

CHAPTER IX. GRANTS ADMINISTRATION POLICY FOR FOR-PROFIT ORGANIZATIONS

A. Preface

The California Institute for Regenerative Medicine (CIRM) intends to open its Requests for Applications for research grants to for-profit organizations. At its December 2006 meeting, the Independent Citizens Oversight Committee (ICOC), CIRM's governing board, adopted the CIRM Grants Administration Policy for Academic and Non-Profit Institutions (Non-Profit GAP). The Non-Profit GAP applies generally to science and medical research grant funding of program costs. This CIRM Grants Administration Policy for For-Profit Organizations (For-Profit GAP) largely adopts the Non-Profit GAP and makes it applicable to for-profit applicants and grantees. The For-Profit GAP deviates in some instances from the Non-Profit GAP where differences between for-profit and non-profit organizations warrant different treatment.

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 CIRM grants or become CIRM grantees, to the extent that it does not conflict with the policies stated herein.

This grants administration policy statement may be updated periodically by CIRM. Any new or amended regulations adopted by the Independent Citizen's Oversight Committee (ICOC), the governing board of CIRM, will be applied to currently active grants on the start date of the next budget period. Principal investigators, program directors and organizational officials with active CIRM grants will receive notification of revised grant terms and conditions or revised editions of the For-Profit GAP 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 For-Profit GAP and all of its appendices shall survive the end of the term of the grant, and should CIRM no longer exist, those rights may be enforced by the State of California.

B. Incorporation by Reference

CIRM's Grants Administration Policy for Academic and Non-Profit Institutions (Non-Profit GAP) and any appendices, as they may be amended from time to time, are hereby made applicable to for-profit organizations that apply for CIRM grants or become CIRM grantees, except as described in subsection "C," below.

Note that this For-Profit GAP is intended to apply to for-profit organizations only to the extent that CIRM funds them through grants. If CIRM decides to fund research by for-profit organizations through a mechanism other than grants, it may provide further amendments to this policy.

C. Provisions of the Non-Profit GAP Modified for this Policy

The specified sections below supersede their counterpart in the Grants Administration Policy for Academic and Non-Profit Institutions, as codified in Title 17, California Code of Regulations, section 100500, and are made applicable to for-profit grant recipients:

II. GRANT APPLICATION AND REVIEW PROCESS

A. Eligibility

1. PI and PD Eligibility

To be eligible to serve as a PI or PD on a CIRM grant-supported project or activity, the individual must at a minimum possess an M.D., Ph.D., or equivalent degree, unless otherwise noted in an RFA. There are no citizenship requirements for PIs.

Principal Investigators or Program Directors from for-profit applicants and grantees must be employed primarily by the for-profit organization (i.e., greater than 50% time) at the time of award and during the entire project period.

[This requirement supersedes 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 grantees shall share biomedical materials first created with CIRM funding and described in published scientific articles for research purposes in California as specified in the CIRM Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations (Title 17, California Code of Regulations, section 100404). Annual reporting requirements pertaining to CIRM-funded patented inventions and projects, which may extend 15 years beyond the project period, may be found in Title 17, California Code of Regulations, section 100402.

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

V. PAYMENT AND USE OF FUNDS

B. Costs and Activities

CIRM grant funds shall only be used for expenditures necessary to carry out the approved project and activities. Specific allowable or unallowable costs may be described in the RFA or the NGA. In accordance with Proposition 71, direct research funding costs include scientific and medical funding for an approved research project and the general operating costs of facilities for conducting the approved project.

1. Allowable Project Costs and Activities

Project costs are those costs that can be specifically identified with a particular project or activity under a CIRM grant. Unless otherwise specified in an RFA or NGA, allowable project costs include salary for investigators (detailed below), fringe benefits, itemized supplies, stipends and tuition and fees (as defined in chapter VI, section C, *Allowable Costs and Activities for Training Grants*), research animal costs, consultants, itemized clinical study costs, travel-related expenses (detailed below), itemized project-related equipment (as approved), publication costs, service contracts, subcontracts, and administrative costs where required to carry out the approved project. For specific allowable costs related to training grants see chapter VI, section C, *Allowable Costs and Activities for Training Grants*).

Investigator salaries shall be limited to an annual rate of \$200,000 per investigator. This limitation shall be adjusted biennially by CIRM beginning January 2, 2008 as follows: (a) the base dollar amount of \$200,000 shall be increased or decreased by the cumulative percentage change in the annual average California Consumer Price Index for All Urban Consumers, June 2006, to the end of the calendar year immediately preceding the year in which the adjustment will take effect and (b) the dollar amount obtained by application of the calculation set forth in subdivision (a) shall be rounded to the nearest \$1,000. The resulting figure shall be the adjusted salary rate limitation in effect until January 1 of the next even-numbered year.

