FACT SHEET

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The California State Auditor released the following report today:

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

BACKGROUND

In 2004, voters approved the California Stem Cell Research and Cures Act (act), which authorized the issuance of $3 billion in general obligation 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 act directs the institute to give priority to research that (1) has the greatest potential for therapies and cures and (2) 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), which is tasked with developing annual and long-term strategic research and financial plans for the institute.

KEY FINDINGS

Our review of the act's implementation and the institute's policies and processes revealed the following:

- The institute's approach to achieving its goals through specific initiatives is clearly defined in its strategic plan, adopted in December 2006. 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 reasonably hindering essential research. However, insufficient documentation prevented us from reviewing analyses of research used in the policy-making process. Further, the policies lack adequate guidance to grantees to ensure access to therapies for uninsured Californians.
- Although the committee has identified standards for discount prices for drugs in its intellectual property policies, it has yet to identify the appropriate benchmarks to use as a standard for establishing discount prices for nondrug therapies.
- The institute developed a grants administration policy for academic and nonprofit institutions but is still in the process of developing a policy for administering future grants to for-profit organizations. It is still implementing a grants monitoring process to ensure grantees comply with the terms of their grants, including grantee auditing procedures.
- 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. The institute's travel reimbursement policy did not provide sufficient control over travel expenses. Policy revisions were made in December 2006 to address all our concerns regarding contracting and some of our concerns regarding travel reimbursements; the institute is developing an internal procedures manual to address additional contracting issues.
- The institute's salary survey and compilation of the data contained enough errors, omissions, and inconsistencies that the committee and the institute cannot ensure the salaries for certain positions comply with the requirements of the act. The institute plans corrective action.

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