

## **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: <a href="mailto:gsambrano@cirm.ca.gov">gsambrano@cirm.ca.gov</a> Phone: (415) 396-9103
Loan Administration Policy	Ian K. Sweedler Email: <a href="mailto:isweedler@cirm.ca.gov">isweedler@cirm.ca.gov</a> Phone: (415) 396-9166
CIRM Intellectual Property and Revenue Sharing Regulations	C. Scott Tocher Email: <a href="mailto:stocher@cirm.ca.gov">stocher@cirm.ca.gov</a> Phone: (415) 396-9136  Nancy J. Koch Email: <a href="mailto:nkoch@cirm.ca.gov">nkoch@cirm.ca.gov</a> Phone: (415) 396-9253

