11

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California State Auditor

California Institute for Regenerative Medicine:

It Has a Strategic Plan, but It Needs to Finish Developing Grant-Related Policies and Continue Strengthening Management Controls to Ensure Policy Compliance and Cost Containment

February 2007
2006-108

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CALIFORNIA STATE AUDITOR

ELAINE M. HOWLE
STATE AUDITOR

DOUG CORDINER
CHIEF DEPUTY STATE AUDITOR

February 27, 2007 2006-108

The Governor of California
President pro Tempore of the Senate
Speaker of the Assembly
State Capitol
Sacramento, California 95814

Dear Governor and Legislative Leaders:

As requested by the Joint Legislative Audit Committee, the Bureau of State Audits presents its audit report concerning the California Institute for Regenerative Medicine (institute) and the Independent Citizens Oversight Committee (committee) that oversees the institute's operations.

This report concludes that the institute analyzed pertinent information, identified long-term research priorities, and considered the planning practices of other entities in creating its strategic plan. The plan contains strategic goals and mechanisms to measure performance, gauge scientific progress, and ensure accountability, but the institute has yet to implement a process to assess annual progress toward attaining the goals. The committee has approved intellectual property policies intended to provide benefit to the State from patents, royalties, and licenses resulting from institute-funded activities without unreasonably hindering essential research. However, insufficient documentation prevented us from reviewing analyses of research used by the committee's task force in the policy-making process. Further, the policies lack adequate guidance to grantees to ensure access to therapies for uninsured Californians.

The institute has developed a grants administration policy for nonprofit grantees, but it is still developing a policy applicable to for-profit grantees. Further, the institute has policies and procedures to identify and prevent conflicts between the personal interests and the work duties of its employees, members of its working groups, and committee members, but they need some improvement. The institute's contracting policy did not ensure that it received appropriate goods and services at reasonable prices, and its travel reimbursement policy did not provide sufficient control over travel expenses. In response to our concerns about contracting and travel reimbursements, the institute revised certain policies in December 2006. Finally, the institute cannot be certain that the salaries for certain of its positions comply with the requirements of the California Stem Cell Research and Cures Act because its salary-determination process contained errors, omissions, and inconsistencies.

Respectfully submitted,

Elaine M. Howle

ELAINE M. HOWLE
State Auditor

BUREAU OF STATE AUDITS
555 Capitol Mall, Suite 300, Sacramento, California 95814 Telephone: (916) 445-0255 Fax: (916) 327-0019 www.bsa.ca.gov

CONTENTS

Summary 1

Introduction 7

Chapter 1

The California Institute for Regenerative Medicine Developed a Detailed Strategic Plan to Guide Its Use of Funds 15

Recommendation 22

Chapter 2

Some Key Tasks Remain for the California Institute for Regenerative Medicine in Developing and Strengthening Grant-Related Policies and Controls 23

Recommendations 55

Chapter 3

To Improve Cost Containment, the California Institute for Regenerative Medicine Modified Its Contracting and Travel Policies and Plans to Conduct Another Salary Survey, but It Needs to Do More 57

Recommendations 78

Appendix

The California Institute for Regenerative Medicine's Process for Developing Its Strategic Plan Outlined Organizational Responsibilities, Guiding Principles, and Timelines 81

Response to the Audit

California Institute for Regenerative Medicine 89

SUMMARY

Audit Highlights . . .

Our review of the California Institute for Regenerative Medicine (institute) revealed the following:

- ☑ ***The institute identified long-term research priorities and considered the industry's best practices to create its strategic plan, but it has yet to implement a process to assess annual progress toward attaining its strategic goals.***
- ☑ ***A task force formulated draft policies for revenue sharing through a public deliberative process but, because of a lack of documentation, we could not independently evaluate any analyses of the information on which the task force members based their revenue-sharing policies.***
- ☑ ***Although it has a grants administration policy for academic and nonprofit institutions, the institute is still developing a for-profit policy and is still implementing a monitoring process to ensure that grantees comply with the terms of their grants.***

continued on next page . . .

RESULTS IN BRIEF

In 2004, voters approved the California Stem Cell Research and Cures Act (act), which authorized the issuance of $3 billion in bonds over 10 years to fund a stem cell research program and dedicated research facilities in California. The act established the California Institute for Regenerative Medicine (institute) as a state agency with the purpose of funding stem cell research activities. The goal of the research is to realize therapies, protocols, and medical procedures that, as soon as possible, will lead to curing or substantially mitigating diseases and injuries. The act directs the institute to give priority to research that has the greatest potential for therapies and cures and that cannot or is unlikely to receive timely or sufficient federal funding. The institute is responsible for supporting all stages of the process of developing cures and establishing appropriate regulatory standards and oversight bodies for research and facilities development.

To oversee the institute's operations, the act established the Independent Citizens Oversight Committee (committee). The act mandates that the committee develop annual and long-term strategic research and financial plans for the institute. The committee adopted the institute's strategic plan during its December 2006 meeting. The plan outlines goals and objectives for spending $3 billion in general obligation bonds authorized by the act and provides a strategy that strives to meet the purpose and intent of the act.

To create the strategic plan, the institute followed a planning process that outlined organizational responsibilities and timelines. The planning process enabled the institute first to analyze pertinent information and then to identify long-term research priorities. To consider the best practices of the industry, the institute consulted various expert stakeholders through interviews, conferences, and focus groups. In addition, the institute reviewed the strategic plans and the strategic planning processes of other entities.

The strategic plan contains essential elements, including a mission statement and a set of goals for fulfilling the mission. The plan's goals depend on scientific discovery, so ensuring

☑ *The institute's recent policy revisions addressed our contracting concerns, but not all of our travel reimbursement concerns.*

☑ *The salary survey conducted by the institute and the compilation of the salary data collected contained enough errors, omissions, and inconsistencies that the institute cannot ensure that the salaries for certain positions comply with the requirements of the law.*

that they are achievable is challenging. However, the outlined goals are specific in nature and were adopted unanimously by the committee, along with the remainder of the institute's strategic plan, in December 2006. Our review concluded that the institute's approach to achieving its goals through specific initiatives is defined clearly. The plan contains an action plan for the first 1,000 days, as well as performance mechanisms and milestones to ensure accountability, assess performance, and gauge scientific progress at years three and seven of the 10-year strategic plan. However, the institute has not yet established a process to track management information from grantees to assess annual progress toward attaining its strategic goals.

The institute has developed several policies and procedures to advance implementation of the stem cell research program approved by voters, including policies that address intellectual property issues resulting from research funded by its grants to nonprofit and for-profit organizations. A particularly important concern for the institute is sharing revenues acquired from the commercialization of institute-funded discoveries. Under the act, the committee must establish standards that balance the State's opportunity to benefit from the patents, royalties, and licenses resulting from the activities funded by the institute with the need to ensure that essential research is not unreasonably hindered by intellectual property agreements. A task force established by the committee formulated draft policies for revenue sharing through a public deliberative process. The committee subsequently adopted the policies. The task force relied on the knowledge and judgment of its members and a broad assortment of information collected and summarized by the committee's vice chair (who served as the chair of the task force) and his deputy. Although we observed that the task force conducted extensive discussions of the information presented, neither the vice chair nor his deputy provided sufficient documentation to demonstrate how they evaluated the information they gathered and how they determined whether the information was appropriate for discussions that would lead to the formulation of the revenue-sharing policy. As a result, we could not independently evaluate any analyses they may have performed of the information on which the task force based its deliberations.

The committee's policies require that grantees provide a plan that ensures that uninsured Californians have access to all therapies developed as a result of the institute's grants. However, the committee has not yet adopted the appropriate language to

define its expectations regarding access. Moreover, although the committee has identified standards for discount prices for drugs, it has not yet identified the appropriate benchmarks to use as a standard for establishing discount prices for nondrug therapies.

In addition, the institute needs to develop a policy for administering certain grants. Although it has developed a grants administration policy for academic and nonprofit institutions, the institute is still developing a policy for administering future grants to for-profit organizations. Moreover, it is still implementing a grants monitoring process that will contain the procedures used to ensure that grantees comply with the terms of their grants, including procedures for performing audits of grantees.

The committee has adopted conflict-of-interest policies to identify and prevent conflicts between the personal interests and the work duties of institute employees as well as members of the committee and the institute's working groups. However, the institute needs more effective policies and procedures. For example, its conflict-of-interest policy for the working group that evaluates applications for program grants does not include experts, known as specialists, who are invited to assist the working group.

The institute did not establish a contracting policy effectively ensuring that it received appropriate goods and services at reasonable prices. Based on language in the act, legal counsel for the institute concluded that it is governed by all the provisions of the Public Contract Code that affect the University of California (UC). Additionally, it is the institute's intent to model its policies substantially after those of UC. However, much of the institute's policy did not conform to UC policy. As a result, the institute awarded multiple contracts without a competitive-bidding process and did not maintain documents that demonstrated it received reasonable prices on the goods and services it purchased.

In addition, the institute's travel reimbursement policy did not provide sufficient control over travel expenses. The institute originally adopted the travel reimbursement policy of the Department of Personnel Administration, but then revised the policy several times to conform more closely to the UC policy. In general, the revisions allowed travelers greater flexibility and more liberal reimbursements. For example, the institute removed maximum reimbursable amounts for some expenses,

such as meals for committee meetings. Moreover, the institute reimbursed costs for air travel and meals without sufficient documentation of travel expenses to ensure that its policies were followed. The revisions also made the policy confusing because they did not use consistent language, and some new provisions did not specify whether they replaced or supplemented existing policies. For instance, the policy contained multiple reimbursement rates for items such as meals but failed to provide clear guidance on when to use each rate.

In response to our concerns about contracting and travel reimbursements, the institute revised certain policies in December 2006. These policy revisions addressed our contracting concerns, but not all of our travel reimbursement concerns. For example, the institute has not revised the form that working group members use to claim travel reimbursement to include information specific enough to allow for a proper review of the claims, and its revised policy specifies that it applies only to institute staff and working group members, not to members of the committee. The institute has indicated to us that it is developing an internal procedures manual that will address additional contracting issues. In addition, the committee chair stated that the committee will consider amendments to the travel policy in the upcoming months.

Finally, the salary survey conducted by the institute and the compilation of the salary data collected contained enough errors, omissions, and inconsistencies that the committee and the institute cannot ensure that the salaries for certain positions comply with the requirements of the act. The institute plans corrective action.

RECOMMENDATIONS

The institute should develop a process to track management information reported annually by grantees, thereby providing accountability and enabling it to assess its annual progress in meeting its strategic goals.

The committee should ensure that it proceeds with its plan to identify the appropriate standard for providing uninsured Californians access to therapies developed with institute funds. Moreover, the committee should ensure that its intellectual property policies clearly convey to grantees its expectations for providing that access. In addition, the committee should

identify practical benchmarks to use as a standard for discount prices for therapies and apply the standard to its policies for grants to nonprofit and for-profit organizations.

The institute should complete its grants administration policy targeted toward for-profit organizations.

To monitor the performance of grantees effectively, the institute should complete the implementation of a grants monitoring process and the development of related procedures.

The institute should amend its conflict-of-interest policies to include any specialists it may invite to participate in stem cell research program activities, such as grant application review.

The institute should strictly follow its newly revised contracting policy, which addresses the concerns raised in our audit. The institute also should amend its travel reimbursement practices for meal reimbursement to ensure its policies are followed. Further, the committee should consider amendments to its travel reimbursement policy that will result in the reimbursement of reasonable and necessary travel expenses, as stated in the act, and that address the concerns we raised in the report.

To ensure that the methodology to set salary ranges complies with the act, the institute should proceed with its plan to resurvey any positions with salary ranges affected by the errors, omissions, and inconsistencies in its initial salary survey and salary-setting activities.

AGENCY COMMENTS

The institute agrees with our recommendations and states that the report makes a useful and important contribution to the institute's effort to operate as effectively and efficiently as possible and in full compliance with the law. ■

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INTRODUCTION

BACKGROUND

In 2004 voters approved the California Stem Cell Research and Cures Act (act), which authorized the issuance of $3 billion in bonds over 10 years to fund stem cell research and dedicated research facilities in California. The act established the California Institute for Regenerative Medicine (institute) with the purpose of funding research into the use of stem cells in developing therapies, protocols, and medical procedures leading as soon as possible to the cure and substantial mitigation of diseases and injuries. The act directs the institute to give priority to research that has the greatest potential for therapies and cures—specifically, stem cell research that cannot or is unlikely to receive timely or sufficient federal funding. The institute is responsible for supporting all stages of the process of developing cures and establishing appropriate regulatory standards and oversight bodies for research and facilities development.

A stem cell is a cell that has the potential to develop into many different cell types in the body. All stem cells are unspecialized cells that are characteristically of the same family type. When a stem cell divides, each new cell has the potential to remain a stem cell or to become another type of cell with a more specialized function, such as a muscle cell, a red blood cell, or a brain cell. Theoretically, stem cells can divide without limit to replenish other cells, serving as a sort of repair system for the body. Scientists hypothesize that stem cells could become the basis for treating ailments such as Parkinson's disease, diabetes, and heart disease.

The National Institutes of Health (NIH), part of the U.S. Department of Health and Human Services, is the primary federal agency conducting and supporting medical research. For the purposes of its research guidelines, the NIH defines a pluripotent stem cell as one of the "cells that are self-replicating, are derived from human embryos or human fetal tissue, and are known to develop into cells and tissues of the three primary germ layers." *Self-replicating* means the cell can divide and form cells indistinguishable from it. The three primary germ layers are

the primary layers of cells in the embryo from which all tissues and organs develop. Pluripotent stem cells also are known as embryonic stem cells.

OVERSIGHT OF THE INSTITUTE

The act established the 29-member Independent Citizens Oversight Committee (committee) to oversee the operations of the institute. Chancellors of the University of California (UC) and certain constitutional officers—the governor, the lieutenant governor, the state treasurer, and the state controller—as well as the speaker of the Assembly and the president pro tempore of the Senate, appoint 27 members. Representatives of 10 disease advocacy groups, also known as patient advocates, and of five UC campuses are appointed for eight-year terms. The remaining 12 members are appointed evenly from other California universities, nonprofit academic and research institutions, and life science commercial entities for six-year terms. The members then complete the selection of the 29-member committee by electing a chair and a vice chair for six-year terms from candidates nominated by the constitutional officers.

Functions of the committee include developing annual and long-term strategic research and financial plans for the institute and making final decisions on research standards and grant awards. The committee must also establish standards requiring that all grants and loan awards be subject to intellectual property agreements. The agreements must balance the State's opportunity to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to ensure that essential medical research is not unreasonably hindered. Further, the committee establishes rules and guidelines for its own operation as well as the operation of the institute's working groups, whose members it must select.

The act established three working groups that are to advise the committee but are to have no final decision-making authority. These working groups assist with awarding grants and establishing research standards. Working group members are appointed for six-year terms by a majority vote of a quorum of the committee and may serve a maximum of two consecutive terms. After the appointment of members to the initial working

group, members' terms will be staggered so that one-third of the members is elected every two years. The composition and key responsibilities of each working group are shown in Table 1.

TABLE 1

Composition and Key Responsibilities of the Working Groups of the California Institute for Regenerative Medicine

Name	Membership	Key Responsibilities
Scientific and Medical Accountability Standards Working Group (standards working group)	19 members: five committee members, nine scientists and clinicians with expertise in specified stem cell research fields, four specialists in medical ethics, and the committee chair.	• Recommends scientific, medical, and ethical standards. • Recommends oversight procedures to ensure that grantees comply with standards.
Scientific and Medical Research Funding Working Group (grants review working group)	23 members: seven committee members representing disease advocacy groups, 15 scientists with expertise in stem cell research, and the committee chair.	• Reviews grant and loan applications based on criteria, requirements, and standards adopted by the committee. • Makes recommendations for awarding grants and loans. • Conducts progress oversight reviews of grantees to ensure compliance with the terms of the award. • Recommends corrective actions for noncompliant grantees.
Scientific and Medical Facilities Working Group (facilities working group)	11 members: six members of the grants review working group, four real estate specialists, and the committee chair.	• Recommends criteria, requirements, and standards for the consideration of applications for, and the award of, grants and loans for buildings, building leases, and capital equipment.

Source: The California Stem Cell Research and Cures Act.

The act allows the committee to determine the total number of authorized institute employees, up to a maximum of 50, excluding working group members, who are not considered employees. As of December 2006 the institute had 22 employees in addition to the president: 10 employees in program positions and 12 in administrative support. The institute has not hired more because of the delay discussed in the next section.

The committee chair manages the committee agenda and work flow, and supervises all annual reports and public accountability requirements. The chair's responsibilities include managing and optimizing the institute's bond financing and funding cash flow plans; leading negotiations for intellectual property agreements, policies, and contract terms; and serving as a member of all

three working groups. The chair is assisted by a vice chair, and as of December 2006, three institute employees work directly in support of the chair.

The president of the institute, who is selected by the committee, serves as the institute's chief executive officer and oversees its staff. The president's primary duties include recruiting working group members; supporting the committee process of evaluating and acting on working group recommendations; hiring, directing, and managing institute staff; developing budgets and cost control programs; overseeing compliance with all rules and regulations of the committee; and executing and managing all intellectual property agreements and any other contracts pertaining to the institute or the research it funds.

FUNDING FOR THE STEM CELL RESEARCH PROGRAM

The act authorizes the institute to use state-issued general obligation bonds in the total amount of $3 billion to fund its operations, as well as medical and scientific research and research facilities. The total amount of bonds that can be issued in one calendar year is $350 million. If less than that amount is issued in a year, the remaining amount can be carried over to subsequent years. For the first five years after the act takes effect, debt service on the bonds is limited to interest payments and is payable from bond proceeds. After that period, the State's General Fund will pay both the principal and interest on the bonds.

Lawsuits filed in 2005 challenging the act's constitutionality have delayed the sale of the bonds, thus hampering implementation of the stem cell research program. In May 2006 the Superior Court of the County of Alameda ruled in favor of the institute and the committee, stating that the plaintiffs had not shown that the act is "clearly, positively, and unmistakably unconstitutional." Plaintiffs appealed the decision to the Court of Appeals in June 2006. As of December 2006 the institute believed that the Court of Appeals' decision likely would be appealed to the Supreme Court and hoped that the lawsuits would be resolved in 2007.

Nevertheless, the committee went forward in September 2005 and approved approximately $12 million in training grants each year over a three-year period. Training grants are designed to help pay the costs of the stem cell research activities of pre- and postdoctoral students and clinical fellows in California's

universities and nonprofit academic and research institutions. The money ultimately was awarded in April 2006, after the institute sold its first set of bond anticipation notes totaling $14 million. The act also provided a $3 million start-up loan from the General Fund for the institute's initial administration and implementation costs. Further, as permitted by the act, the committee accepted a $5 million private gift in June 2005 to be used for creating the infrastructure and systems needed to allow the institute to carry out its grant-making program, to support the institute's scientific planning, and to defray its general operating expenses. The governor directed a $150 million state loan to the institute in July 2006, after the committee chair and vice chair requested help. The institute sold an additional $31 million in bond anticipation notes in November 2006; the money will go toward approximately $150 million budgeted in 2006 for grants to fund human embryonic stem cell research in 2007.

SCOPE AND METHODOLOGY

The Joint Legislative Audit Committee (audit committee) requested that the Bureau of State Audits review the implementation of the act and the performance of the institute and the committee to the extent that the program is operating. The audit committee asked us to review and evaluate the strategic plan and related policies developed by the institute and the committee to determine whether the process for identifying and setting research priorities is outlined clearly, goals are identified clearly and achievable, performance measures have been identified, timelines are realistic, and appropriate staff and resources are assigned. Moreover, it asked us to identify and compare the strategic plan with best practices for the industry.

In addition, the audit committee asked us to review and evaluate the institute's policies and procedures to determine how they were developed, whether they are necessary and designed to carry out the intent of the act as well as other applicable laws and regulations, and whether industry practices were considered. The audit committee requested us to review and evaluate management controls to determine whether they are designed to ensure compliance with the policies and procedures, and to review the internal oversight structure of the institute and the committee. It asked us to include in our analysis policies and procedures relating to protecting and managing the State's financial interest in intellectual property rights associated with research funded or commissioned by

the institute, issuing research and facility grants, identifying and avoiding conflicts of interest for committee and working group members, procuring goods and services, and hiring and compensating staff.

We reviewed the process used to develop the strategic plan, including the institute's consideration of input from key stakeholders through interviews, conferences, and focus groups. We also reviewed the strategic plan to determine whether research priorities are outlined, goals are identified and achievable, and timelines are realistic. We assessed whether performance measures have been identified and whether appropriate staff and resources are assigned. In addition, we reviewed the institute's efforts to consider best practices in its preparation of its strategic plan.

Further, we analyzed the process established to develop the institute's intellectual property policies. We reviewed available documentation, held discussions with key personnel, and attended meetings to evaluate whether the intellectual property policies offer an equitable return to the State without unreasonably hindering research.

Moreover, we reviewed the institute's grants administration policy for academic and nonprofit institutions to verify whether it reflected the significant elements of the act authorizing the program and reviewed related procedures. We also interviewed key personnel at the institute and reviewed relevant documentation to determine whether personnel followed the adopted procedures to review and award grants.

In addition, we reviewed the institute's conflict-of-interest policies to verify if they adhered to the stipulations in the act and reviewed related procedures. We also interviewed key personnel at the institute and reviewed the first set of training grants awarded to determine if conflict-of-interest policies were followed and whether there were any conflict-of-interest violations in the granting process.

To review the institute's process for procuring goods and services, we examined supporting documents to determine whether the institute complied with its contracting policy and that of the UC, as the institute intended. We also reviewed a sample of the institute's expenditures to determine whether they were allowable under the act. Further, we determined whether the institute had a

process in place to ensure it used a private donation in accordance with the terms of the donor. We found the institute had such a process.

Finally, we interviewed key personnel at the institute and reviewed relevant documents, including a survey conducted on the institute's behalf, to verify whether the institute's compensation plan is modeled after that of UC's medical schools and nonprofit and academic and research institutions, as required by the act. We also reviewed a sample of personnel appointments made in 2006 and found that the institute followed procedures that produced a pool of qualified candidates for its open positions. ■

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CHAPTER 1

The California Institute for Regenerative Medicine Developed a Detailed Strategic Plan to Guide Its Use of Funds

CHAPTER SUMMARY

The California Institute for Regenerative Medicine (institute) is a state agency created by the California Stem Cell Research and Cures Act (act). The act requires that the institute's oversight agency, the Independent Citizens Oversight Committee (committee), develop annual and long-term strategic research and financial plans for the institute. During its December 2006 meeting, the committee adopted the institute's strategic plan. The plan outlines the goals and objectives in spending $3 billion in general obligation bonds authorized by the act and provides a strategy that strives to meet its purpose and intent.

Our review of the process the institute used to create its strategic plan revealed that the institute outlined organizational responsibilities and timelines for the process. The planning process enabled the institute to analyze the information needed to identify long-term research priorities. To consider the best practices of the industry, the institute consulted several expert stakeholders through interviews, conferences, and focus groups. In addition, the institute reviewed the strategic plans and planning processes of private, federal, and state entities.

