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## **RFA 12-01: CIRM NEW FACULTY PHYSICIAN SCIENTIST TRANSLATIONAL RESEARCH AWARDS**

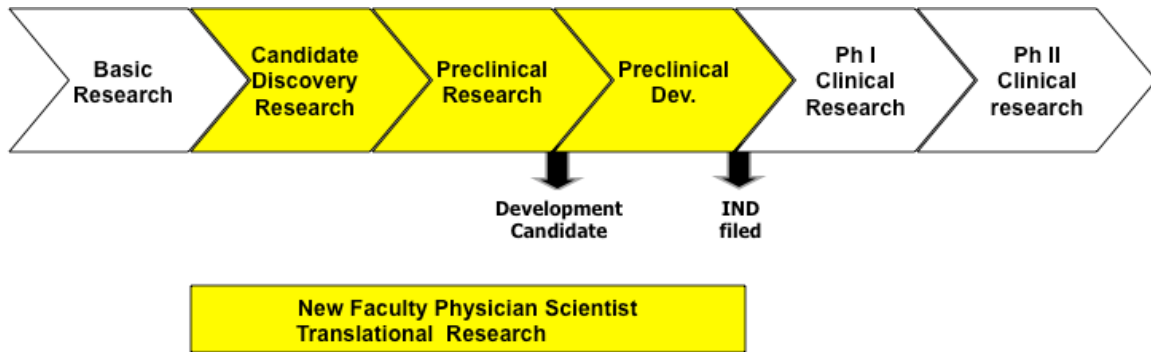
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### **I. Purpose**

The use of stem cells in regenerative medicine is a promising area of research that requires a cadre of well-trained physician scientists to advance innovative translational stem cell science toward clinical development. However, physician scientists in the early stages of their careers face significant challenges in balancing time commitments for clinical service and for the conduct of research. The purpose of the CIRM New Faculty Physician Scientist Translational Research Awards is to encourage and facilitate the career development of physician scientists working in translational stem cell research. This award will fund promising physician scientists in the critical early stages of their careers as independent investigators and faculty members establishing their own laboratories and programs. The award further encourages the career development of these investigators by including a mentoring requirement. CIRM intends to provide salary and support for translational research for up to five years, creating a stable environment for these physician scientist new faculty members to build innovative and robust translational stem cell research programs in the State of California. Successful applicants may also be eligible for CIRM's Medical School Loan Repayment Program.

### **II. Objective and Scope**

The objective of this program is to fund translational stem cell research carried out by physician scientists who are within six years of starting their first independent research programs. The use of human pluripotent stem/progenitor cells must be necessary for the proposed research. Proposals that convincingly target endogenous stem cells in an innovative way, excluding cancer stem cells, are eligible. Priority will be given to proposals that cannot, or are unlikely to, receive timely or sufficient federal funding. The stages of translational research encompassed by this program are highlighted in the figure below and include therapeutic candidate discovery, preclinical research and preclinical development. Proposals that address a translational hurdle (such as ability to differentiate a specific clinically-relevant cell type) are eligible.



Examples of responsive research activities include:

- Identification and characterization of a potentially therapeutic human stem or progenitor cell
- Proof-of-concept characterization of potential therapeutics (molecular or cell-based) using *in vitro* and *in vivo* models
- Development of an efficient, scalable differentiation protocol for a clinically relevant cell therapy
- Maturation of cell phenotypes derived from pluripotent stem cells to adult functional state, e.g. bone marrow colonizing hematopoietic stem cells
- Development of methods for research-scale production of a purified therapeutic candidate
- Pre-clinical IND-enabling studies on a development candidate, including assessment of dose, safety profile and therapeutic window
- Non-clinical studies designed to address questions that arise in the clinic, i.e. “bedside-to-bench” research.

Activities that are out of scope include:

- Projects that are focused on basic molecular and cellular mechanisms and/or on target identification
- Projects based on non-human cells.
- Clinical studies

A strong institutional commitment to new faculty and to translational stem cell research plays an important role in making the field more attractive to physician-scientists. CIRM aims to encourage institutions to identify and invest in promising new physician-scientists who are focused on stem cell translational research. The applicant institutions should have a proven track record in supporting the development of productive, independent physician scientists 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 physician scientists in order to accelerate their research. This combination of independence, stable funding and a supportive research environment

will give new faculty physician scientists the greatest chance for success in developing translational research programs to bring stem cell therapies for patients.

