

Appendix: Overview of Grants Working Group Review Process for High Volume Application Review

Background: Scientific review of CIRM applications by the Grants Working Group (GWG) is time and resource intensive, effectively limiting the number of applications that can be fully reviewed in a single session of the GWG.

To address the strong demand and significant need for earlier stage research programs to support CIRM's mission, CIRM has previously either 1) set limits on the number of applications that it would accept from any given organization or 2) implemented a two-step review process whereby any eligible investigator could submit a short, preliminary application ("PreApp"), a subset of whom would be invited to submit full applications for review by the GWG. Whereas both of these processes resulted in a manageable number of applications for GWG review, the former required applicant institutions to serve as a gatekeeper for principal investigators, creating the potential for institutional bias in selections; the latter required recruitment of as many as 40-50 additional scientists beyond the 15 scientist member GWG panel and added months to the overall time frame required for review.

As part of the new CIRM 2.0 Discovery Program, CIRM seeks to implement a radically new approach to soliciting and funding stem cell research with the greatest potential to promote the discovery of promising new stem cell-based technologies that could be translated to improve patient care. To enable more timely and frequent capture of such research opportunities, CIRM proposes a new Grants Working Group review process for screening high volumes of applications, termed "Positive Selection", as described below.

Positive Selection:

Positive Selection describes one step in the grant review process in which a defined number of applications, received in response to a given funding opportunity are chosen for full review by the GWG. Unlike the PreApp review described above, applications submitted for Positive Selection will be full-length proposals. Applications will not be scored and ranked- they will either be selected for further review, or not. Using review criteria developed for a specific program, Positive Selection will be conducted by Scientific and Patient Advocate members of the GWG, as well as the CIRM Team, as elaborated below.

The Positive Selection process was designed with the following features in mind:

- Allows single step application submission (No Preliminary Applications).
- Can be scaled in response to application volume.
- Can facilitate selection of proposals with high potential for impact from a broad applicant pool

Positive Selection – Process Overview:

Grant applications are submitted in response to a funding call. Applications will include all elements necessary for a full review such as a statement of significance, summary of project aims, key words, and the detailed proposal.

A review panel that includes the seven GWG patient advocate members and the fifteen scientific members with appropriate expertise will be assembled. The twenty two reviewers will participate in the initial selection process and in the final GWG review meeting.

Review will be conducted in phases depending on the number of applications received. A three-phase review will occur when the number of applications far exceeds the number that can be appropriately reviewed by the GWG in single session. If the total number of submissions is manageable by the panel then phases one and two will not be conducted. The following describes a three-phase review process.

The first phase is a blinded selection from the entire pool of applications based on a portion of the application such as the statement of significance and summary of the project aims in the form of a “preview” page to facilitate review by criteria defined in the program announcement. The applicant name and other identifying information will not be shown. Applications will be sortable and searchable for key words. The number of applications examined and selected by each reviewer will depend on the total number of applications submitted. Generally, each reviewer would examine at least 10% of the application pool and select 2.5% of the pool (e.g., examines at least 40 proposals in a pool of 400 and selects 10). The selection process would narrow a pool of 400 applications to ~160 to 220.

The second phase is a non-blinded selection again based on review criteria defined in the program announcement. In this phase, reviewers will have access to the identity of the applicants and the detailed proposal. Generally, each reviewer would examine at least 10% of the pool remaining from the first round (e.g., if 200 remain, 20 proposals examined – 10 selected previously plus 10 more). The reviewers each make a final selection of a number of proposals compatible with the targeted number of proposal to take forward to the third stage. For example, if each reviewer makes a final selection of three proposals, the selection process would narrow the application pool to ~ 45 to 66. In all cases, final selection can only be made on applications with which the reviewer has no conflict.

The President and the CIRM team will examine all non-selected applications to determine whether any additional applications merit a full GWG review. The remaining non-selected applications will be deemed to be denied.

The third phase is a face-to-face meeting of the GWG members to review and discuss the selected applications. Each application will be assigned to 3 reviewers that may include additional ad hoc specialists as needed. Applications will be scored by each on a scale of 1-100, with 100 being the best possible score. The GWG will recommend funding on the most meritorious proposals consistent with the number and/or funding targeted by the program announcement.