



TO: Members, Citizens' Financial Accountability Oversight Committee

FROM: Art Torres, Vice Chair, Governing Board, California Institute for Regenerative Medicine

DATE: January 13, 2012

RE: CIRM's Conflict of Interest Policies

Unfortunately, I will not be able to participate in the upcoming meeting of the Citizens' Financial Accountability Oversight Committee ("CFAOC"). My colleagues plan to provide you with an update regarding the progress made by the California Institute for Regenerative Medicine ("CIRM") since the CFAOC last met on January 28, 2011. At that meeting, several members of the CFAOC raised questions concerning CIRM's conflict of interest policies. We thought it might be helpful to provide you with additional information regarding CIRM's existing conflict of interest policies, as well as our plans to guard against conflicts of interest as we engage industry in an effort to achieve CIRM's goal of finding therapies and cures for Californians who suffer from chronic disease and injury. Our Board counsel, James Harrison, will be available at the meeting to answer any questions you may have regarding CIRM's conflict of interest policies.

Conflict of Interest Overview

Like all state agencies, CIRM is governed by the Political Reform Act, Government Code section 1090, and other conflict of interest laws. Under the Political Reform Act, members of CIRM's Governing Board and staff are required to file annual Statements of Economic Interests (Form 700) and to recuse themselves from making, participating in making, or attempting to influence any governmental decision, including decisions regarding grants and loans, in which the Board member or staff member has a financial interest. In addition, Government Code section 1090 prohibits Board members and staff members from participating in any decision regarding a contract in which they have a financial interest.¹

¹ Proposition 71 established an important exception to this rule to accommodate CIRM's specialized mission. Under Government Code section 1090, when one member of a Board has an interest in a contract, the entire Board is deemed to be interested in the contract and is barred from considering it. Proposition 71 was designed to draw upon the expertise of Californians with a history of: (1) managing large research grants and institutions and conducting major medical research; (2) understanding the critical path for the development and approval of successful experimental medical treatments and

CIRM’s three Working Groups – the Grants Working Group, which makes recommendations regarding research standards and awards, the Facilities Working Group, which makes recommendations regarding facilities standards and awards, and the Standards Working Group, which makes recommendations regarding scientific, medical, and ethical standards – are advisory only and therefore are not subject to state conflict of interest laws.² In order to ensure accountability and to prevent conflicts of interest, however, Proposition 71 mandated that CIRM’s Governing Board adopt specialized conflict of interest rules for members of the Working Groups. These conflict of interest rules are modeled on, but exceed, the standards established by the National Institutes of Health. Members of CIRM’s Working Groups are required to disclose relevant financial interests to CIRM and are precluded from participating in decisions in which they have conflicts of interest.

From its inception, CIRM has taken significant steps to ensure transparency and accountability. The Governing Board has adopted conflict of interest policies for Board members, CIRM staff, and members of CIRM’s Working Groups that go beyond the requirements of state law. Under CIRM’s conflict of interest policies, members of CIRM’s staff are prohibited from holding an interest in a company that devotes more than five percent of its research budget to stem cell research and are barred from participating in a decision regarding a grant or loan to their former employer for a period of one year following the end of their employment. Similarly, members of CIRM’s Grants Working Group (“GWG”) are drawn from outside of California to ensure they cannot personally benefit from CIRM funding, which is restricted to research

directing the development and approval process through the Food and Drug Administration and other regulatory bodies and ethical committees; and (3) advocating on behalf of Californians who suffer from a variety of chronic diseases and injuries. As a result, some of the members of CIRM’s Governing Board are drawn from institutions that are eligible to apply for CIRM funds. In order to allow the Board to consider applications for funding under these circumstances, Proposition 71 includes an exception that permits the Board to vote on a grant award to an institution in which a member has an interest, provided that the member refrains from participating in, or attempting to influence the outcome of, the Board’s decision regarding the grant or loan.

² Under the Political Reform Act, members of an advisory board are not considered “public officials” subject to the Political Reform Act unless the body to which the advisory board reports routinely adopts the advisory board’s recommendations, over an extended period of time, without making substantive changes. (Cal. Code Regs., tit. 2, § 18701.) Proposition 71 avoided the uncertainty of this regulatory scheme by requiring CIRM’s Governing Board to adopt conflict of interest rules modeled on rules promulgated by the National Institutes of Health for members of CIRM’s Working Groups.

conducted in the state, and they are prohibited from participating in the review of applications in which they have a professional or personal conflict of interest, in addition to a financial conflict of interest. The policies for the Board, CIRM staff, and the Working Groups are described below.

Conflict of Interest Policies

Like all state agencies, CIRM has adopted, subject to the review of the Fair Political Practices Commission, a conflict of interest code. CIRM's conflict of interest code requires Board members and staff to broadly disclose their financial interests in an annual financial disclosure form. These forms are made available to the public and the forms filed by members of the Board and CIRM's senior leadership are posted on the agency's website. CIRM has also adopted a Statement of Incompatible Activities which prohibits staff from engaging in activities that are inimical to, or in conflict with, their duties as CIRM employees.

CIRM has gone beyond the requirements of state law by adopting additional conflict of interest policies for Board members and staff. The Governing Board has adopted a conflict of interest policy that prohibits members of the Board from receiving any salary support through a CIRM grant or loan. In addition, CIRM has adopted conflict of interest rules for its staff, including the prohibition described above against holding investments in companies engaged in stem cell research and a requirement that staff members refrain from participating in the review of an application submitted by a former employer for a period of one year following termination of their employment. These rules are rigorously enforced and help to ensure the integrity of CIRM's review process.

