DRAFT

Interim CIRM Grants Administration Policy for Training Grants

Preface

This grants administration policy statement serves as the interim terms and conditions of training grant awards issued by the California Institute for Regenerative Medicine (CIRM). In addition, it provides guidance to recipients on their responsibilities as CIRM grantees. Program directors and organizational officials with grants management responsibilities are urged to read this document carefully and to refer to relevant sections for answers to questions that arise concerning the administration of CIRM training grants.

The CIRM is developing a comprehensive grants administration policy statement that will describe the terms and conditions (including public policy requirements) that apply to all CIRM grants. The comprehensive grants administration policy statement will incorporate the policies described in this document for the CIRM training grants. Grantees should be aware that certain public policies that apply to intellectual property rights and the use of human embryonic stem cells are not yet finalized. Grantees will be expected to comply for the entire period of the grant with the relevant provisions set forth in the comprehensive grants administration policy statement as approved by the ICOC and with any regulations adopted by the ICOC. Any new or revised CIRM policies, including regulations, that are described in the comprehensive grants administration policy statement or that are adopted by the ICOC will be applied retroactively to all awarded CIRM grants. CIRM will notify training grant program directors and grantee organizations when the comprehensive grants administration policy statement and applicable regulations are available and in effect.

The CIRM Training Program will provide support to California public colleges, universities, and non-profit biomedical research institutions to develop or enhance training in stem cell biology. The purpose of the CIRM Training Program is to ensure that highly trained scientists and clinicians are available in adequate numbers and in the appropriate research areas to carry out the goals set forth by the California Stem Cell Research and Cures Act.

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I. GENERAL INFORMATION

A. Abbreviations

CIRM – California Institute for Regenerative Medicine

GMO – Grants Management Officer

ICOC – Independent Citizen's Oversight Committee

NGA – Notice of Grant Award

RFA – Request for Applications

SPO – Scientific Program Officer

SRO – Scientific Review Officer

B. Roles and Responsibilities

1. CIRM Staff:

a. President of CIRM

The President of CIRM is the chief executive of the institute and oversees the implementation and operating requirements of the California Stem Cell Research and Cures Act. CIRM NGAs are signed by the President of CIRM or by a staff member designated by the president.

b. Director of Scientific Activities

The Director of Scientific Activities oversees the planning, management and implementation of the institute's scientific endeavors. Other responsibilities include participation in strategic planning in order to help CIRM meet its mission and goals, oversight of activities to track and analyze the portfolio of funded grants, and the development of reporting capabilities. In particular, the Director of Scientific Activities is responsible for all personnel and efforts involved in scientific, programmatic, review and grants management activities. The director ensures that CIRM issues initiatives such as Requests for Applications (RFAs), accepts and reviews applications, and implements the funding of grants and contracts in full compliance with requirements defined by California Stem Cell Research and Cures Act.

c. Scientific Program Officer (SPO)

The SPO is responsible for the programmatic, scientific, and technical aspects of applications and grants. The SPO's responsibilities include, but are not limited to, developing research and research training programs to support the

CIRM mission; providing consultation and assistance to applicants and grantees in scientific and programmatic areas, including interpretation of CIRM grants policies and procedures, and performing post-award administration such as review of progress reports, coordinating site visits and closing out grants. The SPO works with the SRO in pre-award administration, and with the GMO in post-award activities. The name of the SPO and his/her contact information is provided with the NGA.

d. Scientific Review Officer (SRO)

The SRO is responsible primarily for coordinating and conducting the scientific review of applications by organizing and overseeing the activities of the Scientific and Medical Research Funding Working Group. In fulfilling this function, the SRO is responsible for pre-review activities including receipt and assignment of applications for review to appropriate reviewers based on scientific and technical expertise, and determination of the recusal of reviewers based on each reviewer's conflicts of interest. The SRO's responsibilities also include post-review administration including writing and distribution of review reports, coordination of the ICOC's review of applications, and determination of recusal from participation and voting by ICOC members based on their conflicts of interest with each application. The SRO's activities are complementary to those of the SPO and the GMO; all three work as a team in many of these activities.

e. Grants Management Officer (GMO)

The GMO is responsible for the business management and other non-programmatic aspects of the award. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; providing consultation and technical assistance to applicants and grantees with budgetary and non-programmatic areas (including interpretation of CIRM's grants administration policies and procedures); and administering and closing out grants. The GMO works closely with the SPO. The GMO is the focal point for receiving required reports and acting on requests for CIRM's prior approval. The name of the GMO and his/her contact information is provided with the NGA.

