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FINAL REPORT

California Institute for Regenerative Medicine
FY 2010-2011 Performance Audit

May 14, 2012

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I. EXECUTIVE SUMMARY

A. INTRODUCTION

The California Institute for Regenerative Medicine (CIRM or Institute) is a state agency that was established through the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure provides $3 billion in funding over ten or more years to support and advance stem cell research and regenerative medicine.

CIRM is required to commission a performance audit every three years, beginning with an audit for Fiscal Year 2010-2011. Each performance audit shall examine the functions, operations, management systems, and policies and procedures of the Institute to assess whether the Institute is achieving economy, efficiency, and effectiveness in the employment of available resources. In addition, the first performance audit is required to address policies and procedures for the issuance of contracts, grants, and loans, as well as the protection or treatment of intellectual property rights associated with research funded or commissioned by CIRM.

Moss Adams assessed compliance with policies and procedures for the core functions of grants application and review, grants oversight, loans, contracts, and intellectual property. In addition, we evaluated the economy, efficiency, and effectiveness of supporting functions within CIRM, such as administration, communications, executive leadership, finance, human resources, information technology, and legal. The primary techniques utilized to conduct the performance audit included:

- Interviews: We conducted approximately 40 interviews with personnel throughout the organization, including the Board Chair and Vice Chairs, Board members, Grants Working Group members, Executive Team, and personnel from each CIRM function.
- Document Review: We reviewed dozens of documents to understand relevant policies, procedures, and processes.
- Process Walkthroughs: We had CIRM staff walk us step-by-step through processes associated with core functions.
- Testing: Using standardized sampling methods, we tested internal controls and compliance with policies and procedures for core functions.

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B. OBSERVATIONS

Through the performance audit process, we gained broad and deep exposure to CIRM management and operations. It is evident that CIRM is comprised of a high-performing team of professionals, who can be characterized as:

- Mission-driven;
- Well educated, highly talented, and hard working;
- Dedicated to their stakeholders; and
- Committed to transparency and good stewardship of public funding.

CIRM employees were extremely forthcoming with ideas for improving efficiency and effectiveness, while being mindful of the need to meet public information and process obligations.

C. THEMES

CIRM has a limited timeframe within which to utilize bond proceeds to award grants and loans to support and advance stem cell research and regenerative medicine. The Institute began operations in 2005, and it anticipates making new awards into Fiscal Year 2016-2017 and overseeing award commitments into Fiscal Year 2020-2021. Currently in its seventh year of operation, CIRM faces the unique challenge of still being in a ramp-up mode, while also needing to begin thinking about ramping down and transitioning the organization.

During its first several years of operation, CIRM focused on preparing the organization for developing grant application requests (RFAs), reviewing and selecting applications, and overseeing resulting grants and loans. As such, priorities included hiring scientific personnel, designing and implementing policies and procedures, and engaging the scientific community. In addition, due to the public environment within which CIRM operates as a state agency, the Institute had to accommodate broad stakeholder participation, provide access to information, and ensure operational transparency. As a result, activities to date have largely focused on meeting its obligations effectively.

However, CIRM must operate within resource constraints that limit administrative and implementation costs to not more than six percent of the proceeds of the bonds over the life of the Institute. As the complexity and size of CIRM's research portfolio has increased, the organization has increasingly begun to focus on the need to improve both effectiveness and efficiency.

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This dynamic environment is reflected in many of the twenty-seven findings and recommendations contained in this report, as evidenced by a focus on opportunities to enhance performance reporting and decision making, strengthen effectiveness and efficiency, retain essential human resources, and leverage technology. A summary of findings and recommendations is provided below.

- ***Compliance:*** CIRM's grants application and review, grants oversight, loans, contracts, and intellectual property (IP) processes are in accordance with CIRM's stated policies. In addition, CIRM is continuing to strengthen its IP processes as it learns which are the most efficient and effective.
- ***Performance/Outcomes:*** CIRM communications, decision making, and stakeholder reporting will benefit from enhanced access to performance data aligned with target outcomes.
- ***Efficiency and Effectiveness:*** CIRM has opportunities to improve efficiency and strengthen effectiveness throughout the organization.
- ***Human Capital:*** In order to achieve continued success, CIRM must retain and utilize at their highest and best use its limited human resources.
- ***Information Technology:*** CIRM can leverage technology to more efficiently and effectively manage, communicate, and protect critical data.

In summary, in its formative years, CIRM concentrated on getting its core infrastructure in place to ensure it could effectively carry out its mission. Now the Institute has the opportunity to enhance the efficiency with which it achieves its mission.

D. PRIORITIES

The recommendations described in this report should be considered in the context of the impact on the organization, life expectancy of CIRM, associated risk to the organization, and cost of implementation, which are all important factors in determining the priority and practicality of recommendations. Recommendations are categorized below as Tier 1, Tier 2, or Tier 3, with Tier 1 representing the most pressing needs based on the aforementioned factors. Estimated external costs to implement recommendations are provided where applicable.

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Tier 1

Recommendation	Cost
III.E.1 Continue to work through institutional Technology Transfer Offices (TTOs) to obtain required Invention Disclosure Forms and Invention Utilization Reports and strive to obtain this information in a consistent manner.	In-house
III.E.2 Ensure the Grants Management System (GMS) IP Module specifications for Phase 1 include specific questions about commercialization activity.	In-house
IV.A Build upon current efforts to develop a grants outcome tracking database by creating a digital dashboard and enhanced annual performance report to provide CIRM leadership and other stakeholders with core performance information.	$20,000-$30,000
IV.B Develop a communication plan and comprehensive, results-based annual report, and use the annual report as a cornerstone for external communications.	In-house
IV. C Amend policies to make completion of the grant outcome survey a requirement of the grant closeout process.	In-house
VII. B Develop a detailed plan for completing development of the GMS, and provide ongoing project oversight.	$10,000-$20,000
VII. D Implement a document management system.	$50,000-$60,000
V. D Build upon existing procedures and tools that CIRM has implemented to strengthen bond forecasting and further streamline and integrate the bond forecasting process.	In-house
VI. A Acquire and implement human resource forecasting software.	$25,000-$50,000
VI. B Reevaluate staffing levels if administrative and implementation costs are forecasted to exceed 6% of bond proceeds.	In-house
III.B.2 Implement policies, procedures, and resources to achieve timely review of progress reports, since the review of progress reports is an integral part of understanding the scientific progress being made by grantees.	In-House
III.D Ensure that the required information to document adherence to the procurement policies is retained in a procurement file maintained by the Contracts Administrator.	In-House

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Tier 2

Recommendation	Cost
V.A Develop and implement a relational database to enable more efficient financial analysis and reporting of non-grant contracts and purchase order payments.	In-house
V.B Request authorization to access the SCO's fiscal system.	In-house
V.C Create and implement a comprehensive, formal business development plan.	In-house
V.E Make every effort to manage and operate as one cohesive organization, while recognizing the varying roles, responsibilities, and authorities that exist with positions in both the Chairman's Office and President's Office.	In-house
V.F Incorporate performance metrics reporting into a structured meeting rhythm process and streamline weekly meetings.	In-house
V.G Continue efforts to identify and implement efficiency improvements and strive to quantify efficiency gains.	In-house
VII.A Develop a comprehensive information technology plan to guide information systems decisions, and designate someone to provide ongoing information technology direction for the Institute.	$40,000-$60,000
VII.C Define the role of CIRM's website as part of a comprehensive information technology plan, and establish clear authorities and responsibilities for website administration.	Covered by IT plan

Tier 3

Recommendation	Cost
V.H Develop a formal onboarding process and incorporate it into the overall new employee orientation program.	In-house
VI.C Ensure the Transition Plan addresses CIRM's unique and increasing recruitment and retention challenges, and ensure CIRM leadership clearly and regularly communicates transition plan strategies to all employees.	In-house
VI.D Adopt a Board Code of Conduct.	In-house
III.A.2 Review processes related to conflict of interest forms to assess whether there are redundancies in the process, and, if so, there is a logical reason for the redundancy.	In-House

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E. REPORT CONTENT

The balance of this report consists of seven sections. They include:

- Section II, Objectives, Scope, and Methodology;
- Sections III – VII, Findings and Recommendations for Compliance, Performance/ Outcomes, Efficiency and Effectiveness, Human Capital, and Information Technology;
- Section VIII, Management Response.

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II. OBJECTIVES, SCOPE, AND METHODOLOGY

A. BACKGROUND

The California Institute for Regenerative Medicine (CIRM or Institute) is a state agency that was established through the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure provides $3 billion in funding for stem cell research, research facilities, and other vital research opportunities. CIRM's mission is:

"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."

CIRM funds stem cell research at not-for-profit, government, and for-profit organizations throughout California. Grants and loans are awarded through a process driven by Requests for Applications (RFAs). Applications submitted in response to RFAs are reviewed by a panel of scientific experts and patient advocates, which makes recommendations to the Independent Citizens Oversight Committee (ICOC), which is CIRM's governing board. The ICOC then decides which projects to fund for each RFA.

B. PERFORMANCE AUDIT REQUIREMENTS

2010 California Senate Bill 1064 amended subdivision (c) of California Health & Safety Code 125290.30, Public and Financial Accountability Standards. This amendment mandates that CIRM commission a performance audit every three years. Specifically, the code states:

> "(c) A performance audit shall be commissioned by the institute every three years beginning with the audit for the 2010-11 fiscal year. The performance audit, which may be performed by the Bureau of State Audits, shall examine the functions, operations, management systems, and policies and procedures of the institute to assess whether the institute is achieving economy, efficiency, and effectiveness in the employment of available resources. The performance audit shall be conducted in accordance with government auditing standards, and shall include a review of whether the institute is complying with ICOC policies and procedures. The performance audit shall not be required to include a review of scientific performance. The first performance audit shall include, but not be limited to, all of the following:

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(1) Policies and procedures for the issuance of contracts and grants and a review of a representative sample of contracts, grants, and loans executed by the institute.

(2) Policies and procedures relating to the protection or treatment of intellectual property rights associated with research funded or commissioned by the institute."

Audits performed in accordance with Generally Accepted Government Auditing Standards (GAGAS) provide information used for oversight, accountability, transparency, and improvements of government programs and operations. They provide findings or conclusions based on an evaluation of sufficient, appropriate evidence against criteria. GAGAS audits also provide objective analysis to assist management and those charged with governance and oversight in using the information to improve performance and operations, reduce costs, facilitate decision making by parties with responsibility to oversee or initiate corrective action, and contribute to public accountability.

C. MANAGEMENT RESPONSIBILITIES

CIRM management has many responsibilities that were assessed as part of the Fiscal Year 2010-11 performance audit. These responsibilities include ensuring that:

- CIRM has developed policies and procedures to ensure compliance with all relevant laws and regulations.
- CIRM has established controls to assure compliance with policies and procedures.
- CIRM operates as economically, efficiently, and effectively as possible in the execution of its mission.