The institute's plan contains essential elements of a strategic plan, including a mission statement and goals to achieve the mission. Many of the institute's goals depend on scientific discovery, creating the challenge of ensuring that they are achievable. However, the goals outlined in the strategic plan are specific in nature and were adopted unanimously by the committee, along with the remainder of the plan, in December 2006. Our review concluded that the institute's strategic plan clearly identifies its approach to achieving the scientific goals through specific initiatives. Further, the strategic plan contains an action plan for the first 1,000 days, as well as performance mechanisms and milestones to ensure accountability, assess performance, and gauge scientific

progress at years three and seven of the 10-year strategic plan. However, the institute has not yet put in place a process to track management information from grantees to assess annual progress toward attaining its strategic goals.

Essential Elements of Strategic Planning

- Identify responsibilities, strengths, weaknesses, problems, and opportunities.
- Define the mission, and formulate goals consistent with the mission.
- Identify key issues relating to the mission and the planned activities.
- Establish priorities among the goals, and allocate resources accordingly.
- Define the objectives necessary to achieve each stated goal.
- Establish timelines and action plans to complete each objective.
- Define benchmarks or targets for each appropriate activity.
- Measure the results of planned operations against the benchmarks to evaluate performance and reset targets as necessary.

STRATEGIC PLANNING IS VITAL TO THE INSTITUTE'S MEETING ITS PURPOSE

Strategic planning is a long-term, future-oriented process of assessment, goal setting, and decision making that maps an explicit path between the present and a vision of the future. Essential elements of sound strategic planning include analyzing the environment, defining a mission and goals, establishing priorities among goals and allocating resources, and measuring actual performance against predefined benchmarks (see the text box).

A strategic plan should focus on outcomes or benefits derived from the efforts expended rather than on the efforts themselves. A successful planning process provides many benefits to both the agency and the clients the agency serves. Strategic planning improves an agency's ability to anticipate and accommodate the future by identifying issues, opportunities, and problems. Good planning also enhances decision making at both the operational and executive management levels because it focuses on results; provides information to guide managers in making decisions on resource allocations; and establishes a basis for measuring success. Finally, the fundamental concept underlying strategic planning is its dynamic nature. The planning process is not a one-time project that, once completed, remains static. Instead, it should be an iterative process that is refined and refocused as performance is measured, targets are reset, and new information becomes available.

USING INPUT FROM THE PLANNING PROCESS, THE INSTITUTE DEVELOPED A STRATEGIC PLAN WITH THE ESSENTIAL ELEMENTS

During its December 2005 meeting, the committee charged the president and staff of the institute with developing a strategic plan, subject to modification and approval by the committee.

The institute refers to its plan as a scientific strategic plan because of its focus on scientific goals and the institute's strategy to deliver on those goals by implementing specific initiatives. The institute's planning process established a six-month time frame within which to gather and assess input from stakeholders in the stem cell research program, including scientists, patient advocates, and representatives of the public. The process included hosting scientific conferences; interviewing individuals with knowledge, experience, and perspective relevant to the institute's strategic plan; and hearing testimony at public meetings. The process included identifying organizational responsibilities and establishing an advisory group, coordinating committee, and working group to develop the strategic plan. In addition, the institute considered the strategic plans of other entities in developing its strategic plan. The Appendix contains details on the efforts of the institute and the committee in developing a strategic plan to guide the institute in meeting the act's purpose and intent.

The institute's strategic plan includes an assessment of internal and external opportunities and challenges that face the institute. By addressing the institute's responsibilities, strengths, weaknesses, problems, and opportunities, the assessment is one of the essential elements of planning. The assessment also answers the question "Where are we now?" and is key to achieving the mission and goals specified in the strategic plan. For example, the plan indicates that by outlining specific limits to the size of the institute's staff and its administrative budget, the act itself will pose challenges. While noting that these limits ensure that the institute will operate economically and efficiently, the strategic plan concedes that they restrict the activities the institute may be able to carry out.

Two Elements of the Institute's Strategic Plan

Mission Statement

To support and advance stem cell research and regenerative medicine under the highest ethical and medical standards for the discovery and development of cures, therapies, diagnostics, and research technologies to relieve human suffering from chronic disease and injury.

Values

Accountability, adaptability, collaboration, diversity, excellence, innovation, integrity, service, and urgency.

With direct input and feedback from the committee and the public, the institute developed its mission statement and values in June and August 2006 (see the text box). The broad, comprehensive statement that evolved from these meetings expresses the overarching goal and purpose for the agency's existence, and the values generally describe how the agency will conduct itself in carrying out its mission. In addition, the institute's strategic plan defines a series of principles intended to focus the institute's vision for its direction in the areas of funding research and discovery, seizing opportunities, setting and

achieving targets, and directing efforts. The plan describes these principles as a foundation for the activities that the institute will pursue to accomplish its goals.

The institute's goals depend on the science that it will fund over the next 10 years; therefore, listing achievable and measurable targets for their accomplishment is challenging. The plan clearly states that it is unlikely that a fully developed stem cell therapy will be available in 10 years. Nevertheless, the plan lists 10 specific goals under the overarching goal that the institute will have some therapies in clinical development, with others in the pipeline by the end of the 10-year period covered by the plan. Table 2 presents the institute's 10-year goals.

TABLE 2

The Institute's 10-Year Goals

1	Institute-funded grantees will have clinical proof that transplanted cells derived from pluripotent cells* can be used to restore function for at least one disease.
2	Institute-funded grantees will have therapies based on stem cell research in phase I or phase II clinical trials for two to four additional diseases.
3	Institute-funded grantees will achieve a level of success that will attract private capital for funding further clinical development of stem cell therapies.
4	The institute will have funded new approaches for achieving immune tolerance for transplantation that are in preclinical development.
5	Using stem cell research, institute-funded grantees will have established proof in preclinical animal models for treatment of six to eight diseases.
6	Institute-funded grantees will have created disease-specific cell lines for 20 to 30 diseases and used them to gain new information about pathogenesis†, identify new drug targets, and discover new therapeutics.
7	The institute will have enabled development of new procedures for the production of a variety of stem and/or progenitor cells‡ that meet specified requirements of the U.S. Food and Drug Administration.
8	Through research sponsored by the institute and others, a thorough description of the steps of differentiation leading to the production of the various cells of the body will be achieved.
9	Through research sponsored by the institute and others, the factors regulating the self-renewal and oncogenic§ potential of embryonic stem cells and their derivatives will be identified and characterized.
10	The institute will have enabled development of new methods for tissue replacement based on stem cell research.

Source: The institute's strategic plan.

* Pluripotent cells: Cells derived from human embryos or human fetal tissue that can differentiate into cells that form all three primary germ layers—the layers of cells in the embryo from which all tissues and organs develop.

† Pathogenesis: The production and development of disease.

‡ Progenitor cells: Stem cells that may have a limited ability to replicate and may display a more limited repertoire of cell types that they can become. Progenitor cells are further along in a cell type-specific differentiation pathway than embryonic stem cells, which are pluripotent.

§ Oncogenic: Causing or tending to cause the formation and development of tumors.

In its strategic plan, the institute also recognizes a separation between the aspirations of the institute and the reality of scientific development. To emphasize this distinction, the plan references a study on drug development costs conducted by the Center for the Study of Drug Development at Tufts University, which estimates that development of a "small-molecule therapeutic" requires eight to 10 years and costs more than $800 million. In addition to this study, we found that some of the presenters at three scientific conferences held to address the funding and development of stem cell therapies emphasized that developing a drug or therapy and making it commercially viable is a long and costly process.

The Institute's Initiative Resource Groups

Scientific Training and Development

Innovation Science

Mission-Directed Science

Tools, Technologies, and Infrastructure

Facilities

Communities of Science

Responsibility to the Public

Institute Special Programs

The strategic plan proposes funding 25 initiatives organized into eight resource groups formed to advance stem cell research in California, support the institute's mission, and achieve its goals. The eight resource groups are shown in the text box. In the strategic plan, each initiative is described in detail, including its significance, objectives, proposed institute activities, and a proposed budget estimate. The budget estimate is based on the number of grants to be awarded, the duration of those grants, and the estimated total annual cost (direct and indirect) per grant. For example, one of the initiatives, "New Methods for Development of Stem Cell Lines," proposes biennial workshops on the current status of alternative methods of generating pluripotent human stem cells and their ability to comply with regulations set by the U.S. Food and Drug Administration to control their use in cell replacement therapies. This initiative also proposes funding grants to support the discovery and implementation of alternative methods of generating pluripotent human stem cells with an estimated total cost, including the workshops, of $12.3 million.

The act specifies that its purpose and intention is to enable the institute to maximize the use of research funds by giving priority to stem cell research that has the greatest potential for therapies and cures, focusing on research opportunities that cannot, or are unlikely to, receive timely or sufficient federal funding. Further, the act states that resulting therapies and cures are envisioned to improve California's health care system and reduce the cost of long-term health care. The institute's strategic plan proposes steps toward meeting the act's purpose and intent.

The institute's principal aspirational goal, as described in its strategic plan, is to use stem cells to cure various diseases. The plan reflects what the institute plans to accomplish over the next 10 years to make the promise of stem cell therapy a reality. For example, in the strategic plan the institute recognizes human embryonic stem cells, or pluripotent stem cells, as having extraordinary possibilities because they can differentiate into virtually all cells in the body. Thus, the plan states that the institute's primary task is to explore the possibilities of providing therapies using human embryonic stem cells. Because the federal government has limited federal funding for research in this area, the strategic plan's emphasis on human embryonic stem cell research is consistent with the purpose and intent of the act.

To implement the action plan, the institute acknowledges it needs to hire new scientific and administrative staff and to increase significantly the number of alternates and specialists to assist the Scientific and Medical Research Funding Working Group.

Within the strategic plan, the institute developed an action plan titled "A Fast Start: The First 1,000 Days." The institute established the first 1,000 days as beginning July 1, 2007, because its plan is based on the assumption that the litigation, discussed in the Introduction, will be settled and bond funds available at some time during the second half of 2007. The action plan includes a schedule for grant application requests that the institute will issue before and during the first 1,000 days. The institute also developed a standard timeline for awarding grants that averages six to eight months. The institute considers its schedule for grant application requests to be an aggressive one that will involve up to 12 grant review cycles a year. To implement the action plan, the institute acknowledges it needs to hire new scientific and administrative staff and to increase significantly the number of alternates and specialists to assist the Scientific and Medical Research Funding Working Group.

THE INSTITUTE HAS NOT YET DEVELOPED A PROCESS TO USE ANNUAL GRANTEE DATA AS A STRATEGIC MONITORING TOOL

The institute's strategic plan proposes performance mechanisms to measure results of the research funded under the institute's grants against its strategic goals. However, the institute has not yet developed and implemented the process to accumulate the annual grant-specific data it plans to use to gauge its progress in meeting strategic goals.

The strategic plan proposes that the committee conduct a review of progress at years three and seven of the 10-year span covered by the strategic plan. Listed as a mechanism for revising the plan is a review conducted by an outside committee composed of scientists, clinicians, ethicists, and patient advocates from within and outside California. The review committee would assess progress on the plan and recommend modifications. The plan also states that, when it is revised, institute staff can prepare for committee approval a new three-year operational plan.

The plan states that, at the institute's discretion, evaluation of progress may include surveys, interviews, focus group discussions, advisory committee reviews, and conferences. Another of the plan's performance measures is the use of five-year goals that the institute will use as milestones to gauge its progress toward the 10-year goals. Assessment of the five-year goals, which are listed in Table 3, then will enable the institute to modify the 10-year goals accordingly.

TABLE 3

The Institute's Five-Year Goals

1	Institute grantees will have six therapies based on stem cell research in preclinical development.
2	Institute grantees will have developed new methods of making stem cell lines.
3	Institute grantees will have successfully created disease-specific stem cell lines for four diseases.
4	Institute grantees will have developed methods of growing stem cells in defined media.
5	The institute will have enabled establishment of a stem cell bank.
6	Institute-funded investigators will have demonstrated methods for inducing immune tolerance in animal models.
7	The institute will have increased the workforce of stem cell researchers in California.
8	Institute grantees will have established tools for toxicity testing based on stem cell research.
9	The institute will have established effective partnerships in stem cell research among scientific teams in nonprofit and commercial sectors.
10	The institute will have established national and international collaborations in stem cell research.

Source: The institute's strategic plan.

The plan indicates that one source of data that performance assessment will rely on are the grantee reports of their progress in meeting the purpose of their respective grants. Institute grantees have annual financial and programmatic reporting requirements specified in the interim grants administration

policy they are to follow. However, as of December 2006, the institute had no mechanism to track management information to assess yearly progress toward its strategic goals, and its staff informed us that they are developing such a mechanism to be part of a planned integrated information technology system. The system would allow the institute to pull data from the annual progress reports submitted by grantees, which already are required by the grants administration policy, thereby enabling the institute to monitor various types of information, including progress toward strategic goals and initiatives. The institute also stated it is determining what information grantees must submit with their annual progress reports.

RECOMMENDATION

To provide accountability and assess annual progress in meeting its strategic goals and initiatives, the institute should fulfill its plans to develop a process to track management information reported annually by grantees. ■

CHAPTER 2

Some Key Tasks Remain for the California Institute for Regenerative Medicine in Developing and Strengthening Grant-Related Policies and Controls

CHAPTER SUMMARY

The California Institute for Regenerative Medicine (institute) and its oversight agency, the Independent Citizens Oversight Committee (committee), have developed several policies fostering the implementation of the stem cell research program approved by voters, including policies for administering intellectual property that may result from research funded by grants the institute awards to nonprofit organizations as well as grants targeted toward for-profit entities. A particularly important issue for the institute is revenue sharing from commercializing institute-funded discoveries.

Under the California Stem Cell Research and Cures Act (act), the committee must establish standards that balance the State's ability to benefit from the patents, royalties, and licenses resulting from institute-funded research and therapy development with the need to ensure that essential research is not unreasonably hindered by intellectual property agreements. Specific to this requirement, a task force established by the committee and headed by the committee's vice chair formulated draft intellectual property policies for nonprofit and for-profit grantees, including a revenue-sharing requirement, through a public deliberative process. During this deliberative process, the task force relied on the knowledge and judgment of its members and a broad assortment of information the vice chair and his deputy collected from experts and publications and summarized and presented to the task force. Although we observed that the task force conducted extensive discussions of the information presented, neither the vice chair nor his deputy provided sufficient documentation to demonstrate how they evaluated the information they gathered and how they determined whether the information was appropriate for discussions that would lead to the formulation of the revenue-sharing component that ultimately was adopted by the committee. As

a result, we could not independently evaluate any analyses of the information they may have performed on which task force members based their deliberations.

The committee's policies also require that grantees provide a plan that ensures that uninsured Californians have access to any therapies that are developed as a result of the institute's grants. However, the committee has not yet adopted the appropriate language to define its expectations regarding access. Moreover, although the committee has identified standards for discount prices for drugs, it has not yet identified the appropriate benchmark to use as a standard for establishing discount prices for nondrug therapies.

In addition, the institute needs to develop a policy for administering certain of its grants. Although it has developed a grants administration policy for academic and nonprofit institutions (nonprofit grants administration policy), the institute still is formulating a policy for administering future grants to for-profit organizations. Moreover, it still is developing procedures to implement the nonprofit policy, including procedures for performing audits of grantees.

The committee adopted a conflict-of-interest code and policies to identify and prevent conflicts between the personal interests and work duties of committee members, the institute's working groups, and institute employees. However, the institute needs some improvement in its policies and procedures. For example, the conflict-of-interest policy for the working group that evaluates applications for program grants does not include experts, known as specialists, who are invited to assist the working group.

THE COMMITTEE ESTABLISHED INTELLECTUAL PROPERTY POLICIES, BUT SUFFICIENT DOCUMENTATION IS LACKING FOR AN INDEPENDENT REVIEW OF THE REVENUE-SHARING COMPONENT

The act states that the committee must establish standards requiring that all awards of stem cell research program grants and loans be subject to intellectual property agreements. Those agreements must balance the State's opportunity to benefit from the patents, royalties, and licenses resulting from the basic research, therapy development, and clinical trials funded by the program with the need to ensure that essential medical research is not unreasonably hindered. Specific to

this requirement, we focused our review on the elements of the committee's policies that address sharing revenues from the successful commercialization of products that result from institute-funded research and on affordable access to those products for Californians. A task force established by the committee and headed by the committee's vice chair formulated draft intellectual property policies for nonprofit and for-profit grantees through a public deliberative process. The task force presented draft policies to the committee, which approved the initial policy for nonprofit entities in February 2006 and the initial policy regarding for-profit entities in December 2006. During this deliberative process, the task force relied on the knowledge and judgment of its members and a broad assortment of information the vice chair and his deputy collected from experts and publications and presented to the task force as a working draft policy. Although we observed that the task force conducted extensive discussions of the information presented, neither the vice chair nor his deputy provided sufficient documentation to demonstrate how they evaluated the information they gathered or how they determined that the information was appropriate for discussions that would lead to the formulation of the revenue-sharing component. As a result, we could not independently evaluate any analyses of the information they may have performed on which task force members based their deliberations.

Intellectual Property Can Be a Valuable Asset to Entities Funding Research

Intellectual property exists in several forms. According to the institute, its funding is expected to generate many types of intellectual property, including data, databases, biomedical materials, patents, scientific articles, research tools, and software. Typically, a licensing agreement grants a licensee access to a potential scientific research or therapy in exchange for the licensee's commitment to commercialize the patented invention. A licensing agreement usually requires the licensee to pay agreed-on fees and royalty payments when products reach the marketplace.

However, not all patented research discoveries result in profitable commercial products. For example, according to the 2005 technology transfer report issued by the University of California (UC), the total revenue from the patenting and licensing of inventions for the 10 UC campuses was $109.6 million. Of that amount, $16.7 million was reimbursed

for patent and legal expenses, thus giving a total royalty and fee income of $92.9 million derived from 1,238 technologies. UC also reports that its campuses' top five inventions accounted for 45 percent of the total royalty and fee income.

Because big profits can infrequently occur for patented research discoveries, the importance of intellectual property agreements can vary. However, some discoveries result in very successful commercial products returning large revenues to patent holders, such as the University of Florida's development of the nutritional formula that resulted in Gatorade. These successes underscore the importance and value that intellectual property rights can have. Therefore, an agency such as the institute must have policies and procedures in place to guide its patenting and licensing of intellectual property.

The Committee Developed Intellectual Property Policies for Nonprofit and For-Profit Entities

The institute plans to fund both nonprofit and for-profit research institutions, so the committee has developed two intellectual property policies. The committee gave the responsibility for the initial development of the intellectual property policies that pertain to both nonprofit and for-profit entities to an 11-member task force composed of committee members and headed by the committee's vice chair. As of mid-January 2007, the institute was about to submit the nonprofit policy to the Office of Administrative Law for its final 30-day review. The for-profit policy gained committee approval on December 7, 2006, and was scheduled for submission to the Office of Administrative Law to begin the rule-making process. The policies will be included in the institute's regulations after further modifications are made and approval is received from the Office of Administrative Law.

Policy objectives include advancing stem cell research and regenerative medicine in general, facilitating the commercialization of institute-funded discoveries, and providing a benefit to the State through revenue sharing if valuable diagnostics or medical therapies result from institute-funded discoveries.

The committee's intellectual property policies contain elements intended to benefit the State, including requirements related to reporting, publication, publication-related biomedical materials, patent applications, licensing of institute-funded patented inventions, revenue sharing, and access. Policy objectives include advancing stem cell research and regenerative medicine in general, facilitating the commercialization of institute-funded discoveries, and providing a benefit to the State through revenue sharing if valuable diagnostics or medical therapies result from institute-funded discoveries.

The act requires the committee to establish standards that balance the State's opportunity to benefit from patents, royalties, and licenses that may result from institute-funded research discoveries when developing the intellectual property policies, so we focused on the elements of the policies that address revenue sharing and access to affordable drugs and nondrug therapies.

The intellectual property policy for nonprofit grantees states that a grantee must share the net revenues it receives for an institute-funded invention exceeding $500,000.

To illustrate the revenue-sharing process, we use the example of the committee's policy for nonprofit organizations and a hypothetical grant to UC. The revenue-sharing element of the intellectual property policy for nonprofit grantees states that a grantee must share the net revenues it receives for an institute-funded invention exceeding $500,000. The $500,000 threshold will be adjusted based on the changing consumer price index. A nonprofit grantee's revenues are determined through a negotiated agreement between the nonprofit grantee and the organization the grantee licenses to use its inventions as the basis for commercialization. The grantee's net revenues are its gross revenues minus the direct costs incurred in the generation and protection of the patents. Once net revenues exceed the $500,000 threshold, the State will receive 25 percent of the grantee's net revenues after payments to inventors in excess of the threshold.

UC, which is a major nonprofit researcher the institute likely will fund, determines royalty payments and licensing agreements through a complex negotiation process with the licensee. The specific terms of a licensing agreement take into account the interest of the prospective licensee, the estimated dollar value of the research that led to the discovery, the projected cost of development needed to complete the product, the scope of the license, and royalty rates for similar products. According to the committee's vice chair, royalties that companies typically pay to nonprofit organizations generally vary between 3 percent and 10 percent. After UC pays the inventor, the State receives 25 percent of that rate, or 0.75 percent to 2.5 percent of the royalties negotiated by UC above the $500,000 threshold amount.

The Development of the Revenue-Sharing Element of the Intellectual Property Policy for Nonprofit Grantees Lacks Sufficient Documentation for an Independent Evaluation

According to the committee's vice chair, the task force developed a draft policy, including a revenue-sharing requirement, for nonprofit grantees through a process of meetings to receive testimony from experts, research conducted by the vice chair and deputy of the policies and practices of other entities and presented to the task force as a working draft policy, and finally, through a deliberative process conducted in public meetings to consider policy alternatives. As further explanation of the process, the vice chair and deputy said the committee and task force held several intellectual property policy briefings to inform legislators and legislative staff of the components of the proposed policy and to receive input. The vice chair and deputy indicated that they also attended conferences with the intention of exchanging information and gaining perspectives in areas relevant to intellectual property policies.

The vice chair and deputy were not able to provide sufficient documentation to demonstrate how they analyzed the information they gathered and determined whether the information was appropriate for discussions that would lead to the formulation of the institute's revenue-sharing requirements for grantees.

Our review confirmed that the task force conducted various meetings that included presentations on practices related to intellectual property policy. These presentations looked at various models of intellectual property, including the federal model used by the National Institutes of Health (NIH), the global access plan of the Bill and Melinda Gates Foundation, and the policy of the Juvenile Diabetes Research Foundation. We observed that the task force relied on the research and testimony of the vice chair and deputy when making critical decisions regarding the draft intellectual property policy. This research also was considered in large part to develop the for-profit policy, which we discuss later. However, the vice chair and deputy were not able to provide sufficient documentation to demonstrate how they analyzed the information they gathered and how they determined whether the information was appropriate for discussions that would lead to the formulation of the institute's revenue-sharing requirements for grantees.

