



MOSSADAMS

REPORT

FOR

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

FY 2016-2017 Performance Audit

March 1, 2018

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X	17	-		+	X	17	+	-	X	17
17	+	X		-	X	17	+	-	X	17
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I. EXECUTIVE SUMMARY

A. BACKGROUND, SCOPE, AND METHODOLOGY

The California Institute for Regenerative Medicine (CIRM) 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 provided \$3 billion in funding for stem cell research, research facilities, and other vital research opportunities.

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.

CIRM is required to commission a performance audit every three years. The first performance audit covered Fiscal Year 2010-2011, the second performance audit covered Fiscal Year 2013-2014, and this performance audit covers Fiscal Year 2016-2017. Each performance audit examines the functions, operations, management systems, and policies and procedures of CIRM to assess whether the agency is achieving economy, efficiency, and effectiveness in the employment of available resources. In addition, each performance audit addresses policies and procedures for the issuance of contracts, grants, and loans, as well as the protection and 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 used to conduct the performance audit included:

- **Interviews:** We conducted 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 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 an ICOC meeting.
- **Testing:** Using standardized sampling methods, we tested internal controls and compliance with policies and procedures for core functions.



B. SUMMARY OF 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.

COMPLIANCE		
1	Finding	Of the 40 grant applications tested, one Grants Working Group (GWG) member's rating, as presented to the ICOC, did not match the GMS database; however, this difference did not impact the GWG funding recommendation.
	Recommendation	Increase controls to ensure that any scoring changes are accurately reflected in the GMS database.
2	Finding	During testing of the grants management process, we identified four exceptions to the Grants Administration Policy in a sample of 40 grants in progress, 15 new grants, and 15 closed grants.
	Recommendation	Implement procedures to ensure adherence to the Grants Management standard operating procedures and the completion of the grant closeout checklist.

EFFICIENCY AND EFFECTIVENESS		
Planning		
3	Finding	The ICOC identified a need for \$200 million in funding to continue to meet the organization's programmatic and administrative priorities until a potential initiative in 2020, and CIRM has not formalized its fund development plan.
	Recommendation	Create a formal development plan that identifies roles and responsibilities and the timing of fundraising activities to meet CIRM's programmatic and administrative funding needs.
4	Finding	CIRM 2.0 established strong programmatic reporting goals and measures. However, CIRM does not have metrics associated with the effectiveness of the agency's communication and public education strategy.
	Recommendation	Develop communications and public education metrics that are integrated into CIRM's quarterly reporting.
Employee Engagement		
5	Finding	CIRM 2.0 largely redesigned the organization and its activities, but not all job descriptions have been comprehensively updated to reflect changes in staff responsibilities.
	Recommendation	Continue to revise job descriptions to ensure alignment with current duties, roles, and authorities.
6	Finding	There is significant potential for staff attrition as CIRM plans for a potential wind-down.
	Recommendation	Building on efforts to date, continue to regularly communicate transition plans to staff and consider strategies to retain employees, including implementing staff development programs, recognition and reward opportunities, work-life balance initiatives, and cross-functional initiatives.



EFFICIENCY AND EFFECTIVENESS		
Board Engagement		
7	Finding	The terms of the ICOC Chair, Vice Chair, and other key members expire in 2022, creating a potential loss in leadership and institutional knowledge.
	Recommendation	Develop succession plans for the Chair and Vice Chair, document knowledge of individuals serving in leadership roles, and continue to identify potential highly qualified prospective ICOC members.
8	Finding	ICOC member expertise could be more effectively leveraged, especially since strong Board engagement will be particularly important during organizational transition..
	Recommendation	Proactively engage more Board members in decision-making and policy development activities.
Technology		
9	Finding	CIRM has made significant improvements to the Grants Management System (GMS) in recent years; however, additional opportunities exist to leverage the GMS to improve operational efficiency and effectiveness.
	Recommendation	Continue to identify and pursue opportunities to enhance GMS capabilities to automate processes, reduce paperwork, and enhance information access.
10	Finding	CIRM utilizes multiple document management systems, which result in some inefficiencies.
	Recommendation	Regularly evaluate IT systems to eliminate duplication, ensure systems are adequately meeting CIRM's needs, and consider the impacts of a potential organizational wind-down when making systems decisions.



