CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

RFA 10-02: CIRM Tools and Technologies Awards II

Tools and Technologies for Translational Bottlenecks

I. Purpose

Development of novel stem cell therapies and medical treatments depends on the translation of basic discoveries in stem cell biology. Rapid progress along this translational pathway will require overcoming technical obstacles and translational bottlenecks. Significant advances will be facilitated by the development of new tools and technologies that surmount these bottlenecks, support innovative translational research, and drive the development of novel therapeutic approaches using stem cells. This award program will support projects to develop such tools and techniques that address technical bottlenecks and enable novel translational approaches.

II. Program Objectives

This RFA will support the inception, early stage development and evaluation for stem cell research applications of innovative tools and technologies that will overcome current roadblocks in translational stem cell research. CIRM encourages the submission of proposals that are focused on both the creation and design of novel tools and technologies and the optimization, improvement, standardization or scale up of an existing tool or technology for addressing a translational bottleneck. Proposals should be focused on tools and technologies directly applicable to the use of human cells. These awards will also support the development of human stem cell based disease models ("disease-in-a-dish") that will be valuable tools for assay development, drug screening, and therapeutic analysis. Possible goals for projects under this RFA include but are not limited to:

- Discovery of novel biomarkers (including monoclonal antibodies) for identification, selection, purification, tracking, functional analyses and clinical responsiveness of human stem cells and their derivatives
- Development of safer and more effective methods for genetically manipulating human stem cells

- Development and validation of stem cell scale-up technologies including novel cell expansion methods, bioreactor, and cryopreservation technologies for both human pluripotent cells and differentiated cell types
- Development and optimization of new cell separation and purification technologies to effectively remove undifferentiated or unwanted human cells from differentiated progeny
- Development of technologies for the robust and efficient derivation of functional cell types from human pluripotent stem cells
- Development of sensitive imaging and molecular techniques for tracking transplanted stem cell derivatives *in vivo*
- Development and preclinical testing of devices for clinical delivery of stem cell-derived therapies
- Development of complex tissue scaffold structures for cell and tissue models in vitro and their in vivo functional analysis
- Development of non-genetic methods for identification and purification of specific differentiated human cell types from cellular mixtures
- Development of disease models using human embryonic stem cells (hESC and/or human induced pluripotent stem cells (hiPSC)
- Use of human iPSC for in vitro modeling of late onset disorders
- Development and validation of screens using disease-in-a-dish models
- Development of robust genetic tools for repair of disease-specific mutations in iPSCs
- Development of diagnostic tools based on human stem cell models
- Development of new animal models for testing cellular therapies for specific disease conditions
- Development of models to predict oncogenic potential of gene-modified human stem cell therapies

For all Tools and Technologies II proposals, applicants are expected to substantiate the predicted value and role of the tool or technology in overcoming a specific bottleneck in translational stem cell research.

III. Award Information

Under this RFA CIRM intends to commit up to $40 million to support up to 20 three-year grants with direct project costs of up to $400,000 per year. 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.

IV. Eligibility

A. Institutional Eligibility

All CIRM-supported research must be conducted in California. Principal Investigators may apply from non-profit and for-profit research organizations that are, at the time the Preliminary Application (PreApp) is submitted, conducting research at a site in California.

"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.

"For-profit organization" means: a sole-proprietorship, partnership, limited liability company, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. Such organizations also are referred to as "commercial organizations".

B. Principal Investigator (PI) Eligibility

The PI must have an M.D., Ph.D. or equivalent degree, and must be authorized by the applicant institution to conduct the proposed research in California. By the Pre-Application deadline, the PI must:

- be an independent investigator at a Non-profit applicant institution, or have an equivalent position and be an employee of a For-profit applicant institution
- 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.

In addition, CIRM, mindful of the urgency of its mission, will only fund PIs who are willing to commit a minimum of 20% effort to the proposed project. During review of the full Application, CIRM will instruct reviewers to give added

consideration to the PI's qualifications when the PI commits more than 20% effort to the proposed research.

In extraordinary circumstances, and at the discretion of the President of CIRM, senior research scientists may be permitted to apply as PIs with a commitment of less than 20% effort, if they can demonstrate that doing so will promote the best outcome for the research project. Such exceptions **must** be requested prior to August 5, 2010 (see contact information, section X of this RFA) to allow the President of CIRM adequate time to review and to approve or deny the request prior to the August 26, 2010 deadline for submission of a full Application.