2. Grantee Organization Staff:

a. Authorized Organizational Official

The authorized organizational official is the designated representative of the grantee organization for matters related to the award and administration of CIRM grants. This individual's signature on the grant application certifies that, should the application be awarded, the organization will be accountable both for the appropriate use of funds and for the performance of the grant-supported project or activity resulting from the application. This individual also is responsible to CIRM for ensuring that the organization complies with applicable federal and state laws and regulations, including required

certifications and assurances (e.g., human subjects), and CIRM policies, including the terms and conditions of award.

b. Program Director

The program director is the individual, designated by the grantee organization, responsible for the scientific or technical aspects of the grant and for management of the project or activity. The program director also is responsible for ensuring compliance with the financial and administrative aspects of the award. The program director must work closely with other grantee officials to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge CIRM support of research findings in publications, announcements, news programs, and other media; and ensure compliance with CIRM, federal, state, and organizational requirements. The program director must have a formal written agreement with the grantee organization that specifies an official relationship between the two parties even if the relationship does not involve a salary or other form of remuneration.

C. Policy on Collection and Use of Personal Information

CIRM values and respects an individual's right to keep personal information private. Likewise, CIRM recognizes the need to collect and use personal information that will enable CIRM to perform effectively the responsibilities for which it was created. All personal information collected about individuals is be kept confidential and in a secure environment. However, information that is not protected from disclosure under the California Public Records Act may be subject to disclosure upon request.

D. Public Access to Public Records

In the California Public Records Act (Government Code section 6250 et seq.), the California Legislature declared that access to information concerning the conduct of the people's business is a fundamental and necessary right of every person in this state. The California Public Records Act requires that public records be generally available to the public upon request [Government Code section 6253(a)] but also contains numerous exceptions.

The California Stem Cell Research and Cures Act [Health and Safety Code section 125290.30(e)] provides that the California Public Records Act shall apply to all records of CIRM but does not require disclosure of the following:

- personnel, medical or similar files, the disclosure of which would constitute an unwarranted invasion of privacy;
- records containing or reflecting confidential intellectual property or work product, whether patentable or not, including, but not limited to, any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information, which is not patented, which is known only to certain individuals

who are using it to fabricate, produce, or compound an article of trade or a service having commercial value and which gives its user an opportunity to obtain a business advantage over competitors who do not know it or use it; or

- pre-publication scientific working papers or research data.

Although Proposition 71 also provides that the California Public Records Act shall not apply to CIRM working groups, including the Scientific and Medical Research Funding Working Group [Health and Safety Code section 125290.50(f)], the ICOC has decided that the public shall also have access to the records of the working groups except for, among other things, (i) applications for research, training, and facilities grants, loans, and contracts and evaluations of such applications and (ii) exceptions provided for in the California Public Records Act itself.

For further information, please see the California Public Records Act and Proposition 71. For details on how CIRM responds to Public Records Act requests, see the CIRM guidelines available on the CIRM web site at http://www.cirm.ca.gov/general/pdf/guidelines.pdf.

II. PRE-AWARD PROCESS AND AWARD

A. Liability

CIRM does not assume responsibility for the conduct of activities that the grant supports or for the acts of the grantee as both are under the direction and control of the grantee organization and subject to its organizational policies. Further, grantee organization personnel compensated in whole or in part with CIRM funds are not considered employees of CIRM.

