

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE (CIRM)

Review Report

REVIEW OF CONFLICT-OF-INTEREST POLICIES, GRANT ADMINISTRATION, ADMINISTRATIVE EXPENSES, AND EXPENDITURES

July 1, 2006, through December 31, 2007



JOHN CHIANG
California State Controller

May 2008



JOHN CHIANG
California State Controller

May 1, 2008

Alan O. Trounson, Ph.D., President
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107

Dear Dr. Trounson:

The State Controller's Office completed a review of the California Institute for Regenerative Medicine (CIRM) for the period of July 1, 2006, through December 31, 2007. The objectives of our review were to determine whether CIRM complied with the requirements of Proposition 71, the voter-approved initiative that created CIRM, as it relates to CIRM's conflict-of-interest policies, grant administration, administrative expenses, and expenditures.

Except for the issue concerning specialists' failure to sign post-review conflict-of-interest certification forms, we found that CIRM's conflict-of-interest policies and procedures are adequate, and that they were properly followed.

A draft report was issued on April 1, 2008. Your response to the draft report is included in our final report.

If you have any questions, please contact Casandra Moore-Hudnall, Chief, Financial Audits Bureau, at (916) 322-4846.

Sincerely,

Original signed by

JEFFREY V. BROWNFIELD
Chief, Division of Audits

JVB/sk

cc:

Independent Citizen's Oversight Committee
California Institute for Regenerative Medicine
Financial Accountability Oversight Committee
California Institute for Regenerative Medicine

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Review Report

Results in Brief

Specialists failed to sign post-review conflict-of-interest certification forms.

In our review of the California Institute of Regenerative Medicine's conflict-of-interest processes, we noted that, although the specialists working with the grants working group signed pre-review conflict-of-interest statements and confidential financial disclosure forms, they did not sign post-review certification forms regarding conflicts-of-interest, confidentiality, and non-disclosure of information as required. The specialists participate in meetings via teleconference to provide their scientific expertise on specific items; however, they do not have voting privileges and they are not counted towards a quorum.

Recommendation: We recommend that the specialists also sign a post-review certification form regarding conflicts of interest, confidentiality, and non-disclosure of information for each meeting in which they participate.

Summary

This report presents the results of the State Controller's Office (SCO) review of the California Institute for Regenerative Medicine (CIRM) for the period of July 1, 2006, through December 31, 2007. The objectives of our review were to determine whether CIRM complied with the requirements of Proposition 71, the voter-approved initiative that created CIRM, relative to CIRM's conflict-of-interest policies, grant administration, administrative expenses, and expenditures.

Our review found that CIRM has extensive conflict-of-interest policies and processes that are modeled after and, in some instances, go beyond National Institute of Health requirements. Our conclusion is consistent with the Bureau of State Audits in its audit report of CIRM issued in February 2007. Our review also found that CIRM and its associated committees and working groups adhered to these policies and processes. The specialists used by the grants working group signed pre-review conflict-of-interest statements and confidential financial disclosure forms. However, contrary to CIRM's policy, the specialists used by the grants working group do not sign post-review certification forms regarding conflicts of interest, confidentiality and non-disclosure of information. CIRM uses specialists when specific scientific expertise is needed in evaluating a grant application. The specialists review and participate in discussion on applications but do not have voting privileges; their presence is not counted towards a quorum. The specialists participate in these meetings via teleconference to provide their scientific expertise on specific grants of research fields.

Exhibit 1 provides a detailed description of CIRM's policies and procedures relative to conflicts of interest and the audit procedures that we performed to determine compliance.

We found that CIRM has developed its grants administration policies based on Proposition 71 requirements and industry best practices. Our review disclosed that CIRM is administering its grants in compliance with Proposition 71 requirements and CIRM's policies and procedures. Exhibit 2 provides a detailed description of CIRM's policies and procedures governing grant administration and the audit procedures that we performed to determine compliance.

We also found that CIRM has administrative processes and procedures in place to ensure that its administrative expenses are properly approved, authorized, and in compliance with Proposition 71 requirements. CIRM expenditures also receive additional state oversight, as they are reviewed by the SCO Departmental Accounting Office and the SCO Claims Audit Unit before payments are made.

Our review disclosed that CIRM's expenditures are in compliance with Proposition 71 requirements and CIRM's policies and procedures. Exhibit 3 provides a detailed description of CIRM's policies and procedures governing administrative expense, as well as the audit procedures that we performed to determine compliance.

Introduction

On November 27, 2007, the State Controller directed his office to conduct a review of CIRM in order to determine how grants are allocated and whether CIRM provides adequate oversight once the grants are awarded. In addition, the Controller requested that we review CIRM's expenditure practices, its conflicts of interest standards, and its compliance with State law. Pursuant to Government Code section 12410, the State Controller is to "superintend the fiscal concerns of the state. The Controller shall audit all claims against the state, and may audit the disbursement of any state money, for correctness, legality, and for sufficient provisions of law for payment."

In addition, under Proposition 71, the State Controller appoints members to the Independent Citizen's Oversight Committee (ICOC), which oversees CIRM, and chairs CIRM's Citizen's Financial Accountability and Oversight Committee (CFAOC). CFAOC reviews the annual financial audit, the State Controller's report and evaluation of the audit, and the financial practices of CIRM.

Background

The CIRM is a California state agency formed pursuant to the provisions of Proposition 71, the California Stem Cell Research and Cures Act, approved by voters in November 2004. Although CIRM is a state agency, Proposition 71 allowed it to adopt travel and procurement policies based on University of California policies, which are more liberal than other California state agency travel and procurement policies. Proposition 71 also authorized the issuance of \$3 billion in bonds over ten years to provide funding for stem cell research.

The purpose of the legislation was the formation of an institute to:

- Make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and/or medical procedures that will result in, as speedily as possible, the diagnosis, treatment, and cure for, and/or substantial mitigation of, major diseases, injuries, and orphan diseases.
- Support all stages of the process of developing treatments and cures, from basic research and discovery through preclinical and translational research to the conduct of successful clinical trials.
- Establish the appropriate regulatory standards and oversight bodies for research and facilities development.

Independent Citizen's Oversight Committee

Proposition 71 required the creation of the Independent Citizen's Oversight Committee (ICOC) that governs CIRM and has full power, authority, and jurisdiction over the CIRM. The ICOC has 29 members who are appointed in accordance with specific parameters set forth in Health and Safety Code section 125290.20. The 29 ICOC members elect a chairperson and vice chairperson, who serve six-year terms and meet certain criteria also specified in the code.

The ICOC is required to perform the following functions as they relate to our audit of CIRM:

- Oversee CIRM's operations.
- Develop annual long-term strategic research and financial plans for CIRM.
- Make financial decisions on research standards and grant awards in California.
- Ensure completion of an annual financial audit of CIRM's operations.
- Establish policies regarding intellectual property rights arising from research funded by CIRM.
- Establish rules and guidelines for the operation of the ICOC and its working groups.
- Adopt, amend, and rescind rules and regulations to carry out the purposes and provisions of Health and Safety Code section 125290.20 and to govern the procedures of the ICOC.

Scientific and Medical Working Groups

CIRM is also required to establish three separate scientific and medical working groups as follows: Scientific and Medical Accountability Standards Working Group, Scientific and Medical Research Funding Working Group, and Scientific and Medical Research Facilities Working Group.