II. BACKGROUND, SCOPE, AND METHODOLOGY

A. BACKGROUND

The California Institute for Regenerative Medicine (CIRM) 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 provided \$3 billion in funding for stem cell research, research facilities, and other vital research opportunities. CIRM's mission is to accelerate stem cell treatments to patients with unmet medical needs.

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. CIRM issued its first round of funding in 2006, and the organization expects current funds to support new awards through 2019.

CIRM is required to commission a performance audit every three years. The first performance audit covered Fiscal Year 2010-2011, the second performance audit covered Fiscal Year 2013-2014, and this performance audit covered Fiscal Year 2016-2017. Each performance audit examined the functions, operations, management systems, and policies and procedures of CIRM to assess whether the agency is achieving economy, efficiency, and effectiveness in the employment of available resources. In addition, each performance audit addressed policies and procedures for the issuance of contracts, grants, and loans, as well as the protection and treatment of intellectual property rights associated with research funded or commissioned by CIRM. Complete performance audit requirements and duties are included in Appendix A.

B. SCOPE AND METHODOLOGY

The performance audit had three areas of focus:

- 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.



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 used to conduct the performance audit included:

- Interviews: We conducted 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 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 an ICOC meeting.
- Testing: Using standardized sampling methods, we tested internal controls and compliance with policies and procedures for core functions.

Complete details on the performance audit methodology for each section of this study are included in Appendix B.

C. STATEMENT OF 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.



III. COMMENDATIONS

A. CIRM 2.0

In 2015, CIRM launched its CIRM 2.0 Clinical Program, which shifted the agency's operational approach to be systems-based and focused on partnering with researchers to advance its mission. This approach required the organization to focus on coordinating its efforts to overcome obstacles and accelerate stem cell research. CIRM's organizational shift involved four key system changes:

1. Standardize recurring program offerings
2. Increase speed and cycle frequency
3. Implement milestone-based disbursements
4. Establish objective goals and metrics

These system changes occurred in concert with CIRM's 5-year Strategic Plan, which redefined the future direction of the organization. CIRM's strategic planning process was inclusive of its employees and stakeholders and, overall, redefined its attention to be patient-centered. The strategic plan follows best practices by defining key objectives in alignment with the agency's mission, accompanied by goals and metrics to monitor progress toward objectives. Employees report that they developed a greater understanding of how their individual role supports CIRM's mission, as well as the role and function of other departments.

CIRM continues to be guided by its strategic plan and sets annual performance goals for each department. Based on these annual goals, departments establish quarterly goals that are monitored. At the end of each quarter, staff hold a meeting to review progress toward goals, share achievements, and discuss opportunities for improvement. This structure supports CIRM's ability to operate as a high-functioning, performance-focused organization.

B. ORGANIZATIONAL CULTURE

CIRM has a collaborative, engaged, and performance-oriented culture. Managers, Board members, and staff report improved morale and a more collaborative culture since CIRM 2.0 implementation. CIRM appointed a new president in 2014 and again in 2016. Turnover is often elevated during times of leadership transitions, as noted in 2014 and 2015. However, CIRM's turnover rate dropped to 10 percent in 2016, suggesting stability in the organization's leadership and culture.

