CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

DRAFT Agenda Item # 15 v 12/7/06 ICOC Meeting

Summary of CIRM Policies on Conflict of Interest, Confidentiality and Non-disclosure

It is the personal responsibility of each member of the Scientific and Medical Facilities Working Group (Facilities WG) to: (1) alert the Facilities Grants Review Officer to any possible conflict of interest situation, whether real or apparent, that may have an impact on the review; (2) identify on pre-meeting and post-meeting Conflict of Interest Certification Forms any application where the member has a conflict of interest, and; (3) certify on the premeeting and post-meeting Conflict of Interest Certification Forms associated with each review that the Facilities WG member will not be, and has not been, involved in the review of any application where his or her participation constitutes a conflict of interest. Facilities WG members must also certify that they will maintain the confidentiality of the proceedings and associated materials, and that they will not disclose to another individual any matter or information related to the review proceedings. In addition, CIRM may determine that a particular situation involves a conflict of interest and require that a Facilities WG member be recused from the review of the application(s) or proposal(s) in question.

All members of the Facilities WG attending a particular Facilities WG meeting to review applications are subject to this summary of policies sheet and associated Policies and Certification Forms.

CONFLICT OF INTEREST

There are several bases for a conflict of interest: employment, financial benefit, personal relationships, professional relationships or other interests. If applicable, any one condition may serve to disqualify a Facilities WG member from participating in the review of an application or proposal.

The following conflict of interest guidelines and definitions are representative only and may not include other possible conflicts of interest. Therefore, it is important that you consult the Facilities Grants Review Officer in charge of the meeting when there is any question about your participation in a review.

GUIDELINES AND DEFINITIONS

A Conflict Of Interest in facilities grants review exists when a Facilities WG member has a real or apparent interest in the outcome of an application such that the member is in a position

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to gain financially, professionally or personally from either a positive or negative evaluation of the grant proposal. A Facilities WG member who has a real conflict of interest with an application or proposal may not participate in its review.

Financial:

A member has a financial conflict of interest if:

- (1) The member, his or her spouse or any other person with whom the member has a common financial interest, is an employee of any construction, real estate or development entity on an application.
- (2) The member, his or her spouse or any other person with whom the member has a common financial interest, is under active consideration for employment at an applicant entity.
- (3) A member, his or her spouse or any other person with whom the member has a common financial interest, stands to receive a financial benefit of any amount from an application under review.
- (4) A member, his or her spouse or any other person with whom the member has a common financial interest, has received or could receive a financial benefit of any type from an applicant institution or organization unrelated to the proposal, of over \$5,000 per year. This total includes honoraria, fees, stock and other benefits. It also includes current stock holdings, equity interest, intellectual property or real property interest, but does not include diversified mutual funds.

Professional:

A member has a professional conflict of interest if the reviewer and a project director or manager of an application are engaged in, or are planning to be engaged in, or have been engaged in in the last three years, a joint project.

Personal:

A non-ICOC member has a personal conflict of interest if he or she:

- (1) has a close personal ties to the project director or manager for the applicant institution; or
- (2) serves in an advisory capacity to the applicant institution or any of its departments or affiliated associations, such as an alumni association or athletic foundation; or
- (3) has an immediate family member who is a current student or faculty member of the applicant institution; or
- (4) has long-standing personal or professional differences with the project director or manager for the applicant institution.

A member is required to report to the CIRM staff member any conflict of interest of which he or she is aware, including, but not limited to, those described above. Except under unusual circumstances, any member of the Facilities Working Group who has a real or apparent conflict of interest with respect to an application may not review or vote on the application and must leave the room when that application is discussed. In exceptional cases, the President of the CIRM may decide that the need for special expertise of the reviewer outweighs any possible bias posed by a real or apparent conflict of interest. Under these circumstances, the CIRM staff shall publicly disclose the working group member's interest before the meeting and the working group member shall be permitted to participate in the discussion but will not be permitted to vote on the application or participate in the scoring

All reviewers must sign a pre-review statement indicating any possible conflicts of interest that they have, and must also sign a post-review statement that they did not participate in the discussion or review of any application for which they might have a conflict of interest.

Regardless of the level of financial involvement or other interest, if a Facilities WG member feels unable to provide objective advice, he/she must recuse him/herself from the review of the application or proposal at issue. The review system relies on the professionalism of each Facilities WG member to identify to the Facilities Grants Review Officer any real or apparent conflicts of interest that are likely to bias his/her evaluation of an application or proposal.

Request For Applications (RFA) Or Request For Proposals (RFP): Persons serving as the principal investigator or key personnel on an application submitted in response to an RFA or on a proposal in response to an RFP are generally considered to have a conflict of interest with all of the applications or proposals submitted in response to the RFA or RFP.

CONFIDENTIALITY AND NON-DISCLOSURE OF MATERIALS AND PROCEEDINGS

The California Institute for Regenerative Medicine (CIRM) is committed to maintaining confidentiality during the grant review process to protect the interests of the applicants and to encourage candor on the part of the reviewers as to the scientific and medical value of the applications being reviewed. Applicants provide confidential information to the CIRM as part of their applications and it is the obligation of those participating in the review to safeguard this information.

According to CIRM policy, Working Group members must not disclose the identity of applicants and institutions that they consider. The principal investigator's name and institution, the project title and abstract will be made public for funded grants, but the contents of the applications, even in funded grants, remain confidential for the protection of the applicants.

The applications and proposals and associated materials made available to Facilities WG members, as well as the discussions that take place during Facilities WG review meetings are strictly confidential and must not be disclosed to or discussed with any individual who has not

been officially appointed to participate in the review process. Facilities WG members are not to discuss the identity of the applicants, the contents of the applications or the Working Group discussions with anyone other than Working Group members or CIRM review personnel. If you wish to discuss a technical matter related to an application with a colleague who is not on the Working Group, please do not contact the person directly. Rather, notify the Facilities Grants Review Officer who will review the request and contact the person directly if appropriate.

All hard copy materials associated with the review that you receive or that you generate must not be shared with anyone and must be destroyed after the review is complete.

CERTIFICATION

Under penalty of perjury (California Penal Code section 118), each Facilities WG member must certify that, to the best of his/her knowledge, he/she has disclosed all conflicts of interest that he/she may have with the applications and he/she fully understands the confidential nature of the review process and agrees: (1) to destroy or return all materials related to the application and to the review; (2) not to disclose or discuss the materials associated with the review, their evaluation, or the review meeting with any other individual except as authorized by the Facilities Grants Review Officer or other designated CIRM official; and (3) to refer all inquiries concerning the review to the Facilities Grants Review Officer.