Appointments of scientific and medical working group members are made by a majority vote of a quorum of the ICOC. The working group members may serve a maximum of two consecutive terms; working group members' terms are limited to six years. Each working group's recommendations may be forwarded to the ICOC only by a majority vote of a quorum of the members of each working group. If 35% of the members of any working group join in a minority position, a minority report may be submitted to the ICOC.

The primary functions of the scientific and medical working groups are described below:

Scientific and Medical Accountability Standards Working Group

- Makes recommendations to the ICOC regarding:
 - Scientific, medical, and ethical standards.
 - Standards for all medical, socioeconomic, and financial aspects of clinical trials and therapy delivery to patients including, among others, standards for safe and ethical procedures for obtaining materials and cells for research and clinical efforts for the appropriate treatment of human subjects in medical research and to ensure compliance with patient privacy laws.
 - Oversight of funded research to ensure compliance with the above standards.
- Provides advice to the ICOC, the Scientific and Medical Research Funding Working Group, and the Scientific and Medical Research Facilities Working Group, on an ongoing basis, on relevant ethical and regulatory issues.

Scientific and Medical Research Funding Working Group (also referred to by CIRM as the Grants Working Group)

- Makes recommendations to the ICOC regarding:
 - Interim and final criteria, standards, and requirements for considering funding applications and for awarding research grants and loans.
 - Standards for the scientific and medical oversight of awards.
 - Any needed modifications of criteria, standards, and requirements described above.
- Reviews grant and loan applications based on the criteria, requirements, and standards adopted by the ICOC, and makes recommendations to the ICOC for awards regarding research, therapy, development, and clinical trial grants and loans.

- Conducts peer group progress oversight reviews of grantees to ensure their compliance with the terms of the award, and reports to the ICOC any recommendations for subsequent action.
- Recommends to the ICOC standards for the evaluation of grantees to ensure that they comply with all applicable requirements. Such standards mandate periodic reporting by grantees and authorize the Scientific and Medical Research Funding Working Group to audit a grantee and forward any recommendations for action to the ICOC.

Scientific and Medical Facilities Working Group

- Makes recommendations to the ICOC on interim and final criteria, requirements, and standards for applications for, and the awarding of, grants and loans for buildings, building leases, and capital equipment. Those standards and requirements include:
 - Facility milestones and timetables for achieving such milestones.
 - Priority for applications that provide for facilities available no more than two years after the grant award.
 - All funded facilities and equipment are to be located solely in California.
 - Grantees are to be not-for-profit entities.
 - Awards are made on a competitive basis, requiring the grantee secure matching funds from sources other than CIRM equal to at least 20% of the award and that capital equipment costs/loans be allocated when equipment costs can be recovered in part by the grantee or other users of the equipment. The matching fund requirement can be waived by the Working Group in extraordinary cases of high merit or urgency.
- Makes recommendations to the ICOC on oversight procedures to ensure grantees' compliance with the terms of the award.

Proposition 71 required that a Citizen's Financial Accountability Oversight Committee (CFAOC) be created and chaired by the State Controller. This committee reviews the annual financial audit, the State Controller's report and evaluation of the audit, and the financial practices of the Institute.

The CFAOC consists of public members appointed by the State Controller, the State Treasurer, the President pro Tempore of the Senate, the Speaker of the Assembly, and the ICOC chairperson. Committee members must have medical backgrounds and knowledge of relevant financial matters and provide recommendations on CIRM's financial practices and performance.

Exhibit 4 provides a detailed description of the composition of the working group members.

Objectives, Scope, and Methodology

Our review encompassed the period from July 1, 2006, through December 31, 2007, and was performed in accordance with auditing standards generally accepted in the United States of America, and *Government Auditing Standards* issued by the Comptroller General of the United States.

Through interagency agreements, the SCO has provided non-audit services to CIRM since its inception. The SCO's Departmental Accounting Office and Human Resources Office provide accounting and payroll services to CIRM. In addition, beginning January 1, 2008, the SCO's Departmental Accounting Officer was appointed as CIRM's acting Finance Officer. The appointment was made outside the time period of the scope of this audit. In accordance with generally accepted government auditing standards, the performance of the aforementioned non-audit services and the appointment of the acting Finance Officer do not impair our independence with respect to our review of conflict of interest and grant administration. As an organization, the SCO is not considered independent with respect to expenditure testing because the accounting services provided by the SCO to CIRM included preparing and processing of claims for payment.

Under California's Constitution and statutes, the State Controller is responsible for ensuring the legality and propriety of state disbursements. Consistent with this responsibility, the SCO performs pre-payment audits and, when deemed necessary, post-payment field audits of claims filed against the State Treasury. The expenditure testing in this review was performed pursuant to the State Controller's constitutional and statutory audit authority and responsibility. Within the SCO, the Division of Audits is functionally independent from the units that performed non-audit services to CIRM.

We did not review expenditures for the period of July 1, 2006, through June 30, 2007, because these expenditures were reviewed by an independent auditor as part of CIRM's annual financial audit. Consistent with the State Controller's responsibility under Proposition 71, the SCO reviews the report and working papers of the independent auditor and reports the results of the evaluation to the Citizen's Financial Accountability Oversight Committee. This report was issued on March 14, 2008.

We limited our scope to planning and performing review procedures necessary to obtain reasonable assurance that CIRM complied with the requirements of Proposition 71 relative to its conflict-of-interest policies, grant administration, and administrative expenses and expenditures. We limited our review of CIRM's internal controls to gaining an understanding of the transaction flows and processes necessary to develop appropriate procedures. Government auditing standards require that we plan and perform our review to obtain sufficient, appropriate evidence to provide a reasonable basis for our finding and conclusions based on our review objectives. We believe that the evidence obtained during our review provides a reasonable basis for our finding and conclusions based on our review objectives.

Prior to the commencement of our review, a situation surfaced that raised questions concerning a possible conflict of interest involving members of the Independent Citizen's Oversight Committee (ICOC). The State Controller referred the matter to the Fair Political Practices Commission (FPPC) for investigation on November 27, 2007. The FPPC investigatory procedures may disclose additional issues, facts, and circumstances beyond the matters noted in our review, as our review was not an investigation.

Our review objectives were to:

- Determine the adequacy of CIRM's policies and procedures for grants administration.
- Determine compliance with conflict-of-interest rules and best practices.
- Determine compliance with Proposition 71 requirements related to grants administration.
- Determine the adequacy of the mandated grantee reporting requirements.
- Determine whether CIRM's administrative expenses are in line with Proposition 71 requirements.
- Determine whether CIRM's expenditures were properly approved and authorized.

To accomplish our review objectives, we performed the following procedures:

- Reviewed pertinent laws and regulations, including all documents related to the Proposition 71 initiative.
- Reviewed CIRM's written policies and procedures documents, including: Grants Administration Policies, Conflict of Interest Policies, Expenditure and Travel Policies, Internal Governance Policy, and Hiring Procedures.
- Reviewed the previous audit report, issued in February 2007 by the Bureau of State Audits (BSA), as well as the status of CIRM's corrective actions to determine the scope and findings and to build upon the work the BSA performed. Refer to Exhibit 5 for CIRM's corrective actions in response to the BSA audit.
- Interviewed key personnel to gain an understanding of CIRM's procedures, processes, and control structures related to expenditures, grant administration, and hiring.
- Sampled, on a limited basis, CIRM's expenditures and grant awards to determine whether payments and grants were awarded in accordance with applicable laws, regulations, and policies.

