CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

CIRM TRAINING PROGRAM

REQUEST FOR APPLICATIONS

The goal of CIRM is to use stem cell and related research to develop new therapies for disease. The Institute thus encourages training in stem cell research that fosters an active interest in, and knowledge of, human diseases, as well as a thorough and critical understanding of fundamental biology.

KEY FEATURES OF THE CIRM TRAINING PROGRAM

To accomplish its training goals, CIRM will offer grants to non-profit academic and research institutions to foster training at the level of pre-doctoral students, post-doctoral students and clinical fellows. Not every institution will be able to offer training at all levels; moreover the number of faculty, students and fellows engaged in stem cell research differs widely among institutions. Training grants are thus offered at several levels of support to accommodate the capabilities of different institutions. All training programs must offer one or more classes in stem cell biology and medicine, and a required course in the social, legal and ethical implications of stem cell research, along with other training activities. Moreover, all programs must offer opportunities for laboratory work under the direction of a mentor in stem cell biology or clinical training that is closely related to stem cell research. Stem cell research is interpreted broadly to include research that is closely related to adult and embryonic stem cells in or from all relevant organisms. Because the goal of CIRM is to utilize stem cells to develop new therapies for

disease, the Institute encourages interactions among basic and clinical scientists that may speed the translation of basic findings to clinical treatment.

An important aim of the overall training program is to provide training for a wide variety of trainees from diverse backgrounds including relevant fields of biology (developmental biology, cell biology, molecular biology, etc.), clinical training programs (medicine, surgery, neurology, cardiology, psychiatry, etc.), bioengineering (tissue engineering, biomedical imaging, etc), as well as ethics and law, where appropriate. Although stipends are offered to support a limited number of trainees, the program is intended to be a resource for a much larger number of students, fellows, and interested faculty. CIRM specifically wishes to promote interactions among trainees from different fields, especially between those trained in basic science/engineering and clinical medicine. Thus, each institution is expected to offer a single, integrated program of training appropriate to its trainees and its areas of expertise.

Because of the diversity of the California population, CIRM is particularly interested in training a group of investigators of diverse racial and ethnic backgrounds. We encourage institutions to make special efforts to recruit and retain under-represented minorities as trainees.

All research done under the auspices of this grant will be guided by the CIRM grants policy, which will be issued at a later date.

PROGRAM MODELS

To reflect differences in institutional size and capabilities for different levels of stem cell research training, grants will be awarded for three types of programs.

1. Comprehensive training programs (Type I): Comprehensive programs will offer training at all three levels: pre-doctoral, post-doctoral and clinical. Each institutional grant may support up to 16 trainees, with a total cost/budget of $1.25 M per year. The apportionment of trainees among the different levels of education is to be determined by the institution within the budgetary guidelines given. Type I grants are most appropriate for medical schools or for universities with medical schools that have large research programs in stem cell research and well-established programs of graduate training.

2. Intermediate training programs (Type II): Intermediate programs will offer training at two of the three levels of education (e.g. pre-doctoral and post-doctoral; post-doctoral and clinical; pre-doctoral and clinical). The grants may support up to 10 trainees, with a total budget of $800,000 per year. Type II grants are suitable for institutions with medical schools that may have less extensive programs, for institutions without medical schools, but with predoctoral and post-doctoral training opportunities, or for research institutes or hospitals with extensive stem cell research programs.

3. Specialized training programs (Type III): Specialized programs will offer training at two levels or at only one of the three levels of education. The grants may support up to 6 trainees, with a total budget of $500,000 per year. These grants may be suitable for smaller institutions with relatively small stem cell research programs.

