



RFA 07-02: CIRM NEW FACULTY AWARDS

I. PURPOSE

The CIRM New Faculty Awards will fund promising M.D. and Ph.D. scientists in the critical early stages of their careers as independent investigators and faculty members establishing their own laboratories and programs. CIRM intends to provide salary and research support for up to five years, creating a stable environment for these new faculty members to build innovative and robust stem cell research programs in the state of California.

II. PROGRAM OBJECTIVES

The use of stem cells in regenerative medicine is a promising area of research whose ultimate goal is to develop novel diagnostics and therapies for disease. A cadre of well-trained scientists and physicians is needed to conduct the basic and clinical studies required to achieve this goal, but several obstacles hinder the entrance of new investigators into this rapidly advancing field. First, newly independent investigators face tremendous pressure to obtain results, publish scientific papers, and acquire grants quickly; therefore, they are reluctant to initiate innovative and risky studies. Second, current levels of federal funding have made it more difficult to obtain financial support, especially for investigators in the early stages of their careers. Particular challenges exist in embryonic stem cell research where restrictions and uncertainty in federal funding have discouraged scientists from initiating new projects. Finally, physician-scientists, who are critical to the translation of basic studies into clinical research, face the additional challenge of balancing research with clinical service. Promising physician-scientists require incentives to choose laboratory research over the greater remuneration offered by clinical practice.

The CIRM “New Faculty Awards” program will encourage and foster the next generation of stem cell scientists in the state of California. Successful candidates for New Faculty Awards will be Principal Investigators (PIs) who have already completed their post-doctoral and/or residency training, and who are in the early phases of managing their own independent laboratories and research programs as faculty members at an applicant institution. Because effective stem cell-derived therapies may arise from unexpected sources, CIRM will support a broad range of research using the full spectrum of stem cell types and experimental approaches, including human embryonic stem cells, as well as stem cells from adults, cord blood, and vertebrate and invertebrate animal model systems. Note, however, that it is not the intention of this Request for Applications (RFA) to fund phased clinical trials. The CIRM New Faculty Awards are intended to have a substantial impact on the career

trajectory of successful candidates by offering the opportunity and necessary protected time to take full advantage of stem cells in their research.

A strong institutional commitment to new faculty and to stem cell research plays an important role in making the field more attractive to scientists. CIRM wishes to encourage institutions to identify and invest in promising new basic and clinical investigators. Candidates for this award must have a commitment of independent space and position from their institution. The applicant institutions should have a proven track record in supporting the development of productive, independent investigators as faculty members in biomedical research. In addition, CIRM expects institutions committed to developing stem cell programs to make collaborative resources and technology platforms available to investigators in order to accelerate their research. This combination of independence, stable funding and a supportive research environment will give new faculty the greatest chance for success in developing stem cell therapies for patients.

III. AWARD INFORMATION

Under this RFA, CIRM intends to commit up to \$85 million to support two categories of faculty awards:

1. New Faculty Awards – CIRM anticipates funding up to 15 New Faculty Awards. Each award is eligible for project costs of up to \$300,000 per year for no more than five years.
2. New Faculty Awards for Physician-Scientists – CIRM anticipates funding up to 10 New Faculty Awards for Physician-Scientists for PIs who have completed training in a residency program. Individual project costs can be up to \$400,000 per year for no more than five years. Recipients of New Faculty Awards for Physician-Scientists may qualify for a CIRM Medical School Loan Repayment Program.

IV. ELIGIBILITY INFORMATION

Applications will only be accepted from PIs who 1) have been officially nominated by their home institution and 2) have submitted a Letter of Intent (LOI) that was accepted by CIRM.

A. Institutional Eligibility

This RFA is open to all academic and non-profit research institutions in the state of California. Non-profit means either: (1) a governmental entity of the state of California; or (2) a legal entity that is tax exempt under Internal Revenue Code section 501(c)(3) and California Revenue and Taxation Code section 23701d. Applicant institutions with a medical school accredited by the Liaison Committee on Medical Education (LCME) are eligible to submit applications for two faculty members for each category, for a total of up to four applications. Applicant institutions without an LCME-accredited medical school are eligible to submit up to two applications; each application may belong to either category. Applicant institutions must provide documentation confirming the independent status of each

nominated candidate. In addition, the applicant institution must certify that each candidate will devote a minimum of 33 percent effort to the research funded by this award. **This minimum commitment cannot be reduced, with or without CIRM approval, notwithstanding any provision of the Grants Administration Policy for Academic and Non-profit Institutions.**