- Reviewed meeting files for the Scientific and Medical Research Facilities (Grants Working Group [GWG]) and ICOC to evaluate the effectiveness of controls over conflicts of interest and to determine whether CIRM's processes were effective.

Conclusion

Except for the issue concerning specialists' failure to sign post-review conflict-of-interest certification forms, we found that CIRM's conflict-of-interest policies and procedures are adequate and that they were properly followed.

We reviewed 49 grants, totaling \$74.26 million, of 159 grants totaling \$233.6 million. Our review covered approximately 31% of grants awarded. We did not note any exceptions in our testing. Schedule 1 provides a summary of the grants tested.

For the period of July 1, 2007, through December 31, 2007, we reviewed 25 expenditures totaling \$27.23 million, of a total of \$44.04 million; our review covers approximately 62% of expenditures. We did not note any exceptions in our testing. Schedule 2 provides a summary of the expenditures tested.

Views of Responsible Officials

We discussed our audit results with CIRM's representatives and issued a draft audit report during an exit conference conducted on April 1, 2008. Tamar Pachter, General Council; Robert Klein, Chairman, Independent Citizen's Oversight Committee; and other CIRM representatives agreed with the audit results. Alan O. Trounson, Ph.D., President of CIRM, responded by letter dated April 14, 2008 (Attachment), agreeing with the audit results. This final audit report includes CIRM's response.

Restricted Use

This report is intended for the information and use of the California Institute for Regenerative Medicine, its governing board, and the SCO; it is not intended to be and should not be used by anyone other than these specified parties. This restriction is not intended to limit distribution of the final report, which is a matter of public record.

Original signed by

JEFFREY V. BROWNFIELD, CPA
Chief, Division of Audits

May 1, 2008

Finding and Recommendation

**FINDING—
Specialists failed to
sign post-review
conflict-of-interest
certification forms**

In our review of CIRM's conflict-of-interest processes, we noted that, although the specialists working with the Grants Working Group signed pre-review conflict-of-interest statements and confidential financial disclosure forms, they did not sign post-review certification forms regarding conflicts of interest, confidentiality, and non-disclosure of information as required. CIRM uses specialists when specific scientific expertise is needed in evaluating a grant application. In our discussion with CIRM staff, they explained that although CIRM's policy states that the post-review certification must be signed, they did not have the specialists sign the forms because the specialists participated in the meetings via teleconference and thus were not physically present to sign the form. Even though the specialists are not physically present, because they do participate in the meeting, they should sign the post-review meeting certifications and either e-mail, fax, or mail the certifications to CIRM.

Recommendation

In accordance with CIRM's Grants Working Group conflict-of-interest policy and processes, we recommend that the specialists also sign a post-review certification form regarding conflicts of interest, confidentiality, and non-disclosure of information for each meeting in which they participate.

CIRM's Response

CIRM agrees with the recommendation and implemented it beginning with the most recent meeting of the Grants Working Group on April 9-11, 2008.

Exhibit 1— Conflict of Interest Review July 1, 2006, through December 31, 2007

CIRM's Policy

CIRM has adopted a conflict-of-interest code as required by the Political Reform Act. Additionally, CIRM has adopted a conflict of interest (COI) policy for its ICOC members, CIRM employees, and three working groups (Grants Working Group, Facilities Working Group, and Standards Working Group).

CIRM's COI code for ICOC members is consistent with the Political Reform Act. CIRM's COI policy for members of the Grants Review Working Group and Facilities Working Group is closely modeled on the policies of the National Institute of Health. The working group members are required to disclose any financial, personal, or professional COI. 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.

The Bureau of State Audits (BSA) conducted an audit of CIRM, including its COI code and policies, and published its audit report in February 2007. To accomplish our audit objective, we reviewed the BSA's audit report and recommendations to CIRM for corrective actions regarding CIRM's COI policies, as well as CIRM's corrective actions.

We found that CIRM incorporated the BSA's recommendations in its revised COI policies.

The BSA audit noted that the ICOC COI policy restates stipulations of the Political Reform Act and further limits its members' decision-making opportunities. An example noted in the report is that according to CIRM's policy, committee members cannot receive gifts from entities doing, or seeking to do, business with CIRM if it could reasonably be substantiated that the gift was intended to influence a future official action or reward a past one. In comparison, the report notes that the Political Reform Act permits state officials to receive annually up to \$360 of gifts from a single source for a two-year period.

The BSA audit also noted that the COI policies of the Grants Review and Facilities Working Groups are modeled on the NIH policy but are at times stricter than NIH policy. An example noted in the report is that the NIH considers a reviewer to have a conflict of interest if the reviewer received or could receive from the applicant institution a financial benefit exceeding \$10,000 per year. In comparison, CIRM sets the limit at \$5,000.

Scientific and Medical Research Funding Working Group/Grants Working Group (GWG)

CIRM staff generates a list of all applicant institutions and key personnel from all of the applications submitted for a particular request for application (RFA). That list is made available to all GWG members online. Members must review the list, identify any institution or key personnel with which they have a COI, and sign off on the result. Each member must complete this process before he or she is given access to any application. Once completed, reviewers are given access only to those applications with which they have no COI. In addition, each GWG member must sign a pre-review certification form that identifies all applications with which the reviewer has a COI. These COI forms are compiled and kept in the working group meeting files.

Exhibit 1 (continued)

CIRM staff generates a Conflict of Interest Tracking Form that shows a grid of each application and each member and highlights any COI. This tracking form is used during the working group meetings to record that members left the meeting when applicants with which they had a conflict of interest were discussed. The tracking form with the notations becomes part of the permanent file for each RFA review meeting.

At the beginning of each GWG review meeting, CIRM provides an overview reminder of the COI policy and the objectives of the RFA. Because the meetings are “closed,” individuals who have a COI with a particular application must leave the room during discussion of that application.

CIRM staff members maintain a meeting file/binder that has the “sign in” sheet for the meeting as well as the “sign out” sheet. The sign out sheet also serves as a certification form for non-disclosure of information and confidentiality. The COI certificate form (for all participants in the meeting) and the financial disclosure form (for the GWG members) are also maintained in the meeting file.

SCO Review Procedures and Results

To test for compliance with CIRM’s conflict-of-interest policy and reliability of the summary COI Tracking form for the GWG, we:

- Selected a meeting file for the GWG.
- Verified that the file contained, for each member attending the meeting, signed conflict-of-interest statements; confidential financial disclosure forms; funding recommendation letters; and post-review certification forms regarding conflicts of interest, confidentiality, and non-disclosure of information.
- Verified that that file contained a COI Tracking Form.
- Traced information from each members’ detailed COI statement, funding recommendation letters, and post-review certification forms to the COI Tracking Form.

Based on the results of our testing, we determined that CIRM is following its COI policies and procedures, with the exception of the post-review certification related to specialists. We also determined that the Conflict of Interest Tracking Form was complete and, thus, the form’s information could be relied upon during our testing of grants administration.

The GWG uses specialists in reviewing grant applications. Specialists are used if the GWG needs scientific expertise on a particular issue. The specialists review and participate in discussions on applications but do not have voting privileges; their presence is not counted towards a quorum. The specialists participate in these meetings via teleconference to provide their scientific expertise on specific grants or research fields.