COMPONENTS OF TRAINING PROGRAMS

1. Trainees: Each training program will have its own unique mix of trainees at different levels of scientific education, depending on the expertise and availability of mentors and the pool of potential trainees to be appointed to the training grant.
   a. Pre-doctoral students will be enrolled in doctoral degree programs related to stem cell research or, if an institution chooses, may be a pre-doctoral student in a professional school in a medically related field (e.g., M.D., D.O., D.D.S., D.V.M.) Students may be appointed to the training grant at any point in their doctoral programs.
   b. Post-doctoral fellows will have received a Ph.D. or a professional doctorate in a medically related field (e.g., M.D., D.O., D.D.S., D.V.M.), and will be pursuing laboratory or clinical research with a mentor in some aspect of stem cell biology or medicine.
   c. Clinical fellows will have received a professional doctorate in a medically related field and will pursue stem cell research training either in a laboratory or in the

clinic. Clinical fellows will normally be at the residency or immediate post-residency level of training.

d. Trainees are not required to be California residents or US citizens.

e. There is no trainee payback requirement.

2. Mentors: Each trainee appointed to the training grant will have an assigned mentor, who is an experienced faculty member/scientist in an area related to stem cell biology or disease. Mentors are expected to provide guidance and laboratory or clinical research opportunities to their individual trainees and to participate actively in the overall stem cell research training program. They will provide annual assessments of their trainees' progress and plans for the next phase of their training. These individual assessments will become part of the annual training program report to CIRM. Mentors should be chosen for both their scientific expertise and their mentoring experience and quality.

3. Program Director: Each program will have a senior scientist who leads and coordinates the institutional stem cell research training program. This individual will have primary responsibility for all programmatic and administrative aspects of the training grant, including adherence to budgetary, policy, and reporting requirements. The Program Director will prepare an annual report that describes appointments of trainees and mentors, description of their individual progress and plans for the next budget period, academic and ancillary programs conducted under the aegis of the training grant, actual distribution of budget expenditures, and explanation of any major changes in the program during the past year or proposed for the next year.

4. An Integrated Program of Training

a. Overall Program:

Only a single training grant will be awarded to each institution, regardless of how many schools, departments or graduate programs participate. Moreover, each institution is expected to have a single integrated training program for all

of its trainees. For the purposes of the grant, each campus of the University of California is regarded as a separate institution. If training at the pre-doctoral level is offered, the institution must have relevant graduate programs of high quality from which pre-doctoral trainees may be drawn. Mentors for pre-doctoral training are expected to be members of these programs. Some institutions may not have pre-doctoral training programs, but may offer post-doctoral and/or clinical training. Institutions may thus differ in the components that are offered, but within a single institution, all components of training must be integrated into a single program.

b. Courses:

All institutions are expected to offer, or to have available through a nearby institution, one or more courses in stem cell biology and its application to human disease. Courses for basic scientists that provide exposure to clinical aspects of disease are especially encouraged. The courses that are offered may be new courses or adaptations of pre-existing courses. In addition, each institution must offer a mandatory course for all trainees in the ethical, legal and social implications of stem cell research. Institutions may cooperate with other, nearby institutions to share resources.

c. Program Activities:

The training program should also include activities that keep trainees apprised of recent developments in the stem cell field and that foster interaction among them, such as journal clubs, seminar series or in-house meetings to discuss new data from on-going research. These activities may already be part of existing programs, but the novel elements need to be clearly identified as components of the CIRM training program and must serve the needs of the CIRM trainees.

d. Institutional Collaborations:

Each training grant will be awarded to a single institution for training at that institution. Several institutions may collaborate, however, to offer a more comprehensive training program for all their trainees than any single

institution is able to provide. How this will occur should be spelled out in the application (see below).

e. Clinical Fellows:

Clinical fellows may participate in laboratory research or patient-based clinical research, but should be part of the overall training program. The ways in which the program will direct and enhance their training should be described clearly.

f. Laboratory Course:

CIRM also wishes to support laboratory training courses in stem cell biology. Because of their significant expense, however, these will be the subject of a future initiative.

ELIGIBLE COSTS

1. Trainee Expenses
   a. Stipends
      i. Pre-doctoral: $25,000/year
      ii. Post-doctoral: $36,000-$51,000, depending on seniority level (follow NIH definitions and levels)
      iii. Clinical fellows: $65,000
   b. Trainee Tuition and Fees
      i. Health insurance
      ii. Institutional student fees
      iii. Tuition subsidy for pre-doctoral students (use NIH formula for calculation)
   c. Research related funds: laboratory supplies, travel, books
      i. Pre-doctoral students: $5,000/yr
      ii. Post-doctoral and clinical fellows: $10,000/yr

2. Program Administration (linked to number of trainees)

a. $3500 per trainee/yr
b. May be used for administrative support salaries, seminar speakers, outside speakers for courses, audio-visual equipment or supplies, costs of developing or delivering new courses.

