



REQUEST FOR PROPOSAL

May 15, 2009

**Loan Program - Delegated Underwriter/Financial Services Provider
RFP# CIRM 2210**

You are invited to review and respond to this Request for Proposal (RFP), entitled RFP# 2210 for the California Institute for Regenerative Medicine (CIRM). In submitting your proposal, you must fully comply with these instructions. Missing and/or incomplete information may cause your response to be disqualified from further consideration. The RFP seeks outstanding delegated underwriters/financial services providers to assist CIRM in the implementation and administration of CIRM's Loan Program.

In the opinion of CIRM, this RFP is complete and without need of explanation. However, if you have questions, or should you need any clarifying information, the contact person for this RFP is:

Lynn Harwell
Deputy to the Chair for Finance, Policy & Outreach
lharwell@cirm.ca.gov
(415) 396-9111

All submittals must be received on or before 5 PM Pacific Time, June 8, 2009. Return one signed hard copy original to:

California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
Attn: Cynthia Schaffer
Contracts Administrator
(415) 396-9241

**Faxed and/or email submittals will not be accepted
Late submittals will not be accepted**

Please note that no *verbal* information given will be binding upon the State unless such information is issued in writing as an official addendum.

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A. Purpose and Description of Services

1. Introduction

CIRM was established in 2004 when California voters approved Proposition 71, which authorized the issuance of \$3 billion in bonds to fund stem cell research, related research, and research facilities through grants and loans. CIRM's governing board has indicated that it plans to commit up to \$500 million or more over the next three years to fund loans to for-profit entities and non-profit entities with a for-profit partner for preclinical development and clinical development. Individual loan amounts may range from \$3 million to as much as \$20 million, depending upon the terms of each Request for Application. Loans will be awarded through a competitive evaluation process involving both an assessment of the scientific merit of the proposal and the feasibility of the loan recipient organization. The Interim CIRM Loan Administration Policy, which more fully describes the loan program, along with Frequently Asked Questions regarding the loan program, are attached as Exhibit A.

CIRM is requesting proposals from financial institutions to become Delegated Underwriters/Financial Services Providers (referred to hereafter as "Delegated Underwriters") for the loan program. The Delegated Underwriters will assist CIRM in implementing and administering certain financial aspects of the loan program.

CIRM intends to select two or more firms to act as Delegated Underwriters. The selected firms must be technically and professionally capable of providing the services in all subject areas described in Section A, Item 2, Scope of Services, and must meet the Minimum Qualifications for Proposers in Section B. The selected firms must be free from conflicts of interest, as specified herein. In the event that a Delegated Underwriter has a conflict of interest with respect to a particular loan applicant, CIRM will assign the loan application to another Delegated Underwriter.

The selected firms must be able to commence performance immediately after execution of the agreement with CIRM. CIRM anticipates entering into a multi-year contract, which may be extended upon the mutual agreement of the parties. A copy of CIRM's standard contract, the terms of which are incorporated into this proposal, is attached hereto as Exhibit 1. CIRM reserves the right to terminate the contract pursuant to Section II. B of CIRM's standard contract. For example, CIRM reserves the right to terminate the contract for, among other reasons, failure to achieve CIRM's performance objectives or in the event that CIRM decides to restructure or eliminate its loan program or the role of Delegated Underwriters.

CIRM is also seeking a federal guarantee of a portion of its loan portfolio. Pursuant to this proposal, additional loans, guaranteed by the federal government, could be originated by banks or purchased by investors. In responding to this Request for Proposal, please indicate whether you would be interested in

participating in this program and describe your prior experience, if any, with similar programs. The terms of participation, including compensation, would be negotiated at the time the program is implemented.

2. Scope of Services

The Delegated Underwriter will be expected to perform the following duties with respect to the CIRM loan program:

a. Financial Due Diligence: The Delegated Underwriter will conduct due diligence of loan applicants' business plans and financial status according to the parameters established by CIRM. The due diligence will include a review of the applicant entity's business plan, key financial metrics, bank account verification, and the credit history (such as a Dun & Bradstreet report) and any litigation of record for both the applicant entity and its principals. This review will run concurrently with CIRM's scientific peer review of applicants and is expected to be completed within the approximately one month period between peer review and Governing Board consideration.

b. Assessment of Non-Scientific Risk Factors: In conjunction with the filing of an application for an award, Loan Applicants will be required to identify the key non-scientific risk factors they foresee with regard to their ability to implement the product development plan as submitted. Information requested will include: complete capitalization requirements and sources (beyond the CIRM loan requests), key employee/consultants necessary to achieve the goals of the project, and relevant approvals/timelines. The Delegated Underwriter will use the disclosed risk factors as a basis for advising CIRM whether the applicant, in the opinion of the Delegated Underwriter, has the ability to execute its product development plan. If the Delegated Underwriter determines that there is unusually high risk that the applicant cannot meet its product development plan, the Delegated Underwriter may suggest methods for CIRM to reduce its loan risk (i.e., milestone adjustments, delay project initiation until additional funds are secured, etc). Risk factors should be updated and reviewed as disbursements are made, but may be updated and reviewed more frequently if necessary.

c. Financial Underwriting Review: The Delegated Underwriter will review the status of the applicants' current capitalization and plans for obtaining future capital, analyze the applicants' cash flow plans and internal financial controls, and confirm the lack of material contingent liabilities, liens, or obligations against the applicants. In addition, the Delegated Underwriter will undertake business modeling, collateral reviews, management interviews, management background checks, and investment memorandum development appropriate to the time and scope of review approved by CIRM. This review may include any other areas of research and analysis deemed appropriate by the Delegated Underwriter and CIRM. These loans support cutting edge research, so CIRM understands that each scientific research project will present risks, and does not expect the

Delegated Underwriter to guarantee product development or project results. All final assessments of risk and funding decisions will be made by CIRM.

d. Structuring of Loan and Documentation of Loan Agreement: The Delegated Underwriter will fulfill and/or direct all necessary financial and legal recordings, security agreements and documentation, under CIRM's oversight. This includes preparing the financial components of the loan agreement, subject to CIRM's review and approval. CIRM will make all final decisions regarding risk assessment and loan documentation.

e. Loan Administration: The Delegated Underwriter, in close communication and cooperation with CIRM, will perform certain aspects of loan administration. This includes monitoring compliance with financial milestones and capitalization requirements, if applicable; obtaining CIRM approval for disbursement of funds (if the Delegated Underwriter is responsible for the disbursement of funds); administering and monitoring financial requirements; and, at CIRM's direction, taking one or more designated actions in the event of deficiency or noncompliance with financial requirements, with all of the above at CIRM's sole discretion.

f. Management of Warrants: The Delegated Underwriter will manage all warrants held by CIRM. Delegated Underwriters may be requested, for example, to hold the warrants on CIRM's behalf and to sell the warrants at CIRM's direction.

g. Disbursement and Collection: On behalf of CIRM, the Delegated Underwriter may disburse loan proceeds during the loan disbursement period and collect interest and loan repayments at the end of the loan term.

