

1 Adopt 17 Cal. Code of Regs. section 100700 to read:

2 **§ 100700. Grants Administration Policy for Facilities and Equipment Grants.**

3 (a) In addition to the provisions of Title 17, California Code of Regulations section
4 100500, all recipients of a facilities grant (a grant pursuant to Health and Safety Code section
5 125290.70, subdivision (a)(4)) from the California Institute for Regenerative Medicine
6 (“CIRM”) agree to be bound by the terms and conditions of the CIRM Grant Administration
7 Policy for Facilities and Equipment Grants, as adopted by the Independent Citizens Oversight
8 Committee on December 12, 2007, and incorporated herein by reference as identified below.

9 (b) The CIRM Grant Administration Policy for Facilities and Equipment Grants is
10 incorporated by reference herein in its entirety except for its “Preface.”

11 (c) Amendments to this regulation (and the policy incorporated) herein will be applied to
12 already active grants on the anniversary date of the Notice of Grant Award following the
13 effective date of the regulation’s amendment, unless specified otherwise in the regulation or the
14 incorporated policy amendment.

15 (d) The CIRM’s right to enforce the provisions of the policy incorporated herein shall
16 survive the end of the term of the grant and, should CIRM no longer exist, those rights may be
17 enforced by the State of California.

18 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
19 Health and Safety Code.

20 Reference: Sections 125290.30, subdivision (i), 125290.40, 125290.65, 125290.70, 125292.10,
21 Health and Safety Code.



CIRM GRANT ADMINISTRATION POLICY FOR FACILITIES AND EQUIPMENT GRANTS

OAL Approved – March, 2008

Preface

The California Institute for Regenerative Medicine (CIRM) intends to issue grant applications that address facilities needs that are relevant to research activities promoted by CIRM. The initial facilities grant proposal is contained in RFA 07-01: CIRM Shared Research Laboratory Grant Program and Stem Cell Techniques Course. At its December 2006 meeting, the CIRM's Independent Citizen's Oversight Committee (ICOC) adopted the "Interim CIRM Administration Policy for Academic and Non-Profit Institutions" (referred to hereafter as the CIRM Grants Administrative Policy or GAP). These policies generally apply to science and medical research grant funding of program costs, and do not specifically address facilities costs. Thus, this update of the GAP provides guidance and conditions that apply to grants involving construction, renovations and/or equipment proposed in a CIRM facilities grant.

The GAP and all appendices adopted by the ICOC in December 2006 are hereby adopted to apply to facilities grants. Where the guidelines or policy expressed herein may conflict with the December 2006 GAP, these policies (FGAP) will govern facilities grants. THE GAP will continue to govern science and medical research grants and training grants. CIRM intends to resolve any such conflicts in future amendments to this document. Therefore, any suggested changes to these policies to resolve or further clarify the application of these policies may be directed to CIRM at CIRM.CA.GOV.

TABLE OF CONTENTS

Preface..... 1

VII. POLICIES FOR FACILITIES GRANTS..... 3

 A. General Policies Applicable to Facilities Grants Under Proposition 71 3

 1. Authority to award grants and loans for buildings, building leases and capital equipment 3

 2. Eligibility for Facilities Grants..... 3

 3. Priority for Applications that Provide Facilities within 2 years of Grant 3

 4. Preference for California Suppliers.....3

 B. Construction/Procurement Process 4

 1. Prevailing rate of per diem wages on construction 4

 2. Cost Standards (buildings, leases, other) 4

 C. Provisions Applicable to Equipment Purchases--Shared Use of Equipment and Reimbursement..... 4

 D. Matching Funds..... 5

 1. Cash Match..... 5

 2. Equity Match..... 5

 E. Oversight and Payment Procedures 5

 1. Payment of Construction Grant Funds 5

 2. Funds for Equipment 6

 3. No Transfer of Equipment..... 6

 4. Progress Reports..... 6

 5. Project Close Out. 6

 6. Post Audit..... 6

 7. Initiation of Research Grant Funding..... 7

 F. Additional Glossary of Terms 8

VII. POLICIES FOR FACILITIES GRANTS

A. General Policies Applicable to Facilities Grants Under Proposition 71

1. Authority to award grants and loans for buildings, building leases and capital equipment.

Proposition 71 authorizes CIRM to make both grants and loans for buildings, building leases, and capital equipment (see “facilities,” as defined in subpart “F” of this chapter). (Health & Safety Code § 125290.65, subd. (b)(1).) This Chapter VII addresses the procedures unique to the administration of facilities grants. Provisions governing loan funds will be issued if and when CIRM undertakes a program of facilities loans. The provisions of California Code of Regulations section 100500 apply to these grants, except where those provisions conflict with Chapter VII, in which case the provisions of this chapter control.

2. Eligibility for Facilities Grants.

Eligibility for facilities grants is limited to not-for-profit entities (as defined in the Additional Glossary of Terms, subpart “F” of this chapter).

3. Priority for applications that provide facilities within two years of grant.

Proposition 71 specifies that the criteria, requirements, and standards for awarding facilities grants shall include “Priority for applicants that provide for facilities that will be available for research no more than two years after the grant award.” (Health & Safety Code § 125290.65, subd. (b)(1)(B).) Therefore, applicants are encouraged to consider all opportunities for expediting renovations or construction so that research activities may commence quickly, including the use of interim space while renovations are underway. Facilities grant applications may include a funding plan that will allocate a portion of the grant to pay for interim measures, such as leasing of space, in order to accommodate research activities prior to completion of the main facility funded by the grant.