We noted in our testing that, although the specialists signed pre-review conflict of interest statements and confidential financial disclosure forms, they did not sign post-review certification forms regarding conflicts of interest, confidentiality, and non-disclosure of information as required. In accordance with CIRM’s grants working group COI policy, the specialists should also sign a post-review certifications for each meeting in which they participate. Therefore, we recommend that CIRM require specialists to sign a post-review certification form regarding conflicts of interest, confidentiality, and non-disclosure of information for reviewers of grant applications.

Exhibit 1 (continued)

Independent Citizen's Oversight Committee

CIRM's Policy

In advance of an ICOC meeting, all ICOC members must review the online list of applicant institutions and key personnel to identify any conflicts of interest and must sign off on their review. CIRM's legal office also reviews the members' form 700¹ and disclosures to make sure there is no conflict of interest. CIRM staff compiles these lists and generates for each ICOC member a list that shows which applications for which members have a COI. Because the ICOC meeting is a public meeting, the members are not required to leave the meeting when the applications for which they have a COI are discussed, but they are prohibited from commenting or voting on those applications. CIRM staff members also prepare a listing by application that shows all ICOC members with COIs who are disqualified from participating. Throughout the meeting, CIRM staff members monitor this list, as well as the discussion, motions, and voting, to ensure that all members adhere to CIRM's COI policies.

SCO Review Procedures and Results

To test for compliance with CIRM's conflict-of-interest policy, and to test the reliability of the ICOC summary COI form, we:

- Selected an ICOC meeting file.
- Verified that the file contained, for each member attending the meeting, conflict-of-interest forms for each ICOC member, individual conflict-of-interest recusal forms, and a copy of a signed certification of ICOC conflict-of-interest recusal form.
- Verified that that file contained a summary COI form.
- Traced information from each member's detailed COI statement and post-review certification forms to members' recusal form and to the summary COI form.

We noted that for the ICOC members and CIRM staff, the COI forms were complete and were supported with collaborating original documentation from each person. Based on the results of our testing, we determined that CIRM is following its COI policies and procedures. We also determined that the summary COI form was complete and, thus, the form's information could be relied upon during our testing of grants administration.

¹ Form 700 is the Fair Political Practices Commission's "Statement of Economic Interests" form.

Exhibit 2— Grants Administration Review July 1, 2006, through December 31, 2007

The objective of our review was to determine the adequacy of CIRM's policies and procedures for grants administration, compliance with Proposition 71 requirements related to grants administration, compliance with conflict-of-interest policies, and adequacy of grantee reporting requirements.

CIRM's Policy

Proposition 71 grants administration requirements include the following:

- The ICOC shall:
 - Make final decisions on research standards and grant awards.
 - Award all grants, loans, and contracts in public meetings.
- The Scientific and Medical Research Funding Working Group shall:
 - Review grant and loan applications based on the criteria, requirements, and standards adopted by the ICOC, and make recommendations to the ICOC for awards regarding research, therapy, development, and clinical trial grants and loans.
 - Recommend to the ICOC standards for the evaluation of grantees to ensure that they comply with all applicable requirements. Such standards shall mandate periodic reporting by grantees and shall authorize the Scientific and Medical Research Funding Working Group to audit a grantee and forward any recommendations for action to the ICOC.
 - Base award recommendations upon competitive evaluations. Only the 15 scientist members of the Scientific and Medical Research Funding Working Group shall score grant and loan award applications for scientific merit. The scoring shall be based upon scientific merit in three separate classifications: research, therapy development, and clinical trials and criteria.

The CIRM grants administration process consists of the following six processes:

1. Pre-Review

- CIRM scientific staff members develop a concept for a grant, based on the initiatives in CIRM's strategic plan. The concept describes the proposed Request for Application (RFA), including a description of the objective, high-level eligibility requirements, and the pool of money required for the concept.
- CIRM staff present the written concept to the ICOC for approval. The ICOC discusses the concept and votes to approve or deny the concept.
- If the ICOC approves the concept, CIRM scientific staff members develop the RFA. The RFA is an official solicitation by CIRM for applications directed to a particular funding opportunity. Each RFA specifies the objectives and requirements that apply, eligible costs, and the review criteria that will be used to evaluate the merits of applications submitted in response to the RFA.

Exhibit 2 (continued)

2. Review by Grants Working Group (GWG)

- The GWG completes its Conflict of Interest (COI) process for the application review.
- Each application submitted in response to the RFA is reviewed by two to three reviewers.
- Reviewers submit via secure intranet written critiques of each application to CIRM for all GWG members to review. The reviewers comment on the overall scientific merit of the application and the specific review criteria for the RFA. The comments may address the feasibility of the proposal and whether or not it meets the objectives of the strategic plan.
- The GWG has a review meeting to discuss the applications. The GWG review meeting comprises two parts – a scientific review and a programmatic review.
 - During the scientific review, the GWG members discuss the merits of each application and score the applications on a scale from 1 to 100. Members who have a conflict of interest with an application under consideration during scientific review must leave the room during this discussion. CIRM staff members create a histogram displaying the distribution of scores for all applications (the histogram does not identify the applications by name or number; it simply shows a score for anonymity). The GWG uses the histogram to break the list of applications into three different categories. The three categories are: rank 1–recommended for funding, rank 2–recommended, if funds are available, and rank 3–not recommended for funding. CIRM staff members then create a listing of all applications by rank order showing the budget for each application.
 - During the programmatic review, the GWG members take into account programmatic issues and any other issues that are outside the pure scientific score. During this time, they will also consider how each application fits into the CIRM’s overall strategic plan. Working group members may also make a motion to move a particular application from one category to another. Members who have a conflict of interest with an application under consideration during programmatic review must leave the room during this discussion. A vote is taken on the motion, and if it carries, the application is moved pursuant to the vote from one category to another, although the scientific score remains the same. When there are no more motions to move applications between categories, the members vote to make their recommendations to the ICOC by category: recommended for funding; recommended if funds are available; and not recommended for funding. CIRM staff members then create a table of applications identifying three categories of recommendation.

3. ICOC Approval

- After the GWG review meeting, the CIRM science office takes the initial critiques and notes from the meeting and creates summary reports for each application. They prepare two different types of summary reports; one is confidential and the other is non-confidential. The confidential summary is provided to the applicant so that it can understand the score that its application received. The non-confidential summary is provided to the ICOC members and is also available to the public. The summaries are posted on CIRM’s Web site prior to the ICOC meeting (“Summaries of Review for Application to RFA”). This public summary shows only the score for applications that are being recommended for funding. It also shows which GWG members had a conflict of interest, so that the public will know those members did not participate in the discussion or scoring of that particular application.