3. Indirect Costs:
   a. Indirect costs will be given at a level of 10% of the total direct costs

APPLICATION PROCEDURE

Letter of Intent

All institutions planning to apply for a CIRM Training Grant should notify CIRM in a one page letter of intent that must be received by **XXXX**. The letter should describe the type of training grant (Type I, II, III), and the educational levels of trainees receiving the training that they will provide (pre-doctoral, post-doctoral and clinical). If collaboration with other institutions is planned, this should also be described Letters of intent will be non-binding, but applications may not be accepted from institutions that have not provided such a letter.

Full Application Instructions

A. Overall Description of the Program (3 pages):
   1. Describe the specific focus and purpose of the training program, including level(s) of proposed trainees (Type I, II, or III).
   2. Describe the formal training to be offered as part of the program.
      i. Required courses: describe briefly the material to be covered in each; state whether each is a modification (specify how) of an existing course or a course to be developed specifically for this program.
      ii. Optional courses: describe content and whether pre-existing or designed for this program.
   3. Describe related activities that are integral to the program

i. e.g., seminar series (existing or new?), journal clubs, field trips to other labs, group meetings of program participants, etc.

4. Describe plans for the scientific and administrative leadership and oversight of the program.

5. Describe any plans to collaborate with programs at other institutions to provide a more effective overall training program; include a letter of agreement from the other institution(s) concerning the collaboration.

B. Trainees (4 pages for trainees, mentoring assessment of progress):

1. Selection of trainees

i. Pre-doctoral students:

1. Describe the size (number of training faculty and students) and scope (related courses) of pre-doctoral programs from which students might be drawn for this program.
2. Give indications of the quality of these existing programs: years in existence, NIH Training Grant history, average GPA and GRE of entering students, other indications of the quality of the program (i.e. prestigious fellowships won by recent graduates).

ii. Post-doctoral and clinical fellows: Describe selection criteria.

iii. Selection process: How will trainees at each level be selected for appointment to this training grant? Will new appointees be selected each year or will trainees continue for several years in the program?

iv. Describe efforts that will be made to ensure a racially and ethnically diverse group of trainees and to encourage and train under-represented minorities.

2. Mentoring: Describe how trainees at each level of training will be mentored. How will the quality of mentoring received by each trainee be assessed?

C. Mentoring

1. Describe the expectations for the types of mentors that are being proposed for this training program (e.g., laboratory in which trainee would work, other faculty to provide additional mentoring).

D. Assessment of Progress

1. Trainees: How will progress be assessed for trainees at each level? How will the structure of the training program modify the training plans of individual trainees where necessary?
2. Overall program: How will the effectiveness of the overall training program be evaluated?

E. Key Personnel (pages as needed)

1. For each proposed mentor, provide an NIH biographical sketch and an indication of the number of previous pre- and post-doctoral and clinical students trained.

Review and Award Process

CIRM Training Grant applications will be reviewed by the Grants Review Working Group of CIRM. The Working Group consists of fifteen basic and clinical scientists from outside California, seven patient advocates who are members of the Independent Citizen's Oversight Committee (ICOC), and the Chair of the ICOC. The ICOC was established by the California Research and Cures Act (Proposition 71) to oversee CIRM.

The fifteen scientists will review the applications and rate them according to scientific and training merit. Among the qualities to be considered are: overall quality of the planned training program, strength of stem cell research at the institution, qualifications of the program leadership, research and training strength of the mentors, and quality of the existing training programs. Each of the three types of training awards (Type I, II and III) will be ranked separately. The full Grants Review Working Group will then choose those awards to be considered by the ICOC. The ICOC will make the final decision on the grants to be funded at one of its monthly meetings.