4. Preference for California Suppliers.

Proposition 71 specifies that the ICOC establish standards to ensure that grantees purchase goods and services from California suppliers to the extent reasonably possible, in a good faith effort to achieve a goal of more than 50 percent of such purchases from California suppliers. (Health & Safety Code § 125290.30, subd. (i).) Applicants are therefore required to show how they propose to achieve the stated goal with respect to any award of a facilities or equipment grant including associated matching funds.

B. Construction/Procurement Process

1. Prevailing rate of per diem wages on construction.

Proposition 71 specifies that the criteria, requirements, and standards for awarding facilities grants shall include the requirement that all workers employed on projects funded by a CIRM facilities grant receive the prevailing wage. (Health & Safety Code § 125290.65, subd. (b)(1)(E).) This requirement applies generally to California state agencies. Private non-profit entities that are facilities grant recipients will be required to certify compliance with prevailing wage requirements for work undertaken using CIRM funds. CIRM will not release construction funds until the grantee and its general contractor complete this certification in the form attached as Appendix B to Chapter VII.

2. Cost standards (buildings, leases, other).

Proposition 71 specifies that the criteria, requirements, and standards for awarding facilities grants shall include the requirement that grantees comply with reimbursable building cost standards, competitive building leasing standards, capital equipment cost standards, and reimbursement standards and terms recommended by the Facilities Working Group and adopted by the ICOC. (Health & Safety Code § 125290.65, subd. (b)(1)(D).) Pending adoption of these standards, the Facilities Working Group has adopted Interim Procedures directing that these standards be incorporated where appropriate into the Shared Research Laboratory Request for Application (RFA 07-01 – Appendix A to Chapter VII). Under RFA 07-01, CIRM has established a maximum building cost reimbursement of \$10.50 per gross square foot per year for operation and maintenance of space devoted to CIRM grant activities where CIRM also has funded improvements to the space. In evaluating applications submitted under RFA 07-01, CIRM will consider whether or not the application meets the generally accepted standards currently in use in the community as part of its cost assessment. For example, the cost of specific items of equipment should be within the range of costs that are generally available within the market for a particular item of equipment. Where the cost of equipment items appear to be outside the usual and customary range to accommodate convenience, customization or sole source acquisitions, the application will receive a lower score.

C. Provisions Applicable to Equipment Purchases - Shared Use of Equipment and Reimbursement

For equipment to be purchased with CIRM and matching funds, applicants may propose cost sharing of equipment based on shared use with other programs within the host institution, provided this cost sharing maintains the separation from National

Institutes of Health-funded space and equipment (“NIH free”) conditions that CIRM is seeking under this program.

D. Matching Funds

Applications for CIRM shared laboratory and stem cell techniques course facilities grants carry a minimum 20 percent matching requirement. Health & Saf. Code, § 125290.65(b)(1)(G). This matching requirement can be met in one of two ways:

1. Cash Match.

The applicant can match CIRM funds with a minimum of 20 percent from applicant sources provided on a cash basis. CIRM funds provided to the applicant through another CIRM grant will not qualify. (Health & Safety Code § 125290.65, subd. (b)(1)(G)(i).)

2. Equity Match.

RFA 07-01 provides that renovations and equipment purchases undertaken after January 2005 for hESC facilities will qualify as matching CIRM funds. Applicants that choose this option to match will be required to provide documentation that demonstrates: (1) the capital investments and equipment purchases used for the match relate specifically to construction and equipment used for “NIH-free” space; and (2) the source of funds for the construction or equipment identified as matching. Proposition 71 specifies that matching funds must be from sources other than CIRM. (Health & Safety Code § 125290.65, subd. (b)(1)(G)(i).)

E. Oversight and Payment Procedures

1. Payment of Construction Grant Funds.

- a.** For RFA 07-01, CIRM will disburse grant funds as follows: 10% of the construction grant funds at the time of acceptance by the grantee of the Notice of Grant Award; 80% of the construction grant funds upon receipt of bids and certification from the grantee that sufficient funds will be available to award a contract based on the approved project budget plus any augmentation from institutional sources; and 10% of the construction grant funds at the time that the “Notice of Completion” (filed pursuant to California Civil Code section 3093) has been filed for the project. CIRM reserves the right to request information from the grantee on the actual final costs and funding sources.
- b.** For future projects over \$5 million, CIRM will provide progress payments based on the percentage of completion that has been achieved.

When issued, the RFA for such facilities grants will detail the milestones and amounts for progress payments.

2. Funds for Equipment.

CIRM will reimburse applicants for the cost of equipment based on actual costs after payment has been made. Applicants may request reimbursement for items of equipment on a phased basis as items are procured.

3. No Transfer of Equipment.

Notwithstanding the provisions of Section V, subsection E of the Grants Administration Policy for Non-Profit and Academic Institutions, grantees may not transfer to any other institution equipment purchased under RFA 07-01 in support of Shared Laboratory Renovations and Stem Cell Techniques Course.

4. Progress Reports.

Applicants are required to provide a progress report (Appendix C to Chapter VII) to CIRM every three months after issuance of the Notice of Grant Award. This progress report must compare the grantee's actual progress to date with the schedule in the grant application. All variances must be explained, and a revised completion date indicated.

A grantee's success in timely completing a facilities project funded under previous grants may be a factor considered in evaluating future grant requests from the same institution.

CIRM staff may periodically visit the site of CIRM funded facilities projects to review progress. Grantees shall provide access to CIRM or its designated representative as requested by CIRM.

5. Project Close Out.

On completion of CIRM-funded facility, a Notice of Completion filed pursuant to California Civil Code section 3093 shall be delivered to the CIRM indicating that the contracted work has been completed. The Notice of Completion may be preceded by a Notice of Beneficial Occupancy that grants access to the facility under renovation pending final resolution of any remaining contract performance issues.

