

**ENHANCEMENT POLICIES RECOMMENDED BY
THE LEGISLATIVE SUBCOMMITTEE OF THE ICOC**

At its June 20, 2005 meeting, the Legislative Subcommittee of the ICOC recommended that the ICOC adopt the following policy enhancements to address concerns raised by the Legislature and to reassure the public regarding the CIRM's commitment to transparency and to the highest ethical standards. With respect to each of these policies, the Legislative Subcommittee recommended that the ICOC require notice to the Legislature and the public and a vote of 70 percent of a quorum of ICOC members to amend the final policies. Current CIRM policies and the recommended policy enhancements are set forth below. Please note that Legislative Subcommittee modified some of these items during its meeting. CIRM staff has attempted to include these changes below; however, this draft may be modified to reconcile it with the transcript of the Legislative Subcommittee meeting.

Conflict of Interest Policies for Working Group Members

Current Policy and Procedures: It is the responsibility of the CIRM to ensure that grants are awarded and policies established in a way that is fair and free from bias. To accomplish this, the ICOC has adopted Conflict of Interest (COI) Policies for each of its three working groups: Grants (adopted April 7, 2005); Standards (adopted April 7, 2005 and amended May 23, 2005); and Facilities (adopted May 23, 2005). These policies are based on those used by the National Institutes of Health, the National Academy of Sciences and the University of California Special Research Programs. Because each of the working groups has different functions, each of the three policies is different. At the time of appointment each working group member is given a copy of the appropriate policy and asked to sign a statement that he or she agrees to follow the CIRM COI policy.

The Grants and the Facilities Working Groups evaluate grant or facilities applications, respectively, and recommend them for funding to the ICOC. The CIRM staff is responsible for ensuring that working group members do not participate in discussions or evaluations of any application for which they have a conflict of interest. Prior to each working group meeting, every member of the working group is sent a list of the applications to be reviewed and asked to complete a pre-review certification form on which he or she identifies, under penalty of perjury, any grant applications for which he or she has a scientific, professional or personal conflict of interest. At the meeting, prior to consideration of each application, CIRM staff asks any working group member with a conflict in that application to leave the room during its discussion and evaluation. Staff maintains a record of which members voted on each application. After the meeting, all present sign a post-review certification form, again under penalty of perjury, confirming that they did not violate CIRM Conflict of Interest or Confidentiality Policies during the meeting. The pre- and post-review certification forms were approved at the ICOC meeting of April 7, 2005.

The Conflict of Interest Form for Standards Working Group members, whose task is to develop medical and ethical standards, describes several types of conflict of interest and asks members to identify and describe in detail the source of any conflict of interest that corresponds to the listed types. If a conflict of interest is identified, the CIRM President, or delegated staff member, is responsible for ensuring that the member does not participate in discussing or voting to recommend policies that would present a conflict of interest. A revision adopted May 23, 2005 restricts Standards Working Group members from deriving direct financial benefit from CIRM through grants, loans, or contracts.

Recommended Enhancement of Procedures:

1. Financial Disclosure

To aid in implementing CIRM Conflict of Interest Policies, each non- ICOC working group member will be asked to disclose to the CIRM, confidentially and under penalty of perjury, companies, institutions and real property in which he or she has an interest that could present a conflict. The categories are slightly different for each working group:

Grants Working Group:

- a) All California-based academic or non-profit research institutions from which they receive current income or other benefit of \$5,000 or more.
- b) All biotechnology and pharmaceutical companies from which reviewers and their spouses receive current income or other benefit or investments of \$5,000 or more.
- c) Real property interests in California.

Standards Working Group:

- a) All California-based academic or non-profit research institutions from which reviewers, close family members, or others with whom reviewers have a substantial common financial interest receive current income of \$10,000 or more.
- b) All biotechnology and pharmaceutical companies from which reviewers or their spouses receive current income or other benefit or investments of \$10,000 or more.
- c) All property interests in California of \$10,000 or more (including real estate interests and interests in intellectual property such as patents and copyrights) held by reviewers, close family members or others with whom reviewers have substantial common financial interest.

Facilities Working Group:

- a) All California-based academic or non-profit research institutions from which they receive current income or other benefit of \$5,000 or more.
- b) All construction, real estate or development firms from which they or their close family members receive current income or other benefit, or hold an investment, of more than \$5,000.
- c) All real property interests in California.

Each non-ICOC member of the Grants and Facilities Working Groups will be sent a copy of his or her disclosure form before each meeting and asked to update it. This will take place at the same time as the working group member receives the list of applications to be reviewed and completes the pre-review certification form for conflict of interest, described above.

2. Availability for Audit

The confidential disclosure forms for Grants and Facilities Working Group members will be kept on file at the CIRM offices where they will be available for review by a State or independent auditor. Also available will be the records of those present and voting during discussion and evaluation of each grant or facilities application. Comparison of the disclosure forms and meeting records will indicate whether any non-ICOC member of a Working Group has participated in a decision in which he or she has a financial interest, as defined above.