According to the vice chair and deputy, they conducted a wide variety of research activities over a period spanning from several months to a year or more to identify viable options for the institute's policy. According to the vice chair and deputy, after conducting the research, it was decided that the appropriate guidelines related to intellectual property would be developed best with input from representatives from state entities with expertise, opinions, and concerns about issues related to

intellectual property. They further stated that their research into issues relevant to the development of intellectual property terms and conditions for institute grantees provided a foundation on which to build proposals for policy components. They stated that research was a top priority and was composed of many approaches: hundreds of Internet searches, dozens of literature searches through library sources, and interviews with more than 100 people with expertise in areas relevant to the development of comprehensive policy that considers intellectual property of all types. For example, the deputy provided notes for nearly all the 106 interviews she reported conducting while researching intellectual property policies. However, most of the information in the notes consisted of stand-alone sentences and references with very little or no context. In fact, it was often unclear what questions the deputy asked during the interview.

The deputy also provided reports developed by the California Council on Science and Technology and the National Research Council, a white paper issued by the Burnham Institute and three California universities, and other research materials she said were used in developing the working draft policy presented to the task force. These reports included recommendations or considerations for intellectual property development. However, the documentation provided to us did not indicate how the vice chair and deputy used recommendations or research materials or how they were analyzed and accepted or rejected for use in developing the working draft policy presented to the task force.

The vice chair and deputy could provide very little support for their development of the $500,000 minimum threshold amount and the 25 percent royalty-sharing rate contained in the policy.

Specific to the revenue-sharing formula in the intellectual property policy for nonprofit entities, the vice chair and deputy could provide very little support for their development of the $500,000 minimum threshold amount and the 25 percent royalty-sharing rate contained in the policy. As a result, we could not verify the extent of their efforts to investigate options and determine the appropriate intellectual property policy that would most effectively balance California's opportunity to benefit from any scientific discoveries while not unreasonably hindering research. We specifically asked for any analysis conducted by the committee to demonstrate how information it gathered was used to develop the revenue-sharing policy; however, no such analysis was provided.

The deputy said she and the vice chair arrived at the $500,000 threshold after analyzing a matrix of information from other entities' grant policies. Although the matrix identifies thresholds

for a few entities, no analysis was provided as to how it was determined what threshold amount was appropriate for the institute's program. In addition, in the January 2006 meeting of the task force, the vice chair stated that the $500,000 minimum amount came from a survey of the general expenses incurred by grantees for sharing in revenues from licensing agreements and the policies of other inventors who garner returns on their inventions. The vice chair added that the threshold seemed to be validated by a number of third parties as essentially the average cost of keeping a patent portfolio in business and going through all the licensing and patenting processes. He stated that it was a number used by the American Heart Association, the American Cancer Society, and he thought by others. He stated these entities probably obtained the number from working with similar grantee organizations in the past. However, according to the vice chair's deputy, the survey the vice chair referred to in the January 2006 task force meeting is the matrix we previously discussed.

According to the deputy, the 25 percent component of the formula reflects the risks and rewards expected by the institute's grantees and represent an acceptable return to the State, as evidenced by the lack of debate by and the acceptance of the task force.

The institute's revenue-sharing formula requires grantees to pay the State 25 percent of their net royalties after payment to inventors resulting from patents or licenses they hold on institute-funded research discoveries. Our review of transcripts of task force meetings found little discussion on the determination that the 25 percent amount represents an equitable return to the State. When we asked how the 25 percent in the policy proposal was determined, the deputy told us that the vice chair conducted an informal survey. According to the vice chair, the 25 percent was arrived at by trying to determine a meaningful number that would address the intent of the act to ensure a return to the State while providing some incentive as well as the opportunity for grantee organizations to recoup patent expenses. However, the vice chair and deputy also stated that they conducted the survey informally and confidentially and that no documentation exists. According to the deputy, the 25 percent component of the formula reflects the risks and rewards expected by the institute's grantees and represents an acceptable return to the State, as evidenced by the lack of debate by and the acceptance of the task force. In addition, the deputy reported that the vice chair's informal survey was limited to five individuals from universities in California.

The Policy for the Intellectual Property of For-Profit Grantees Includes Several Elements Similar to the Policy for Nonprofit Entities; Its Development Also Lacks Adequate Documentation

The committee also has adopted a policy addressing intellectual property developed by for-profit entities using program funds. As with the policy for nonprofit entities, the vice chair and deputy could not provide adequate documentation to demonstrate the development of the policy.

As mentioned previously, the committee and task force relied on research conducted to formulate the nonprofit policy to develop the for-profit policy. Thus, many of the elements of the for-profit policy are similar to the policy for nonprofit entities, with some adaptations for the competitive nature of for-profit entities. One significant difference between the two policies is the committee's desire to encourage public-private relationships through intellectual property agreements with for-profit entities. According to the committee's for-profit policy, private investment to develop new technology can be impeded by factors such as project scale and cost, dispersed expertise, and technical and commercial risk, even if the investment offers the prospect of substantial benefits to the company, the industry as a whole, and to society. The committee's for-profit policy states that public-private relationships can represent a means of achieving government goals and exploiting technological opportunities that benefit the public.

The deputy reported that there is no appropriate example for California to follow in establishing an intellectual property policy aimed at for-profit organizations.

However, the deputy reported that there is no appropriate example for California to follow in establishing an intellectual property policy aimed at for-profit organizations. She commented that this is primarily because most government agencies that fund for-profit research do not require a return on investment. For example, the NIH has no revenue-sharing requirement for its grants. As part of the U.S. Department of Health and Human Services, the NIH is the primary federal agency for conducting and supporting medical research. The institute identified four other states that have established programs for financial support of embryonic stem cell research: Connecticut, Illinois, Maryland, and New Jersey. Our review found that Connecticut and New Jersey require an economic return for intellectual property developed under awarded grants.

The deputy identified some granting entities with intellectual property policies that require a financial return for funded inventions. The deputy used these policy components from

the granting agencies to research industry practices and to help develop a policy proposal for the institute. Table 4 compares the policies of various grant-making entities to that of California.

The committee's vision for public-private relationships is anchored in intellectual property policy regarding revenue sharing from any successful commercial products that may result from funding provided by the institute. The revenue-sharing provision of the for-profit policy contains a basic revenue-sharing formula and a formula for increased royalty payments, referred to as blockbuster payments, for grants that lead to very successful commercial products. The basic revenue-sharing formula for determining royalty payments uses the same minimum revenue threshold amount of $500,000 used in the policy for nonprofit entities. For the basic revenue-sharing formula, once revenues from institute-funded products exceed the threshold, the State will receive royalties equal to three times the amount of grant funding provided by the institute.

This basic revenue-sharing formula essentially places a cap on the royalties owed from successful products. For example, if the institute awards $1 million in grant funding that generates revenues exceeding the threshold amount, the State would receive a total of $3 million in royalty payments. The payment schedule for the royalties will be negotiated using a range of 2 percent to 5 percent of revenues.

For blockbuster payments, in addition to the basic revenue-sharing formula, the State will receive an additional royalty in the amount of three times the grant funding provided by the institute when annual revenues from a product exceed $250 million and again at $500 million. In addition, for any successful products for which the institute provided more than $5 million in grants and an institute-funded patent was used to develop a product that generated more than $500 million per year, the State will receive a royalty equal to 1 percent of revenues that exceed $500 million for the life of the patent.

As with the revenue-sharing policy for nonprofit entities, sufficient documentation was not provided for us to evaluate effectively the for-profit policy's provision for revenue sharing.

As with the revenue-sharing policy for nonprofit entities, sufficient documentation was not provided for us to evaluate effectively the policy's provision for revenue sharing. For example, the policy regarding for-profit entities states, "Empirical evidence was collected that suggests that requiring a return greater than that originally awarded does not present a de facto impediment to research progress." However, the policy also

TABLE 4

Comparison of Revenue-Sharing Provisions of the For-Profit Intellectual Property Policy of California With Those of Other Grantor Entities

	State			Federal	Private
	California	New Jersey	Connecticut	National Institutes of Health (NIH)	Juvenile Diabetes Research Foundation (JDRF)
Revenue-Sharing Requirement	Varies based on revenue received	1 percent	5 percent	None	Negotiated on case-by-case basis
Revenue Threshold Amount	$500,000	None	None	None	None
Policy Description	If commercialization occurs, all for-profit grantees will return three times total grant award after revenues exceed $500,000 threshold. Tiered blockbuster payment (three times grant award) expected when revenues reach $250 million and again at $500 million per year. In addition, if the institute invested more than $5 million, revenues exceed $500 million per year, and an institute-funded patent is involved, 1 percent royalty expected for revenues in excess of $500 million for life of patent.	One percent of net sales resulting from intellectual property developed under grant, up to original amount of grant. One percent of royalty payments received by company for licensing intellectual property developed under grant, up to 10 times original amount of grant.	Applicants must submit a proposed arrangement concerning financial benefits to the state as a result of any patent, royalty payment, or similar rights developing from any stem cell research made possible by awarding of such grants-in-aid. In evaluating proposed arrangements, it is expected that, at a minimum, the state shall be entitled to a 5 percent share of royalties and other income directly resulting from any covered invention conceived and reduced to practice with financial contribution from state's grant, but not limited to the amount of the grant.	Although NIH does not require revenue sharing, for grantees to retain intellectual property rights, they must report every invention to NIH, make efforts to commercialize the invention through patent or licensing, formally acknowledge the federal government's support in all patents that arise from the invention, and grant the federal government a limited-use license to the invention.	Collaborating companies must demonstrate a matching resource commitment to proposed program that is equal to or greater than that requested from JDRF. JDRF-funded companies will be expected to enter into a research agreement with JDRF regarding milestones to be met in relation to anticipated funding. These will be negotiated on a case-by-case basis.

Sources: Information for California is from the California Institute for Regenerative Medicine's for-profit intellectual property policy. Information for other entities is from documentation, such as grants policies, guidelines, terms and conditions, and grant announcements, obtained from the entities' Web sites as of February 2007.

states that several organizations have reported that uncapped royalty expectations can have adverse effects on prospective for-profit sector awardees in later financing rounds or business development activities. The evidence cited in the policy proved important to task force discussions on whether capping royalty payments is consistent with ensuring a return to the State and prompted debate among task force members about the logic of capped returns.

No analysis was provided that demonstrates why the capped royalty provision included in the policy is appropriate for California.

We requested documentation from the deputy regarding the evidence used in deciding to include the capped-royalty requirement for the basic revenue-sharing formula in the policy. The deputy responded that the empirical evidence exists in the form of transcripts from task force meetings and in notes from telephone interviews with representatives from funding organizations and companies. The deputy specifically referenced two interviews and testimony from one intellectual property task force meeting, which she said recommended capped royalties. Our review of the testimony that the deputy referenced indicated that a model of capped returns was presented to the task force. In addition, our review of the interview notes provided by the deputy found mention of capped returns. However, no analysis was provided that demonstrates why the capped royalty provision included in the policy is appropriate for California.

In addition, a review of the task force meeting transcripts showed that the task force discussed and developed the investment threshold of $5 million as well as the 1 percent royalty for inventions that generate revenues exceeding $500 million. These elements of the for-profit policy of revenue sharing were not proposed by the vice chair and deputy but were developed as a consensus among task force members during open debate of the policy. There were no tangible data we could analyze to determine if the elements adopted would provide an equitable return to the State.

Moreover, the for-profit revenue-sharing policy explains that for-profit research entities may, on occasion, license their discoveries to other companies to develop and market products. To cover these cases, the for-profit policy resembles that for nonprofit entities, with a slight modification: the State receives payments equal to 17 percent of net royalties paid to the grantee in excess of the threshold, rather than the 25 percent paid by nonprofit entities. To justify the change in the percentage, the vice chair explained in a task force meeting that a UC campus

typically shares one-third of its royalties with inventors. In addition, the for-profit policy states that generally 30 percent to 40 percent of royalty revenues in universities go to the inventors responsible for the patents. The vice chair commented that the percentage of royalties paid to the State was adjusted to reflect that, typically, for-profit research institutions do not compensate inventors. Specifically, the for-profit policy adjusts the percentage downward by one-third, from 25 percent to 17 percent.

We asked the deputy to provide us with documentation confirming the information cited in the policy that universities typically share 30 percent to 40 percent of their royalties with inventors. The deputy's response was that the information we requested was common knowledge to those who work in the field of biomedical discovery. She reported that as a researcher, patent holder, and postdoctoral fellow, she was aware of university revenue-sharing practices without having to read any formal documentation. She was able to provide notes from an interview with a representative of a private university that referenced a one-third split among the inventor, the research department, and the school. However, as we discussed earlier regarding the policy for nonprofit grantees, the vice chair and his deputy could not provide adequate documentation to demonstrate why the 25 percent figure is an appropriate payment from nonprofit organizations. As such, they also could not demonstrate that 17 percent is an appropriate payment from for-profit grantees.

THE COMMITTEE HAS NOT COMPLETED PROVISIONS OF ITS INTELLECTUAL PROPERTY POLICIES REGARDING DISCOUNTED PRICES AND ACCESS TO THERAPIES

The policy does not define what is meant by access to therapies for uninsured Californians, and without a clear definition or expectation of access, grantee organizations will be left to apply their own interpretations.

The committee's intellectual property policy for nonprofit organizations requires that grantees award exclusive licenses involving institute-funded therapies and diagnostics only to entities that agree to have a plan to provide access to those therapies and diagnostics for uninsured Californians. However, the policy does not define what is meant by *access*. The committee could not agree on the language to refine this provision. The committee discussed that amending the policy and regulations would delay implementing its regulations regarding intellectual property developed for grants to nonprofit organizations, and it took no action to amend the

policy and regulations. However, without a clear definition or expectation of access, grantee organizations will be left to apply their own interpretations.

In addition, the intellectual property policy for nonprofit grantees states that licensees must agree to provide drugs at prices pursuant to the California Discount Prescription Drug Program (discount drug program) to Californians eligible for that program. State law specifies various criteria under which Californians are considered eligible. For example, any California resident without prescription drug coverage and with an income not exceeding 300 percent of the federal poverty level is eligible for the discount drug program. As a condition of participating in the discount drug program, drug manufacturers must provide their products at prices no greater than the lowest price paid by any commercial purchaser in California. In addition, the Department of Health Services will work to negotiate additional discounts from drug manufacturers to maximize the benefits to discount drug program participants. As such, the levels of discount prices for drugs produced through institute-funded grants will depend on the Department of Health Services' ability to secure discount prices from drug manufacturers.

Language in the originally proposed policy linking discount prices for drugs and nondrug therapies to federal Medicaid prices was abandoned when the task force became concerned that using the Medicaid language might affect future Medicaid drug prices.

The task force deleted language regarding the provision that drugs and therapies be provided at Medicaid prices in the nonprofit policy it proposed to the committee in December 2006. Language in the originally proposed policy linking discount prices for drugs and nondrug therapies to federal Medicaid prices was abandoned when the task force became concerned that using the Medicaid language might affect future Medicaid drug prices. According to the institute's legal counsel, the task force's concerns centered specifically on the possibility that requiring manufacturers to supply drugs at the federal Medicaid price might inadvertently trigger the federal "best price" recalculations, which would affect pricing for given drugs throughout the country and increase the amounts of certain rebates pharmaceutical companies are required to make to the federal government. The task force was concerned about the possibility that the liability for the institute that could result from those increased rebates might put the entire policy at risk because members of the regulated community might resort to litigation to mitigate the effects of the Medicaid price recalculation on affected rebate amounts. As a result, the task force separated drugs from therapies and linked drug prices to the discount drug program.

Moreover, the institute's legal counsel stated that the task force abandoned language linking nondrug therapies to Medicaid prices. He said linking pricing for nondrug therapies to a statutory system designed only to price drugs is unworkable because nondrug therapies do not have a federal Medicaid price under the federal statute. The committee plans to continue work on identifying the proper regulatory framework for ensuring discount pricing for nondrug therapies that result from institute-funded research for California residents. However, as of mid-January 2007, the institute was about to submit the nonprofit policy to the Office of Administrative Law for its final 30-day review without the therapy provision.

The committee agreed that once a practical benchmark is identified, it will apply the benchmark as a standard for discount prices for therapies resulting from institute-funded research to the policies for both nonprofit and for-profit organizations.

The policy for intellectual property that results from grants to for-profit entities similarly includes a provision linking drug prices to the discount drug program. The for-profit policy also stipulates that grantees will provide therapies at discount prices to residents whose therapies are purchased in California with public funds; however, the for-profit policy does not describe how prices will be discounted for therapies. During the December 2006 committee meeting, the vice chair explained that the task force had difficulty finding practical benchmarks for the lowest available prices. He further stated that the portions of the policies for both nonprofit and for-profit entities that address discounted prices for therapies are works in progress. The committee agreed that once a practical benchmark is identified, it will apply the benchmark as a standard for discount prices for therapies resulting from institute-funded research to the policies for nonprofit and for-profit organizations.

Moreover, the for-profit policy requires every grantee to develop a plan to provide uninsured Californians with access to therapies that result from institute-funded research. However, as with the nonprofit policy, the for-profit policy does not define its expectations for access. According to the transcripts of the December 2006 committee meeting, the task force deliberately did not include specific requirements for an access plan. According to the vice chair, it is difficult to specify what should be in a plan for access to future products. As such, the task force believes that most companies working in areas of great concern to public health do end up with plans for access, and that those plans differ from one company to the next.

Unable to reach agreement on the exact language the policy should contain regarding access to therapies, the committee decided to adopt the policy but continue to work on the language to be contained in the regulations regarding access. Therefore, as a placeholder for this provision in the regulations that will be developed further in the future, the committee added language to the policy requiring access plans to be consistent with industry standards that may exist at the time products are commercialized.

A PROVISION ALLOWING RESEARCHERS ACCESS TO INSTITUTE-FUNDED INVENTIONS WARRANTS FURTHER ATTENTION

The vice chair stated that industry representatives expressed concerns that a research exemption might have the effect of decreasing investment if they could not take patented inventions under license from universities and exploit those patents to make them profitable.

Although our review of the policies focused on revenue sharing and access to affordable drugs and therapies, we noted a separate matter that warrants the committee's monitoring. The intellectual property policy for nonprofits initially included a research use exemption (research exemption) provision that sought to ensure that patented inventions made in the performance of institute-funded research be made freely available for research purposes in California research institutions. The provision was eliminated from the nonprofit policy in the July 2006 task force meeting after some members expressed concern over industry opposition to the research exemption provision. The vice chair stated at the meeting that industry representatives expressed concerns that a research exemption might decrease investment if they could not take patented inventions under license from universities and exploit those patents to make them profitable.

One task force member, unconvinced that the committee needed to exert leadership in the area of research exemptions, led a debate whether such an exemption was contrary to the committee's public policy goals to encourage development. As the committee discussion continued, members questioned if a problem existed that justified the need for a research exemption. The meeting concluded after the vice chair commented that he had been persuaded by the arguments of task force members that no problem existed in a meaningful way in the research community; however, he expressed his hope that the research exemption proposal would be revisited within two years or at any time when it becomes a problem.

In the August 2006 task force meeting, a modified research exemption was reintroduced for consideration in the nonprofit policy after new information from universities expressed that not having a research exemption has been a problem. According to the vice chair, although the task force decided not to pursue a broad research exemption in the July meeting, it realized that the intention behind the exemption was the ability of a nonprofit organization to use its own intellectual property and make it available for other nonprofit activities. Thus, new language for a more narrow research exemption was included in place of the original language. However, the new language of the research exemption still received considerable objection from industry representatives.

The institute president raised concerns over whether including the phrase "reasonable terms" in the compromise language was good regulatory language and questioned who would decide what are reasonable terms.

As a consequence, the task force agreed on compromise language during the meeting in place of the modified research exemption that was presented. The result of this compromise states that in licensing institute-funded patented inventions, a grantee organization agrees that it shall retain the rights to institute-funded patented inventions for its noncommercial purposes and agrees to make its institute-funded patented inventions readily accessible on reasonable terms to other grantee organizations for noncommercial purposes. The institute president raised concerns over whether including the phrase "reasonable terms" in the compromise language was good regulatory language and questioned who would decide what are reasonable terms. Nevertheless, the task force adopted the language and sent it to the Office of Administrative Law for review. The effect of the language on advancing stem cell research is not yet known. However, we believe that this area warrants continued monitoring by the committee.

THE COMMITTEE HAS ADOPTED A NONPROFIT GRANTS ADMINISTRATION POLICY BUT NEEDS TO BOLSTER PROCEDURES TO ENSURE THAT GRANTEES FOLLOW IT

The committee has adopted a policy, developed by the Scientific and Medical Research Funding Working Group (grants review working group) and institute staff, to review applications for and administer research grants to nonprofit entities. However, the institute has not yet developed sufficient procedures to ensure that the policy is followed and is still developing a policy for administering grants to for-profit entities. According to the institute's director of scientific activities, the nonprofit policy was created before the for-profit one because the institute

As of early January 2007, the institute was at the early stages of developing the for-profit grants administration policy and was unable to predict how long the process would take.

anticipates that most of the fundamental research will be conducted by nonprofit organizations and because it believes that information on grants administration policy is more readily available for nonprofit entities than for profit-making organizations. In addition, the grants review working group and the institute intend to use the nonprofit grants administration policy as a template for the for-profit policy. According to the director of scientific activities, as of early January 2007, the institute was at the early stages of developing the for-profit policy and was therefore unable to predict how long the process would take.

Although the nonprofit grants administration policy incorporates significant elements of the act, the institute needed to strengthen its procedures to ensure that the voting process used to recommend grant awards is documented properly. Further, even though the committee awarded training grants and approved issuing requests for application for certain innovation grants before it actually adopted a strategic plan, these actions were consistent with the goals of the plan. Finally, the institute is still implementing a grants monitoring process.

The Institute's Nonprofit Grants Administration Policy Contains Significant Elements of the Act

To fulfill the act's requirements for awarding and administering grants, the committee appointed a grants review working group that, with institute staff, developed a policy for administering research grants awarded to nonprofit institutions. Modeled substantially on policies from other grant-awarding organizations, such as the NIH, the nonprofit grants administration policy was adopted by the committee in June 2006. Its purpose is to serve as the terms and conditions of grant awards issued by the institute and to provide guidance to recipients on their responsibilities.

The nonprofit grants administration policy implements the research grants program established in accordance with the act's requirements (see the text box). For example, policy appendices consist of the medical and ethical standards and intellectual property policy required by the act. The nonprofit grants administration policy reiterates that the 15 scientists of the grants review working group must score grant applications for scientific merit in research, therapy development, and clinical trials, and includes review criteria closely modeled after the act.

Significant Requirements of the Act Related to Grants Administration

- Scientific and medical standards to regulate stem cell research funded by the institute.
- Standards mandating periodic reporting by grantees and authorizing the grants review working group to audit grantees.
- Peer group reviews of grantees to ensure compliance with the terms of award and report recommendations for subsequent actions to the committee.
- Grant application scoring performed only by scientists in the grants review working group. Scoring must be based on scientific merit in research, therapy development, and clinical trials, and must include specific review criteria.

For instance, grant applicants must demonstrate that they have the necessary training and experience to carry out their research plans, which are evaluated in terms of their impact, significance, quality, feasibility, and innovation. The proposed research also must be ineligible for or unlikely to receive federal funding, unless it presents a vital research opportunity that will materially aid the objectives of the institute. The policy also has specific criteria for reviewing training grants and explains how grantees are expected to demonstrate compliance with award requirements and report their results annually (as discussed in a later section).