D. PERFORMANCE AUDIT METHODOLOGY

The performance audit conducted by Moss Adams consisted of three areas of focus, and we developed audit objectives for each area. These areas included:

- Assessing compliance of CIRM policies and procedures with applicable regulations and laws.
- Assessing compliance of CIRM processes with its policies and procedures and testing key internal controls.
- Evaluating functions, operations, management systems, and policies and procedures to determine whether CIRM is achieving economy, efficiency, and effectiveness in the employment of available resources.

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Assessments related to all three areas were performed for the core functions of grants application and review, grants management, loans, contracts, and intellectual property. In addition, economy, efficiency, and effectiveness evaluations were performed for supporting functions within CIRM, such as administration, communications, executive leadership, finance, human resources, information technology, and legal.

Areas of audit focus within each function were determined by a risk assessment that we developed through an iterative process of fact finding activities, including a kickoff meeting, interviews, document review, and walkthroughs. The risk assessment was updated after each fact finding activity. Our audit approach for both core functions and supporting functions is described below.

1. **Core Functions**

   The detailed methodology utilized to audit each of the core functions (i.e., grants application and review, grants management, loans, contracts, and intellectual property) is described in the Findings and Recommendations section of this document. The general audit methodology for each core function is summarized below.

   - Performed document review, interviews, and walk throughs to understand work flow processes, key controls, and population sizes;
   - Established sample sizes and sample selection methods in accordance with guidance from the American Institute of Certified Public Accountants Audit Guide, *Audit Sampling*;
   - Selected samples prior to onsite fieldwork and provided CIRM a list of documents required for each sample;
   - Performed testing of key controls and compliance requirements;
   - Documented test results and performed follow-up procedures to ensure we were aware of all relevant facts and circumstances;
   - Assessed whether CIRM is achieving economy, efficiency, and effectiveness in the employment of available resources.
   - Discussed our findings and recommendations with CIRM management to verify facts contained in our findings and test the practicality of our recommendations.

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2. Supporting Functions

This facet of the performance audit provided insights regarding how CIRM can operate more efficiently and effectively. Functions of the organization that were addressed included, but were not limited to, administrative support, communications, executive leadership, finance, human resources, information technology, and legal. Key audit objectives included:

- *Assessing how CIRM can more efficiently utilize its resources (i.e., minimize time and effort) to conduct its business.*
- *Assessing how CIRM can more effectively utilize its resources (i.e., maximize achievement of intended purpose) to conduct its business.*

Assessments focused on management and operational performance (e.g., how the organization is being administered to make grants and loans) and not on the scientific performance of its grantees (e.g., the impact of the grants and loans), which was beyond the scope of this performance audit. Efficiency and effectiveness were evaluated through conventional fact finding and analytical activities, as described below.

Fact Finding

Fact finding consisted of interviews, operational observations, and additional document review. Based on interview results, we updated our risk assessment and prioritized areas of focus for observation and additional document review. In addition to the personnel identified in the core function components of the audit plan, the following individual and small group interviews were conducted:

Group	Positions
ICOC	Chair, Vice Chairs, and selected other members
Grants Working Group	Selected members
Executive Team	All members
Science Office	Lead Science Officers for Development and Basic Research, Lead IT Contractor, and Marketing Manager
General Counsel & Business Development	Deputy General Counsel and Chief Human Resources Officer
Finance	Deputy of Finance, Policy, and Outreach; and Financial Services Officer

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Group	Positions
Other	Executive Director to the Governing Board, Collaborative Funding Partner Manager, Assistant Secretary to the ICOC Board, Legal Counsel to the Chairperson, and Outside Counsel

We observed operations and reviewed additional information associated with priority areas of focus to document workflows, identify relevant operational statistics, and determine the basis for comparing to best practices. Based on these fact finding activities, we developed findings in the form of "conclusive facts." Our findings were prepared by 1) documenting the key issue, 2) describing the issue, and 3) defining the impact on CIRM. Evidence was cited during this process. Findings were reviewed with CIRM to validate facts.

Analysis

The analysis phase of the performance audit moved from identifying findings to determining the significance of each finding, as well as defining approaches to improving efficiency and effectiveness. Current CIRM operations were compared to best practices to identify opportunities where changes could occur to enhance the current level of efficiency and effectiveness. Each major area that was identified as having the potential to achieve a higher level of efficiency and/or effectiveness was addressed through various means. Alternatives ranged from minimal action to significant change. Alternatives analysis was conducted in an abbreviated cost-benefit format inherent to our analysis. Each alternative solution was scrutinized for pros, cons, resources, budget, training, and risks, if relevant. The alternatives analysis was utilized to formulate recommendations. We documented relevant assumptions as part of our recommendations. At this point, findings and recommendations were reviewed with CIRM to again verify facts and also test the practicality of our recommendations.

E. DELIVERABLES

Moss Adams was responsible for submitting four deliverables to CIRM as part of the performance audit. These deliverables included:

- Audit Plan
- Draft Report
- Draft Final Report
- Final Report

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In addition, Moss Adams delivered preliminary findings at the conclusion of the fact finding phase, findings and associated recommendations at the conclusion of the analysis phase, and the final report in presentation format for a meeting with the ICOC Governing Board at the conclusion of the project. Our performance audit report is limited to those areas specified in the Performance Audit Requirements section of this report.

F. STATEMENT ON COMPLIANCE WITH GAGAS

Moss Adams conducted this performance audit in accordance with Generally Accepted Government Auditing Standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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San Francisco, California
May 14, 2012

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III. COMPLIANCE FINDINGS & RECOMMENDATIONS

A. GRANTS APPLICATION AND REVIEW

1. **Finding: Based on the results of testing a sample of 20 pre-applications from a population of 271 pre-applications submitted in Fiscal Year 2010-2011 and testing a sample of 20 applications from a population of 206 applications submitted in Fiscal Year 2010-2011 for the applicable compliance requirements listed below, CIRM's grants application, review, and approval processes are in accordance with CIRM's stated policies.**

   We reviewed the grants application, review, and approval processes as guided by Proposition 71, CIRM's Grants Administration Policy, and CIRM's Grants Working Group (GWG) By-laws. Key audit objectives included evaluating whether:

   - *The grants application, review, and approval processes were in accordance with CIRM's stated policies.*
   - *Conflicts of interest were considered for all reviewers, Independent Citizens' Oversight Committee (ICOC) members, and CIRM staff.*

   During onsite fieldwork, we interviewed the Grants Review Officer and Grants Review Specialist and performed walkthroughs of several Requests for Applications (RFAs), pre-applications, applications, GWG Reviews, and ICOC Reviews. Interviews and walkthroughs ensured we understood workflow processes of the entire application, review, and approval processes, as well as the key controls employed at each stage to ensure adherence to the aforementioned guidance. Walkthroughs were also utilized to establish the reliability of procedures by observing processes, as well as discussing the procedures with key personnel. Key controls that were identified during the walkthrough process and tested using sampling techniques included:

   - ICOC approved the written concept.
   - Conflict checks were performed prior to review of pre-applications and applications. The conflict check process was monitored by Grants Review.
   - Science Officers and external reviewers assessed grant pre-applications and documented their review, scoring, and recommendation.
   - GWG reviewed grant applications and documented their review, scoring and recommendation.
   - ICOC approved or denied the application.

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In addition to testing key internal controls, we tested compliance with the grants application, review, and approval processes. Compliance requirements tested using the samples described above included:

- RFA was issued by CIRM.
- Pre-application and/or application was submitted by applicant.
- Reviewers disclosed financial interests to CIRM by completing confidential disclosure forms.
- CIRM retained documentation to substantiate the review and scoring process completed for pre-application review or Letter of Intent processing.
- CIRM retained documentation to substantiate scoring of applications and recommendations of the GWG.
- CIRM retained documentation to substantiate ICOC's selection of applicants.

Recommendation: Continue to use controls and processes to adhere to stated policies.

2. **Finding: We noted one Conflict of Interest Policy Certification Form and one Confidentiality Nondisclosure Form that were not retained, but we able to ascertain that these forms were completed by the reviewers through additional procedures.**

   For each pre-application or application sampled, we determined whether the reviewers completed the conflict of interest policy certification form and the confidentiality nondisclosure form. We noted for one Conflict of Interest Policy Certification Form that the version with the signature was not retained. However, through review of the Grants Management System, we determined that the form was completed electronically. In addition, although the Confidentiality Nondisclosure Form for one reviewer was missing in the pre-application process, CIRM did have a similar form completed for this reviewer when the reviewer was originally appointed as a Grants Working Group member.

   Recommendation: Continue to use controls and processes to consider all conflicts of interest. In addition, review processes related to conflict of interest forms to assess whether there are redundancies in the process, and, if so, there is a logical reason for the redundancy.

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B. GRANTS OVERSIGHT

1. **Finding: Based on the results of testing a sample of 11 new grants and 1 new loan from a population of 131 new grants and loans in Fiscal Year 2010-2011, 6 closed grants from a population of 36 grants that were closed in Fiscal Year 2010-2011, and 20 ongoing grants and 1 ongoing loan from a population of 289 grants and 2 loans that were in progress in Fiscal Year 2010-2011 for the compliance requirements listed below, CIRM's grants management process is in accordance with CIRM's stated policies.**

   We reviewed the grants management process (i.e., pre-award review, award acceptance, and/or monitoring processes) for RFA 06-01, RFA 06-02, RFA 07-01, RFA 07-02, RFA 07-03, RFA 07-05 RFA 08-01, RFA 08-02, RFA 08-03, RFA 08-04, RFA 08-05, RFA 08-06, RFA 08-07, RFA 09-01, RFA 09-02, RFA 09-03, RFA 09-04, RFA 10-01, RFA 10-02, and RFA 10-04 as guided by CIRM's Grants Administration Policy and internally documented policies and procedures. Key audit objectives included evaluating whether:

   - *Grants were only awarded to eligible entities.*
   - *Grants were managed in accordance with CIRM's policies.*
   - *CIRM identified award information and compliance requirements to grantees.*
   - *Award monitoring provided reasonable assurance to CIRM that grantees were administering the award in compliance with CIRM requirements.*
   - *CIRM ensured the required reports are received from grantees and are reviewed.*

   During onsite fieldwork, we interviewed the Grants Management Officer, the Deputy Grants Management Officer, and Grants Management Specialists, as well as some Science Officers. We performed walkthroughs of the processes related to review and approval of pre-funding checklists, Notices of Grant Awards (NGA), payments, scientific progress reports, financial and administrative reports, award modifications, and grant close-outs. Interviews and walkthroughs ensured we understood workflow processes for pre-award review, award acceptance, and monitoring, as well as the key controls employed at each stage to ensure adherence to aforementioned guidance.

