FINAL REPORT FOR

# CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

FY 2013-2014 PERFORMANCE AUDIT

May 12, 2015

Prepared by:

**Moss Adams LLP**

999 Third Avenue
Suite 2800
Seattle, WA 98104
(206) 302-6500

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Certified Public Accountants | Business Consultants

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# 1. 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 10 or more years to support and advance stem cell research and regenerative medicine.

CIRM is required to commission a performance audit every three years. The first performance audit covered Fiscal Year 2010-2011, and this performance audit covers Fiscal Year 2013-2014. 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, each performance audit shall 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 25 interviews with personnel throughout the organization, including the Board Chair and Vice Chair, Board 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, and we attended a Grants Working Group Meeting.

- Testing: Using standardized sampling methods, we tested internal controls and compliance with policies and procedures for core functions.

## B. OBSERVATIONS

Through the performance audit process, we gained broad and deep exposure to CIRM management and operations. Recent leadership changes and introduction of CIRM 2.0 have positioned the organization for sustained success. CIRM employees offered ideas for improving efficiency and effectiveness and enhancing commitments to transparency and good stewardship of public funding.

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## C. RESULTS

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 listed below.

| No. | Recommendation |
| --- | --- |
| 1 | Continue to use systems controls implemented in July 2014 to ensure the consistent collection of Financial Interest Disclosure Forms in accordance with stated policies. |
| 2 | Document procedures for the Financial Interest Disclosure Forms review and reporting processes, and work with IT to develop fields within the GMS for the Grants Review Staff to use to record evidence of the review activities performed. |
| 3 | Implement policies, procedures, and resources to achieve more timely review of progress reports, since the review of progress reports is an integral part of understanding the scientific progress being made by grantees. |
| 4 | Implement procedures to ensure adherence to the Grants Administration Policy. |
| 5 | Implement enhancements to the GMS to support increased accountability for, and enforcement of, Annual Utilization Report requirements. |
| 6 | As CIRM-funded IP developments increase and advance toward commercialization, increase efforts to protect IP by modifying the GMS to gather more data on IP commercialization events and continue to strengthen its process for monitoring and detecting non-disclosure. |
| 7 | Develop a slate of operational performance measures aligned with CIRM's strategic plan and report regularly to the ICOC. |
| 8 | Continue to proactively focus on improving employee engagement through effective employee outreach, team building, and communication. |
| 9 | Ensure performance evaluation and merit increases occur in a timely manner. |
| 10 | Continue to monitor current trends in web application development to determine the best development applications to support the GMS moving forward. |
| 11 | Continue to identify and pursue opportunities to enhance GMS capabilities to automate processes, reduce paperwork, and enhance information access. |
| 12 | Continue implementation of FY 2010-2011 performance audit recommendations. |

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## D. REPORT CONTENT

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

- Section 2; Objectives, Scope, and Methodology
- Section 3; Commendations
- Section 4; Compliance Findings and Recommendations
- Section 5; Efficiency and Effectiveness Findings and Recommendations
- Section 6; Management Response
- Appendix: Progress Toward FY 2010-2011 Performance Audit Recommendations

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# 2. OBJECTIVES, SCOPE, AND METHODOLOGY

## A. BACKGROUND

The California Institute for Regenerative Medicine (CIRM) is a state agency that was established in 2004 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). CIRM issued its first round of funding in 2006, and the organization expects current funds to support new awards through 2020.

## 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:

(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.

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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 RESPONSIBLITIES

CIRM management has many responsibilities that were assessed as part of the Fiscal Year 2013-2014 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 ensure compliance with policies and procedures; and
- CIRM operates as economically, efficiently, and effectively as possible in the execution of its mission.

## D. PERFORMANCE AUDIT METHODOLOGY

The performance audit of FY 2013-2014 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 activities with applicable laws, policies, and procedures;
- Testing key internal controls; and
- 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.

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 general audit methodology for each core function is summarized below.

- Performed document review, interviews, and walkthroughs to understand workflow processes, key controls, and population sizes;

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- 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; and
- Discussed our findings and recommendations with CIRM management to verify facts contained in our findings and test the practicality of our recommendations.

In addition to the general methodology described above, we have provided our specific methodology for each core function as follows:

**Grants Application and Review**

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 performed in accordance with CIRM's stated policies; and
- 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 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 to discuss the procedures with key personnel. We also attended a GWG Review meeting. 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, and the conflict check process was monitored by Grants Review;
- External reviewers assessed grant pre-applications and documented their review, scoring, and recommendation;
- GWG reviewed grant applications and documented their review, scoring, and recommendation; and
- ICOC reviewed and approved the slate of applications.

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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 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; and
- CIRM retained documentation to substantiate ICOC's selection of applicants.

## Grants Management

We reviewed the grants management process (i.e., pre-award review, award acceptance, and/or monitoring processes) as guided by CIRM's Grants Administration Policy and internally documented policies and procedures for active grants during fiscal year 2013-2014. 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; and
- CIRM ensured the required reports were received from grantees and were reviewed.

During onsite fieldwork, we interviewed the Grants Management Officer, 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 for a sample of grants were as follows:

- The Grants Management Officer and a Science Officer approved the pre-funding administrative review (PFAR) checklist;
- The NGA was reviewed and approved by Legal 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;

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- 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; and
- Final reports were reviewed by Grants Management and the appropriate Science Officer, and 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 were tested using samples 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, and 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, and initiated follow up if progress reports did not meet content or timing requirements; and
- For grant close-out, final reports were received and processed by CIRM.

**Loans**

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. The procedures that were 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; and
- CIRM obtained, and appropriate personnel reviewed, information required to determine borrower's compliance with the loan agreement.

The key control identified during the walkthrough process and tested for a sample of active loans were as follows:

- Financial viability was reviewed and documented annually.

In addition to testing the key internal control specific to active loans, we tested compliance with the loan management process. The compliance requirement tested specific to active loans was as follows:

- Pertinent information was obtained to ascertain borrower ability to repay loans.

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**Contracts**

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; and
- 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. Key controls that were identified during the walkthrough process and tested for a sample of contracts 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, and signature of contract was indication of approval of contract;
- Procurement files documented the basis of selection;
- A standard CIRM Independent Consultant Agreement was used, and 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, then 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, then 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; and
- 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, and these reports were reviewed by the Subcommittee/Board.

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

- If sole source was used, CIRM documented the justification for sole source;
- 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, and 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; and
- 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.