### **III. Award Information**

Under this Request for Applications (RFA), CIRM intends to commit up to \$80 million to support approximately 20 awards. Projects will be funded for up to 5 years, with justifiable direct project costs of up to \$2 million allocated over the term of the project. Given the urgency of CIRM's mission, all approved applications must be initiated (grant start date in issued and signed Notice of Grant Award) within 6 months of approval and authorization for funding by the Independent Citizen's Oversight Committee (ICOC), CIRM's Governing Board.

Successful applicants may qualify for CIRM's Medical School Loan Repayment Program, which will provide loan repayment of up to \$35,000 per year for up to five years of work under this Award.

### **IV. Award Mechanism**

CIRM expects to fund approved proposals from academic and non-profit research institutions in the state of California, through grants.

Grant Terms: Non-profit institutions will receive grant funding in quarterly disbursements, and be subject to all terms of CIRM's regulations governing research awards, including the Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees (17 Cal. Code Regs. § 100600 et seq.).

### **V. Eligibility**

#### **A. Institutional Eligibility**

Academic and other non-profit research organizations in California are eligible to apply.

"Non-profit organization" means: (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.

The number of applications that an institution may submit is determined by the type of applicant institution. Applicant institutions with a medical school accredited by the Liaison Committee on Medical Education (LCME) are eligible to submit up to four applications in support of four new physician-scientist faculty members. Applicant institutions without an accredited medical school may submit up to two applications in support of new physician-scientist faculty members.

## B. Principal Investigator (PI) Eligibility

The PI must have an M.D., D.O., or equivalent degree, and, at the time of funding, be licensed to practice medicine in California by a California member organization of the Federation of State Medical Boards. By the application deadline, the PI must:

- Be an independent investigator holding a full-time, faculty-level position and must be a paid employee in residence at the applicant institution in California at the time the application is submitted. At academic institutions with tenure tracks, the PI must hold a tenure track position. **Notwithstanding any provision of the Grants Administration Policy for Academic and Non-profit Institutions, changes in PI are not allowed under this RFA.**
- Have documented authority from the applicant institution to staff the proposed project.
- Have documented commitment from the applicant institution to provide laboratory space and shared resources sufficient to carry out the proposed research.
- Be within six years of starting his/her first independent faculty position.
- Be nominated by their institution to apply for this grant using a Candidate Nomination Form (see Section IX).

In order to broaden the pool of applicants engaged in stem cell research and to encourage leveraging of CIRM's investment, CIRM is limiting the number of active CIRM research awards in which an investigator may participate as PI or Co-PI. This RFA is not open to investigators who are already a PI or Co-PI on 3 or more active CIRM awards as of July 10, 2012, the deadline for submission of the application.

The limit includes all CIRM awards that have been approved but not yet closed out, with the exception of the following CIRM RFAs/PAs: Shared Research Labs, Major Facilities, Research Training Awards I & II, Bridges to Stem Cell Research, Disease Team Planning Awards, Disease Team Therapy Development Part I Planning Awards, or Conference Grants.

This RFA does not allow designation of a Co-Principal Investigator (Co-PI).

## C. Percent Effort Requirements

CIRM, mindful of the urgency of its mission, will only fund PIs who are willing to commit a minimum of 33% effort to the proposed project. **This minimum commitment must be maintained throughout the life of the award. CIRM will not approve a reduction below 33%, notwithstanding any provision of the Grants Administration Policy.**

## VI. Collaborative Funding Partners

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This RFA does not allow designation of a Collaborative Funding Partner.

## **VII. Application and Evaluation Process**

Submission of an application for this RFA involves a two-step process. First, the applicant institution must file a Candidate Nomination Form (CNF) listing all PIs at the institution who are nominated to apply for this award. In addition, each nominated PI must submit a Letter of Intent (LOI). The deadline for receipt of the CNF and LOI at CIRM is no later than 5:00 p.m. (PDT) on May 23, 2012. Second, applications are due at CIRM no later than 5:00 p.m. (PDT) on July 10, 2012.