   Key controls that were identified during the walkthroughs and tested using the samples described above were as follows:

   - The Grants Management Officer and a Science Officer approved the pre-funding administrative review (PFAR) checklist.

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- The NGA was reviewed and approved by Legal, Financial, and a scientific executive, and the scientific executive signed the NGA.
- Payments issued by the State Controller's Office to grantees were reconciled to the NGA and payment request by CIRM staff.
- Progress reports were reviewed by Grants Management and Scientific Officers and follow up was initiated, if required.
- Grant modifications were approved by Grants Management and applicable Science Officer.
- Final reports were reviewed by Grants Management and the appropriate Science Officer. The Grant Close-Out Checklist was completed.

In addition to testing key internal controls, we tested compliance with the grants management process requirements. Compliance requirements tested using the samples described above were as follows:

- CIRM determined that the grantee met eligibility requirements and provided CIRM with the necessary assurance and approvals.
- CIRM prepared and provided NGAs and compliance requirements for awards to each grantee.
- CIRM prepared a pay memo for each grantee and sent it to the California State Department of General Services. The amount of the warrant issued to the grantee matched the amount and terms of the NGA.
- If CIRM postponed payments to a grantee, the postponement was in accordance with CIRM's Grants Administration Policy.
- CIRM received progress reports (financial and technical) from grantees as required. If progress reports did not meet content and/or timing requirements, then follow up was initiated by CIRM.
- For grant close-out, final reports were received and processed by CIRM.

Recommendation: Continue to use controls and processes to adhere to stated policies.

2. **Finding: For the progress reports tested, Scientific Officer review was completed, on average, four to five months after receipt of the progress report, compared to a goal of completing review of 75% of progress reports within eight weeks of receipt.**

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Progress report review is an iterative process. The results of this test include instances when an initial progress report was reviewed and a Science Officer required a grantee to submit additional information before final approval was achieved. The iterative aspect of some reviews can extend the review process. In addition, progress report review appears to be impacted by resource constraints.

Recommendation: Implement policies, procedures, and resources to achieve timely review of progress reports, since the review of progress reports is an integral part of understanding the scientific progress being made by grantees.

In order to facilitate more timely review of progress reports, determine resource requirements necessary to achieve stated progress review goals. (See the finding and recommendation on Resource Forecasting.)

C. LOANS

Finding: Based on the results of testing a sample of one new loan and one loan in process, which represent the only two active loans in Fiscal Year 2010-2011, CIRM's loan management process is in accordance with CIRM's stated policies.

Since the loan process is similar to the grant process, many aspects of the audit plan for loans were similar to those for grants management. As part of the testing performed for grants management, we tested one new loan and one loan in process. For Fiscal Year 2010-2011, CIRM had only one new loan and one loan in process. The procedures that are different for loan testing than for grants management testing are described below.

Key audit objectives included evaluating whether:

- *CIRM performed due diligence in accordance with its internal procedures to ascertain borrower's ability to repay the loan.*
- *CIRM obtained, and appropriate personnel reviewed, information required to determine borrower's compliance with the loan agreement.*

Key controls that were identified during the walkthrough process and tested were as follows:

- Loan agreement was reviewed and approved by legal counsel.
- Financial viability was reviewed and documented annually.

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In addition to testing key internal controls, we tested compliance with the loan management process. Compliance requirements tested using the samples described above were as follows:

- Loan agreement was signed by legal counsel for each borrower.
- Pertinent information was obtained to ascertain borrower ability to repay loans.

Recommendation: Continue to use controls and processes to adhere to its stated policies.

D. CONTRACTS

Finding: Based on the results of testing a sample of 16 contracts (6 of which were initiated in Fiscal Year 2010-2011) from a population of approximately 60 contracts, CIRM's contracts process is in accordance with CIRM's stated policies; however, although CIRM was able to produce the needed information to ascertain compliance with contracting requirements, this information was not always kept in a procurement file with the Contracts Administrator.

We reviewed key provisions of procurement policies contained in California Public Contract Code Chapter 2.1 University of California Competitive Bidding, University of California Business and Finance Bulletin 34, and CIRM's Policy on Contracting and Services of Independent Consultants. The University of California competitive bidding requirements were reviewed, since Proposition 71 stipulates that CIRM shall be governed by these requirements.

Key audit objectives included evaluating whether:

- *CIRM's contracting policies were compliant with California Public Contract Code Chapter 2.1 University of California Competitive Bidding, University of California Business and Finance Bulletin 34.*
- *Contracts were procured in accordance with CIRM's Policy on Contracting and Services of Independent Consultants.*
- *Payments to contractors were made in accordance with CIRM's Policy on Contracting and Services of Independent Consultants.*

During onsite fieldwork we interviewed the Contracts Administrator and Finance Officer and performed walkthroughs of several procurement transactions to ensure we understood workflow processes of the procurement cycle.

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Key controls that were identified during the walkthrough process and tested using the samples described above were as follows:

- The Responsible Administrative Official from CIRM monitored procurement of the service to ensure the procurement was in accordance with University of California Code and CIRM's policy.
- The Responsible Administrative Official signed all agreements, including amendments. Signature of contract was indication of approval of contract.
- Procurement files documented the basis of selection.
- A standard CIRM Independent Consultant Agreement was used. Any modifications to the standard agreement were approved.
- If there was modification to the standard agreement form or material modification of the approved scope of services, the change was reviewed and approved by the Responsible Administrative Official, who consulted with CIRM legal counsel as appropriate.
- If the agreement was extended or the scope was expanded, there was written approval by the Responsible Administrative Official.
- Prior to payment for services, the invoice was compared to the payment terms of the signed agreement and evidence was obtained that services had been performed.
- Contracts in excess of certain thresholds had required Board and/or President approval.
- The Responsible Administrative Official submitted a report to the Governance Subcommittee two times per year and submitted an annual report to the Governing Board. The report included a statement indicating compliance with the provisions of CIRM's Policy and listed all agreements and amendments executed in the reporting period that were for amounts above $20,000. These reports were reviewed by the Subcommittee/Board.

During our testing, we noted one instance where the proposals and analysis of proposals were not retained by the Contracts Administrator. Instead, they were retained by the person requesting the services.

In addition to testing key internal controls, we tested compliance with contract policies, rules, and requirements. Compliance requirements tested using the samples described above were as follows:

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- If sole source was used, CIRM documented the justification for sole source.
- Prior to preparation of request for proposals, the requestor at CIRM submitted a written presentation for the need for an independent consultant to the Responsible Administrative Official.
- Proposals for independent consultants were obtained in writing in accordance with CIRM's thresholds for solicitations.
- Selection of the independent consultant was made on the basis of qualifications, resources, experience, needs of CIRM, and cost to CIRM. The basis for selection was documented by CIRM in the procurement file.
- CIRM executed an agreement using the standard CIRM Independent Consultant Agreement form.
- The contractor completed and submitted a Payee Data Record form to CIRM prior to CIRM issuing payment.
- CIRM did not issue payment to an independent consultant prior to signing of the agreement, unless expressly approved in writing by the Responsible Administrative Official.
- Payments to the independent consultant were in accordance with the signed agreement.
- The Responsible Administrative Official submitted a report on procurement transactions to the Governance Subcommittee two times per year and submitted an annual report to the Governing Board.

Recommendation: Continue to use controls and processes to adhere to its stated policies. Ensure that the required information to document adherence to the procurement policies is retained in a procurement file maintained by the Contracts Administrator.

Having the information retained in one central location reduces the risk of a critical part of the documentation being misplaced or lost.

E. INTELLECTUAL PROPERTY

1. **Finding: CIRM grantees have not consistently submitted the Invention Disclosure Forms and Annual Utilization Reports required by CIRM's Intellectual Property (IP) Regulations.**

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We reviewed the intellectual property process as guided by CIRM's Grants Administration Policy, Intellectual Property and Revenue Sharing Requirements, and internally documented policies and procedures. Key audit objectives included evaluating whether:

- *CIRM ensured that grants triggering the IP Policy included required disclosure documentation.*
- *CIRM ensured that grantees were conforming to invention and licensing requirements.*

During onsite fieldwork, we interviewed the General Counsel, Grants Management Officer, Deputy Grants Management Officer, Deputy General Counsel, and Legal Counsel to the Chairperson. We performed walkthroughs of the processes related to IP regulations, including examples of follow-up communications with grantees, subsequent process changes to the IP process, and plan for IP process improvement. Interviews and walkthroughs ensured we understood workflow processes for IP, as well as the key controls employed to ensure adherence to aforementioned guidance. We reviewed all of the institutions (16 in total) that reported invention disclosures and licensing activities to determine if grantees were complying with the reporting requirements under CIRM's IP regulations.

Through our interview process and testing, we found that under CIRM's current Intellectual Property and Revenue Sharing Requirements (17 Cal. Code Regs. § 100600 et seq), grantees are required to notify CIRM about certain IP-related developments that arise from CIRM funding. For inventions, a grantee must submit an Invention Disclosure Form within 60 days after the CIRM-funded researcher reports the invention to the grantee. (Research institutions generally require their researchers to report inventions to institutional technology transfer offices.) Grantees are also required to submit Annual Utilization Reports to CIRM, disclosing progress toward exploitation of CIRM-funded technology. This reporting provides CIRM with information about outcomes of CIRM-funded research and supports implementation of revenue sharing requirements and other elements of CIRM's IP regulations. CIRM's former IP regulations, which apply to grants initiated before December 17, 2009, have similar reporting requirements.

Beginning in Fiscal Year 2007-2008, CIRM provided grantees with Invention Disclosure Forms and Annual Utilization Report forms, either as stand-alone PDF forms or as part of the Annual Progress Report. When it seemed to CIRM that the number of IP activities being reported was fewer than expected, CIRM staff began actively seeking to understand the impediments to compliance and to identify process changes that could make it easier for grantees to submit complete, timely, and accurate reports.

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In addition, CIRM is in the process of transitioning from standalone PDF forms to interactive web-based submissions through CIRM's Grants Management System for IP reporting and other types of post-award reporting.

The key problem identified by CIRM was the expectation that Principal Investigators (PIs) would be the appropriate personnel to be responsible for IP reporting. At most institutions, technology transfer offices (TTOs) are responsible for maintaining records related to inventions and IP utilization. In August 2010, CIRM held a workshop with TTOs from grantee institutions to discuss IP regulations and reporting requirements and confirmed the need to obtain reporting directly from the TTOs. As a result, in FY 2011 CIRM's Grants Management Office (GMO) began collecting IP information directly from TTOs through a targeted annual survey. The survey is limited to institutions that have a) award types that have the potential for an invention with CIRM funds (e.g., excluding Conference Grants) and b) awards that have been active for more than 6-9 months (including both active/closed awards). The GMO conducted two surveys, one in August 2010 and a second in August 2011. This information was collected in spreadsheets and other manual compilations to supplement the forms submitted by PIs.