CALENDAR YEAR	TURNOVER RATE
2011	15%
2012	9%
2013	17%
2014	19%



CALENDAR YEAR	TURNOVER RATE
2015	21%
2016	10%

C. PROCESS IMPROVEMENT

With the implementation of CIRM 2.0, the organization improved many of its processes to be more efficient and effective. Examples of key process improvements include:

- Standing program offerings creating continuous and predictable funding opportunities with ongoing program announcements.
- Establishing “The Wall” by developing a policy clarifying the roles and responsibilities of CIRM employees within and outside the grant review process to ensure it remains fair and impartial.
- Streamlined the review summary process by reducing the time to summarize grant applications from six weeks to approximately three weeks.
- Reduced grant processing time by reducing the time required to process grants from 22 months to 120 days.
- Incorporated milestone-based payments in contracts by shifting the responsibility for project progress to grantees and ultimately holding them responsible for achieving research objectives.

D. STAKEHOLDER ENGAGEMENT

CIRM’s strategic plan emphasized that CIRM is patient-centered. As such, CIRM has increased its stakeholder engagement, particularly with patient advocates. The agency hosts patient events and trainings across the State of California and has at least 1,000 patient advocates registered.

Additionally, CIRM’s Science Officers now proactively search for viable projects, helping engage researchers and increase the quality of proposed grants.

E. GMS IMPROVEMENTS

CIRM continued to improve its GMS system to meet its specific business needs and automate additional functions. For example, CIRM added an administrative task for Grants Review staff to record evidence of review activities performed, such as capturing comments and indicating that disclosures were examined. Additionally, CIRM included fields to capture critical IP information pertaining to clinical milestones, licensing, and commercial activity. The organization also developed a GMS enhancement plan to identify, evaluate, and prioritize additional enhancement opportunities.



IV. COMPLIANCE FINDINGS AND RECOMMENDATIONS

A. GRANTS APPLICATION AND REVIEW

1. **Finding: Of the 40 grant applications tested, one Grants Working Group (GWG) member's rating as presented to the ICOC did not match the GMS database; however, this difference did not impact the GWG funding recommendation.**

Since the implementation of CIRM 2.0, the number of grant cycles and applications has significantly increased. CIRM revised the application-to-award process, which once took up to two years, so that it now takes only 90 days. As a result, the Grants Review Team and Working Group review considerably more applications than in the past.

As part of our testing, we tested the documentation for GWG's scoring of applications, as well as the scoring presented to the ICOC when considering applications to select for funding. Of the 40 applications we tested, we found one instance in which the scoring recorded by the GWG was not consistent with the scoring presented to the ICOC.¹ In particular, in one instance we found that the GWG scores recorded in the GMS were 11 for Tier 1, 0 for Tier 2, and 1 for Tier 3. In contrast, on the slides presented to the ICOC, the scores were 10 for Tier 1, 1 for Tier 2, and 1 for Tier 3.

Upon discussion with CIRM, it was explained that the score changed after the GWG review meeting and that this change was not reflected in the system. According to CIRM, the score was changed following a polling of the GWG regarding a staffing change to the applicant team which arose after the GWG review. As a result, one reviewer changed their score from a "1" to a "2." As stated above, this did not change the overall recommendation to the ICOC because the application remained a Tier 1 recommendation. While differences in the GWG scores compared to the scores presented to the ICOC were minimal and did not influence the ICOC's decision, this instance represents a weakness in fully documenting post-review changes in the GMS.

Recommendation: Increase controls to ensure that any scoring changes are accurately reflected in the GMS database.

The Grants Review Team, in collaboration with the IT Department, should consider implementing improvements to the GMS to strengthen controls related to scoring presentation. If a change occurs to an application during the review process, CIRM should ensure that documentation of those changes is included in the GMS. CIRM should also develop a pre-ICOC checklist, including a step to compare the presentation to the database, to ensure the information matches.

