

**RFA 10-01 CONCEPT PROPOSAL
CIRM EARLY TRANSLATIONAL II RESEARCH AWARDS**

Purpose and Objectives

The purpose of the CIRM Early Translational II Research Awards is to fund studies to move promising basic research in stem cell science toward the clinic. To this end, these awards will support two research project categories:

- 1) Research that results in a stem cell-derived development candidate that meets an unmet medical need and has substantially completed all necessary activities to move into preclinical development
OR
- 2) Research conducted in order to identify and/or establish the feasibility of a specific potential stem cell-derived development candidate. These awards are designed for projects that, by the end of the project will not have completed all necessary activities to move a development candidate into preclinical development. Rather, these awards are intended to address a specific subset of activities designed to determine the feasibility of a specific approach to achieving a development candidate or to move a prospective candidate further along the path to achieving a development candidate (i.e. selecting a lead candidate, establishing disease modifying activity,).

Applicants for either category of award must have already identified the target for the proposed development candidate or development candidate feasibility award and have justifiable rationale for it as a target for therapeutic (diagnostic) intervention.

CIRM will prioritize projects:

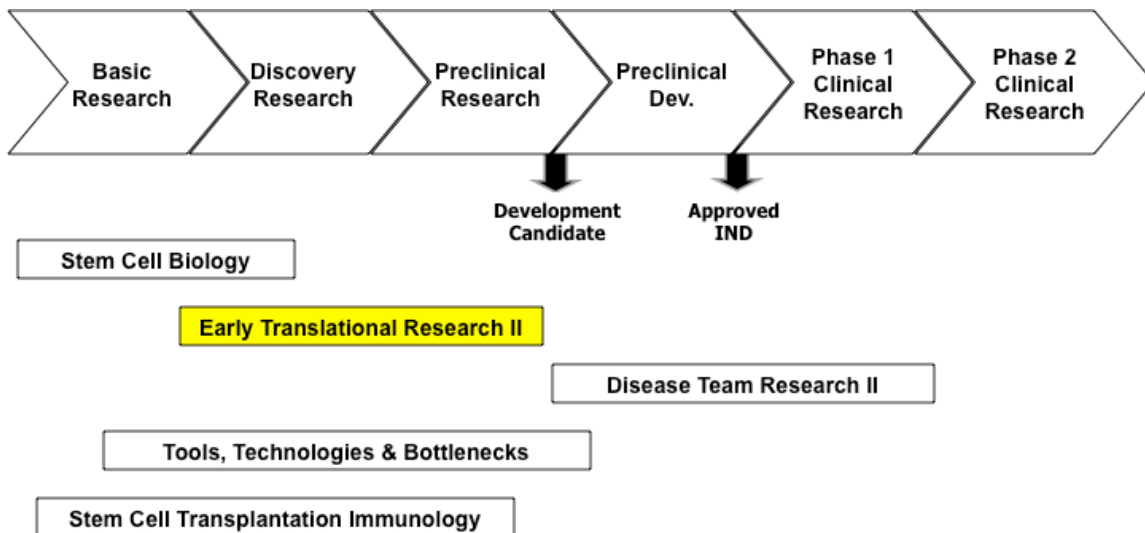
- Leading to cell-derived, especially pluripotent cell-derived development candidates
- Based on pluripotent stem cells (SCs). Pluripotent SCs may be used either for discovery or as a candidate for therapy.
- Ineligible for or unlikely to receive funding from the United States Federal government.

This award will not fund:

- Target discovery.
- Preclinical development (IND enabling) activities such as GMP process scale-up and production, GLP toxicology and tumorigenicity studies.
- Clinical studies. Analysis of human subject samples, if directly related to the proposed research, can be funded.
- Research on bottlenecks or the generation of tools or technologies broadly applicable to the stem cell/regenerative medicine field.
- Research on the induction of transplantation tolerance

The above research activities are or will be the subject of current or upcoming RFAs.

Diagram of Stage Specificity of Current and Upcoming RFAs



CIRM Award Information

CIRM proposes to fund:

- Development Candidate awards with justifiable total project costs of up to \$6.0 million each over three years for a total of up to \$60 million
- Development Candidate Feasibility awards with justifiable total project costs of up to \$2 million each over three years for a total of up to \$20 million
- Total program cost of up to \$80 million.

For-profit applicant organizations will be permitted to apply for either grants or loans. Non-profit applicant organizations will be funded through grants.

Loan Information

Loans will be administered over a six- or ten-year term to be determined by the loan applicant. Loans will be recourse or non-recourse. The interest on six-year loans will be prime plus 300 basis points; the interest on ten-year loans will be prime plus 500 basis points. The prime rate will be that on the date the ICOC authorizes funding of the loan.

CIRM Institutional Eligibility

- All CIRM supported research must be conducted in the state of California
- Open to all academic, non-profit and for profit institutions in the state of California
- If pre-application process approved, no limits will be applied on the number of pre-applications an institution can submit.

If no pre-application process

- Non-profit applicant institutions with accredited medical schools: up to 3 applications
- Non-profit and for profit applicant institutions with 250 employees or more in California: up to 2 applications

- Non-profit and for profit applicant institutions with fewer than 250 employees in California: 1 application

CIRM Investigator Eligibility

As a multidisciplinary team often most effectively conducts translational research, this award will be open to:

- A Principal Investigator (PI) and up to 1 Co-Principal Investigator (Co-PI) with Ph.D., M.D or equivalent degrees who are authorized by the applicant and Co-PI institution to conduct the proposed research in California.
- PIs and Co-PIs must commit 20% and 15% effort respectively towards programs supported under this RFA.

CIRM encourages collaborative endeavors between non-profit and for-profit institutions.

Collaborative Funding Partner Participation

CIRM has established a program with several other government agencies that fund stem cell and regenerative medicine research. Through this Collaborative Funding Partner program, California-based PIs can collaborate with a Funding Partner PI from a Funding Partner applicant institution eligible for funding from one of CIRM's collaborative funding partners to bring important additional resources to proposed projects. If a collaborative funding proposal is approved CIRM will fund all project work done within the State of California and its Funding Partner will fund all project work within its jurisdiction.

Provisional Time Table:

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| • Release of RFA 10-01 | Feb | 2010 |
| • (Pre-Applications due | Mar | 2010) |
| • Applications due | July | 2010 |
| • Grants Working Group Review of Applications | Sept | 2010 |
| • ICOC Approval | Oct | 2010 |