3. Budget

Expected Range for this Award will depend on the fee and program structure agreed to by CIRM and the Delegated Underwriter. A Delegated Underwriter may collect fees for the services described above in one or more of four ways.

First, the Delegated Underwriter may receive a specific, fixed spread on the interest rate on the loan to be repaid on a quarterly basis or as a balloon payment with the principal at the end of the loan term.

Second, a Delegated Underwriter may propose to receive compensation for handling warrants. Warrant strike prices will be set at par value to the previous round of equity financing prior to loan approval. If there is no applicable previous round, the strike price will be floated until the next funding round. Warrants will issue on the date of the loan and expire 10 years after.

Third, Delegated Underwriters may charge fees in the form of management, processing or research fees to be paid by the Loan Recipient out of funds received by the Loan Recipient from each disbursement of loan funds. These fees may be recovered on a quarterly basis or based on each disbursement.

Fourth, if the Delegated Underwriter proposes to undertake any additional services or proposes an alternative model for providing the services specified herein, please describe the services and/or model and the proposed compensation.

The Delegated Underwriter may select one or more of the above fees as compensation for the activities required by CIRM. Given that the RFP process is competitive, **the price and amount of the fees will be a significant factor in CIRM's selection of approved Delegated Underwriters** and a potential Loan Recipient's selection and acceptance of a CIRM loan.

Proposals for Delegated Underwriter should specify which fee structure they will employ and should demonstrate, by way of example, how that fee structure would operate, and the total fees (in dollars) that would be assessed, in performing the requested services for a \$20 million, 6 year loan. Assume a fixed interest rate of 5% with disbursements that occur over a period of four years (i.e., \$5 million each year distributed on a quarterly basis). For purposes of this example, please assume that the warrants would be sold at the end of the loan term.

B. Minimum Qualifications for Proposer(s)

1. The Delegated Underwriter will be expected to have significant experience in either financial services or underwriting matters. Applicants should demonstrate their ability to successfully complete all aspects of the Scope of Services, making concrete reference to successful completion of similar projects.
2. CIRM expects the Delegated Underwriter to have a close working relationship with CIRM staff in all aspects of the loan administration program. Proposer must demonstrate an ability to communicate effectively, internally and with CIRM. Please indicate how your organization would staff this work.
3. The Delegated Underwriter must have an ability to communicate effectively in writing and in oral presentation to CIRM staff.
4. The Delegated Underwriter must develop with CIRM a written conflicts policy to assure full and accurate conflicts checks and conflicts monitoring throughout the term of the contract. CIRM recognizes that a Delegated Underwriter may have preexisting relationships with some loan applicants. At a minimum, therefore, the conflicts policy must require disclosure by the Delegated Underwriter of any preexisting financial or other relationship with a loan applicant and the manner in which the Delegated Underwriter would propose to address the potential for a conflict of interest. CIRM reserves the right to reassign the loan applicant to another Delegated Underwriter for any reason, including if CIRM determines, in its sole discretion, that the advantage of the Delegated Underwriter's familiarity with the loan applicant is outweighed by the potential for a conflict of interest. The policy must also require that the Delegated Underwriter disclose its intention to enter into a financial relationship with a loan recipient. CIRM reserves the right to reassign the loan to another delegated underwriter if it determines that the benefit of additional financing is outweighed by the potential for a conflict of interest. In addition, the policy must ensure that employees who have a financial

interest in a loan applicant do not participate in any of the Delegated Underwriter's work with respect to that applicant. For these purposes, a financial interest is defined as an investment of \$2,000 or more or the receipt of income of \$500 or more in 12-month period. Finally, the policy should include a requirement that the Delegated Underwriter disclose to CIRM, and obtain CIRM's approval, if any employee would be entitled to performance-based compensation for his or her work on a CIRM loan.

5. Independent Consultant Insurance Requirements

a. General Liability

i. Comprehensive or Commercial Form (minimum limits)

1. Each Occurrence	\$2,000,000.00
2. Products/Completed Operations Aggregate	\$2,000,000.00
3. Personal and Advertising Injury	\$1,000,000.00
4. General Aggregate*	\$1,000,000.00

*Not applicable to comprehensive form.

If the above insurance is written on a claims-made form, it shall continue for three years following termination of the agreement. The insurance shall provide for a retroactive date of placement prior to or coinciding with the effective date of the agreement.

b. Business Automobile Liability (minimum limits): For owned, scheduled, non-owned, or hired automobiles with a combined single limit of not less than \$1,000,000 per occurrence.

c. Workers' Compensation: as required under California State Law.

d. Professional Liability Insurance (minimum limits):

i. Each Occurrence	\$2,000,000
ii. Project Aggregate	\$2,000,000

e. Other insurance in amounts which from time to time may reasonably be required by the mutual consent of CIRM and the Independent Consultant against other insurable hazards relating to performance.

f. And other insurance customarily carried by financial institutions, per agreement with CIRM

C. Proposal Requirements and Information

1. Key Action Dates

It is recognized that time is of the essence. All Proposers are hereby advised of the following schedule and will be expected to adhere to the required dates and times:

<u>Date</u>	<u>Action</u>
<u>May 15, 2009</u>	RFP available to prospective respondents
<u>June 8, 2009</u>	Final Date for Proposal Submission. Proposals must be received at CIRM at 210 King Street San Francisco, CA by 5:00 P.M.
<u>June 15, 2009</u>	Proposed Award Date (Note: The actual award date may vary.)

2. References

- a) References-Submit a list of at least three references (clients) to which you have provided similar services within the past five years and contact numbers for each. See Attachment 1.

