

Strategic Partnership IV Awards

RFA 14-03: CIRM Strategic Partnership IV Awards

The purpose of the Strategic Partnership Awards Initiative ("Initiative") is to attract industry engagement and investment in CIRM funded stem cell research. The intent of the Initiative is to create incentives and processes that will:

(i) enhance the likelihood that CIRM funded projects will obtain funding for future clinical trials (e.g. follow-on financing), (ii) provide a source of co-funding for the earlier stages of clinical development, and (iii) enable CIRM funded projects to access expertise within pharmaceutical and large biotechnology partners in areas such as discovery, preclinical, regulatory, clinical trial design and manufacturing process development.

This Initiative requires applicants to show evidence of either having the financial capacity to move the project through development or of being able to attract the capital to do so. This may be evidenced by, for example, (i) significant investment by venture capital firms, large biotechnology or pharmaceutical companies, disease foundations and/or through the public markets; and financial statements evidencing significant liquid assets; or (ii) a collaborative research agreement with a large biotechnology or pharmaceutical company executed at least two weeks prior to the review by the Application Review subcommittee of CIRM's Governing Board, the Independent Citizen's Oversight Committee (the "ICOC"); such review will be approximately Q1, 2015. These requirements are described further in Section V.D. The agreement with the large biotechnology or pharmaceutical company needs only cover co-funding and collaboration support for the proposed project (and not future development).

CIRM intends to offer repeat calls under this initiative every 6-9 months. The focus, scope and objective may differ with each solicitation.

The objective of this fourth call under the Initiative, Strategic Partnership IV Awards, is to achieve, in 3 years or less, the completion of a Phase 1 or Phase 2 clinical trial under an Investigational New Drug (IND) application filed with the Food and Drug Administration (FDA).

Please see the RFA for full details.

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CIRM has conducted a **webinar** for prospective applicants on May 14, 2014 at 11:00 am PT to address questions about the RFA and application process. The following materials can be viewed/listened to:

1. Presentations Slides
2. Session Recording
3. Q&A session

Application Process

Submission of an application for the CIRM **Strategic Partnership IV Awards** RFA involves a two-step process. An eligible applicant must first submit a Letter of Intent (LOI) to CIRM following the instructions below. In the second step of the process, eligible applicants will submit a full application. The Principal Investigator and the project proposed in the application must be the same as those described in the LOI; otherwise, the application is deemed ineligible.

LOI Submission Instructions:

The Letter of Intent (LOI) must be submitted via the CIRM Grants Management Portal, as follows:

1. Go to the Grants Management Portal 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 create a CIRM Username and password.
2. After logging in, your home page will display a list of open RFAs or LOIs. Click on the "**Start a Letter of Intent**" link located to the

right of the section labeled "RFA 14-03: CIRM Strategic Partnership IV Awards: Letter of Intent".

3. Complete the LOI by following the posted instructions.
4. The "Done with Letter of Intent" button becomes enabled when all sections are complete. Select this button to complete your LOI submission. Once this button has been selected, you will no longer be able to make changes to your LOI.
5. To ensure the process is complete, go back to your home page and check for "RFA 14-03: CIRM Strategic Partnership IV Awards " in the section titled "Your Submitted Applications".

The LOI must be received by CIRM no later than 5:00 pm PT on June 19, 2014 via the CIRM Grants Management Portal. **No exceptions to this deadline will be made.**

Application Instructions and Forms

Application forms will be available on the CIRM website in late July 2014. Only those applicants that submitted an LOI that was accepted by CIRM may submit an application. Applicants will be notified if their LOI was NOT accepted.

The application for RFA 14-03 consists of **up to ten parts**:

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

Part B: Strategic Partnership IV Award Proposal (MS Word template)

Part C: Biographical Sketches for Key Personnel (MS Word template)

Part D: Due Diligence Report.

Part E: Activity Based Budget

Part F: FDA correspondence.

Part G: Clinical Protocol

Part H: Investigator Brochure.

Part I: Copies of authorization for cross reference of Drug, Device or Facility master files.

Part J: Licenses and agreements (MTAs).

All applicable parts of the Application for RFA 14-03: CIRM Strategic Partnership IV Awards must be submitted together and received by CIRM no later than 5:00 pm PT on September 9, 2014 via the CIRM Grants Management Portal. It is the applicant's responsibility to meet this deadline; No exceptions will be made.

Schedule of CIRM Deadlines and Reviews

LOI due	5:00 pm PT, June 19, 2014
Applications due	5:00 pm PT, September 9, 2014
Supplemental Information Due	5:00 pm PT, November 15, 2014
Scientific Review of Applications by Grants Working Group (GWG)	December, 2014

Review and Approval by ICOC/Application Review Subcommittee	Q1, 2015
Earliest Funding of Awards	Q2, 2015

Contacts:

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Source URL: <https://www.cirm.ca.gov/our-funding/research-rfas/strategic-partnership-iv-awards>