principal of the Product-Backed Loan.

iii. Upon generation of \$600 million of Product Revenue cumulatively, Loan Recipient shall pay to CIRM an amount equal to two hundred percent (200%) of the amount of the principal of the Product-Backed Loan.

d. **Product Revenue:**

i. ~~Definition: Product Revenue shall be defined in accordance with an Advisory Letter and Term Sheet issued by CIRM following discussions with the Loan Recipient prior to the Loan Recipient’s submission of its application in response to a Request for Application.~~ “Product Revenue” shall include ~~income~~Net Commercial Revenue received by the Loan Recipient or by any joint venture or subsidiary created by Loan Recipient, ~~including but not limited to,~~ and any upfront licensing fees, development milestone payments received from a product development partner, and ~~revenues from commercial sales, or~~ royalties on commercial sales, which arise from or are related to development and/or commercial sale of the ~~product or service~~CIRM-Funded Research. Recognizing that CIRM-Funded Research can support multiple therapeutic indications, the Loan Agreement will set for the specific stream of revenue that applies for purposes of this Subpart.

~~ii. Exclusions and Deductions: The following shall be excluded from Product Revenue in the event that they are included in the gross sales amount invoiced:~~

~~—deductions for returns (including withdrawals and recalls);~~

~~2) rebates or price reductions for government programs (e.g., Medicaid);~~

~~3) volume or quantity discounts or other discounts offered at the time of invoicing; and~~

~~4) sales and other taxes directly linked to the gross sales amount.~~

~~In addition, Product Revenue shall exclude, to the extent such costs were incurred in connection with the sale of a product or service included in Product Revenue, any freight and postage costs, transportation insurance, packaging materials for transporting the product, customs duties, and discounts for prompt payment or similar discounts applicable after the time of invoicing.~~

e. Conditions and Timing of Payment:

i. Upon achievement of the revenue thresholds described in Subparts “2.b” and “2.c” of this Subpart “DE,” Loan Recipient shall pay CIRM the Risk Premium Payment quarterly in equal installments over 12 months starting in the first quarter following the achievement of such revenue threshold, provided, however, that no Risk Premium Payments shall be due prior to the end of the initial term of the Loan.

Notwithstanding the foregoing, the first Risk Premium Payment due with respect to Product-Backed Loans upon generation of Product Revenue of \$50 million in a fiscal year shall be paid in equal quarterly installments over 18 months starting in the first quarter following the achievement of the threshold.

ii. In the event that a Product-Backed Loan is forgiven, Loan Recipient shall have no obligation to make the Risk Premium Payments unless and until the Loan is reinstated.

iii. Pre-commercial revenues such as development milestone payments will trigger a Risk Premium Payment only in the event that the CIRM-Funded Project results in revenues from commercial sales and the revenue thresholds described in Subparts “2.b” (for Company-Backed Loans) and “2.c” (for Product-Backed Loans) of this Subpart “D” are satisfied.

3. Sunset Provision: This Subpart “D” (“Risk Premium Alternative to Warrants”) shall remain in effect until all loans made pursuant to RFA 11-02 CIRM Early Translational Awards III, RFA 10-05 CIRM Disease Team Therapy Development Awards, and any earlier requests for applications, have been issued unless this provision is earlier terminated or made permanent by subsequent action of the ICOC. Loans already entered into pursuant to this regulation shall be subject to these provisions, provided the Loan Recipient elected to make the risk premiums set forth in this chapter in lieu of providing warrants as set forth under Subpart “C” of this policy.

ED. Loan Period

The term of CIRM loans shall be 5 years, subject to modification on an RFA by RFA basis by the Finance-Intellectual Property and Industry 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 HI. A term of more than ten years shall require the approval of the Finance-Intellectual Property and Industry Subcommittee, based upon the recommendation of the President.

FE. 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.

GF. Loan Acceleration

Subject to Section VII.G.1, in the event of any eChange 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-Intellectual Property and Industry Subcommittee, based on the recommendation of the President. If the proposed change of control is not a matter of public knowledge, the Finance-Intellectual Property and Industry Subcommittee shall consider the matter in closed session to protect the confidentiality of the proposal.

1. Change of Control: In the event of any Change in Control, the Loan shall not be accelerated in the event that all of the following are satisfied:

- a. Both immediately before and immediately after such Change in Control no event of default shall have occurred and be continuing under the CIRM loan documents, and
- b. The surviving entity satisfies the following conditions:

(i) it is incorporated or organized under the laws of any state of the United States;

- (ii) it has executed an instrument satisfactory to CIRM assuming the obligations of the Loan Recipient;
- (iii) it has shareholder's equity no less than the most recently reported shareholder's equity of the Loan Recipient, as shown on pro forma financial statements for the entity; and
- (iv) it has a market capitalization/post-money valuation less than \$10 billion.