3. Submission of Proposal

- a) Proposals should provide straightforward and concise descriptions of the Proposer's ability to satisfy the requirements of this RFP. The proposal must be complete and accurate. Omissions, inaccuracies or misstatements will be sufficient cause for rejection of a proposal.
- b) The proposal package should be prepared in the least expensive method. Please submit a document that is easy to copy and/or scan through a machine or include a computer disk with your hard copy submission.
- c) All proposals must be submitted to the California Institute for Regenerative Medicine by the dates and times shown in Section C, Proposal Requirements and Information, Item 1) Key Action Dates.
- d) Proposal should identify the total dollar amount of consulting work Proposer has contracted with CIRM for in the last 12 months.
- e) Submit one original. All documents contained in the original proposal package must have original signatures and must be signed by a person who is authorized to bind the proposing firm.
- f) The proposal envelope(s) should be addressed as follows and must be plainly marked with the RFP number and title and should be mailed or delivered to:

Cynthia Schaffer
Contract Administrator
California Institute for Regenerative Medicine
210 King Street
Subject: **Loan Program Delegated Underwriter**
RFP# CIRM 2210

- g) All proposals shall include the documents identified in Section D, Required Attachments. Proposals not including the proper "required attachments" shall be deemed non-responsive. A non-responsive proposal is one that does not meet the basic proposal requirements.
- h) If the proposal is made under a fictitious name or business title, the actual legal name of the proposer must be provided.
- i) Proposals must be submitted for the performance of all the services described herein. At its option, a Delegated Underwriter may also propose additional services and/or an alternative model for providing the services specified herein, along with the proposed compensation.
- j) A proposal may be rejected if it is conditional or incomplete, or if it contains any alterations of form or other irregularities of any kind. CIRM may reject any or all proposals and may waive any immaterial deviation in a proposal. CIRM's waiver of immaterial deviation shall in no way modify the RFP document or excuse the proposer from full compliance with all requirements if awarded the agreement.
- k) Costs incurred for developing proposals and in anticipation of award of the agreement are entirely the responsibility of the proposer and shall not be charged to CIRM.
- l) An individual who is authorized to bind the proposing firm contractually shall sign the Attachment 2, Payee Data Form. The signature must indicate the title or position that the individual holds in the firm. An unsigned proposal may be rejected.
- m) A Proposer may modify a proposal after its submission by withdrawing its original proposal and resubmitting a new proposal prior to the proposal submission deadline as set forth in Section C, Proposal Requirements and Information, Item 1) Key Action Dates. Proposal modifications offered in any other manner, oral or written, will not be considered, unless CIRM specifically requests, in writing, that a Proposer consider modifications or alternatives as part of negotiating an agreement.
- n) A Proposer may withdraw its proposal by submitting a written withdrawal request to CIRM, signed by the Proposer or an authorized agent, addressed in accordance with f above. A Proposer may thereafter submit a new proposal prior to the proposal submission deadline. Proposals may not be withdrawn without cause subsequent to proposal submission deadline.

- o) CIRM may modify the RFP prior to the date fixed for submission of proposals by the issuance of an addendum to all parties who received a proposal package.
- p) CIRM reserves the right to reject all proposals. CIRM is not required to award an agreement.
- q) Before submitting a response to this solicitation, Proposers should review, correct all errors and confirm compliance with the RFP requirements.
- r) Where applicable, Proposer should carefully examine work sites and specifications. No additions or increases to the agreement amount will be made due to a lack of careful examination of work sites and specifications, if applicable.
- s) More than one proposal from an individual, firm, partnership, corporation or association under the same or different names, will not be considered.
- t) No oral understanding or agreement shall be binding on either party.

4. Evaluation Process

- a) At the time of proposal opening, each proposal will be checked for the presence or absence of required information in conformance with the submission requirements of this RFP.
- b) Proposals that contain false or misleading statements, or which provide references that do not support an attribute or condition claimed by the proposer, may be rejected.
- c) Award, if made, will be to the highest scoring responsible proposal. If a tie occurs the most competitive cost proposal will be the determining factor.
- d) Proposal Evaluation

The proposals that meet the Minimum Qualifications in Section B and the Proposal Requirements and Information in Section C will be evaluated and scored according to the criteria indicated below. The recommendation will be made by an evaluation committee organized by CIRM on the basis of the following weighted factors (Maximum points available for each criterion is noted.)

- (1) Qualification and Experience as a Loan Program Delegated Underwriter 45 points
CIRM will evaluate the proposal on the basis of the firm and/or individual's overall experience demonstrating their ability to successfully complete the requirements identified in 1) Introduction and 2) Scope of Services, Section A.

- (2) Responsiveness to the Scope of Work 20 points
 CIRM will evaluate the proposal on the basis of the firm and/or individual's overall understanding and description of the Scope of Work.
- (3) Cost 35 points
 CIRM will score the cost upon the competitive cost proposal, Scope of Services, Section A, Item 2.
- (4) Innovation 20 points
 CIRM will award up to 20 points for the innovativeness of the proposal and its effectiveness in advancing CIRM's mission.
- Maximum Total Possible Points** **120 points**

5. Disposition of Proposals

- a) Upon proposal opening, all documents submitted in response to this RFP will become the property of CIRM, and will be regarded as public records, subject to the redaction of confidential or proprietary information as permitted by Proposition 71 and the California Public Records Act (Government Code Section 6250 et seq.) and subject to review by the public.
- b) Proposal packages may be returned only at the Proposer's expense, unless such expense is waived by CIRM.

6. Agreement Execution and Performance

- a) Service shall start on the express date set by CIRM and the Consultant, after all approvals have been obtained and the agreement is fully executed. Should the Consultant fail to commence work at the agreed upon time, CIRM, upon five (5) days written notice to the Consultant, reserves the right to terminate the agreement.
- b) All performance under the agreement shall be completed on or before the termination date of the agreement.

D. Required Attachments

For your proposal to be considered responsive, all required attachments must be included with the RFP by the dates and times shown in Section C, Proposal Requirements and Information, Item 1, Key Action Dates.

Attachment 1 – Proposer References

Attachment 2 – Payee Data Record (STD 204)

ATTACHMENT 1

Proposer References

Submission of this attachment is mandatory. Failure to complete and return this attachment with your bid may cause your bid to be rejected and deemed non-responsive.

