ICOC Meeting **Agenda Item 11**
April 7, 2005

Zach W. Hall, Ph.D., Interim President

WORKING GROUPS: Consideration of Confidentiality, Meeting Format, Conflict of Interest, Compensation, and Working Group Chairs

BACKGROUND: To begin the scientific programs of the CIRM as soon as possible, the ICOC intends to name members of the Grants Review and Medical and Ethical Standards Working Groups at its May meetings and to hold initial meetings of these groups early in the summer. Several issues need to be resolved by the ICOC in order to meet this schedule. In particular, nominees for the Working Groups, who will be contacted before the May meeting, need to be advised of CIRM policies with regard to confidentiality, meeting format, conflict of interest and compensation. The ICOC will also need to identify Chairs for the respective Working Groups.

INTRODUCTION

The goal of the CIRM is to sponsor and facilitate research in regenerative medicine that will advance our scientific understanding and result in the development of therapies and treatments for a wide range of devastating diseases. To help us 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 discussions or for 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 we ask outside experts to aid us in formulating and recommending the medical and ethical policies that guide our work. The work of this committee differs from the other two in that it does not consider requests for funding. The committee does, however, consider highly sensitive, and sometimes controversial, matters.

The functions of the committees differ, and their needs for confidentiality and conflict-of-interest guidelines differ accordingly. For the Grants Review and Facilities working groups, which evaluate confidential material and make technical evaluations that influence funding, confidentiality and broad issues of conflict-of-interest, especially

financial conflict of interest, apply. For the Medical and Ethical Standards Working Group, issues of confidentiality must be balanced with those of transparency and public accessibility.

Because we have an immediate need to have policies in place for the Grants Review and Standards Working Groups, we will consider issues primarily related to these groups at this Board meeting, and will consider similar issues for the Facilities Working Group at a later time.

CONFIDENTIALITY

The scientists who submit applications for research funding bring to us their latest results, often unpublished, and their best ideas for future experiments. They may have preliminary data that make a particular experimental approach look promising, or a fresh new idea that they seek funding to explore. Further, investigators may present unpublished data, technology or ideas that represent valuable intellectual property. To protect scientists from premature disclosure or appropriation by others of their ideas or techniques, and to protect the potential intellectual property rights of the state of California in this research, we have a strong obligation to maintain the confidentiality of their applications. Those who participate in the review, either as reviewers, patient advocates, or as CIRM staff, must agree not to identify applicants by name or institution or to discuss applications outside of the review setting, and not to retain any materials from the review. These are well-established policies used for review of NIH grants, and by many private funding agencies. They are also used by the University of California for grants review. We have incorporated these principles into a confidentiality agreement statement that we will ask each reviewer, patient advocate and staff member to sign at the time they are appointed or assigned to the review committee. At the end of each review meeting we will ask all participants to sign a statement saying that they have conformed to these principles for that particular review meeting.

I enclose a draft of a recommended statement (Appendix A) which is based on NIH standards as adopted for use by the University of California. We seek the approval of the ICOC to use this policy and these forms, or a version amended as you specify, as interim standards until new policies are approved based on recommendation from the Medical and Ethical Standards Working Group.

MEETING FORMAT

If confidentiality of grant applications is to be maintained, it follows that grant review meetings cannot be public meetings, but must be attended only by the outside expert reviewers, patient advocates and CIRM staff, all of whom must agree to abide by the confidentiality agreement.

As those who are familiar with peer review know, confidential meetings have a second benefit in that discussions of scientific quality, the scientific and clinical qualifications of the applicants and the potential promise of different approaches is much more candid when the discussions occur in private. Scientists who make strong judgments in private

are often reluctant to do so publicly, particularly when it could affect the funding of a colleague's laboratory. Indeed, this principle is so well-established that we believe that many scientists would refuse to participate in public grant review meetings.

The principle of confidential peer review is extremely well-established in the scientific community and is the gold standard by which the NIH, the National Science Foundation and private funding foundations make funding decisions. It's also essential to protect the intellectual property rights in this research funding for the state of California. Inability to use this mechanism would be a severe blow to our efforts to fund the very best biomedical science and thereby to obtain best use of the state funds that have been entrusted to us.

Because of the importance of peer review, we strongly recommend that the Grants Review Working Group meetings remain confidential, as mandated by Proposition 71.

For the Medical and Ethical Standards Working Group, three models are possible: confidential meetings as proposed by Proposition 71, open meetings that meet Bagley-Keene standards, or a mixed model, as used by the National Academies, with a combination of open data-gathering meetings, at which the public is invited to testify, and confidential deliberative sessions. The importance of public input for the Standards Working Group seems indisputable. Thus, we recommend to the ICOC that the Standards Committee either adopt open meetings or a combination of open and closed meetings on the National Academies model.

