

Targeted Clinical Development

RFA 10-03: CIRM TARGETED CLINICAL DEVELOPMENT AWARDS

Pluripotent stem cells, due to their high replication capacity and ability to differentiate into all cells in the body, offer great potential to restore tissues damaged by disease or injury. The purpose of this CIRM Targeted Clinical Development Award RFA is to facilitate clinical development of novel cell therapies derived from pluripotent stem cells that may offer unique benefit with well considered risk to persons with disease or serious injury. This award will support the conduct of early clinical trials (e.g. Phase 1, Phase 1/2, Phase 2a) as well as ancillary activities that will enable these trials. For purposes of this RFA, pluripotent stem cells are defined as human embryonic stem cells or human induced pluripotent stem cells.

The key objectives of the CIRM Targeted Clinical Development Award RFA are the completion of early stage clinical trial(s) for a cell therapy derived from human pluripotent stem cells, that will within three years: 1) evaluate preliminary safety in humans, and 2) provide evidence of mechanism in humans as well as preliminary evidence of clinical efficacy that could lead to more definitive efficacy studies.

Please see the RFA for full details.

RFA 10-03: CIRM Targeted Clinical Development Awards [pdf] (amended 10/15/10)

Note: Section IX B 10 has been modified to increase the page limit from 2 pages plus timeline to 4 pages plus timeline.

Application Process

Submission of an application for the CIRM Targeted Clinical Development Awards RFA involves a two-step process. Any eligible applicant may submit a Letter of Intent (LOI). Applications will only be accepted from Principal Investigators (PIs) who submitted an LOI that was accepted by CIRM. The PI, Co-Principal Investigator (if applicable), and the clinical development project proposed in the application must be the same as those described in the LOI; otherwise, the application is deemed ineligible.

Letter of Intent (LOI) Instructions

A PI may submit only a single Letter of Intent for this RFA. The LOI and accompanying signature page must be submitted online using the CIRM Grants Management Portal, and must be received by CIRM no later than 5:00 pm (PDT) on September 29, 2010. No exceptions to this deadline will be made.

To submit a Letter of Intent:

1. Go to the **Grants Management Portal** (<https://grants.cirm.ca.gov>) and log in with your existing CIRM Username and Password. If you do not have a Username, Click on the "**New User**" link and follow the instructions to obtain a CIRM Username and password.
2. After logging in, your home page will display a list of open RFAs. Click on the "**Apply for this grant**" link corresponding to the CIRM Targeted Clinical Development Awards.
3. Select the "**Upload Required Documents**" link to navigate to the submissions page. Clicking the "**Upload**" links will allow you to upload your completed and saved LOI pdf form and executed signature page. The signature page may be a scanned document; **the completed Letter of Intent must be submitted as an interactive form.**
4. The "**Done with Letter of Intent**" button becomes enabled when all required documents have been uploaded. Your LOI will be submitted once the "**Done with Letter of Intent**" button is selected. After it has been submitted, you will no longer be able to make changes to your Letter of Intent.
5. To ensure the process is complete, go back to your home page and check under the section "**Your Preliminary Applications**". The status for CIRM Targeted Clinical Development Awards should read "**submitted**".

You will need a fully functional copy of Adobe Acrobat version 8 or 9 (Standard or Professional) to complete and save the LOI Form prior

to uploading it online. We recommend using Adobe Acrobat Version 8.1 or later. Using **Adobe Acrobat reader will not permit you to save information** that is entered in the form.

- Targeted Clinical Development Letter of Intent Form (pdf)

The LOI must be received by CIRM no later than 5:00 pm (PDT) on September 29, 2010 via the online submission process. No exceptions to this deadline will be made.

Application Instructions and Forms

Click on the link below for application forms and instructions. Only those applicants that submitted an LOI that was accepted by CIRM may submit an application.

The Application for the CIRM Targeted Clinical Development Awards consists of five parts: **Part A:** Application Information Form and subparts, **Part B:** Targeted Clinical Development Award Proposal and subparts, **Part C:** Biographical Sketches for Key Personnel (including clinical investigators) and letters of collaboration and/or institutional support, **Part D:** Reference Materials, **Part E:** Related Business Entities Disclosure Form.

All five parts of the Application for CIRM Targeted Clinical Development Awards must be submitted together and received by CIRM no later than 5:00PM PST on December 1, 2010, in both electronic form and in hard copy (a signed original and five copies). It is the applicant's responsibility to meet this deadline; No exceptions will be made.

Submit an original hard copy of the Application (consisting of Parts A-E) plus 5 hard copies (preferably double-sided). The original hard copy must be signed by both the PI and the applicant institution's Authorized Organizational Official (AOO). Applications designating a Co-PI must also be signed by the Co-PI and the Co-PI's institutional AOO. Send the hard copies via express mail or courier service to:

Targeted Clinical Development Awards Application
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107

You will need a fully functional copy of Adobe Acrobat version 8 or 9 (Standard or Professional) to complete, print, and save Parts A and E of the full Application. We recommend using Adobe Acrobat version 8.1 (or the latest version). Using Adobe Acrobat Reader will not permit you to save information that is entered in the form.

- **View complete application instructions and forms**

Schedule of Deadlines and Reviews	Date
Letters of Intent due	5:00 pm (PDT), on September 29, 2010
Full Applications due	5:00 pm (PST), on December 1, 2010
Anticipated Review of Applications by Grants Working Group (GWG)	February 2011
Anticipated Review and Approval by ICOC	May 2011
Earliest Funding of Awards	Summer 2011

No exceptions will be made to the indicated deadlines.

ICOC approval:

May 4, 2011

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