List below three references for services performed within the last five years, which are similar to the scope of work to be performed in this contract.

REFERENCE 1			
Name of Firm			
Street Address	City	State	Zip Code
Contact Person		Telephone Number	
Dates of Service		Value or Cost of Service	
Brief Description of Service Provided			
REFERENCE 2			
Name of Firm			
Street Address	City	State	Zip Code
Contact Person		Telephone Number	
Dates of Service		Value or Cost of Service	
Brief Description of Service Provided			
REFERENCE 3			
Name of Firm			
Street Address	City	State	Zip Code
Contact Person		Telephone Number	
Dates of Service		Value or Cost of Service	
Brief Description of Service Provided			

EXHIBIT 1

Agreement No. CIRM ____

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
INDEPENDENT CONSULTANT AGREEMENT

THIS AGREEMENT to furnish certain consultant services is made by and between the California Institute for Regenerative Medicine hereinafter called (CIRM), and _____ [Name] _____ hereinafter called (the Consultant).

I. NATURE AND PLACE(S) OF SERVICE

- A. The Consultant shall furnish to CIRM the following described services including a time schedule by which the Consultant is to produce or provide specified materials or perform certain consulting services as well as reports on the progress of the services:
See attachment A submitted by Consultant to CIRM.
- B. In addition to the services described in subparagraph A. above, the Consultant's proposal to CIRM shall be incorporated herein by reference and made part of this Agreement.
- C. If the Consultant is an entity other than an individual, CIRM requires that staff be assigned according to Attachment A to perform the work set forth herein. No reassignment of work to any other individual(s) other than those described in Attachment A shall be made without the written approval of CIRM.
- D. Place(s) of performance of such services shall be:

Consultant's location:

94107

CIRM's location:

210 King Street
San Francisco, CA

- E. CIRM will provide working space, equipment, furniture, utilities, and services, as follows:

II. TERM OF AGREEMENT

A. The term of this Agreement shall be from _____ through _____.

B. CIRM reserves the right to terminate this Agreement subject to 30 days written notice to the Consultant. Consultant may submit a written notice to terminate this Agreement only if CIRM should substantially fail to perform its responsibilities as provided herein. In addition, this Agreement may be terminated immediately for cause. The term “for cause” shall mean that the Consultant fails to meet the terms, conditions, and/or responsibilities of this Agreement. In this instance, the termination shall be effective as of the date indicated on CIRM’s notification to the Consultant.

C. The term of this Agreement may be extended by the mutual, written consent of both parties.

III. COMPENSATION AND REIMBURSEMENT FOR EXPENSES

A. CIRM shall pay the Consultant for services performed on the following basis:

1. Professional Fees:
2. Other Expenses

MAXIMUM TO BE PAID UNDER THIS AGREEMENT

\$ _____

* Reimbursement for travel and per diem shall be in accordance with established CIRM rates and policies.

B. Payments shall be made upon the Consultant's submission of invoices indicating the Agreement Number and setting forth charges in accordance with rates detailed in Article III-A. Each invoice shall include the Consultant's taxpayer identification number (Social Security or employer identification number). Invoices shall be submitted not more frequently than monthly in arrears to:

California Institute for Regenerative Medicine
President
210 King Street
San Francisco, CA 94107

Payment will be made in accordance with, and within the time specified in, Government Code Chapter 4.5, commencing with Section 927. The following link will take you to the Government Code cited for further

information. <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=gov&group=00001-01000&file=927-927.12>

IV. REPORTING

In performing consulting services under this Agreement, the Consultant shall be accountable to CIRM and shall provide progress reports to CIRM upon CIRM's request.

V. NOTIFICATION

Notices concerning this Agreement shall be addressed as follows:

CIRM: TO
CONSULTANT:

[Insert name and address]

VI. TAXES

The compensation stated in Article III includes all applicable taxes and will not be changed hereafter as the result of Consultant's failure to include any applicable tax or as the result of any change in the Consultant's tax liabilities. The Consultant acknowledges that compensation payable hereunder may be subject to withholding of state and federal income tax, including state income tax subject to withholding pursuant to California Revenue and Taxation Code Sections 18661-18677.

VII. INDEPENDENT CONSULTANT STATUS

- A. Both parties agree that in the performance of this Agreement the Independent Consultant shall not be an agent or employee of CIRM, shall not be covered by the State of California Worker's Compensation Insurance or Unemployment Insurance, shall not be eligible to participate in CIRM's retirement programs, and shall not be entitled to any other CIRM employee benefits.
- B. The Consultant shall be solely responsible for the conduct and control of the work to be performed by the Consultant under this Agreement, except that the Consultant is accountable to CIRM for the results of such work. The Consultant's services for CIRM shall be performed in accordance with currently approved methods and ethical standards applicable to the Consultant's professional capacity.

California State Contract Code 10515 (a) states: No person, firm, or subsidiary thereof who has been awarded a consulting services contract may submit a bid for, nor be awarded a contract on or after July 1, 2003, for the provision of

services, procurement of goods or supplies, or any other related action that is required, suggested, or otherwise deemed appropriate in the end product of the consulting services contract.

VIII. ASSIGNMENT OR SUBCONTRACTING

The Consultant may not assign or transfer this Agreement, or any interest or claim, or subcontract any portion of the work, without the prior written approval of CIRM. The withholding or granting of such approval is totally discretionary with CIRM. If CIRM consents to such assignment or transfer, the terms and conditions of this Agreement shall be binding upon any assignee or transferee.

IX. PROPERTY RIGHTS, INCLUDING PATENTS AND COPYRIGHTS

All written and other tangible material ("Material") produced pursuant to this Agreement by the Consultant shall be considered a work-made-for-hire under the Copyright Act. To the extent said Material does not qualify as a work-made-for-hire, Consultant hereby assigns all right, title, and interest, including, but not limited to, copyright and all copyright rights in the Material to CIRM and shall execute any and all documents necessary to effectuate such assignment. In the event Consultant uses any individual who is not a full-time employee of Consultant or uses any other entity to perform any of the work required by Consultant hereunder, Consultant shall require said individual or entity to sign an agreement before commencing work that contains identical wording to the foregoing two sentences except that the word "Consultant" shall be replaced with the individual's or entity's name.