V. Collaborative Funding Partners

CIRM has established a program with several other agencies that fund stem cell and regenerative medicine research. Through this Collaborative Funding Partner (CFP) program, California-based Principal Investigators (PIs) can collaborate with a Funding Partner PI ("Partner PI") from a Funding Partner applicant institution ("partner applicant institution") eligible for funding from one of CIRM's CFP's to bring important additional resources to the project. If a collaborative funding proposal is approved (a "CIRM/Funding Partner Award") CIRM will fund all project work done within the State of California and its Funding Partner will fund all project work within its jurisdiction. For this RFA, the German Federal Ministry of Education and Research (BMBF) is participating as a Funding Partner.

To apply for a collaboratively funded project, applicants must satisfy both the CIRM requirements (Section VII below) and any additional requirements put forth by the BMBF. Please see Appendix A for information concerning BMBF requirements.

Before funding contracts are signed, successful CIRM/BMBF applicant teams must have a signed written agreement adequately addressing Intellectual Property (IP) issues relating to the collaborative project and must provide CIRM and the CFP with copies. These IP Agreements will be reviewed by both CIRM and BMBF to ensure that they are consistent with CIRM's applicable IP regulations and with the Agreement between the co-funders.

Before funding contracts are signed, successful CIRM/BMBF applicant teams must obtain all necessary approvals for animal protection, human subject protection, and use of human embryonic stem cells, unless the approval is not required to initiate the award. CIRM and the CFPs will monitor compliance with approval procedures required in their respective jurisdictions.

Both CIRM and BMBF may be involved in the management/oversight of the CIRM/BMBF Award, by participating in mutually agreed upon joint award

administration activities. These activities may include but are not limited to participation in progress monitoring via progress reports.

VI. Application and Evaluation Process

Submission of an application for the CIRM Tools and Technologies II RFA involves a two-step process. Any qualified applicant may submit a brief Preliminary Application (PreApp). Applicants submitting the most promising, competitive, and responsive PreApp proposals will be invited to submit a detailed, full Application. All other applicants will be deferred; they may revise their proposals or submit a new proposal for consideration as part of a subsequent RFA covering Tools and Technologies planned for issue in 12 to 24 months, or they may submit an application in response to another RFA to which the proposal is responsive.

PreApps should emphasize the significance of the proposed tool or technology and explain how the proposed research will address a specific translational bottleneck. PreApps will be evaluated by scientific specialists from outside California who are experts in specific areas of research described in the PreApp and by CIRM scientific staff, based on the scientific review criteria described in section VII below. Applicants whose projects are judged as most promising, competitive, and responsive to the RFA will be invited to submit a full Application. The research project proposed in the full Application must be the same as that described in the PreApp; otherwise, the full Application will be deemed ineligible.

Full applications will be evaluated by the CIRM Grants Working Group using the criteria described in the RFA. CIRM's confidentiality and conflict screening rules will apply to everyone who will have access to the applications or attend the review meeting, including CIRM staff, external reviewers, and representatives of Collaborative Funding Partner Agencies. (Disclosure to collaborative funding agencies is protected by inter-governmental agreement, per Gov. Code § 6245.2(e).)

Full 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 the Independent Citizen's Oversight Committee, CIRM's Governing Board (the "Governing Board"), and the Chair of the Governing Board. The membership of the GWG can be found at http://www.cirm.ca.gov/GrantsWkgGrpMembers. The composition of the Governing Board can be viewed at http://www.cirm.ca.gov/ICOCMembers. The fifteen scientists on the GWG will review the applications and score them according to scientific and technical merit applying the review criteria described in section VII below. The full membership of the GWG will then review the entire portfolio of applications, taking into consideration the following criteria:

• Appropriate balance among applications addressing various bottlenecks in translational research.

• Appropriate balance between risk and feasibility.

• Other considerations from the perspective of patient advocates.

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

VII. Review Criteria

A. Preliminary Application

The goal of the PreApp review process is to identify the most promising, competitive, and responsive proposals. The PreApp will be evaluated in three areas: 1) impact of the research to overcome current road blocks and advance translational development in the stem cell field, 2) design and feasibility of the research plan, and 3) responsiveness of the proposal to the goals of the RFA. The quality of appropriate preliminary results is an important factor in assessing feasibility of the proposals.

1. Impact

   - The proposed tools and/or technologies will contribute to overcoming a significant roadblock in translational stem cell research.

   - The proposed research will significantly impact existing concepts or methods and drive the stem cell field forward towards clinical application.

2. Design and Feasibility of the Research Plan

   - The rationale for the development and testing of a novel tool and/or technology is convincing.