For Fiscal Year 2010-2011, CIRM reported that 6 Invention Disclosure Forms associated with 6 awards were received, and 37 inventions associated with 31 awards were disclosed using the Annual Progress Reporting module. The Annual Utilization Survey tracked reporting of 70 inventions associated with 49 grant awards. The GMO determined that the responses from TTOs were the most complete and accurate. CIRM has focused on obtaining accurate and current information through Annual Invention Utilization Reports, while also educating TTOs on the 60-day invention disclosure reporting requirement for future reporting.

Although these approaches have increased the amount and accuracy of IP information submitted by grantees, CIRM plans to implement additional steps to improve reporting. These steps include:

- Adding an IP reporting module to the interactive Grants Management System (GMS) system that PIs already use to submit progress reports;
- Giving TTO personnel access to the GMS, so that they can submit the required IP reporting directly; and
- Scheduling another workshop in July 2012 for TTO officials to review regulations, reporting requirements, and reporting tools.

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It should be noted that during Fiscal Year 2010-2011, no grantee reported activity that would trigger the IP policy's revenue sharing, access, or price protection requirements, and it is unlikely that such activity would have occurred without CIRM finding out through progress reports or other channels. However, as CIRM-funded inventions continue to mature, IP reporting will become increasingly important. In addition, current reports about invention co-funding will be useful when products are commercialized and CIRM's revenue sharing requirements are applied.

Recommendation: Continue to work through institutional TTOs to obtain required Invention Disclosure Forms and Invention Utilization Reports, and strive to obtain this information in a consistent manner.

2. **Finding: The new Grants Management System IP module, currently under development, does not include provisions to address commercialization activity.**

   As part of the ongoing development of the GMS, CIRM plans to implement a module that will allow for direct, online submission of IP reporting. For Phase 1 of the IP Module, CIRM has targeted full interactive functionality for reporting of invention disclosures and basic functionality for reporting of ongoing IP activity. CIRM's rationale was to focus on reporting of the activity that is currently most active. The IP module will be the first to bring TTO personnel in as GMS users. As CIRM and TTO personnel develop experience with the Phase 1 module, CIRM expects to identify improvements that can be incorporated into Phase 2, which will introduce detailed functionality for reporting IP utilization.

   Phase 1 functional specifications are scheduled to be complete by May 2012, and the module is expected to be deployed in August 2012. We reviewed the draft Phase 1 functional specifications to determine whether they would capture the data elements required to meet CIRM's Phase 1 goals.

   As defined by the draft Phase 1 functional specifications, the Phase 1 IP module will accommodate appropriate data for invention disclosures. For annual utilization reporting, the functional specifications address required information. For progress toward commercialization, the specifications provide for a narrative description of activity. CIRM's IP regulations call for grantees to report on three specific commercialization events. While grantees would be able to provide that information in the narrative, CIRM should consider separate fields for each of the three elements. This would facilitate complete reporting, and produce data that will help CIRM more efficiently and effectively track activities.

   Recommendation: Ensure the GMS IP Module specifications for Phase 1 include specific questions about commercialization activity.

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IV. PERFORMANCE/OUTCOMES FINDINGS & RECOMMENDATIONS

A. ACCESS TO KEY PERFORMANCE INFORMATION

Finding: Key performance information is not readily available to CIRM leadership and other stakeholders on an ongoing basis.

CIRM board members and senior management do not receive regularly updated, enterprise-level performance information. The ability to evaluate performance against strategic goals is critical to effective leadership and program monitoring, evaluation, and reporting.

CIRM does not currently have a formal performance reporting program. However, there are several sources of existing performance goals, outcomes, and data, including periodic reports to the Board and the following documents:

- Strategic plan;
- Budget;
- Annual reports (financial statements and progress milestones); and
- Economic impact report.

Key sources of performance outcomes are Science Officers' review of progress reports and management updates on Disease Teams in the context of Clinical Development Advisory panels. The Science Office is working to enable retrievable information on programs. For instance, CIRM's outcome-based evaluation of grants and programs provides a significant amount of performance data. Grants are coded in GIFTS, CIRM's grants management software, with keywords based on which five- and ten-year goals each grant addresses. Grants are evaluated on an annual basis for their "impact factor" to the five- and ten-year goals. Impact ratings are also entered in GIFTS, so reports can be developed to show the quantitative impact toward CIRM's strategic goals. These reports must be created by the Program Officer trained in GIFTS, and they are distributed on an as-needed basis and incorporated into the strategic plan update process.

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An effort is underway to develop an online database for grants outcome tracking that will be accessible by CIRM staff and integrated into day-to-day operations. A project team is in place with participation from throughout CIRM. The project is in the early definitional phase. The ultimate goal of the system is to enable CIRM leadership, stakeholders, staff, and the public to query CIRM's grants for progress, outcomes, and impact relative to strategic goals.

Recommendation: Build upon current efforts to develop a grants outcome tracking database by creating a digital dashboard and enhanced annual performance report to provide CIRM leadership and other stakeholders with core performance information.

The current grant outcome reporting and online database under development provides a solid foundation for outcome-based performance reporting. It should be expanded to create a robust decision support tool and comprehensive annual report that demonstrate the nexus between strategic goals, performance metrics, and outcomes.

A cohesive and robust performance reporting program should encompass the following elements:

- Goals defined in terms of target outcomes expressed in the strategic plan;
- Qualitative and quantitative performance metrics to measure progress towards each target outcome;
- Data elements and sources required to report progress on each outcome;
- Roles and responsibilities for collecting and reporting data elements;
- Procedures for assimilating and disseminating performance reports; and
- Performance report format.

Performance reporting should be tailored to internal and external audiences and their respective information needs, as described below.

Internal Communications – Digital Dashboard: A web-based dashboard of key performance indicators would provide easy access to performance information by CIRM board members, management, and staff. A dashboard that consolidates grant performance data across CIRM programs would give executives and managers greater insight into progress towards achieving outcomes. Specifications for the functionality of a digital dashboard should be incorporated into the grants outcome reporting and online database.

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External Communications – Annual Report: CIRM's annual report should include a performance summary. Currently, CIRM's annual report is comprised of several non-narrative documents that primarily show financial data, prefaced by letters from CIRM's Chair and President. The annual report should convey CIRM's strategic goals and outcomes, and report on progress toward achieving those goals and outcomes.

B. COMMUNICATIONS

Finding: CIRM does not have a communication plan, and there is lack of clarity on how to address mission-based communication to CIRM's various target audiences, especially the general public.

CIRM recently commissioned an assessment of its communication activities by Townsend Raimundo Besler & Usher, a northern California public affairs and political consulting firm. The firm issued a report in October 2011 entitled "Strategy for Building A Strong Communication Program." It recommended a number of strategic approaches to help CIRM meet its communication objectives and identified the primary audiences a communication plan should address. The report indicated that CIRM has been generally successful communicating with the scientific community, but it has been inconsistent and reactive when communicating to political audiences and the general public. CIRM recently hired a Senior Director of Public Communications and Patient Advocacy Outreach, who will direct activities in response to this assessment, including development of a communication plan.

In addition, CIRM's annual report lacks correlation between program implementation and impacts/outcomes. A recent CIRM effort to move in that direction is the portfolio report entitled "Funding therapies. Fueling hope." that CIRM presented to the Board of Directors in August 2011. However, this report would also benefit from providing information not only on program implementation, but also on program impacts/outcomes. (See Appendix 1 of CIRM's 2009-2010 Strategic Plan Update for an example of outcome-based reporting.)

Recommendation: Develop a communication plan and a comprehensive, results-based annual report, and use the annual report as a cornerstone for external communications.

The best way to facilitate results-based communications is to 1) quantify goals and outcomes in CIRM's strategic plan and 2) report on achievement of those goals and outcomes by enhancing CIRM's annual report with additional performance-based information. This information should form the core content of CIRM's external communications, which can be appropriately multi-purposed to meet the information

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needs of CIRM's various audiences as guided by a communications plan. A great local example of this type of approach is the annual report prepared by the Independent Monitoring Committee (IMC) for the Santa Clara Valley Water District. The IMC's annual report addresses implementation progress of the Clean, Safe Creeks and Natural Flood Protection Program, which is funded by a time-limited tax measure.

CIRM's annual report should not only define in detail what it has accomplished during the previous year, but also from inception to date. In addition, it is critical for CIRM to ensure consistency between its strategic plan, communications plan, and transition plan. The annual report can serve as an integrating and unifying document by incorporating both backward- and forward-looking information relative to goals, outcomes, and performance.

C. PROJECT CLOSEOUT AND OUTCOMES REPORTING

Finding: CIRM does not receive completed grant closeout surveys from all grantees, because the closeout survey is optional.

At the end of each grant, there is an optional closeout survey that can be completed by grantees. The closeout survey is designed to collect crucial outcome data at the end of the project to assess the impact of the project and program, as well as to guide future decisions made by CIRM related to development of requests for applications. This information is essential to documenting program outcomes and progress achieving the Institute's strategic plan.

CIRM does not always receive a completed survey from each grantee, because completion of the survey is optional. Since the inception of the closeout survey, CIRM has continued to make progress regarding the number of responses received. However CIRM still does not receive completed surveys from all grantees.

Recommendation: Amend policies to make completion of the grant outcome survey a requirement of the grant closeout process.

CIRM is currently in the process of amending the Grants Administration Policy (GAP) to make completion of the closeout survey a mandatory requirement. The proposed GAP amendments were published for public comment on February 17, 2012, as part of the regulatory change process. CIRM has also introduced appropriate questions into the annual reporting process to gain timelier outcome information.

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V. EFFICIENCY AND EFFECTIVENESS FINDINGS & RECOMMENDATIONS

A. NON-GRANT CONTRACTS AND PURCHASE ORDER PAYMENTS

Finding: The spreadsheet-intensive environment in which CIRM Finance processes non-grant contracts and purchase order payments is inefficient, time consuming, and prone to error.

CIRM does not have an integrated financial information system. CIRM's accounting functions are contracted to the Department of General Services (DGS), which enters financial information into the state's 30-year-old California State Accounting and Reporting System (CalSTARS). CIRM has recently gained read-only access to CalSTARS, but that system only shows information that has been processed by DGS. In order to prepare and track non-grant contract and purchase order transactions, CIRM's Finance Office relies on a series of spreadsheets.

