

## Strategic Partnership I

### RFA 12-05: CIRM Strategic Partnership I Awards

The purpose of the Strategic Partnership Awards 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 Phase III clinical trials (e.g. follow-on financing), (ii) provide a source of co-funding in the earlier stages of clinical development, and (iii) enable CIRM funded projects to access expertise within pharmaceutical and large biotechnology partners in the areas of 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 and/or disease foundations; or (ii) a licensing and development agreement with a large biotechnology or pharmaceutical company or a commitment to enter into such an agreement executed prior to the disbursement of CIRM funding

The objective of the first call under this Initiative, the Strategic Partnership I Awards, is to achieve, in 4 years or less, the completion of a clinical trial under an Investigational New Drug (IND) application filed with the Food and Drug Administration (FDA).

Please see the RFA for full details.

RFA 12-05: CIRM Strategic Partnership I Awards (**Amended 05.08.12**) [pdf]

Appendix A (Loan Information) [pdf]

**CIRM conducted a webinar for prospective applicants on Wednesday, April 25th, 2012 to address questions about the RFA and application process. For a recording of this webinar (including the slides and Q&A), please visit CIRM's website at: <https://www.cirm.ca.gov/our-fundingstrategic-partnership-webinar>**

## Application Process

Submission of an application for the CIRM Strategic Partnership I 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 ([https://grants.cirm.ca.gov/login/upgrade\\_browser](https://grants.cirm.ca.gov/login/upgrade_browser)) 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 12-05: CIRM Strategic Partnership I 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 12-05: CIRM Strategic Partnership I Awards**" in the section titled "**Your Submitted Applications**".

The LOI must be received by CIRM no later than 5:00 pm (PDT) on May 16th, 2012 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 early May 2012. Only those applicants that submitted an LOI that was accepted by CIRM may submit an application.

The application for RFA 12-05 consists of up to twelve parts:

- Part A: Application Information Form (Web-based form)
- Part B: Strategic Partnership I 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)
- Part K: Evidence of Commercial Validation
- Part L: Related Business Entities Disclosure Form (Adobe PDF template)

All applicable parts of the Application for RFA 12-05: CIRM Strategic Partnership I Awards must be submitted together and received by CIRM no later than 5:00PM PDT on June 26th, 2012, 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	Date
LOI due	5:00 pm (PDT), May 16, 2012
Applications due	5:00 pm (PDT), June 26, 2012
Scientific Review of Applications by Grants Working Group (GWG)	September, 2012
Review of Evidence of Commercial Validation by the IP and Industry Subcommittee	4th Quarter 2012
Review and Approval by ICOC	October or December 2012
Earliest Funding of Awards	January, 2013

## Contacts

### For information about this RFA:

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### For information about the review process:

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**ICOC approval:**

Oct 25, 2012

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