   - The specific aims are logical and well organized with achievable milestones or timeline provided for the 3-year timeframe.

   - The preliminary data are compelling and supportive of the proposed concepts and approaches.

3. Responsiveness to the RFA

   The proposed research project adequately and appropriately addresses the goals and objectives of the RFA.

B. Full Application

The full Application will be evaluated in three key areas: 1) significance and innovation of the proposed project, 2) feasibility and design of the proposed research, and 3) the qualifications of the Principal Investigator and research team. A key component for assessing feasibility will be the quality of the preliminary data. The specific criteria for review of applications (below) are elaborated from the standard review criteria described in the CIRM Grants Administration Policy (GAP, see section X.A of this RFA).

1. Significance and Innovation

   - Significant bottleneck: The project is focused on tools or technologies that will enable researchers to overcome a significant bottleneck in translational stem cell research.

   - Innovative Approach: The project provides an innovative approach to alleviating a translational roadblock.

   - Logical Rationale: The rationale for the tools or technologies is logical and scientifically sound.

   - Major Impact: If successful, the project would have a major impact on potential applications of stem cell research and regenerative medicine, rather than incrementally advancing the field.

2. Feasibility and Experimental Design

   - Sound Approach: The proposed research is carefully designed to give meaningful results.

   - Achievable Aims: The aims of the research can be reasonably achieved within the proposed timeframe.

   - Alternative Plans: Potential difficulties are acknowledged, and alternative plans are provided should the proposed strategies fail.

   - Appropriate Timeline and Milestones: The milestones are well described, scientifically justified and provide a quantitative assessment of research outcome(s). The scope of the proposed work justifies the timeline and the proposed project budget.

   - Success Criteria: The proposed success criteria provide scientifically or clinically meaningful quantitative measures to determine if the aims and objective(s) of the proposal have been achieved.

   - Compelling Preliminary Data: The preliminary data are compelling and supportive of the proposed concepts, hypotheses and approaches.

3. Principal Investigator and Research Team

- Training and Experience: The PI and key members of the research team have the training and experience to conduct the proposed research.
- Track Record: Evidence of prior success and track record supports the qualification of the PI to develop tools and/or technologies as proposed.
- PI Commitment: The PI is committing the percent effort to the proposed research to maximize achievement of the aims and milestones.
- Appropriate Team: The research team has appropriate expertise to conduct the proposed research.
- Collaborations: Proposed collaborations (including, if applicable, those with a Partner PI) are critical and integral to the success of the proposed research.
- Budget: The budget is appropriate for the research proposed.

VIII. Application Procedure

Applicant Institutions and PIs must follow these instructions for submission of a PreApp and, if invited, a full Application for the CIRM Tools and Technologies II Research Award. Full Applications will only be accepted from applicants who 1) submitted a PreApp and 2) are invited by CIRM to submit a full Application.

A. Preliminary Application Forms

Each applicant must submit a Pre-Application (PreApp) using the PreApp template provided at http://www.cirm.ca.gov/RFA_10-02. The PreApp should emphasize the significance of the work for the field and describe how the proposed research will address and alleviate a translational bottleneck.

The PreApp for the Tools and Technologies Awards II consists of the following sections:

1. *Cover Page*
   Provide identification information about the PI and Institutional Official. For CIRM/BMBF collaborations, include the name of the Partner PI and the Partner applicant institution.

2. *Title of Proposed Project (limited to 90 characters)*

3. *Specific Aims of Proposed Research (limited to 1500 characters)*
   Describe concisely the objective of the research and the specific aims to be achieved by the proposed project to realize the

objective. Explain the overall objective(s) for the development of novel tools and technologies.

4. *Preliminary Results (limited to 3800 characters)*
   Summarize concisely the preliminary data that support the proposed study. Figures or Tables cannot be included in the PreApp.

5. *Experimental Approach and Design (limited to 2900 characters)*
   Describe concisely the experimental approaches proposed for accomplishing the project goals within 3 years including appropriate milestones or timeline. Highlight novelty or creative use of approaches and methods.

6. *Significance of Proposed Research (limited to 2800 characters)*
   Describe the importance of the proposed research for stem cell biology and regenerative medicine. Identify the specific translational bottleneck to be addressed by the proposed research and, most importantly, describe how proposed tool or technology will overcome the bottleneck and significantly advance the field.