The Grants Review Working Group Substantially Followed Its Policy When It Reviewed Training Grants, but It Lacked Voting Records

Our review of the institute's available records indicated that the institute, the grants review working group, and the committee substantially followed the grants review and award processes during the review and award of training grants. However, we found that the institute did not maintain records of the grants review working group's votes on grant applications. As a result, we could not conclude that the grants review working group complied fully with the nonprofit grants administration policy. As of December 2006 the only grants the institute had awarded were training grants, which are designed to help pay the costs of the stem cell research activities of pre- and postdoctoral students and clinical fellows in California's universities and nonprofit academic and research institutions.

The institute developed a process describing the various steps that employees of the institute, members of the grants review working group, and members of the committee must follow to review and award grants. This grants review and award process covers the committee's approval of a request for application, which states the objectives and features of the available grant, and the application procedures that must be followed to receive it. The process also includes the receipt of grant applications by the institute, and activities of the grants review working group and the committee to evaluate and award grants. In addition, the institute developed procedures for the grants review working group to follow during grant application review

meetings. These procedures cover processes for evaluating and scoring grant applications and for voting on recommendations to the committee. Our review verified that the institute, the committee, and the grants review working group substantially followed the current process and procedures, although the process and procedures were not fully developed or documented during the review and award of training grants.

Without voting records, we could not conclude whether funding recommendations presented to the committee were in fact the result of the working group's vote, or determine that only authorized working group members voted.

Although the institute maintained records of how the applications were scored, it did not maintain records of the working group's vote to provide recommendations regarding the funding of grant applications to the committee. Thus, we could not conclude whether the funding recommendations presented to the committee were in fact the result of the working group's vote. Further, without voting records, we could not determine that only authorized individuals voted. According to the director of scientific activities, the vote on the working group's recommendations was verbal and in closed session, as votes are done at the NIH. Moreover, the director of scientific activities did not perceive the need to record the vote because it was unanimous. After we shared our concerns with the institute, it developed new procedures designed to ensure that every voting action is recorded. Further, according to the institute's president, the new procedures were implemented when the grants review working group voted to recommend funding for innovation grants in late November 2006, subsequent to our fieldwork.

Training Grants Awarded and Innovation Grants Approved Before Adoption of the Strategic Plan Meet the Plan's Goals

Even though the committee awarded training grants and approved the issuance of requests for application for certain innovation grants before it approved a strategic plan, the nature of those grants is consistent with the goals and initiatives contained in the strategic plan adopted by the committee in December 2006. This consistency exists because both the strategic plan and the institute's decisions on the types of grants it initially issued reflect the institute's approach to carrying out the requirements of the act.

The institute commented on the need for the 16 grants awarded by the committee to foster training in stem cell research. First, it considers that reduced federal support for human embryonic stem cell research has limited the entry of young people into the field. This is a reference to a presidential ban on awarding federal funds for human embryonic stem cell research using stem cells

obtained by processes initiated after August 9, 2001. Second, the institute believes that California will need a vastly expanded workforce to carry out the work of the act. Moreover, the institute reported that, despite being understaffed at the time, it thought it could handle training grants because, with only one application required from each institution, they generate fewer applications than research grants.

The institute also commented on the need for innovation grants, which are intended to jump-start human embryonic stem cell research in California. First, the act requires the institute to place a high priority on funding embryonic stem cell research that cannot receive timely federal funding. The institute explained that the emphasis on human embryonic stem cells is consistent with the act. Second, the institute believes that a scientific meeting held in October 2005 revealed that, because of the gap in federal funding, research on human embryonic stem cells represents the greatest scientific need. Recommendations from that meeting mention that the field of stem cell research is new and that scientists lack a comprehensive understanding of the basic biology of embryonic stem cells. The institute does not expect the first set of these grants to be funded before spring 2007.

The Institute Is Developing Procedures to Ensure That Grantees Comply With the Terms of the Awards

Although the committee has approved a policy for administering nonprofit grants, the institute still is developing procedures to monitor grantees' compliance with the terms of the grants. For example, the act requires the grants review working group to conduct oversight reviews of grantees and to recommend standards to the committee to ensure that grantees comply with the terms of awards. Although the grants review working group and the institute, through the nonprofit grants administration policy, developed these standards, the institute has not yet implemented a strategy to conduct the reviews. Moreover, the director of scientific activities stated that the institute intends the grants monitoring process to cover both nonprofit and for-profit grant recipients. She explained that the procedures for this process must be tailored for both types of recipients because the institute expects nonprofit and for-profit grant recipients to be ruled by very similar, though not identical, grants administration policies.

Although the act requires the grants review working group to conduct oversight reviews of grantees, the institute has not yet implemented a strategy to conduct the reviews.

The institute intends to conduct reviews of grantees through mandated reports. The nonprofit grants administration policy requires each grantee to submit an annual financial report containing all actual costs incurred under the grant during the completed budget period. Each year, grantees also must submit programmatic reports that include the following:

- Personnel who participated in the project.
- Publications resulting from the grant.
- Inventions disclosed, patents filed, or licenses granted for the project.
- Applicable assurances of compliance with public policies, such as medical, ethical, and conflict-of-interest standards for conducting research.

The institute intends its staff to review these reports. Failure to submit a report promptly may result in the reduction, delay, or suspension of a grant award. Moreover, the institute expects each grantee to maintain an accounting system and records demonstrating compliance with the public policies. According to the director of scientific activities, when institute staff cannot resolve a problem regarding compliance with the grants administration policy, the matter first will go to the institute's president. If the issue cannot be resolved easily, the grants review working group will review it and recommend actions to the committee.

As of December 2006 the institute had not completed the format of the financial and programmatic reports, but it requires recipients of a training grant to submit to the institute a trainee appointment form. This form provides information such as the names of the trainee and the mentor, the anticipated period of training, the level of stipend support, and the proposed research project. Once completed and signed by the trainee, mentor, and program director, the form becomes the official document for establishing the stipend.

The institute reserves the right to conduct audits, but it has not yet established systematic audit procedures because it still is implementing the grants monitoring process, of which the audit procedures will be a part.

The institute reserves the right to conduct audits, but it has not yet established systematic audit procedures because it still is implementing the grants monitoring process, of which the audit procedures will be a part. In addition, the institute has not yet fully assembled a team to administer the financial aspect

of the grants. As of early December 2006 the institute still had substantial work to do in developing procedures pertaining to the grants monitoring process, and the director of scientific activities did not know when these procedures would be complete. However, until the institute and the working group put in place the procedures and team members to monitor grantees' compliance with the terms of the grants, the institute runs the risk that grant funds will not be used for their intended purpose. Fully implementing the grants monitoring process and establishing its procedures takes on added importance as the committee approves more grants—it already has budgeted approximately $150 million in innovation grants for 2007.

ALTHOUGH THE INSTITUTE DEVELOPED A CONFLICT-OF-INTEREST CODE AND POLICIES, IMPROVEMENTS ARE NEEDED TO ENSURE THAT THEY ARE FOLLOWED

With certain exceptions, committee members and institute employees are subject to the requirements of the Political Reform Act.

With certain exceptions, committee members and institute employees are subject to the requirements of the Political Reform Act of 1974 (Political Reform Act). The purpose of the Political Reform Act, in part, is to ensure that public officials perform their duties impartially, free from bias resulting from their own financial interests or the financial interests of those supporting them. In response, the committee adopted a conflict-of-interest code—a set of rules intended to identify and prevent conflicts of interest that institute employees and committee members might have with entities with financial interests in the stem cell research program, as required by the Political Reform Act and state regulations pertaining to the Fair Political Practices Commission (FPPC).

To supplement the code, the committee also adopted policies designed to ensure that committee members and institute employees avoid conflicts of interest, and that the public views its conduct as open, fair, and free from bias. In addition, the committee adopted conflict-of-interest policies for the working groups that advise and assist it in establishing policies and standards, as well as evaluating grant applications. However, the FPPC has raised questions about the applicability of the Political Reform Act to the institute's working group members, and improvements were needed in the committee's conflict-of-interest policies, as well as its procedures, to ensure that the policies are followed.

The FPPC Has Questioned the Exclusion of the Working Groups From the Institute's Conflict-of-Interest Code

Key Requirements of a Conflict-of-Interest Code as Specified by the Political Reform Act

- Agency positions, known as designated employees, that participate in making decisions that might materially affect their financial interests.
- The types of investments, business positions, real property interests, or sources of income that might be materially affected by decisions made by designated employees. These are considered reportable financial interests.
- Requirements that designated employees periodically file Statements of Economic Interest disclosing their reportable financial interests.
- Specific circumstances that would require designated employees to disqualify themselves from making decisions or influencing the making of decisions. Disqualification is required when a designated employee has a financial interest that could be affected materially by the decision.

The institute formulated and the committee adopted a conflict-of-interest code. With certain exceptions, the institute's act requires that the committee and the institute comply with the Political Reform Act, which includes the requirement to prepare a conflict-of-interest code. The Political Reform Act also specifies the required contents of such a code. The key requirements are presented in the text box.

To provide information on employees designated as decision makers that may affect financial interests and the types of financial interests those designated employees must disclose, government agencies that do not wish to draft their own conflict-of-interest codes may adopt a model code provided by state regulations. This model code may be modified to designate the employees who must disclose financial interests and the extent to which they make disclosures. The committee adopted a modified model code.

The Political Reform Act requires that the institute submit its conflict-of-interest code to the FPPC for review and approval. The FPPC must review the code to determine if it provides reasonable assurance that all foreseeable conflicts of interest will be disclosed or prevented, all affected persons have clear and specific statements of their duties under the code, and the code differentiates between designated employees with different powers and responsibilities. The institute submitted its code to the FPPC in July 2005, and after an exchange of correspondence between the FPPC and the institute, the FPPC approved the institute's code in May 2006. Subsequent to FPPC approval, the institute submitted the conflict-of-interest code to the Office of Administrative Law for its review and inclusion in state regulations. The Office of Administrative Law approved the institute's code in September 2006.

However, the FPPC has raised questions about the exclusion of the working groups from the institute's conflict-of-interest code. The FPPC believes that members of working groups, who perform duties such as advising the committee on standards

and policy or evaluating grant applications and making award recommendations to the committee, may need to be included in the conflict-of-interest code. Specifically, the FPPC believes that, under state regulations, working group members may act as decision makers if they make substantive recommendations that are, over an extended period, regularly approved without significant amendment or modification by the committee. Thus, as decision makers, working group members would need to be subject to the conflict-of-interest code. This would mean that working groups would be subject not only to the financial disclosure requirements of the Political Reform Act but also to the prohibition against a member participating in a government decision in which that member has a disqualifying financial interest and may be subject to the penalties that may be imposed on individuals who violate that act.

In response to questions raised by the FPPC, the institute stated that the language in its act expressly exempts members of its working groups from the financial disclosure requirements of the Political Reform Act.

In response to the FPPC, the institute stated that members of the working groups are not subject to the pertinent requirements because the language in the institute's act expressly exempts those members from the Political Reform Act, even when the recommendations of a working group are approved over an extended period. Therefore, according to the institute, it is not necessary to engage in ongoing analysis to determine whether, over time, the committee routinely approves the working groups' recommendations. The FPPC responded that the language of the act "is no basis for exempting working group members from the [Political Reform Act's] most fundamental disclosure rules if it becomes apparent that the working group's role in governmental decisions is more than purely advisory." It concluded that this issue may need to be revisited in the future.

The institute requires working group members to make financial disclosures (as discussed later). However, there are some differences between the Political Reform Act and the institute's requirements for working group members that would apply if the FFPC's view were correct. One key difference is that, under the Political Reform Act, the financial disclosures must be made public; the institute's requirements keep the disclosures private. Also, an individual who is subject to the Political Reform Act may be subject to certain penalties if the individual violates the requirements of that act. As of December 2006, it was too early to assess whether the working groups will make recommendations on grant funding or other substantive recommendations that the committee will accept without significant amendment or modification that might result in a challenge to the institute's interpretation.

The Superior Court of the County of Alameda concluded that the committee is the "ultimate decision-making body" and not the working group, but the case is pending appeal.

The committee chair commented that the Superior Court of the County of Alameda, when it ruled in May 2006 on the legal challenge to the constitutionality of the institute's act, considered the question of whether the grants review working group was a decision-making body. The court, based on the evidence presented at trial, including testimony of committee members and the experiences at the one grant award meeting that had been held, concluded that the committee is the "ultimate decision-making body" and not the working group. However, this ruling is not binding as the case is pending appeal.

Our legal counsel advised that, although a court will give deference to the institute's interpretation of the act, ultimately only a court of law can make the determination of which interpretation is correct. Our legal counsel also noted that other provisions governing conflicts of interest that the act specifically references, and that the institute believes the act also exempts working groups from, may be implicated if the FFPC's interpretation is correct. For example, California Government Code, Section 1090, prohibits a public official from being financially interested in any contract made in his or her official capacity. Various judicial decisions have held that Section 1090 also applies to those who advise the members of the governing body. The attorney general has opined that an adviser who has a financial interest in a contract or grant must abstain from giving any advice on that matter to avoid a conflict of interest. A violation of Section 1090 may result in a felony conviction and void a contract.

In view of the seriousness of a violation of conflict-of-interest laws and the concerns raised by the FPPC, we believe that it would benefit the institute to seek a formal opinion from the attorney general regarding whether the exemptions created for working groups from conflict-of-interest laws are intended to exempt them from the conflict-of-interest provisions that apply if the recommendations of an advisory body are adopted routinely and regularly by the decision-making body to whom they are made.

The Institute Has Established Processes to Disclose Financial Interests

Committee members and institute employees are required to disclose their financial interests, such as investments and incomes, that meet thresholds identified by the Political Reform Act. These financial interests are reported on Statements of

Economic Interest, which are public documents. The Political Reform Act sets timelines for public officials to file these forms. Committee members are required to file within 30 days of assuming office, annually thereafter, and within 30 days of leaving office. All committee members and their alternates filed their Statements of Economic Interest from 2004 to 2006. We found 10 occurrences of late filings by members and alternates during 2004 and 2005. The number of late filings decreased to four in 2006.

Institute employees were not required to file their initial Statements of Economic Interest until 30 days after the conflict-of-interest code became effective. However, to promote transparency, the institute asked its employees to file their statements before the required date. After the conflict-of-interest code became effective, institute employees filed their statements again, within the required time frame.

The institute's act requires the committee to adopt conflict-of-interest rules for noncommittee members of the working groups, such as scientists and other experts.

Although the institute maintains that working group members are not subject to the Political Reform Act, the institute's act requires the committee to adopt conflict-of-interest rules for noncommittee members of the working groups, such as scientists and other experts. These rules must be based on standards applicable to members of scientific review committees of the NIH. NIH standards require reviewers to alert officials to any possible conflict of interest and, before and after every meeting, identify any application on which they have a conflict of interest and certify that they will not be, and have not been, involved in the review of any application in which their participation constituted a conflict of interest.

In response to the act's requirements, the committee has adopted conflict-of-interest policies modeled after the NIH for its two working groups that review grants. The standards used for the rules of the third working group are described in the next section. In addition, although not required by NIH standards, the non-committee members of the three working groups are required to file confidential financial disclosure statements signed under penalty of perjury. The institute considers these conflict-of-interest policies to be so significant to the public interest that it has submitted them to the Office of Administrative Law to have them included in the institute's regulations.

During the public comment portion of this rulemaking process, members of the public expressed concern that the act does not preclude the institute from publicly disclosing the working

group members' confidential financial disclosure statements and urged the committee to require public disclosure. The committee disagreed with the suggestion. According to the institute's president, making the financial disclosure statements public would deter scientists from joining the working groups because grant reviewers feel that a public disclosure is an invasion of their privacy. Further, the institute's president stated that grant reviewers consider the confidential disclosure statements to be sufficient because they sign them under penalty of perjury, and they believe their work is an act of "good will" because it helps their competitors get funded and because their per diem rate is low.

The financial disclosure statements for working group members require information similar to what is required from the committee members and institute employees, but are not subject to public disclosure.

The financial disclosure statements for working group members require information similar to what is required from the committee members and institute employees, such as sources of income of $5,000 or more from biotechnology and pharmaceutical companies, as well as California-based academic or nonprofit institutions. All noncommittee members of the Scientific and Medical Accountability Standards Working Group (standards working group) and the Scientific and Medical Facilities Working Group (facilities working group) who participated in committee meetings, as well as all the members of the grants review working group who reviewed training grant applications, filed confidential financial disclosure statements, as required.

The Institute Recently Modified Its Conflict-of-Interest Policies to Address Concerns

To supplement the institute's conflict-of-interest code, the committee has adopted a number of conflict-of-interest policies tailored to institute employees, working group members, and committee members, including alternates for appointed members when they cannot attend meetings. All committee members, their alternates, institute employees, standards working group members, facilities working group members who participate in meetings, and members of the grants review working group who reviewed training grant applications signed their respective conflict-of-interest policies.

However, during our review, we noted several opportunities for the institute to improve its conflict-of-interest policies further. Although the institute implemented some improvements during the course of our fieldwork (as discussed later in this section), it has not yet amended its policy for working groups

Although the institute took action to implement improvements during the course of our fieldwork, it has not yet amended its policy for working groups to include specialists it might enlist to assist in evaluating grant applications.

to include specialists it might enlist to assist in evaluating grant applications. It plans to propose such an amendment at the February 2007 committee meeting.

The committee adopted a conflict-of-interest policy for its members to ensure that they act according to the highest ethical standards and avoid potential conflicts of interest. The policy mostly consists of elements either recalling the stipulations of the Political Reform Act or further limiting the members' decision-making opportunities. For example, according to the policy, committee members cannot receive gifts from entities doing, or seeking to do, business with the institute, 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 Political Reform Act permitted state officials to receive annually up to $360 of gifts from a single source for the two-year period ending December 2006, as updated through state regulations.

However, our review revealed one item in the conflict-of-interest policy for committee members that would have permitted a violation of the Political Reform Act because it allowed committee members to vote on matters on which they had conflicts of interest if the matters were on the consent list of the meeting's agenda. Items are placed on the consent list and voted on as a group without discussion when the committee members agree there is no need for discussion. When we brought this issue to the institute's attention, it responded that this provision of the conflict-of-interest policy was an error caused by the repeated editing of the document. The institute amended the policy to remove the exception, and the committee approved the amended policy in October 2006. The institute claims that no consent item ever created a conflict-of-interest situation requiring any members to disqualify themselves while the former policy was still active. We reviewed the committee's past agendas and did not note any item in the consent lists that would have created a conflict of interest for the committee members, such as awarding grants.

The committee also has adopted a conflict-of-interest policy for institute employees to ensure that their activities are conducted in a way "that is perceived to be open, fair and free from bias." For example, the policy prohibits employees from participating in the review of grant applications from which they or a close family member could receive a financial interest. It also prohibits employees from preparing a contract

or an application for a grant (except to provide information to the applicant) or to engage in compensated or uncompensated employment for any institution engaged in stem cell research funded by the committee, although it does not preclude giving a single talk or lecture.

The conflict-of-interest policies of the grants review and facilities working groups are modeled on the NIH policy but are at times more strict. For example, 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, the institute sets the limit at $5,000 per year.

However, we noted a need for improvement in the policy for the facilities working group. For example, the policy for the grants review working group allows a reviewer to discuss particular grant applications on which he or she has a conflict of interest if the matter is disclosed publicly and if the institute's president decides that the need for the reviewer's special expertise outweighs any possible bias posed by a conflict of interest; however, the reviewer is forbidden to score and vote on the grant application for purposes of recommending funding. In contrast, although the policy for the facilities working group mentioned that reviewers waived by the institute's president from the obligation of disqualifying themselves from discussion were forbidden to vote on applications on which they had conflicts of interest, the policy did not stipulate that they were forbidden to score applications. Moreover, unlike the conflict-of-interest policy of the NIH, the facilities working group's policy did not cover conflicts of interest arising from personal relationships, past professional relationships, and long-standing scientific and personal differences. These missing items could have allowed conflict-of-interest situations in the facilities working group.

In response to our concerns, the institute amended the facilities working group policy to cover conflicts of interest arising from personal relationships, past professional relationships, and long-standing scientific and personal differences.

In response to our concerns, the institute amended the conflict-of-interest policy and regulations for the facilities working group accordingly. In December 2006 the committee approved the amended regulations to be submitted to the Office of Administrative Law.

During our review, we also found that the committee has not included grants review specialists in its conflict-of-interest policies for the grants review working group. The institute recruited 32 out-of-state specialists in November 2006 to

assist in reviewing innovation grant applications because it believed that the number of reviewers, which the act limits to 15, is not large enough for the number of grant applications it received. In the future, the institute intends to use specialists as needed. Specialists are individuals with scientific expertise on a particular issue who do not have a voting privilege and whose presence is not counted toward a quorum. According to the director of scientific activities, they are contacted through teleconference during the review meeting, act as secondary reviewers, and do not score or vote on any application. The institute's process is for specialists to disclose conflicts of interest before the review meeting and file confidential financial disclosure statements. When we made the institute aware that these specialists were not addressed in the conflict-of-interest policy for the grants review working group, it agreed to propose an amendment that it intended to present to the committee at its February 2007 meeting.

The committee and the institute determined that standards of the National Academies were a more appropriate model for the conflict-of-interest policy for the standards working group.

Although the grants review and facilities working groups are responsible for reviewing grant applications, the purpose of the standards working group is to formulate standards. Therefore, the committee and the institute determined that standards of the National Academies were a more appropriate model for the conflict-of-interest policy for the standards working group than were the ones applicable to members of scientific review committees of the NIH required by the act. The National Academies consist of private organizations that bring together committees of pro bono experts in all areas of scientific and technological endeavor to address critical national issues and give advice to the federal government and the public. In contrast, the NIH is the primary federal agency for conducting and supporting medical research, and its conflict-of-interest standards focus on grant reviewers. Based on our review, the conflict-of-interest policy for the standards working group appears to be based appropriately on a modification of the National Academies standards.

Improving Some Procedures Would Help Ensure Compliance With the Institute's Conflict-of-Interest Policies

The institute has taken steps to help ensure that its conflict-of-interest policies are followed, but some procedures should be improved. Examples of efforts to help ensure compliance with policies include documentation the institute has distributed to committee members regarding institute policies and ethical guidelines. The institute also gives its employees a handbook

informing them about institute policies and warning that a violation of the conflict-of-interest policy will result in immediate and appropriate discipline, including termination. The committee also adopted procedures to remove working group members who violate the conflict-of-interest policy. Such violations must be reported to the Legislature, along with a review of corrective actions taken to prevent future occurrences.

The institute has not developed procedures to inform its employees of the organizations that apply for grants. Thus, institute employees may not have the information needed to ensure that they comply with the conflict-of-interest policy.

However, the institute could take steps to assist its employees in complying with its conflict-of-interest policies. For example, one item of the conflict-of-interest policy prohibits institute employees from having more than $10,000 of financial or property interests in any organization that is applying for funding with the institute. Nonetheless, the institute has not developed procedures to inform its employees of the organizations that apply for grants. Thus, institute employees may not have the information needed to ensure that they comply with the conflict-of-interest policy. According to the institute, such notification has not been necessary because, as of December 2006, all grants were awarded to nonprofit institutions, which do not have shareholders or other investors. However, the institute reports that it will advise its employees of the identity of the applicants when it starts issuing requests for applications to for-profit organizations.