B. Principal Investigator (PI) Eligibility

Individual PIs may be nominated for only one category of award, and may submit only one application under this RFA. As of August 30, 2007, candidates must be within six years of the start date of their first independent position. The candidate must be an independent investigator, which is defined as a faculty member with a multi-year commitment of support from the applicant institution. This commitment must include adequate laboratory space that is dedicated to and supervised by the PI, and start-up funding that includes financial support, equipment, and other resources. At academic institutions, independent investigators are expected to be tenure-track faculty members. Candidates must hold full-time, faculty-level positions and must be paid employees in residence at the applicant institution at the time the application is submitted and throughout the life of the grant award. **Notwithstanding any provision of the Grants Administration Policy for Academic and Non-profit Institutions, changes in PI are not allowed under this RFA.** Candidates for New Faculty Awards must have an M.D., Ph.D., or equivalent degree. Candidates for New Faculty Awards for Physician-Scientists must have completed training in a residency program.

PIs for each category of award must devote a minimum of 33 percent effort exclusively to research proposed in their application. **This minimum commitment cannot be reduced, with or without CIRM approval, notwithstanding any provision of the Grants Administration Policy.** In addition to this commitment, any teaching, clinical, administrative and other duties must be clearly related to the development of the candidate's career in stem cell research. In addition to the minimum time commitment of 33 percent effort, physicians may not expend more than 25 percent of their total effort on clinical duties other than those that are clearly related to their research program(s).

V. REVIEW CRITERIA

Applications will be evaluated in three areas: the Research Plan, the Principal Investigator, and the Institutional Commitment.

A. Research Plan

- Significance and Innovation
 - Does the proposed research address an important problem in the stem cell field? How original and innovative is the research concept and approach? Will the proposed research significantly move the field forward, either scientifically or medically?
- Design and Feasibility of Research Plan

Is the proposed research carefully designed to give meaningful results? What potential difficulties are acknowledged, and what are the alternative plans should the proposed strategies fail? Are the preliminary data compelling and supportive of the proposed concepts, hypotheses and approaches? Do the PI and key personnel have the training and experience to conduct the proposed work? Can the aims of the research be reasonably achieved within the proposed timeframe?

B. Principal Investigator (PI)

- **Qualifications and Potential**
What is the potential of the PI to become a leader in the stem cell field and make seminal contributions to its development? What evidence of prior success supports the future potential of the PI (e.g., funding record, publications, invited presentations)?
- **Career Development Plan**
How effective is the candidate's plan for developing a successful career in stem cell research? How will this award allow the PI to achieve his or her stated goals and become a mentor for the next generation of scientists? Are the milestones realistic and achievable? For physician-scientist candidates, how are clinical responsibilities and other duties integrated into the plan?

C. Institutional Commitment

- **Commitment to the Investigator**
What is the nature of the institution's commitment to the candidate's career, including laboratory space, salary and research support, and mentoring? How does the institution support the candidate's research (e.g., are the necessary technology platforms, collaborative environment, and core facilities available to the candidate)? How will the institution continue to promote the scientific and leadership development of the candidate? What are the institution's plans for recruiting more faculty and fellows that could enhance the research environment?
- **Institutional Track Record and Future Plans**
What aspects of the institution's track record demonstrate its ability to promote the development of new biomedical research faculty? What is the evidence of both prior and continuing support for stem cell research programs? What are the future plans of the institution for supporting new faculty and promoting stem cell programs?

VI. APPLICATION PROCEDURE

Applicant institutions and candidates must follow these instructions for submitting a Candidate Nomination Form, Letter of Intent, and Application for the CIRM New Faculty Awards. Applications will only be accepted from PIs who 1) have been officially nominated on a Candidate Nomination Form (CNF) from their home institution and 2) have submitted a Letter of Intent (LOI) that was accepted by CIRM.

A. Candidate Nomination Form (CNF)

Applicant institutions must submit to CIRM a single Candidate Nomination Form (CNF) using the CNF template provided at <http://www.cirm.ca.gov/grants/default.asp>. The CNF must list the name, degree and employment title of each of the PI(s) the institution wishes to nominate for these awards. CIRM will accept only one CNF from each institution; this form must be signed by an institutional official authorized to nominate candidates on behalf of the entire institution. The signed original CNF must be received by CIRM no later than **5:00pm (PDT) on August 9, 2007. No exceptions will be made.**

Mail the signed original CNF to:

New Faculty Award Candidate Nomination Form
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107

B. Letter of Intent

Candidates for either category of award must submit a letter of intent (LOI) using the LOI template provided at <http://www.cirm.ca.gov/grants/default.asp>. The letter should describe concisely the overall goals of the proposed research and technical approaches used to achieve these goals. Completed LOIs should be sent as an email attachment to loi@cirm.ca.gov, and must be received by CIRM no later than **5:00PM (PDT) on August 9, 2007. No exceptions will be made.** Letters of intent are non-binding, but applications will not be accepted if an LOI has not been received by CIRM by the stated LOI deadline.