### Intellectual Property

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

- CIRM ensured that grantees triggering the IP Reporting requirements reported the required disclosure information; and
- CIRM ensured that grantees were conforming to invention and licensing requirements.

During onsite fieldwork, we interviewed the Associate General Counsel and Grants Management Officer. We performed walkthroughs of the processes related to IP regulations, including examples of follow-up communications with grantees, and process changes to the IP process. 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 a sample of the invention disclosures reported during fiscal year 2013-2014, as well as the subsequent annual utilization reports to determine if grantees were complying with the reporting requirements under CIRM's IP regulations. We also performed interviews and inspections of documents related to CIRM's procedures to detect failures of institutions to disclose IP.

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

- The Life Sciences Transactions Attorney performed procedures to detect failures of institutions to disclose inventions and utilization activities; and
- The Grants Management Office considered available enforcement actions and applied these actions to institutions with late Annual Utilization Reports.

In addition to testing key internal controls, we tested compliance with the IP reporting process. Compliance requirements tested were as follows:

- Annual Utilization Reports were required from Institutions who submitted invention disclosures; and
- Grants Management Specialists communicated with the Technology Transfer Offices (TTOs) regarding utilization report submissions.

## 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; and
- 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 interviews were conducted:

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| Function | Position |
|---|---|
| ICOC | Chair, Vice Chair, and selected other members |
| President's Office | President |
| Grants Management | Grants Management Officer |
| Grants Review | Director of Portfolio Development and Review, Grants Review Specialists |
| Science Team | Executive Director of Scientific Activities, Associate Director of Research, Associate Director of Review |
| Legal | General Counsel, Associate General Counsel, Business Development Officer |
| Administration | Executive Director of the Governing Board, Senior Executive Assistant to the President, Office Manager, Chief Human Resources Officer, Senior Executive Assistant to the Vice Chairman, Senior Director of Public Communications and Advocacy, Deputy to the Chairman |
| Finance | Director of Finance, Contracts Administrator |
| IT | Director of IT, Systems Engineer, IT Architect |

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 focused on determining the significance of each finding and 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.

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## 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

In addition, Moss Adams delivered 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.

*Moss Adams LLP*

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Seattle, Washington
May 12, 2015

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# 3. COMMENDATIONS

The purpose of a performance audit is to identify opportunities to improve accountability and execution. Before identifying opportunities for improvement, it is important to acknowledge that CIRM has many strengths. In particular, the organization has made significant strides in the following three areas since the FY 2010-2011 performance audit:

- Grants management system
- Grants process improvements
- Organizational culture

## A. GRANTS MANAGEMENT SYSTEM

CIRM has made substantial progress developing its Grants Management System (GMS) to meet the specific business needs of the organization. The legacy system, GIFTS, has been fully retired. The GMS now addresses functional needs throughout the life cycle of a grant, from application to close-out. In addition, website integration has been implemented. Key system improvements include:

- Automated feeds to CIRM's website;
- A rich set of automated features to better support CIRM and grantee tasks, including progress reporting, financial reporting, and publication disclosure;
- Basic workflow capabilities, including automated alerts;
- Annual progress reports, including financial reporting and publication disclosure; and
- Electronic signatures for documenting the review of the PFAR, NGA, and Close-Out checklists.

## B. GRANTS PROCESS IMPROVEMENTS

In December 2014, CIRM's Governing Board approved a major restructure of the process utilized to evaluate, award, and oversee grants. The new process, "CIRM 2.0," aims to accelerate the progression of research through:

- Open, rolling applications;
- Shortened review period;
- External budget review;
- More standardized contracts focused on operational milestone delivery; and
- Standing advisory panels for each project, with quarterly progress reviews.

In the past, the grant award process took an average of 22 months from application to award, with a five-to-seven month review period. Under CIRM 2.0, the review period is shortened to 81 days. Rolling applications rather than annual, limited application periods should provide more opportunities for strong projects to apply for funding. In addition, applications must be for projects that are ready to start within 45 days of funding approval, further accelerating the pace of research.

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As part of CIRM 2.0's efficiency improvements, the organization was restructured to align scientific staff within therapeutic areas and consolidate support functions. Science Officers are now organized in one of six specialty areas (Application and Review, Discovery, Neuro/Ocular, Blood and Cancer, Organ Systems, and Projects and Centers), and administrative and operations staff are organized in three units (Administration, Finance, and Legal). This structure is flatter, with each of the nine units overseen by a Director, who reports to the President.

CIRM 2.0 began roll-out in 2015 with the clinical program, and translational and discovery grants will follow this year. At the time of this report, CIRM was actively recruiting for three scientific Director positions. Once these positions are filled, the new organization structure will be fully in place.

## C. ORGANIZATIONAL CULTURE

During the course of fieldwork for the performance audit, the audit team observed a more stable environment, enhanced communication and collaboration, and improved staff morale compared to 2011 and 2012 when the previous performance audit was conducted. A number of factors contributed to the improvements in organizational culture, including

- Enhanced seamlessness between the President's Office and Chairman's Office;
- Revised financial forecasts that project new awards through at least 2020;
- Efficiency improvements including investments in document management and grants management systems; and
- Renewed energy under CIRM's new President, in part due to CIRM 2.0.

Process improvements, organization structure changes, and upcoming strategic planning efforts should continue to bolster CIRM's culture.

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# 4. COMPLIANCE FINDINGS AND RECOMMENDATIONS

## A. GRANTS APPLICATION AND REVIEW

1. **Finding: Although changes to the Grants Management System (GMS) have been implemented to prevent potential non-compliance with financial interest disclosures, we found that CIRM did not fully meet its compliance requirements regarding financial interest disclosures in FY 2013-14.**

   To ensure that integrity and objectivity of the grant application and review process, CIRM screens individuals involved in the process to ensure they do not have any conflicts of interest that would compromise their ability to review applications. As described in the Performance Audit Methodology, this screening is accomplished with a Conflict of Interest Form and Financial Disclosure Form. Under CIRM's current Conflict of Interest and Disclosure Requirements (17 Cal. Code Regs. § 100003 et seq), non-ICOC members of the Grants Working Group, also referred to as scientific reviewers, must disclose potential personal, professional, and financial conflicts of interest. Within the GMS, Conflict of Interest Forms allow members to indicate any type of conflict with applicants or applicant institutions. A separate form, the Financial Interest Disclosure Form, is focused on collecting information about members' financial interests before the review of applications in response to a particular RFA.