The grantee organization represents and warrants to CIRM that it shall be solely responsible for and agrees to indemnify CIRM, protect and defend with counsel acceptable to CIRM, and hold CIRM harmless from and against any claims (including, without limitation, third party claims for personal injury or real or personal property damage), actions, administrative proceedings (including informal proceedings), judgments, damages, punitive damages, penalties, fines, costs, liabilities (including sums paid in settlement of claims), interest or losses, attorney's fees (including any fees and expenses incurred in enforcing this indemnity or a judicial appeal in connection with such enforcement), consultant fees, and expert fees that arise directly or indirectly from or in connection with : (i) the research conducted by such grantee organization whether or not funded by CIRM or (ii) any breach of the representations and covenants in the grant application or any other document delivered to CIRM by or on behalf of such grantee organization.

CIRM's right to enforce the provisions of liability stated above 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. Administrative Review

All applications approved by the ICOC for funding are reviewed by the GMO to determine if they meet all applicable CIRM funding requirements. The GMO reviews the application budget to ensure that all proposed costs are allowable for the proposed project or activity.

The GMO may require that the applicant submit an amended budget that removes costs determined to be unallowable. Even if an amended budget is not required, the costs will be unallowable under the award.

Issues that arise during the administrative review must be resolved by the GMO and the authorized organizational official before the award is made but no later than the initial payment (see below).

C. Award Notice

Once CIRM funding requirements are fully met, a notice of grant award (NGA) is sent to the program director. A copy is also sent to the authorized organizational official designated in the application. The NGA specifies the project period (start and end dates of the project or program) as well as the monetary allocations (itemized direct costs and amount allocated for indirect costs) for each budget period. The NGA also incorporates this grants administration policy statement by reference and specifies any special terms and conditions of the award.

III. AWARD ACCEPTANCE AND PAYMENT

A. Award Acceptance

In accepting a CIRM grant, the grantee assures that any funds expended under the award will be for the purposes set forth in the approved application. Further, the grantee agrees to comply with terms and conditions of this interim CIRM grants administration policy for training grants. Grant recipients shall also be required to comply with all applicable CIRM regulations and standards, including research standards, and any changes to those regulations and standards adopted by the ICOC. The program director and authorized organizational official must sign the NGA within 30 days of receipt to accept officially the CIRM grant. Payment will not be issued until an NGA is signed by the grantee, and returned and received by CIRM. If the grantee cannot accept the award, including the legal obligation to perform in accordance with its provisions, it should notify CIRM immediately upon receipt of the NGA. If resolution cannot be reached, CIRM will void the grant.

To handle CIRM funds, an organization must have:

- adequate organization, management, and accounting systems to administer the award and assure compliance with award terms and conditions;
- adequate financial resources, equipment, facilities, and technical skills to perform the proposed work, or the ability to obtain them;
- the ability to perform the proposed work within the approved period, taking into consideration all existing commitments;
- a satisfactory performance record; and
- a satisfactory record of integrity and business ethics (e.g., liability insurance, bonding, indemnification, and evidence of nondiscrimination and affirmative action in employment).

B. Payment

The initial payment for an approved application is made only after award acceptance. Payment for each additional budget period is made as soon after the start date of that period as possible, and is contingent on the receipt and acceptance by CIRM of the progress report for the prior budget period and requests for anticipated budget changes during that budget period.

IV. SPECIAL POLICIES FOR TRAINING GRANTS

A. Trainee Policy

1. Appointment

The program director should appoint trainees, giving appropriate consideration to the level of training, academic qualifications, and the inclusion of women and minorities. The award notice specifies the maximum number and type (e.g., pre-doctoral, post-doctoral, clinical fellow) of trainees that may be appointed and supported by the CIRM training grant. Each trainee must be sponsored by an eligible faculty mentor who will supervise the training and research experience. The program director must complete and sign a Trainee Appointment Form for each trainee and submit the form to CIRM at the time of appointment (see *Reporting Requirements* below).