C. Application Instructions

The application for CIRM New Faculty Awards consists of four parts:

Part A: Application Information Form (Adobe PDF template provided at <http://www.cirm.ca.gov/grants/default.asp>.)

Part A includes: Abstract, Public Abstract, Statement of Benefit to California, Key Personnel, and Budget (section numbers 1, 2, 3, 12, and 13 below).

Part B: New Faculty Award Research Proposal (MS Word template provided at <http://www.cirm.ca.gov/grants/default.asp>.)

Part B includes: Rationale and Significance, Specific Aims, Research Design and Methods, Preliminary Results and Feasibility, References, Laboratory/Clinical Facilities including major equipment, and Career Development Plan (section numbers 4, 5, 6, 7, 8, 9, and 11 below).

Part C: Biographical Sketches for Key Personnel (MS Word template provided at <http://www.cirm.ca.gov/grants/default.asp>.)

Part D: Institutional Letter of Commitment (No template provided)

Part D includes: Institutional Commitment (section number 10 below).

The application for New Faculty Awards includes the following sections:

1. *Abstract (up to 3000 characters in Part A)*
State the goals of the proposal; summarize the overall plans of the proposed research and how they will meet the stated objectives of the proposal. Describe the rationale for these studies and techniques employed to pursue these goals. Explain the likelihood of this proposal being funded by the federal government.
2. *Public Abstract (up to 3000 characters in Part A)*
Briefly describe in lay language the proposed research and how it will, directly or indirectly, contribute to the development of diagnostics, tools or therapies. This Public Abstract will become public information; therefore, do not include proprietary or confidential information or information that could identify the candidate and applicant institution.
3. *Statement of Benefit to California (up to 3000 characters in Part A)*
Describe in a few sentences how the proposed research will benefit the state of California and its citizens. This Statement of Benefit will become public information; therefore, do not include proprietary or confidential information or information that could identify the candidate and applicant institution.
4. *Rationale and Significance (up to 1 page in Part B)*
Summarize the context and background of the present application and the specific rationale for the work proposed. Evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. State how the proposed research meets CIRM's goals of funding innovative, perhaps scientifically risky and untested research. If the aims of the application are achieved, state how this information will contribute to the development of diagnostics and/or therapies based on stem cell research.
5. *Specific Aims (up to 1 page in Part B)*
Explain the long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or practice, develop a new therapy, address a critical barrier to progress in the field, or develop new technology. Identify and enumerate each specific aim of the proposal in a concise and step-wise fashion, and describe how each aim will lead to the broad goal of this research.
6. *Research Design and Methods (up to 5 pages in Part B)*
Describe concisely, but in sufficient detail to permit evaluation of the merit of the research, the experimental design, methods and techniques to be employed to achieve the goals specified in the proposal. Identify the new or risky aspects of the research, anticipated pitfalls, and plans to overcome or circumvent difficulties that may arise. Describe the methods of analysis of results, including criteria for success of the proposed studies. If collaboration is integral to the success of the project, describe how this will be achieved. Provide a realistic timetable for completing each proposed specific aim of the

project; where appropriate provide specific milestones for evaluating the achievement of each specific aim.