Further, the institute could improve steps to detect conflicts of interest before meetings of the grants review working group. These procedures require the institute to review the confidential financial interest disclosure statements of noncommittee members of the working group, but not the Statements of Economic Interest of the committee members of the working group. Therefore, the institute could overlook a conflict of interest. After we shared our concern with the institute, it agreed in December 2006 to revise its procedures to require a review of Statements of Economic Interest to identify potential conflicts of interest before each grants review meeting. Our examination of the Statements of Economic Interest revealed nothing to indicate such a conflict of interest existed during the review of training grants in August 2005.

In addition, the institute's incomplete records of the activities related to the meetings of August 2005 to review training grants do not clearly demonstrate its efforts to follow its procedures and ensure that no conflicts of interest existed. The institute compiles a recusal list—a list of members of the grants review working group who should be disqualified from reviewing,

scoring, and voting on certain grants with which they have a conflict of interest—based on its study of reviewers' published articles and the disclosures that working group members make before the grants review meetings. We found that data explaining why certain members were added and removed from the recusal list during the review meeting were lost. Further, the director of scientific activities stated that the institute gathered data, some of which dealt with past collaborations of reviewers, but destroyed it to maintain the confidentiality of the grants review process, as is the practice at the NIH.

Lacking the necessary data, we were not able to ensure the accuracy of the recusal list the institute used to determine which grants review working group members had to recuse themselves during the review of training grants.

Lacking the necessary data, we were not able to ensure the accuracy of the recusal list the institute used to determine which grants review working group members had to recuse themselves during the review of training grants. This is problematic because we found that the sheets reviewers used to score applications had three unexplained differences from the institute's recusal list, one of which indicates that a reviewer scored an application on which he may have had a conflict of interest. The director of scientific activities believes her personal records of the meetings would show that the reviewer did not have a conflict of interest with respect to the application he scored; however, she has not been able to locate her personal records since the institute moved to its current location in November 2005.

RECOMMENDATIONS

The committee should ensure that it follows through with its plan to identify the appropriate standard for providing uninsured Californians access to therapies developed using institute funds and to convey clearly to grantees its expectations for providing access in its intellectual property policies. In addition, the committee should identify practical benchmarks to use as a standard for discount prices for therapies and apply the standard to its policies for grants to nonprofit and for-profit organizations.

The committee should monitor the effectiveness of its policy to make institute-funded patented inventions readily accessible on reasonable terms to other grantee organizations for noncommercial purposes to ensure that it does not inhibit the advance of stem cell research.

The institute should complete the development of its grants administration policy targeted toward for-profit organizations.

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 that it maintains those records.

To monitor the performance of grantees effectively, the institute should complete the implementation of a grants monitoring process, including audits, and the development of related procedures.

The institute should seek a formal opinion from the attorney general regarding whether the exemptions created for working groups from conflict-of-interest laws are intended to exempt them from the conflict-of-interest provisions that apply if the recommendations of an advisory body are adopted routinely and regularly by the decision-making body to which they are made.

In addition, the institute should follow its plans to amend its conflict-of-interest policies to include specialists invited to participate in stem cell research program activities, such as grant application review.

To provide employees with the information they need to disclose all potential conflicts of interest, the institute should develop the necessary procedures to ensure that its employees are aware of the companies that apply for funding.

To ensure compliance with its conflict-of-interest policies, the institute should revise its procedures 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. ■

CHAPTER 3

To Improve Cost Containment, the California Institute for Regenerative Medicine Modified Its Contracting and Travel Policies and Plans to Conduct Another Salary Survey, but It Needs to Do More

CHAPTER SUMMARY

The California Institute for Regenerative Medicine (institute) did not establish a contracting policy that effectively ensured that it received appropriate goods and services at reasonable prices. Based on language in the California Stem Cell Research and Cures Act (act), legal counsel for the institute concluded that it is governed by all the provisions of the Public Contract Code that affect the University of California (UC). Additionally, it is the institute's intent to model its policies substantially after those of UC. However, much of the institute's contracting policy did not conform to the UC policy. As a result, the institute awarded multiple contracts without a competitive-bidding process and did not maintain documents that demonstrated it received reasonable prices on the goods and services it purchased.

In addition, the institute's travel reimbursement policy did not provide sufficient control over travel expenses. The institute originally adopted the travel reimbursement policy of the Department of Personnel Administration (Personnel Administration) but revised that policy several times to conform more closely to the UC policy. In general, the revisions allowed travelers greater flexibility and more liberal reimbursements. For instance, the institute removed maximum reimbursable amounts for meals it provided for meetings of the Independent Citizens Oversight Committee (committee). Moreover, certain costs that the institute reimbursed for air travel and meals appeared excessive without sufficient documentation needed to justify deviations from its policy. Compliance with the travel reimbursement policy was hampered further by the series of revisions, which did not use consistent language and added new provisions without always addressing whether the provisions replaced or supplemented

existing policy. For example, the policy contained multiple reimbursement rates for meals but failed to provide clear guidance as to when each rate should be used.

In response to our concerns about contracting and travel reimbursements, the institute revised certain policies in December 2006. These policy revisions addressed our contracting concerns, but not all of our concerns regarding travel reimbursement. The institute has indicated that it is developing an internal procedures manual that will address additional contracting issues.

Finally, the salary survey conducted by the institute and the compilation of the salary data collected contained enough errors, omissions, and inconsistencies that, for certain positions, the committee and the institute cannot be certain that the salaries are appropriate. The institute substantially agrees with our assessment and plans corrective action.

THE INSTITUTE'S CONTRACTING POLICY DID NOT PROVIDE ADEQUATE CONTROLS

The institute's policy contained significant differences from the UC policy that altered the competitive-bidding requirements.

The contracting policy the institute developed did not provide controls sufficient to ensure that the institute procured goods and services at competitive or reasonable prices. The act requires the institute and the committee to award contracts in accordance with certain provisions of the Public Contract Code that apply to UC. The institute's legal counsel concluded that, even though the requirements of the act cover only construction projects, the institute is governed by all the provisions of the Public Contract Code that affect UC. Additionally, it is the institute's intent to model its policies substantially after those of UC. However, as shown in Table 5, at the time of our review the institute's policy contained significant differences from the UC policy that altered the competitive-bidding requirements. In addition, the institute's policy did not define the contracting process adequately because its vague language allowed for various interpretations of the bidding requirements. The institute's policy did not provide adequate control on its contracts and, as we discuss later in this chapter, allowed for the awarding of multiple contracts without a competitive-bidding process. In December 2006 the institute implemented a new contracting policy to address our concerns.

TABLE 5

A Summary of Differences Between the Institute's and UC's Contracting Policies as of November 30, 2006

	Institute Policy	UC Policy
Selection of Independent Consultants	**Definition of Consultant**	
	An independent consultant is an individual who is not employed by the institute, has "some" professional or technical competence, and provides primarily professional or technical advice to the institute.	An independent consultant is an individual not employed by UC, has "proven" professional or technical competence, and provides primarily professional or technical advice to UC.
	Competitive Bidding Requirement	
	The institute's policy does not require that contracts for independent consultants be bid competitively, but if the service is needed for an extended period, bidding should be considered.	If the total amount of the contract of the independent consultant agreement is or will be $15,000 or more, the responsible official must assure that, if possible, proposals are solicited from three or more qualified independent consultants.
Procurement of Common Goods and Services	**Competitive Bidding Process**	
	The institute's policy does not contain a stipulation for public advertisement. A bidding process is defined as the solicitation of at least three bids.	Competition must be sought by public advertisement where feasible and practicable. If public advertisement is not used, competition must be sought by as broad a solicitation of qualified bidders as the situation indicates. Such solicitation must be from at least three sources.
Sole Source Justifications	**Contracting Process**	
	Contract requests must indicate whether a bid will be used to select the vendor or whether a specific person or firm has already been preselected. If the latter, a rationale for selecting this specific person or firm should be provided.	Prior to the soliciting a quotation, the responsible official must determine that specification requirements, such as goods or services designated as unique or sole source, are reasonable and necessary.
	Required Justification	
	When a bid process is not required or necessary, a contract can be negotiated directly with a single person or firm, but the institute is obligated to be cautious in such negotiations to get the best price possible.	When competition is not sought for an independent consultant contract of $15,000 or more, the reason for not seeking competition must be documented and retained. When it is determined that a product or nonconsultant service valued at more than $50,000 is unique, the responsible official must document the reasons for the determination that the product is unique.
	The institute's policy does not address documentation requirements or how to determine reasonable price.	For all purchase contracts, the responsible official must determine that the price to be paid is reasonable. Prices will be considered reasonable when the responsible official has determined that competition has resulted in a reasonable market test, or when prices are set by applicable law or regulation. Lacking these assurances, reasonableness will be determined by appropriate price or cost analysis.

Sources: The institute's *Policy and Procedures for Contracting* adopted on August 5, 2005; UC Business and Finance Bulletins (BUS-34 and BUS-43).

The Institute's Policy on Selecting Independent Consultants Did Not Consistently Reflect the UC Policy

The institute's contracting policy language could allow the selection of a consultant with insufficient professional or technical competence.

Several components of the institute's contracting policy differed from those of UC. One instance in which the institute deviated from the UC policy was in its definition of independent consultant services. As shown previously in Table 5, the institute's policy used the term "some" in reference to the desired level of a consultant's professional or technical competence, whereas the UC policy specified that the consultant must have "proven" professional or technical competence. The institute's language could allow the selection of a consultant with insufficient professional or technical competence. When we asked why the institute changed the language from that of the UC policy, the institute's former chief administrative officer agreed that the requirement in the institute's contracting policy would be clearer if the original language had been left alone. In his opinion, however, the institute has only contracted consultants with "demonstrable" competence.

To procure the services of an independent consultant, the UC policy states that the "requesting unit shall make a written presentation of its requirement for the services and submit it" to the program review official. The institute's equivalent to the program review official was the chief administrative officer, who was the only contracting official specified in the institute's policy. In this report, we use the term *responsible official* when referring to comparable positions. Among the information that UC requires to be included in the request for bid is a description of the problem, an explanation of why the services cannot be provided internally, the scope of the work, and a schedule for the service. The UC policy also stipulates that the consultant must be able to prepare a proposal based on such a request, and the proposal must contain a description of the consultant's qualifications, an outline of the techniques the consultant intends to use to approach the problem, and a breakdown of the anticipated total cost of the service. If the service is worth more than $15,000, the responsible official must ensure that, if possible, at least three proposals are solicited from qualified independent consultants.

The institute's policy stated that contracts with independent contractors and consultants need not be bid competitively.

On the other hand, the institute's policy stated that contracts with independent contractors and consultants need not be bid competitively.[1] In place of the threshold amount specified in the UC policy, the institute's policy stated vaguely that bidding should be considered "if the service will be needed for an extended period of time." Thus, the policy indicated that the extent of the institute's obligation was to "consider" a competitive bid. When we asked why the institute's policy did not include the threshold amount, the former chief administrative officer stated that he believed the UC policy did not appear to require that all contracts exceeding $15,000 have three solicitations. Instead, he believed UC established the $15,000 figure to give guidance. However, the institute's policy not only omitted that guidance but also was constructed in a way that competitive bidding on independent consultant contracts would not be required under any circumstances.

The Institute's Policy on Procuring Common Goods and Services Did Not Include All the Requirements in the UC Policy

Although the institute's policy on common goods and services agreed in part with that of the UC policy, the requirements in the two policies were not the same. For example, like UC, the institute included in its policy the requirement that contracts valued at more than $50,000 be bid competitively; however, it did not provide that competition must be sought by public advertisement when feasible and practicable. Instead, the institute's policy defined the competitive-bidding process as "the solicitation of at least three bids," as shown previously in Table 5.

Although the UC policy allows the use of solicitation to seek competition, it states that solicitation can replace public advertising only if public advertising is not feasible or practical. Furthermore, the UC policy indicates that solicitations should be sent to as many qualified bidders as would ensure the conduct of a reasonable market test. However, the institute abridged this provision to require only the minimum effort of soliciting three bids. By mandating a lesser effort on the part of its contracting staff, the institute had more limited assurance that the bids it solicited represent competitive prices.

[1] According to UC policy, an independent contractor relationship exists when the contractor has the right to control only the manner of performance, not the result of the service. An independent consultant is a special type of independent contractor with the distinction that the consultant controls both the manner of performance and the result of the service.

The Institute's Policy Did Not Provide Adequate Controls for the Use of Sole Source Contracts

The institute's policy did not include all the procedures that the UC policy stipulates must be followed when a competitive-bidding process is not used. Further, the institute's language on this point was vague. The UC policy exempts contracts from competitive bidding if the product or service is considered unique or available only from a sole source, as determined by a responsible official. When determining a product or service's unique or sole source status, the responsible official is supposed to develop sufficient information on the available goods and services to permit reasonable consideration of alternatives and to assess the capabilities of potential suppliers, as well as other considerations. In contrast, the institute's policy allowed for a specific person or firm to be preselected, as long as a rationale was provided.

One of the rationales the institute allowed for sole source contracts was vague and inconsistent with both a reasonable definition and UC's definition of a unique service.

Moreover, one of the rationales the institute allowed for sole source contracts was vague and inconsistent with both a reasonable definition and UC's definition of a unique service. The institute permitted sole source contracting "when the services are so unique that only a few contractors are likely to be able to perform them." In contrast, UC defines unique services as those available from only one source, not a few sources. If a "few" contractors can provide a service, then under the UC policy, the service does not qualify as unique and the responsible official should solicit a bid from each contractor. The institute's policy, therefore, exempted it from seeking competition for a contract that would be required under UC policy.

The institute's policy regarding sole source contracting also was unclear. The former chief administrative officer indicated that the institute's policy was meant to require that every proposed sole source contract have an adequate rationale for omitting competitive bids. Although this may have been the intention, there was little indication that the section of the policy on allowable rationales applied to all contracts. In particular, as mentioned earlier, the institute's policy expressly stated that contracts for independent consultants or contractors were not required to be bid competitively, suggesting that no rationale was needed to justify a sole source contract. As a result, control over the awarding of these types of contracts was limited.

Unlike UC, the institute did not stipulate in its policy that the rationale justifying a sole source contract be formally documented or retained.

Additionally, the institute did not include all the UC policy requirements regarding documentation when competition is not sought for a contract. Unlike UC, the institute did not stipulate that the rationale justifying a sole source contract be formally documented or retained. Rather, it required only that the requestor of a contract provide a rationale for not seeking competition. Without sufficient documentation, the institute leaves itself vulnerable to criticism that it has not conducted a fair procurement process.

Also under UC policy, the responsible official must document that the price to be paid is reasonable for all contracts. The UC policy states that a reasonable price can be established by a market test, price or cost analysis, or the judgment and experience of the procurement manager. The UC policy specifies what to consider when judging reasonable prices, such as quality, quantity, delivery, and service. Further, a reasonable price must not exceed a price that would be incurred by a prudent person operating a competitive business. The institute's policy had no such provision; therefore, the institute could not ensure that public funds would be used effectively.

THE INSTITUTE DID NOT PROPERLY SEEK COMPETITION OR DOCUMENT THAT IT OBTAINED REASONABLE PRICES FOR ITS CONTRACTS

As of August 2006 the institute had entered into 31 contracts, totaling $3.7 million, with parties other than state agencies. For our testing, we determined primarily whether the institute had complied with the contracting policy of UC. The decision to test the institute's contracts for compliance with the UC policy was based on our conclusion that the institute's contracting policy had insufficient controls. Thus, we focused our testing on 18 contracts that were not for legal services and were above the competitive-bidding thresholds of $15,000 (for independent consultant contracts) and $50,000 (for other contracts) used by UC. All 18 contracts were delegated properly and were for allowable costs, as required by institute policy. However, our review revealed 10 contracts for which the institute did not properly follow the competitive-bidding rules contained in the UC policy. These 10 contracts (two for independent contractors and eight for independent consultants) constituted $1.5 million (41 percent) of the total $3.7 million awarded.

The institute did not publicly advertise or solicit at least three proposals for the 10 contracts, and only one had a sole source justification that explained the institute's decision not to seek competition. Moreover, as explained later, the institute's sole source justification for that contract was questionable. Further, the institute did not document how it determined that it obtained a reasonable price for these contracts in the absence of competition. When we asked the institute why it did not seek competition for most of its contracts, it cited time and staff limitations, as well as its being a newly formed agency at that time. However, these reasons do not excuse the institute from seeking competition or retaining documentation that would support its contracting decisions. As a result of its actions, the institute cannot ensure that it obtained a reasonable price for its noncompetitive contracts.

The contract with the Arlington Group was the largest for which the institute did not follow the provisions of the UC policy intended to ensure the receipt of goods and services at a competitive or reasonable price. The Arlington Group contract was for the licensing and support of its grants management software, Easygrants, in the amount of $537,000. For a contract of that size, the UC policy requires that specific steps be taken to gain competitive pricing if possible, as shown in the text box.

Requirements in the UC Contracting Policy Related to Unique Products and Services

Presolicitation investigations: Prior to soliciting quotations for unique or proprietary products and services, the responsible official must develop sufficient information on the available goods and services to permit reasonable consideration of alternatives, to assess the capabilities of potential suppliers, to aid in design work, to develop complex specifications, to estimate costs, or to establish time for delivery or performance. Care must be taken to ensure that supplier effort is reasonable.

Specification development: Requirements must be specified adequately in accepted industry design, performance, or other definitive terms to ensure a reasonable basis for securing quotations, forming a sound purchase contract, and determining acceptability of products or services furnished.

Form and content: Quotations must be secured or confirmed in writing. All information necessary to prepare and submit quotations must be given to potential suppliers including appropriate provision for negotiation.

Documentation: The responsible official must document the reasons for determining that a product is unique.

The institute did not properly document its presolicitation investigations for the Arlington Group contract according to all the requirements in the UC policy. The institute stated that it spent several months meeting with other grant-making institutions to gather sufficient information on the available goods and services. Using the information it collected, the institute decided that Easygrants would best meet its needs. To support that decision, the institute cited the names of other grant-awarding organizations that use the software (among them, the Bill and Melinda Gates Foundation and the David and Lucile Packard Foundation).

However, the choice to use Easygrants is difficult to justify because the institute could not provide sufficient evidence that it exercised due diligence

in assessing the capabilities of other potential suppliers. By performing a simple query on the Internet, we obtained the names of several grants management programs that appeared to meet the general requirements listed. The institute's chief information officer (CIO) stated that he also looked at other programs online and was able to determine that these programs would not meet the institute's needs based on the literature from their respective Web sites. The CIO also said that the institute obtained quotes for other grants management software. However, he did not provide us with documentation detailing other programs he assessed, quotes he received, or factors he considered in rejecting them.

In addition, the CIO stated that the institute never drafted a formal set of specifications when researching software solutions. Although the institute's justification document does include a set of general system requirements, the institute formed those requirements after it already had decided to use Easygrants. The CIO explained that the institute never drafted a request for proposal or advertised the technical specifications because he believed that he was more qualified to assess the program's needs. However, the UC policy states that specifications are to be developed as part of the presolicitation investigation.

The sole source documentation that the institute drafted did not properly justify its decision.

Moreover, the sole source documentation that the institute drafted did not properly justify its decision. The documentation presented four programs for consideration; however, two of the eliminated programs were from the same core software, and the institute acknowledged in its justification document that the third eliminated program was designed for small foundations with much simpler requirements. In addition, the CIO never obtained a formal quote for the third eliminated program, even though it was included in the cost and quality analyses of the software choices, because the vendor would not provide a quote without a full proposal. The CIO noted in the document that the amount used in the analyses was estimated from public information, rather than from the company itself.

The institute did not properly follow the procedures for determining whether Easygrants was uniquely able to meet its needs, so it cannot justify its decision to award the contract without advertising and seeking competition. As a result, there is little assurance that the institute procured the most appropriate grants management software at a reasonable cost.

The Institute's Recently Revised Contracting Policies Addressed Our Concerns

Our review of the revised policy shows that the institute addressed the concerns we had regarding independent consultant contracts and its controls over the use of sole source contracts.

In December 2006 the institute revised its procurement policy to address our concerns related to contracting independent consultants. The policy for "contracting and services of independent consultants" was presented before the committee on December 7, 2006, and was formally approved. Our review of the revised policy shows that it addressed the concerns we had regarding independent consultant contracts and the institute's controls over the use of sole source contracts.

The institute revised its policy so that it now mirrors the UC policy regarding independent consultants. The institute now requires the same level of qualifications for its independent consultants, as well as the same procedures and bid requirements for procuring an independent consultant's service, as UC. In addition, the institute's revised policy includes UC's requirements that sole source justifications be documented and retained in the agreement file when competitive proposals are not solicited. Further, the institute's policy requires the responsible official to document for every contract that the price to be paid is reasonable, as required by the UC policy.

The institute also has addressed our concerns regarding public advertisement and sole source justification for nonconsultant contracts by referencing the UC policy for procuring goods and services. In addition, the current chief finance and administrative officer stated that she is developing an internal procedures manual that will have more-detailed requirements for the contractor selection process.

THE INSTITUTE'S TRAVEL REIMBURSEMENT POLICY LACKED SUFFICIENT CONTROL OVER COSTS

The institute's policy and practices for reimbursing travel to committee members, institute employees, working group members, and certain guests did not provide adequate controls. The institute made several changes to the policy after originally adopting the guidelines of Personnel Administration for travel and meal reimbursements. In April 2005, the committee approved a change from Personnel Administration's reimbursement policy to that of UC. The institute then made two policy amendments that allowed more-generous reimbursements. As a result, its policy no longer fully reflected that of UC, and some parts of the institute's policy were

confusing. In December 2006 the institute implemented a new travel reimbursement policy that addresses some but not all of our concerns.

The Institute Increased the Flexibility and Allowable Reimbursements of Its Travel Reimbursement Policy

The institute originally adopted Personnel Administration's travel reimbursement policy but, beginning in April 2005, revised the policy several times to conform more closely to the UC policy. In general, the revisions, except the most recent (discussed later in the report), have allowed travelers greater flexibility and more liberal reimbursements for costs they incur. The series of revisions also made some parts of the policy confusing.

After an April 2005 committee meeting, the policy was changed to reflect more closely the UC policy. The agenda for that committee meeting characterized the UC policy as having fewer limitations and higher allowances than Personnel Administration's policy. According to the meeting agenda, the policy change was allowable because the act specifies that the institute should base its compensation plan on UC's. When asked for the rationale behind the policy change, the institute's former chief administrative officer stated that the change was made because UC's policy is more flexible.

The new policy included a provision that allowed the institute to contract lunches for committee and subcommittee meetings without a maximum.

The April 2005 policy change started a trend in making amendments that rendered the travel reimbursement policy unclear and increasingly allowed for more generous reimbursements. For example, whereas Personnel Administration's policy would reimburse lunches only up to $10, the new policy included a provision that allowed the institute to contract lunches for committee and subcommittee meetings without a maximum. The institute's change to the policy was entered into the April 2005 committee agenda as a consent item and was approved with no documented discussion.

