CALIFORNIA'S STEM CELL AGENCY

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

December 11, 2014 Board Meeting
Agenda Item 9.d

Consideration of Adoption of Interim GWG COI Policy

Background

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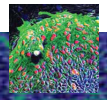
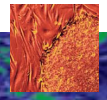
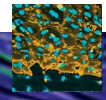
- Prop. 71 requires Board to adopt COI rules for non-ICOC members of the GWG modeled on NIH rules.
- Board adopted these rules in 2005; no amendments since 2008.
- Current policy includes ambiguities, fails to capture some interests that could be perceived as conflicts, and covers some instances that do not present real conflicts.
- Current policy also diverges from NIH's rules.
- Goal of proposed amendments is to provide greater clarity and to refine the rules to ensure that we are appropriately capturing COIs.

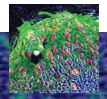
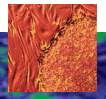
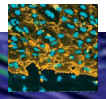




Expanded Scope of Financial Conflict of Interest

- Under current rules, financial conflicts are limited to a member's financial interest in the applicant institution and the application under review.

- Expand the scope of financial conflicts to include financial interests in subcontractors and partners, i.e., entities that are significant participants in the proposed project or that stand to benefit financially if the project is successful.

> "Partner" means an organization that, in exchange for the right to the opportunity for a future financial return, has (1) agreed to provide matching funds for the proposed project or (2) entered into an agreement with the applicant organization relating to the commercialization of the proposed project.
>
> "Subcontractor" means an organization (other than the applicant organization) that is expected to: (a) contribute to the scientific development or execution of the project in a substantive, measurable way and (b) receive $50,000 or more through the proposed project. "Subcontractor" does not include suppliers of widely available goods.

Professional Conflicts

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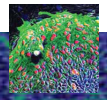
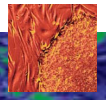
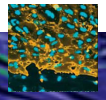
- Under current rules, profession conflict includes long-standing scientific differences or disagreements with the applicant that are known to the professional community and could be perceived as affecting the member's objectivity.

- Differences of scientific opinion are common and help illuminate issues of concern; difficult to discern when a difference of opinion crosses the line into a "long-standing scientific difference"; NIH does not have an analogous provision.

- Eliminate "long-standing scientific differences" as a basis for recusal.

- Add requirement that member recuse himself or herself if the member believes his or her objectivity could be compromised for any reason.

- Add screening mechanism to permit applicants to identify up to a total of three individuals (including labs and companies) whom the applicants believe could be biased (whether for personal, professional, competitive, or any other reasons). Individuals identified by applicants pursuant to this screening mechanism would not be permitted to review the applicant's application.

Personal Conflicts

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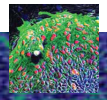
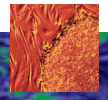
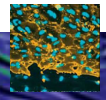
- Under current rules, personal conflict includes “long-standing personal differences” with the applicant.
- Difficult to apply rule because it is so subjective; NIH does not have an analogous provision.
- Modify rule to apply it to situations in which the reviewer and an applicant have been on opposing sides of a formal legal dispute.
- Add requirement that member recuse himself or herself if the member believes his or her objectivity could be compromised for any reason.
- Add screening mechanism to permit applicants to identify up to a total of three individuals (including labs and companies) whom the applicants believe could be biased (whether for personal, professional, competitive, or any other reasons). Individuals identified by applicants pursuant to this screening mechanism would not be permitted to review the applicant’s application.

Definitions

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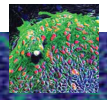
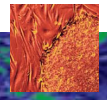
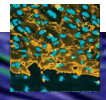
- Clarify the policy by providing definitions of key terms, such as key personnel, research collaboration, subcontractor, partner and immediate family.

- Definitions will assist both reviewers and applicants in identifying potential conflicts and will facilitate CIRM's administration of the policy.

Requested Action

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- Approve amendments as Interim Policy for purposes of review of clinical stage research applications and initiate the administrative rule-making process to apply the rules to the review of all applications.