6. Post Audit.

CIRM reserves the right to conduct a post-completion audit of project expenditures to ensure that the grantee has complied with CIRM's grant

administration policies. The final payment of facilities grant funds may be adjusted if CIRM determines an adjustment is warranted.

7. Initiation of Research Grant Funding.

Funding of research grants approved under RFA 07-01 will be effective upon completion of the renovations/development of the Shared Research Laboratory or Stem Cell Techniques Course space. In the event interim space has been used to launch these activities that are funded under Part One of the RFA, the grantee can request reimbursement for the interim use within the funding limits of the approved grant.

F. Additional Glossary of Terms

In addition to the terms defined in the GAP approved December 7, 2006, the following additional terms are defined for purposes of interpreting the meaning and intent of this Chapter.

- 1. Facility.** Building, building lease, or capital equipment eligible for funding under Proposition 71.
- 2. Not-for-Profit and Nonprofit.** Either: (1) a governmental entity of the state of California; (2) a legal entity that is tax exempt under Internal Revenue Code section 501(c)(3) and California Revenue & Taxation Code section 23701d; or (3) an entity that is a combination of other entities, if each constituent is also an entity described under (1) or (2) and the joint entity has filed for a section 501(c)(3) determination from the IRS.
- 3. O&M.** “Operations and Maintenance.” Means the ongoing services and tasks associated with operating a building for its intended function, consisting for example of maintenance, custodial services and utilities.

Appendix A – Chapter VII

RFA 07- 01: CIRM PROGRAM FOR SHARED RESEARCH LABORATORIES AND STEM CELL TECHNIQUES COURSES.

INTRODUCTION

The goal of the California Institute for Regenerative Medicine (CIRM) is to develop stem cell and related research for the diagnosis, prevention and treatment of disease. Toward that end, CIRM plans to fund a broad and varied program of stem cell research and training, and has developed a scientific strategic plan to guide this program. As a first step in the CIRM research program, the initiative, *Innovation in Human Embryonic Stem Cell Research*, is intended to “jump-start” research on human embryonic stem cells (hESCs) in California. At a later time, CIRM will offer opportunities for funding across a broader area. The current programs are intended to expand the range and numbers of investigators in the field of hESC research.

The CIRM research grant initiative, *Innovation in Human Embryonic Stem Cell Research*, is being carried out through three Requests for Applications (RFAs), two for individual investigator projects (which have already been issued) and one, the current RFA, for institutional shared research laboratory space:

RFA 06-01: CIRM SEED Grants

RFA 06-02: CIRM Comprehensive Grants

RFA 07-01: CIRM Shared Research Laboratory Grants and
Stem Cell Techniques Course

OBJECTIVES OF THE CIRM PROGRAM FOR SHARED RESEARCH LABORATORIES AND STEM CELL TECHNIQUES COURSES – RFA 07- 01

The objectives of the Shared Research Laboratory Grant Program are twofold:

1. To create dedicated laboratory space for the culture and maintenance of hESCs, in particular the hESC lines that fall outside the federal guidelines, by supporting the creation of core laboratories to be used by multiple investigators conducting research in the home institution and neighboring research institutions, and
2. To provide an environment through CIRM-funded space and equipment for the conduct of scientific research on hESCs without regard to federal limits.

The objective of the Stem Cell Techniques Course Program is:

3. To train scientists and technical staff in the growth and maintenance of hESCs by funding a number of hands-on courses teaching hESC culture techniques to be given several times a year for California investigators.

KEY FEATURES OF THE CIRM PROGRAM FOR SHARED RESEARCH LABORATORIES AND STEM CELL TECHNIQUES COURSE PROGRAM

This RFA is open to all academic and non-profit research institutions in the State of California. Each eligible institution may submit only **one** application for a Shared Research Laboratory Grant. It is possible to apply for a Shared Research Laboratory Grant without applying for the Techniques Course Program. It is not, however, allowable to apply only for a Stem Cell Techniques Course Grant without a concurrent application for a Shared Research Laboratory Grant.

Shared Research Laboratory

The primary goal of this RFA is to provide dedicated laboratory space that is free of NIH support, equipped to grow and maintain hESCs, where investigators can conduct research on hESC lines including those that are prohibited by current federal policy. Funds will be provided for renovation of laboratory space and for major equipment necessary for culturing and analyzing hESCs. The laboratory must serve as a shared resource with available core equipment and trained personnel; this resource should be available not only to stem cell scientists at the grantee institution but also to those from nearby institutions without such facilities. These dedicated, common laboratories should encourage optimal sharing among individual investigators, research groups and departments, foster a collaborative, multidisciplinary research environment, and promote cost effectiveness.

Stem Cell Techniques Course

The RFA offers a separate option of additional funding to up to five institutions that provide a specialized, hands-on training course in the expansion, maintenance and other important aspects of hESC culture to be given several times a year (three or more) to scientists and technical staff from California institutions. The maintenance and care of hESCs is a labor-intensive activity requiring specialized knowledge, skills and protocols. As more laboratories in California become involved in hESC research, training of individuals in hESC culture will be required for the research to progress most rapidly. CIRM aims to accelerate research in California by supporting courses to train personnel and by making this much needed training widely available in the state.

For the creation of these core resources, funding will be provided for space renovation, major equipment and operations. The program will be administered in accordance with the CIRM Grants Administration Policy for Academic and Non-Profit Institutions (<http://www.cirm.ca.gov/policies/pdf/InterimGAP.pdf>) and by the CIRM Grants Administration Policy for Facilities, which is currently being developed.