7. *Preliminary Results and Feasibility (up to 2 pages in Part B)*
Provide preliminary data to support the concepts, hypotheses and/or approaches proposed in the application. Provide any information that will help to establish the experience and competence of the investigator to pursue the proposed project.
8. *References (up to 3 pages in Part B)*
List all references used in the body of the proposal.
9. *Laboratory/Clinical Facilities including major equipment (up to 1 page in Part B)*
Provide a short description of the facilities and environment in which the work will be done, and the major equipment and resources available for conducting the proposed research. Discuss ways in which the proposed studies will benefit from unique features of the scientific environment or employ useful collaborative arrangements where applicable.
10. *Institutional Commitment (up to 2 pages in Part D)*
The applicant institution must provide a letter of support signed by the Dean or Departmental Chair documenting in specific terms the nature of the institution's current and future commitment to the candidate's development into a productive, independent investigator during the period of the award. This statement must indicate the institution's support for the candidate's proposed level of effort related to this award, commitment to release time if necessary, and the availability of appropriate facilities, collaborative resources and administrative support during the award period. A discussion of the institution's track record and future plans for developing new biomedical research faculty, and the commitment to on-going development of stem cell programs should also be included.
11. *Career Development Plan (up to 2 pages in Part B)*
Describe the PI's plan for developing a successful career in stem cell research. State the key goals that will define success, the milestones that must be reached, and potential obstacles to overcome. How will this award help the PI achieve these goals? Describe the metrics to be used in monitoring progress against the plan, and the processes for receiving formal evaluations and feedback from mentors. The career development plan must justify the need for a five-year period of sustained research funding, and must be tailored to the individual needs of the candidate.
12. *Key Personnel (included in Part A)*
List all key personnel and their roles on the project. Key personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Key personnel may include any technical staff, trainees, co-investigators (collaborators), or consultants who meet this definition. A minimum of one percent effort is required for each key person. For each key scientific person listed (except for

technical staff and students), provide a 2 page biographical sketch using the template provided. The sketch should highlight prior research experience and/or special skills related to the proposed research. Include relevant publications.

13. *Budget (included in Part A)*

Provide all budget information requested in the budget section of in the application form. All allowable costs for research grants are detailed in the CIRM Grants Administration Policy (GAP, http://www.cirm.ca.gov/reg/pdf/reg100500_policy.pdf). Under this RFA, allowable costs include the following:

○ Salaries for Key Personnel

Salaries for Key Personnel may include the Principal Investigator, Co-Investigators, Research Associates, and technical support staff (all of whom must be resident and work in California) based on percent of full time effort commensurate with the established salary structure of the applicant institution. The total salary requested by the PI must be based on a full-time, 12-month staff appointment. Because CIRM considers pre-doctoral, post-doctoral and clinical fellows as trainees and not as employees, institutions may request stipend, health insurance and allowable tuition and fees as costs for trainees. Administrative support salaries are expected to be covered by the Indirect Costs for the grant.

○ Supplies

Supplies, including specialized reagents and animal costs may be purchased with grant funds. Minor equipment purchases (< \$5,000 per item) are considered Supplies and may be included as direct costs in the budget.

○ Travel

Recipients (PIs) of CIRM New Faculty Awards are required to attend an annual CIRM-organized meeting in California and should include in the budget the travel costs for this meeting. Travel costs associated with collaborations necessary to the grant are allowable. Details of allowable travel costs can be found in the CIRM GAP.

○ Equipment

Major equipment (> \$5,000 per item) necessary for conducting the proposed research at the applicant institution should be itemized. Equipment costs should not be included as allowable direct costs in indirect cost calculations.

○ Indirect Costs

Indirect costs will be limited to 25* percent of allowable direct research funding costs awarded by CIRM (i.e., project costs and facilities costs), exclusive of the costs of equipment, tuition and fees, and subcontract amounts in excess of \$25,000.

VII. SUBMITTING AN APPLICATION

Applications will only be accepted from PIs who 1) have been officially nominated on a Candidate Nomination Form (CNF) from their home institution and 2) have submitted a Letter of Intent (LOI) that was accepted by CIRM.

The application for CIRM New Faculty Awards consists of four parts:

Part A: Application Information Form (Adobe PDF template provided at <http://www.cirm.ca.gov/grants/default.asp>.)

Part B: New Faculty Award Research Proposal (MS Word template provided at <http://www.cirm.ca.gov/grants/default.asp>.)

Part C: Biographical Sketches for Key Personnel (MS Word template provided at <http://www.cirm.ca.gov/grants/default.asp>.)

Part D: Institutional Letter of Commitment (no template provided)

All four parts of the application for CIRM New Faculty Awards must be submitted together and received by CIRM no later than **5:00PM (PDT) on August 30, 2007**. **No exceptions will be made.** Candidates must use the appropriate CIRM templates to complete Parts A, B and C. These templates will be available on the CIRM website by July 11, 2007. Send electronic copies of all four parts of the application as attachments in a single email to NewFacultyAwards@cirm.ca.gov. In addition to the electronic submittal, candidates must submit an original copy of the application signed by both the PI and the institution's AOO, plus 5 copies of the application to:

New Faculty Award Application
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107

The original application plus the five copies must be received by CIRM no later than **5:00PM (PDT) on August 30, 2007**. **No exceptions will be made.**

