

# RFA 09-01

## CIRM Disease Team Research Awards

### Preliminary Application

Applicants for a CIRM Disease Team Research Award must submit a Preliminary Application (PreApp) using this form. **Before completing this form, you should carefully review the complete RFA, including the instructions for PreApp submission.**

Applicants for a CIRM Disease Team Research Award must submit the completed PreApp (together with the Related Business Entities Disclosure Form) by email to DiseaseTeamPreApp@cirm.ca.gov, and a hard copy of the cover page, with original signature, by mail to Disease Team Research Award PreApp, CIRM, 210 King St., San Francisco, CA 94107. Additionally, applicants whose proposals involve a Collaborative Funding Partner must send a copy of this PreApp to the Partner organization at the appropriate email address listed in the Appendices of the RFA.

**Both electronic and hard copy submissions must be received at CIRM by 5:00p.m. PDT on March 26, 2009. No exceptions for late applications will be made.**

#### Principal Investigator (PI)

Name	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Prefix	First	Middle	Last	Suffix
Degree	<input type="text"/>	Choose the highest degree(s) earned. If your degree is not listed, enter it in the box.			Title <input type="text"/>
Email	<input type="text"/>				
This email address identifies you to CIRM. Please use this email address for all correspondence with CIRM. Confidential information about your application may be sent to this address.					
Institution	<input type="text"/>				If your institution is not listed please choose "other" and enter the name of the institution
Other Institution	<input type="text"/>				
Type of Institution	<input type="radio"/> For-profit Institution		<input type="radio"/> Non-profit Institution		

#### Primary Mailing Address

Address	<input type="text"/>	Please provide a complete mailing address to which confidential information about your application may be sent.
	<input type="text"/>	
City	<input type="text"/>	Zip Code <input type="text"/>
		Phone <input type="text"/>

#### Collaborative Funding Partner

If your proposal includes a Collaborative Funding Partner, choose the applicable partner from the adjacent list and enter the Partner PI information on page 2.

#### Authorized Organizational Official from the Applicant Institution

Name	
Title	Phone Number
Address	
City	Zip Code

I hereby certify that I have reviewed the eligibility requirements in the RFA, and that the PI and applicant institution meet those requirements.

Signature	Date
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### Co-Principal Investigators (Co-PIs)

Provide the information requested below if your proposal includes Co-PIs as defined in the RFA. Designating Co-PIs is not a requirement of this award. A maximum of 2 Co-PIs is acceptable. Only California-based Co-PIs, who are eligible to receive funding from CIRM, should be listed here.

Name	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Prefix	First	Middle	Last	Suffix
Degree	<input type="text"/>	Choose the highest degree(s) earned. If degree is not listed, enter it in the box.		Title	<input type="text"/>
Email	<input type="text"/> This email address identifies the Co-PI to CIRM.				
Institution	<input type="text"/>				If the Co-PI's institution is not listed please choose "other" and enter the name of the institution
Other Institution	<input type="text"/>				
Type of Institution	<input type="radio"/> For-profit Institution		<input type="radio"/> Non-profit Institution		

Name	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Prefix	First	Middle	Last	Suffix
Degree	<input type="text"/>	Choose the highest degree(s) earned. If degree is not listed, enter it in the box.		Title	<input type="text"/>
Email	<input type="text"/> This email address identifies the Co-PI to CIRM.				
Institution	<input type="text"/>				If the Co-PI's institution is not listed please choose "other" and enter the name of the institution
Other Institution	<input type="text"/>				
Type of Institution	<input type="radio"/> For-profit Institution		<input type="radio"/> Non-profit Institution		

### Partner Principal Investigator (Partner PI)

Provide the information requested below about the Partner PI if your proposal includes a Collaborative Funding Partner which you have indicated on page 1.

Name	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Prefix	First	Middle	Last	Suffix
Degree	<input type="text"/>	Choose the highest degree(s) earned. If degree is not listed, enter it in the box.		Title	<input type="text"/>
Email	<input type="text"/> This email address identifies the Partner PI to CIRM.				
Institution	<input type="text"/>				

## Named Research Personnel

List below all research personnel (team members) who are named in the text portion of your PreApp with the exception of the PI, Co-PIs, and Partner PI. You are not required or encouraged to include the names of research personnel in the PreApp, but you must list them here if they appear in any of the text sections.

In the text sections of the PreApp, you may name up to 10 individuals who are members of your research team (in addition to the PI, Co-PIs, and Partner PI). Exceeding this limit may result in disqualification of your PreApp. In the boxes below, list these named individuals. Do not re-list the PI, Co-PIs, and Partner PI here.