   To assess compliance with these requirements, we tested a sample of 25 pre-applications and 15 applications submitted in FY 2013-2014. Based on the test results, CIRM followed its stated policies requiring the completion of Conflict of Interest Forms. In fact, CIRM's GMS system automatically restricts individuals' access to grant application materials prior to completing the conflict of interest check. This system facilitates compliance with this requirement.

   However, CIRM did not fully follow its stated policies requiring the completion of Financial Interest Disclosure Forms by the scientific reviewers. While all financial conflicts of interests in a particular application should be disclosed through the Conflict of Interest Form, the Financial Interest Disclosure Form was developed by CIRM to provide an additional level of assurance about financial independence.

   These Financial Interest Disclosure Forms require members to disclose confidentially and under penalty of perjury the following financial interests:

   > (1) All California-based academic or non-profit research institutions from which members, their spouses, or others with whom the member has a common financial interest receive income or other benefit of $5,000 or more.

   > (2) All publicly-held biotechnology and pharmaceutical companies from which members, their spouses, or others with whom a member has a common financial interest receive current income or other benefit, or hold an investment, of $5,000 or more.

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(3) All privately-held biotechnology companies in which reviewers, their spouses, or others with whom a member has a common financial interest have an equity interest.

(4) Real property interests in California held by members, their spouses, or others with whom a member has a common financial interest.

During our testing, we identified missing Financial Interest Disclosure Forms for reviewers of pre-applications and applications within our samples. Specifically, we found that of the 25 pre-applications we tested, three reviewers were missing Financial Interest Disclosure Forms in connection with the review of applications submitted in response to a particular RFA. These three reviewers participated in the review of four of the 25 pre-applications. Similarly, for the 15 applications we tested, which related to five different RFAs, we found that Financial Disclosure Forms were missing for eight different reviewers. For each of the 15 applications, we found that CIRM was missing a Financial Disclosure form for one or more reviewers who participated in the application review process for a particular RFA. In each of these cases, however, the reviewers completed their Conflict of Interest Form for that review.

In FY 2013-14, Financial Interest Disclosure Forms were submitted by reviewers via email or fax, and the Grants Review Team had to manually ensure the receipt of these forms. Unlike the Conflict of Interest Form, which had already become an integrated element in the GMS in fiscal year 2013-14, no system restrictions were in place to prevent participation in reviews prior to the receipt of Financial Interest Disclosure Forms. Without these system restrictions, compliance with this requirement lapsed and reviewers with missing Financial Interest Disclosure Forms were allowed to review and score pre-applications and applications.

In July of 2014, significant improvements to the Financial Interest Disclosure Form were implemented within the GMS. As a fully integrated element within the GMS, Financial Interest Disclosure Forms are now completed and submitted online, and the system restricts access to pre-applications or applications prior to the completion of both the Conflict of Interest Form and Financial Interest Disclosure Form. By successfully implementing these system improvements, CIRM has successfully mitigated future instances of this type of non-compliance.

**Recommendation: Continue to use systems controls implemented in July 2014 to ensure the consistent collection of Financial Interest Disclosure Forms in accordance with stated policies.**

CIRM has already implemented the necessary systems improvements to prevent this issue from reoccurring. CIRM should maintain the controls within its systems to ensure compliance with these requirements regarding conflicts of interest and financial interest disclosure.

2. **Finding: The processes that CIRM instituted for reviewing Financial Interest Disclosures Forms and associated results have not been formally documented.**

According to CIRM Regulations, non-ICOC members of the Grants Working Group (scientific reviewers) must report to CIRM any conflict of interest, including financial, of which he or she is aware. Members disclose personal, professional, and financial conflicts using the Conflict of

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Interest Form. CIRM gathers additional information, as outlined within regulations, about member financial interests, which can be used to provide additional assurance of member financial independence.

Within CIRM's regulations, a financial conflict of interest is defined as:

> (1) The member, his or her spouse, or any other person with whom the member has a common financial interest, is an employee of either the institution or the Principal Investigator on an application.

> (2) The member, his or her spouse, or any other person with whom the member has a common financial interest, is under active consideration for a faculty or administrative position at an applicant institution.

> (3) A member, his or her spouse, or any other person with whom the member has a common financial interest, stands to receive a financial benefit of any amount from an application under review.

> (4) A member, his or her spouse, or any other person with whom the member has a common financial interest, has received or could receive a financial benefit of any type from an applicant institution or organization unrelated to the proposal, of over $5,000 per year. This total includes honoraria, fees, stock and other benefits.

> It also includes current stock holdings, equity interest, intellectual property or real property interest, but does not include diversified mutual funds.

Members should report any financial conflicts of interest on both the Conflict of Interest Form and Financial Interest Disclosure Form. The Conflict of Interest Form lists all of the applicants' names and institutions associated with the grant pre-application or application under consideration, and members must indicate all applicants or institutions with which they have a conflict of interest, whether personal, professional, or financial. The Financial Interest Disclosure Form is designed to capture information about member financial interests, which may be relevant in determining financial conflicts of interest. If the financial interests disclosed within this form qualify as financial conflicts of interests, then the conflicts should also be indicated on the Conflict of Interest Form. Within the GMS, if conflicts are indicated on the Conflict of Interest Form, then the system automatically restricts member access to pre-applications and/or applications involving the applicant or institution with whom there is a conflict. In contrast, disclosed financial interests provided on the Financial Interest Disclosure Form, even if they qualify as financial conflicts of interest, will not automatically result in restricted system access or automatically be noted as a conflict. Instead, to prevent participation by members with financial conflicts, the Grants Review Team is responsible for manually reviewing and identifying any financial conflicts in these disclosures and verifying that these conflicts were reported on the Conflict of Interest Form.

The process to detect unreported financial conflicts of interest includes the Grants Review Staff comparing the list of applicant names and institutions on the conflict of interest list to the

financial interests disclosed on the Financial Interest Disclosure Forms. Through this comparison, staff should verify that all of the disclosed financial interests that qualify as financial conflict of interests under CIRM regulations have been also been noted in the Conflict of Interest Forms and, thus, system access has been restricted.

Currently, there are no written policies or procedures outlining this process. While CIRM regulations define what constitutes a financial conflict of interest, the Grants Review Staff does not have additional written guidance to follow when performing these reviews. Moreover, because the Grants Review Staff does not document the performance of these reviews, we could not verify that these reviews were performed or assess the manner in which they were performed. Without procedures that formalize this process or internal records that document the performance of these reviews, CIRM cannot fully demonstrate its performance of due diligence to ensure the financial independence of reviewers.