X. CONSULTANT'S LIABILITY AND INSURANCE REQUIREMENTS

- A. The Consultant agrees to defend, at CIRM's election, indemnify, and hold harmless CIRM, its officers, agents, and employees from and against any and all claims, losses, expenses (including costs and reasonable attorney's fees), claims for injury, or damages that are caused by or result from the negligent or intentional acts or omissions of the Consultant, its officers, employees, or agents or Consultant's breach of this Agreement. In addition, Consultant agrees to defend, at CIRM's election, indemnify, and hold harmless CIRM, its officers, agents, and employees from and against any and all claims, losses, expenses (including costs and reasonable attorney's fees), claims for injury, or damages accruing or resulting to any and all contractors, subcontractors, suppliers, or any other person, firm or corporation furnishing services or supplying goods in connection with Consultant's performance of this Agreement
- B. The Consultant shall furnish a Certificate of Insurance or statement of self-insurance (contractual liability included) showing minimum coverage as follows:

1. (Minimum Limits)	General Liability: Comprehensive or Commercial Form	
	(i)	General Aggregate (BI, PD)* \$2,000,000
	(ii)	Products, Completed Operations Aggregate \$2,000,000
\$1,000,000	(iii)	Personal and Advertising Injury
\$1,000,000	(iv)	Each Occurrence

* (not applicable to comprehensive form)

However, if such insurance is written on a claims-made form following termination of this Agreement, coverage shall survive for a period no less than three years. Coverage must include a Primary and Non-Contributory provision and a Severability of Interest provision. Coverage shall also provide for a retroactive date of placement coinciding with the effective date of this Agreement.

2. Business Auto Liability: (Minimum Limits) for Owned, Scheduled, Non-Owned, or Hired Automobiles with a combined single limit of no less than \$1,000,000 per occurrence.
3. Workers' Compensation: as required under California State Law.
4. Professional Liability Insurance: (Minimum Limits)

(1) Each occurrence	\$2,000,000
(2) Project Aggregate	\$2,000,000

If this insurance is written on a claims-made form, it shall continue for three years following termination of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the effective date of this Agreement. The insurance must include Contractual Liability Coverage and Defense and Indemnification of CIRM by the contracting party.

5. Other insurance in amounts as from time to time may reasonably be required by the mutual consent of CIRM and the Consultant against such other insurable hazards relating to performance.

Certificate(s) shall name CIRM as an additional insured under 1, 2 and 4 above, obligate the insurer to notify CIRM at least thirty (30) days prior to cancellation of or changes in any of the required insurance and include a provision that the coverage will be primary and will not participate with nor be excess to any valid and collectible insurance program of self-

insurance carried or maintained by CIRM. Premiums on all insurance policies shall be paid directly by the Consultant.

XI. RECORDS ABOUT INDIVIDUALS

- A. The Consultant acknowledges that the creation and maintenance of records pertaining to individuals is subject to certain requirements set forth by the California Information Practices Act (Civil Code 1798, et seq.) and by CIRM policy. Such requirements include provisions governing the collection, maintenance, accuracy, dissemination, and disclosure of information about individuals, including the right of access by the subject individuals.
- B. If the Consultant creates confidential or personal records about an individual, as defined by the Information Practices Act, including notes or tape recordings, the information shall be collected to the greatest extent practicable directly from the individual who is the subject of the information. When collecting the information, the Consultant shall inform the individual that the record is being made and of the purpose of the record.
- C. Records containing confidential or personal information about individuals are the property of CIRM and subject to CIRM's policies and applicable federal and state laws. The Consultant agrees to deliver all such records, including originals and all copies and summaries, to CIRM upon termination of this Agreement.
- D. The Consultant shall not use recording devices in discussions with CIRM's employees without notifying all parties to the discussion that the discussion is being recorded.

XII. EXAMINATION OF RECORDS

The Consultant agrees that CIRM and its authorized agents shall have the right to review and copy any records and supporting documentation pertaining to the performance of this Agreement including, but not limited to, all documents, records and work papers whether obtained or copied from CIRM or developed by the Consultant. Consultant agrees to maintain such records for a minimum of five (5) years after final payment, unless a longer period of records retention is stipulated. Consultant agrees to allow CIRM and its authorized agent's access to such records during normal business hours. Further, Consultant agrees to include a similar right of access in any subcontract related to the performance of this Agreement.

In accordance with state law, the Consultant agrees that CIRM, its authorized agents, the State Controller's Office, and the Bureau of State Audits (collectively, the "Auditors") shall have the right, in connection with an audit, to review and copy any records and supporting documentation pertaining to the performance of

this Agreement including, but not limited to, all documents, records and work papers whether obtained or copied from CIRM or developed by the Consultant. Consultant agrees to maintain such records for possible audit for a minimum of five (5) years after final payment, unless a longer period of records retention is stipulated. Consultant agrees to allow the Auditors access to such records during normal business hours and to allow interviews of any employees who might reasonably have information related to such records. Further, Consultant agrees to include a similar right of the Auditors to audit records and interview staff in any subcontract related to the performance of this Agreement.

XIII. CONFLICT OF INTEREST

- A. The Consultant will not hire any officer or employee of CIRM to perform any service covered by this Agreement. If the work is to be performed in connection with a federal or state contract or grant, the Consultant will not hire any employee of the government concerned to perform any service covered by this Agreement.
- B. The Consultant affirms that to the best of his/her knowledge there exists no actual or potential conflict between the Consultant's family, business or financial interest and the services provided under this Agreement, and in the event of change in either private interests or service under this Agreement, any question regarding possible conflict of interest which may arise as a result of such change will be raised with CIRM.
- C. The Consultant shall not be in a reporting relationship to a CIRM employee who is a near relative, nor shall the near relative be in a decision-making position with respect to the Consultant.
- D. The Consultant shall report to CIRM staff who will provide intervening substantive review of any recommendations made by the Consultant.

XIV. AFFIRMATIVE ACTION

The Consultant recognizes that as a state government contractor or subcontractor, the Consultant is obligated to comply with all state laws and regulations regarding equal opportunity and affirmative action in government contracts. When applicable, the Consultant agrees that all such laws and their implementing regulations are incorporated herein as though set forth in full. These laws include the nondiscrimination requirements of Government Code sections 12990 and 11135, and the nondiscrimination program and clause required by Title 2, Division 4, Chapter 5 of the California Code of Regulations.