Exhibit 2 (continued)

- Prior to the ICOC meeting, the ICOC completes its COI process for the meeting.
 - At the meeting, the ICOC is presented with the table of applications identifying the three categories of recommendations and a list of the application summaries. The ICOC chairman asks whether anyone has a comment on any particular application and/or wants to move any application from one recommended category to another. During this discussion, a screen shows the ICOC the real-time funding impact of any changes. When all discussions are completed, the chairman extends a motion to approve all applications in the category “recommended to fund.” A roll call vote is taken and the members vote to either fund or not fund the entire block of applications (excluding any applications for which they have a COI).
 - When approved, the ICOC commits to funding the block of applications. CIRM then issues a press release.
4. Pre-Funding Administrative Review
- After the applications are approved by the ICOC, CIRM staff members create a grant file for the approved applications.
 - CIRM’s Grants Management Officer (GMO) and Scientific Program Officer (SPO) perform a pre-funding administrative review prior to funding an approved application. Both the GMO and SPO have a pre-funding checklist that details what they must review. Contact with the applicant and any notes regarding the pre-funding review are noted on the checklists.
5. Award Acceptance and Funding
- After the SPO and the GMO have completed and signed off on their checklists, CIRM grants management staff prepares the Notice of Grant Award (NGA). The NGA includes any special terms and/or any budget adjustments noted on the checklists.
 - The NGA is reviewed and signed off on by the CIRM’s General Counsel, Chief Operating Officer, and Chief Scientific Officer. Once these staff members have signed off on the NGA, it goes to the CIRM President for approval and signature.
 - The grants management staff then mail the NGA to the applicant/grantee. The grantee signs the NGA and returns it to CIRM. When CIRM receives the signed NGA, grants management staff members prepare a pay memo.
 - The pay memo is reviewed and signed off on by the Chief Financial Officer and the Chief Scientific Officer. Once signed/approved, the pay memo is sent to the SCO to request issuance of a warrant and release of funds to the grantee.
 - The SCO sends a warrant to the grantee. The SCO keeps the original pay memo and sends a copy of it back to CIRM with the warrant information listed on the pay memo. The pay memo is then filed in the grants file.

Exhibit 2 (continued)

6. Post-Award Follow-Up

- The grantee must provide CIRM with various progress reports after the grant has been awarded. CIRM's grant administration policy lists everything that grantees must report.
- As listed in Chapter 6 of the policy, training grant grantees must report the following:
 - Estimated Budget Overview: The grantee lists the amount of the grant award, actual expenditures and any anticipated expenditures for the next budget period, and any anticipated carry forward amounts. The grantee must explain and justify any changes or any anticipated carry forward amounts. Any changes greater than 25% require prior CIRM approval.
 - Trainee Overview and Roster: The grantee institution appoints the specific trainees that will receive the training funds. In the progress report, the institution must list the number of approved trainees, the number of trainees appointed for the budget period, the number of trainees appointed for the next budget period, and the number of new trainees expected. The institution must also list each trainee, along with the appointment start and stop dates and type as well as their mentor.
 - Training Program Overview: The grantee describes the trainee selection process, the program activities (such as any seminars or workshops), the training courses implemented, any course developments or changes, any changes in program administration and staffing, and any plans or changes for the upcoming year.
 - Trainee Appointment Form: In addition to the annual programmatic report, when the institution appoints a trainee, they complete a trainee appointment form and submit it to CIRM. These forms are kept in the grant file.
 - Trainee Progress Report: The trainee also completes a progress report form, which is submitted to CIRM. This report lists what the trainee has been doing during the reporting period, including any coursework, the trainee must also include an updated Curriculum Vitae and a list of any publications they publish using CIRM support. These items are also kept in the grant file.
 - Financial Report: Financial reports are due CIRM from the grantee 90 days after the anniversary of the grant award date. CIRM sends the grantees a progress report template to use. The annual financial report must include all actual costs incurred under the CIRM grant during the expired budget period and any carry forward amounts. The report must also include any adjustments made to the grant as a result of prior approval requests or budgetary changes. Additionally, all CIRM grantees must report on interest earned on CIRM grant funds and must use those funds in support of the CIRM grant before grant close-out.
 - Annual Progress Report Funding Checklist: A subsequent year of funding for a grant is not approved until all annual progress reports are received by CIRM. The grants management staff use an Annual Progress Report Funding Checklist to check for any scope, budget, or outcome changes. A checklist is completed and signed off on by both the Scientific Program Officer and the Grants Management Officer.

If any budgetary discrepancies or changes are noted, they are taken out of the next year's funding amount. For example, if the second year funding was originally approved at \$100,000 but the year one progress report shows a \$10,000 discrepancy, the \$10,000 will be taken out of the year two funding, making the adjusted year two funding \$90,000. Any funding adjustments are noted in the grants file.

Exhibit 2 (continued)

SCO Review Procedures and Results

We obtained a listing of all of the grants awarded by CIRM. From this list of 158 grants totaling \$233,595,002, we selected 49 grants totaling \$74,257,101 to review. The grants selected for testing covered 31% of the total number of grants and 32% of the total dollar amount of all grants.

For each grant selected, we performed the following procedures to determine whether the grant was administered in compliance with Proposition 71 and CIRM's policies and procedures.

1. Pre-Review

- Verified that the ICOC voted on and approved a grant concept.
- Reviewed the Request for Application (RFA) for each grant.

2. Review by Grants Working Group

- Verified that the application and all other documents required by the RFA were maintained by CIRM.
- Verified that the application was reviewed by two to three reviewers who do not have a conflict of interest.
- Verified that the application is in rank 1 on the listing of recommendations to the ICOC from the GWG (and Facilities Working Group, where applicable).
- Verified that any conflicts noted on the GWG COI Summary Sheet are included in the Public Application Summary written by CIRM staff, so that the public is made aware of members with conflicts of interest. Also verified that the Summary Sheet shows that members were recused when the application was discussed.

3. ICOC Approval

- Verified that the COI Summary lists members who must be and were recused during discussion and voting on given applications.
- Verified that the ICOC approved the application and the grant amount.

4. Pre-Funding Administrative Review

- Verified that the Grants Management Officer (GMO) Review checklist is completed and signed by the GMO.
- Verified that the Scientific Program Officer (SPO) Review checklist is completed and signed by the SPO.
- Verified that the GMO has explained and reconciled any differences between the ICOC approved amount and the funded amount. Funding differences are noted by the GMO in instances where the applicant included ineligible costs or used incorrect or non-approved indirect cost rates. Verified that the GMO adjusted the funding amount. Also verified that the adjusted funded amount was not greater than the ICOC approved amount (any adjustments above the ICOC-approved amount would require ICOC approval).

Exhibit 2 (continued)

5. Award Acceptance and Funding

- Reviewed terms on the Notice of Grant Award (NGA).
- Verified that the NGA is approved and signed by appropriate CIRM staff.
- Verified that the NGA is signed by grantee.
- Verified that the amount on the pay memo from CIRM to the SCO requesting payment on grant agrees to NGA and budget worksheet.
- Verified that the pay memo was approved by appropriate CIRM staff members.

6. Post-Award Follow-Up

- Verified that various progress reports due CIRM from the grantee are submitted and in the grant file.
- Verified that grants management staff complete an Annual Progress Report Funding Checklist (signed by the Scientific Program Officer and Grants Management Officer).
- Verified that any budgetary discrepancies or changes noted on the Annual Progress Report Funding Checklist are taken out of the grantee's next-year funding amount.

Based on the grants reviewed, we determined that CIRM is allocating and administering its grants in compliance with Proposition 71 and CIRM's policies and procedures.

Exhibit 3—
Administrative Expense Review
and Expenditure Testing
July 1, 2006, through December 31, 2007

The objective of our review was to determine whether CIRM's administrative expenses are in line with Proposition 71 requirements and whether CIRM expenditures were properly approved and authorized.