Further, in July 2005 the institute amended its policy a second time to allow the use of a rental vehicle with a driver in place of air travel between specified cities. The institute indicated that the UC policy allows the use of a rental vehicle with a driver as surface transportation as long as it is cheaper than air transportation. However, the UC policy requires advance approval, and we found it did not refer to a hired driver. According to the institute, this second policy change, described in a memorandum, spoke to the use of a rental vehicle with

a driver to travel between designated cities when the cost was cheaper than airfare or when the mode of travel typically used was unavailable. However, the amendment was not clear on the type of vehicle the guidelines intended to address. According to the former chief administrative officer, the institute and committee deliberately avoided using the term *limousine*. He added that the services that have been used involved large-sized vehicles rather than the type of vehicle traditionally thought of as a limousine.

The policy memorandum prescribes that the use of a rented vehicle with a driver is available only to committee members and their designated representatives, the chair and vice chair of the committee, and the institute's president. The memorandum further states that these individuals may use rental vehicles with drivers only for transportation to and from their homes, airports, and meeting locations. The policy recommends—but does not require—that these individuals contact at least two services and choose the one that is less expensive.

The memorandum also included a provision for reimbursing guests who attend administrative meetings but are not part of the committee, working groups, or institute staff. The reimbursement rates listed in the amendment ($18 for breakfast, $30 for lunch, $45 for dinner) are based on the UC policy's rates for business meetings, entertainment, and other occasions when UC provides the meals. The last part of the memorandum includes a separate document, labeled an "interpretation," which states that working group members can receive the same benefits as committee members and institute staff, including the benefit of no maximum on contracted meals originally intended to apply only to committee and subcommittee meetings, as discussed earlier.

The institute amended its policy for a third time in December 2005, expanding on the provisions it established in the previous revisions. With this amendment, all members of the committee and its working groups and institute staff could claim reimbursements at the rates formerly established for guests attending administrative meetings; this change effectively doubled the $50 per day they formerly could claim for meals. In addition, whereas the policy previously allowed contracted lunches at no maximum cost, the amendment expanded that policy to include all contracted meals. Thus,

instead of correcting a weak control in its policy, the policy change further weakened the institute's control over its costs by expanding its reach.

The sources of the confusion are the inconsistent language used in some of the amendments and lack of clarity concerning whether some new provisions replace or supplement existing policies.

Another effect of the institute's changes to its travel reimbursement policy is increasing confusion about which policy should be followed. The sources of the confusion are the inconsistent language used in some of the amendments and lack of clarity concerning whether some new provisions replace or supplement existing policies. For example, the institute established a $13 limit on lunch for a "business meeting" in April 2005, a $30 limit on lunch for a guest at an "administrative meeting" in July 2005, and a $30 limit on lunch for any other person under "specific limited circumstances—usually involving a business meeting" in December 2005. However, by failing to define the distinction, if one exists, between a business meeting and an administrative meeting, the policy is unclear whether the December amendment supersedes or is in addition to the provisions of the April policy. Therefore, it is difficult to determine which rates are to be followed for a given meal. To further complicate this problem, the policies were available in three documents. Thus, it is difficult to ascertain which provisions of the travel reimbursement policy to follow.

The Institute Reimbursed Airfare Without Obtaining Documentation to Justify the Costs

The institute violated its travel reimbursement policy when it reimbursed first-class and business-class airline tickets without retaining proper documentation to justify the reimbursements. The institute's travel reimbursement policy, which is based on the UC policy, states that the traveler is required to fly "coach only" and submit receipts for costs over a designated amount. No other requirements for airfare are stated in the memorandum communicating this policy to institute staff. The former chief administrative officer explained in the memorandum that the institute's policy was not intended to be a complete listing of all travel rules in the UC policy, just those commonly applicable to institute activities. When the memorandum did not address a particular issue, it was intended that the UC policy be followed. Under certain circumstances, the UC policy allows flights that are not coach, but justifications for those flights must be attached to the travel expense claims.

The institute could not locate documentation to support one first-class ticket that cost more than two times the state rate.

Our test of selected institute expenditures identified two first-class tickets, two business-class tickets, and several coach tickets that were not procured at the state-contracted rate. We used the state rate as our benchmark of cost because it is a discounted refundable ticket that allows an economical mode of transportation. The institute could not locate documentation to support one first-class ticket that cost more than two times the state rate. According to the interim financial officer, the other first-class ticket, costing four times the state rate, was for the reasonable accommodation of the passenger's back condition. Although the institute provided us a copy of the doctor's note justifying the reasonable accommodation, it did not include any such justification as part of the claim.

The institute also did not require or did not retain documentation justifying its payments for several coach tickets that substantially exceeded the state rate. The tickets had full-fare coach prices rather than the state rate, and three tickets cost more than double the state rate. Although the full-fare coach tickets complied with the provisions stated in the travel reimbursement policy memorandum, they did not conform to the UC policy to procure the "most economical mode" of travel. When asked to explain the purchase of these tickets, the institute's interim financial officer stated that, for two of them, she could "only assume" the travel agency had done its due diligence in attempting to procure tickets at the state rate. She also indicated that a third ticket was purchased at the last minute, resulting in a higher cost, and that a fourth ticket was canceled. However, no documentation of these circumstances accompanied the reimbursement requests. When the institute does not oversee its own travel payments or require documentation to justify its actions, it has little assurance that costs are reasonable and appropriate.

There Were Not Sufficient Controls to Prevent the Institute From Paying Twice or Otherwise Overpaying for Meals

The institute ran the risk of paying twice for the meals of attendees of certain meetings at which contracted meals were served. Moreover, the costs of both the contracted meals and the separately purchased meals could be substantial. As discussed earlier, the institute's policy on allowable costs for meals was unclear, and one part of the policy stated that there was no maximum rate for contracted meals. The institute also did not require attendees of certain meetings to provide sufficient

information for it to determine which meals and which days were included in a reimbursement claim. As a result, it may have overpaid for meals claimed.

In addition to paying for the contracted meals at some of its meetings, the institute may reimburse attendees for meals they separately purchase when they opt not to eat the contracted meals. We acknowledge that legitimate circumstances for permitting separately purchased meals exist—when the attendee's dietary needs require it, for example. However, the institute does not require preapproval for the separate purchase and reimbursement. Without accurate information on the number of attendees not eating contracted meals, it may order and pay for too many.

The institute's claim form does not require meeting attendees to identify which meals they were claiming. The claim form asks only for a total for meals for the entire trip and does not require receipts.

In our review of several travel expense claims from attendees at various meetings, we noted claims for separately purchased meals when contracted meals had been provided. For example, we reviewed four attendees' claims totaling more than $280 for meals at a two-day meeting with five contracted meals: breakfast, lunch, and dinner on the first day and breakfast and lunch on the second. However, the institute's claim form does not require these attendees to identify which meals they were claiming: one or more of the contracted meals, dinner the night before the first day of the meeting, or dinner after the second day of the meeting. The claim form asks only for a total for meals for the entire trip and does not require receipts.

The institute did not have adequate information to review the claims because there was no preapproval of separate purchases and because the claim forms provided no way for attendees to indicate which meals they were claiming. Nevertheless, it paid all four claims. Contracted meals at the two-day meeting cost $125 per person for the first day ($24 for breakfast, $36 for lunch, and $65 for dinner) and $64 per person for the second day ($29 for breakfast and $35 for lunch). For perspective, these contracted lunches cost roughly 3.5 times the amount a state traveler is allowed to charge under Personnel Administration's rules on which the institute based its original travel reimbursement policy.

For one additional claim we reviewed, double payment was deliberate. The institute revised the attendee's claim for lunch and breakfast totaling $28, explaining to the attendee that he was eligible for actual meal costs up to $33, which it then put in the dinner category "since lunch was a catered meal."

Recent Revisions Do Not Address All the Weaknesses of the Institute's Travel Reimbursement Policy

The revised travel reimbursement policy specifies that it applies only to institute staff and working group members, not to committee members.

When the institute revised its contracting policy in December 2006, it also revised its travel reimbursement policy to address certain concerns we raised during the audit. The new travel reimbursement policy was presented before the committee on December 7, 2006, and was formally approved. Our review of the policy confirmed that it addresses certain concerns we had regarding airfare procurement and its handling of contracted meals, and it eliminated the use of rental cars with a driver. However, the revised policy specifies that it applies only to institute staff and working group members, not to committee members. According to the institute president, institute staff did not presume to suggest a policy for the committee.

In large part, the institute's revised policy mirrors the UC reimbursement policy more than it had previously. By modeling its policy after that of UC, the institute has eliminated much of the confusion caused by inconsistent language and multiple reimbursement rates. For example, the institute's revised policy indicates that meals furnished by the institute are subject to a set of maximum amounts. The current chief finance and administrative officer stated that the institute recently implemented the practice of monitoring staff attendance at its meetings. In addition, the institute's revised policy includes stipulations that were absent from its original policy, such as requiring that justifications for airfares other than coach be attached to the expense claim.

Although the institute addressed some of our concerns in its policy revision, it did not address others. For instance, the new policy does not address the inadequacies of its claim forms for working groups, nor does it apply to committee members and meetings. Therefore, because the positive changes in the policy do not improve controls over committee members' travel, the institute made only moderate progress. Subsequent to our review, the committee chair stated that the committee will consider amending its travel policy in the upcoming months.

THE INSTITUTE'S SALARY SURVEY AND SALARY-SETTING PROCESS DID NOT ENSURE COMPLIANCE WITH THE ACT

The act states that the committee must set compensation for the chair and vice chair of the committee and the president, officers, and staff of the institute within the compensation levels of specified categories of public and private universities and private research institutes in the State. The entities prescribed by the act are shown in the text box. As part of the salary-setting process, the institute conducted a salary survey that included not only the entities specified in the act but other entities as well in an attempt to ensure that the established salary levels would be in compliance with the act and justifiable to public inquiries. We noted that the committee and the institute thoughtfully considered the originally approved salary schedules, and for some positions reduced the salaries from those derived from the survey data. However, because of errors, omissions, and inconsistencies in the survey and in the compilation of the salary data collected, the committee and the institute cannot be certain that all salaries comply with the act's requirements. The institute substantially agrees with our assessment of its salary-setting activities and stated it will conduct another survey to identify the appropriate comparable positions to use to set the salaries for 11 positions.

Entities Whose Salaries the Committee Must Consider When Establishing Salary Ranges for Its Positions

- University of California (UC) medical schools.
- Other universities in the State that have demonstrated leadership in stem cell research, a recent history of administering large grants, and national recognition of their research hospital and medical school and their research or clinical faculty.
- California nonprofit academies and research institutions that are not part of UC and have demonstrated success and leadership in stem cell research, are nationally recognized, and have a history of administering large grants.

The Institute Could Not Show That Its Salary Survey Produced Data Representative of the Entities Specified by the Act

The institute could not support that it surveyed all or even a representative sample of the universities and institutions specified in the act. According to the chief human resources officer, the institute identified the universities to be surveyed, other than UC campuses, by looking at the universities represented on the committee without conducting any investigation to identify others. Among the UC responses, the institute ultimately included only those from campuses with medical schools, in accordance with the act's provisions.

For the private institutions, the chief human resources officer stated that she looked for relevant data where it could be found. She said she began by selecting 19 California members of the Association of Independent Research Institutes. The institute's president contributed his knowledge of the industry to her efforts and selected one additional institute. The chief human resources officer then surveyed those 20 institutes for salary data. However, the officer indicated that not all the eligible institutes were surveyed and did not provide any evidence that the selected entities were either all, or even a representative sample, of the population of private institutions.

Some subcommittee members questioned whether the survey participants were comparable to the institute based on budget and staffing levels.

Further, the subcommittee considering salary levels had substantial concerns about the salaries the institute originally proposed. In a meeting in March 2006, the governance subcommittee delayed forwarding the institute's salary proposal to the full committee for approval, requesting additional information. Its specific concerns centered on the comparability of the institutions surveyed and the appropriateness of the salary levels. Although the institutions surveyed met the legal definition for participants, some subcommittee members questioned whether the participants were comparable to the institute based on budget and staffing levels. The subcommittee also discussed how well data from private institutions applied to the publicly funded institute. In response to our questions, the chief human resources officer stated that salary surveys can be compiled based on organization size, location, budget, or other factors, but she admitted that the institute's survey was not adjusted for organization size.

Another concern expressed by some members of the subcommittee related to the level of funding the institute proposed within the ranges of salaries the participants reported. Specific positions they questioned included general counsel, chief information officer, chief communications officer, and chief finance and administrative officer. In a May 2006 meeting, the subcommittee again rigorously discussed the salary proposal, ultimately voting to forward the proposal to the full committee for consideration. The salaries the committee voted to approve in June 2006 were within the ranges reported in the survey but were lower than those the institute originally proposed. For example, for the position of general counsel, the committee approved a salary range of $150,000 to $225,000, whereas the range originally proposed was $150,000 to $240,000, and the survey reported a range of $175,000 to $250,000.

The Institute's Salary Survey Instrument Produced Limited Responses and Contained Inconsistent Job Descriptions

From its salary survey, the institute sought to obtain salary ranges from entities identified in the act for positions it believed to be comparable to its positions. To accomplish this, according to the chief human resources officer, the institute and its consultant identified positions that they believed matched the institute's positions and would be known to the surveyed entities. However, the institute received very few responses for some positions included in the survey document. For example, the institute received no survey response for positions that, according to the chief human resources officer, the institute's consultant considered comparable to two high-level positions: the chief of staff to the chair of the committee and the chief communications officer, both with a salary range of $130,000 to $195,000 per year. Moreover, about half of the positions surveyed generated four or fewer responses from the eight universities and four private institutions that responded to the survey. (The institute surveyed 20 private research institutes. Only four of the 12 that responded met the specifications contained in the act.)

The survey document also contained errors, and the job duties descriptions sent to the universities were not consistent with those sent to the private institutions. For example, the survey position of vice president of marketing was identified in the survey as a third-level management position when, according to transcripts of the committee meeting in which salaries were considered, the position would report directly to the institute's president, putting it at the second level of management. This error is important because the committee used reporting relationships as one of the criteria for setting salaries. Further, the job description for this position in the salary survey document that was sent to private institutions was incorrect because it matched the job description for a lower-level director position. The job descriptions sent to universities for the positions of principal research scientist, research scientist 2, and research scientist 1 did not agree with the job descriptions sent to private institutions for the same positions. Thus, it is unlikely the salary survey produced consistent results for these positions.

Another problem with the salary survey was a possible mismatch between the position titles sent to survey participants and the current positions at the institute.

Another problem with the salary survey was a possible mismatch between the position titles sent to survey participants and the current positions at the institute. For example, the survey used the position of vice president of marketing to represent the positions of chief of staff to the

chair of the committee and the chief communications officer. However, the job description for the surveyed position did not convey well the responsibilities of the two positions. Also, we noted that many of the universities and institutions we observed had functions for media, community relations, communications, publications, and other related functions that resembled the responsibilities included in the duty statement for the institute's chief communications officer. As a result, it was not clear why the institute did not survey for a chief communications officer, rather than vice president of marketing.

The chief human resources officer stated that the titles chosen for the survey were the most generic titles possible to accommodate the wide range of organizations participating in the survey. However, as mentioned earlier, the institute did not receive any responses for the position of vice president of marketing. According to the chief human resources officer, the institute's consultant determined the survey position titles based on its experience with surveys. She added that the institute's position titles, developed in early 2005, were given to the consultant, who derived survey titles that it felt were most applicable to entities outside the institute. She further stated that the institute requested salary data and the surveyed institutions provided data for the positions they considered good matches to the institute's positions. According to the chief human resources officer, following up with all surveyed entities that do not provide individual salary information for a specific position on the survey is not customary and is too time consuming. However, the institute distributed its salary survey in May 2005, and the committee did not approve the salaries until June 2006.

The Salaries Established for Some Positions Raise Questions

The committee and institute did not always set salaries that matched the data generated by its survey. According to the chief human resources officer, after the institute surveyed the position of vice president of marketing to set the salary for the chief of staff position, the executive committee—composed of the chair and vice chair of the committee and the institute's president—determined that vice president of marketing did not include all the duties of chief of staff to the chair. Instead, the executive committee decided to use a combination of salaries from other positions to establish the salary for this position.

The institute disregarded the salary data it received from its survey when setting salaries for some of its positions.

The institute disregarded the salary data it received from its survey when setting salaries for some of its positions. For example, the institute received four reported salary amounts from universities for the surveyed position of manager of events and trade shows, a position matching the institute's position of director of committee relations. However, the institute did not present data from the surveyed universities to committee members for their consideration when setting salaries, but instead presented salary data from two private research institutes that did not meet the categories specified in the act. The committee ultimately approved a salary range for this position that is roughly $23,000 to $32,000 higher than the salaries the universities reported for this position.

In addition, after reviewing salary survey data, the institute determined and reported to the committee that the data were not sufficient to set salaries for its positions of chief of staff to the chair, deputy chief of staff, senior communications officer, and executive assistant to the chair of the committee. However, the survey results show data were received for these positions. The chief human resources officer explained that the duties of the deputy chief of staff had changed to include facilitating the work with the State Treasurer's Office on the issuance of bonds and bond anticipation notes and its work with the Department of Finance on loans. However, we believe the job description for the deputy chief of staff position overstates its bond-related activities, which, according to the duty statement, consist of assisting the chief of staff in the "development of bond placement activities."

The Institute Plans to Conduct a Second Salary Survey That Corrects the Shortcomings of the First

The institute agrees substantially with our assessment of its efforts to obtain appropriate salary data and establish salary ranges for its positions in accordance with the act. According to the chief finance and administrative officer, at the time the survey was conducted, the institute was a new state agency with a staff of only 10 full-time employees, three of whom were on loan from other agencies and institutions. She further explained that the institute undertook the survey with the best intentions of developing compensation ranges comparable to those of the institutions listed in the act as quickly and efficiently as possible and consistent with state requirements.

The institute plans to conduct another salary survey in 2007, with the assistance of a qualified firm that is knowledgeable in the organization and practices of university medical centers and nonprofit research and academic institutions.

The chief finance and administrative officer added that the institute has concluded that the survey does, in fact, have shortcomings. Consequently, the institute plans to conduct another salary survey in 2007, with the assistance of a qualified firm that is knowledgeable in the organization and practices of university medical centers and nonprofit research and academic institutions. The survey results are to be presented to the committee and adjustments in salary ranges are to be proposed as needed. The chief finance and administrative officer said the new survey will identify appropriate, comparable positions at the entities to be surveyed for 11 of the institute's positions. She also noted that the institute is not funding the position of deputy chief of staff to the chair at this time.

RECOMMENDATIONS

The institute should ensure that it follows its newly revised policies that address some of the concerns raised in our audit. The institute also should amend its policies further to include the rest of the concerns we have raised. Those concerns are as follows:

- Although the institute now monitors staff members who attend its meetings, it should implement a preapproval requirement for travelers who want to claim meals separately.
- The institute should revise its travel reimbursement claim form for working groups to require sufficient information that would allow an adequate review of amounts claimed.
- The committee should adopt a travel reimbursement policy for its members that will result in the reimbursement of reasonable and necessary travel expenses, as stated in the act, and that addresses the concerns we raised in the report.

To ensure that the methodology to set salary ranges complies with the act, the institute should follow through with its plan to resurvey any positions whose salary ranges were affected by the errors, omissions, and inconsistencies in its initial salary survey and salary-setting activities.

We conducted this review under the authority vested in the California State Auditor by Section 8543 et seq. of the California Government Code and according to generally accepted government auditing standards. We limited our review to those areas specified in the audit scope of this report.

Respectfully submitted,

Elaine M. Howle

ELAINE M. HOWLE
State Auditor

Date: February 27, 2007

Staff: Karen L. McKenna, CPA, Audit Principal
Norm Calloway, CPA
Joseph Archuleta, MPA
Simon Jaud, Ph.D.
Andrew J. Lee

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APPENDIX

The California Institute for Regenerative Medicine's Process for Developing Its Strategic Plan Outlined Organizational Responsibilities, Guiding Principles, and Timelines

During its December 2005 meeting, the Independent Citizens Oversight Committee (committee) charged the president and staff of the California Institute for Regenerative Medicine (institute) with developing a strategic plan, subject to modification and approval by the committee. The institute refers to its plan as a scientific strategic plan because its focus is on the institute's scientific goals and its strategy to deliver on those goals through the implementation of specific initiatives.

Principles Guiding the Institute's Development of a Strategic Plan

Science in the service of therapy: The strategic plan will be solidly based in science and clearly directed toward the development of specific therapies and diagnostics.

A working plan: The strategic plan will set overall goals and objectives and direction for their implementation, including a set of priorities, approximate budgets, and a coordinated timetable for achieving scientific and clinical objectives. The plan will outline a detailed program for the first two years and be more flexible in future years. The plan must ensure that institute funds are used prudently and to maximum scientific and medical benefit.

A living plan: The plan will be reviewed periodically, its progress evaluated according to built-in milestones, and its strategies updated in response to new scientific opportunities or challenges.

Stakeholder participation: At all stages, the planning will reflect the input of stakeholders, including basic and clinical scientists, patient advocates, and representatives from nonprofit research institutions, philanthropic institutions, the private sector, and government.

Transparency: The development of the plan will be carried out transparently. Progress will be reported and input sought at public meetings. Participants and accounts of all meetings will be made available. Progress in development of the plan can be followed from the institute's Web site.

During the April 2006 committee meeting, the institute's president presented a document, titled "The Development of a Scientific Strategic Plan for the California Institute for Regenerative Medicine," detailing the process the institute would follow to develop a draft of the strategic plan to be presented to the committee within a six-month time frame. The document outlined the steps in gathering and assessing input from experts and stakeholders in preparation for drafting the strategic plan. It also included guiding principles (see the text box), as well as an organizational process, a timeline, and an approach to achieve the plan.

In addition, the document outlined the organizational responsibilities of the president and staff of the institute in developing a draft of the strategic plan in consultation with stakeholders, including scientists, patient advocates, and representatives of the public. This draft then would be presented to the committee for consideration, modification, and final approval. The process identified the committee's responsibilities as formulating the scientific mission statement and

overall long-term objectives of the strategic plan. The committee also was expected to provide advice, suggestions, and input at public meetings and at each committee meeting.

Primarily because of the timeline and personnel limitations imposed by the California Stem Cell Research and Cures Act (act), the committee approved a contract with a consultant to help the institute in developing a strategic plan. According to the institute's president, having a consultant was not only necessary but also was cost-effective and provided the institute with the expertise, workforce, and technical support needed to complete the strategic plan within the proposed time frame.

Committee Members and Institute Officers Steered the Planning Process

A diligent, organized process was used to develop a strategic plan in several stages—from the data gathering and assessment to presenting the draft to the committee in time to meet the six-month deadline in October 2006. The committee ultimately adopted the final strategic plan in December 2006.

The document specified that in organizing development of the strategic plan, members of the committee and institute staff would work through the Strategic Plan Advisory Committee (advisory committee), the coordinating committee, and a working group composed of institute employees and consultant staff. The 10-member advisory committee consisted of the institute's president, the chair of the committee, several professors (some of whom are physicians), and others with interests in stem cell research (see the text box). The advisory committee met publicly seven times to review progress, suggest direction, and give general guidance and oversight to the strategic planning process. The meetings often had specific topics for discussion that focused on the institute's role in various strategic planning considerations, including funding options for the private sector, data banks for human embryonic stem cells, and new technologies within the industry.