Applications will be evaluated by the CIRM Grants Working Group (GWG), which is composed of fifteen scientific experts from outside California, seven patient advocate members of CIRM's Governing Board, and the Chair of the Governing Board. The list of scientific members who may participate in the GWG review can be found at <http://www.cirm.ca.gov/GrantsWkgGrpMembers>. The composition of the ICOC can be viewed at <http://www.cirm.ca.gov/GoverningBoard>. The fifteen participating scientists on the GWG will review the applications and score them according to scientific and technical merit applying the review criteria described in Section VIII below. The GWG (scientists and patient advocates) will then review the entire portfolio of applications, taking into consideration the following criteria:

- Appropriate balance among feasibility, risk and innovation.
- Other considerations from the perspective of patient advocates.

The GWG will make funding recommendations to the ICOC, which will make final funding decisions.

CIRM's confidentiality and conflict screening rules will apply to everyone who will have access to applications or who will attend the review meeting, including CIRM staff and external reviewers.

## **VIII. Review Criteria**

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

### **A. Research Plan**

#### **1. Rationale, Significance and Impact**

- The scientific and medical rationales are logical and compelling.
- The project goal is significant, it addresses an unmet medical need and/or a significant hurdle to translation of a stem cell derived therapy.

- The project, if successful, will substantially advance the translation of a stem cell derived therapy.

## **2. Design and Feasibility of Research Plan**

- The proposed research is innovative and is designed to yield meaningful results.
- Potential difficulties are identified, and alternative strategies are provided should initial approaches fail.
- Preliminary data are compelling and supportive of the proposed research.
- The research team has the expertise needed to conduct the proposed work.
- The material resources are confirmed to be available, including key cell lines, animal models and equipment necessary for the proposed studies.
- The aims of the research can be achieved within the proposed timeframe and budget.

## **B. Principal Investigator (PI)**

### **1. Qualifications and Potential**

- The PI has a track record of past successes and accomplishments, including those achieved during training. Examples include publications, prior research awards, and specific experience in stem cell or translational research.
- The PI has high potential to become a leader in stem cell translational research and to make seminal contributions to their field.
- The PI has clinical duties, preferably relevant to their proposed research.

### **2. Career Development and Mentoring Plans**

- The candidate has proposed an effective plan for developing a successful career in stem cell translational research.
- Milestones in career development are realistic and achievable.
- Time budgeted for clinical responsibilities and other duties must be integrated into the plan.
- Named mentors have appropriate qualifications, including a track record of mentoring successful physician-scientists.
- The award will contribute significantly to enabling the PI to achieve his or her career goals.

## **C. Institutional Commitment**

### **1. Commitment to the Investigator**

- The institution has made a commitment to the candidate's translational research career, providing laboratory space, salary and research support, and mentoring.
- The institution provides significant support for the candidate's research (e.g., necessary technology platforms, collaborative environment, and core facilities).
- The institution will continue to promote the scientific and leadership development of the candidate.
- The institution will enhance the research environment by recruiting additional faculty and fellows whose research interests link with those of the candidate.

## **2. Institutional Track Record and Future Plans**

- The institution's track record demonstrates its ability to promote the development of new physician-scientist faculty.
- The institution is committed to the continuing support of translational stem cell research programs and plans future expansion in this area.

### **D. Responsiveness**

The proposed research must address the RFA's objectives and be within the scope defined by the RFA (see Section II). In particular:

- Human pluripotent stem/progenitor cells must be necessary for the proposed research. Proposals that convincingly target endogenous human stem cells, excluding cancer stem cells, are also eligible.
- The research must be translational in nature, including, for example, therapeutic candidate discovery, and/or preclinical research and/or preclinical development. Proposals that address a specific translational hurdle (such as ability to differentiate a specific clinically-relevant cell type) are also eligible.
- The proposed research cannot, or is unlikely to, receive timely or sufficient federal funding

## **IX. Application Procedure**

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

### **A. Candidate Nomination Form**



Applicant institutions must submit to CIRM a single Candidate Nomination Form (CNF) using the template provided together with this RFA on the CIRM website. 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. The form must be signed by an institutional official (or his/her designate) who is authorized to nominate candidates on behalf of the entire institution. **This institutional official cannot be a member or alternate member of the ICOC.** The signed original CNF must be submitted by email to [RFA12-01@cirm.ca.gov](mailto:RFA12-01@cirm.ca.gov) and be received by CIRM no later than **5:00 pm (PDT) on May 23, 2012. No exceptions will be made.**

