

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

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California Institute for Regenerative Medicine's response as of September and December 2007

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. To oversee the institute's operations, the act established the Independent Citizens Oversight Committee (committee).

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. In addition, the audit committee asked us to review and evaluate certain institute policies and procedures and related management controls to determine whether they are necessary and designed to carry out the intent of the act as well as other applicable laws and regulations, and to review the internal oversight structure of the institute and the committee.

Finding #1: The institute has developed a detailed strategic plan but lacks a process to use annual grantee data as a strategic monitoring tool.

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 revealed that the institute's strategic plan contains essential elements, 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. Our review also concluded that the institute's strategic plan clearly identifies its approach to achieving the scientific goals through 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.

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.*
- » *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.*

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 institute's 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.

We recommended that the institute fulfill its plans to develop a process to track management information reported annually by grantees, thereby providing accountability and enabling it to assess annual progress in meeting its strategic goals and initiatives.

Institute's Action: Partial corrective action taken.

At the October 3, 2007, committee meeting, the institute presented the grants management system software and services provider recommended by institute staff and the process staff used to select the provider. The committee granted the institute approval to contract with the provider for a grants management system.

Finding #2: The committee has not completed provisions of its intellectual property policies regarding discounted prices and access to therapies.

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, but because the committee did not want to delay implementing its regulations regarding intellectual property developed for grants to nonprofit organizations, it took no action to amend the policy and regulations.

In addition, 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 expectation for access. According to the transcripts of the December 2006 committee meeting, the task force established by the committee to create the policies 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. Without a clear definition or expectation of access, however, grantee organizations will be left to apply their own interpretations.

Further, the intellectual property policies for nonprofit entities and for-profit entities do not describe how prices will be discounted for therapies that result from institute-funded research. 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 entities 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 discounted prices for therapies resulting from institute-funded research to the policies for both nonprofit and for-profit organizations.

We recommended that the committee 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.

Institute's Action: Partial corrective action taken.

The institute reports that it remains committed to ensuring that therapies developed through institute-funded research projects are accessible to uninsured patients and discounted prices for California patients whose drugs and non-drug therapies are purchased with public funds. The institute states that it held public meetings to allow interested parties to review and consider relevant regulatory issues and standards in both issues and is continuing to develop the appropriate regulations governing both nonprofit and for-profit grantees.

Finding #3: A provision of the institute's intellectual property policy allowing researchers access to institute-funded inventions warrants further attention.

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 meeting of the task force after some members expressed concern over industry opposition to the research exemption provision. The committee's 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.

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 had been a problem. However, the new language of the research exemption still received considerable objection from industry representatives. As a consequence, the task force agreed on compromise language. The compromise language 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 such inventions readily available on reasonable terms to other grantee organizations for noncommercial purposes. Although concerns were raised over whether including the phrase "reasonable terms" was good regulatory language and over who would decide what are reasonable terms, the task force adopted the language. Although the effect of the language on advancing stem cell research is not yet known, we believe that this area warrants continued monitoring by the committee.

We recommended that the committee 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.

Institute's Action: Pending.

As part of its grants management process, the institute states that it will monitor compliance with its regulations regarding access to institute-funded patented inventions by requiring grantees to submit annual reports that identify licensed patented inventions, as well as any requests for access by other scientists for noncommercial research purposes.

Finding #4: The institute is still developing a policy for administering grants to for-profit entities.

Although the committee has adopted a policy to review applications for and administer research grants to nonprofit entities, it has not yet adopted a similar policy regarding 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 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.

We recommended that the institute complete the development of its grants administration policy targeted toward for-profit organizations.

Institute's Action: Partial corrective action taken.

The institute began drafting a grants administration policy targeted toward for-profit organizations in December 2006 and held meetings for interested parties in fall 2007 to discuss issues related to the policy. The proposed policy was included in the agenda for the December 12, 2007, committee meeting for its consideration.

Finding #5: 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, its 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. After we shared our concerns with the institute, it developed new procedures designed to ensure that every voting action is recorded. 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 postdoctorate students and clinical fellows in California's universities and nonprofit academic and research institutions.

To provide increased accountability over the grants award process, we recommended that the institute 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.

Institute's Action: Corrective action taken.

In 2006 the institute developed new procedures designed to ensure every voting action is recorded. Shortly after, it implemented those procedures during its grants working group meetings held during November 28 through November 30, 2006, and January 8 through January 10, 2007. The institute now retains these records as part of its documentation of the grant award process.

Finding #6: 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.

The institute intends to conduct reviews of grantees through annual financial and programmatic reports mandated by the nonprofit grant administration policy. Failure to submit the reports promptly may result in the reduction, delay, or suspension of a grant award. However, as of December 2006 the institute had not completed the format of the financial and programmatic reports.

In addition, 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.

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

Institute's Action: Partial corrective action taken.

The institute's grants administration policy for nonprofit organizations requires an administrative review prior to issuing a formal notice of grant award and before funds are released. According to the institute, for research grants it has developed a coding system to monitor the types of research that it funds. For facilities grants, the institute's interim grants administration policy states that requests for grant applications will detail the milestones and amounts for progress payments. The institute states that it continues to develop a web-based reporting system for grantees to facilitate the grants monitoring process.