2. Degree Requirements

To qualify for appointment, a trainee must have acquired the necessary academic preparation and degree(s) that are appropriate for the level of proposed training. Specifically, a graduate student must have received a bachelor's degree and must be enrolled in a degree-awarding graduate program. A pre-doctoral student must be enrolled in a doctoral degree program in a basic science program or medically-related professional program such as medicine, dentistry, or veterinary medicine. Post-doctoral fellows must have earned a Ph.D., M.D., or equivalent degree. Clinical fellows must

have received a professional doctoral degree in a medically-related field and should be training in a residency or immediate post-residency program.

3. Training Period

The appointment period for any individual trainee is limited to 36 months and should not be less than 12 consecutive months (clinical trainees may request prior approval for a shorter appointment period, but only with written justification). An awarded trainee position cannot be shared among multiple individuals. CIRM expects trainees to devote full time to training activities, which, in addition to their research, may include relevant coursework, workshops, and scientific conferences. Clinical trainees are expected to confine clinical duties to those that are an integral part of their training experience. Clinical trainees may not expend more than 25% of their appointment time on clinical duties that are unrelated to or independent of the CIRM training program.

Program directors of CIRM training grants are encouraged to appoint individuals who are committed to a career in research and plan to remain in the CIRM training program for a minimum of 2 years. The CIRM training grant is not intended to provide opportunities to participate in short-term research assignments during the summer or other "off-quarter" periods.

B. Allowable Costs/Activities

CIRM supports direct costs for the training program that are specifically associated with trainee support (i.e., items 1-4 below) and program administration (i.e., item 5), including administrative support salaries. Indirect costs, which cannot be specifically associated with the training grant program, are limited to 10 percent of the total direct costs.

1. Stipend Levels

Trainee stipend levels should be commensurate with the individual's experience and the level of training. CIRM supports pre-doctoral students with a maximum annual stipend of $25,000. Postdoctoral fellows are supported at the levels recommended by the National Institutes of Health (NIH), which currently range from $35,568 to $51,036, depending on years of experience (see the NIH website at http://grants.nih.gov/training/nrsa.htm). Clinical fellows are supported at a range of $65,000 to a maximum of $75,000, depending on experience. The CIRM encourages the grantee organization to supplement trainee stipends when necessary to meet institutional requirements and maintain equity among trainees, provided the supplementation is without obligation to the trainee.

CIRM expects grantees to re-budget within the total amount already awarded to accommodate any variation in stipend levels. For example, if the application states that three trainees are to be appointed at postdoctoral level 1 and the three trainees are appointed at postdoctoral level 3, the added expense

is to be accommodated under the awarded support. CIRM will not provide additional funds. (See *Prior Approvals* below)

Since CIRM trainee stipends and allowances are not provided as a condition of employment with the CIRM, the state government, or the grantee organization, institutions may not seek funds, or charge training grant awards, for costs that normally would be associated with employee benefits (e.g., FICA, workman's compensation, and unemployment insurance).

A CIRM trainee may not be concurrently supported with another fellowship or similar award that provides a stipend or otherwise duplicates provisions of the CIRM training grant award.

2. Tuition and Fees

Tuition and fees are allowable CIRM training grant costs if such charges are applied consistently to all individuals in a similar training status at the grantee organization, without regard to the source of support. CIRM awards 100 percent of the first $3,000 incurred for tuition and fees (excluding health insurance) and 60 percent of expenses in this category incurred thereafter. CIRM does not cover tuition and fees that are otherwise subsidized by the grantee organization.

Tuition at the postdoctoral or clinical trainee level is limited to specific courses in support of the approved CIRM training program.

3. Health Insurance

If the trainee's health insurance is not otherwise covered by the grantee institution, CIRM covers 100 percent of basic health insurance costs for the trainee and immediate family (if applicable). Health insurance can include coverage for costs such as vision and/or dental care if consistent with organizational policy.

4. Trainee-Related Research and Travel Funds

CIRM provides trainees with an annual allowance for research training-related expenses such as books and laboratory supplies and for trainee travel to scientific conferences or workshops.