## **B. Letter of Intent**

Each nominated candidate must submit a Letter of Intent (LOI) via the CIRM Grants Management Portal (<https://grants.cirm.ca.gov/>). The LOI should describe concisely the overall goals of the proposed research and technical approaches used to achieve these goals. Completed LOIs must be submitted to CIRM no later than **5:00 pm (PDT) on May 23, 2012. No exceptions will be made.** LOIs are non-binding, but applications will not be accepted if an LOI has not been received by CIRM by the stated deadline.

## **C. Application Forms**

Applications for this RFA may be submitted only by applicants who 1) were nominated by their institution and 2) submitted a Letter of Intent. Application forms will be available via the Grants Management Portal at <https://grants.cirm.ca.gov> by May 23, 2012.

The application for the CIRM New Faculty Physician Scientist Translational Research Award consists of **four parts**:

**Part A: Application Information Form** (Web-based form)

**Part B: Proposal** (MS Word template)

**Part C: Biographical Sketches and Letters of Support** (MS Word template)

**Part D: Institutional Letter of Commitment**

The Application includes the following sections:

### **1. Abstract (up to 1500 characters in Part A)**

State the goal of the proposal. Summarize the proposal and how it will meet the stated objectives of the RFA. Summarize the proposed research and career plan.

### **2. Public Abstract (up to 1500 characters in Part A)**

In lay language, briefly describe the proposed research and how the PI and the research will contribute to the advancement of stem cell biology and regenerative medicine. This Public Abstract will become public information and posted on the



CIRM website; therefore, do not include proprietary or confidential information or information that could identify the applicant (e.g., PI name, applicant institution name or location).

**3. Statement of Benefit to California (up to 1500 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 and posted on the CIRM website; therefore, do not include proprietary or confidential information or information that could identify applicant (e.g., PI name, applicant institution name or location).

**4. Key Personnel (included in Parts A and C)**

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, or consultants who meet this definition. A minimum of one percent effort is required for each key person, except the PI, who is required to commit a minimum of thirty-three percent (33%) effort.

For each key person listed, provide a two-page biographical sketch using the template provided under Part C. The sketch should highlight prior relevant translational research experience, accomplishments and/or special skills related to the proposed research. Include relevant publications and/or patents or patent applications.

**5. Budget (included in Part A)**

Provide all budget information requested in the budget section of Part A. Budgets must be justified in detail, including all subcontracts and consulting fees

If, to achieve the objective of the project described in Part B, the applicant will require funding from sources other than CIRM, then the applicant must specify and justify the added cost and identify funding sources that will enable conduct of the project (in the Part A section "Budget Justification").

All allowable costs for research funded by CIRM are detailed in the CIRM Grants Administration Policy (GAP, see Section XII.A of this RFA).

Under this RFA, CIRM-funded allowable costs include the following:

**• Salaries for Key Personnel**

Salaries for Key Personnel may include the Principal Investigator, Research Associates, and technical support staff, each of whom must perform the subject work in California, based on percent of full time effort commensurate with the established salary structure of the applicant institution. The total salary requested must be based on a full-time, 12-month staff appointment.

Institutions may request stipend, health insurance and allowable tuition and fees as costs for trainees. Administrative support salaries should be covered exclusively by allowed Indirect Costs.

• **Supplies**

Grant funds will support supplies, including specialized reagents and animal costs. Minor equipment purchases (less than \$5,000 per item) are considered supplies and may be included as direct costs in the budget.

• **Travel**

Recipients (PIs) of CIRM New Faculty Physician Scientist Translational Research Award are encouraged to attend a CIRM-organized grantee meeting in California and should include travel costs for this meeting in the budget. Travel costs associated with collaborations necessary to the grant are allowable. Details of allowable travel costs can be found in the GAP (see Section XII.A of this RFA).

• **Equipment**

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

• **Consultants/Subcontracts**

Grantees that subcontract CIRM-funded work should note that CIRM-funded **research** must generally be conducted in California. Examples of such research include study design and conduct of experiments; analysis and interpretation of data; development of new methods.