¹ Sample #4 CLIN1-09472 #3



B. GRANTS MANAGEMENT

2. **Finding: During testing of the grants management process, we identified four exceptions to the Grants Administration Policy Standard Operating Procedures in a sample of 40 grants in progress, 15 new grants, and 15 closed grants.**

Exceptions to the Grants Administration Policy Standard Operating Procedures identified during the testing of the grants management process were related to new grants, specifically:

- For the sample of 15 new grants issued during Fiscal Year 2016-17, we identified four grants in which certain events did not adhere to the intended timeline for establishing new grants. We tested the following attributes:
 - Pre-funding administrative review (PFAR) checklist completion date on or prior to (Notice of Grant Award) NGA issuance
 - PFAR checklist completion date prior to contract execution
 - PFAR checklist completion date prior to first payment scheduled
 - Executed contract completed prior to scheduled first payment

We found that four grants had PFAR completion dates that occurred after the date of NGA issuance.² Additionally, we found that for one grant, the PFAR checklist was dated completed after the contract was executed.³ Upon inquiry with the Grants Management Team, we learned that a variety of different issues contributed to these instances. In particular, we found that the NGA issue date is automatically populated when the NGA template is first downloaded. Until the implementation of DocuSign in August 2017, CIRM signatures were not dated. Therefore, it is not surprising that some PFAR were dated after the “issue” date, because this date represents the date of initial routing and not actual issuance. Moreover, we found that the routing form used to obtain CIRM signatures on the NGA was not dated prior to the PFAR checklist. While the explanations and documentation of the specific circumstances provided by CIRM staff for each of these grants were reasonable, any variations from the intended timelines related to these key controls could allow NGA issuance prior to the completion of all due diligence.

Recommendation: Implement procedures to ensure adherence to the Grants Management standard operating procedures and the completion of the grant closeout checklist.

The Grants Management Team should work with the IT Department to add functionality to the GMS to ensure the completion of the grant closeout checklist and increase system controls to ensure the appropriate sequence of key controls is adhered to. CIRM plans to integrate the closeout checklist into the GMS this year.

C. LOANS

No findings. Based on testing a sample of two loans in process of a total of two loans in process in Fiscal Year 2016-2017, there are no findings since we did not identify any non-compliance with policy or internal controls.

² III.a.1 Exceptions: Samples #58, 65, 67, 69

³ III.a.2 Exception: Sample #58



D. CONTRACTS

No findings. Based on testing a sample of 22 contracts (including two contracts over \$250,000) of a total of 103 contracts in Fiscal Year 2016-17, there are no findings since we did not identify any non-compliance with policy or internal controls.

The rollout of the State's FISCAL system has unified the procurement, payment, and budget systems. Now that CIRM is using FISCAL, CIRM works with the Department of General Services (DGS) and State Controller's Office (SCO) to streamline the payment of grants, honoraria, purchase orders, and contracts by becoming more paperless. Both DGS and SCO audit 100 percent of the payments initiated by CIRM through the FISCAL system before payments are made to the payee or grantee.

E. INTELLECTUAL PROPERTY

No findings. Based on testing all 16 invention disclosures made in Fiscal Year 2016, there are no findings since we did not identify any non-compliance with policy or internal controls.

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 on 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.

Approximately two months before the due date, CIRM send emails to grantees notifying them of the utilization report requirement, due date for submission, and instructions for completion. If reports are not received by the due date, CIRM follows up with reminder emails. In accordance with CIRM Regulations and its Grants Administration Policies, if reporting requirements are not met, then CIRM can take 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.



V. EFFICIENCY AND EFFECTIVENESS FINDINGS AND RECOMMENDATIONS

A. PLANNING

BRIDGE FUNDING

3. **Finding: The ICOC identified a need for \$200 million in funding to continue to meet the organization's programmatic and administrative priorities until a potential initiative in 2020, and CIRM has not formalized its fund development plan.**

In its transition plan, CIRM leadership identified \$200 million in additional required funding to continue operating at existing capacity between 2019 and the potential bond measure in 2020. This additional funding would enable the organization to maintain current annual grant awards and staffing levels. Currently, key board members are leading fundraising efforts, which have remained largely confidential. In order to secure this significant amount of funding, additional resources are likely required to demonstrate CIRM's funding needs, seek donors of varying size and requirements, and provide overall support for fundraising efforts.