Applications for a basic Shared Research Laboratory Grant may request one-time, total space development/renovation costs of up to \$1,000,000, as well as equipment/instrumentation costs of up to \$1,000,000. In addition, applicants may request up to \$200,000 per year for three years for personnel and supplies required by the facility. Applicants may also apply for annual operation and maintenance (O&M) expenses for the laboratories for three years. Allowable O&M expenses will be based on operating costs for personnel and supplies, calculated at the federally negotiated rate for the applicant institution with a maximum allowance of \$10.50 per gross square foot/year. Indirect costs of 25% will be provided for the sum of operating costs for personnel and supplies and O&M, but not for the costs of space development/renovation and equipment.

An application for a Shared Research Laboratory that also includes a stem cell techniques training course (i.e. all three objectives listed above) may request an additional, one-time amount of \$500,000 for space development/renovation and equipment and an additional \$200,000 per year for three years for personnel and supplies (operating costs) to support the instructional component. As with the Shared Research Laboratory, an application with a course component may request O&M expenses for three years based on the O&M component of the federally negotiated rate with a maximum allowance of \$10.50/gross square foot/year. Indirect costs of 25% will be provided for operating costs plus O&M, but not for the costs of space development and equipment.

In summary, maximum one-time funding to cover space development/renovation and equipment for each award is \$2,000,000 for renovating and equipping the shared research laboratory, and \$2,500,000 for a shared research laboratory providing a hESC techniques course. Each grantee may also receive up to \$200,000 per year for three years for resources (personnel and supplies) to maintain a CIRM-funded shared research laboratory. If a hESC techniques course is funded as part of the award, additional support of up to \$200,000 per year for three years will be awarded as operating costs. In addition, CIRM will provide for up to \$10.50 per gross square feet for the Shared Research Laboratory and hESC techniques course per year for up to three years for operations and maintenance of the space.

FUNDS AVAILABLE

CIRM intends to commit approximately **\$48.5** million over a three year period for this RFA, of which up to \$32.5 million is one-time funding for space development/renovation and equipment. The Institute plans to award up to **15** Shared Research Laboratory Grants of which up to **5** will also be awarded funds for a Stem Cell Techniques Course. These awards will be funded for a period of no more than three years each. CIRM reserves the right to discontinue or change funding levels from year to year if significant scientific progress has not been demonstrated.

ELIGIBLE COSTS AND INSTITUTIONAL COMMITMENT

CIRM will support the following costs for creating and maintaining a Shared Research Laboratory:

- 1. Development/Renovation.** Funds for renovating space, including casework and benches, to create a Shared Research Laboratory may be included in the budget request. Costs for site preparation and installation of major equipment may also be included. No more than 15% of the CIRM funds may be used for planning and design and administrative costs. Costs incurred before the time of the grant award for construction or renovation of space for hESC research outside the Federal guidelines cannot be reimbursed but may be used as matching funds if costs were incurred after January 1, 2005.
- 2. Equipment.** Purchases of major equipment such as incubators, hoods, freezers, liquid nitrogen containers and microscopes are anticipated under this program and may be included in the budget request. Costs for equipment bought to be used for hESC research outside the federal guidelines before the time of the grant award

cannot be reimbursed but may be used as matching funds if costs were incurred after January 1, 2005.

3. **Salaries for key personnel.** Salaries for personnel providing services directly to oversee and support the Shared Research Laboratory may be included in the budget request. This may include support for the Project Director (PD), laboratory manager, and/or technical staff based on percent of full-time effort commensurate with the established salary structure of the applicant institution.
4. **Supplies.** Supplies for maintaining the Shared Research Laboratory and hESC lines used in the laboratory, including specialized reagents and media costs may be included in the budget for operating costs.
5. **Operations & Maintenance (O&M).** Costs for utilities, building maintenance, security, police and environmental health and safety services for space which would receive funding in this RFA can be included in the budget request covering three years. The amount budgeted is to be based on a maximum allowance of \$10.50 per gross square foot of space based on the O&M component of the institutions federally negotiated overhead rate.

Stem Cell Techniques Course (if applicable). Institutions may request an additional \$500,000 in total renovation/development and equipment costs and an additional \$200,000 per year for up to three years in operating funds for costs specifically associated with the instructional program. The application must describe separately and justify the additional renovation, equipment, salary and supply costs related specifically to the course.

Institutional Commitment. Applicant institutions will be expected to provide at least a 20% match of the total cost for renovation and equipment, including funds for development/renovation and equipment for the Stem Cell Techniques Course. Funds that have been spent since January 1, 2005 for renovation of shared research space for hESC research outside the federal guidelines or for equipment to be used in such space may be designated as matching funds provided that the institution can document these expenditures.

APPLICATION PROCEDURE

Letter of Intent

All institutions and investigators planning to apply for a CIRM Shared Research Laboratory Grant must notify CIRM in a letter of intent (LOI) that must be received by February 2, 2007. Please use the template for the LOI provided on the CIRM website. The letter should provide a concise description of the renovations and equipment planned for creating the Shared Research Laboratory space, and a plan for its management, maintenance and use by stem cell scientists from the applicant institution and from neighboring institutions. Other nearby California institutions whose scientists may be eligible to use the shared laboratory should be named.

Programs that also propose a Stem Cell Techniques Course should include a description of an instructional plan, a plan for the management of the course, and how this plan integrates with other uses of the planned laboratory space and equipment.

Letters of intent are non-binding, but applications will not be accepted if an LOI has not been received by the deadline. Letters of intent must be sent as an email attachment to Laboratory@cirm.ca.gov.

Application Instructions

The application process for the CIRM Shared Research Laboratory Grants will be split into two parts, each with separate submission dates: a scientific application (Part One) and a facilities application (Part Two). Some parts of the application will be in both Part One and Part Two, and some in only one of the two parts.

- Part One applications (with or without requests for support of a CIRM Stem Cell Techniques Course) must be received by **February 23, 2007**.
- Part Two applications must be received by **March 16, 2007**.