The use of spreadsheets results in labor intensive processes to generate reports and respond to information inquiries, since data must be pulled from multiple spreadsheets, a process that may be prone to error. The spreadsheets that CIRM Finance maintains to track non-grant contracts and purchase order payments include:

- The Annual DGS Tracking Log, which is used to track all invoices, honorariums, and expense claims that are submitted to the Department of General Services for payment.
- Out-of-state travel spreadsheets, which CIRM maintains for each of four cost centers. These spreadsheets match actual expenditures against approved travel expenses, which are monitored by the State Controller's Office (SCO).
- Contract pay sheets, which CIRM creates for each contract that requires multiple payments. These contract pay sheets track a contract's running balance and any amendments. CIRM maintains 60 to 100 contract pay sheets per fiscal year.

CIRM Finance staff also maintains multiple PDF files for every invoice, honorarium, and travel expense claim that is processed, as well as the Payee Data Record that the State requires for every vendor.

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In addition, administrative staff maintains a purchase order log. Spreadsheets are not linked to each other or a master report. CIRM does not have a comprehensive list of spreadsheets or instructions for how to maintain the files or generate reports from them. This system is inefficient for current Finance staff, and new staff has a steep learning curve due to the lack of documentation and integration.

The lack of integrated data and reporting is a barrier to CIRM management's ability to efficiently ascertain the accurate transaction status at any point in time or the costs associated with a particular project or event. For instance, when the Finance Office receives inquiries regarding certain costs, such as the total cost of a grantee meeting, there is no single place that Finance staff can go to secure all relevant information. Instead, they have to pull information from multiple files and spreadsheets to prepare a comprehensive report. This process is prone to inaccuracies due to the manual process employed and lack of spreadsheet controls.

Recommendation: Develop and implement a relational database to enable more efficient financial analysis and reporting of non-grant contracts and purchase order payments.

CIRM has a strong need for a relational database to administer non-grants contract and purchase order payments. The database should contain all vendor and contract information, individual payment data, and purchase orders. A relational database would provide a single repository for all payment data, a simple interface for easy data entry and information retrieval, and the ability for multiple personnel to more securely access the same data at the same time.

A relational database would support a number of efficiency improvements. For example, invoices could be retrieved automatically through preset reports. Ad-hoc reports and responses to inquiries could be generated by simple queries.

CIRM's application development group could build a robust relational database using software such as Microsoft SQL Server. Now that CIRM has access to CalSTARS data, the Institute will need to determine how best to integrate DGS data into the relational database.

B. ACCOUNTING SERVICES

Finding: Contracting with DGS has led to inefficient and limited access to information.

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The Department of General Services performs accounting functions for CIRM, and the State Controller's Office issues warrants and releases funds to CIRM grantees. As part of the accounting responsibilities it performs for CIRM, DGS enters payment request information into CalSTARS and forwards the request to the SCO. The SCO processes the request through its own system, and then it uploads the final warrant information into CalSTARS.

Until recently, the only way for CIRM to get current information about transactions was to ask DGS to look it up in CalSTARS or in the SCO's fiscal system. Now that CIRM has read-only access to CalSTARS, it can access much of this information directly. In addition, CIRM now utilizes special software to convert downloads from CalSTARS into spreadsheets. However, CIRM still does not have access to view information in the SCO's fiscal system, which would also provide valuable information for use by CIRM.

Recommendation: Request authorization to access the SCO's fiscal system.

With access to CalSTARS and the SCO's fiscal system, CIRM will not only have more timely access to payment information, but CIRM also should be able to streamline its information tracking efforts, since dual tracking of information should be able to be reduced. CIRM is pursuing SCO authorization.

C. BUSINESS DEVELOPMENT

Finding: Despite plans to make business development with biopharmaceutical companies a strategic initiative, as evidenced by CIRM's business development goals, the Institute has not developed a detailed business development plan.

CIRM is increasingly looking to the private sector, and biopharmaceutical companies in particular, to expand and extend its work and translate the research it has funded to products serving patients. This progression can be observed in CIRM's strategic planning documents and the activities of CIRM management. However, CIRM has not prepared a detailed business development plan to clearly and comprehensively define roles, responsibilities, actions, and timing to achieve its increasing focus on business development with biopharmaceutical companies.

For instance, the foundation for collaboration with biopharmaceutical companies was established in CIRM's first strategic plan, which was prepared in 2006. The 2006 Strategic Plan included a five-year goal stating "CIRM will have established effective partnerships in stem cell research between scientific teams in non-profit and commercial sectors." The 2006 Strategic Plan also stated that "CIRM can create new, innovative models for partnerships between the public and private sectors."

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The 2009-2010 Strategic Plan Update included five strategic objectives for building on the values and foundation expressed in the 2006 Strategic Plan. One of the five objectives focused on acceleration of therapeutic discoveries. A number of strategies were identified to achieve this objective, and one of those strategies focused on partnering with industry. Specifically, the strategy stated "Enhance CIRM's relationships with the venture capital, biotechnology and pharmaceutical industries — relationships essential to delivering life-saving therapies based on stem cell research to patients." The 2009-2010 Strategic Plan Update also referenced adding critical private sector capabilities and experience within the senior management team through the positions of General Counsel and Senior Vice President of Research and Development. Through these positions, CIRM has added expertise needed to implement CIRM's programs as they advance toward the clinic, including configuring CIRM regulations to align with the corporate sector and enhancing the prospects for clinical applications by working closely with teams of academic, medical, biotechnological, and pharmaceutical interests.

Business development with biopharmaceutical partners is a focus of CIRM's Draft 2012 Strategic Plan Update. "Build partnerships with industry" is a draft scientific and medical objective, and "leverage investment through partnership" is a draft economic objective. As stated in the 2012 Draft Strategic Plan Update, a long-term goal of CIRM is to "facilitate commercialization of therapies," and a five-year goal is to "drive clinical trials for patients." Creating strategic partnerships with the biopharmaceutical industry is essential to achieving these goals.

In 2011, CIRM expanded the role of the General Counsel to General Counsel and Vice President of Business Development, added a Senior Vice President of Research and Development, and added a Chief Financial Officer. All of these individuals offer experience, knowledge, and specialized skills that will benefit business development initiatives with biopharmaceutical companies.

CIRM's current business development industry engagement goals and initiatives include:

- Developing a model for linking CIRM basic research and translational-clinical projects with appropriate financing to complete product development and delivering treatments to patients with appropriate returns to California;
- Leading the Institute in establishing significant financial and working partnerships between CIRM and industry; and

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- Providing an effective contact for all industry and business issues that evolve from CIRM programs, including IP, freedom to commercialize, legal, and financial matters of concern to biotech- and pharmaceutical-enhanced outcomes.

Specific business development activities to date include the Strategic Partnership Funding Program, Investor and Partnering Conference, JP Morgan Annual Healthcare Conference, IP Patent Funding Program, aiding California research support companies, and attracting co-funding and follow-on financing of CIRM projects.

Recommendation: Create and implement a comprehensive, formal business development plan.

With multiple CIRM executives expected to contribute to business development with the biopharmaceutical industry and so much importance placed on expanding business with the private sector, CIRM should develop a formal biopharmaceutical business development plan. Entering partnerships with biopharmaceutical companies will be instrumental in meeting the goals of clinical trials and commercialization of therapies. The business development plan should clearly identify the roles of key CIRM executives, especially the Chair, President, CFO, General Counsel and Vice President of Business Development, and Senior Vice President of Research and Development.

The business development plan should include business goals and objectives, industry analysis (including trends), assessment of strategic partnering opportunities, financial plan and assumptions, staff roles and responsibilities, and anticipated outcomes.

D. BOND FORECASTING

Finding: Bond forecasting has been hampered by the lack of an enterprise financial system to integrate information from multiple sources internal and external to CIRM.

Proposition 71, which was approved by California voters in 2004, authorized the sale of $3 billion of California general obligation bonds to fund stem cell research. Under the California Constitution, the funds are continuously appropriated solely for the purposes of funding stem research, research facilities, and CIRM's administration. The funds are not subject to transfer or appropriation by the Governor or the Legislature.

Developing the strategic financing structure for CIRM is critical to ensure the maximum amount of funding is available for grant and loan funding. The Chairman of the Governing Board has primary responsibility to manage and optimize CIRM's bond financing and cash

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flow plans. The Chairman coordinates with the President, as well as Science, Finance, and Administrative offices to meet CIRM's financing objectives.

CIRM's bond forecasting is a continuous process that includes gathering input from sources both internal and external to the Institute. Externally, the Chairman's Office works with the Department of Finance and the State Treasurer's Office, the bodies that have primary responsibility for planning and executing the state's bond sales. Additionally, the California Stem Cell Research and Cures Finance Committee (Finance Committee) is the body responsible for directing the structure and timing of the sale of CIRM bonds. The Finance Committee consists of the California State Treasurer, Controller, and Director of Finance, as well as the Chairman of CIRM's Governing Board and two other members of CIRM's Governing Board.

Approximately twice a year, the Department of Finance requests information from CIRM regarding its bond cash needs covering the next three fiscal years in six-month increments. A multiyear forecast is challenging, since it requires CIRM to forecast expenditure timing in a highly dynamic environment.

When CIRM receives a request for information from the Department of Finance, the Deputy to the Chair for Finance, Policy, and Outreach takes the lead in gathering expenditure estimates. Estimates are obtained from the following sources:

- ICOC public meetings and approved strategic funding plans;
- Future program funding estimates (President's Office and Science Office);
- Administrative and operational costs and bond cash balances (Finance Office);
- Drawdown commitments of current and existing funding programs (Grants Management System); and
- Other expenditure information (e.g., ICOC concept approved programs that are in process, but that have not yet resulted in funding commitments).

This information is gathered from each office and is consolidated and updated by the Chairman's Office to respond to requests by Department of Finance and the Treasurer. The Department of Finance and the Treasurer use this information, as well as data supplied by other bond-funded agencies, to determine the size and timing of the State's bond sale and the allocation of bond proceeds.

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Recommendation: Build upon existing procedures and tools that CIRM has implemented to strengthen bond forecasting and further streamline and integrate the bond forecasting process.

To enhance bond forecasting, CIRM has instituted monthly meetings of representatives from the Grants Management Office, Financial Services, and the Chairman's Office to reconcile data and review changes in forecasts related to current and existing funding programs. These meetings have led to more efficient data collection and more accurate forecasting.

In addition, CIRM's new CFO has consolidated the financial information sourced from various groups internally into a common spreadsheet on a shared drive, which can also be utilized for the bond forecasting process. Because the Grants Management System does not maintain historical data, a common spreadsheet, updated monthly by the Deputy to the Chair for Finance, Policy, and Outreach, supports enhanced bond forecasting accuracy and trend analysis.

In addition to the aforementioned process and tool improvements to enable CIRM to more efficiently and effectively respond to Department of Finance and other financial requests, CIRM should consider posting the bond forecasting master spreadsheet on its intranet site and set up check-in and check-out protocols, which will ensure version control.