Aside from small consulting contracts, Grantees may not use CIRM funds to contract for research to be performed outside of California. Consulting contracts for out-of-state research are limited to \$15,000 per year for a single contract, and \$25,000 per year in aggregate. (CIRM may allow modest increases to these limits in exceptional circumstances.)

For activities **other than research**, Grantees may subcontract outside California, but must make a good faith effort to use California suppliers for more than half of their contracts and purchases in accordance with CIRM's California Supplier regulation (Cal. Code Regs. tit. 17, § 100502). Examples of such activities include generation of a cell line/research cell bank that is GMP compliant, or humanizing a murine monoclonal antibody performed according to an existing, standard protocol.

• **Indirect Costs**

Indirect costs will be limited to 20 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.

#### **6. Related Business Entities (Part A)**

In order to comply with state law, CIRM checks conflicts for businesses that will get some part of a grant's funding AND for their related business entities (such as subsidiaries). Without that information, CIRM may not be able to effectively avoid conflicts of interest. A conflict error could delay review of an application or even make it ineligible for funding, so it is essential that we get complete information. It is important for all applicants to provide complete information on related business entities for any application that, if awarded, would fund a for-profit organization either as: 1) a subcontractor or 2) the employer of a co-investigator, consultant or subcontractor. If for-profit funding is sought, include the following for each for-profit organization to be funded:

- A list of any parent organization that owns 50% or more of the for-profit's voting shares;
- A list of all subsidiaries in which the for-profit owns 50% or more of the voting shares; and

A list of all other related business entities (i.e., entities with which the for-profit shares management and control, or shares a controlling owner).

#### **7. Rationale, Significance and Impact (up to 1 page in Part B)**

Summarize the context and background of the application and the specific rationale for the proposed research. Specifically identify the gaps in current therapies or the translational hurdles that the project is intended to address. If the aims of the application are achieved, state how the findings will make a critical contribution toward development of a needed therapeutic.

#### **8. Specific Aims (up to 1 page in Part B)**

Explain the long-term objective and the goal of the specific research proposed. Identify and enumerate each Specific Aim of the proposal in a concise and step-wise fashion, and describe how each aim will support the goal of this research.

#### **9. Preliminary Data (up to 4 pages in Part B)**

Provide preliminary data to support the concepts, hypotheses and/or approaches proposed in the application. Clearly indicate data generated by the applicant PI. Provide any information that will help to establish the experience and capability of the investigator to pursue the proposed project.

#### **10. Research Design and Methods (up to 4 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. Describe specific

criteria for success including meaningful quantitative measures to determine if the objectives of the proposed studies have been achieved.

**11. Project Timeline (up to 1/2 page in Part B)**

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.

**12. References (up to 2 pages in Part B)**

List all references used in the body of the proposal.

**13. Collaboration and Environment, Including Laboratory Facilities and 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. If collaboration is integral to the success of the project, describe how the collaboration will be managed.

**14. Career Development Plan (up to 2 pages in Part B)**

Describe the plan for developing a successful career in stem cell translational research. Describe how the research builds upon your past or current clinical experience. State the key goals that will define success, the milestones that must be reached, and potential obstacles to overcome. How will this award help to achieve these goals? Describe the metrics to be used in monitoring progress against the plan. 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.

**15. Mentoring Plan (up to 1 page in Part B)**

Provide the name of one or more individuals who will serve as mentors to the PI during the duration of the project. Describe the nature and frequency of mentorship activities. Describe the processes for receiving formal evaluations and feedback from mentors. For each named mentor provide a 2 page biographical sketch using the Named Mentor Biosketch template provided (include in Part C).

**16. Institutional Commitment (up to 2 pages in Part D)**

The applicant institution must provide a letter of support, signed by a senior organizational official who has the authority, or who has been delegated the authority, to commit the applicant institution to support the candidate, 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. The 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. **Please note that the institutional official who signs this commitment letter cannot be a member or alternate member of the ICOC.**

#### **D. Application Submission Instructions**

Applications will only be accepted from applicants who 1) were nominated by their institution and 2) submitted a LOI that was accepted by CIRM.