Grant funds may be used to cover the costs of a trainee's travel to attend a scientific meeting that would benefit the trainee's research experience. Funds may not be expended to cover the costs of travel between the trainee's place of residence and the training institution or to the training institution for the purpose of recruitment.

Research training experiences away from the parent organization must be justified on the basis of the type of opportunities for training available, the opportunities offered that are different from those at the parent organization,

and the relationship of the proposed experience to the trainee's career stage and career goals. Expenditure of CIRM grant funds for this type of research training requires prior approval by the CIRM.

Textbooks required for coursework, specialty volumes that will enhance training, laboratory and technical manuals are appropriate for purchase provided they are not available in the grantee organization's library. Professional journal subscriptions covering the period of the appointment are not allowable costs to the CIRM training grant.

If personal computers are purchased under the CIRM training grant, they are to remain at the grantee institution for the benefit of all trainees in the CIRM training grant program.

5. **Program Administration Funds**
   CIRM supports administrative costs with an annual direct cost allowance. Eligible administrative costs include administrative support salaries, seminar speakers, outside speakers for courses, audio-visual equipment or supplies, and costs of developing or delivering new courses. Up to 25% of the amount awarded in this category (i.e., program administration funds) may be used for the program director's salary support.

   The cost of advertising the training program to all prospective candidates may be allocated to program administration costs under the CIRM training grant.

   The cost of food and meals served at a seminar or meeting may not be charged to the CIRM training grant.

6. **Indirect Costs**
   Reimbursement for indirect costs is limited to 10 percent of the total direct costs.

C. Prior Approvals

To obtain prior approval, the grantee must send a written request to the GMO. The request must be signed by the grant program director and the authorized organizational official. The documentation must support the need for the prior approval and include an estimate of the expected duration of the change, and any budgetary modifications that are the result of the request. The prior approvals required for training grants include:

- **Stipends** – Re-budgeting funds out of the stipend category.

- **Training Period for Clinical Trainees** – An appointment for clinical trainees that is less than 12 consecutive months requires written justification and prior approval from CIRM.

- **Trainee-Related Funds/Program Administration Support/Indirect Costs** – Re-budgeting between any of these categories; however, funds may be re-budgeted into the stipend category without prior approval.

- **Carryover of Funds** – The grantee must obtain prior approval from CIRM to carry forward unexpended funds from one budget period to the next that exceed 25 percent of the annual direct cost award amount for the expiring budget period.

- **Extensions** – CIRM grantees may request a one-time no-cost extension for up to one year beyond the scheduled project period and date. A written prior approval should be submitted to CIRM at least one month in advance of the scheduled award project period end date.

- **Change in Program Director** – The grantee must obtain prior approval from CIRM to appoint a new program director for the training grant program.

- **Change in Sponsor or Mentor** – The grantee must provide an explanation for requesting a change in a trainee sponsor or mentor. Any mentor changes approved by CIRM should be reported in the annual progress report (see *Reporting Requirements* below).

Additions to the total number of approved trainee positions or to any one type of trainee position are not permitted. The grantee organization must submit a competitive application for a supplement to increase the number of approved trainees.

D. Procurement System Standards and Requirements

Grantees should follow their own procurement requirements, or, if a state instrumentality, State of California requirements, when acquiring goods and services in connection with CIRM grant-supported activities. To the extent reasonably possible, the grantee shall purchase from California suppliers the goods and services used in its CIRM supported research and activities.

E. Reporting Requirements

The program director of a CIRM training grant must report financial and programmatic progress to the CIRM on an annual basis. The interim financial report and the programmatic report are due two months prior to each anniversary of the award start date indicated in the NGA. The subsequent year's funding will not be awarded until these reports have been received, reviewed, and approved by CIRM. In addition, the program director must submit a final financial report that is due 90 days after each anniversary of the award start date.

1. **Interim Financial Report**
   The program director must submit to the GMO an interim financial report, which is due two months prior to each anniversary of the award start date indicated in the NGA. The interim financial report should include costs incurred for trainee support, program administration, and program activities. The GMO reviews the interim financial report to assess budgetary progress and anticipated expenses for the remainder of the expiring award year. A financial report form will be made available.