7. *Project Keywords*
   Select one keyword in each category (from the list provided) that best describes the proposed research. If appropriate, supply additional keywords that are central to the proposed project

   In addition to the PreApp form, all applicants must submit a Related Business Entities Disclosure Form (Adobe PDF template provided at http://www.cirm.ca.gov/RFA_10-02). Applicants (PIs) from a for-profit institution (including Partner PIs from a for-profit institution to be funded by a CFP) must complete the form by listing all related business entities. Applicants, who do not have any related business entities to declare, must so certify and submit the form. The information in this form is required for compliance with the Conflict of Interest policy under which CIRM operates. The Related Business Entities Disclosure Form should be submitted electronically as a distinct attachment together with the PreApp form.

B. Preliminary Application Submission Instructions

A PI may submit only a single PreApp for this RFA. **The complete PreApp must be received by CIRM no later than 5:00 pm (PDT) on May 19, 2010.** No exceptions will be made for late submissions. It is

the PI's responsibility to ensure that all required documents are received by the deadline.

A complete PreApp submission includes the following 3 components:

1. A completed **PreApp form** (less the AOO signature).

2. A **Related Business Entities Disclosure Form** if the applicant institution or Partner PI institution is a for-profit company

3. A **signed copy of the PreApp form signature page**.

The PreApp form and Related Business Entities Disclosure form must be saved in their original interactive PDF format and submitted as attachments via email to TT2PreApp@CIRM.ca.gov.

The signed copy of the PreApp form signature page may be submitted as a scanned PDF document that is included with your submission to the email address above. Alternatively, you may send a hard copy of the signature page (via mail, express mail or courier service) to Tools and Technologies II PreApp, CIRM, 210 King St., San Francisco, CA 94107 or a fax copy (415-396-9142).

C. Full Application Forms

Full Applications for the CIRM Tools and Technologies Awards II may be submitted only by applicants who 1) submitted a PreApp (as described above) and 2) are invited by CIRM to submit a full Application. Application forms will be available on the CIRM website (http://www.cirm.ca.gov/RFA_10-02) in mid July, 2010.

The full Application for the CIRM Tools and Technology Awards II consists of four parts:

Part A: Application Information Form (Adobe PDF template). Part A includes: Abstract, Public Abstract, Statement of Benefit to California, Key Personnel, and Budget (section numbers 1-5 below).

Part B: Tools and Technology Award Research Proposal (MS Word template). Part B includes: Rationale and Significance, Specific Aims, Preliminary Data, Research Design and Methods, Project Timeline, References, and Environment including Laboratory Facilities and Major Equipment (section numbers 6-12 below).

Part C: Biographical Sketches for Key Personnel (MS Word template) and letters of collaboration.

Part D: Related Business Entities (Adobe PDF template). In order to comply with the Conflict of Interest policies under which CIRM operates, Part D must be submitted to indicate whether the application would, if awarded, provide funding from CIRM or (if applicable) from a CIRM CFP to a for-profit organization that is either: 1) the applicant organization; 2) a subcontractor; or 3) the employer of a co-investigator, consultant or subcontractor (section number 13 below).

The application for Tools and Technology Awards II 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 these will meet the stated objectives of the RFA. Summarize the rationale for the studies and techniques employed to pursue these goals.

2. Public Abstract (up to 3000 characters in Part A)

In lay language, briefly describe 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 and will be available online; therefore, do not include proprietary or confidential information or information that could identify the PI and applicant institution or, if applicable, the Partner PI and his/her 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 and will be available online; therefore, do not include proprietary or confidential information or information that could identify the PI and applicant institution or, if applicable, the Partner PI and his/her applicant institution.

4. Key Personnel (included in Part 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, co-investigators (collaborators), or consultants who meet this definition. For CIRM/CFP team applications, key personnel sponsored by the CFP, their

contributions to and percent effort towards the project must be listed in this section of Part A.

For CIRM funded key personnel, a minimum of one percent effort is required for each key person, except the PI, who is required to commit a minimum of twenty percent (20%) effort, unless the President of CIRM approves an exception pursuant to Section IV.B, above.

For each key personnel (except for technical staff and students) listed, provide a two-page biographical sketch using the template provided. The sketch should highlight prior relevant research experience, accomplishment and/or special skills related to the proposed research. Include relevant publications and/or patents or patent applications. Following biosketches for the PI and, if applicable, the Partner PI, include all remaining biosketches in alphabetical order.

5. Budget (included in Part A)

Provide all budget information requested in the budget section of the Application Information Form. For CIRM/CFP teams, the funding requested from the CFP (total requested and per year) must be indicated and justified in sufficient detail (under "Budget Justification") for reviewers to assess the appropriateness of the non-California research budget.