Membership of the Advisory Committee (Titles and Affiliations)

- President, California Institute of Technology*
- Cahill Professor of Biochemistry, Emeritus, Stanford University School of Medicine*
- Associate professor of pediatrics and biological chemistry, Children's Hospital Boston and Harvard Medical School and associate director of the Stem Cell Program at Children's Hospital Boston
- Professor of hematology/hematopoietic cell transplantation, City of Hope National Medical Center, and chair of the Division of Hematopoietic Cell Transplantation, City of Hope National Medical Center
- President of the institute
- Chair of the committee
- Vice chair of the committee and president of the Gordon and Betty Moore Foundation
- Founder and chief executive officer, Sherry Lansing Foundation*
- Former president and chief executive officer, Biogen Idec
- Communications director of the AIDS Research Institute, University of California, San Francisco*

* Also a member or alternate member of the committee.

The coordinating committee consisted of the institute's president and four scientific staff members of the institute, including the scientific program officer who had past strategic planning experience. The coordinating committee was to meet weekly to monitor the scope and progress of the planning process and approve procedures. It also was to monitor and modify assignment of duties and proposed changes in work plan or scope as needed.

The working group was responsible for daily progress and organization of strategic planning. It included the consultant staff headed by the institute's scientific program officer, as well as other institute staff as needed. The consultant staff consisted of a project team of eight staff members from a consulting firm, three of whom worked full time in the institute's offices to assist institute staff in the daily development of a strategic plan. This included assisting with the interview process and recording notes as well as creating an internal Web site for the strategic planning process to record, schedule, communicate, and share data.

The Planning Process Included Input From Experts and Stakeholders

Institutions With Representatives Presenting at the Symposium

UC Irvine; UC Los Angeles; UC San Francisco

Duke University; University of Wisconsin

Harvard Medical School; Stanford University

Massachusetts Institute of Technology

Hebrew University of Jerusalem (Israel)

University of Lund (Sweden)

University of Sheffield (United Kingdom)

U.S. Food and Drug Administration

Salk Institute and Scripps Research Institute (California)

Geron Corporation (California)

Cognate Therapeutics (Maryland)

Monash Institute of Medical Research (Clayton, Australia)

Mount Sinai Hospital (Toronto, Canada)

Our review of the institute's data-gathering and assessment stage of strategic planning revealed that a convergence of expert stakeholders—including scientists, public interest groups, patient advocates, and members of the public—expressed their opinions, perspectives, and recommendations as to the current state and best practices of stem cell biology. According to the institute, this stage of the strategic planning process started in October 2005, when the institute hosted a two-day symposium titled "Stem Cell Research: Charting New Directions for California." Presenters and moderators at the two-day symposium included representatives of several prestigious institutions from various nations as well as members of the institute and the committee (see the text box). The goal of the symposium was to focus on the science of human embryonic stem cell research and to identify scientific opportunities that would advance the field and expedite the development of therapies and diagnostics using stem cells. The symposium

developed recommendations for the institute in the areas of basic and clinical research, tools, core facilities, and strategic approaches, which provided the basis for subsequent data collection efforts.

Institute staff developed criteria for putting together a list of more than 200 potential interviewees who would have relevant knowledge, experience, and perspective on the institute's strategic plan. The working group also developed questionnaire templates to provide a consistent structure of capturing data during the interviews. One template included general questions, and other templates were tailored for potential interviewees' specific areas of knowledge: the commercial sector; cord blood research; ethical, legal, and social implications; and creation of new embryonic stem cell lines. Following are examples of interview questions:

- In 10 years, what will success for the institute look like?
- What are the most important ethical, legal, and social issues related to stem cell research for which empirical data are needed?
- What are the most pressing needs that the institute must address immediately to achieve its goals?
- What specific objectives should the institute pursue to realize that vision of success? What are the concrete measures of progress along the way to those objectives?
- What do you think is the most promising research currently being done both domestically and internationally to develop new embryonic stem cell lines?

The institute selected and conducted approximately 70 interviews from the list of more than 200 potential interviewees. Many interviews were with stem cell scientists and clinicians from academia, the private sector, and government and represented a wide array of institutions, universities, and organizations. The interviews were conducted by telephone and in person. One or more members of the institute's scientific staff were present for all the interviews.

Scientific Conferences and Focus Meetings Helped Shape the Strategic Plan

The institute conducted three scientific conferences to address specific questions related to funding stem cell research and developing stem cell therapies. These conferences were conducted for the committee and the public. Each conference included presentations built around a series of questions. A panel discussion followed each presentation, and the conference concluded with an open discussion and questions from the audience. For the May 25, 2006, conference, "Funding Structures to Advance Stem Cell Research and Therapy," presenters included affiliations with the University of Ottawa, National Institute of Standards and Technology, Juvenile Diabetes Research Foundation, High Q Foundation, and Cure Autism Now Foundation. This conference focused on funding structures and, more specifically, how the institute can develop initiatives that maximize progress, enhance basic science, and use technologies from other areas. The conference also explored how to encourage and facilitate interactions between nonprofit research institutions and the commercial sector.

Discussion Questions for July 13, 2006, Conference

- What scientific strategies will be required to advance stem cell research from the laboratory to the clinic?
- Are there special projects or approaches for which the institute can make a unique contribution?
- What is the institute's role in supporting clinical research and/or the clinical development of therapies?
- What tools and technologies do we need? What are the needs for trained personnel?
- How can the institute facilitate partnerships with other organizations, in the United States and abroad?

The July 13, 2006, conference, "The Scientific Challenge: From Basic Research to the Clinic," included presenters affiliated with Harvard Medical School, National Institute of Neurological Disorders and Stroke, Albert Einstein College of Medicine, Cell Genesys Inc., and the Parkinson's Action Network. The text box lists the issues discussed at this conference.

For the conference held on July 25, 2006, "Industry and Stem Cells in California: Fostering Research and Development," presenters included representatives from the Genomics Institute of the Novartis Research Foundation, Cellerant Therapeutics, Burrill & Company, StemCells Inc., Geron Corporation, Cognate BioServices, Advanced Cell Technology Inc., and Novocell Inc. This conference discussion focused on fostering research and development in the stem cell industry in California and partnering with the private sector.

The institute's data gathering involved two focus meetings centered on a series of questions specifically developed for the focus groups. These meetings occurred in July and August 2006. The meetings were intended to solicit thoughts and opinions from patient advocates and, at the second meeting, from individuals able to speak to the issue of diversity. Both meetings were closed to the public with the hope that the participants would feel more comfortable speaking candidly about these issues. The patient advocate focus group consisted of 17 people representing various organizations, such as Cystic Fibrosis Research Inc., the Autism Society of America, and Children's Neurobiological Solutions. The diversity focus group was composed of 16 individuals, including the clinical professor of medicine and director of minority affairs at Thomas Jefferson University, the chair of the Health Committee for the Afro-American Action Network, and a health policy associate from the Greenlining Institute.

The Institute Considered Other Strategic Plans While Developing Its Own

The institute's scientific program officer reported that during the data-gathering process, the working group reviewed strategic plans representative of funding agencies from the federal government and the State as well as private funding organizations. The institute chose the strategic plans listed in Table A for review because they were provided through professional contacts, obtained after their mention by interviewees at one of the conferences, or located through Internet searches. The institute's primary interest in reviewing these other entities' plans was with the processes the organizations used in developing their strategic plans. The institute also considered the content and organization of the planning processes when reviewing the strategic plans.

In addition, as indicated in the institute's strategic plan, the planning process included consideration of best practices of the industry by soliciting the expert opinions of 171 scientists and clinicians from academia and the private sector, and government and other stakeholders through interviews, conferences, focus groups, and strategic planning meetings. The process generally was conducted in a public manner, which resulted in a transparent analysis to determine research priorities.

TABLE A

Entities Whose Strategic Plans the Institute Reviewed

Private Foundations	State Government	National Institutes of Health	Other Federal Entity
• Bill and Melinda Gates Foundation • Wellcome Trust	Tobacco Education and Research Oversight Committee for California	• National Eye Institute • National Heart, Lung, and Blood Institute • National Institute of Arthritis, and Musculoskeletal and Skin Diseases • National Institute of Biomedical Imaging and Bioengineering • National Institute of Child Health and Human Development • National Institute of Diabetes and Digestive and Kidney Diseases • National Institute of Environmental Health Sciences • National Institute of Mental Health • National Center for Research Resources • Office of Behavioral and Social Sciences Research	National Science Foundation

Source: Information provided by institute staff.

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Agency's comments provided as text only.

California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107-1702

February 9, 2007

Ms. Elaine Howle
State Auditor
Bureau of State Audits
555 Capital Mall, Suite, 300
Sacramento, CA 95814

Dear Ms. Howle:

We have carefully reviewed the draft copy of the audit report entitled "California Institute for Regenerative Medicine: It Has a Strategic Plan, but It Needs to Finish Developing Grant-Related Policies and Continue Strengthening Management Controls to Ensure Policy Compliance and Cost Containment".

We appreciate the care and effort of the audit team members who prepared the report. We are pleased by the many positive findings made by the auditors, and view the report overall as accurate and fair. The team's careful examination of the policies and procedures of the Institute has been very valuable in helping us to assess our performance, as have the suggestions for specific areas for improvement. Indeed, we have already addressed many of the issues identified in our policies and procedures in advance of receiving the final audit report.

When the audit began, the agency had been in operation barely 18 months and had a staff of just 20. As a very young state agency, we are still in the process of establishing and refining key policies and procedures. The audit report makes a useful and important contribution to our effort to operate the Institute as effectively and as efficiently as possible and in full compliance with the law. As a state agency, we are not only committed to our scientific mission to advance stem cell science to therapies, we are also committed to earning the trust of the public as responsible stewards of the state's funds. In this regard, the audit report has been helpful and has made us a stronger agency.

We respond below to each of the recommendations offered in your report.

Chapter 1.

Recommendation:
The institute should develop a process to track management information reported annually by grantees, thereby providing accountability and enabling the institute to assess its annual progress in meeting its strategic goals.

CIRM agrees with this recommendation. To assess progress toward fulfillment of our strategic plan and to assure accountability, we will need to have a system to accumulate and organize information about the research that we have funded. We are currently in the process of developing procedures to track scientific advances and progress generated by grantees through a variety of venues including an annual scientific meeting for CIRM grantees, at which they will report progress that they have made, a required annual report on scientific achievements such as publications, citations, and presentations made at national and international meetings and on-site visits and audits of individual laboratories by CIRM staff. We will also develop a process for organizing this information in ways that will allow us to chart our progress against the goals of the scientific strategic plan. These results will be reported annually to the Grants Working Group, to our board (ICOC), and to the public.

Chapter 2.

Recommendation:
The committee should ensure that it follows through with its plan to identify the appropriate standard for providing uninsured Californians access to therapies developed using institute funds and clearly convey to grantees its expectations for providing access to its intellectual property policies. In addition, the committee should identify practical benchmarks to use as a standard for discount prices for therapies and apply the standard to its policies for grants to both nonprofit and for-profit organizations.

We agree and have undertaken the processes required to follow through on this recommendation. CIRM policies require that for-profit licensees of CIRM-funded patented inventions and for-profit grantees provide plans for access to therapies for uninsured Californian residents as well as discounted therapies for Californian residents whose therapies will be purchased in California with public funds. At the December 6, 2006 ICOC meeting, we were specifically requested to provide more precise language regarding the access plan requirement as clear guidance to grantees. As a result of this request, the ICOC agreed to include a clarifying statement in the policy that will require regulated parties to comply with existing industry standards for access provisions at the time of commercialization of the product. CIRM subsequently received valuable input from legislative staff suggesting that a survey be conducted to outline industry standards prior to commercialization of a product that results from CIRM funding.

CIRM agrees that a practical benchmark for discount therapies is very important. At the December 6, 2006 ICOC meeting, the ICOC directed CIRM staff to identify appropriate low cost benchmarks for the provision of therapies by the regulated community to residents of California whose therapies will be purchased with public funds. These efforts are currently underway, and include consultations with a wide variety of interested parties.

Recommendation:
The committee should monitor the effectiveness of its policy to make institute-funded patented inventions readily accessible on reasonable terms to other grantee organizations for noncommercial purposes to ensure that it does not inhibit the advance of stem cell research.

We agree to monitor the effectiveness of our policy to make CIRM-funded patented inventions readily accessible on reasonable terms to other grantee organizations in the interest of promoting stem cell research in California. We are committed to modifying CIRM regulations in the event that the intent of the policies is not realized. CIRM will closely monitor activities involving CIRM-funded patented inventions via annual reporting requirements and appropriate evaluation to ensure that the public benefit of CIRM-funded inventions is maximized.

Recommendation:
The institute should complete the development of its grants administration policy targeted toward for-profit organizations.

CIRM agrees and began drafting that policy in December, 2006. We anticipate presenting a draft to the Scientific and Medical Research Funding Grants Working Group (Grants Working Group) for review and comments in May, 2007. The Grants Working Group's comment and recommendation will be presented to the ICOC for its consideration later in the year.

Recommendation:
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.

We agree with the recommendation and have already adopted and implemented new procedures. In this case, we are particularly grateful to the auditors who identified a problem that we were unaware of, and we have moved quickly to rectify it. We have now adopted new procedures to record the votes of each member of the Working Group for each application for which they do not have a conflict of interest. These procedures were followed both at the Grants Review Working Group meeting on November 28-30 to review SEED grant applications and at the meeting on January 8-10 for the Comprehensive Research grant applications. The procedures worked very well; the records from these meetings will be available for future audit.

Recommendation
To effectively monitor the performance of grantees, the institute should complete the implementation of a grants monitoring process, including audits, and the development of related procedures.

We agree completely. The Institute has long planned to have a grants monitoring process that would include financial audit, as well as adherence to CIRM Grants Administration Policy. Because of limited personnel, we will explore the feasibility of engaging the help of other state agencies in refining the design and implementation of this process.

Recommendation:
The institute should seek a formal opinion form the attorney general regarding whether the exemptions created for working groups from conflict-interest laws are intended to exempt them from the conflict-of-interest provisions that apply if the recommendations of an advisory body are routinely and regularly adopted by the decision-making body to whom they are made.

CIRM is committed to ensuring that the evaluation of grant applications is free from both real and apparent conflicts of interest. For this reason, the ICOC has adopted conflict of interest policies for members of the working groups that go beyond the requirements of the Political Reform Act ("PRA"). As the audit notes, however, CIRM disagrees with the FPPC's opinion that members of CIRM's working groups might be subject to the PRA at some point in the future.

Although we believe that Proposition 71 clearly exempts the working groups from the Political Reform Act, we understand the merits of seeking an opinion from the office of the Attorney General and we will seriously consider the recommendation to do so. But for the record, it is important to consider what is not in dispute

First, even under the FPPC's interpretation of the law, the members of CIRM's working groups are not currently subject to the PRA's economic disclosure and disqualification requirements. As the Alameda County Superior Court found, the ICOC made significant changes to the Grants Working Group's recommendations regarding the training grants. The ICOC, the Court concluded, is the ultimate decision-making body, not the Grants Working Group. Second, as required by Proposition 71, the members of CIRM's working groups are currently bound by conflict of interest rules adopted by the ICOC. These rules, which are modeled on the National Institutes of Health and National Academies of Science's conflict provisions, require disclosure and disqualification, but unlike the Political Reform Act, they also extend to "personal" and "professional" conflicts of interest. Because the FPPC's opinion may lead to the erroneous belief that working group members are not currently subject to conflict of interest rules, or that the PRA's provisions are stronger than those adopted by the ICOC, we believe a brief discussion of the law and the ICOC's policies and regulations is warranted.

Health and Safety Code section 125290.50, enacted by Proposition 71, requires the ICOC to adopt conflict of interest rules for the working groups based on standards applicable to members of scientific review committees of the National Institutes of Health ("NIH") and to appoint an ethics officer from among the staff of the institute. Importantly, it also exempts members of the working groups from the PRA and other Government Code provisions:

> "(3) Because the working groups are purely advisory and have no final decisionmaking authority, members of the working groups shall not be considered public officials, employees, or consultants for purposes of the Political Reform Act (Title 9 (commencing with Section 81000) of the Government Code), Sections 1090 and 19990 of the Government Code, and Sections 10516 and 10517 of the Public Contract Code."

These provisions establish a regime by which the members of the working groups are covered by conflict of interest rules based on the NIH standards as opposed to the PRA. This makes sense for two reasons: First, the working groups are closest to the peer review committees of the National Institute for Health; no similar body exists under state law. Thus, it is logical to look to federal conflict of interest policies as the model for CIRM's working groups. Second, the PRA would impose narrower conflict of interest rules on the working groups and it would impose such rules *only* after certain requirements are satisfied, i.e., if a working group makes substantive recommendations that are, and over an extended period of time have been, regularly approved without significant amendment or modification by the ICOC (FPPC Regulation 18701). If these conditions were never met, the working groups would not be subject to PRA conflict of interest rules. Furthermore, because FPPC Regulation 18701 requires an analysis of past conduct, it necessarily draws a line that is visible only *after* it is crossed.

Section 125290.50 avoids this uncertainty by declaring that the working groups are advisory, exempting them from the PRA, and by imposing separate and more extensive conflict of interest rules on working group members. In so doing, this section ensures that conflict of interest disclosure and disqualification rules are in place from the outset of working groups' work.

As stated in the audit report, the success of the CIRM research program and its ability to maintain the confidence of the people of California depends critically upon the agency's ability to fund the highest quality research proposals, chosen without bias. Strong CIRM conflict of interest policies are therefore essential. Thus, the ICOC adopted conflict of interest policies in 2005 to apply to each working group. These rules were inspired by policies of the National Institutes of Health, as required by Health and Safety Code section 125290.50, subdivision (e)(1). The ICOC did not stop there - the ICOC has taken the unprecedented step of codifying these policies in regulations. Unlike the Political Reform Act, these regulations encompass not only *financial* sources of conflicts but also address professional and personal sources. Thus, the working groups, under Proposition 71 and the policies and regulations adopted by the ICOC, are subject to more stringent rules than non-advisory public officials under the Political Reform Act.

Moreover, the members of the two grants working groups, research and facilities, undergo a pre- and post-award review of their required disclosures and the potential sources of conflict, and attest under penalty of perjury that they have not participated in review of any application for which they might have a conflict of interest. This is not required of any public official under the PRA.

CIRM will maintain appropriate records of the disclosures and participation of working group members to make them available for audit AND will report to the Legislature any violations of the rules AND describe corrective actions taken to prevent future occurrences. Neither the report nor corrective action is required under the Political Reform Act.

These regulations strike the proper balance between the privacy of volunteer advisory body members and the public's desire for information about the individuals. The review by staff and independent auditors, and the records that substantiate those reviews, ensure that the utmost vigilance will be maintained to ensure the integrity of the working groups' efforts. As a result, the Institute has in place conflict of interest regulations and policies that are stronger than either the PRA or NIH standards.

Recommendation:
In addition, 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.

We agree completely with the recommendation. While as a matter of practice the institute has always treated specialists in the same manner as other members of the working group in requiring them to follow the disclosure and disqualification rules of the working group, their omission in the written policy was an inadvertent error that we have quickly moved to clarify. Consideration of this matter is on the agenda for the ICOC meeting of February 15-16, 2007.

Recommendation:
To provide employees with the information they need to disclose all potential conflicts of interest, the institute should develop the necessary procedures to ensure that its employees are aware of the companies that apply for funding.

We agree and will certainly develop procedures that will help our employees identify and disclose any conflict of interest with a company. We have not yet done this because we are not yet currently accepting applications from for-profit entities, but will certainly do this in the near future before we begin to accept applications from for-profit entities for funding.

Recommendation:
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.

We agree on both counts. To be clear, the institute has always reviewed the disclosure statements of its non-ICOC working group members, who are not subject to the Political Reform Act, as a backup to the working group member's own screening to identify potential conflicts of interest. This was not done on behalf of the ICOC members of the working group, who are subject to the Political Reform Act which places the burden on the public official, not his or her agency, to identify potential conflicts of interest. Nevertheless, the procedures were revised and followed in the recent grant review meetings in November of 2006 and January of this year to include a back-up review of all working group members, including ICOC members, to screen for potential conflicts of interest.

In addition, the Institute has refined its documentation policies to ensure that, in addition to the documentation retained to show recusals of working group members on individual grant applications, which the institute maintains in its files, the Institute shall also ensure that documentation of the working group's final recommendation vote to the ICOC is maintained, as well. The records with respect to the November 2006 and January 2007 meetings are complete in this respect.

Chapter 3.

Recommendation
The institute should ensure that it follows its newly revised policies, which address some of the concerns raised in our audit. The institute should also further amend its policies to include the rest of the concerns that we have raised.

CIRM would like to take this opportunity to thank the auditors for confirming that the ICOC at its December 2006 meeting took positive steps forward by approving a new contracting policy that not only strengthen the internal controls for the institute but "addressed our [auditors] contracting concerns." At that same meeting the ICOC approved new travel policies that strengthened the internal controls for CIRM staff and working group members. At the direction of the ICOC, we have implemented these new policies and are committed to ensure compliance by developing internal procedure manuals for CIRM staff.

Those concerns are as follows:

- *Although the institute now monitors staff members that attend its meetings, the institute should implement a pre-approval requirement for travelers that want to claim meals separately from the contracted meals provided by the institute.*

We agree and will include this practice in our new internal procedures manual on travel. It is our intention to allow for reimbursement of meals separate from the contract meals provided by the institute on an exception basis only.

- *The institute should revise its travel reimbursement claims form for working groups and require sufficient information that would allow an adequate review of the amounts claimed.*

We will use the same form for travel reimbursements for working group member as we do for staff and ICOC members. We will implement this new practice immediately.

- *The committee should adopt the same 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.*

We agree with the recommendation, and, as noted in the audit report, the ICOC intends to consider amendments to the travel reimbursement policy for members to clarify and enhance the policy and to ensure that only reasonable and necessary expenses are reimbursed.

Recommendation
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.

We agree and expect to issue a Request for Proposal shortly that seeks a highly qualified firm to assist with this effort.

Under the limitations of Proposition 71, CIRM will never have a large operating budget nor a large staff. To achieve its mission, the agency must be managed as efficiently and effectively as possible. It is equally important for 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 audit report will help us achieve both objectives. Again, please extend our appreciation to your staff for their thoughtful and thorough professionalism.

Sincerely,

(Signed by: Zach W. Hall)

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

(Signed by: Robert Klein)

Robert Klein
Chair, ICOC

cc: Members of the Legislature
Office of the Lieutenant Governor
Milton Marks Commission on California State Government Organization and Economy
Department of Finance
Attorney General
State Controller
State Treasurer
Legislative Analyst
Senate Office of Research
California Research Bureau
Capitol Press

12

CIRM ONE-YEAR RESPONSE TO BSA AUDIT

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February 26, 2008

BY FEDEX AND ELECTRONIC MAIL

Ms. Elaine M. Howle
California State Auditor
Bureau of State Audits
555 Capital Mall, Suite 300
Sacramento, CA 95814
[illegible]

Dear Ms. Howle:

We are pleased to submit our one year response outlining our efforts to implement the recommendations your office made in its February 2007 report, "California Institute of Regenerative Medicine: It Has a Strategic Plan, but It Needs to Finish Developing Grant-Related Policies and Continue Strengthening Management Controls to Ensure Policy Compliance and Cost Containment."

