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**CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE**

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**TO:** Members of the ICOC  
**FROM:** Zach Hall  
**SUBJECT:** AGENDA ITEM 16 “Consideration of Adoption of Conflict of Interest Regulations for CIRM Working Groups” – Regulations 100001 – 100004.”  
**DATE:** July 25, 2006

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**Executive Summary**

In 2005, the ICOC developed and adopted policies governing conflicts of interest for non-ICOC members of the three working groups created by Proposition 71 to advise the ICOC on certain matters. The working groups are the Grants Review, Facilities, and Medical and Ethical Standards. The policies have been converted into regulatory language, which began the official adoption process in April of this year. The draft regulations have been developed with invaluable input provided by the public at six different public meetings of the ICOC and Legislative Subcommittee and informed by national and state policies addressing these issues in similar contexts. In many cases the regulations are more stringent than existing provisions in state law governing public officials.

The proposed regulations, attached as Exhibit 1 to this memorandum, have completed the Administrative Procedure Act-required public notice period and have been refined as a result of that process. The regulations are now in final form and ready for permanent adoption by the ICOC. This is the last step in the regulatory adoption process and will initiate the Office of Administrative Law’s (“OAL”) final review. If approved by the OAL, the regulations will be published by the Secretary of State and carry the force and effect of law.

**Staff recommends the ICOC adopt the staff responses to public comment and adopt the regulations as written.**

**I. Background**

A. General:

The goal of the CIRM is to sponsor and facilitate research in regenerative medicine that will advance scientific understanding and result in the development of

therapies and treatments for a wide range of devastating diseases. To help in this task, the Act created three working groups, called Grants Review, Facilities, and Medical and Ethical Standards, which draw on outside experts for advice. Each of the working groups has patient advocates, as well as outside experts, among its members.

The goal of two of these groups, Grants Review and Facilities, is to provide expert technical evaluation of applications either for research grants or for research facilities. Neither of these committees is responsible for policy or funding decisions. In both cases, all policy decisions related to the grants and facilities programs and all final decisions about funding are made by the ICOC in open meeting, either upon recommendation by an ICOC Sub-Committee or by the CIRM staff.

In the case of the third committee, Medical and Ethical Standards, the policy decisions are so important and of such general interest that outside experts to aid the CIRM in formulating and recommending to the ICOC the medical and ethical policies that guide the CIRM's work. The work of this committee differs from the other two in that it does not consider requests for funding.

Because the working groups are purely advisory, members of the groups are not subject to the conflict of interest disclosure and disqualification laws of the Political Reform Act. (Health and Safety Code § 125290.50, subd. (e).) That the working groups are purely advisory was confirmed in the recent opinion of Alameda County Superior Court Judge Sabraw in litigation challenging the agency. Nevertheless, the ICOC has taken the unprecedented step of subjecting these advisory bodies to stringent conflict of interest requirements as detailed in the draft regulations. The success of the CIRM research program and its ability to maintain the confidence of the people of California depends critically upon the agency's ability to fund the highest quality research proposals, chosen without bias. Strong CIRM conflict of interest policies are thus essential.

#### B. Regulation Formation Process:

Development of the policies embodied in the proposed regulations began over a year ago. The conflict of interest policies for each working group were tailored to reflect the unique subject area of each group, although some aspects of the policies are identical for each group. The policies were refined with the assistance of public input received at six public meetings conducted by the ICOC and its subcommittees on: April 7, 2005; May 6, 2005; May 23, 2005; June 20, 2005; July 12, 2005; August 5, 2005. These policies were translated into draft regulatory language and on April 14, 2006, the Office of Administrative Law published the draft regulations. Even though the regulations themselves have not been finalized, the working groups have always operated pursuant to the policies adopted last year. The publication of the regulations initiated a 45-day public comment period, which concluded May 29, 2006. The agency received one comment

from the public, which is discussed below. Further refinement of the regulations was made, resulting in an additional 15-day comment period, which concluded July 20, 2006. No additional public comments were received during the final period.

## **II. Proposed Regulations 100001 – 100004.**

The proposed regulations embody the principles already adopted by the ICOC last year for the respective working groups. In translating those policies into a regulatory scheme, four sections were created – the first contains definitions of terms used in the policies (100001), and the remaining three pertain to a particular working group.