We designed our testing to review administrative expenses and expenditures in response to concerns brought to the SCO regarding CIRM's compliance with administrative expense limits set forth in Proposition 71, as well as concerns regarding CIRM's adherence to proper procedures, authorizations, and approval for expenditures.

Proposition 71 restricts how CIRM moneys can be spent. It limits the amount that CIRM can spend on administrative costs as follows:

- No less than 97% may be used for grants and grant oversight.
- No more than 3% may be used for general administration of the institute.
- No more than 3% may be used for research facilities implementation costs, including the development, administration, and oversight of the grant-making process and the operations of the working groups.

SCO Review procedures and results

We verified that CIRM properly categorized expenditures. SCO Departmental Accounting has a system in place to monitor expenditure categorization and to ensure that expenditure percentages are in accordance with Proposition 71 limitations.

We also obtained an expenditure summary for two time frames (July 1, 2006, through June 30, 2007) and (July 1, 2007, through December 31, 2007) and reconciled them against the detail ledger. Because the expenditures during July 1, 2006, through June 30, 2007, were reviewed during CIRM's annual financial audit, we reviewed expenditures between July 1, 2007, and December 31, 2007. The annual financial audit did not disclose any findings relating to expenditure testing.

We selected 25 expenditures for testing. The selected expenditures covered 62% (\$27,230,875 out of \$44,039,447) of the total expenditures for July 1, 2007, through December 31, 2007.

We verified that each expenditure was within the allowable activities of the CIRM program by determining whether:

- Adequate documentation is maintained to support all expenditures;
- Expenditures are properly authorized and put out for bid (if applicable);
- Expenditures are related to the CIRM program and salary rates are correct; and
- Contracts and personnel records (if applicable) are maintained.

Exhibit 3 (continued)

We reviewed Proposition 71 in regards to the eligibility of expenditures for certain legal counsel. Proposition 71 states that given the scientific, medical, and technical nature of the issues facing the ICOC, CIRM is authorized to retain outside counsel when the ICOC determines that CIRM requires specialized services not provided by the Attorney General's Office. Therefore, CIRM is legally authorized to retain outside counsel when the ICOC deems it to be necessary.

We also reviewed CIRM's Internal Governance Policy to determine whether salary expenditures were allowable and within CIRM's administrative expense limits. We verified that the current organizational structure and number of employees were properly authorized by the ICOC and that CIRM is paying its employees in accordance with Proposition 71.

In accordance with the Internal Governance Policy, CIRM's president recommends to the Governance Subcommittee for its consideration organizational structure. The policy further states that the ICOC shall approve CIRM's organizational structure based on the recommendation of the Governance Subcommittee. The Subcommittee approved the current organizational chart and proposed it to the ICOC at the January 16-17, 2008, ICOC meeting. The ICOC voted on and approved the current Internal Governance Policy.

This policy provides the organization and administrative structure of CIRM. It stipulates that CIRM's staff, other than the President, shall be organized into four offices: Office of the President, Office of the Chair, Office of the Chief Scientific Officer, and Office of the Chief Operating Officer. It states that the Office of the Chair shall be limited to no more than six employees whose primary duties are to support the Chairperson and two employees whose primary duties are to support the Vice-Chairperson. The President may assign additional CIRM staff members to assist the Chairperson or Vice-Chairperson as necessary, consistent with CIRM's priorities. The Governance Subcommittee may review these staff allocations on a periodic basis and recommend any adjustments to the ICOC. The policy also sets forth how salaries will be set for all employees.

With regard to CIRM staff salary, the BSA audit noted that there were deficiencies with CIRM's initial salary survey and recommended that CIRM proceed with its plan to obtain another salary survey. In response, CIRM issued a request for proposal (RFP) to contract with an experienced firm for the review and survey of all CIRM salaries. CIRM subsequently contracted with Mercer Human Resources Consulting (Mercer). Mercer completed the survey and delivered the results to CIRM in 2007. We reviewed the Mercer survey results against CIRM's current salary ranges and determined that CIRM's salary ranges are within or below the Mercer results. Based on our review, CIRM's salary ranges are in accordance with Proposition 71.

Proposition 71 states that the ICOC shall, from time to time, determine the total number of authorized employees for CIRM, up to a maximum of 50 employees—excluding members of the working groups—who shall not be considered institute employees. In our review, we noted that CIRM is operating within its 50-employee limitation and also within its administrative costs restrictions.

Exhibit 4— Composition of Scientific and Medical Working Groups July 1, 2006, through December 31, 2007

Appointments of scientific and medical working group members are made by a majority vote of a quorum of the ICOC. The working group members may serve a maximum of two consecutive terms; working group members' terms are limited to six years. Each working group's recommendations may be forwarded to the ICOC only by a majority vote of a quorum of the members of each working group. If 35% of the members of any working group join in a minority position, a minority report may be submitted to the ICOC.

The Scientific and Medical Accountability Standards Working Group (SMASWG) has 19 members:

- Five ICOC members from the ten disease advocacy groups described in Health and Safety Code section 125290.20;
- Nine scientists and clinicians nationally recognized in the field of pluripotent and progenitor cell research;
- Four medical ethicists; and
- The ICOC chairperson.

The Scientific and Medical Research Funding Working Group (SMRFWG), also referred to by CIRM as the Grants Working Group (GWG), has 23 members:

- Seven ICOC members from the ten disease advocacy groups;
- Fifteen scientists nationally recognized in the field of stem cell research; and
- The ICOC chairperson.

The Scientific and Medical Facilities Working Group (SMFWG) has eleven members:

- Six members of the Scientific and Medical Research Funding Working Group;
- Four real estate specialists who must be residents of California, are prohibited from receiving compensation from any construction or development entity providing services to the research facilities, cannot provide brokerage services to any research facility applicant, and shall not receive compensation from any grant recipient awarded by CIRM; and
- The ICOC chairperson.

**Exhibit 5—
CIRM’s Corrective Actions for
Bureau of State Audits’ Findings²
July 1, 2006, through December 31, 2007**

Bureau of State Audits’ Recommendation	CIRM’s Corrective Action Noted During SCO’s Review
CIRM should complete the development of its grants administration policy targeted toward for-profit organizations.	At its December 12, 2007, meeting, the ICOC approved the Interim CIRM Grants Administration Policy for For-Profit Organizations to go forward to the Office of Administrative Law (OAL). OAL’s notice of proposed regulation adoption states a deadline for submission of written comment of March 24, 2008.
To provide increased accountability over the grants award process, the institute should ensure that the grants review working group follows the new procedures to record its votes to recommend funding for stem cell research grants, and maintains those records.	CIRM is applying its new procedures. CIRM maintains records of the Grants Working Group (GWG) meeting. These records show members participating in a given meeting, the members recused from discussing or voting on applications due to conflicts of interest, and the members’ votes. Additionally, the names of the recused members are publicly disclosed on the summary review of each application, which is given to the ICOC and posted on CIRM’s Web site.
To effectively monitor the performance of the grantees, the institute should complete the implementation of a grants monitoring process, including audits, and the development of related procedures.	CIRM’s grants administration process (GAP) includes a pre-funding administrative review by both the Scientific Program Officer and the Grants Management Officer prior to issuing a Notice of Grant Award. The grant is not funded until the grantees submit all required documentation as requested by CIRM. CIRM’s current GAP requires grantees to submit various progress reports to CIRM after the grant has been awarded. For CIRM’s training grants (the only grants that have gone beyond the initial year of funding), the GAP lists, in Chapter 6, the reports that the grantee must submit (see Attachment B for more detail on required reporting and CIRM’s Post Awards Follow-up).
The institute should follow its plans to amend its conflict-of-interest policies to include any specialists it might invite to participate in stem cell research program activities, such as grant application review.	In March 2007, the ICOC adopted a conflict-of-interest policy for the Grants Working Group (GWG) that specifically includes specialists. The GWG is currently using this policy.

