



TO: Members of the ICOC

FROM: Legal

DATE: December 4, 2022

RE: **Item 12:** Consideration of Conflicts of Interest Policy for the Accessibility and Affordability Working Group

### Summary

Proposition 14 created a new working group to advise the ICOC, the Treatments and Cures Accessibility and Affordability Working Group (“AAWG”). Because the AAWG (and the other CIRM working groups) are purely advisory bodies exempt from the state’s conflict of interest rules applicable to public officials, the ICOC is charged with adopting conflict of interest rules to govern the participation of non-ICOC working group members. This item proposes adoption of rules to apply to the AAWG (*based on rules already adopted by the Board and applicable to the Grants Working Group*) on an interim basis and to be used to initiate a formal rulemaking process for their permanent adoption.

### Background

Non-ICOC members of the Grants, Standards, and Facilities working groups are subject to conflict of interest (“COI”) rules adopted by the ICOC and promulgated as regulations through a process overseen by the California Office of Administrative Law. In 2016, CIRM conducted a rigorous review of the COI policy applicable to the Grants Working Group and revised that policy based on Board and stakeholder input. The amendments updated the COI policy to make its provisions clearer and more objective and subsequently were reviewed and approved by the Office of Administrative Law and enacted as a regulation. The amendments have proven effective in fulfilling the institute’s responsibility to avoid COI’s in the consideration of scientific applications for funding.

Proposition 14 created a fourth working group, the AAWG, and the Board recently adopted bylaws that envision the working group evaluating, among other

things, any grant applications related to the AAWG functions for merit and for voting on recommendations regarding an application or proposal. To fulfil the Board's obligation to adopt a COI policy to govern the non-ICOC members of this new working group, CIRM proposes the text in the attached draft.

**The proposed text for the AAWG leverages the Board's efforts made during the recent amendment process engaged for the Grants Working Group, aligning the provisions of both groups with minor modifications that reflect the particular mission of the AAWG. The following is a brief discussion of the primary elements of the proposed COI policy.**

### **Financial Conflicts of Interest**

The proposed language identifies three types of potential conflicts of interest: 1) Financial; 2) Professional; and 3) Personal.

Financial conflicts of interest rules seek to identify circumstances where a financial benefit may accrue to the non-ICOC member or his or her immediate family as a result of a given outcome on an application or contract before the working group. Here, the member will have a conflict if they have an employee of or otherwise has a financial interest in the applicant institution, subcontractor, or other key person on the application. The member also will have a conflict if the member is under consideration for employment with the applicant or key parties on the application or stands to benefit in any amount from the applicant under review. Key terms such as "Subcontractor," "Partner," "Key Personnel," and "Financial Interest" are defined in the policy and are identical to their usage in the Grants Working Group ("GWG") context, as well.

### **Professional Conflicts of Interest**

A non-ICOC member will have a professional conflict of interest if the member and key person on the application are engaged in or planning to be engaged in a joint project. This rule follows the rule as applied in the GWG context but is modified to exclude rules that reached research collaborations unique to the types of reviewers on the GWG.

### **Personal Conflicts of Interest**

Finally, a non-ICOC member of the AAWG will have a personal COI in two circumstances: 1) where a family member or close friend is a key person on the application; and 2) where there member and a key person have been on opposing sides of a lawsuit or similar dispute. This provision is identical to the rule applied to the work of the GWG.

### **Disclosures**

To aid in implementing the COI rules, each non-ICOC member will be asked to disclose to CIRM, confidentially, companies, institutions and real property in which the member has an interest that could present a conflict. The categories mirror those of the GWG, and include income or gifts received from a California-based academic or non-profit research organization, income from or investments in a publicly-held biotechnology or pharmaceutical company, income from a privately-held biotechnology company, and certain real property interests in California.

Each non-ICOC member of the AAWG will be sent a copy of their disclosure form before each meeting and asked to update it. This will take place on or about the time that the member receives the list of applications to be reviewed and completes the screen for conflicts of interest described above.

### **Exceptional Circumstances**

In alignment with the Institute's COI policies applicable to the other working groups and advisory panels, the proposed policy allows CIRM's President/CEO to allow participation by an otherwise conflicted member where the need for special expertise of the reviewer outweighs any possible bias. Under such circumstances, the member will be permitted to participate in the discussion but not permitted to vote or participate in the scoring.

**Requested Action:** *Recommend approval of the proposed AAWG conflict of interest policy as an interim policy, effective January 15, 2023, and direct CIRM to initiate the rule-making process to adopt the policy permanently.*

Exhibit to Memo: Proposed text of Section 100006