CIRM's conflict of interest policies for members of its Working Groups are tailored to the functions of the particular Working Group. Members of the Grants Working Group, for example, are required to recuse themselves from participating in the review of an application submitted by a collaborator, someone with whom the member has authored a paper in the last year, and someone with whom the member is known to have a difference of opinion regarding a scientific matter, in addition to individuals and institutions with which the member has financial ties. Similarly, members of the Facilities Working Group are prohibited from providing real estate facilities brokerage services for any applicant for a facilities grant, or for any entity that receives funding from the Facilities Working Group, and they are barred from receiving compensation from any recipient of CIRM funding grants. They are also prohibited from participating in the review of an application in which they have a financial interest, as well as an application that includes a project director or manager who is a collaborator of the

member. All members of the Working Groups are required to submit financial disclosures to CIRM.

CIRM makes the records of its compliance with the conflict of interest rules available for audit. In 2008, the Controller conducted a review of CIRM's compliance with its conflict of interest policies and found that CIRM was in compliance.³ The Controller also found that CIRM has "extensive conflict of interest policies that are modeled after and, in some cases, go beyond the National Institute[s] of Health requirements."

Conflict of Interest Procedures for the Review of Applications for Grants and Loans

CIRM has implemented rigorous conflict of interest procedures in order to ensure that all decisions are made on their merits and not due to any improper influence. The process begins with CIRM staff members and members of the Grants Working Group, who are screened for conflicts when applications for grants and loans are submitted to the agency. CIRM staff involved in the review process, GWG scientific reviewers, and GWG patient advocates are provided with a personal login and password to the CIRM Grants Management Portal web site to complete their conflict of interest review. The names of institutional applicants, key personnel, and consultants associated with an application are provided to GWG participants, who review the comprehensive list and declare their conflicts before participating in a review. GWG scientific reviewers must also complete and submit a financial disclosure form that is examined for any possible conflicts of interest. Staff members and Board members who participate in the Grants Working Group disclose their financial interests on Form 700.

GWG scientific reviewers and GWG patient advocates who are in conflict with an application cannot view the application or be assigned as a reviewer of the application, and they are recused from discussing, scoring, and voting on the application. In addition, they are required to leave the room when an application in which they have a conflict of interest is discussed. CIRM staff in conflict with an application are recused from pre-award activities in connection with that application, and along with members who have a conflict of interest, they must leave the room during GWG discussion of the application.

³ The Controller recommended that CIRM require the external scientific specialists with whom CIRM consults regarding applications to file post-review certifications attesting to their lack of conflicts, a practice that CIRM has implemented.



At the end of each meeting, members of the GWG must certify, under penalty of perjury, that the member has not participated in the review of an application in which the member has a financial, professional, or personal conflict of interest.

The Board has also established an extensive process to avoid conflicts. In advance of each meeting at which the Board will be considering applications for funding, CIRM staff provides each Board member with a list of all applicant institutions, principal investigators, and collaborating organizations and investigators (all without reference to application numbers) that would receive funding pursuant to the application. Along with this list, counsel provides a memorandum to the members describing the Board's conflict of interest rules and state conflict of interest laws and asking members to identify those institutions and investigators in which the member has a financial interest. Board members then submit a certified list identifying their conflicts to CIRM staff prior to the scheduled meeting. CIRM staff members also review each Board member's Statement of Economic Interests (Form 700) to screen for additional conflicts that a member may have overlooked. With this information in hand, staff compiles: (1) a master list identifying by application those members who have a financial interest in the application, and (2) a list for each member identifying the member's conflicts by application number. Each member receives a copy of his/her conflict list prior to the meeting.

At the Board meeting, the Board considers the rankings and recommendations of the Grants Working Group in three categories: (1) recommended for funding (Tier 1); (2) recommended for funding if funds are available (Tier 2); and (3) not recommended for funding (Tier 3). The Board can and has funded and denied the funding of grants from all three categories; by utilizing the combined expertise of all 29 members, the Board – at times – perceives opportunities or obstacles to specific grants, that the members of the peer review committee may not have fully appreciated. Applications are presented by application number, without reference to the name of the applicant institution or the principal investigator. Thus, Board members generally do not know the source of the application when they vote.

Generally, the Board first considers motions to move individual applications from one tier to another (e.g., from Tier 3 to Tier 1). Before a particular application is discussed, the Chair of the Board asks counsel to screen for members who are ineligible to participate in the discussion. Counsel reminds members to consult their conflict list before participating in the Board's discussion of a particular application. Staff members then monitor the discussion and the vote to ensure that disqualified Board members abstain, and when a roll call vote is taken on a specific application, conflicted Board members are not called.



The number of potential conflicts for each Request for Applications is often very large. In recent grant cycles, Board members, staff, and scientific reviewers have each had to evaluate over 200 potential conflicts. Such conflicts can exist at the institutional level (for example, the home university of an award applicant) and the individual level (for example, the Principal Investigator on an application). Generation of this list of potential conflicts has been a major focus of the IT spending for our grants management system. Today, the list of these potential conflicts is automatically generated, although each Board member, staff member, and scientific reviewer must review the entire list.

CIRM applies the same rigorous conflict of interest standards to the individuals whom CIRM asks to assist the agency in evaluating the scientific progress of its grantees and loan recipients. Thus, individuals who participate on CIRM's clinical and development advisory panel are subject to the same disqualification requirements as members of the GWG. To the extent that CIRM relies on other experts to provide guidance regarding its grants and loans, it will apply the same standards to ensure the integrity of its decisions.

Conclusion

Nothing, including these stringent rules and procedures, can completely eliminate the possibility of an unintended conflict of interest, but they represent CIRM's best efforts to ensure that decisions are made solely on the merits of an application and to eliminate even the appearance of impropriety.