CALIFORNIA'S STEM CELL AGENCY

TO: Chairman Thomas and Members of the ICOC

FROM: C. Scott Tocher and Ben Huang

DATE: September 28, 2017

RE: Final Adoption of Intellectual Property rules for New Awards.

Executive Summary

In January of this year, the IP and Industry Subcommittee reviewed proposed revisions to CIRM's rules regarding intellectual property, and unanimously recommended to the Board that the agency begin the regulatory adoption process to implement the changes. The Board agreed in February and the new rules were circulated for public comment per the requirements of the Administrative Procedure Act. After three rounds of public comment during which the CIRM team integrated input from stakeholders and identified further areas for refinement, the rules are now ready for final adoption. **As part of that process, the rules are presented here for consideration of a final adoption. The IP Subcommittee met earlier this week and unanimously recommended approval of the policy**. The rules will then be subject to a final review by the Office of Administrative Law before going into effect.

The objective of these revisions is unchanged from when this subcommittee reviewed the project in January: to streamline the administration of the rules and simplify their application. Specifically, the new policy eliminates the distinction between not-for profit and for-profit awardees; eliminates the concept of pre-commercial licensing revenue; and focuses revenue sharing on successful products and therapies.

The final proposed policy and incorporating regulation are attached to this memorandum. Changes to the text since originally proposed is reflected by ~~strikethrough~~ and underline.

I. Policy Components

The CIRM team drafted revisions to the current IP regulations and such revisions were circulated for public comment for several rounds this year. Though edited to address issues raised by commenters from the University of California Office of the President and Stanford University, the policy revisions maintain the primary goals and mechanisms of the project as reviewed earlier this year:

1) Eliminate licensing revenue;
2) Treat Awardees the same regardless of profit status; and
3) Focus revenue sharing on successful drugs and therapies created through "regulatory use" of CIRM-funded research or successful non-drugs which have been exclusively licensed.

Additionally, the revisions clean up the invention reporting rules for awardees (Part II) and allow an option to apply CIRM's revised regulations when a new Award and prior Awards may cover the development of a particular invention or technology (Part XII).

II. Modifications Since Initial Subcommittee Consideration

In addition to minor changes to clarify the operation of the new policy and other non-substantive corrections, the Policy further refines definitions to key terms. For instance, revisions to "Collaborator" and "CIRM-Funded Invention" clarify the scope of the revenue sharing obligations and reporting requirements and ensure Awardees will be able to more easily identify downstream parties that may carry these obligations going forward. In addition, CIRM has eliminated the term "CIRM-Funded Research" to further simplify how the rules operate. Finally, CIRM added the term "Target CIRM-Funded Technology." This new term provides a defining scope of what the Awardee is expected to license in CLIN and TRAN applications, and can be amended in the event the project changes. This addition addresses key concerns of commenters that the policy might have reached beyond technology directly funded by CIRM and might deter future research and commercialization partners.

III. Requested Action:

The CIRM team requests the ICOC's approval of the proposed regulation and policy with Option A language in Decision Point 1.

Attachments:

Section 100650 and Policy