**Recommendation: Document procedures for the Financial Interest Disclosure Forms review and reporting processes, and work with IT to develop fields within the GMS for the Grants Review Staff to use to record evidence of the review activities performed.**

The Grants Review Team should develop detailed procedures that define the review process and the specific steps required to validate that no conflicts of interest exist. Additionally, the Grants Review Team should collaborate with IT to define and incorporate additional fields into the GMS where the performance of these review activities could be recorded. Both of these activities should be relatively straightforward to accomplish and support efficient and effective reporting.

## B. GRANTS OVERSIGHT

3. **Finding: For the sample of 43 progress reports tested, 16 progress reports took more than 10 weeks after the report was submitted to CIRM for the review to be completed by a Science Officer, and the timeliness of reviews by Science Officers varied from 1 to 56 weeks in the sample tested.**

On average, Science Officer reviews were completed in 12 weeks, and CIRM strives to complete the review of 100% of progress reports within 8 to 10 weeks of receipt. The review of progress reports by Science Officers has improved since the FY 2010-2011 performance audit, which revealed an average review time of four to five months. Including progress reports electronically within GMS facilitated improvements in the review process.

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 more timely review of progress reports, since the review of progress reports is an integral part of understanding the scientific progress being made by grantees.**

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CIRM should formalize the goal of having progress reports reviewed within 8 to 10 weeks of receipt of the progress report and implement monitoring procedures to measure progress in meeting this goal. Quarterly statistics should be compiled by Science Officers by grant that show the number of days from report submission to completion of review. For reviews that are outside the 8 to 10 week range, Science Officers should provide reasons for delay in the review. Ongoing monitoring will help to identify if the delays in review are due to resource constraints or other reasons.

4. **Finding: During testing of the grants management process, we identified two exceptions to the Grants Administration Policy in a sample of 40 grants in progress and 14 closed grants.**

Exceptions to the Grants Administration Policy identified during the testing of the grants management process included:

- One grant was classified as closed within the GMS, but the final progress report was not received. This was a manual error whereby grants management personnel inadvertently marked a grant as closed in the GMS, even though the final progress report had not yet been received.

- One grantee had an annual progress report that was more than 90 days overdue, but CIRM did not postpone grant payments. In accordance with CIRM's Grants Administration Policy, payments to the grantee should have been put on hold until the annual progress report was received.

**Recommendation: Implement procedures to ensure adherence to the Grants Administration Policy.**

For the grant that was closed within GMS, even though the final progress report was not received, monitoring controls should be designed and implemented to help prevent these errors. For instance, create a business rule that requires a final progress report to be submitted before a grant can be closed.

With implementation of the payments module in the GMS, payments are now automatically flagged if a report is late to prevent inadvertently paying a grantee that has an overdue report. This will help ensure compliance with the Grants Administration Policy.

## C. LOANS

No findings. Based on testing a sample of two loans in process of a total of two loans in process in FY 2013-2014, there are no findings since we did not identify any non-compliance with policy and/or internal controls.

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## D. CONTRACTS

No findings. Based on testing a sample of 11 contracts (including one contract over $250,000) of a total of 43 contracts in FY 2013-14, there are no findings since we did not identify any non-compliance with policy and/or internal controls.

The institution of Great Plains has standardized the information that is entered for contracts initially and enabled Finance to have more control over contract and purchase order reconciliation, reporting, and management. It has required the Contract Administrator to become more aware of funding sources by having to enter account coding and enter contract information consistently. Rollout of the State's FI$Cal system will be next. CIRM will be obligated to use it, and CIRM started to receive training on the system in February 2015.

## E. INTELLECTUAL PROPERTY

5.  **Finding: CIRM grantees have not submitted the Annual Utilization Reports required by CIRM's Intellectual Property (IP) Regulations in a timely manner, and CIRM's enforcement actions for late reports have not been consistently applied.**

CIRM's IP regulations are designed to protect the IP developed using CIRM funding by requiring initial invention disclosures, as well as related progress reporting about the utilization of the inventions. Under these regulations, grantees are required to notify CIRM about certain IP-related developments that arise as a result of CIRM-funded activities.

In particular, grantee institutions must submit an Invention Disclosure Form within 60 days after the CIRM-funded researcher reports the invention to the institution. Each year thereafter, institutions that have submitted invention disclosures must submit an Annual Utilization Report to CIRM by October 1st. In accordance with CIRM's IP regulations, these reports require institutions to disclose progress made during the year toward the exploitation of CIRM-funded IP developments, including patents, licensing agreements, and revenue related to the disclosed invention.

To assess adherence to CIRM's policies and procedures, we selected a sample of 12 invention disclosures from the 71 disclosures reported to CIRM through the IP module of GMS in fiscal year 2013-2014. These disclosures originated from eight different institutions. For our sample, we reviewed the invention disclosures, as well as the subsequent Annual Utilization Reports, which were due on October 1, 2014.

Based on the results of our testing, we found that the majority of the utilization reports in our sample were submitted late. Specifically, six of the reports were more than 120 days late. As of March 24, 2015, nearly six months after the due date, one report was still outstanding.

Grants Management Specialists are responsible for communicating with TTOs about utilization reports. Approximately two months before the due date, Grants Management Specialists send emails to TTOs notifying them of the utilization report requirement, due date for submission, and instructions for completion. If reports are not received by the due date, then Grants

Management Specialists follow up with reminder emails reiterating the reporting requirement, due date, and instructions for completion. The Grants Management Specialists send these reminders at roughly the same intervals used for other overdue reporting reminders (e.g., one day, 30 days, 60 days, and 90 days after the due date). There are no written policies or procedures for Grants Management Staff to follow regarding these communications.

In accordance with CIRM Regulations and its Grants Administration Policies, if reporting requirements are not met, then CIRM takes a variety of actions, including withholding payment. In the case of overdue progress reports, after 60 days CIRM has withheld payments for the associated grant award and after 90 days it has withheld payments to the institution for all CIRM awards. All written documentation regarding utilization report, including reminder notifications and warning of possible payment withholdings, is maintained within the individual email accounts of the Grants Management Specialists. Some communication regarding utilization reports may be conducted by phone, such as troubleshooting technical problems, but documentation of these communications is not maintained.

