



M E M O R A N D U M

October 13, 2012

From: Alan Trounson, President
To: Independent Citizens Oversight Committee (ICOC)
Subject: Extraordinary Supplements to Existing Awards

The President and other senior members of Management are occasionally presented with unique opportunities to potentially turn a granted study into a very major development in science or opportunity in translational medicine. While these are rare moments, they do arise and at present we can only advise grantees to reapply for the next appropriate RFA, often a year or more before they can expect any support. The capacity to consider an exceptional proposal that arises during the period of a funded project in which additional funding would allow an ongoing CIRM-funded project to achieve very significant transformational and translational results, would be important for CIRM's mission. These supplements would be carefully considered, rare as an event and limited in scope and size.

We propose two ways to address these opportunities.

Level 1: Minor Supplement

A modest time dependent supplement, authorized administratively through Prior Approval Request. Maximum increase would be the **lesser of 10%** of the original award amount, or up to \$500,000. They would only be awarded once during the lifetime of a specific award. They may not be requested until after project has completed the first year, and making satisfactory progress. They would only be available if the supplement will allow the grantee to pursue a critical research study based on very exciting new research results that will elevate the significance of the project substantially, or allow the grantee to make use of a specialized resource that was not available when the project began. The President would seek advice of two members of the present GWG, the Program Officer on the award and senior management in making a decision to agree or deny the supplement.

Recommendations for a minor supplement will be reported to the Board at the next available Board Meeting. Total funds available to be awarded as supplemental funds: limited to \$4 million or Board replenishment by request.

Level 2: Major Supplement

There may be exceptional circumstances in supplemental funding that will allow a current CIRM project to achieve transformational results -- results that would change the field of stem cell research, or establish proof of concept for a new therapeutic. Maximum increase would be the **lesser of 50% of the original award amount, or up to \$3 million.**

Process:

- The grantee may not submit a request until after project has completed first year, making satisfactory progress.
- Grantee would submit a brief proposal.
- President, following discussion with Program Officer on the award and senior management, would have sole discretion to decide whether full application would be permitted.
- Fully documented application, to be reviewed by CDAP for FDA mandated supplementary study for a DT or SP award or a full GWG recommendation for other supplements, and final decision by ICOC. Maximum of \$12M

Recommendation:

1. That the ICOC endorse a Prior Approval Request for Minor Supplements by the President to awarded grantees to make an exceptional advance in science or technology as recommended in the concept proposal. Allocated fund \$4M
2. That the ICOC support the process by which Major Supplements can be awarded to current grantees to enhance the probability of conversion of funded projects to unexpected and transformational benefits, and raise translational projects to a high probability of clinical benefit. Allocated Fund \$12M