

Expansion of Disease Team I Activities

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The Board has previously requested staff to determine means for allowing Disease Team I grantees to move into post-IND activities if they are able to reach the approvable IND filing ahead of schedule with grant funds unspent. CIRM will use its standard “prior approval” process further informed by advice from an external expert advisory committee to enable continued CIRM research support. Disease Team I grantees will be notified of this opportunity. Further detail is provided below.

Researchers receive funding to pursue the research proposal approved by the board. Because of changes in science, intermediate results or other circumstances, researchers sometimes need to deviate from the original plan.

The rules adopted by the board say that significant changes require CIRM approval. Most of the changes involve budgetary matters, and are resolved by the grants management staff. If a proposed change would affect the research aims (a change in scope), the science staff will want to ensure that the project would continue to meet the objectives of the mission, the scientific strategic plan, and the RFA.

CIRM receives hundreds of these “prior approval requests” every year. They are a regular part of how we manage funded grants.

Because of the scale and importance of the Disease Team awards, the RFA noted that the science office will be establishing expert advisory committees to consult on major scientific decisions about these projects, including “Go/No Go decision points and substantial changes to the project including changes in scope. As noted in the RFA, grantees participate in evaluation meetings. As with all post-award changes, the decisions will be up to the President or his designee.

Awards under the Disease Teams RFA (09-01) are for work within the scope defined by that RFA, which does not extend beyond the filing of an IND. The upcoming Disease Teams II RFA (RFA 10-05) will encompass more advanced work, following the filing of an IND. CIRM has been asked whether a Disease Team I project that can complete its objectives may use any remaining funds for more advanced work on the candidate therapeutic that was the subject of a Disease Team I IND filing. Staff will notify recipients of Disease Teams I awards that staff will consider proposals from awardees for a change in scope to include additional work within the scope of the Disease Teams II RFA.

We will use the expert advisory committee process to evaluate any proposal to change the scope of a project to include post-IND research. That is consistent with our current regulations and with the project management approach that has been communicated to grantees since the RFA was posted in early 2009. Because the science staff and the expert advisory committee will have been involved at prior stages of the project, they will be able to reach an informed conclusion without delay.