To assess CIRM's practices relating to overdue utilization reports, we reviewed the email communication between the Grants Management Specialists and the TTOs. Based on the written communication we reviewed, Grants Management Specialists did not send emails to TTOs at the desired intervals. For example, for two institutions in our sample we found that the Grants Management Specialist sent one email roughly 2 months prior to the due date, but sent no reminder emails after the due date passed.

In the case of another institution, after the due date passed no reminder emails were sent until more than 90 days had passed and the institution was notified that future payments may be withheld. While some communication by phone may have occurred during this timeframe, no documentation of these conversations was maintained and the timing of these communications is unknown.

As evidenced by our examination of the written communication relating to overdue and outstanding reports, the Grants Management Office does not communicate in a timely and consistent manner with the TTOs. Unlike the modules in the GMS for progress and financial reporting that automatically generate and send email reminders about upcoming or overdue reports at specified intervals, the IP module does not have this functionality. Instead, the Grants Management Specialists are individually responsible for manually generating and sending reminders to TTOs. As demonstrated by the results of our testing, the current practice of manually managing reminders does not result in consistent communication at consistent intervals. Since the implementation of automated reminder emails for progress and financial reporting, the Grants Management Office has found that the timeliness of these report submissions has improved. This suggests that adding similar functionality to the IP Module may improve the timeliness of Utilization Report submissions as well.

Additionally, enforcement actions, such as withholding payments, were not consistently applied for failure to submit utilization reports. In accordance with CIRM's regulations and policies described above, after 60 days or more CIRM may impose a variety of disciplinary actions,

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including withholding payments from institutions for individual grant awards or all grant awards. In our sample, three institutions were more than 120 days late in submitting utilization reports. However, no payments were withheld. The Grants Management Office has been reluctant to withhold payments for failure to submit utilization reports for a variety of reasons. In particular, the utilization reporting requirement and process is still relatively new. As such, institutions may not have received comprehensive information at the beginning of its grant award about this reporting requirement and the potential implications of non-compliance. Additionally, unlike overdue progress and financial reports, overdue utilization reports are not displayed on the payments management screen that the Grants Management Office uses to administer payments. Thus, withholding payments for these reports currently requires staff to perform additional manual steps for administration and monitoring. Moreover, in the absence of regular or fully documented communication, CIRM cannot demonstrate that its consistent efforts to communicate and, thus, enforcement actions may be perceived as unfair or inconsistently applied.

The current process for collecting information regarding utilization activities may also contribute to delayed or outstanding utilization reports. For example, even if no utilization activities have occurred during the year for an invention, the TTO must still answer every question regarding the specific type of utilization activities related to that invention. Thus, the effort required to report no activity can seem excessive.

Also, the timing of this reporting poses a challenge for some TTOs. Utilization activities, such as patent applications, patent approvals, and licensing agreements, take place throughout the year and new developments may emerge near the report deadline. Or, some utilization activities, particularly those occurring at the beginning of the reporting year, may not be recalled or included in the utilization report prepared for October. Currently, the IP module does not allow TTOs to submit any information about utilization activities throughout the year that could help populate the annual report.

The lack of timeliness in the submissions we reviewed, coupled with the inconsistencies in communication with TTOs, suggest that CIRM's current methods for monitoring and enforcing IP reporting compliance could be strengthened. However, it should be noted that during Fiscal Year 2013-2014 no grantee reported activity that would trigger revenue sharing, access, or price protection requirements of the IP policy, 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. Because IP reporting will only grow in importance, it is critical for CIRM to address issues of non-compliance now and implement an effective system for enforcement going forward.

**Recommendation: Implement enhancements to the GMS to support increased accountability for, and enforcement of, Annual Utilization Report requirements.**

CIRM should leverage the GMS to further improve the timeliness and accountability of utilization report submittal. Potential improvements include incorporating the reminder notification function into the IP Module, expanding information provided to institutions at the time of grant awards about IP reporting requirements and non-compliance consequences, and incorporating overdue utilization reports into the payment management screen.

6. **Finding: While CIRM's practices are appropriate for ensuring the protection of current CIRM-funded IP, these practices may not be adequate to ensure the protection of future CIRM-funded IP.**

   CIRM has made significant strides in developing practices and tools to protect CIRM-funded IP. Perhaps most notably, CIRM has made significant improvements to the IP module within the GMS since completion of the FY 2011-2011 performance audit. Specifically, CIRM has successfully implemented the majority of its planned Phase 1 improvements, such as the transition to a direct, online submission of IP reporting. In addition, CIRM has provided access to the GMS for TTO personnel to enable them to submit IP reports directly. With these improvements, IP reporting has become an integrated part of the grants process.

   Also, the Associate General Counsel developed and implemented new initiatives to increase efforts to protect CIRM-funded IP. In particular, multiple initiatives have been launched to detect inventions and patents that were not disclosed to CIRM through the invention disclosure and utilization reporting processes. These initiatives are also designed to validate the completeness and accuracy of information contained in the required IP reports.

   These achievements notwithstanding, as CIRM-funded inventions increase and progress is made towards commercialization, current practices may not be as effective as they could be. For example, some opportunities for additional improvements to the IP module remain, especially related to information relevant to CIRM's IP regulations. The regulations require grantees to report on three commercialization events, specifically 1) initiation of clinical testing, 2) initiation of pivotal studies, and 3) application for marketing approval. The IP module of the GMS does not have separate fields to capture this information. As a result, the lack of dedicated fields in the GMS for these events makes it difficult for CIRM staff to access and monitor this information. Since the number of projects in clinical trials is relatively small, it is easy to track progress of these events. However, as the number of IP commercialization events increases, tracking progress make become more difficult.

   In addition, while the process for monitoring and detecting non-disclosure is reasonable in the current climate, it may not be robust enough to ensure the protection of IP in the future. Due to the nature of grantee work, there are complexities to funding, collaboration, and personnel that often make monitoring non-disclosures and enforcing IP requirements inherently difficult. Currently, CIRM's IP regulations require all grantees to report inventions through the initial invention disclosure and then report utilization activities annually thereafter. This disclosure process relies heavily on grantees, and their associated institutions, to proactively self-report this information both accurately and completely.

Until now, CIRM has funded many grants that are in early stages of development and, therefore, many grantees do not have any inventions to disclose. While non-disclosure is still a concern with grants at early stages of development, the likelihood of invention is relatively smaller and, thus, the possibility of non-disclosure is relatively smaller. In contrast, grants made at later stages of development are more likely to result in inventions and, therefore, the possibility of non-disclosure is relatively higher for these grants. As CIRM begins increasing its funding for later stage grants, the current reporting requirements may not be effective in mitigating the increased chance of non-disclosure.