Administrative continuity is critical to CIRM's long-term sustainability. Retaining key staff members and process owners is particularly important given CIRM's unique position of potentially ramping down and ramping back up shortly thereafter. Loss of employee knowledge of the organization, colleagues, processes, and grantees is often difficult to replace and can translate into compromised productivity and results. If CIRM receives continued funding through an initiative, the agency will be expected to resume operations at current capacity in a short period of time. As such, it is important for CIRM to utilize funding to retain key staff and process owners during the transition so the organization does not have to ramp down and start over.

Recommendation: Create a formal development plan that identifies roles, responsibilities, and timing for fundraising activities to meet CIRM's programmatic and administrative funding needs.

Because the level of funding required to sustain CIRM's operations is significant, CIRM should develop a formal fundraising plan to identify required resources, activities, and strategies. CIRM's fundraising plan should identify additional resources and support within the organization required to help potential funders understand the benefit of their investment. For example, the role of the communications team could be expanded to develop fundraising materials that detail CIRM's goals, plans, and successes as well as funding requirements.

A written plan will help communicate CIRM's funding needs and strategies to potential donors, as well as staff and board members. Additionally, a plan may help CIRM diversify its funding strategies, which could increase its chances of securing additional funds. A strong fundraising plan includes the following elements:

- Mission and vision: Beyond the information readily available in CIRM's strategic plan and annual reports, this should describe CIRM's niche and added value to the field of stem cell research.



- **Funding needs:** Describe the need for additional funds and how funds would be allocated, including unrestricted, restricted, or special purpose funds. Because funders are primarily interested in funding research activities, potential donors should be aware of CIRM's eligibility requirements and proposal review process. The scrutiny applied to awards by staff and grants working groups places CIRM in a unique position to make objective, scientifically sound funding decisions. Donors who are interested in funding stem cell research should understand how their funds would be applied by CIRM in comparison to a research institution directly.
- **Donor targets:** Identify donors by type (i.e., individual, foundations, e-giving, corporate giving programs).
- **Funding strategies:** Identify strategies to conduct outreach and engage target donors, including who is responsible for each donor type or specific high potential donors. For example, the approach CIRM takes to request funding from a foundation should be tailored and likely differs from a corporate social responsibility program.
- **Implementation plan:** The funding plan should include an implementation plan defining key activities, timeframes, and responsible practices. The plan should also include a process for monitoring and sharing progress.

Fundraising activities are typically the responsibility of board members. However, staff resources could be leveraged to help create collateral and other communication materials for fundraising purposes.

COMMUNICATIONS AND PUBLIC EDUCATION

4. Finding: CIRM 2.0 established strong programmatic reporting goals and measures. However, CIRM does not have metrics associated with the effectiveness of the agency's communication and public education strategy.

CIRM's strategic goals that relate to communications primarily address increased patient involvement. For example, the Communications Effectiveness metric measures success based on the number of new patient advocates actively working with CIRM. In alignment with this strategic goal, the Communications Department's goals include organizing public events across the state to recruit and train patient advocates, feature patient advocates at Board meetings, make improvements to CIRM's website to increase its usability and overall visibility of projects, and create videos and reports that demonstrate CIRM's operations and impact. Notably, CIRM's Communications Department has been successful in each of these areas.

Patient advocates are significant stakeholders for CIRM and have the opportunity to spread the organization's message through their own networks. However, the communications metrics currently used by CIRM do not track or analyze the extent to which their message is reaching the residents of California. CIRM produces high-quality, accessible communication materials such as its annual report and daily blog posts that can help educate California residents on the value of their investment and work to come.

Recommendation: Develop communications and public education metrics that are integrated into CIRM's quarterly reporting.

