

RFA Concept Proposal: Disease Team Planning Awards

Pluripotent stem cells have the potential to play a role in the development of treatments and diagnostics in chronic disease and serious injury. To date only a handful of stem-cell based therapies have progressed into clinical testing. In part, this is because stem cell research is an emerging field. The purpose of the CIRM Disease Team Initiative is to explore a new method of integrating and organizing the highest quality basic, translational and clinical research with the specific aim of producing a therapy or diagnostic for a particular disease or serious injury. This approach allows the use of innovative research models such as requiring active team management and emphasizing defined milestones to better support and to accelerate research that is poised for the development of stem-cell based treatments.

CIRM held a Workshop in July 2007 to explore the scope, resources, management and funding of effective teams, and to evaluate the strengths and weaknesses of various approaches of team support. Three main findings emerged from discussions. First, translational research does indeed benefit from team-based research, which encourages early consultation and cooperation with researchers of diverse skills and expertise. Second, strong scientific leadership and project management are essential for team recruitment, motivation, and success. Third, active management and oversight provided by the funding organization can maintain focus and increase the rate of successful translation to the clinic.

Beginning in 2008, CIRM intends to support multi-year Disease Team Grants. To encourage planning for Disease Team Grant applications, CIRM proposes the "Disease Team Planning Award". The objective of the planning award is to enable a Principal Investigator to recruit a team, and to enlist the team to develop the content, management, and administration of the proposed disease team. Ultimately, the team would develop a formal research proposal for an application for a Disease Team Grant.

With funds from a Disease Team Planning Award, an investigator will be able to construct a proposal that contains the following:

- A scientifically mature opportunity, with strong, preclinical proof-of-concept, to use stem cells in the development of a therapy or diagnostic; and, the significance of the work
- A route to advance the potential therapy toward clinical testing, including:
 - A clear, step by step project plan, complete with milestones and deliverables
 - A justification for a team approach
- A description of the organization, management and plan for sustaining the disease team
- Plans for how the team will approach the anticipated regulatory hurdles

Each Planning Award will provide short-term, one-time only support for the planning process and development of a disease team proposal. CIRM intends to provide total costs of up to \$50,000 for each award. No facilities or indirect costs will be provided in this award. The Principal Investigator must be the individual who will be solely responsible for team assembly and organization, and proposal development. Applicants must be employed by an academic or not-for-profit research institution in California at the time of application. Each institution may submit no more than four applications for planning awards; each application must be devoted to a different disease or serious injury. CIRM proposes to fund up to 20 planning awards, at a total cost of \$1 million for this aspect of the program. CIRM anticipates a call for applications for the Disease Team Grant in Fall 2008.

Provisional Timetable

Planning Grant RFA Release:	November 2007
Planning Grant Review of Applications:	Winter 2007-08
Planning Grant ICOC Approval for Funding:	Spring 2008