² We reviewed the BSA findings related to our review objectives and CIRM’s corrective actions.

Exhibit 5 (continued)

Bureau of State Audits' Recommendation	CIRM's Corrective Action Noted during SCO's Review
<p>The institute should develop the necessary procedures to ensure that its employees are aware of the companies that apply for funding to provide employees with the information they need to disclose all potential conflicts of interests.</p>	<p>CIRM's current conflict-of-interest policies and procedures include a process in which all entities that have applied for funding are identified and require CIRM employees to review a listing of the entities and to note any conflicts. Employees who identify a conflict of interest with any given application are disqualified from reviewing or participating in discussions on that application. Any employee conflicts of interest are also noted and maintained in CIRM's meeting files of the GWG meeting.</p>
<p>To ensure compliance with its conflict-of-interest policies, the institute should revise its procedure for reviewing grants to include a review of the Statements of Economic Interest for committee members of the working groups before every grants review meeting. Moreover, it should revise its procedures for grants review meetings to ensure that it retains documentation regarding conflicts of interest of the working groups, including information that it took appropriate recusal actions.</p>	<p>CIRM's current procedures to identify conflicts of interest of members of the Grants Working Group include a staff review of conflict-of-interest disclosures prior to each grant review meeting. In addition, CIRM now documents the recusal actions of each member (including any specialists) with respect to each application reviewed to ensure that no one participating in the review of a particular application has a conflict of interest. CIRM maintains these records.</p>
<p>The committee should adopt a travel reimbursement policy for its members that will result in the reimbursement of reasonable and necessary expenses, as stated in the act, and that address the concerns we raised in the report.</p>	<p>The ICOC approved CIRM's Policy Governing Travel. This policy applies to all official CIRM travel and was adopted on January 18, 2008. This policy can be found on CIRM's Web site.</p>
<p>To ensure that the methodology to set their salary ranges complies with the act, the institute should follow through with its plan to resurvey any position whose ranges were affected by the errors, omissions, and inconsistencies in its initial salary survey and salary setting activities.</p>	<p>CIRM issued a request for proposal (RFP) to contract with an experienced firm for the review and survey of all CIRM salaries and subsequently contracted with Mercer Human Resources Consulting (Mercer). Mercer completed the survey and delivered the results to CIRM in 2007.</p>

Schedule 1— Grants Selected for Review July 1, 2006, through December 31, 2007

Grant Number	Institution	Grant Amount
T1-00001	Stanford University	\$ 3,708,301
T1-00005	University of California, Los Angeles	3,695,407
T2-00006	California Institute of Technology	2,071,823
T2-00001	Scripps Research Institute	1,051,380
T3-00006	University of California, Santa Cruz	1,132,201
RS1-00163-1	Buck Institute for Age Research	728,950
RS1-00169-1	Human BioMolecular Research Institute	596,910
RS1-00174-1	The Salk Institute for Biological Studies	760,042
RS1-00183-1	Stanford University	629,952
RS1-00200-1	Burnham Institute for Medical Research	708,000
RS1-00210-1	The J. David Gladstone Institutes	725,132
RS1-00239-1	University of California, Merced	350,797
RS1-00249-1	Children's Hospital of Los Angeles	633,120
RS1-00262-1	University of Southern California	632,407
RS-100288-1	The Salk Institute for Biological Studies	770,400
RS1-00292-1	Ludwig Institute for Cancer Research	691,489
RS1-00295-1	University of California, Berkeley	477,894
RS1-00302-1	Scripps Research Institute	784,900
RS1-00317-1	The J. David Gladstone Institutes	721,163
RS1-00323-1	Stanford University	629,952
RS1-00331-1	Burnham Institute for Medical Research	708,000
RS1-00381-1	University of California, San Francisco	240,214
RS1-00409-1	University of California, Irvine	368,081
RS1-00420-1	University of California, Los Angeles	550,241
RS1-00428-1	Beckman Research Institute of the City of Hope National Medical Center	357,978
RS1-00452-1	University of California, San Francisco	329,245
RS1-00462-1	The J. David Gladstone Institutes	748,800
RS1-00464-1	University of California, Davis	352,944
RC1-00100-1	Stanford University	2,518,405
RC1-00108-1	Children's Hospital of Los Angeles	2,392,807
RC1-00115-1	The Salk Institute for Biological Studies	2,749,293
RC1-00116-1	University of California, San Diego	1,859,430
RC1-00123-1	CHA Regenerative Medicine Institute	2,556,066
RC1-00125-1	Burnham Institute for Medical Research	2,832,000
RC1-00133-1	Stanford University	1,710,817
RC1-00142-1	The J. David Gladstone Institutes	2,994,719
RC1-00354-1	Stanford University	2,513,953
CL1-00507-1	Children's Hospital of Los Angeles	1,983,009
CL1-00518-1	Stanford University	2,439,590
CL1-00519-1	University of California, Berkeley	1,263,431
CL1-00521-1	University of California, Santa Barbara	1,407,192
CL1-00523-1	University of California, San Francisco	2,278,648