VIII. SCHEDULE OF RECEIPT AND ANTICIPATED REVIEW

Receipt of Candidate Nomination Forms and Letters of Intent:	5:00PM (PDT) on August 9, 2007
Receipt of Applications:	5:00PM (PDT) on August 30, 2007
Review of Applications by Grants Working Group (GWG):	October, 2007
Review and Approval by ICOC:	December, 2007
Earliest Funding of Awards:	April, 2008

IX. REVIEW AND AWARD PROCESS

CIRM New Faculty Award applications will be reviewed by the CIRM Scientific and Medical Research Funding Working Group (the Grants Working Group, or GWG). The GWG consists of fifteen basic and clinical scientists from institutions outside California, seven patient advocates who are members of the Independent Citizen's Oversight Committee (ICOC), and the Chair of the ICOC. The membership of the GWG can be viewed at <http://www.cirm.ca.gov/workgroups/pdf/GrtWkgGpMbr.pdf>. The ICOC 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/faq/pdf/Members.pdf>.

Fifteen scientists on the GWG will review the applications and rate them according to scientific and technical merit. For New Faculty Award applications, particular emphasis will be placed on the innovation and design of the research plan, the qualifications and career development plan of the Principal Investigator, and the commitment and track record of the applicant institution.

The full membership of the GWG will then review the entire portfolio of applications, taking into consideration the following criteria:

- Appropriate balance between innovation and feasibility.
- Where relevant, the appropriate balance between fundamental research, therapy development and clinical application.
- Where relevant, the appropriate balance and range of diseases addressed.
- Other considerations from the perspective of patient advocates.

The GWG's final recommendations for funding will then be forwarded to the ICOC, which will make all final funding decisions.

X. CONTACTS:

For review information:

Kumar Hari, Ph.D.
Scientific Officer
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San Francisco, CA 94107
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Phone: (415) 396-9123
FAX: (415) 396-9141

Gilberto R Sambrano, Ph.D.
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California Institute for Regenerative Medicine

210 King Street
San Francisco, CA 94107
Email: gsambrano@cirm.ca.gov
Phone: (415) 396-9103
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For information about electronic forms:

Ed Dorrington
Director of Grants Management Systems
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
Email: edorrington@cirm.ca.gov
Phone: (415) 396-9108
FAX: (415) 396-9141

For programmatic information:

Patricia Olson, Ph.D.
Interim Director of Scientific Activities
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210 King Street
San Francisco, CA 94107
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Phone: (415) 396-9116
FAX: (415) 396-9141

XI. OTHER REQUIREMENTS

A. CIRM Grants Administration Policy:

CIRM's Grants Administration Policy (GAP) for Academic and Non-profit Institutions serves as the standard terms and conditions of grant awards issued by CIRM except as noted herein. All research conducted under this award must to comply with the stated policy, which can be found on the CIRM website at http://www.cirm.ca.gov/reg/pdf/reg100500_policy.pdf. Funding from year to year will depend on scientific progress achieved.

B. Evaluation of the Program

In fulfilling our commitment to the State of California, CIRM may request information essential to an assessment of the effectiveness of this program. Accordingly, recipients are hereby notified that they may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

C. 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/reg/pdf/AdoptedRegs_100010.pdf

While these regulations prohibit donors of gametes, embryos, somatic cells or human tissue from receiving valuable consideration for their donation, they do allow for reimbursement for permissible expenses as determined by an IRB. “Permissible Expenses” means necessary and reasonable costs directly incurred as a result of donation participation in research activities and may include costs such as those associated with travel, housing, child care, medical care, health insurance and actual lost wages. For research activities proposing to obtain gametes, embryos, somatic cell or human tissue from human subjects, CIRM requires the candidate to submit, at the time of application, their reimbursement policy describing how they intend to calculate permissible expenses.

D. Use of Human Fetal Tissue

Adult stem cells are derived from various differentiated tissues, including human fetal tissue. When using human fetal tissue in research, CIRM grantees shall abide by any regulations developed by the CIRM Scientific and Medical Accountability Standards Working Group and ratified by the ICOC (see Title 17, California Code of Regulations, sections 100085 et seq.). CIRM human fetal tissue regulations can be viewed at <http://www.cirm.ca.gov/reg/pdf/RegSect10085.pdf>.

E. Intellectual Property Policy for Non-profit Organizations:

CIRM has adopted policies that govern intellectual property resulting from CIRM-funded research that also govern this award. This policy can be viewed at: <http://www.cirm.ca.gov/reg/pdf/IPPNPO.pdf>.