**Recommendation: As CIRM-funded IP developments increase and advance toward commercialization, increase efforts to protect IP by modifying the GMS to gather more data on IP commercialization events and continue to strengthen its process for monitoring and detecting non-disclosure.**

CIRM should add fields in the GMS to facilitate the capture of data related to the initiation of clinical testing, initiation of pivotal studies, and application for marketing approval. By creating fields for this data, CIRM will be able to more effectively collect, analyze, and report on commercialization activity. In addition, given the increased likelihood that later stage projects could result in activities that require disclosure, CIRM should modify its IP reporting requirements. New reporting requirements should require all late stage grantees to submit annual invention and utilization disclosures even if these disclosures contain no reportable activities (in other words, certify that there is nothing to report). These changes should reduce the risk of non-disclosure going forward.

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# 5. EFFICIENCY AND EFFECTIVENESS FINDINGS AND RECOMMENDATIONS

## A. OPERATIONAL PERFORMANCE MEASURES

7. **Finding: CIRM has a strong culture of accountability and transparency, and this culture could be strengthened by tracking and reporting on non-scientific operational performance measures.**

CIRM has a strong culture of accountability through regular reporting to the ICOC. During CIRM's annual budgeting process, performance goals are submitted by each department. These goals are reviewed by the Chair and President, and they range from workload and efficiency goals to project-based goals. These goals can change from year to year, and reflect varying levels of measurability. For example, the current Legal Department budget includes the following performance goals:

- Finalize all policies necessary to implement CIRM 2.0, and revise such policies as necessary
- Assist in completing CIRM's relocation
- Ensure compliance with CIRM's public accountability requirements
- Support efforts to sustain CIRM's mission

Performance measures have been developed for scientific, grant-related functions, but administrative and other non-science functions have not yet been addressed. Performance metrics can help organizations to provide executive visibility and achieve greater efficiency and effectiveness. The Government Finance Officers Association (GFOA) recommends "that program and service performance measures be developed and used as an important component of long-term strategic planning and decision making, which should be linked to governmental budgeting."

**Recommendation: Develop a slate of operational performance measures aligned with CIRM's strategic plan and report regularly to the ICOC.**

In addition to annual performance goals, operational performance measures could serve as a valuable tool to assess CIRM's performance, particularly considering the major changes to the grant process and organizational structure as part of CIRM 2.0. CIRM leadership also plans to develop a strategic plan in 2015. As part of strategic plan development, CIRM should develop operational performance measures linked to strategic goals and objectives. Performance measures should be reported regularly (e.g., quarterly) to the ICOC and serve as a mechanism to convey progress to the public in a straightforward and intuitive manner. Sample operational objectives and performance measures for CIRM's non-science functions are provided in the table below.

| Function | Objective | Measures |
|---|---|---|
| Human Resources | Support efficient and effective employee recruitment, retention, and development. | Number of working days to complete external recruitment |
| | | Turnover rate |
| | | Percentage of employees receiving external professional development and training |
| Information Technology | Provide staff, grantees, and the public efficient and reliable access to information. | System uptime (percentage) |
| | | Percentage of projects delivered on-time and/or on-budget |
| | | Total IT operating and maintenance expenditures as a percentage of CIRM operating expenditures |
| Communications | Increase public understanding of CIRM's mission through outreach, education, and awareness. | Number of positive media placements |
| | | Website visitors and click-through |
| | | Social media conversion, applause, and/or amplification rate |
| Legal | Provide legal representation and strategic support to CIRM's staff and governing board. | Number of adverse matters opened |
| | | Resolution rate |
| Contract Management | Minimize risk and maximize accountability in CIRM's contracting process. | Processing time for new contracts and/or change orders |
| | | Percentage of payments withheld for non-compliance |
| Business Development | Develop CIRM's portfolio of grantees and partners. | Number of new contacts engaged |
| Finance | Efficiently and effectively manage CIRM's resources. | Invoice processing time |
| | | Percentage of monthly closings completed within (goal) |

## B. EMPLOYEE ENGAGEMENT

8. **Finding: While morale has noticeably improved since the FY 2010-2011 performance audit, CIRM should continue to focus on increasing employee engagement.**

Like many organizations that undergo significant change, CIRM turnover increased during the most recent fiscal year, as shown in the table below.

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| Fiscal Year | Turnover Rate |
|-------------|---------------|
| 2011-2012 | 15% |
| 2012-2013 | 9% |
| 2013-2014 | 17% |

During leadership transitions, changes in business philosophy and model can result in desired and undesired turnover. CIRM's new president, hired in 2014, has acted as a strong agent for organizational change. The recent rollout of CIRM 2.0 and a revamped organizational structure have had significant positive impacts on the day-to-day operations of the organization, as a result of both the changes themselves and the engagement of employees in the evaluation and planning process.

**Recommendation: Continue to proactively focus on improving employee engagement through effective employee outreach, team building, and communication.**

CIRM leadership should continue to solicit feedback from employees on how to improve processes and build morale, leverage training for team-building, and encourage cross-functional communication. Examples are described below.

To seek feedback from employees, CIRM could facilitate dialogue with employees through surveys and discussion groups. Responses from employees will inform various improvements that management may want to employ. Furthermore, the surveys and discussions will enable employees to be heard, valued, and impact the work environment.

CIRM is committed to professional development for all staff members. Training opportunities are an excellent, purpose-driven way to encourage cross-functional team building and knowledge transfer. Engaging employees with expertise, specialized knowledge, and/or an interest in developing and delivering training is an excellent opportunity to share knowledge, collaborate, and build relationships across the organization. Empowering staff to design and provide training will engage employees, develop leadership and communication skills, share knowledge, and improve morale.

Clear, frequent communication is critical to high-performing organizations. As CIRM continues to evolve, the President should continue to communicate regularly, consistently, and through multiple channels to ensure that CIRM employees are aware of how changes impact them personally.

In a revenue-constrained government environment, there may not be the ability to provide the types of awards and recognition to employees that are provided in the private sector. However, there are many free and low-cost ways to boost morale. Sharing positive feedback, taking time in staff meetings to recognize employees for great work, and meaningfully engaging all employees in the upcoming strategic plan update are all steps that management can take today to improve morale.