E. CHAIRMAN'S AND PRESIDENT'S OFFICE RELATIONSHIP

Finding: The working relationship between the Chairman's Office and the President's Office has vastly improved over the past year, but there are still opportunities for improvement.

Over the past several years, the Office of the Chairman (Chairman's Office) and the President's Office have experienced a number of challenges. These challenges were, in part, due to the unique dual reporting structure that exists at CIRM relative to the Chairman's and President's Offices.

Throughout CIRM, it is clear that the issues that existed between these two offices are largely a thing of the past. CIRM has taken a number of measures to improve the situation. For example, CIRM has carefully recruited to fill leadership positions, such as the Chief Financial Officer (CFO) and Executive Director to the Board of Directors, to attract personnel with the ability and affinity to facilitate collaboration and coordination between the two offices.

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Other factors that have contributed to improving the work environment include, but are not limited to:

- Further delineation by the Governing Board of the responsibilities of the Chairman and President, particularly in the areas of finance and communications; and
- Renewed commitment to, and participation in, weekly President-initiated Executive Committee meetings, with attendance by the Chairman, Vice Chairmen, President, CFO, SVP of Research and Development, Executive Director of Scientific Activities, General Counsel & Vice President of Business Development, Deputy General Counsel, Outside Counsel, and Executive Director to the Governing Board.

However, there is room for more collaboration and coordination between the Chairman's and President's Offices. For instance, although members of both the offices participated in the hiring process for the positions of CFO, which was filled in 2011, and Senior Director of Public Communications and Patient Advocacy Outreach, which was filled in April 2012, Human Resources, which resides in the President's Office, was not fully involved in the process. This not only resulted in inefficiencies, but placed CIRM at risk of not complying with its hiring policies and procedures.

Recommendation: Make every effort to manage and operate as one cohesive organization, while recognizing the varying roles, responsibilities, and authorities that exist with positions in both the Chairman's Office and President's Office.

Continue to foster collaboration between the Chairman's Office and President's Office through:

- Joint participation in standing meetings, as appropriate;
- Full utilization of functional resources (e.g., communications, finance, human resources, information technology, and legal) across both offices; and
- Development of tools to provide access to core performance information.

Also, consider resurrecting the Remuneration Committee, an internal committee, to review and recommend changes to CIRM's compensation philosophy and levels to ensure compensation strategies are applied consistently throughout the Institute.

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F. MEETING RHYTHM

Finding: CIRM follows a typical meeting process, involving members of both the Chairman's Office (CO) and President's Office (PO), when appropriate, but the meetings do not involve the review of key performance metrics and the standing meeting schedule consumes more time than necessary.

As reported by CIRM, the Institute's standing meeting schedule is summarized below.

Meeting	Group (Number of Attendees)	Frequency
All Staff	All Employees (51)	Weekly
Executive Committee	CO and PO Executives (14)	Weekly
Senior Staff	PO Functional Executives (9)	Biweekly
Counsel Call	CO and PO Counsel (6)	Weekly
Communications	CO and PO Communications (7)	Weekly
Grant Reconciliations	CO and PO Staff (4)	Monthly
GMS Project Team	Business Owners and Developers (10)	Weekly
GMS Development Team	Development Team (5)	Weekly
Office of the Chair Staff	Chair's Direct Reports (9)	Weekly
President's Office	President's Staff (5)	Weekly
Science Team	All Science Office Staff (30)	Weekly
Science Senior Staff	Science Office Leadership (8)	Biweekly
Review Office	Grants Review Staff (3)	Biweekly
Early Translation Team	Early Translation Staff (5)	Monthly
Clinical/Development Team	Clinical/Development Staff (8)	Biweekly
Grants Management	Grants Management Staff (6)	Weekly
Finance Team	Finance and Chairman's Office Staff (5)	Biweekly

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As described in the findings and recommendations addressing Access to Key Performance Information and Communications in Section IV, CIRM does not effectively communicate outcome-based performance internally or externally. As such, CIRM does not focus on performance metrics as part of its meeting process.

Recommendation: Incorporate performance metrics reporting into a structured meeting rhythm process and streamline weekly meetings.

Once CIRM has established a digital dashboard, it should incorporate the review of this information into a monthly, quarterly, and annual meeting rhythm. Specifically, key performance metrics should be reviewed by the Executive Committee more comprehensively from monthly to quarterly to annually and shared with the rest of the organization during All Staff meetings.

CIRM should consider making the following additional adjustments to its meeting process to achieve enhanced efficiency and effectiveness:

- Conduct All Staff meetings monthly, since all members of the Agency meet on a weekly basis with their functional unit.
- Strive to limit weekly meetings to 30 minutes. If run efficiently, then these meetings should not require 60 minutes. Topics requiring additional discussion should be taken "off line."
- Use exception reporting as a strategy for weekly meetings by focusing on activities requiring coordination, issue resolution, or a decision.

G. ONGOING EFFICIENCY IMPROVEMENTS

Finding: CIRM's Science Office recently initiated an efficiency improvement process, which resulted in the identification of a number of low-value, high-effort activities performed in the normal course of their meeting their objectives.

CIRM is keenly aware that it must keep administrative and implementation costs below six percent of proceeds from bond sales. As a result, the Science Office has been exploring ways to work more efficiently.

Current efficiency initiatives include, but are not limited to, Science Team meetings focused on addressing specific efficiency needs and technology implementation. For instance, Science Officers, Grants Management staff, and Grants Review staff have formed a task force to prioritize activities in a level-of-work versus value-of-work matrix. This developing matrix requires linking day-to-day activities with strategic objectives and

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considering efficiencies across the organization. Activities that are of low value to the organization are considered for de-prioritization and may be removed from the work plan. An example of a work product from these meetings is provided below.

Value	High Effort Activities
High	• Subject area workshops • Reportable progress to ICOC, public including summaries of progress, program updates, performance against metrics • SO project documentation – appropriate to multiple stakeholders • Program management, including actions to strengthen, redirect, and or stop • CFP project interaction • More effective ways to address progress against strategic goals • IT Development (often underlies increasing efficiency and effectiveness)
Low	• Standardize grantee reporting (e.g., for DT projects, the same report format for grantee irrespective of quarter) • Grants Management processes to ensure reporting compliance/ completeness (alerts) • CFP workshops to promote interaction and collaboration between CA and CFP scientists, value may depend on which stakeholder. Are there more effective ways to bring together potential collaborators? • Eligibility or process exceptions to a RFA (e.g., the recent Disease team exception route) • Effort spent on Review Summaries for applications not recommended by the GWG, particularly lower scoring applications

Initial discussions were held during Science Team meetings that took place the weeks of November 15, 2011 and November 22, 2011 to assess how Science Team members spend their time. In particular, the group identified high-effort activities and categorized them as either high value or low value. A subsequent discussion was held with Science Office senior staff on December 16, 2011.

Recommendation: Continue efforts to identify and implement efficiency improvements and strive to quantify efficiency gains.

CIRM should continue to use the task force approach to seek ways to minimize low-value high-effort activities. The task force should identify efficiency improvements and select improvement projects to undertake each quarter. Linking this process to the budget will help CIRM to remain under the six percent administrative and implementation spending limit, as well as gain efficiencies in program spending.

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Where possible, CIRM should quantitatively measure efficiency improvements with output-to-resource ratios. Seeking additional ways to measure efficiency has benefits to the organization beyond identifying areas of potential productivity improvement. For instance, measuring efficiency can facilitate management control of processes, serve as a scorecard of management's progress, and provide additional accountability. It can also aid in prioritizing activities and resource utilization.

H. ONBOARDING

Finding: CIRM has a formal new employee orientation process, but it lacks some elements of a comprehensive onboarding program, which limits new employee productivity in the early stages of employment.

All new CIRM employees participate in a thorough orientation process. However, new employees do not participate in a formal onboarding process. Onboarding programs typically prepare new employees for their specific role and show them how to achieve maximum productivity as quickly as possible during the early stages of employment.

Recommendation: Develop a formal onboarding process and incorporate it into the overall new employee orientation program.

CIRM is a fast-paced organization with many processes and procedures that reflect interdependencies between functions across the organization. New employees should be oriented to the organization with a formal onboarding process. Onboarding should expose new employees to CIRM's culture and expectations, the employee's role, and key people in each interrelated group.

There are many benefits to a formal onboarding process. Reducing new employee anxiety by equipping them with the information they need to get their job done also reduces manager and peer time needed to answer questions, explain processes, and clarify issues. It also increases productivity as an employee assumes new responsibilities and settles into their job. Establishing the organization's culture, values, expectations, and operations at the outset of the new employee relationship helps employees feel comfortable with their new position and responsibilities. New employees who are comprehensively introduced to their jobs become productive employees and effective team members faster.

A typical new employee orientation program has two components:

1. *General Orientation* applies to all employees and covers basics such as personnel, payroll, benefits, and employee rights. The general orientation packet should

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include required paperwork, employee handbook, benefits information, personnel directory, training materials, and office equipment instructions.

During the general orientation, employees should be introduced to the mission and values, taken on a tour of the office, and walked through important procedures such as time entry. Developing a consistent orientation process for all new employees helps to establish and reinforce the culture.

2. *Job-specific Onboarding* is different for each new employee and applies to their specific responsibilities and relevant policies and procedures. CIRM should create onboarding templates for each group or function that extend past the first day of employment. The onboarding process should address the "ramp-up" period, during which employees acclimate to the organization and strive to enhance their contributions and impact as rapidly as possible. For instance, an effective onboarding process should introduce new employees to the full interworking of the organization so they understand how their role fits into the overall landscape and mission achievement. Many organizations assign mentors or peer "buddies" to provide guidance to new employees. These experienced staff act as a built-in knowledge center for new employees and help to maximize assimilation and productivity.

Job-specific onboarding is of particular importance for CIRM, because the Institute is dynamic and roles have many interdependencies. Job-specific onboarding should include introductions to colleagues in other departments and process walkthroughs with supervisors and peers. These meetings should be scheduled within the first week of employment. They should be supported with documentation in the job-specific orientation packet. While this part of orientation will vary from team to team, CIRM human resources personnel should create a template and work with managers to develop full orientation materials.

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VI. HUMAN CAPITAL FINDINGS & RECOMMENDATIONS

A. RESOURCE FORECASTING

Finding: CIRM does not use a comprehensive forecasting tool to determine human resource capacity and prioritize resource utilization to perform core activities.

CIRM is a scientifically focused, professional services organization with a substantial, continuously changing workload. The organization does not use a comprehensive forecasting tool to determine human resource availability and capacity to meet the workloads associated with grant review, management, and scientific oversight. CIRM's dynamic human resource requirements can make it difficult to balance workload and demonstrate the need for additional staff resources. CIRM does not have full understanding of the resource requirements associated with all active and planned RFAs. It is not common practice for CIRM to forecast resource requirements for Science Officers, Grants Review staff, or Grants Management staff based on RFA schedules and resulting application approvals.