Applications received after these dates will not be accepted.

For both Part One and Part Two submittals, applicants must use the Shared Research Laboratory Grant Application Form which will be available on the CIRM website by February 2, 2006.

PART ONE: The application for Part One of the Shared Research Laboratory Grant must include the following components:

- ***Scientific Abstract*** (up to 3,000 characters): This abstract consists of a summary of the overall plans for the creation of an hESC culture center and shared laboratory, and the stem cell research programs that will benefit from use of the CIRM Shared Research Laboratory. Applicants should include a brief description of the instructional program if applying for the additional funds to support a Stem Cell Techniques Course.
- ***Public Abstract*** (up to 3,000 characters): This abstract briefly describes, in lay language, the proposed Shared Research Laboratory, the research programs that would use the laboratory and how it will directly or indirectly contribute to the development of diagnostics, tools or therapies. Applicants should include a separate description for the Stem Cell Techniques Course if applying for course funding.
- ***Statement of Benefits to California*** (up to 2,000 characters): Describe in a few sentences how the proposed Shared Research Laboratory (and techniques course, if applicable) will benefit the State of California and its citizens.
- ***Scientific Need and Research Use*** (up to 4 pages): Identify the amount of space, expressed in assignable square feet, for development/renovation justified by the scientific need for, and the projected use of, space for hESC research by Principal Investigators (PIs) at the home institution and at neighboring institutions.
 - ***Investigators and Current Research***: Describe the PIs and types of investigations that will take place in the proposed space and with the equipment requested. Descriptions of research should be concise and should focus on the benefit of the Laboratory to research objectives. Include projects that are "pilot"

projects (not externally funded) which are developing preliminary data. Explain how the size and organization of the laboratory will match the anticipated scope of work on hESCs.

- Currently Available Space: Describe the space currently available in your institution for hESC research outside the federal guidelines. Explain how this space will be related to the proposed CIRM Shared Research Laboratory and why more space is being requested.
- Feasibility and Track Record: Provide any information that establishes the experience, competence and fitness of the institution to serve as a site for this type of Shared Research Laboratory and to operate a core service in hESC research. Include other core facilities and the grantee institution's track record (i.e., how well managed, productive) in operating core services.
- Laboratory Equipment and Management Plan (up to 3 pages):
 - Describe the major equipment and resources needed for the creation of the Shared Research Laboratory. Provide a justification for major equipment (e.g., culture hoods, incubators, freezers, microscopes) costing over \$5,000. Describe any special circumstances regarding the acquisition or installation of the equipment. Indicate the estimated useful life of the equipment.
 - Describe plans for development as well as oversight, supervision, management and maintenance of the core laboratory and equipment. Explain how access will be provided for research use of the laboratory and how it will be managed, maintained and made available for investigators at the home institution and investigators from neighboring institutions. The laboratory shall have an Oversight Committee that will be responsible for assuring quality, developing policies, and overseeing the budget and management. Describe the qualifications and expertise of those who will be on the Oversight Committee. Also describe the qualifications and responsibilities of the Laboratory Manager and other personnel. Specifically:
 - Describe proposed guidelines for optimal utilization of the Laboratory including time allocation among investigators;
 - Describe a detailed plan for the day-to-day management and safe operation of the equipment;
 - Describe a plan to ensure that access to the Laboratory is limited to users with appropriate training and whose projects have received appropriate approvals;
 - Describe a plan to ensure that access to the Laboratory is permitted to appropriate investigators, limited to California scientists at the grantee institution and neighboring institutions.
- Key Personnel (up to 2 pages excluding biographic sketches):
 - List the proposed personnel for managing the Shared Research Laboratory. Include participants and their roles in the relevant section of the application form, regardless of whether they will receive salary support from the grant. These

may include the Program Director (PD) who is managing the Laboratory, the key associates and technicians who are operating the Laboratory. For each key personnel listed, provide a 2- page biographical sketch that highlights prior stem cell (especially hESC) research experience and/or special skills related to the management of the proposed Laboratory. If in-house expertise is already in place, note the credentials of the personnel.

- Budget for Part One (please use the appropriate budget template provided in the CIRM application form for this RFA):
 - Describe a financial plan for the operation and maintenance of the Shared Research Laboratory during the grant period, including a commitment to provide institutional support and services as needed.
 - Include a list of all equipment and the in-place costs associated with the Shared Research Laboratory. Identify the amount of CIRM funds requested and the matching funds provided by the applicant institution.
 - Provide a complete budget for the salaries of key personnel, including benefits, and supplies for the period of time which the applicant seeks funding.
 - Identify the amount of CIRM funds requested for each year funding is requested.
 - Include a request for annual O&M funding of up to \$10.50 per square foot per gross square feet for up to three years and any institutional matching funds committed.

- Stem Cell Techniques Course Description: To apply for resources to conduct the Stem Cell Techniques Course, the following additional information is required (up to 4 pages, excluding budget requirements):
 - An outline of the curriculum indicating how graduates will acquire the skills to culture, expand and maintain hESCs;
 - The faculty who will teach the course and their qualifications;
 - The institution's plans to advertise and promote the course, and how students will be selected for the course;
 - The expected class size of the course and the number of sessions given per year;
 - Tuition/fees to be charged, if any;
 - Services and resources that would be available to graduates after completion of the course, how they would be accessed and how long they would be made available.

- Stem Cell Techniques Course Budget: excluding development/renovation costs, provide the following additional budget information (please use the appropriate budget template provided in the CIRM application form for this RFA):
 - Additional equipment costs
 - Additional support costs including justification for personnel, supplies and other operating costs dedicated to the course.
 - Administrative costs at 25% of additional operating costs
 - Additional O&M costs for additional space provided.

