

Disease Team Therapy Development - Research

RFA 10-05: CIRM Disease Team Therapy Development Awards

UPDATED September 1, 2011

The Disease Team Therapy Development Award initiative is an expansion of our original Disease Team Award Initiative. The purpose of the CIRM Disease Team Therapy Development Awards is to advance preclinical and/or early clinical development of novel therapies derived from or targeting stem cells or utilizing direct reprogramming, potentially offering unique benefit with well-considered risk, to persons with disease or serious injury.

The key objectives of the Research Award are to achieve, within 4 years of the Research Award start date, one or more of the following: 1) file a complete and well-supported IND with the Food and Drug Administration (FDA) (and, if desired, other regulatory agencies) and/or 2) complete a Phase I and/or Phase I/II clinical study evaluating preliminary safety and preliminary biological activity/early efficacy in humans and/or 3) complete a Phase II clinical study evaluating efficacy and could lead to more definitive efficacy studies.

Please see the **Supplement to RFA 10-05: CIRM Disease Team Therapy Development Awards for full details** This RFA Supplement is intended to be a complete description of the requirements for the Research Award. Applicants for the Research Award need not refer back to the original RFA.

CIRM conducted a **webinar on Friday, September 9, 2011** to review the objectives of the Research Award and the application process. Archived resources from this webinar are available [here](#).

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Supplement to RFA 10-05: CIRM Disease Team Therapy Development Awards

- Appendix A: (CIRM's Translational Portfolio) [pdf]
- Appendix B: (Loan Information) [pdf]
- Appendix C: (CSCC) [pdf]
- Appendix D: (BMBF) [pdf]
- Appendix E: (IATA) [pdf]

Research Award Application Process

With limited exceptions (see section V.D-F of this RFA), receipt of a Planning Award is a prerequisite for submission of an application for a Research Award. **The research project proposed in the Research Award Application should be substantively the same as that described in the successful Planning Award application.** Please see section V of the RFA for eligibility criteria.

Applicants seeking permission to apply for an exception must use the Exception Request Form and meet the criteria in section V. D-F.

[Exception Request Form](#)

Application Instructions and Forms

Application forms will be available via the Grants Management Portal at <https://grants.cirm.ca.gov> no later than November 3, 2011. (Updated 11/01/11)

To assist in your preparation for the research award application the following sample documents of key application components are provided:

- Sample A: CIRM Target Product Profile (TPP) (pdf)
- Sample B: CIRM Clinical Protocol Synopsis (pdf)

- Sample C: CIRM Manufacturing Plan Synopsis (pdf)

Additionally, a description of all application components can be found within the Supplement to RFA 10-05 document.

All applicable parts of the Disease Team Therapy Development Awards application must be submitted to CIRM no later than 5:00PM PDT on January 25, 2012 in both electronic form (via the Grants Management Portal) and in hard copy (a signed original plus five copies). It is the applicant's responsibility to meet this deadline; no exceptions will be made. Both the PI and the applicant institution's Authorized Organizational Official (AOO) must sign the original hard copy of the application (consisting of Parts A-K). The original application plus 5 hard copies (preferably double-sided) should be sent via express mail or courier service to:

CIRM Disease Team Therapy Development Awards Applications
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107

Schedule of Deadlines and Review

No exceptions will be made to the indicated deadlines.

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ICOC approval:

Jul 26, 2012

Source URL: <https://www.cirm.ca.gov/our-funding/research-rfas/disease-team-therapy-development-research>