To date, human resource planning at CIRM has been primarily directed toward assigning Science Officers to projects once funding is approved by the ICOC. Resource planning based on project assignment is needs-based, driven by the estimated effort required to manage a project. Project assignment planning, which is performed utilizing a spreadsheet originally generated by Grants Management, takes into account Science Officer expertise, interests, number of projects currently being managed, and estimated effort per project (e.g., amount of project oversight, project progress reporting frequency, and involvement of collaborative funding partners). In addition, another spreadsheet-based resource forecasting tool is currently being developed by CIRM's CFO. The tool is in the early stages of development, focuses on the Institute's finances, addresses high-level resource requirements, and has not yet been applied to day-to-day operations.

An example of the fluid nature of the resource requirement environment is the recent additions to the 2012 RFA schedule already in place, all of which will require Science Officer oversight. These additions include key novel initiatives (e.g., hPSC and genomics), a new RFA for New Faculty Physician Scientists, and implementation of Opportunity Fund programs (i.e., Strategic Partnership, Bridging Fund, and External Innovation) that address recommendations from the October 2010 External Advisory Panel Report.

The current spreadsheet-based approach is becoming more cumbersome as the organization grows and its portfolio of programs and projects becomes more complex and

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diversified. Since CIRM does not have a workflow management system, the organization does not have the ability to track the grant review and management process at an individual staff member level and efficiently and effectively forecast and manage the interdependencies of projects, activities, and resources.

Recommendation: Acquire and implement human resource forecasting software.

Resource forecasting software should have the ability to forecast specific staff resources for Science Officers, Grants Review staff, and Grants Management staff, and reflect efficient and effective coordination between these specialties. The software should address resources at the organizational, program, and project level, since there are significant interdependencies between staff members and programs at CIRM that must be reflected in resource planning and allocation. Robust human resource forecasting software should include:

- Integration of other planning processes, including the strategic plan, budget, and project plans;
- Workforce supply analysis, including resource levels and expected retirements;
- Forecast of workforce needs, identifying any new competencies and skills needed;
- Strategies and actions to address deficiencies and surpluses; and
- Regular evaluation of the tool to ensure its effectiveness.

Comprehensive resource forecasting software can also facilitate organizational continuity by linking recruitment, training, and retention requirements to organizational goals.

Examples of resource forecasting software that CIRM could consider include Artemis, Planisware, Microsoft Project, Saviom, Smartsheet, and Unanet. A software package suitable for CIRM's needs is estimated to cost $25,000 to $50,000.

B. ORGANIZATION AND STAFFING

Finding: CIRM's Science Officers, the Grants Review Office, and Grants Management staff are stretched thin, especially due to the addition to the funding plan of programs that include twice annual submission and review of applications. As a result, Science Officers in particular struggle to spend as much time as necessary overseeing each funded project.

As noted in findings and recommendations addressing Grants Oversight and Resource Forecasting, CIRM is challenged each year to implement the annual RFA schedule and

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spend sufficient time monitoring the progress of each project. However, Grants Management staff is optimistic that the near-term planned implementation of key additions to the Grants Management System will increase their efficiency and effectiveness. In addition, the Grants Review Office is proposing to add a Review Specialist to increase efficiency and effectiveness.

Section 125290.70 of Proposition 71 limits both administrative and implementation costs to a combined total of six percent of the proceeds of the bonds authorized by Proposition 71. As organizations grow, it is easy for administrative and implementation costs to increase. CIRM must be especially careful to keep these costs below the six percent limit. Through January 1, 2011, CIRM operated under a more restrictive staffing limitation with a maximum allowable staffing level of 50 FTEs. This limitation was removed by SB 1064.

As the organization has matured, the Institute has increased the number of science and direct science support positions to meet the needs of its growing grant portfolio. At the same time, functional support staffing levels have remained about the same.

Recommendation: Reevaluate staffing levels if administrative and implementation costs are forecasted to exceed 6% of bond proceeds.

Utilize resource forecasting software recommended in the finding and recommendation on Resource Forecasting to project staffing requirements. The software should take into consideration forecasted workloads, staffing mix, and service level standards.

If the Institute forecasts administrative and implementation costs to reach the 6% cap at some point in the future, then it should reevaluate its staffing mix well in advance. Under a constrained staffing scenario, CIRM should carefully consider the required staffing levels for science and direct science support positions (e.g., scientific leadership, Science Officers, Grants Review staff, and Grants Management staff) versus functional positions (e.g., communications, finance, human resources, information technology, and legal).

C. RECRUITMENT AND RETENTION

Finding: Employee retention is a significant challenge for CIRM.

Employee retention at CIRM will become a more prominent issue as the Institute nears the end of its bond funding. There are two major factors that impact CIRM's ability to attract and retain quality employees: They include 1) uncertainty around the lifespan of the Institute and 2) difficulty addressing retention in a public sector compensation setting.

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Positions at CIRM are less stable than at competing organizations, since CIRM plans to make its last awards around fiscal year 2016-2017 (see CIRM's Transition Plan, dated January 31, 2012). As such, CIRM cannot offer tenured positions like those in academic or research institutions, nor can it offer the stability traditionally found in state agency employment. As the end of CIRM's funding nears, employees are likely to begin searching for new opportunities.

Recent turnover at CIRM is due in part to higher private sector salaries, limited opportunities for advancement at CIRM, and more stability in other organizations. Turnover at CIRM decreased consistently from 2007 to 2010 as CIRM grew, with very little turnover in 2009 and 2010. However, turnover increased four-fold, from 5% to 20%, between 2010 and 2011. Twenty percent turnover is a significant amount and represents a major loss of human capital.

Year	Peak Employment	Departures	Turnover Rate
2007	28	11	39%
2008	35	5	14%
2009	43	3	7%
2010	44	2	5%
2011	51	10	20%

CIRM has a comprehensive compensation philosophy that acknowledges the Institute's recruitment and retention challenges, which include a restrictive conflict of interest policy. For instance, CIRM targets base salary compensation at the 80th percentile of comparable positions in medical schools within the University of California system and private research institutes that receive and administer large grants and are involved in stem cell research.

Employees in positions at grades 1-9 are eligible for merit compensation of up to 5% of their base salaries, and employees in positions at grades 1-6 are eligible for a performance bonus. The ICOC Chair and President are not eligible for merit pay. Historically, CIRM has awarded merit compensation but not cost of living adjustments (COLA). CIRM's compensation philosophy also relies on the ability to attract employees that are mission driven and committed to stem cell research.

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Recommendation: Ensure the Transition Plan addresses CIRM's unique and increasing recruitment and retention challenges, and ensure CIRM leadership clearly and regularly communicates transition plan strategies to all employees.

CIRM is developing a transition plan as required by Senate Bill 1064, which became effective January 1, 2011. As the Institute further develops its transition plan, it needs to address its increasing recruitment and retention challenges. CIRM leadership should be as transparent as possible with employees about potential scenarios for transition, timelines for these scenarios, and the Institute's preferred course of action. Transparent communication will mitigate concerns that will rapidly increase if employees do not have visibility to the Institute's transition strategies and how their positions may be impacted.

Where possible, CIRM should seek flexibility in its compensation strategies, such as the use of retention bonuses, in order to retain key employees. For instance, CIRM could consider expanding performance bonus compensation to grade 7 through 10 and building a "retention reserve" by setting aside merit compensation and/or performance bonus compensation that would have otherwise been awarded over the next few years to accumulate enough funds to support a retention compensation program as the organization nears potential transition milestones.

Also, consider resurrecting the Remuneration Committee, an internal committee, to review and recommend changes to CIRM's compensation strategy to address retention challenges.

D. BOARD CODE OF CONDUCT

Finding: CIRM does not have a Board Code of Conduct.

CIRM is governed by a 29 member Independent Citizen's Oversight Committee (ICOC), the Governing Board. The ICOC is comprised of members appointed from the University of California campuses with medical schools, other California universities and California medical research institutions, California disease advocacy groups, and California experts in the development of medical therapies. Each board member brings a different perspective, many members are involved in disease advocacy groups, and all members are passionate about CIRM's mission.

Many government agencies and non-profit organizations, such as the Regents of the University of California, have adopted codes of conduct to set expectations for board members, and codes of conduct are considered to be "best practices" for organizations like CIRM. At the request of the Chair of the Governance Subcommittee, CIRM's outside counsel prepared a draft code of conduct, which was presented for consideration by the

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Governance Subcommittee during its June 13, 2011 meeting. CIRM's outside counsel has subsequently revised the draft code of conduct based on comments provided by the Subcommittee.

Recommendation: Adopt a Board Code of Conduct.

Given the size, diverse composition, responsibilities to the public, necessity for transparency, and passionate views of CIRM's board members, CIRM's Governance Subcommittee should approve and recommend for adoption by the ICOC a Board Code of Conduct, and the ICOC should adopt it.

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VII. INFORMATION TECHNOLOGY FINDINGS AND RECOMMENDATIONS

A. INFORMATION TECHNOLOGY PLAN

Finding: CIRM utilizes a number of disparate information systems to manage the significant amount of data associated with the programs and projects it funds, and the lack of systems integration reduces reporting efficiency and effectiveness.

CIRM faces challenges associated with the relatively unique information technology requirements of a complex RFA application and grants management program. CIRM utilizes a combination of off-the-shelf and internally-developed solutions, and the Institute has made system solution decisions without the benefit of an information technology (IT) plan. CIRM's information system needs have been met by a variety of tools, including in-house developed applications, off-the-shelf applications, databases, and spreadsheets, most of which are not integrated.

CIRM has been developing its core grants information system for several years, and it still has considerable development activities remaining. The partially completed Grants Management System, which has been developed through contracted applications development resources, will serve as a cornerstone solution, since it will encompass grants review and grants management activities. In 2012, the GMS is planned to replace the GIFTS system, which currently meets many of the organization's grants management needs, but it is not integrated with grants review information. A recent initiative was undertaken by the Communications Department to integrate the GMS with the website to enable automated population of key web content.

To complicate matters, the California State Department of General Services performs accounting functions for CIRM, and the State Controller's Office, another California state agency, issues warrants and releases funds to CIRM grantees. As a result, core CIRM financial data resides in DGS and SCO systems, to which CIRM does not have full access. In November 2011, CIRM gained approval from DGS for read-only access to CalSTARS. CIRM is in the process of obtaining software required to facilitate access to CalSTARS.

In addition, CIRM's information technology resources consist of a team of five (5) full-time equivalent (FTE) contractors, including a lead contract developer to direct the other contract developers. CIRM does not have a technology leader with responsibility for establishing the Institute's overall technology strategy.