Conflict of interest and financial disclosure forms for the Standards Working Group and a record of who participated or voted on particular recommendations of the Working Group will also be on file at CIRM for audit by an independent or State investigator.

If CIRM or the auditor discovers a violation of conflict of interest, a report will be made to the Legislature along with a review of corrective actions taken by CIRM to prevent future occurrences.

Funding recommendations to the ICOC

Current Policy and Procedures: Consistent with Proposition 71, the applications recommended by the Grants and Facilities Working Groups for funding will be submitted to the ICOC by CIRM staff with the following information: (1) Title; (2) a Summary of the Proposal written by the applicant that includes a description of how the proposal could benefit the State of California; (3) a brief summary of the scientific evaluation and the reasons for recommendation, along with any minority report, as applicable; (4) the scientific score of the application, based on criteria decided by the ICOC; and (5) the recommendation of the full Working Group.

Recommended Enhancement of Procedures: All of the information to be presented to the ICOC will be made available on the CIRM web site ten days before the ICOC meeting at which the grants will be considered.

Annual Report

Current Policy and Procedures: Proposition 71 requires the CIRM to submit an annual report to the public that sets forth its activities, grants awarded, grants in progress, research accomplishments and future program directions

Recommended Enhancement of Procedures: CIRM will submit an annual report to the Legislature that includes the following information:

- 1) The identity of recipients of research, training and facilities grants, loans and contracts awarded that year and the amount awarded in each case;
- 2) The disease and/or science category to which the grant, loan or contract relates;
- 3) The total number and total amount of grant applications awarded, with breakdown by disease and/or science category;
- 4) The total number and total amount of grant applications received with breakdown by disease and/or science category.

Meeting Procedures for Working Groups

Current Policies and Procedures: Under Proposition 71, the ICOC is required to consider and approve in public session all medical and ethical standards and all criteria and standards for considering funding applications, for awarding research and training grants, and for scientific and medical oversight of awards. In addition, the ICOC must make all decisions about funding grants, loans and contracts for research, training and facilities in public session. At its April meeting, the ICOC approved the practice of holding confidential Grants Working Group meetings for consideration of grant applications. At its May meeting, the ICOC approved open meetings procedures for the Standards Working Group, with provisions for public hearings to provide input and to make comments on draft findings and recommendations, and public votes on decisions and recommendation to the ICOC. The Standards Working Group will meet in confidential session only when needed to protect patient privacy or to review a complaint regarding compliance, with final action to be taken in a public meeting. The ICOC also approved the concept of public meetings for the Facilities Working Group (May 23, 2005).

Recommended Enhancement of Procedures:

1. **Grants Working Group: Development of Criteria**

The Grants Working Group will meet in public session except for discussions related to evaluation of grant applications and recommendation of applications to the ICOC or discussions of other matters that may be considered in closed session under the Bagley-Keene Open Meeting Act or under Health & Safety Code section 125290.30. The Grants Working Group may request other mission-critical exceptions.

2. Facilities Working Group

The Facilities Working Group will meet in public, as approved by the ICOC in May, except where necessary to discuss scientific evaluation of proposals, to consider real estate negotiations or to consider other matters that may be discussed in closed session under the Bagley-Keene Open Meeting Act or under Health & Safety Code section 125290.30. The Facilities Working Group may request other mission-critical exceptions.

Records of the Working Groups

Current Policy and Procedures: Under Proposition 71, records of the working groups are exempt from the Public Records Act, with the exception of those records that are provided to the ICOC as part of the working groups' recommendations to the ICOC.

Recommended Enhancement of Policy: Provide public access to working group records, except for: (1) records that may be withheld under the Public Records Act and Health & Safety Code section 125290.30; (2) applications for research, training, and facilities grants, loans, and contracts and evaluations of such applications; and (3) economic disclosure forms filed by members of the Grants, Standards, and Facilities Working Group.

Conflicts of Interest Policy for Board Members and President

Current Policy: Proposition 71 requires board members and the CIRM staff to disclose economic interests consistent with the Political Reform Act. Thus, Board members and the CIRM staff are held to the same standards applicable to constitutional officers, members of the Legislature, and designated state employees. In addition, the ICOC has adopted a conflict of interest policy that requires board members to recuse themselves from participating in any decision regarding a grant, loan or contract with their employer, and any decision regarding a grant, loan or contract that financially benefits the member or his or her employer. The ICOC has also adopted a policy to preclude board members from applying for, or receiving salary support through, grants, loans or contracts from the ICOC.

Recommended Enhancement of Policy: Require board members and the CIRM president to divest themselves of, or to place in a blind trust, any investment or real property interest of \$2,000 or more in any business organization that receives funding from, or research contracts with, the CIRM, and in any business organization that

allocates more than five percent of the business organization's current annual budget to stem cell therapy.

Intellectual Property

Current Policy: Proposition 71 requires the ICOC to adopt standards that require that all grants and loans be subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties and licenses that result from the research with the need to assure that essential medical research is not unnecessarily hindered by intellectual property agreements.

Recommended Policy Enhancement: The Subcommittee did not have an opportunity to discuss a proposed enhancement to strengthen the CIRM's intellectual property agreements.