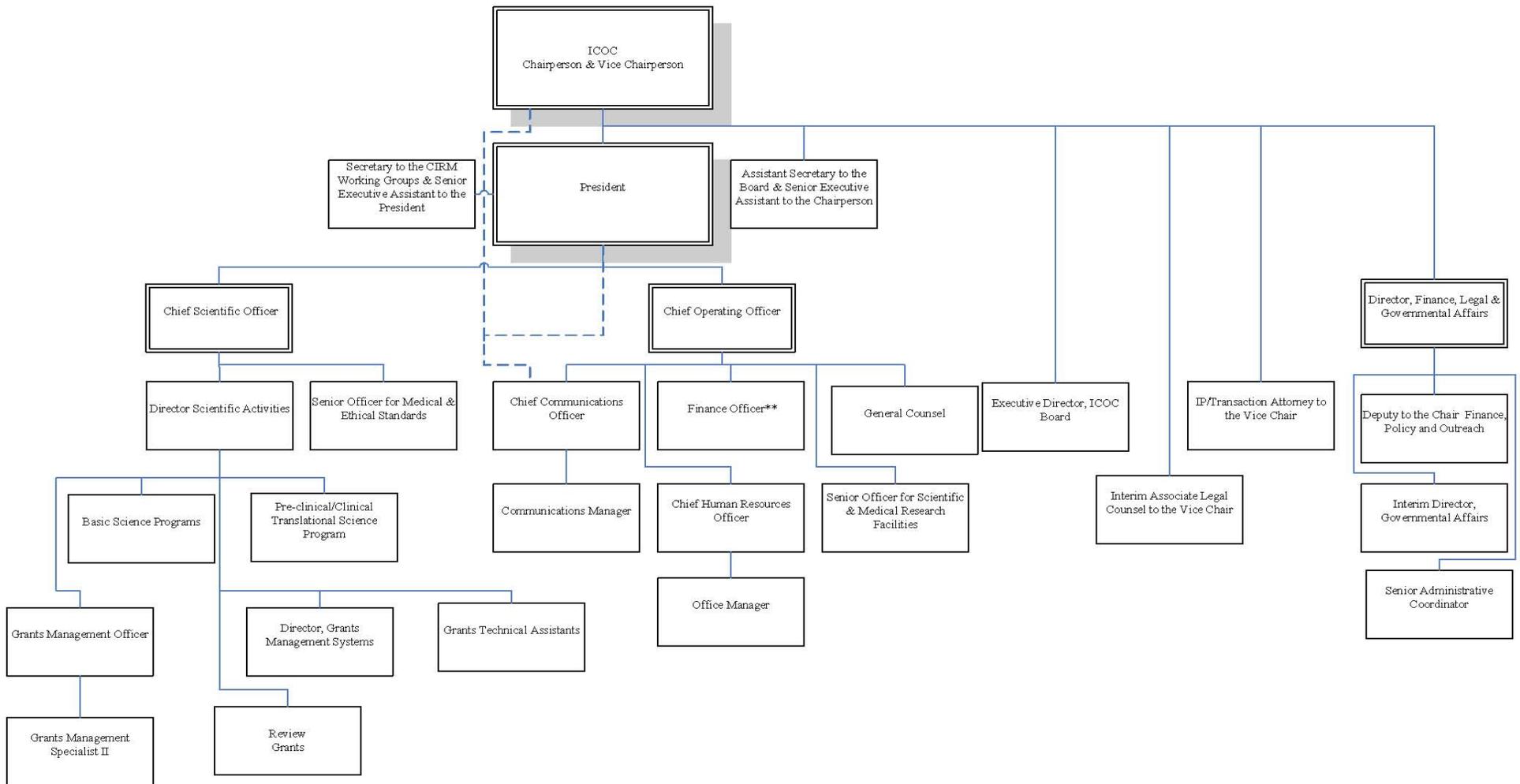
Schedule 1 (continued)

<u>Grant Number</u>	<u>Institution</u>	<u>Grant Amount</u>
RN1-00525-1	City of Hope National Medical Center	1,623,064
RN1-00529-1	Stanford University	3,028,926
RN1-00536-1	Scripps Research Institute	2,943,375
RN1-00550-1	University of California, Los Angeles	3,063,450
RN1-00554-1	University of California, Merced	1,581,056
RN1-00566-1	University of California, Irvine	2,108,683
RN1-00572-1	University of Southern California	3,253,464
Total		<u>\$ 74,257,101</u>

**Schedule 2—
Expenditures Selected for Review
July 1, 2007, through December 31, 2007**

Vendor Name	Expenditure Amount
Chief Financial Officer	\$ 107,139.90
Grants Management Specialist II	62,630.78
Chief Communications Officer	<u>55,567.00</u>
	\$ 225,337.68
Stephen P. Teale Data Center	18,160.53
Stuart Laff	2,000.00
I.M.P.A.C. Government Services	2,190.27
Nextel Communications	1,024.25
Feinstein Kean Healthcare	6,997.50
Remcho Johansen & Purcell	12,595.22
Spencer Stuart	9,257.00
CIRM Revolving Fund – Nielsen & Naylor	4,100.00
CIRM Revolving Fund – Remcho & Purcell	10,631.72
CIRM Revolving Fund – Impact Government Services	7,369.20
Research America	7,500.00
State Controller's Office	23,608.34
Remcho Johansen & Purcell	15,136.92
CIRM Revolving Fund – Nielsen & Naylor	4,100.00
Ian Duncan	1,056.00
The New England Journal	4,299.00
I.M.P.A.C. Government Services	11,683.28
CIRM Revolving Fund – Various	8,607.44
Clark Creative Group	9,500.00
Senate Rules Committee	16,861.14
Various grant awards	22,956,412.00
Burnham Institute for Medical Research	<u>3,872,448.00</u>
	<u>27,005,537.81</u>
Total expenditures tested	<u>\$ 27,230,875.49</u>
Total program expenditures	<u>\$ 44,039,447.32</u>
Percentage tested	<u><u>62%</u></u>

**Attachment A—
CIRM Organization Chart**



*Personnel in the Office of the Chair will report to the Chairperson and Vice Chairperson and through them to the President.
 **On loan from State Controller's Office.

**Attachment B—
CIRM’s Response**

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE



Writer's Direct Dial: 415/396-9104
ATrounson@cirm.ca.gov

April 14, 2008

BY USPS EXPRESS MAIL

Cassandra Moore-Hudnall
Chief, Financial Audits Bureau
Division of Audits
State Controller's Office
P.O. Box 942850
Sacramento, CA 94250-5874

Dear Ms. Moore-Hudnall:

We have carefully reviewed the draft copy of your office's audit Review Report of the California Institute for Regenerative Medicine (CIRM), entitled *Review of Conflict-of-Interest Policies, Grant Administration, Administrative Expenses, and Expenditures July 1, 2006-December 31, 2007*.

We are very pleased by the many positive findings made by the auditors, and we view the report overall as accurate and fair. We greatly appreciate the care and effort of the audit team members who conducted the audit and prepared the Review Report. Their careful examination of CIRM's policies and procedures, and documentation of our adherence to those policies and procedures in the areas of grant administration, conflicts of interest, and expenses, is very gratifying and helpful in demonstrating to Californians that we are succeeding in our efforts to be good stewards of state funds. The team's one recommendation was well-taken, and we have already taken action to address it.

As a young state agency, we are always in the process of refining key policies and procedures. The Review Report makes a useful and important contribution to our effort to operate as effectively and efficiently as possible, in full compliance with governing law. We are committed not just to our scientific mission of advancing stem cell science to therapies and cures, but also to earning the public's trust. In this regard, the Review Report has been helpful and has made us a stronger agency.

Casandra Moore-Hudnall
State Controller's Office
April 14, 2008
Page 2

We respond below to the recommendation in the Review Report.

Recommendation:

In accordance with CIRM's Grants Working Group conflict-of-interest policy and processes, we recommend that the specialists also sign a post-review certification form regarding conflicts of interest, confidentiality, and non-disclosure of information for each meeting in which they participate.

CIRM agrees with this recommendation, and implemented it beginning with the most recent meeting of the Grants Working Group on April 9-11, 2008. These completed forms will be maintained in each meeting file, along with the post-review certification forms of working group members. We note that specialists, unlike working group members, do not vote to score scientific applications, nor do they participate in the programmatic review of applications by the working group. Specialists participate by telephone in the discussion of a limited number of applications to which they bring a particular expertise. Because they do participate in the discussion of the scientific merit of applications, as the Review Report notes, CIRM has always required specialists to submit pre-review financial disclosures and conflict of interest disclosures, like the other members of the working group. We agree that for the same reason, they should also submit post-review certifications.

It is of overriding importance to us to ensure that Californians have full confidence in the integrity of the processes we use to commit public funds to stem cell research. Your Review Report will help us to achieve this objective. Please extend our appreciation to your staff for their thoughtful and thorough professionalism.

Sincerely,


Alan O. Trounson, Ph.D.
President

cc: John Chiang, California State Controller
Jeffrey V. Brownfield, Chief, Division of Audits (SCO)
Robert N. Klein, Chairman, Independent Citizens Oversight Committee (CIRM)

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