As CIRM's Proposition 71 funding is exhausted, the role of the Communications Department should be elevated to serve a strategic function in educating the public. It is imperative that members of the public are aware of and understand CIRM's activities and impact while CIRM remains fact-based and objective



about its role as a state agency. To achieve this, CIRM should establish metrics focused on external communication and public awareness. Examples of these metrics include:

- Number of posts on social media accounts
- Number of press mentions
- Follower growth on social media accounts
- Number of “likes” or “shares” on social media accounts
- Growth in website visitors
- Citations of CIRM-funded research in publications

These metrics provide insight on the organization’s communications output, reach, and engagement with audiences beyond patient advocates.

B. EMPLOYEE ENGAGEMENT

JOB DESCRIPTION UPDATES

5. Finding: CIRM 2.0 largely redesigned the organization and its activities, but not all job descriptions have not been comprehensively updated to reflect changes in staff responsibilities.

The implementation of CIRM 2.0 resulted in a significant shift in the organization, establishing a strategic plan with measurable goals and streamlining operations. With this shift in the organization, many job duties changed to encompass new activities and workload distribution. For example, the therapeutics team began “hunting” for potential projects, adding a completely new function to their duties. Additionally, grant application cycles were offered four additional times throughout the year, from biennially to bimonthly, resulting in additional review work for the grants review team.

Staff have largely embraced these new responsibilities and overall see the benefits of CIRM 2.0 in the organization. However, not all job descriptions have not been updated to reflect these new duties. Continuing to update job descriptions can help staff define their discreet roles and responsibilities, and potentially demonstrate alignment with other positions in the marketplace.

Recommendation: Continue to revise job descriptions to ensure alignment with current duties, roles, and authorities.

CIRM should continue to update job descriptions to reflect duties, supervisory roles, and authority levels. Job descriptions serve as a communications tool to inform employees what tasks they are expected to perform and may also address quality and quantity of performance standards. Accurate job descriptions are a useful tool for other functions, such as wage setting and performance evaluations. Job descriptions should be used as a tool for training and other opportunities for staff development. When taken as a whole, job descriptions help organizations with workforce planning by defining how talent is used throughout the organization and, ultimately, fits together in its operations.

Job description updates should include input from employees, managers, and the Human Resources Department (HR). Employees are able to vouch for their duties, while managers should ensure



responsibilities align with the requirements for each role. HR owns job descriptions and should analyze each position for similarities across departments to establish consistent workload and responsibility levels. It is also important to note that during this process, job descriptions should not be created around each individual's skills and abilities, but rather their function and role in the organization.

Updated job descriptions can also serve as an input to CIRM's transition plan. By analyzing current jobs, the leadership team can evaluate current roles and understand how those roles could change in a potential wind-down scenario. If CIRM anticipates certain roles changing, the agency should also develop potential job descriptions for those functions and communicate job duties to staff who may fill those roles.

TRANSITION RESOURCES

6. Finding: There is significant potential for staff attrition as CIRM plans for a potential wind-down.

CIRM's uncertain future funding results in employee concerns related to job security. These concerns can, in turn, translate into poor employee morale and reduced organizational productivity. Employees facing potential layoffs often experience elevated stress and anxiety that can become evident in their day-to-day interactions with colleagues and grantees. Because individual employee performance and team performance impact overall organizational performance, declining employee morale can negatively impact CIRM's ability to efficiently and effectively achieve its mission.

In Fall 2017, CIRM's Board created a subcommittee to discuss and ultimately develop the organization's transition plan for a potential wind-down as funds deplete. This subcommittee developed a plan that identifies the organization's administrative budget under multiple funding scenarios, while ensuring that grants awarded through 2019 are managed to completion. As grants are awarded through 2019, CIRM must have the administrative resources to manage awards through 2024. The transition plan establishes funding for different award categories to ensure CIRM has enough funding to maintain operations and continue awarding grants into 2019. Accordingly, the transition plan shows a wind-down in the agency's administrative budget beginning in 2020, depending on whether or not leadership is able to secure bridge funding to fill its anticipated funding gap. This plan was presented to staff in November 2017, in advance of its presentation to the full Board the following month.