XV. CONFIDENTIALITY

The Consultant shall keep confidential any information provided by CIRM or any information conveyed orally to the Consultant by CIRM with oral notification of its confidentiality (the "Confidential Information"), Consultant agrees to maintain the secrecy of CIRM's Confidential Information and agrees not to use it except in performing the Services under this Agreement and not to disclose it to anyone outside CIRM or anyone within CIRM's organization who does not have a need to know it to perform under this Agreement. This non-disclosure provision shall not apply to any of the following:

1. Information which the Consultant can demonstrate by written records was known to him or her prior to the effective date of this Agreement;
2. Is currently in, or in the future enters, the public domain other than through a breach of this Agreement or through other acts or omissions of the Consultant; or
3. Is obtained lawfully from a third party.

XVI. APPLICABLE LAW

The laws of the State of California shall govern this Agreement.

XVII. TERMS TO BE EXCLUSIVE

This Agreement constitutes the entire understanding between the parties regarding the subject matter hereof and supersedes any prior understanding between the parties, oral or written, regarding the same subject matter.

XVIII. WAIVER OR MODIFICATION OF TERMS

No waiver, amendment or other modifications of the terms of this Agreement shall be binding upon either party unless expressed in writing and signed by both parties hereto.

XIX. STANDARD FOR PERFORMANCE

The parties acknowledge that CIRM, in selecting the Consultant to perform the services hereunder, is relying upon the Consultant's reputation for excellence in the performance of the services required hereunder. The Consultant shall perform the services in the manner of one who is a recognized specialist in the types of services to be performed. All deadlines set forth in the Agreement are binding and may be modified only by subsequent written agreement of the parties. The Consultant shall devote such time to performance of its, her, or his duties under this Agreement as is reasonably necessary for the satisfactory performance of such duties within the deadlines set forth herein. Nothing in the foregoing shall be construed to alter the requirement that time is of the essence in this Agreement.

Interim CIRM Loan Administration Policy
Adopted by ICOC January 30, 2009, effective June 15, 2009

Preface

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

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

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

I. INCORPORATION BY REFERENCE

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

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

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

C. Defined terms

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

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

D. Types of support

1. CIRM may offer support in the form of Grants or Loans. In an RFA for which the ICOC has budgeted less than \$3 million per award, CIRM will only offer Grants. For RFAs targeting larger awards, eligibility for each type of funding will be decided by the ICOC when it authorizes CIRM to prepare and issue the RFA. The ICOC may direct that an RFA offer only Grants, only Loans, or some combination, subject to the following guidelines.
2. The ICOC may provide that For-Profit Applicants are only eligible for Loans, or that they can choose between Grants and Loans. When a For-Profit Organization receives a Loan, that organization is both the Loan Recipient and the Debtor.
3. The ICOC may permit Non-Profit Applicants to apply for Loans, but only if the Application includes a Co-PI from a For-Profit Organization that agrees to be the Debtor. The Non-Profit Applicant would be the Loan Recipient.

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

E. Roles and Responsibilities

3. Financial Services Provider:

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

II. LOAN APPLICATION AND REVIEW PROCESS

A. Eligibility

1. PI and PD Eligibility

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

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

III. PRE-AWARD AND AWARD

C. Public Policy Requirements

9. Sharing of Publication-Related Biomedical Materials

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

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

V. PAYMENT AND USE OF FUNDS

B. Costs and Activities

1. Allowable Project Costs and Activities

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

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

3. Facilities Costs

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

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

5. Indirect Costs

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

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

6. Interest Earned on CIRM Funds

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

D. Prior Approval Requirements

5. Relinquishment of Award and Award Transfer

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

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

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

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

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

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

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

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

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

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

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

H. Reporting Requirements

3. Other Reports

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

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

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

5. Reporting Related to Loan Terms

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

I. Project Close-Out

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

As part of close-out of a project funded by a Non-Recourse Loan, the Loan Recipient and Debtor must submit a plan for continued development of the project. CIRM approval of the plan is necessary to complete close-out, and will be based on whether the plan, in the judgment of the President of CIRM, appropriately balances the considerations specified in Section 125290.30, subdivision (h), of the Health and Safety Code.

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

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

J. Failure of Compliance

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

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

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

VII. LOAN TERMS

A. Recourse and Non-Recourse Loans

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

B. Interest Rate

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

C. Warrants

1. Requirement

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

2. Warrant terms

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

D. Loan Period

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

E. Repayment at End of Loan Period

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

F. Loan Acceleration

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

- 1. Change of Control**
If there is a change of control of the Debtor, including a merger with a public or private company, and if the combined enterprise value exceeds \$100 million, the Loan Balance becomes due and payable to CIRM 30 days after the effective date of the change of control.
- 2. Follow-on Financing**
If the Debtor secures follow-on financing that exceeds \$60 million or 20 times amount of the Loan authorized by the ICOC, whichever is less, the Loan Balance becomes due and payable to CIRM 30 days after the close of financing.
- 3. Relinquishment or Termination**
If the Loan Recipient relinquishes the Loan, or if CIRM terminates the Loan for any of the reasons stated in chapter V of the Non-Profit GAP and the LAP, the Loan Balance becomes due and payable to CIRM 90 days after the effective date of the relinquishment or termination.
- 4. Pivotal Trial**
If the Loan Recipient, Debtor or a licensee begins a pivotal trial based on the CIRM-funded research, the Loan Balance becomes due and payable to CIRM six months after the start of the trial, but this acceleration trigger does not apply to Loans with a Loan Period shorter than 10 years.

G. Suspension and Forgiveness of Non-Recourse Loans

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

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

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

the considerations specified in Section 125290.30, subdivision (h), of the Health and Safety Code.

The Debtor must also agree to terms for repayment of the Loan Balance if the Debtor resumes development of the project or otherwise derives revenue from CIRM-Funded Invention* or CIRM-Funded Technology* arising from the Loan-funded project. Suspension of repayment will not be granted unless the terms for resumption 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 Debtor must promptly notify CIRM and make whatever payments are owed under those terms.

