



M E M O R A N D U M

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To: Science Subcommittee, Independent Citizens Oversight Committee (ICOC)
Subject: Modified Process proposed for Disease Team III

The specific modification to the most recent Disease Team Therapy Development concept is to have a single review of the research application by the Grants Working Group with narrowing of inclusion criteria, and not to include a planning award process. The use of a planning award would lengthen the time to research award by one year. An alternative would be the use of a pre-application process, which would lengthen the time to research award minimally by one quarter. Neither of these pre-review approaches is required as we are narrowing the inclusion criteria, all in accord with the goals of our Scientific Strategic Plan (May 2012).
<http://www.cirm.ca.gov/files/PDFs/Publications/2012CIRMstratplan.pdf>.

Specifically, the concept proposal addresses the continuation of CIRM's Disease Team Therapy Development initiative. This program provides funding support for preclinical development and early clinical trials, and targets CIRM's key clinical goals articulated in that Scientific Strategic Plan. The Disease Team initiative was created to encourage researchers to work in multi-disciplinary teams, assembling all the skills necessary to complete key preclinical research and development activities. CIRM has awarded 2 prior Disease Team rounds (RFA 09-01 in Oct, 2009, 14 disease teams, funding initiated 2010; and recently, RFA 10-05 in Sept 2012, 11 disease teams, funding later in 2012 and early 2013), in multiple therapeutic areas. With advancing science in the field, subsequent rounds of Disease Team Awards have addressed activities at a more mature stage in the therapy development process. For example, the first round of disease teams had as their goal filing an approvable IND with the US Food and Drug Administration (FDA) to enter human clinical trials. The second round of disease teams added the aim of completing early phase clinical trials. This third round of disease teams will focus on mature projects that can complete early phase clinical trials within the planned 4 year project period.

CIRM actively manages these milestone-driven disease team projects, including evaluation by CIRM's Clinical Development Advisors Panel (CDAP). Outcomes from the initial cohort of 14 teams to date include: 1 team has achieved an IND filing and has successfully competed for funding of the clinical trials; 1 project was terminated as it was not able to meet its milestones, while the remaining 12 projects are completing their CDAP assessments in moving towards their goal of filing an IND by the end of the project period in 2014. Projects in the second round are just getting underway later in 2012 and early 2013.