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## C. PERFORMANCE EVALUATION

9. **Finding: CIRM's performance evaluation and merit increase processes have not been consistently performed in a timely manner.**

   CIRM's performance evaluation policy is to annually assess employee performance and award merit pay increases "based on performance reviews, duties and responsibilities, equitable considerations, and the current budget of the organization." Supervisors are expected to evaluate employees on nine standard performance factors, as well as four goals or objectives specific to each position. The policy and process are aligned with best practices. However, execution of performance evaluations has regularly been delayed until October or November, with merit increases coming afterward. For example, FY 2013-2014 performance evaluations, which were scheduled to occur during significant leadership changes, did not occur until January 2015.

   While there may have been valid reasons to delay recent performance evaluations, delays have caused frustration among CIRM's staff. Late performance evaluations send a message that employees are not important enough to set aside sufficient time to conduct evaluations in a timely manner. Since merit pay adjustments for CIRM employees are tied to the completion of staff evaluations, delays in evaluations result in delays in merit pay increases, which can negatively impact morale and productivity.

   CIRM recently began making revisions to the evaluation form for the current fiscal year and plans to have a revised process in place for FY 2015-2016 evaluations.

   **Recommendation: Ensure performance evaluation and merit increases occur in a timely manner.**

   CIRM's administrative leadership should continue to pursue improvements to the performance evaluation form and process and ensure that evaluations are conducted in a timely manner. Additionally, annual employee training plans should be aligned with individual performance improvement opportunities and organizational and position goals. Quarterly or semi-annual informal performance check-ins should be implemented to encourage communication and ensure that employees are on track to meet goals.

   CIRM's Human Resources Department is pursuing updates to the form. The Department should engage employees, perhaps through a survey or a cross-functional committee or task force comprised of management and staff, to identify opportunities to improve performance evaluation factors, form design, and the evaluation process. Training should be provided to supervisors regarding any changes to factors, form, or process. Training could also be provided on goal setting and constructive conversations, which are two keys to effective performance reviews.

## D. GRANTS MANAGEMENT SYSTEM DEVELOPMENT ENVIRONMENT

10. **Finding: The GMS continues to mature, while the underlying development environment is becoming dated.**

CIRM has established a development environment that is founded on the following components:

- The Linux operating system, which is a favorite of software engineers due to its scalability, performance, security, and limited need for maintenance.

- "Ruby on Rails" for application programming and data access and abstraction. This is an open source web application framework that encourages the use of industry-proven software engineering design patterns to facilitate fundamental object oriented principals (e.g., decoupling, inheritance, and encapsulation), while supporting software development across a number of popular database platforms.

- Cucumber, which is an automated test platform that enables scripting to occur at the user-interface level via HTML.

CIRM maintains current versions for its development components and tools, and current indications are that the Ruby on Rails as an application programming environment still has a strong following. However, Ruby on Rails is beginning to fall out of fashion in the development community at large.

**Recommendation: Continue to monitor current trends in web application development to determine the best development applications to support the GMS moving forward.**

Technical obsolescence is a "fact of life" facing every software development organization. Lifecycle management is the main theme here. Not unlike COBOL or FORTRAN, continued reliance on this or any given development environment may eventually hinder CIRM's ability to recruit and retain talented software developers. While it is difficult to predict which software development platforms and toolsets will be industry front-runners three to five years in the future, it is safe to say that Java Virtual Machine (JVM) and its suite of frameworks and languages is one logical alternative. While Java technologies have been popular development platforms for well over a decade, they continue to evolve and still command a strong following in the development community. As an example, Twitter recently migrated away from Ruby on Rails and has adopted Java technologies throughout (e.g., Scala and Blender).

## E. GRANTS MANAGEMENT SYSTEM FUNCTIONAL IMPROVEMENTS

11. **Finding: Additional opportunities exist to leverage the GMS to improve operational efficiency and effectiveness.**

CIRM has made significant progress in developing its Grants Management System to date. We noted the following potential opportunities to further improve the GMS:

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- Prior Approval Requests are currently being managed outside of the GMS by using hard copies and the DocuShare document management system (DMS).

- The Notice of Grant Award (NGA) is being managed in the GMS, along with access to signed contracts and amendments. Budget worksheets are also provided in the GMS to help manage grant lifecycles. However, external spreadsheets are currently used to support budget versioning, which demonstrates another opportunity for potential system and process improvement in the GMS.

- Invention disclosures and utilization reports are submitted by grantees as a matter of due process. CIRM's intellectual property (IP) transaction attorney needs the ability to access and review these documents. As part of this process, the attorneys need to query the GMS to find the disclosures, at which point it would be helpful to provide an automated checklist or task list in the GMS to guide and memorialize their discovery and review processes.

- Payment memos are currently being printed out for Finance to review and sign off. Once signed, they are sent to the State Department of General Services (DGS) for payment processing. DGS plans on adopting a new financial system (FISCAL, an Oracle ERP platform), which is scheduled for rollout in July 2015. CIRM had hoped to be able to issue payments for NGAs by uploading them from the GMS to the FI$Cal system. However, CIRM requires expedited payment (within three days) for all grant payments, and FI$Cal will not support payments paid within five days or less of submission to SCO. As such, DGS will need to continue to submit them manually. Future system upgrades may provide an opportunity for CIRM to eliminate payment memos altogether and, instead, provide a batch file for import and processing by DGS.

- CIRM has an enterprise subscription to Drop Box, which provides a secure portal for the receipt and submission of documents. In addition, CIRM utilizes DocuShare as its document management system, which has been a significant step in eliminating the need for paper file storage and management. The GMS does not have any automated integration capabilities with either of these platforms. This could provide an additional opportunity to leverage and streamline document management for the organization.

- Paper checklists are still in use for the grant close-out review process and other review checklists (e.g., NGA), and these documents do not appear in the GMS.

**Recommendation: Continue to identify and pursue opportunities to enhance GMS capabilities to automate processes, reduce paperwork, and enhance information access.**

IT should continue to maintain and execute against the GMS enhancement plan, which requires ongoing identification, evaluation, and prioritization of enhancement opportunities to meet the needs of the organization.

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## F.  FY 2010-2011 PERFORMANCE AUDIT RECOMMENDATIONS

**12. Finding: CIRM has made progress toward implementation of all 24 recommendations presented in the FY 2010-2011 performance audit, and completed implementation of 17 recommendations.**

A description of CIRM's progress on the seven recommendations from the FY 2010-2011 performance audit that have not fully completed is provided below.

