CONSIDERATION OF PROCESS FOR REVIEW OF REQUESTS FOR CHANGE IN SCOPE TO PERMIT UNUSED AWARD FUNDS TO BE USED IN HUMAN CLINICAL TRIALS

Background

At the last Board meeting, the Board endorsed the staff's policy regarding the use of unused Disease Team Research I Award funds in human clinical trials. Pursuant to this policy, a Disease Team grantee or loan recipient may request a change of scope in its research proposal to permit unused funds to be applied to post-IND research, including a human clinical trial. After review of the request by an external expert advisory committee, the President will approve or disapprove the request for change of scope pursuant to the existing policy in the Grants Administration Policy and will notify the Board of his determination.

The discussion of the application of this policy to Disease Team Research Awards I prompted a broader discussion of the policy implications of permitting CIRM funds to be used for human clinical trials where the original application did not contemplate such research and where, as a result, the proposal to use CIRM funds for a human clinical trial was not subject to review by the Grants Working Group or the Board. To advance the discussion of this item and to consider what role, if any, the Board should play when a change in scope request involves the application of CIRM funds to a human clinical trial, the Science Subcommittee considered a draft proposal at its meeting on September 29, 2010. This draft policy would apply prospectively and would not apply to the Disease Team Research I Awards. By a vote of 9 to 0, the Science Subcommittee recommended that the Board consider the following proposal:

Proposal

If a grantee or loan recipient requests a change of scope to permit CIRM funds to be used in a human clinical trial, the President's determination should be subject to Board approval. The Board's consideration of the President's determination would not involve a detailed examination of the proposed techniques, but would instead constitute a concept review that would focus on the risks and benefits for patients and therapy development. After a general description of the item to be considered, the Board would convene in closed session to consider proprietary information. The Board would then reconvene in open session for public discussion and a final determination. This policy shall apply prospectively to grants awarded after the Board's adoption of the policy.

Justification

- Of all of the research that CIRM funds, clinical trials involve the greatest risk and the greatest potential benefits for patients and therapy development. Clinical trials, therefore, have significant implications for CIRM and for the field of stem cell research.

- While ordinary requests for change in scope may involve new aims or a different direction for the proposed research, a request to change the scope of a research proposal to include human clinical trial work is different in kind because of the use of human subjects.

- Although each application that is the subject of a request for change of scope will previously have been subject to review by the GWG and the Board, the cost/benefit analysis of conducting human clinical trials will not have been subject to review because, by definition, the original application will not have encompassed human clinical research.

- Consideration by the Board of a request for change in scope to permit CIRM funds to be applied to a human clinical trial creates a platform for informing the public regarding the risks and benefits of such research.

- All of these requests will come to the Board after FDA approval of a human clinical trial; the Board will therefore have the benefit of the FDA's extensive review as part of its approval process.