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Recommendation: Develop a comprehensive information technology plan to guide information systems decisions, and designate someone to provide ongoing information technology direction for the Institute.

To meet all of CIRM's various technology requirements, the Institute should commission the development of a comprehensive information technology plan. The plan should address how to efficiently and effectively incorporate data from CalSTARS into CIRM information systems. In addition, CIRM should provide ongoing information technology leadership, either through internal or external resources, to ensure the information technology plan is being implemented and the information technology needs of the Institute are being met.

The information technology plan should address CIRM's scientific and business needs through the use of technology. The plan should include:

- A clear vision for information technology consistent with CIRM's vision and goals.
- Alignment of technology initiatives with institutional priorities, ensuring that IT programs support CIRM's business objectives.
- Technology needs and constraints, focused on aligning technologies throughout the Institute. Needs and constraints should address, but not be limited to:
    - Information access requirements for the various types of users;
    - Plan for system integration and consistency between programs and departments;
    - System risks associated with physical and electronic security, information access, data loss/redundancy, contingency plans, and risk methodology;
    - Hardware and software standards; and
    - Limitations at the institutional, policy, program, personnel, and funding levels.
- Gap analysis between CIRM's technology needs and existing systems.
- A list of new IT projects and funding requirements to address technology needs.
- A technology management strategy, including IT organization structure, governance, roles, and responsibilities.

A common technique to aid the planning process is developing an "as-is diagram" of the current processes, entities, and systems in use that identify the current issues that impact process efficiency and data integrity. An "as-is" diagram is typically followed by a "to-be

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diagram" that depicts the organization's future vision of how technology systems will support the relevant entities and the flow of information for mission critical operations.

Development of a comprehensive information technology plan by an experienced IT consulting firm for an organization like CIRM is estimated to cost $40,000 to $60,000.

B. GRANTS MANAGEMENT SYSTEM

Finding: Grants Management System development is effectively managed at a tactical level, but it lacks dedicated, strategic governance and oversight, which has resulted in an elongated development process and requirements conflicts.

CIRM initially considered using Grantium, an off-the-shelf grants management system. The vendor's approach followed a traditional "waterfall" approach that necessitates a comprehensive set of requirements to be defined prior to performing any development work. CIRM decided that this type of approach would not be adaptive enough to suit their needs, as each RFA potentially introduces new data elements that need to be captured and processed.

CIRM determined that it needed customized functionality in order to meet its unique business requirements, so it chose an in-house development approach. Development and support of the GMS is being accomplished by a team consisting of five (5) full-time equivalent (FTE) contractors, including a lead contract developer to direct the other contract developers.

The development team is utilizing proven tools for release planning and management, code repository, application development, testing and deployment, and delivery. Each tool is briefly described below.

- Mingle is the system of record for release planning and management, providing the means for tracking bugs, enhancement requests, and task workflow. Mingle provides a dashboard view of development activity, recent releases and their actual durations, planned features, and expected percentage of effort for each functional category.
- Git is the code repository, and it is used with Mingle to facilitate application management.
- Ruby On Rails (RoR), an industry-leading open source development environment, is the application framework. RoR facilitates rapid creation of highly scalable solutions, while emphasizing efficient code reuse.

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- Cucumber provides a standardized platform for automated testing and deployment and facilitates the definition, execution, and management of test and deployment scripts.
- Application delivery is provided by industry standard components, which include a PostgreSQL database engine and Apache web servers.

Data from Mingle indicated there are approximately 894 person-days worth of development effort remaining for new features as of January 2012, with the majority of this effort focusing on core technical capabilities and post-award functionality. Key areas of development focus for 2012 include core functionality to support post-award processes for Grants Management, which is currently being accomplished with the GIFTS system and spreadsheets, and integration with the CIRM website.

An example of a key strategic accomplishment for the Grants Review process is the ability of GMS to accommodate variations in RFAs. A metadata framework was created by the development team to address the adaptive needs associated with RFA composition. As a result, RFA implementation has been reduced from 6-8 weeks to typically 2-3 hours.

While CIRM stakeholders appear to be providing adequate participation to inform the tactical needs of each GMS release (e.g., RFA mark-ups to drive development tasks and acceptance testing prior to deployment), GMS development lacks proper governance. For instance, the needs of Grants Review and Grants Management can compete with each other, reportedly sometimes causing newly introduced functionality to conflict with existing functionality. In addition, requirements continue to grow and change, usually due to the needs of new funding programs.

Recommendation: Develop a detailed plan for completing development of the GMS, and provide ongoing project oversight.

Under the guidance of the new CFO, CIRM recently developed a detailed list of specifications and corresponding timelines for substantial completion of the GMS project. The completion plan should define and prioritize all remaining development, testing, and deployment activities to achieve stakeholder requirements. In addition, the plan should specify the costs of each activity. CIRM would benefit from an external review of the internally-developed completion plan. A review by an experienced consultant is estimated to cost $10,000 to $20,000.

A consensus-based process for decision making and prioritization has also been implemented. The GMS project requires dedicated, ongoing project oversight, either through internal or external resources, to ensure the project is meeting the strategic needs

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of the Institute and each facet of the organization that it will support. Strategic project oversight will complement the tactical project management that is being performed by the contract development lead.

C. WEBSITE CONTENT MANAGEMENT

Finding: Integration of website content management has not been an integral part of the GMS development process, which could result in suboptimal operational efficiency and effectiveness.

The CIRM Communications Manager currently acts as the "webmaster," maintaining CIRM's current website using the Drupal 7 open-source content management system. CIRM utilizes outsourced services from Acquia and Chapter3 for development of the new website, integration with GMS, and day to day support. The webmaster lacks formal training on website design and administration and does not have authority to govern website content.

The current website provides lists of RFAs and grants and the ability to search grants by attributes such as institution, disease, funding type, human stem cell used, new cell line generation, and international collaborator. This information is maintained manually, which presents challenges for coordination with Grants Management. Examples include difficulty tracking changes associated with grant recipient reallocation and differing dollar amounts between the CIRM website, grant recipient brochures, and other publications.

Integration of the GMS with the new website is expected to enable grant information to be updated automatically. Part of this solution will include a "staging area" where grant information will be subject to review and approval by grant owners prior to publication. The new website will poll for updates from the GMS on a weekly basis, while allowing for manual overrides for updates from the staging area.

However, website development and tie-in with GMS are limited by similar challenges associated with lack of IT governance. For instance, requirements for website integration with the GMS are being impacted, and at times overridden, by changes driven by GMS development. In addition, some of the older information provided through the current website came from legacy databases, instead of the GMS, and this information has to be retrieved from these databases since it has not been incorporated into the GMS.

The items on a five page punch-list pertaining to the new website development, which address functionality, press releases, grant awards, and application review, are expected to be completed in the first or second quarter of 2012. The remaining tasks for website

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integration are underway. Ultimately, the current lack of governance and coordination could result in website and GMS solutions that may not optimally meet the needs of all parties and could necessitate "work-abounds" to remediate functional shortcomings.

Recommendation: Define the role of CIRM's website as part of a comprehensive information technology plan, and establish clear authorities and responsibilities for website administration.

While a punch list is in place to help drive website completion, CIRM's information technology plan needs to address the goals for its website. The plan should:

- State the mission of CIRM's website in supporting both communications and operations;
- Specify the web-based information needs of CIRM's target audiences;
- Define the roles and responsibilities necessary to govern website content and functionality in order to ensure requirements for each department are met; and
- Delineate the IT actions required to achieve the website mission, content, and functionality.

D. DOCUMENT MANAGEMENT

Finding: Data and document access are inefficient as a result of CIRM operating without a document management system.

CIRM has outgrown its current document management methods, and there is a need for improved document management. In most cases, CIRM staff cannot access information without human interface. Information is stored in multiple locations, which are not linked or indexed. For instance, some information is located in the GMS, some in GIFTS, and some on the shared drive, and there is not clarity on which takes precedence.

While the GMS provides the ability to support file attachments in a referential fashion, document versioning and ownership control are functions that are not in scope for GMS. The lack of a document management system could result in documents and data being lost or, at a minimum, being difficult and inefficient to find due to reliance on location knowledge by process owners.

Recommendation: Implement a document management system.

A document management system (DMS) provides the functionality to support document creation, capture, version control, and access control. Benefits of a DMS include reducing

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the need for human interface when searching for information, decreasing the time required to respond to requests for information, providing version control, and managing access authorization. Other DMS functionality includes support of collaboration and workflow management. For instance, CIRM could use a DMS to efficiently develop and route policies for review and sign-off, as well as other business decisions that require multiple approvals.

CIRM should identify and prioritize its document management needs, and select a system to address priority needs. Some examples of document management systems include Archive Power, Captaris, Doc-Link, DocStar, DocuTREEV, iCompass, ImageNow, ImageTek, LaserTek, LaserFiche, Optix, ProFile, Questys, SIRE Technologies, and SmeadSoft. A typical document management system has five primary functions. They include:

1. *Defining:* Metadata is defined and stored for each document in a DMS. The level of detail is determined in the needs assessment and should include the date the document was created, the user who created it, and any keywords that will enable search and retrieval. The DMS can either extract metadata automatically or prompt the user to enter identifying data.
2. *Storing:* Storage can be on-site or off-site, depending on CIRM's needs and capabilities. Document storage requirements identified in the needs assessment should specify how long documents are stored, archive management, and when they should be destroyed.
3. *Indexing:* Like a paper file system, documents in a DMS are labeled, sorted, and indexed, but with metadata. A robust index supports the quick and accurate retrieval of documents. The needs assessment will help CIRM to create an index topology, including the format of unique document identifiers.
4. *Retrieving:* A simple DMS uses a unique identifier for each document to retrieve it. The stronger the indexing system, the more flexible and powerful the retrieval can be. Allowing users to specify partial identifiers and keywords will generate a list of documents matching the search criteria. An even more complex retrieval system will search the documents themselves for keywords and phrases.
5. *Controlling Access:* As determined by the needs assessment, the DMS will assign different, appropriate levels of access to documents for different types of users. Without compromising privacy and confidentiality, users can access the information they need. System administrators can adjust access as needed. Another benefit of a DMS is the ability to remotely and securely access documents.

A DMS appropriate for CIRM is estimated to cost $50,000 to $60,000.

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VIII. MANAGEMENT RESPONSE

CIRM management concurs with the findings and recommendations in the Fiscal Year 2010-2011 Performance Audit Report. The recommendations are focused and constructive. CIRM is already implementing many of these recommendations, and we will be investigating the others in the coming months.

We want to acknowledge that the Moss Adams team put a great deal of time and effort into learning about CIRM, and that is reflected in the accuracy and relevance of the findings and recommendations.

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