- *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.*

  This is an ongoing effort, and CIRM continues to make progress toward consistent, timely, submission of required information. However, there are still issues related to timely submission (see Finding 5).

- *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.*

  Progress reports have been integrated into the GMS, which has helped the timeliness of reviews. However, there are still issues with timely review (see Finding 3).

- *Incorporate performance metrics reporting into a structured meeting rhythm process and streamline weekly meetings.*

  Standing meetings have been streamlined and science-related performance metrics are in use. See Finding 7 for further information regarding operational performance measures.

- *Continue efforts to identify and implement efficiency improvements and strive to quantify efficiency gains.*

  This is an ongoing effort, and CIRM continues to identify and address areas for efficiency improvements.

- *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.*

  Updating the Transition Plan is an ongoing effort, and CIRM continues to refine the Plan.

- *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.*

  Changes to the GMS have increased the capabilities of grant outcome tracking and reporting on an as needed basis. CIRM continues to evaluate what would be useful to present in digital dashboard.

**Recommendation: Continue implementation of FY 2010-2011 performance audit recommendations.**

CIRM should continue to seek opportunities to improve efficiency, effectiveness, and compliance, including implementation of performance audit recommendations from the FY 2010-2011 performance audit.

# 6. MANAGEMENT RESPONSE

CIRM management appreciates Moss Adams' efforts and findings in the Fiscal Year 2013-14 Performance Audit Report. The recommendations are focused and constructive and CIRM will consider them, along with other options, all geared to improve the efficiency and effectiveness of the agency's operations, as part of our comprehensive review of CIRM's operational policies pursuant to CIRM 2.0.

We would like to acknowledge the diligence and thoughtfulness of the Moss Adams team. They put a great deal of time and effort into learning about the progress CIRM has made since the last audit, examining the agency's compliance with the myriad rules and regulations pursuant to which it operates, and making constructive recommendations in an effort to improve the agency's performance.

# APPENDIX: PROGRESS TOWARD FY 2010-2011 PERFORMANCE AUDIT RECOMMENDATIONS

| Tier 1 Recommendation | Status | Validation | Basis of Validation |
|---|---|---|---|
| **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. | Implemented processes such as working with TTOs to obtain required Invention Disclosure Forms and Invention Utilization Reports. | Partially complete | Interviews and testing of Annual Utilization reports |
| **III.E.2** Ensure the Grants Management System (GMS) IP Module specifications for Phase 1 include specific questions about commercialization activity. | GMS IP Module includes specific questions about commercialization activity. | Partially complete | Observation of GMS IP Module |
| **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. | Reporting progress made, but digital dashboard not in place yet. | Partially complete | Annual performance reporting |
| **IV.B** Develop a communication plan and comprehensive, results-based annual report, and use the annual report as a cornerstone for external communications. | Developed a Communications Strategy. | Completed | Document review |

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| Tier 1 Recommendation | Status | Validation | Basis of Validation |
|---|---|---|---|
| **IV.C** Amend policies to make completion of the grant outcome survey a requirement of the grant closeout process. | Mandatory Grant Outcome Closeout Survey in place. | Completed | Observed Grant Outcome Closeout Survey was part of Final Report |
| **VII.B** Develop a detailed plan for completing development of the GMS, and provide ongoing project oversight. | Grants Management System IP module released. | Completed | Observed module |
| **VII.D** Implement a document management system. | Document Management System implementation complete. | Completed | Observed system |
| **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. | Bond forecasting procedures implemented. | Completed | Interviews, monthly ICOC Minutes |
| **VI.A** Acquire and implement human resource forecasting software. | HR Forecasting Model created and staff trained to use it. | Completed | Interviews, reviewed forecasting model user's guide |
| **VI.B** Reevaluate staffing levels if administrative and implementation costs are forecasted to exceed 6% of bond proceeds. | Monitor 6% administrative cap with the use of modeling and evaluation of staffing and resource needs. | Completed | Interviews, monthly ICOC Minutes |

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| Tier 1 Recommendation | Status | Validation | Basis of Validation |
|---|---|---|---|
| **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. | Accelerated Progress Report Review with online access. | Partially complete | Observed online access |
| **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. | Central location for procurement documentation completed. | Completed | Tested sample of procurements and no exceptions noted during testing |

| Tier 2 Recommendation | Status | Validation | Basis of Validation |
|---|---|---|---|
| **V.A** Develop and implement a relational database to enable more efficient financial analysis and reporting of non-grant contracts and purchase order payments. | Implemented Great Plains. | Completed | Implemented Great Plains, moving to FI$Cal |
| **V.B** Request authorization to access the State Controller's Office's fiscal system. | Gained SCO system access. | Completed | Interviews |
| **V.C** Create and implement a comprehensive, formal business development plan. | Created Business Development Plan. | Completed | Annual business development plan provided |

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| Tier 2 Recommendation | Status | Validation | Basis of Validation |
|---|---|---|---|
| **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. | OOC/OOP Cooperation. | Completed | New president hired, org structure changes |
| **V.F** Incorporate performance metrics reporting into a structured meeting rhythm process and streamline weekly meetings. | Streamlined standing meetings. | Partially complete | CIRM 2.0 |
| **V.G** Continue efforts to identify and implement efficiency improvements and strive to quantify efficiency gains. | Finance workflow database in place. | Partially complete | CIRM 2.0 |
| **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. | Prepared in 2013. | Completed | Reviewed technology plan |
| **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. | Developed website plan. | Completed | Website/GMS integration complete; technology plan includes website |

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| Tier 3 Recommendation | Status | Validation | Basis of Validation |
|---|---|---|---|
| **V.H** Develop a formal onboarding process and incorporate it into the overall new employee orientation program. | Implemented a formal onboarding program. | Completed | Reviewed onboarding documents |
| **VI.C** Ensure the Transition Plan addresses CIRM's unique and increasing recruitment and retention challenges and CIRM leadership clearly and regularly communicates transition plan strategies to all employees. | Recruitment and retention addressed in transition plan. | Partially complete | Exploring multiple avenues for sustainability |
| **VI.D** Adopt a Board Code of Conduct. | Completed ICOC Board Code of Conduct. | Completed | ICOC Minutes, adopted May 2012 |
| **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. | Evaluated COI redundancies. | Completed | Tested sample of conflict of interest forms, no exceptions noted |

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