2. Assignees:

Unless the Loan Recipient agrees to acceleration of the Loan and pays all principle and interest, upon assigning CIRM-Funded Technology and/or CIRM-Funded Research arising from the CIRM-Funded Project, the assignee shall have the same obligations the Loan Recipient has under CIRM's Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees (commencing with Title 17, California Code of Regulations section 100600, *et seq.*) in all respects except that the revenue sharing obligations of Section 100608 shall not apply to such assignee.

H.G. Suspension and Forgiveness and Reinstatement of Product-Backed Loans

(1) A Product-Backed Loan shall be automatically forgiven in the event that all of the following have been satisfied:

(a) The ~~Borrower~~ Loan Recipient has complied with all reporting requirements;

(b) The ~~Borrower~~ Loan Recipient abandons the CIRM-Funded Project during or after the Loan Period, submits a declaration to this effect and does not resume work on such Project, or CIRM terminates the Project; and

(c) To the extent that the ~~Borrower~~ Loan Recipient obtains ~~revenue~~ Net Commercial Revenue arising in whole or in part from the CIRM-Funded Project in an amount less than the amount of the loan, the ~~Borrower~~ Loan Recipient has repaid CIRM the ~~principal and interest on the loan~~ Loan Balance up to the amount of revenue generated less reasonable costs (up to a maximum of 50% of such costs) incurred in seeking to bring and CIRM-Funded Inventions or CIRM-Funded Technology to practical use as required by Title 17, California Code of Regulations section 100606.

(2) Notwithstanding subpart (1) above, a Loan ~~which~~ that has been forgiven will automatically be reinstated in the event that the ~~Borrower~~ Loan Recipient obtains revenue arising in whole or in part from the CIRM-Funded Project. If the ~~Borrower's~~ Loan Recipient's obligation to repay has been forgiven and if further activity results in a repayment obligation under this provision, the Product-Backed Loan Recipient must

promptly notify CIRM. The Product Backed Loan will automatically be reinstated under terms that the Finance Intellectual Property and Industry Subcommittee shall approve (which may, for example, preclude rights to extend the term), except that in no event will the interest rate be higher than in the per annum rate equal to LIBOR for a one-year deposit in U.S. dollars, as published by the Wall Street Journal (or if the Wall Street Journal is not available, a comparable source) on the date of reinstatement plus 2%. The Principal and interest owed shall be reduced by any amount previously repaid to CIRM prior to forgiveness. Upon reinstatement of the Loan, the Product-Backed Loan Recipient shall be eligible for subsequent forgiveness and reinstatement in accordance with the terms of this section.

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.~~

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

IH. 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 termination by CIRM or of acceleration, 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.

JI. Subordination

CIRM will not subordinate to company-wide debt in the case of a Company-Backed Loan. 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~~ Intellectual Property and Industry Subcommittee, based on the recommendation of the President. Such consent may not be unreasonably withheld.

KJ. Loan Application Process

1. ~~CIRM Loan Application Form~~ **Documentation**
~~By the application deadline for an RFA that offers Loan funding, a Loan applicant must submit a Loan application form. Within 14 days of being notified of the ICOC's approval of the award, t~~ The Loan Applicant must shall indicate in writing to CIRM its preference choice of among available

~~Loan terms for that RFA, e.g., for a Product-Backed or Company-Backed-ete loan. 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. The Loan Applicant will be required to submit financial information, pursuant to CIRM's or its agents' request. CIRM's Governing Board may decline to award a Loan on one or more legal or financial grounds, including but not limited to risk of attachment, bankruptcy, or insolvency, or failure to meet industry standards for financial practices or adhere to generally accepted accounting principles.~~

2. Scientific Review

~~Loan Applications for a CIRM award that is in the form of a loan will be subject to the same scientific review by the Grants Working Group as a Grant application, and final determination of scientific merit by the ICOC.~~

23. Financial Feasibility Review

~~CIRM will assign each Loan applicant (or Borrower) to a Financial Services Provider. Each applicant or Borrower-Loan Recipient 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. CIRM may assign each Loan applicant to a Financial Services Provider or perform such diligence internally. CIRM will deduct the costs of the financial due diligence from the indirect costs awarded to the Loan Recipient. The Financial Services Provider will collect from the applicant a processing fee to offset the cost of financial feasibility review.~~