3. Loan Forgiveness

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

H. Extension of Loan Period for Recourse and Non-Recourse Loans

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

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

I. Loan Application Process

1. CIRM Loan Application Form

By the application deadline for an RFA that offers Loan funding, a Loan applicant must submit a Loan application form. The applicant must indicate its preference among available Loan terms for that RFA, e.g., Recourse, Non-Recourse, Loan Term, etc. If an Application seeks

Recourse Loan funding for a project with scientific merit, the ICOC may deny the Application if the applicant does not meet the credit standards for Recourse Loans. Accordingly, applicants that prefer Recourse Loans must indicate whether they would accept Non-Recourse Loan funding as an alternative. Applicants must also indicate on the application whether they seek a Loan Period of six or ten years (or other Loan Period that the Finance Subcommittee has authorized for the RFA). If a Loan applicant is a Non-Profit Organization, the loan application form must be submitted by the proposed Debtor.

2. Financial Feasibility Review

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

J. Loan Administration Fee

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

K. Intellectual Property and Revenue Sharing Regulations

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

Frequently Asked Questions Regarding Interplay Between the CIRM Interim Loan Policy the CIRM IP Regulations and the Disease Team RFA

Proposition 71 empowers CIRM to use both grants and loans to fund research projects. Until now, CIRM's funding has been accomplished solely through grants. In December 2008, CIRM's governing body, the Independent Citizen's Oversight Board (ICOC), decided to allow funding by grants and loans for successful Disease Team ("DT") RFA applicants. In January, 2009, the ICOC adopted an Interim Loan Administration Policy.

Thus, the Disease Team RFA marks the first time CIRM has implemented a loan program. In addition, the DT RFA introduces the option of including Co-PIs in an application. The designation of a Co-PI may be relevant to applicants' decisions about the loan program.

To help potential applicants better understand how the interim loan program works, and how it interacts with both the Co-PI option and CIRM's IP Regulations, CIRM provides answers to the following Frequently Asked Questions.

Please note that the Disease Team Awards are subject to the terms of the DT RFA and CIRM Regulations, including CIRM's Grants Administration Policies and Interim Loan Administration Policy. This document addresses some common questions about typical arrangements, but does not encompass all details or possibilities. Provided for guidance only, it does not alter or waive any regulatory requirements. The Regulations are available at <http://www.cirm.ca.gov/reg/>. Full text of the Interim Loan Policy may also be found on CIRM's website.

Question 1: What are the key loan terms for the DT RFA?

Answer:

Loan Period: At the time of application, borrowers may choose between a six-year or a ten-year loan term.

Loan Type: At the time of application, borrowers choose between a recourse or non-recourse loan. If they choose a recourse loan, borrowers must indicate whether they will accept a non-recourse loan if they do not qualify for a recourse loan.

Payments: No periodic payments. Repay with interest at the end of the loan term, unless the loan repayment is accelerated as a result of a specified trigger (see below).

Interest Rate: For six year loans, interest = prime + 300 basis points; for ten year loans, interest = Prime + 500 basis points, set at time of ICOC approval

Warrants: For Profit entity must issue stock warrants proportional to amount loaned.
Recourse loans: Warrants equivalent to 10% of amount loaned.
Non-recourse loans: Warrants equivalent to 100% of amount loaned.

Fees: CIRM will contract with financial institutions to handle financial aspects of loan processing and administration. Their fees, if any, have not yet been determined.

Acceleration: Loan becomes due early if any of the following occur:

- Change of control, with value of new company over \$100 million
- Follow-on Financing over \$60 million or 20 times the amount of the loan
- Termination of research project
- Start of pivotal trial (only applies to 10-year loans)

Question 2: What are the main differences between a loan award and a grant award?

Answer:

In most respects, CIRM's loan awards will work just like its grant awards. Grants and loans are both subject to the same rules and procedures about organizational and PI eligibility, application process, scientific review, allowable expenses, research conduct, and financial and scientific reporting. There are, however, three main differences worth noting in this context:

First, the payback requirements are different. "Recourse" loans must be paid back with interest at the end of the loan term. Grants do not carry any requirement of repayment. "Non-recourse" loans carry only a conditional repayment obligation. Debtors who take non-recourse loans that produce commercially successful projects must satisfy their repayment obligations. By contrast, if the project funded by a non-recourse loan fails or is abandoned because the Debtor determines that it is not commercially feasible to continue product development, then the Debtor may seek suspension of the loan repayment obligations. In cases where suspension is permitted, non-recourse loans function more like grants and repayment is not required. See Section VII (A) and (G) of CIRM's Interim Loan Administration Policy for details;

Second, for-profit organizations that receive loans must give CIRM stock warrants proportionate to the loan amount; and

Third, loan recipients are exempt from the revenue-sharing requirements contained in CIRM's Intellectual Property Regulations. By contrast, grant recipients are subject to these revenue sharing provisions. Thus, grant recipients, unlike loan recipients, are required to share a defined percentage of their resultant net sales and licensing revenues with the State of California.

Question 3: What determines whether a particular DT RFA Applicant Team is eligible for a grant or a loan?

Answer: Generally, the organizational structure of the designated PI's institution determines whether the project is eligible for funding by a grant, a loan or both. However, as explained below, the organizational structure of a Co-PI's institution may also be relevant.

Each DT application must designate a single PI, from a single applicant institution located in California. DT applications may also, but need not, include one or two Co-PIs (from the same or other California institutions), and a Partner PI from an institution in the jurisdiction of one of CIRM's collaborative funding partners.

If the designated PI's institution is a For-Profit organization, then the project is only eligible for loan funding.

If the designated PI's institution is a Non-Profit organization, then the project generally will only be eligible for grant funding. However, if an application from a Non-Profit institution includes a Co-PI from a For-Profit organization that is willing to undertake the required loan obligations, then the project may be funded by either grant or loan, at the choice of the applicant. See Section VII (A) and (G) of CIRM's Interim Loan Administration Policy for details.

The definitions of For-Profit and Non-Profit organizations are set forth in Section IV.A of the DT RFA.

Question 4: Does CIRM make loans to Non-Profit applicants? How does that work? Why would a Non-Profit applicant prefer a loan?

Answer:

The only way a Non-Profit applicant can receive a loan is if the application designates a Co-PI from a For-Profit organization, and that For-Profit organization agrees to the loan terms described above,. Under this arrangement, the Non-Profit organization remains the

primary award recipient for administrative, scientific and accounting purposes.

Non-Profit and For-Profit organizations that collaborate in this way may prefer loan funding for a variety of reasons related to their business and product development plans, primarily because loan awards are exempt from CIRM's revenue sharing requirements.