Finding #7: The Fair Political Practices Commission has questioned the exclusion of the working groups from the institute's conflict-of-interest code.

The Political Reform Act requires that the institute submit its conflict-of-interest code to the Fair Political Practices Commission (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.

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 fundamental disclosure rules if it becomes apparent that the members' role is more than purely advisory. As such, the FPPC concluded that this issue may need to be revisited in the future.

In view of the seriousness of a violation of the 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 the matter.

We recommended that the institute 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.

Institute's Action: None.

➔ The institute states that it has given careful consideration to our recommendation and has decided that it is not appropriate to implement it at this time. The institute states that in almost three years of operation and approval of four rounds of grants, the committee has never routinely or regularly adopted the recommendations of the institute's working groups. Until the time that such a pattern is detected, the institute believes the question we raise is hypothetical and not appropriate for submission to the attorney general. However, the institute states that it will continue to monitor the committee approvals for such a pattern and will reconsider our recommendation if such a pattern emerges.

Finding #8: The institute had not included in its conflict-of-interest policy provisions for specialists it might enlist to assist in evaluating grant applications.

Although, during our review, the institute implemented some improvements in its conflict-of-interest policies, it had not yet amended its policy for working groups to include specialists it might enlist to assist in evaluating grant applications. 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.

We recommended that the institute 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.

Institute's Action: Corrective action taken.

In March 2007 the committee adopted a change in the conflict-of-interest policy for the grants working group to include specialists.

Finding #9: Institute employees may not have the information they need to comply with the conflict-of-interest policy.

The institute's conflict-of-interest policy prohibits institute employees from having more than \$10,000 of financial interests in any organization that is applying for funding with the institute. However, the institute has not developed procedures to inform its employees of the organizations that apply for grants. 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.

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

Institute's Action: Corrective action taken.

The institute's conflict-of-interest procedure for institute employees now incorporates a mechanism that identifies all entities that have applied for funding pursuant to a particular request for applications. Employees are to review a list of applicants to note any conflicts and disqualify themselves from reviewing any application with which they may have a conflict of interest.

Finding #10: The institute could improve steps to detect conflicts of interest before meetings of the grants review working group.

The institute's procedures to avoid conflicts of interest in grants review working group activities require it 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—the only grants awarded at the time of our review.

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.

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 National Institutes of Health—the federal agency on which the institute modeled its conflict-of-interest policies related to reviewing 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.

To ensure compliance with its conflict-of-interest policies, we recommended that the institute 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, we recommended it 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.

Institute's Action: Corrective action taken.

The institute's current procedures to identify conflicts of interest of members of the grants working group include staff review of their conflict-of-interest disclosures prior to each meeting. The institute further reports that it now documents the recusal actions of each member with respect to each application reviewed to ensure that no one participating in the review of a particular application has a conflict of interest. The institute reports that it maintains these records.

Finding #11: The institute's contracting policy and travel reimbursement policy did not provide adequate controls.

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, including provisions related to hiring consultants, procuring goods and services, and awarding sole source contracts, 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 response to our concerns about contracting, in December 2006 the institute revised its procurement policy to mirror the UC policy, thereby addressing our concerns. In addition, the institute has indicated to us that it is developing an internal procedures manual that will have more-detailed requirements for the contractor selection process.

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, but with certain deviations. 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. 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. Moreover, the institute reimbursed costs for air travel and meals without sufficient documentation of travel expenses to ensure that its policies were followed.

In response to our concerns over travel reimbursements, the institute revised its travel reimbursement policy in December 2006. However, the revised policy did not address all of our concerns. For example, the institute did not revise the form that working group members use to claim travel reimbursement to include information specific enough to allow institute staff to properly review the claims to ensure reimbursement policies for meals are followed. Moreover, the revised policy specifies that it applies only to institute staff and working group members, not to members of the committee. The committee chair stated that the committee will consider amendments to the travel policy in the upcoming months.

To ensure adequate controls over its contracting and travel reimbursements, we recommended that the institute ensure that it follows its newly revised policies that address some of the concerns raised in our audit. The institute also should amend its travel reimbursement policies further to address the remaining concerns we raised.

Institute's Action: Partial corrective action taken.

The institute reports that under its policy and practice, employees are not reimbursed for meals at meetings where meals are provided without prior authorization. The institute reports that it monitors the travel claims of staff who attend meetings to ensure that reimbursement is not claimed when the institute provides a meal.

The institute states that as of March 1, 2007, it uses the standard state travel claim form to process claims for all members of working groups. The institute reviews and allows these claims in accordance with the same policy and procedure applicable to institute employees.

On April 5, 2007, the committee's governance subcommittee adopted a recommendation to the full committee that it adopt for its members the policies and procedures for travel for institute staff and working group members. The committee did not adopt the policy for its members in its April 10, 2007, meeting. However, according to the institute in September 2007, the committee chair has asked that reimbursements to committee members conform to the proposed policy, assuming adoption in October or December 2007.

Finding #12: 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 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.

To ensure that the methodology to set salary ranges complies with the act, we recommended that the institute 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.

Institute's Action: Partial corrective action taken.

The institute reports that it has hired Mercer Human Resources Consulting to review and survey all institute salaries and, as of September 2007, expected a report within the next few weeks that will be discussed with the committee.