When the audit began, the agency had been in operation barely 18 months, had a staff of just 20, and was hindered in its growth and in its mission by litigation challenging Proposition 71. A year after publication of the audit, CIRM has been operating for three years, the litigation has fully and finally resolved in CIRM's favor, the first issue of $250 million in general obligation bonds has been sold, staff has increased to 28 full time equivalent, and all the recommendations of your report have been implemented or otherwise resolved.

We want to thank you and your fine staff again for the care and effort that went into preparation of the audit and in the way staff has continued to work with us over the past year. The audit process made a useful and important contribution to our effort to operate the Institute effectively and efficiently in the service of our mission, and in full compliance with state law. As a young state agency, we are still establishing and refining key procedures and policies. The audit process has provided us a framework in which to

consider new issues as they arise. We recognize that to effectively serve our scientific mission to advance stem cell science to therapies, we must build public trust in our ability to be responsible stewards of public funds.

Chapter 1: ***The California Institute for Regenerative Medicine Developed a Detailed Strategic Plan to Guide its Use of Funds***

Recommendation:
To provide accountability and assess annual progress in meeting its strategic goals and initiatives, the institute should fulfill its plans to develop a process to track management information reported annually by grantees.

CIRM agreed with this recommendation and has implemented three processes for tracking information to assess progress in meeting our strategic goals: a comprehensive computerized grants management system, annual progress reporting requirements that will be incorporated into that system, and annual meetings for CIRM grantees.

You will recall that our initial effort to create a comprehensive grants management system suffered a set-back when the vendor encountered serious financial difficulties, leaving CIRM without a work product. We learned from that experience and conducted a comprehensive bidding process to select a new vendor. First, we carefully defined our functional requirements, including those for scientific information capture, tracking and management reporting. When fully configured, the system will allow the following: "tagging," to allow Institute staff to tie an RFA to specific goals in the Strategic Plan; the ability to track outcomes of CIRM-funded scientific research, such as publications, patent applications and awards, Investigational New Drug applications, and license agreements; and the ability to code grants to categories such as disease focus, type of research and stage of research.

On May 25, 2007, we issued a detailed Request for Proposals (RFP) that requested responses based on a pay for performance schedule. Five firms submitted responsive proposals. (An electronic copy of the RFP is attached.) These were scored by a team of staff and invited experts, based on criteria stated in the RFP. Based on the scoring, during the summer of 2007 CIRM invited three firms to respond to specific questions, and to make a four-hour presentation to staff to highlight the attributes of their proposed systems. In October 2007, CIRM's governing board, the Independent Citizens Oversight Committee (ICOC), approved Institute staff's recommendation and awarded the contract to Grantium. (The agenda item for this approval and links to the corresponding documentation presented to the ICOC can be found at http://www.cirm.ca.gov/meetings/2007/10-05-07.asp.) Since that time, we have been negotiating the precise terms of the contract, to insure that we achieve a true pay for performance standard. We hope to execute that contract next month.

Under the terms of the CIRM Grants Administration Policy, all recipients of CIRM research grants must submit annual progress reports; recipients of facilities grants must submit quarterly reports. These progress reports will be a crucial part of our management reporting system and of our grants management system. (CIRM's Grants Administration Policies can be found at http://www.cirm.ca.gov/policies/grp.)

In addition, in September 2007 CIRM held its first annual meetings for CIRM scholars, who were the first recipients of CIRM grants -- the Training Grants, which were awarded and funded in 2006 – and the only grantees who have had funding for a full year. CIRM held two meetings, one in Northern California and another in Southern California, to provide the trainees the opportunity to present preliminary data, engage in scientific discussion, and exchange ideas. Both meetings included three basic elements: short oral presentations from one trainee per institution funded; a two-hour poster session during which all trainees were encouraged to display and discuss their research with others one-on-one; and a session during which trainees led and participated in discussion groups on topics of interest including Stem Cell Self-Renewal and pluripotency, Translational Challenges, and Career Transitions. In preparation for the meetings CIRM published a compendium of the 115 abstracts submitted by the trainees. (This compendium can be found at http://www.cirm.ca.gov/pub/pdf/annualtmtg.pdf.)

In the fall of 2007, CIRM also published a booklet titled *Awards and Applications Approved for Funding 2007* which included abstracts of all applications approved for funding and that cleared administrative review through CIRM's first four Requests for Applications (RFAs): the CIRM Training Program (RFA 05-01), which in 2006 funded 16 of 26 applications received; the Leon J. Thal SEED Grant Program (RFA 06-01), which in 2007 funded 73 of 231 applications received; the Comprehensive Research Grants Program (RFA 06-02), which in 2007 funded 28 of 70 applications received; and the Shared Research Laboratory and Stem Cell Techniques Program (RFA 07-01), which funded 17 of 22 applications received for shared labs, and six of nine applications received for stem cell techniques courses. (A copy of this booklet can be found at http://www.cirm.ca.gov/pub/pdf/Compendium.pdf.)

Responsible Staff: Patricia Olson, Director of Scientific Activities; Ed Dorrington, Director of Grants Management Systems.

Chapter 2: *Some Key Tasks Remain for the California Institute for Regenerative Medicine in Developing and Strengthening Grant-Related Policies and Controls.*

Recommendation:
The committee should ensure that it follows through with its plan to identify the appropriate standard for providing uninsured Californians access to therapies developed

using institute funds and to convey clearly to grantees its expectations for providing access in its intellectual property policies. In addition, the committee should identify practical benchmarks to use as a standard for discount prices for therapies and apply the standard to its policies for grants to nonprofit and for-profit organizations.

CIRM agreed with this recommendation and has implemented it. In connection with development of its intellectual property policies for non-profit organizations, beginning prior to the audit and thereafter CIRM held a series of public meetings to discuss ways to identify benchmarks for discount prices for uninsured California patients and those whose drugs and non-drug therapies may be purchased with public funds.

On July 14, 2007, CIRM's Intellectual Property Policies for Non-profit and Academic Institutions became final and codified at Title 17, California Code of Regulations sections 100301-100310. Section 100306(d) provides in pertinent part that CIRM grantees may grant exclusive licenses "only to persons that agree to have a plan in place at the time of commercialization to provide access to resultant therapies and diagnostics for uninsured California patients. In addition, such licensees will agree to provide drugs at prices negotiated pursuant to the California Discount prescription Drug Program (commencing with California Health & Safety Code section 130500, et seq.) to eligible Californians under that program." In addition, these regulations require annual reporting to CIRM regarding any such licensing activity, so that CIRM can monitor performance. (The intellectual property regulations applicable to non-profit and academic institutions can be found at http://www.cirm.ca.gov/reg/pdf/IP_Regs_100300.pdf.)

In March 2007, the ICOC initiated the administrative law process for adoption of Intellectual Property Policies for For-Profit Organizations. These draft regulations have completed several rounds of public comment and include similar, but more specific requirements for access and discount pricing. These can be found in draft regulation for Title 17, California Code of Regulations section 100407 Access Requirements for Products Developed by For-Profit Awardees. The final regulations have been adopted by the ICOC and are awaiting final approval by the Office of Administrative Law (OAL). (The intellectual property regulations applicable to for-profit organizations can be found at http://www.cirm.ca.gov/reg/pdf/IP_CompRegs.pdf.)

The for-profit regulations execute a three-pronged policy with respect to access and pricing. First, at the time of commercialization, they require grantees to develop and provide a plan for access by uninsured Californians. Second, the regulations require that CIRM-funded therapies be available according to CalRX benchmarks to institutions purchasing such therapies with public funds. Third, the regulations anticipate state efforts to offer a discount prescription drug program to underinsured Californians, and require grantees to participate in this type of program.

Once the for-profit regulations have been approved by OAL (forecast for March 2008), the Institute intends to propose to the ICOC modifications to the non-profit regulations where appropriate to harmonize them with the more specific requirements contained in the for-profit regulations.

Responsible Staff: C. Scott Tocher, Interim Associate Legal Counsel to the Vice Chair

Recommendation:
The committee should monitor the effectiveness of its policy to make institute-funded patented inventions readily accessible on reasonable terms to other grantee organizations for noncommercial purposes to ensure that it does not inhibit the advance of stem cell research.

CIRM agreed with this recommendation and has implemented it. Scientific advances depend on the ability of researchers to replicate and extend the results of prior research findings, and access to materials described in scientific publications facilitates this process. Indeed, it is customary for scientists to share materials described in their published research, and some journals require it as a condition of publication. Similarly, the intent of CIRM's regulations is to promote rapid advancement of the field. These regulations require CIRM grantees to give other researchers access to biomedical materials discussed in published research, at cost, for non-commercial purposes. See Title 17 California Code of Regulations section 100304, and draft regulation 100404. CIRM monitors compliance with these regulations by requiring grantees to submit annual progress reports that identify publications and licensed patented inventions, as well as any requests for access by other scientists for non-commercial research purposes.

Responsible Staff: C. Scott Tocher, Interim Associate Legal Counsel to the Vice Chair

Recommendation:
The institute should complete the development of its grants administration policy targeted toward for-profit organizations.

CIRM agreed with this recommendation and has implemented it. Following a series of interested persons meetings held by Institute staff in the fall of 2007, the ICOC adopted an Interim Grants Administration Policy for For-Profit Organizations on December 12, 2007. These regulations are now beginning the administrative law process. As a result of the adoption of these interim regulations, CIRM opened its two most recent RFAs – the New Cell Lines Awards (RFA 07-05) and the Disease Team Planning Awards (RFA 07-04) – to for-profit organizations. (The for-profit GAP can be found at http://www.cirm.ca.gov/reg/pdf/Reg100501_ICO.pdf.)

Responsible Staff: Patricia Olson, Director of Scientific Activities

Recommendation:
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 agreed with this recommendation, implemented the recommendations of your staff before issuance of the audit, and has continued to maintain those records. In 2006, CIRM adopted new procedures to record the votes of each member of the Grants Working Group participating in a given meeting, and to identify members recused from discussing or voting on applications under consideration due to potential conflicts of interest. At every Grants Working Group meeting held since November 2006 each participating member signed a statement that documents their voting record and recusal record at those meetings. In addition, CIRM staff records the member's participation and presence inside and outside the meeting room for discussion of particular applications, and maintains these records. CIRM retains these records as part of its documentation of the grant award process. The names of working group members recused from discussion are provided to the ICOC before their vote on grant funding, are publicly disclosed in the summary reviews of each application (which are available on our Web site), and are part of the public record. We have also implemented similar procedures for the confidential scoring of the Facilities Working Group.

Responsible Staff: Gilberto Sambrano, Senior Officer to the Grants Working Group; Tamar Pachter, General Counsel

Recommendation
To monitor the performance of grantees effectively, the institute should complete the implementation of a grants monitoring process, including audits, and the development of related procedures.

CIRM agreed with this recommendation and has implemented it. CIRM takes very seriously its obligation to monitor the performance of its grantees. As part of the grants monitoring process, CIRM conducts a complete administrative review prior to issuing formal Notices of Grant Award and before funds are released. CIRM also has written procedures for the process of that review, and for auditing of that process. In addition to its other capabilities, the new grants management system will allow CIRM to track grantees to make sure they have certified current compliance with ethical review and notification requirements for funded research. For facilities grants (including the approved shared laboratories grants and major facilities grants that are expected to be approved in May 2008) CIRM has developed a set of performance milestones that require review throughout the life of the grants. (An electronic copy of the administrative review procedures is attached.)

CIRM has also designed an audit process with spot checks to ensure that grantees comply with required medical and ethical standards. A similar audit process with spot checks is being designed for financial compliance, and is expected to be in place by summer of 2008, when research grantees will have completed the first year of funding. (An electronic copy of the procedures for standards audit is attached.)

In addition, CIRM has added special provisions to the Grants Administration Policy for Non-Profit and Academic Institutions that govern facilities grants, specifically the Shared Laboratory Program and the Major Facilities Program. These additions establish criteria and benchmarks specific to the demands of capital grant programs. (These amendments to the Grants Administration Policy can be found at
http://www.cirm.ca.gov/reg/pdf/FinAP_policy.pdf and
http://www.cirm.ca.gov/reg/pdf/Reg100701_MFOAP.pdf.)

Responsible Staff: Patricia Olson, Director of Scientific Activities; Amy Lewis, Grants Management Officer; Rick Keller, Senior Officer to the Facilities Working Group; Geoff Lomax, Senior Officer to the Standards Working Group

Recommendation:
The institute should seek a formal opinion from the attorney general regarding whether the exemptions created for working groups from conflict-interest laws are intended to exempt them from the conflict-of-interest provisions that apply if the recommendations of an advisory body are routinely and regularly adopted by the decision-making body to whom they are made.

We have given careful consideration to your recommendation and have decided that the concerns raised have been fully resolved by subsequent events and court decisions. First, as you noted in the audit report at page 47: "As of December 2006, it was too early to assess whether the working groups will make recommendations on grant funding or other substantive recommendations that the committee will accept without significant amendment or modification . . . ." We now have a record of more than three years of operation and approval of five rounds of grants, in which the recommendations of the CIRM working groups have never been routinely and/or regularly adopted by the ICOC.

Second, you noted in the audit report at page 48 that the Superior Court's legal conclusion that the ICOC, not the working groups, is the "ultimate decision-making body" for CIRM was not binding because, at that time, the case was pending on appeal. Since then, however, the Court of Appeal affirmed the decision of the Superior Court, and the decision became binding on May 16, 2007, when the Supreme Court denied review. In its opinion, the Court of Appeals expressly affirmed the Superior Court's conclusion that the ICOC, not the working groups, exercises all decision-making authority. (See *California Bioethics Council v. California Institute for Regenerative*

Medicine (2007)147 Cal.App.4th 1319, 1364; an electronic copy of the Court of Appeals opinion is attached.)

CIRM now has an authoritative, binding legal ruling that as a matter of law, the working groups do not exercise decision making authority. We hope that your counsel will agree that no opinion of the attorney general could provide greater authority or confidence on this point, and therefore there is no longer any reason to request it.

Responsible Staff: Tamar Pachter, General Counsel

Recommendation:
[T]he institute should follow its plans to amend its conflict-of-interest policies to include specialists invited to participate in stem cell research program activities, such as grant application review.

CIRM agreed with this recommendation, has interpreted its policies to include specialists, and has implemented the recommendation. In March 2007, the ICOC amended the conflict of interest policy for the Grants Working Group to specifically include specialists. (The amended conflict of interest policy can be found at http://www.cirm.ca.gov/meetings/pdf/2007/021507/item_1c.pdf.)

Responsible Staff: Gilberto Sambrano, Senior Officer to the Grants Working Group; Tamar Pachter, General Counsel

Recommendation:
To provide employees with the information they need to disclose all potential conflicts of interest, the institute should develop the necessary procedures to ensure that its employees are aware of the companies that apply for funding.

CIRM agreed with this recommendation and has implemented it. At the time of our earlier responses, CIRM had not yet opened any RFA to for-profit organizations. The first two RFAs open to for-profit organizations were RFA 07-05, the New Cell Lines Awards and RFA 07-04, the Disease Team Planning Awards. There are two processes in place to ensure that employees are aware of for-profit companies that apply for CIRM funding.

These two RFAs required all applicants to submit Letters of Intent (LOIs) by a deadline prior to the application deadline. Once CIRM received these LOIs, General Counsel requested a list of the for-profit applicants from the Science Office. At a staff meeting held the week after the LOI deadline, General Counsel reminded all employees of the divestiture provisions in the Conflict of Interest Policy for CIRM Employees, and followed up by sending an email to all employees with the list of for-profit organizations that submitted LOIs in response to these RFAs. (An electronic copy of this email is

attached.) This procedure will be followed with all future RFAs open to for-profit organizations.

In addition, the agency has in place a conflict of interest procedure that follows receipt of actual applications. Specifically, CIRM employees must review a list of all entities that have applied for funding pursuant to a particular RFA, note any conflicts, and sign the result. Employees are then disqualified from participating in the review of applications as to which they have identified a conflict. They are not given access to any such applications, and they must leave the room during review of any such application.

Responsible Staff: Gilberto Sambrano, Senior Officer to the Grants Working Group; Tamar Pachter, General Counsel

Recommendation:
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.

CIRM agreed with this recommendation and has implemented it. Since November 2006, staff has performed a back-up review of all working group members, including ICOC members, by reviewing their pre-meeting disclosures against their Statements of Economic Interests. In addition, as specifically noted above, since November 2006, CIRM staff has documented actual disqualification actions at meetings of the Grants Working Group and all working groups, and maintains these records.

Responsible Staff: Gilberto Sambrano, Senior Officer to the Grants Working Group; Tamar Pachter, General Counsel

Chapter 3: *To Improve Cost Containment, the California Institute for Regenerative Medicine Modified its Contracting and Travel Policies and Plans to Conduct Another Salary Survey, but It Needs to Do More.*

Recommendation
The institute should ensure that it follows its newly revised policies, which address some of the concerns raised in our audit. The institute also should amend its policies further to include the rest of the concerns that we have raised.

Although the institute now monitors staff members who attend its meetings, it should implement a preapproval requirement for travelers that want to claim meals separately.

CIRM agreed with this recommendation and has implemented it. Under CIRM's Travel Policy and Business Meeting Expenditure Policy and practice, employees are not reimbursed for meals at meetings where meals are provided without prior authorization. CIRM continues to monitor the travel claims of staff who attend meetings to insure that reimbursement is not claimed when CIRM provides a meal. (The Travel Policy and Business Meeting Expenditure Policy adopted by the ICOC at its January 2008 meeting can be found at http://www.cirm.ca.gov/files/pdf/Travel%20policy.pdf and http://www.cirm.ca.gov/files/pdf/Business%20Meeting%20Policy.pdf.)

Responsible Staff: Richard Murphy, Interim President; Alan Trounson, President

Recommendation
The institute should revise its travel reimbursement claims form for working groups to require sufficient information that would allow an adequate review of the amounts claimed.

CIRM agreed with this recommendation and has implemented it. Since March 1, 2007, members of CIRM working groups have submitted all travel reimbursement claims on the standard state travel claim form (STD 262). CIRM reviews and allows these claims pursuant to the same policy and procedure applicable to CIRM employees.

Responsible Staff: Richard Murphy, Interim President; Alan Trounson, President

Recommendation
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.

CIRM agreed with this recommendation and has implemented it. At its January 17, 2008 meeting the ICOC amended the Travel Policy previously adopted for CIRM employees and working group members (and observed by the ICOC) to apply to members of the ICOC. Under this policy, ICOC members are governed by the same rules applicable to employees, working group members, and indeed, anyone filing a travel claim with CIRM. Other amendments adopted at the January meeting were designed to align CIRM policy more closely to that of the Regents; deviations from the policy of the Regents were adopted where Regents policy did not address the requirements of CIRM's mission, or did not make sense in the context of CIRM's organization. (The CIRM Travel Policy can be found at http://www.cirm.ca.gov/files/pdf/Travel%20policy.pdf.)

Responsible Party: Robert Klein, ICOC Chairman; Richard Murphy, Interim President; Alan Trounson, President

Recommendation
To ensure that the methodology to set salary ranges complies with the act, the institute should follow through with its plan to resurvey any positions whose salary ranges were affected by the errors, omissions, and inconsistencies in its initial salary survey and salary-setting activities.

CIRM agreed with this recommendation and has implemented it. CIRM issued an RFP to contract with an experienced firm for the review and survey of all budgeted CIRM positions, including those about which your report expressed concerns. CIRM received two responsive bids and signed a contract with Mercer Human Resources Consulting on April 30, 2007. In addition, based on the requirements of Proposition 71, CIRM has documented its salary administration philosophy and practice. Under its Total Compensation Philosophy, adopted in January 2008, CIRM will target base pay at the 80th percentile of relevant market data. (The Compensation Philosophy can be found at http://www.cirm.ca.gov/meeting/pdf/2008/022008/item 3b.pdf.)

Mercer delivered its final report to CIRM on January 14, 2008. (The Mercer report, including a list of the participating organizations, cane be found at http://www.cirm.ca.gov/meeting/pdf/2008/022008/item 3a.pdf.)

It is important to note that since your audit report was published, the Institute has significantly changed its staffing model and in the process eliminated positions that were among the eleven you thought required a new survey. In addition, our review of functional needs have suggested that some blending and integrating of responsibilities would allow for the most robust and efficient use of our limited staff resources. As a result, CIRM has several hybrid positions that encompass responsibilities that cross multiple positions at other institutions. (CIRM's current Organization Chart can be found at http://www.cirm.ca.gov/meeting/pdf/2007/121207/item [illegible].) The Mercer report nevertheless surveyed those positions, and includes information about new positions that were created during data gathering, but does not include data for new positions created after Mercer's data gathering process closed. A list of surveyed positions is in the Mercer report.

In addition, the Institute has updated its job descriptions to improve accuracy and consistency. CIRM is in the process of evaluating Mercer's data to ensure that the job descriptors used were accurate based on current expectations.

Based on Mercer's data, the positions of Executive Assistant to the ICOC Chair and Senior Executive Assistant to the President are the only positions about which your report expressed concerns for which salary exceeds the 75th percentile reported. In addition, there are two other positions not mentioned in your report, Director of Grants Management Systems and Grants Management Specialist II that were surveyed, for which salaries exceed the 75th percentile (for historical reasons or because it was

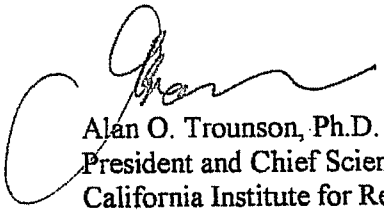
necessary to successfully recruit). Under Mercer's methodology, there was insufficient data reported to allow it to calculate the 80th percentile. CIRM is comparing actual job descriptions and responsibilities with the survey job descriptors to ensure they were benchmarked against proper criteria.

CIRM staff plans to discuss the Mercer survey with the ICOC at its March 2008 meeting, and at that time to propose any changes to salary ranges indicated by the survey report, in keeping with CIRM's Compensation Philosophy. (A list of CIRM's current salary ranges can be found at http://www.cirm.ca.gov/jobs/pdf/Salary_Structure.pdf.) Where there is insufficient data available from UC and private research institutions, CIRM will use relevant general market data if available from established salary surveys, giving emphasis to non-profits and/or California health science organizations to establish an appropriate metric.

Responsible Staff: Alexandra Campe, Human Resources Officer

We are very pleased to be able to report full implementation of your recommendations. Again, we very much appreciate the diligence and professionalism your staff has demonstrated and continues to demonstrate throughout this process, the contributions they have made to improving the processes of the agency, and to ensuring that Californians can have full confidence in the integrity of the processes that we use to commit public funds to stem cell research. We at CIRM are confident that your input has significantly improved important operational components of the Institute, and for that we thank you.

Sincerely,



Alan O. Trounson, Ph.D.
President and Chief Scientific Officer
California Institute for Regenerative Medicine