Each of the three working group regulations contains separate subdivisions that prohibit participating in decisions in which the member has a conflict of interest, define the types of conflicts of interests applicable to that working group, define the types of economic interests that must be disclosed, and describe the procedures for disqualification of a working group member to avoid a conflict of interest. Sections 100003 and 100004, pertaining to the research and facilities groups respectively, contain additional provisions that require members to sign pre- and post- grant review statements affirming disclosure of potential sources of conflict and assuring the member did not participate in matters in which the member might have a conflict of interest. (§§ 100003, subd. (g), 100004, subd. (g).)

Finally, all financial disclosure documents for each group shall be kept confidentially by the CIRM and preserved for review by staff, the State or other independent auditor, or any other audit as required by law. (§§ 100002, subd. (d); 100003, subd. (h); 100004, subd. (h).) Records will be kept indicating those members who participated in or voted on a particular recommendations – any violation of the rules will be reported to the Legislature, as well as a review of the corrective actions taken to prevent future occurrences. As a result, the regulations ensure proper oversight of the working group recommendations and act as a double-check to prevent conflicts of interest.

## **III. Public Comment and Recommendations.**

In accordance with the Administrative Procedure Act, this agency is required to respond to all public comments received during the official public comment period(s) that are triggered when the regulations are initially noticed with the OAL (in April) and subsequently amended during the drafting process. The agency's response must indicate how either an amendment to the regulation is thought to address the issue raised or why the agency disagrees with the comment. As indicated above, there were two official public comment periods – the initial 45-day period that ended in May, and the additional 15-day period that ended in July. A total of one comment was received during this

process. The Foundation for Taxpayer and Consumer rights raised two issues, each addressed as follows:

1. Require public disclosure of working group conflict of interest forms.

The commenter asserts that failure to require public disclosure of working group conflict of interest forms renders the rules “virtually meaningless.” The commenter recommends amending the regulations to eliminate the confidential disclosure of financial interests and make publicly available those documents, as well as documents indicating who participated in particular recommendations.

**Recommendation: Staff recommends rejecting the proposed amendments.**

Proposition 71 expressly provides that documents of the working groups, except those submitted as part of their recommendations to the ICOC, are not subject to the Public Records Act. (Health and Safety Code § 125290.50, subd. (f).) This sensible policy is consistent with the fact that working group members are voluntary members of purely advisory bodies, which typically do not fill out financial disclosure forms in other California agencies. The ICOC and working groups have received input warning that an unnecessarily burdensome and invasive requirement for disclosure of private financial data will have a detrimental impact on the ICOC’s ability to attract and retain the best individuals possible to serve on the working groups. This, in turn, will impact the quality of evaluation and recommendations made by the groups to the ICOC.

Nevertheless, the working group members, under the proposed regulations, will disclose confidentially pertinent financial information. In the context of the grant working groups (research and facilities), these disclosures will be assessed before and after each grant session to ensure compliance, an additional requirement not found in the Government Code provisions that govern public officials and conflicts of interest. Moreover, these records are preserved so that compliance can be assured by independent auditor reviews – again, an additional check not required under the Government Code. By preserving the documentation for purposes of audit, the purpose of public disclosure of the information is served – to wit, ensuring independent confirmation of compliance – while maintaining the balance of interests with ensuring the best participation possible on the working groups.

As to the second aspect of the suggestion, making public the documents indicating which members participated in a given grant recommendation, this issue is best addressed in the non-regulatory CIRM policies describing the process of presenting working group recommendations to the ICOC. Staff anticipates bringing the issue before the ICOC at a future board meeting to provide for disclosure of participation information in a manner that does not jeopardize the anonymity of the grant review process.

2. Conforming language from Section 100002, subdivision (d), referencing reports to the Legislature, should be included in Sections 100003 and 100004, as well.

**Recommendation: Accept suggestion.** Subdivision (h) of Section 100003 (research grant working group) and Section 100004 (facilities grant working group) were amended to mirror the language in Section 100002 requiring a report to the Legislature of any violations of conflict of interest rules and the corrective actions taken.

**IV. Recommendation.**

**Staff recommends the ICOC adopt the attached regulations without modification for the reasons stated in this memorandum.**