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.

2. Unallowable Project Costs and Activities

Unallowable project costs and activities are costs that cannot be charged to a CIRM grant and include visa expenses for foreign nationals, malpractice insurance, membership dues, furniture, telephone equipment, personnel

recruitment, receptions, and cost of food or meals unrelated to allowable travel expenses.

3. Facilities Costs

Facilities costs cover general operating costs of the grantee'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.

4. Unallowable Facilities Costs

Costs already provided for by a facilities or infrastructure grant (from any source) are not allowable facilities costs in a CIRM research grant.

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. of the Non-Profit GAP.]

D. Prior Approval Requirements

5. Award Transfer

With prior approval, the continuation of CIRM grant activities may be transferred to another eligible organization in California in the event that:

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

The CIRM grantee organization must submit to CIRM no less than 90 days before the effective date of award transfer a written request and justification that the prospective organization has the intent and means to continue the proposed research. If the initial request to transfer the award is approved, final approval will be contingent upon the current grantee organization relinquishing rights to the grant. Furthermore, the grantee organization may be required to transfer to the new organization any equipment purchased under the grant. Before the transfer can take place, the original grantee organization must submit to CIRM a relinquishing statement that includes an estimate of the unexpended balance of any funds paid to the grantee and an assurance that all unexpended funds will be transferred to the new grantee organization or returned to CIRM within 90 days of the relinquishing date.

The new grantee organization must submit to CIRM a letter that states their intention to assume responsibility for the award, including all provisions of this Grants Administration Policy for For-Profit Organizations and the CIRM Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations, 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 grantee)
- c. Biographical sketches for new key personnel
- d. Other support for new key personnel
- e. Facilities and resources
- f. Public policy assurances (e.g., human subjects, animal, biohazard), where applicable.

CIRM will issue a new NGA to the PI and the new grantee organization when all required documents have been received and the transfer has been approved by CIRM. Transfer of the award is effective when the NGA is signed by the PI and the authorized organizational official of the new grantee organization and returned to and received by CIRM. Payment will not be issued until the award transfer is effective.

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 grantee organization will be required to submit a final report on the project and a final financial report within 90 days of the effective date of award termination. All unexpended funds as of 30 days of the date of award termination must be returned to CIRM within 120 days of termination of the award. Further, the grantee organization shall continue to be responsible for all ongoing obligations of the award under the CIRM Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations.

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

H. Reporting Requirements

3. Other Reports

Grantees shall report to CIRM publications, inventions, patent applications, licensing and invention utilization activities that result from CIRM funding, as detailed in Title 17, California Code of Regulations, section 100402.

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

I. Grant Close-Out

CIRM will close out a grant 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 grantee or CIRM. CIRM may withhold funds from the awardee organization for future or concurrent awards if a grant close-out is pending the submission of overdue reports.

Close-out of a grant does not cancel any requirements for property accountability, record retention, reporting or financial accountability. Following close-out, the grantee 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 period of grant support. In addition, the grantee is obligated to report to CIRM after grant close-out any patents filed, patents issued, licenses granted, or revenue received that resulted from CIRM-funded research (see Title 17, California Code of Regulations, sections 100400 *et seq.*).

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

K. Written Notification Requirements

During the project period and for 15 years after the period of grant award, grantee organizations must provide written notification to CIRM within 30 days of the occurrence of any of the post-award changes described below:

1. Change in organizational status, including but not limited to a corporate acquisition, consolidation, dissolution or merger. In the case where intellectual property exists as a result of CIRM-funded programs, any acquiring organization shall assume responsibility for all provisions of the CIRM Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations (see Title 17, California Code of Regulations, sections 100400 *et seq.*).
2. Licensing activity related to CIRM-funded research.
3. Termination of a program that is currently funded by CIRM. The grantee organization will be required to submit a final report on the project and a final financial report within 90 days of the effective date of award termination. All unexpended funds as of 30 days of the date of award termination must be returned to CIRM within 60 days of termination of the award. Further, the grantee organization shall continue to be responsible for all ongoing obligations of the award under the CIRM Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations (see Title 17, California Code of Regulations, sections 100400 *et seq.*).

[This section is an addition to the requirements of section V. of the Non-Profit GAP, as modified above.]