

**POLICY ENHANCEMENTS RECOMMENDED BY  
THE ICOC PENDING REFINEMENTS - PART I**

**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 Review (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 Review 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 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 Review Working Group:*

- a) All California-based academic or non-profit research institutions from which reviewers, their spouses or others with whom a reviewer has a common financial interest receives current income or other benefit of \$5,000 or more.
- b) All publicly held biotechnology and pharmaceutical companies from which reviewers, their spouses or others with whom a reviewer has a common financial interest receive current income or other benefit or investments of \$5,000 or more.
- c) All privately held biotechnology companies in which reviewers, their spouses or others with whom a reviewer has a common financial interest have an equity interest.
- d) Real property interests in California held by reviewers, their spouses or others with whom a reviewer has a common financial interest.

*Standards Working Group:*

- a) All California-based academic or non-profit research institutions from which SWG members, their spouses or others with whom an SWG member has a common financial interest receive current income of \$5,000 or more.
- b) All biotechnology and pharmaceutical companies from which SWG members, their spouses or others with whom an SWG member has a common financial interest receive current income or other benefit or investments of \$5,000 or more.
- c) All real property interests in California of \$5,000 or more (including real estate interests and interests in intellectual property such as patents and copyrights) held by SWG members, their spouses or others with whom an SWG member has a common financial interest.

*Facilities Working Group:*

- a) All California-based academic or non-profit research institutions from which reviewers, their spouses or others with whom a reviewer has a common financial interest receives current income or other benefit of \$5,000 or more.
- b) All construction, real estate or development firms from which reviewers, their spouses or others with whom a reviewer has a common financial interest receive current income or other benefit, or hold an investment, of more than \$5,000.
- c) All real property interests in California held by reviewers, their spouses or others with whom a reviewer has a common financial interest.

Each non-ICOC member of the Grants Review 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 non-ICOC Grants Review 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**

**Recommended Procedures:** Applications will be submitted to the ICOC by the Grants Review Working Group in three groups: those recommended for funding; those recommended, but not funded; and those not recommended for funding at this time. For all applications in the first two groups, CIRM staff will provide the following information: (1) application number and title; (2) abstract of the proposal that includes a statement of how the proposal could benefit the State of California; (3) a synopsis of the scientific evaluation and reasons for recommendation, along with any minority report, as applicable; (4) the scientific score of the application, based on criteria decided by the

ICOC; (5) the recommended budget and (6) the recommendation of the Working Group with respect to Groups I and II. The following information will be submitted to the ICOC for applications (Group III) not recommended for funding at the current time: (1) application number and title; (2) an abstract of the proposal that includes a brief statement of how the proposal could benefit the State of California and (3) a synopsis of the scientific evaluation. The general range of scientific scores of applications not recommended for funding (Group III) will also be provided, and the specific score as well as the budget of a particular application will be submitted upon request by the ICOC. All 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 Procedures:** CIRM will submit an annual report to the Legislature that includes the following information:

- 1) The identity of institutional 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.