PART TWO: The application for Part Two of the Shared Research Laboratory Grant includes information from Part One and facilities-related information as follows:

- Scientific Abstract (up to 3,000 characters): This abstract consists of a summary of the overall plans for the creation of a hESC culture center and shared laboratory, and the stem cell research programs that will benefit from use of the CIRM Shared Research Laboratory. Applicants should include a brief description of the instructional program if applying for the additional funds to support a Stem Cell Techniques Course. (Same as Part One.)
- Public Abstract (up to 3,000 characters): Briefly describe in lay language the proposed Shared Research Laboratory and how it will, directly or indirectly, contribute to the development of diagnostics, tools or therapies. Include a separate portion for the Stem Cell Techniques Course, if applying for course funding. (Same as Part One.)
- Statement of Benefits to California (up to 2,000 characters): Describe in a few sentences how the proposed Shared Research Laboratory (and hESCcourse, if applicable) will benefit the State of California and its citizens. (Same as Part One.)
- Laboratory Renovation Plan (up to 3 pages of narrative plus two 11x14 page floor plans and one 8x10 page timeline, excluding budgets):
 - Describe plans for development/renovation of the shared Laboratory space including fixed equipment costs. Include a description of the current space and how it will be renovated and reconfigured to form the Laboratory. Include one 11x14 page of the current floor plan space and one 11x14 page of proposed floor plan of the renovated space. Describe all renovations that will be done. Describe how the project will be managed and tracked, including the project manager and construction supervisor assigned to the project as well as how change orders will be handled.
 - For laboratories that are proposed to be located in leased space, provide information regarding the institution's long-term access to the leased space.
 - Describe plans and a schedule for all phases of development including design, construction, and installation of equipment leading to a functional laboratory. Give a proposed date for occupancy and contingency plans in case of cost overruns. Any additional costs due to budget overruns will be the responsibility of the grant recipient.
 - Timeline (1/2 page): Provide a realistic timetable for completing each proposed specific aim of the project including the timeline for the renovation of the space and acquisition of equipment, operations, and maintenance and where appropriate provide specific milestones for evaluating the achievement of each specific aim.
- Budget for Part Two – Renovation and Equipment Installation: (up to 3 pages)
 - Provide a complete budget for the renovation that includes construction costs, design fees, administration of the project, other costs (i.e. installation of

- equipment) and a construction contingency (limited to 7-10% of the construction budget). Include a draw-down schedule for the use of CIRM funds. Identify the amount of CIRM funds requested and the matching funds. (requires 20% matching funds)
 - Provide a complete budget for movable equipment. (requires 20% matching funds)
- Institutional Commitment: (up to two pages)
 - Provide a detailed description of the amount and source of matching funding for each request that requires matching funds.
 - The requirement of matching funds can be satisfied if the institution can document funds, excluding other grant funds, committed to similar projects (i.e., renovation of lab space and equipment purchase) after January 1, 2005.
 - Detail the use of the space after the three year period.
- Stem Cell Techniques Course: To apply for facilities resources to conduct the Stem Cell Techniques Course the following additional information is required (up to 5 pages, excluding budget requirements):
 - Describe the proposed Stem Cell Techniques Course (Same as Part One)
 - Based on the information provided on the course, include a justification of the space required, if any.
- Stem Cell Techniques Course Facilities Budget: Provide budget information for additional development/renovation costs as indicated on the application form (up to 3 pages):
 - Identify the renovation costs for additional space dedicated to course. Please follow requirements for detailed budgets as describe in the section on Budgets (above) for renovation and equipment, include additional square footage as well as a 11x14 page floor plan of the space. (requires 20% matching funds)
 - Provide a complete budget for movable equipment. (requires 20% matching funds)

REVIEW AND AWARD PROCESS

The scientific components (*Part One*) of CIRM Shared Laboratory Grant applications (Scientific Need and Research Use, Laboratory Equipment and Management Plan, Stem Cell Techniques Course) will be reviewed by the CIRM Scientific and Medical Research Funding Working Group (Grants Working Group). The scientific review will take place in a confidential session. Plans for the development and renovation of the Shared Laboratory (*Part Two*) will be evaluated by the CIRM Scientific and Medical Research Facilities Working Group (Facilities Working Group) and will occur in a meeting that is open to the public with certain exceptions allowed under Article VI, Section 3 of the Bylaws of the Facilities Work Group . Thus, all documents provided under Part Two are public. Final decisions for award will be made by the Independent Citizens' Oversight Committee (ICOC) which is the governing board for CIRM that was established by the California Stem Cell Research and Cures Act (Proposition 71) to oversee CIRM and makes all final funding decisions. The composition of the ICOC can be viewed at:

<http://www.cirm.ca.gov/icoc/pdf/Members.pdf>

Part I: Scientific Review

The Grants Working Group consists of fifteen basic and clinical scientists from institutions outside California, seven patient advocates who are members of the ICOC, and the Chair of the ICOC. The roster of the Grants Working Group can be viewed at:

http://www.cirm.ca.gov/working_group/pdf/GrtWkgGpMbr.pdf.

The fifteen scientists on the Grants Working Group shall review *Part One* of the applications and score them according to scientific and technical merit. The following are among the qualities to be considered for evaluation of the research and teaching components of the grant applications. For Shared Research Laboratory grant applications, particular emphasis will be placed on evaluating the scientific need and the proposed scientific use of the laboratory, and the appropriateness of the size and scale of the facility for the proposed use for hESC research; the quality of the laboratory management plans; and the institutional commitment.