CONFLICT OF INTEREST

The success of the CIRM research program and its ability to maintain the confidence of the people of California depends critically upon our ability to fund the highest quality research proposals, chosen without bias. Strong CIRM conflict of interest policies are thus essential. Their need is most obvious for the Grants Review and Facilities Working Groups, that are responsible for technical evaluation of research and facilities applications, but are also important for the Standards Working Group, which will be recommending policy.

For the Grants Review Working Group, we have adopted policies and procedures that are closely modeled on those of the NIH for its outside reviewers. This model is appropriate because the NIH is the largest funding source for biomedical research, and has used these policies successfully for many years. In a Policy Statement (Appendix B), we identify three kinds of conflicts of interest: financial, professional and personal and in each case define the types of conflicts that are possible. At the time of appointment to the Working Group, all reviewers and patient advocate members will be asked to sign a statement that asserts that they have read and understand the CIRM policy.

We will have additional procedures before and after each review session. We anticipate a procedure in which each application is considered and discussed in turn; reviewers then give a rating to the application. If Working Group members have a conflict of interest with respect to any application, they will not be allowed to review or vote on that

application nor will they be allowed to hear or participate in the discussion of it. Prior to a review meeting, Working Group members will be sent a list of all applications to be considered along with a form (Appendix C) that asks them to identify any and all applications for which they might have a conflict of interest. At the time of review, as each application is considered in turn, CIRM staff will insure that particular members with a conflict of interest absent themselves from the room during discussion and voting on that application. At the end of the meeting all Working Group members will be asked to sign a form (Appendix D), that states, under penalty of perjury, that they have observed confidentiality and that they did not participate in the review of any application for which they had a conflict of interest.

Similar policies and procedures, with appropriately modified forms, will be followed for the Facilities Working Group, which will also consider applications for funding.

Conflict of interest issues for the Standards Working Group are somewhat different, as this working group will not be considering applications for funding, but will be formulating and recommending to the ICOC policies for medical and ethical standards. Here the appropriate model is not the NIH policy for grant reviewers, but rather the policy that the National Academies uses for its committees, in which a group of outside (i.e. non-employee) experts are called upon to analyze a topic and make policy recommendations. Hence, we have adopted for CIRM a modification of the policy and conflict of interest forms used by the National Academies. All Medical and Ethical Standards Working Group members will be asked at the time of their appointment to sign a statement (Appendix F) disclosing any financial or other conflict of interest that they may have regarding the issues to be discussed by the Working Group. As stated in the form, they will also be required to disclose any new conflict of interest that arises during their term of service. Except for specific exceptions in which the in which the ICOC judges that the disadvantages of a person's conflict of interest are outweighed by the need for their particular expertise, individuals with a significant conflict of interest will not be permitted to serve on the Standards Working Group.

CONSULTING RATE

For CIRM to achieve its purpose of funding the highest quality basic and clinical science and having that science done according to the highest medical ethical standards, we will need to attract to our working groups scientists, ethicists and other specialists of the very best quality. The best people are, by definition, those who are already heavily committed to other endeavors and who have limited time. To encourage their participation, we need to offer a reasonable consulting rate and also provide such clerical help as they may need for preparation. The need for help will be particularly acute for Grant Review Working Group members, whose work load will be very large due to the large number of applications that we expect to receive. We may expect that for every day the Working Group is in session, each member will spend one to two additional days in preparation. It is worth noting that unlike NIH reviewers, who are usually recipients of NIH grants to fund their research and thus feel a sense of responsibility to the NIH grant application evaluation process, the reviewers of grant applications submitted to CIRM will NOT benefit from CIRM research funding. We propose offering each member an consulting

rate of $500 per day of meeting, with an additional supplement of $500 per member for clerical support reimbursement for each meeting plus travel cost and out-of-pocket expenses.

CHAIR

Each Working Group will need a Chair who will work with CIRM staff to organize and prepare meetings, will preside over the meetings and, working with CIRM staff, will be responsible for assuring the accuracy of meeting reports that are submitted subsequent to the meeting. We propose that the ICOC request that the Sub-Committee Chairs nominate a Working Group Chair at the time that Working Group nominees are proposed. We further suggest that Chairs be given additional consulting rate above the basic per diem compensation. This additional consulting rate would be set at $500 per day with a stipulated allowance of 5 days per Working Group meeting to reflect their additional work load. The CIRM will also reimburse the Chair of the Working Group for reasonable expenses for clerical support.

ACTION ITEMS REQUESTED OF THE ICOC:

1) A resolution approving the policies and forms of CIRM, with appropriate modification by the ICOC as needed, with respect to confidentiality.
2) A resolution establishing the meeting format for the Grants Review, Medical and Ethical Standards and Facilities Working Groups.
3) A resolution approving the policies and forms of CIRM, with appropriate modification by the ICOC as needed, with respect to conflict of interest.
4) A resolution establishing the consulting payment and staff reimbursement that can be offered to the Working Group members.
5) A resolution requesting each of the Sub-Committees to submit a nominee for Chair at the time nominees for the Working Group are submitted.