**All four parts of the New Faculty Physician Scientist Translational Research Award application must be submitted to CIRM no later than 5:00 PM PDT on July 10, 2012 via the Grants Management Portal. It is the applicant's responsibility to meet this deadline; no exceptions will be made.**

#### **E. Submission of Supplemental Information**

If necessary, the PI may submit limited supplemental materials that provide critical new information related to their research proposal after the application deadline but not later than 5:00 pm PDT on September 4, 2012. Supplementary materials will not be accepted after this deadline. CIRM will accept a one-time-only submission of materials from the PI only if it conforms to the requirements described below. Accepted submissions will be forwarded to reviewers for their consideration.

The submission should be in the form of a one-page letter addressed to the Senior Review Officer and submitted via email to [gsambrano@cirm.ca.gov](mailto:gsambrano@cirm.ca.gov). The body of the letter may not exceed 500 words and should briefly describe the type of information submitted and when the information became available. The following materials qualify for submissions of supplemental materials:

1. Within the one-page letter, provide specific citation(s) to journal publications related to the proposed project that were published or accepted for publication after the application submission deadline. You may briefly describe the significance of the publication(s) to the proposal in the cover letter.
2. Within the one-page letter, confirmation of funding secured from other sources or regulatory (e.g., IND, IDE) filings or approvals acquired after the application submission deadline.
3. Within the one-page letter, notice of patent application(s) filed, notice of allowance received or patent(s) issued, or notice of license(s) to relevant intellectual property granted or received after the application submission deadline.

The letter may not be used to describe any additional data or experiments. Changes in scope, experimental approach, or research design are not allowed.

## **X. Schedule of Deadlines and Reviews**

CNF and LOI due	5:00 pm (PDT), May 23, 2012.
Applications due	5:00 pm (PDT), July 10, 2012
Review of Applications by Grants Working Group (GWG)	September/October, 2012
Review and Approval by ICOC	December, 2012
Earliest Funding of Awards	Winter, 2013

## **XI. Contacts**

For information about this RFA:

Lisa Kadyk, Ph.D.  
Science Officer  
California Institute for Regenerative Medicine  
Email: [lkadyk@cirm.ca.gov](mailto:lkadyk@cirm.ca.gov)  
Phone: (415) 396-9304

For information about the review process:

Gilberto R. Sambrano, Ph.D.  
Senior Review Officer  
California Institute for Regenerative Medicine  
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Phone: (415) 396-9103

For programmatic information:

Patricia Olson, Ph.D.  
Executive Director of Scientific Activities  
California Institute for Regenerative Medicine  
Email: [polson@cirm.ca.gov](mailto:polson@cirm.ca.gov)  
Phone: (415) 396-9116

## **XII. CIRM Regulations**

Grant awards made through this RFA will be subject to CIRM regulations. These regulations can be found on CIRM's website at <http://www.cirm.ca.gov/reg/default.asp>.

### **A. CIRM Grants Administration Policy**

CIRM's Grants Administration Policy (GAP) for Academic and Non-Profit Institutions (Non-Profit GAP) and the GAP for For-Profit Institutions (For-Profit GAP) serve as the standard terms and conditions of grant awards issued by CIRM. All research conducted under this award must comply with the stated policy. Progress reports of research, as required by the GAP, are important to CIRM: Funding from year to year will depend on adequate scientific progress as outlined in the grant application timeline. CIRM's GAP is available at <http://www.cirm.ca.gov/our-funding/our-regulations/stem-cell-regulations-governing-cirm-grants#GAP>.

## **B. Intellectual Property Regulations**

CIRM has adopted intellectual property and revenue sharing regulations for non-profit and for-profit organizations. By accepting a CIRM Grant, the Grantee agrees to comply with all such applicable regulations.

## **C. Human Stem Cell Research Regulations**

As reflected in CIRM's GAP, CIRM has adopted medical and ethical standards for human stem cell research (Title 17, California Code of Regulations, sections 100010-100110 available at <http://www.cirm.ca.gov/our-funding/our-regulations/stem-cell-regulations-governing-cirm-grants#standards>). All research conducted under this award will be expected to comply with these standards. This information can be found on the CIRM website.

## **D. California Supplier Regulation**

CIRM has adopted a regulation to implement the requirement in Proposition 71 that grant and loan recipients make a good faith effort to achieve a goal of purchasing more than 50% of their goods and services from California suppliers (Title 17, California Code of Regulations, section 100502). Grant and loan recipients are required to comply with this standard.