All allowable costs for research funded by CIRM are detailed in the CIRM Grants Administration Policy (GAP, see section X.A of this RFA). For CIRM/CFP teams, allowable costs for research funded by the CFP may differ. Guidance will be provided separately by CFP (see Appendix A).

Under this RFA, CIRM-funded 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 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, or for a private institution, the individual's annual salary. Institutions may request stipend, health insurance and allowable tuition and fees as costs for trainees. Administrative support salaries are expected to be covered exclusively by allowed Indirect Costs.

• Supplies

Grant funds will support supplies, including specialized reagents and animal costs. Small 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 Tools and Technologies Awards II are strongly 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 X.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.

• 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. Rationale and Significance (up to 1 page in Part B)

Summarize the context and background of the application and the specific rationale for the work proposed. Specifically identify the translational bottleneck that the proposed tool or technology is intended to address. If the aims of the application are achieved, state how the tool or technology will make a critical contribution to the stem cell field by overcoming a specific road block in basic, translational or clinical stem cell research.

7. Specific Aims (up to 1 page in Part B)

Explain the objective 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 objective of this research.

8. Preliminary Results (up to 4 pages in Part B)

Provide preliminary data to support the concepts, hypotheses and/or approaches proposed in the application.

9. 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 aims 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 objective of the proposed studies has been achieved.

For applications from CIRM/CFP teams, the proposed work should be presented as an integrated project. However, applicants must clearly delineate the research that will be performed in California and funded by CIRM from the research that will be funded by the CFP. This delineation is essential for review of the research plan and the appropriateness of the budget.

10. 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.

11. References (up to 2 pages in Part B)

List all references used in the body of the proposal.

12. 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 (including CIRM/CFP collaborations) is integral to the success of the project, describe how the collaboration will be managed.

13. Related Business Entities (Part D)

All applicants (including, if applicable, a Funding Partner applicant institution) must provide information on related business entities for any application that, if awarded, would fund a for-profit organization

either as: 1) the applicant organization; 2) a subcontractor or 3) the employer of a co-investigator, consultant or subcontractor. If the application does not seek funding for any such for-profit organizations, indicate that on Part D and submit the form. 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).

D. Full Application Submission Instructions

Full Applications will only be accepted from applicants who 1) submitted a PreApp and 2) were invited by CIRM to submit a full Application.

The full Application consists of four parts: Part A: Application Information Form, Part B: Basic Biology Award Research Proposal, Part C: Biographical Sketches for Key Personnel and letters of support/collaboration, and Part D: Related Business Entities. **All four parts of the full Application for CIRM Tools and Technologies Awards II must be submitted and received by CIRM no later than 5:00 pm (PDT) on August 26, 2010, in both electronic form and in hard copy (a signed original and five copies)**. **No exceptions to this deadline will be made.**

Submit electronic copies of all parts of the application as attachments in a single email to TT2Awards@cirm.ca.gov.

In addition, **submit an original hard copy** of the application (consisting of Parts A-D) signed by both the PI and the institution's Authorized Organizational Official (AOO), **plus 5 hard copies** of the full Application (preferably double-sided) via express mail or courier service to:

Tools and Technology Awards II Application
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107

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 5:00pm PDT on October 8, 2010. 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 meets the submission deadline and conforms to the requirements described herein. 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. The body of the cover 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 cover letter, provide specific citation(s) to journal publications related to the proposed project that were published or accepted for publication since 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 cover letter, confirmation of funding secured from other sources or regulatory (e.g., IND, IDE) filings or approvals acquired since the application submission deadline.

3. Within the one-page cover 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) since 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.

IX. Schedule of CIRM Deadlines and Reviews

Pre-Applications due	5:00 pm (PDT), Wednesday, May 19, 2010
Invitations for full Applications sent out by CIRM	July 22, 2010
Full Applications due	5:00 pm (PDT), Thursday, August 26, 2010

Review of full Applications by Grants Working Group (GWG)	November 2010
Review and Approval by ICOC	January 2011
Earliest Funding of Awards	Spring 2011

X. Contacts

For information about this RFA or the review process:

Gilberto R. Sambrano, Ph.D.
Senior Review Officer
California Institute for Regenerative Medicine
Email: gsambrano@cirm.ca.gov
Phone: (415) 396-9103

XI. 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.

B. Intellectual Property Regulations

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

C. Human Stem Cell Research Regulations

CIRM has adopted medical and ethical standards for human stem cell research (Title 17, California Code of Regulations, sections 100010-100110). All research conducted under this award will be expected to comply with these standards.