- **Impact and Significance.** What are the scientific questions the users will address? Are the approaches original? Does it incorporate novel methods for the development of a hESC culture Laboratory? What are the users' (PIs') qualifications and productivity? How much of the proposed research activity is ineligible or unlikely to receive Federal funding? Is the research activity sufficiently compelling in that it presents "a vital research opportunity" that will materially aid the objectives of CIRM?
- **Appropriateness of the size and equipment of the Laboratory to the scope of research planned?** Is the scale of the Laboratory appropriate to the number of proposed users and the types of hESC research that it will house?
- **Quality of the Plan.** Is the Laboratory carefully planned? Are the possible difficulties acknowledged, with alternative plans in place should the proposed strategy fail? What is the timetable for achieving such significant results?
- **Management.** How well will the Laboratory be managed? Can the aims of the Laboratory be reasonably achieved? Does the staff have the training and experience required to design, develop and manage the Laboratory and the related research programs? Will the management plan provide investigators adequate access/resources to perform the indicated research? Do the past performance, experience, and qualifications of the institution indicate a capability to operate and maintain the equipment proposed for purchase? Do the past performance, qualifications, and experience of the Program Director, Laboratory Manager, and other key personnel indicate an ability to manage the Laboratory consistent with CIRM objectives? Does the proposal reflect realistic and reasonable costs?
- **Access.** Is the plan sound regarding management of the Laboratory as a shared resource, assuring access to stem cell scientists and trainees from the home institution as well as other neighboring California institutions?

Additional criteria for the Stem Cell Techniques Course Program include the content of the course, plans to reach the appropriate scientists and technical staff, and institutional experience.

- **Curriculum.** Does the curriculum of the proposed Stem Cell Techniques Course provide those who take it with the skills needed for culture of hESCs? What are the qualifications of instructional staff for handling hESC?
- **Reach.** How well will the advertising plans, curriculum, class size, class offerings per year and access described in the proposal maximize the return on CIRM's investment in providing training in the culture of hESCs?
- **Track record for offering similar coursework.** Does the institution have an established experience base for offering laboratory-based instruction that would be similar to the proposed course?

The entire Grants Working Group will then make recommendations for funding to the ICOC based on the scientific quality, institutional need, and the ability of the Shared Research Laboratory (and if included, the Stem Cell Techniques course) to serve the broad needs of stem cell research in California.

Part Two: Facilities Review

The Laboratory Renovation Plan will be evaluated by the Scientific and Medical Research Facilities Working Group (Facilities Working Group). The Facilities Working Group consists of eleven members as follows: six members of the ICOC, four real estate specialists who are residents of California, and the Chair of the ICOC. The roster of the Facilities Working Group can be viewed at: http://www.cirm.ca.gov/working_group/pdf/FacilitiesMembers.pdf .

The members of the Facilities Working Group shall evaluate *Part Two* of each application and assign a numerical score to each application based on common factors and criteria described below.

- **Feasibility:** Are the plans for construction and renovation reasonable? Are they well-organized, with sufficient detail to justify how the project will be managed and carried out?
- **Cost:** Is the overall budget for the project reasonable? Is the cost per assignable square foot comparable to that of other construction projects at other similar institutions? Does the cost per researcher allow for maximum use of the space requested? If there are discrepancies between the cost per square foot and cost per researcher comparable to other similar projects, are there good rationales for them? Has the institution leveraged the CIRM resources?
- **Timeline and Milestones:** How soon can the project be operational? Can the project be completed in a reasonable time? Is the schedule realistic? Are the appropriate licenses, permits and assurances in place or can they be obtained so that construction will not be delayed. Are the milestones listed? Are they clear and reasonable?
- **Institutional Commitment:** Is the institutional commitment of funding to this project sufficient? Is the institution committed to continuing to use the space for stem cell research past the three year period?

- **Historical Performance:** What is the applicant's experience in developing similar projects? What is the applicant's track record on delivering such projects? Have they been completed on time and on budget, and if not, what is the applicant's explanation for cost-overruns and delays?
- **Responsive to the RFA:** Is the proposal responsive to the criteria and objectives states in the RFA?

The Facilities Work Group will then make recommendations for funding to the ICOC based on the technical merits of the plans for renovation and the ability of the Shared Research Laboratory (and if included, the Stem Cell Techniques Course) to serve the broad needs of stem cell research in California.

Recommendations for funding will be made by the Grants Working Group and by the Facilities Working Group. The ICOC will make the final decisions for funding.

REPORTING AND ANNUAL SITE VISIT

After the completion of construction documents, a report shall be submitted to CIRM with the drawing, a complete cost estimate and an updated timeline. If the project has changed from the original application, the applicant shall provide a solution to address the issues prior to proceeding or receiving any additional funding. Beginning at the construction award date (beginning of construction for design/build projects), a report shall be submitted to CIRM either every thirty days or each quarter depending on construction delivery, giving the progress of the project, any problems encountered and a forecast of progress for the next quarter.

After completion and occupancy, each CIRM Shared Research Laboratory shall organize an annual site visit for CIRM program staff to meet with the PD and investigators who use the laboratory to assess the program. An update and summary of research activities and the results that have been generated using the Shared Laboratory shall be presented as a report for discussion and review. These presentations shall include summaries of goals or milestones reached during the funded period, a description of problems encountered that will impact the achievement of particular goals and milestones as outlined in the Laboratory Development Plan, and proposed approaches to overcoming problems encountered. The PD and others shall also describe objectives for the coming year. Reports must include abstracts of scientific work being conducted utilizing the resources of the Shared Laboratory and a list of investigators using the space.

Grantees providing the Stem Cell Techniques Course will present in their annual progress report information regarding the development, implementation and content of the course, the number and source of students taking the course and follow-up information on the annual progress of these students after they return to their home institutions.