First Name	Last Name	Institution
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>

## Title of Proposed Project

## Project Objective

Provide a target profile for the proposed therapeutic candidate. Briefly address each of the following aspects of a target profile: 1) Description; 2) Scientific Rationale; 3) Indication(s) / Target; 4) Activity (in vitro/in vivo) / Efficacy Endpoint (patients); 5) Safety / Contraindications; 6) Route; 7) Regimen; 8) Risk versus benefit; and 9) Clinical Competitiveness. For allogenic cell therapy candidates, immune tolerance or immunosuppression strategies should be addressed. Limit to 3000 characters.

## Project Status

Summarize the preliminary results and other supporting data for the project including disease-modifying (or injury-modifying) activity of the proposed therapeutic candidate. Indicate data that were generated by the applicant PI and if applicable, Co-PIs and Partner PI. Figures or tables cannot be included. Limit to 3000 characters.

### **Preclinical Research and Development Plan and Milestones**

Include an overall plan for therapy development, including the experimental approaches, methods and techniques proposed for accomplishing the project goals within 4 years. The goals must include preparing and filing an IND. The plan must be based on a clearly stated project timeline that outlines project activities and includes all key milestones, including an estimate of the timing for Go/No Go decision milestones. Milestones should describe precise, quantifiable study outcomes for key project activities, not simply work to be conducted. Include FDA interactions in the milestones. For Year 1, summarize planned activities and experimental design. For example, include rationale for choice of in vitro or in vivo models, parameters to be tested, study design and outcome analyses. State the success criteria. Include important details for years 2-4. Limit to 9000 characters.

### **Research Team Leadership**

List the PI and Co-PIs (if applicable). For each PI or Co-PI include: name and a brief description of role on the project (i.e. describe which studies listed in the section above they will supervise or execute). Describe the leadership credentials of the PI. For CIRM/Funding Partner teams, include the above required information for the Partner PI. Limit to 3000 characters.

## Project Keywords

Identify keywords appropriate to your proposal. For Disease Category, Therapeutic Approach, and Cell Type, select **one** Keyword that most accurately reflects your proposed research. For Specialized Methods, select all keywords that are applicable to your proposal.

Disease Category		Therapeutic Approach	
<input type="checkbox"/> Alzheimer's disease	<input type="checkbox"/> HIV / AIDS	<input type="checkbox"/> Cell therapy	
<input type="checkbox"/> Autoimmune diseases	<input type="checkbox"/> Huntington's disease	<input type="checkbox"/> Cell and gene therapy	
<input type="checkbox"/> Burns and skin wounds	<input type="checkbox"/> Liver disease - acute	<input type="checkbox"/> Small molecule	
<input type="checkbox"/> Cancer - breast	<input type="checkbox"/> Liver disease - chronic	<input type="checkbox"/> Biologic	
<input type="checkbox"/> Cancer - colon	<input type="checkbox"/> Lung disease		
<input type="checkbox"/> Cancer - leukemia	<input type="checkbox"/> Lysosomal storage disease	Cell Type	
<input type="checkbox"/> Cancer - lung	<input type="checkbox"/> Motor neuron disease	<input type="checkbox"/> embryonic stem cells	
<input type="checkbox"/> Cancer - malignant glioma	<input type="checkbox"/> Musculoskeletal diseases	<input type="checkbox"/> adult stem cells	
<input type="checkbox"/> Cancer - melanoma	<input type="checkbox"/> Neonatal brain ischemia	<input type="checkbox"/> induced pluripotent stem cells	
<input type="checkbox"/> Cancer - prostate	<input type="checkbox"/> Neurological disorders - other	<input type="checkbox"/> cancer stem cell	
<input type="checkbox"/> Cancer - other	<input type="checkbox"/> Orofacial defects	<input type="checkbox"/> other cell type	
<input type="checkbox"/> Cardiovascular disease	<input type="checkbox"/> Parkinson's disease	Specialized Methods	
<input type="checkbox"/> Cartilage or bone diseases	<input type="checkbox"/> Peripheral vascular disease	Select all Specialized Methods applicable to your proposal	
<input type="checkbox"/> Cerebral palsy	<input type="checkbox"/> Sickle cell anemia	<input type="checkbox"/> Imaging	
<input type="checkbox"/> Diabetes	<input type="checkbox"/> Spinal cord injury	<input type="checkbox"/> Bioengineering	
<input type="checkbox"/> Eye diseases	<input type="checkbox"/> Stroke	<input type="checkbox"/> Gene therapy	
<input type="checkbox"/> Hematopoietic disorders	<input type="checkbox"/> Other disease category	<input type="checkbox"/> RNAi	

Additional keywords central to proposed research (separate each keyword by a comma):

## Survey Questions

Please answer the following questions to help CIRM to analyze and further improve the application process.

**Your answers to these questions will have no impact on the evaluation of your PreApp or influence whether or not you will be invited to submit a Full Application.**

Have you previously submitted an application (as a PI) to CIRM?	<input type="radio"/> Yes	<input type="radio"/> No	
Do you currently have an active or pending grant from CIRM?	<input type="radio"/> Yes	<input type="radio"/> No	