Question 5: At what point in the RFA process must DT applicants indicate whether they seek funding via a loan or grant?

Answer: Teams invited to submit full DT applications (following pre-screening) will be required to indicate the funding structure sought on July 16, 2009 when they submit their full applications.

Question 6: What is the difference between recourse and non-recourse loans?

Answer: At the end of the loan period (six or ten years), a recourse loan must be repaid in full, with interest, regardless of the success or failure of the subject research. Repayment of a non-recourse loan depends on the outcome of the CIRM-funded research. "Non-recourse" loans carry only a conditional repayment obligation. Debtors who take non-recourse loans that produce commercially successful projects must satisfy their repayment obligations. By contrast, if the project funded by a non-recourse loan fails or is abandoned because the Debtor determines that it is not commercially feasible to continue product development, then the Debtor may seek suspension of the loan repayment obligations. In cases where suspension is permitted, non-recourse loans function more like grants and repayment is not required. (For more information about repayment of non-recourse loans, see sections VII.G. and VII.H. of the Interim Loan Administration Policy.)

Question 7: At what point in the RFA process must DT loan applicants indicate its preferred loan terms?

Answer: Every applicant seeking a loan must choose between recourse and non-recourse loans, and between six-year and ten-years loans. An applicant requesting a recourse loan must also indicate whether it would accept a non-recourse loan if it does not meet the higher credit standards for recourse loans. All of these choices must be indicated on July 16, 2009 when the full application is due.

Question 8: Can a DT Applicant change its mind about the type of funding sought after the preliminary application submission deadline?

Answer: It is possible to change funding type election after a preliminary application is submitted and with submission of the full application. However, there cannot be any material difference in the proposed project between these two documents. So, the basis for a change in elected funding type could not stem from a material change in the proposed project. Moreover, applicants cannot change their funding mechanism selection after submitting a full DT application.

Whether an application is eligible for a grant or a loan is closely related to the selection of PI, applicant organization and Co-PIs. Those factors generally cannot change between the preliminary application and the full application. However, an applicant team could change its election of funding mechanism based upon other changes such as changes to the financial arrangement between the team members.

For those applicants eligible to choose between loans and grants, and for loan applicants choosing among available loan terms, those choices need not be made until the deadline for the full application.

Question 9: What CIRM Intellectual Property (“IP”) regulations apply to the DT RFA?

Answer: The CIRM IP Regulations in effect on the date when the Notices of Grant or Loan Award are signed for each successful Disease Team will apply. We currently expect that these Notices of Grant or Loan Award will be signed in late 2009.

We direct your attention to proposed Chapter 6 of the CIRM Regulations (Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees (17 Cal. Code of Regs. Sections 100600 to 100611). Chapter 6 currently is in the process of permanent adoption pursuant to the California Administrative Procedure Act. It is anticipated that the regulations will be finalized by Summer, 2009.

Grant recipients will be subject to Chapter 6 as finally adopted. Loan recipients also will be subject to Chapter 6 of the CIRM Regulations **except that loan recipients will not be subject to the revenue sharing provisions** contained in Section 100608.

Question 10: What is the difference between the CIRM IP Regulations that apply to grant recipients versus those that apply to loan recipients?

Answer: Loan and grant recipients are bound by the same CIRM IP regulations with one main exception: In exchange for their commitment to issue warrants and to repay principal and interest, loan recipients are excused from complying with the CIRM IP Regulations concerning revenue sharing. (Section 100608)

Thus, both grant and loan recipients will have similar obligations concerning Invention and Licensing reporting, Publication, Biomedical material Sharing, Patents, and Licensing or otherwise developing CIRM-Funded Inventions and Technology. Additionally, all grant and loan recipients must implement Access Plans for resulting Products, comply with the California Discount Prescription Drug Program when selling to Californians eligible under said program, and also comply with the

California Discount Drug Program when selling resultant Drugs purchased in California with Public Funds.

However, while grant recipients are required to share with the State a defined fraction of licensing revenues and/or net revenues they generate from CIRM-Funded Inventions or Technology, loan recipients do not have any such obligation. Loan recipients do not directly share with the State any royalty on resulting inventions or technology. Their financial obligations come in the form of repaying the loan amount, plus interest (subject to non-recourse provisions) and issuing warrants as required.

Question 11: If an award includes Co-PIs, how are they affected by the differences between grants and loans?

Answer: If the award is made as a grant, Co-PIs are subject to CIRM's revenue-sharing requirements. If the award is made as a loan, they are not.

With one exception described below, Co-PIs and their institutions have no obligation to CIRM to repay loans or issue warrants. The PI's institution, as the loan recipient, is responsible for repayment of the entire award, including amounts that fund Co-PIs. (The loan recipient institution and the Co-PI's institution are free to agree that the latter will contribute toward the repayment. For example, a non-profit entity could agree with its for-profit partner to help repay the loan amount plus interest from the non-profit's share of commercial proceeds resulting from sale of a successful CIRM-Funded Product. Such private agreements have no effect on the loan recipient's repayment obligations to CIRM.)

The one exception occurs when a loan award is made to a non-profit organization with a Co-PI sponsored by a for-profit organization. This type of award will only be made when the for-profit organization assumes the entire loan repayment and warrant obligations. In the case of such loans, the non-profit entity has no repayment obligation to CIRM.

Questions 12: Where can I find resources on-line to help understand the IP Regulations and Loan policies?

Answer: The CIRM website provides access to essentially all the information needed. The CIRM IP regulations, Chapter 6, and the Interim Loan Administration Policy can be found at <<http://www.cirm.ca.gov/reg/>>.

Question 13: Who can I contact if I have questions concerning these matters?

Answer:

Topic	CIRM Contact
Applicant eligibility, application review, and other issues related to the Disease Teams RFA	Gilberto R. Sambrano, Ph.D. Email: gsambrano@cirm.ca.gov Phone: (415) 396-9103
Loan Administration Policy	Ian K. Sweedler Email: isweedler@cirm.ca.gov Phone: (415) 396-9166
CIRM Intellectual Property and Revenue Sharing Regulations	C. Scott Tocher Email: stocher@cirm.ca.gov Phone: (415) 396-9136 Nancy J. Koch Email: nkoch@cirm.ca.gov Phone: (415) 396-9253