SUBMITTING AN APPLICATION

Only applicants who have sent in an official LOI by February 2, 2007 using the template available on the CIRM website (available January 12, 2007) will be allowed to submit an application. The full application consists of *Part One* and *Part Two* which have different due

dates. The electronic submittal for *Part One* of the application must be received by **February 23, 2007**. The electronic submittal for *Part Two* of the application must be received by **March 16, 2007**. Applications will not be accepted after these deadlines. Both parts of the application must be prepared using the appropriate CIRM Shared Laboratory Grant Application Form available on the CIRM website by February 2, 2007.

In addition to the electronic submittal, please submit a signed original of the application plus 5 copies to:

Shared Laboratory Grant Application
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107

The original and 5 copies of *Parts One* and *Two* of the application must be postmarked by the relevant dates.

RECEIPT AND ANTICIPATED REVIEW AND START DATES

Receipt of letters of intent: February 2, 2007
Receipt of *Part One* application: February 23, 2007
Receipt of *Part Two* application: March 16, 2007
Grants Work Group Review of *Part One* application: April, 2007
Facilities Work Group Review of *Part Two* application: May, 2007
ICOC Review of full application: June, 2007
Announcement of awards: July, 2007
Earliest funding of awards: July/August, 2007

Contact Information

Please contact the following individuals (e-mail is preferred) regarding specific questions as appropriate:

For Information on *Part One* of the Application:
Arlene Chiu, Ph.D.
Director of Scientific Activities
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
Email: achiu@cirm.ca.gov
Phone: (415) 396-9104
FAX: (415) 396-9141

For Information on *Part Two* of the Application::
Richard Keller
Senior Officer for Scientific & Medical Research Facilities
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107

Email: rkeller@cirm.ca.gov
Phone: (415) 396-9130
FAX: (415) 396-9141

OTHER REQUIREMENTS

CIRM Grants Administration Policy:

CIRM's governing board, the ICOC, has adopted general Grant Administration Policies that are posted on the CIRM website. In the future, the ICOC will be adopting standard terms and conditions of grant awards issued by the Institute for facilities funding previously referred to as the CIRM Grants Administration Policy for Facilities. Recipients of CIRM support will be advised of these new standards when they are adopted. All recipients of funds awarded pursuant to this RFA are expected to comply with the current stated standards and will need to comply with future facilities-related standards and policies. CIRM reserves the right to discontinue or change funding levels from year to year if significant progress has not been demonstrated.

Human Stem Cell Research Regulations:

CIRM has adopted medical and ethical standards for human stem cell research. All research conducted under this award will be expected to comply with these standards which can be viewed at: http://www.cirm.ca.gov/laws/pdf/Proposed_Interim_Guidelines_ICOC_Modified.pdf

Intellectual Property Policy for Non-profit Organizations

CIRM has adopted policies that govern the intellectual property created under grant awards issued by CIRM to non-profit organizations. Research conducted under this award will be expected to comply with the terms and conditions stated in this policy which can be viewed at: <http://www.cirm.ca.gov/policies/pdf/IPPNPO.pdf>

**Appendix B - Chapter VII
Facilities GAP**

Statement of Assurances Relating to State Prevailing Wage Compliance

Project Name: _____

Grant No.: _____

Construction Start Date: _____

Pursuant to the requirements of Health and Safety Code, section 125290.65, subdivision (b) (1) (E), Grantee and contractor hereby assure and certify as follows:

1. The Grantee, as the body awarding the contract, shall perform the duties associated with the “awarding body” that are enumerated in the Labor Code, Sections 1720, et seq. Duties include obtaining the prevailing wage rate in the locality for each covered worker from the Director of the Department of Industrial Relations. The Grantee shall insure that the general construction contractor will maintain labor records as required by the Labor Code and shall require such records be made available to any enforcement agency upon request.

2. The general contractor and all sub tier subcontractors shall pay laborers, mechanics, and all other construction workers associated with the Project at least the state prevailing wages, in accordance with the requirements of Chapter 1 (commencing with Section 1720) of the Labor Code, for all construction work. The construction contract provides sufficient funds to comply with this requirement. The Grantee shall also insure that the construction contract for the development of the Project contains language-requiring payment of at least the state prevailing wages pursuant to Section 1720 of the Labor Code.

3. The undersigned acknowledges that the availability of grant funds from the California Institute for Regenerative Medicine is expressly made upon reliance to the representations made in these assurances and certification.

GRANTEE:

GENERAL CONTRACTOR:

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date Signed: _____

License #: _____ Date signed: _____

Appendix C – Chapter VII

RFA 07-01 applicant institution _____

Date prepared: _____ Prepared by: _____

Title: _____

Contact info: tel _____

Email: _____

CIRM SHARED LABORATORY AND STEM CELL TECHNIQUES COURSE				
QUARTERLY PROGRESS REPORT				
Please complete the information below based on the current status of the project. Attach an explanation of the variances between the adjusted schedule (the schedule included in the RFA with a start date of the notice of grant award) to the current schedule.				
ACTIVITY/MILSTONE	Schedule Dates from original RFA	Adjusted to Notice of Grant Award Date	Current Schedule as of _____.	Variance (attach explanation)
Prepare Preliminary Plans (from/to)				
Approval of PPs (date)				
Prepare Working Drawings (from/to)				
Approval of WDs (date)				
Advertise for Construction Contract (date)				
Construction Activities (from/to)				
Beneficial Occupancy (date)				
Notice of Completion (date)				
Equipment Purchases (from/to)				

“Preliminary Plans” (PPs) represent approximately 35 percent of the design effort, or would be considered completion of the "Design Development" (DDs) phase of architectural work.

“Working Drawings” (WDs) represent drawings and specifications from which a contractor may determine the full extent of work contemplated in the project for purposes of submitting a bid; may be referred to as completion of “Construction Documents” (CDs) phase of architectural work