   The entire 12-month stipend and tuition for each trainee is to be charged to the current year of the award. An appointment period can technically overlap into the next year of the award. Since the entire 12-months stipend and tuition is charged at the time of the appointment, the full amount not yet expended at the end of the award year should be reported on the financial expenditure report as an unliquidated obligation. An unliquidated obligation is a cost incurred but not yet paid or recorded.

2. **Final Financial Report**
   The program director must submit to the GMO a final financial report, which is due 90 days after each anniversary of the award start date indicated in the NGA. The final financial report must include all actual costs incurred during the expired year of award.

3. **Programmatic Report**
   The program director must submit to CIRM an annual report detailing progress and activities of the training program. This, together with the interim financial report, is due two months prior to the anniversary of the award start date indicated in the award notice. The programmatic report includes two components: a description of the training program and an account of the appointed trainees.

   a. Training Program Report
   A programmatic description of progress made since the initiation of the award is required. A reporting form will be made available that requests the following information:
   - Trainee selection process
   - Current number and type of trainees in the program
   - Program activities (e.g., seminars, workshops, retreats)
   - Course developments or changes
   - Course roster, syllabus, and evaluations
   - Changes in the administration of the program
   - Plans for the upcoming year

   b. Trainee Report

In addition to the training program description, the annual progress report is to include data for all trainees who were or are supported by the training grant. A trainee reporting form will be made available that requests the following information:

- Mentor and trainee assignments
- Description of proposed trainee research and progress
- CV of each trainee
- List of relevant publications
- For trainees who have completed the program, a list of their current position, affiliation, and contact information.

Trainee Appointment Form—A Trainee Appointment Form must be completed for each trainee and submitted to the CIRM at the time of appointment. The form requests information about the appointment including the name of trainee, name of mentor, anticipated period of training, level of stipend support, and anticipated program of training (e.g., proposed research project). The mentor, trainee, and program director must sign the form and in so doing all parties agree to comply with the proposed training program, period of support, stipend level, and the terms and conditions specified in this grants administration policy statement. The completed and signed form is the official document for establishing the stipend, which should be reflected in the annual financial reports and on the Trainee Termination Form. This form will be available on the CIRM website (www.cirm.ca.gov).

Trainee Termination Form—The Trainee Termination Form is the basis for validating the total period of support. The grant program director is responsible for submitting to CIRM a Trainee Termination Form for each trainee within 30 days of the end of the trainee's support. This form will be available on the CIRM website (www.cirm.ca.gov).

4. Overdue Reports

Failure to provide financial, progress, or other reports on time will result in CIRM's reducing, delaying or suspending a CIRM award until required materials are received. Further, if a report is delinquent for more than 3 months beyond its established due date, CIRM will require the grantee to immediately return grant award funds.

5. Intellectual Property

The Intellectual Property Task Force Subcommittee of the ICOC is currently developing the intellectual property (IP) rights and policies that will be applied to CIRM grants. The CIRM Grants Administration Policy will incorporate these policies when appropriate and grantees will be expected to comply with the provisions of the IP policies as approved by the ICOC.

6. Ethical Research Practices

CIRM expects appointed trainees and their faculty mentors to conduct research in accordance with the highest medical and ethical standards, including compliance with institutional requirements, and standards and regulations set forth and approved by the ICOC.

Upon appointment of a trainee, the Program Director must submit to CIRM documentation (where appropriate) pertaining to the trainee's research project that:

- verifies Institutional Animal Care and Use Committee approval of the project's proposed use of live vertebrate animals;
- certifies Embryonic Stem Cell Research Oversight approval of the project's proposed use of human embryonic stem cells;
- certifies Institutional Review Board approval of the project's proposed use of human subjects;
- provides evidence that all key personnel have received training in the protection of human subjects (as outlined in the NIH grants policy under *Education in the Protection of Human Research Participants*) if the use of human subjects is proposed in the project.