Transition planning status updates are provided during quarterly staff meetings. In addition, members of CIRM's leadership team provide information to staff using a "cascading messages" model as information becomes available. Frequent, consistent communication of transition planning efforts will be key to maintaining staff morale during this uncertain time.

CIRM leadership strives to be supportive of employees in their pursuit of other employment opportunities given CIRM's uncertain future. Leadership has expressed their willingness to support staff with professional development opportunities, such as attending conferences, training, and undertaking new activities to develop new skills. While leadership has made staff aware of their support, this approach could be strengthened by proactively encouraging staff to consider opportunities to develop skills and opening the door to discussing the future.

Next year, CIRM plans to offer external resources for job seeking activities such as resume and cover letter development. Employees may feel more comfortable leveraging an outside resource to protect the sense



that their jobs are secure with CIRM. CIRM's HR manager may continue to serve as a resource for employees if they are interested in other state service opportunities.

Recommendation: Building on efforts to date, continue to regularly communicate transition plans to staff and consider strategies to retain employees, including implementing staff development programs, recognition and reward opportunities, work-life balance initiatives, and cross-functional initiatives.

Transition plans and associated strategies should continue to be deployed as living documents that are continually updated and available to Board members, staff, and external stakeholders. Future iterations should also include organizational structure options during a potential wind-down process. For example, grant funds are currently expected to be exhausted by 2019; grant monitoring, management, clinical trials, and closeout will continue past that date; and intellectual property reporting will be required for 10 years. Eventually, some CIRM activities could be transferred to another state agency. As the transition proceeds, stakeholders and grantees should be made aware of staffing changes to help preserve continuity.

CIRM should also continue to incorporate discussion of transition plans into quarterly meetings, in addition to providing information to staff when information becomes available. Providing communication regarding sensitive issues at regular and reliable intervals can help alleviate anxiety among employees. Particularly as transition plans evolve, leadership should continue to provide timely communication to employees and afford opportunities for employees to ask questions and prepare for upcoming changes.

If a new initiative is proposed, CIRM should develop a mid-term (two to three year) strategic plan based on the goals and requirements of the initiative. Because CIRM has no control over the language included in any potential measure, the agency should refrain from planning ahead until the potential future options are more clear.

CIRM leadership should continue to explore opportunities to support and retain employees, including increasing formal employee recognition and identifying opportunities for departments to work cross-functionally. Cross-functional initiatives can strengthen staff relationships and help managers identify individuals in other departments who may be candidates for training in other roles. Additionally, CIRM should consider providing supplemental work-life balance options such as flexible schedules and working remotely to support employee wellbeing.

Leadership has expressed support for employee professional development, which will be a key retention strategy during organizational transition. Particularly during 2020, as layoffs would become increasingly likely during a wind-down scenario, CIRM leadership should take a proactive approach in supporting staff. For instance, during employee performance reviews, managers and HR should discuss employee goals and opportunities for professional development to more actively support employees during CIRM's potential transition. Based on these conversations, CIRM could help employees establish individualized training and development programs.



C. BOARD

TERM LIMITS AND SUCCESSION PLANNING

7. Finding: The terms of the ICOC Chair, Vice Chair, and other key members expire in 2022, creating a potential loss in leadership and institutional knowledge.

The ICOC is comprised of 29 members (patient advocates, researchers, and biotechnology industry) from across California. Most members are appointed by Constitutional Officers for the State of California and may serve a maximum of two six- or eight-year terms, depending on their category. CIRM's Chair and Vice Chair's appointments are set to expire simultaneously in 2022. Many other board members' terms expire in 2021, including eight patient advocates' terms, four of which are eligible for reappointment. CIRM's Chair and Vice Chair are working officers, providing leadership in key areas, including government relations and fundraising, that CIRM staff do not currently fill.

CIRM does not currently have succession plans in place for ICOC officers or members. While a new initiative may change or even nullify term limits or change the structure and membership of the ICOC, CIRM should plan for ICOC leadership succession. Succession planning is best practice in the event of planned and unplanned vacancies.

Recommendation: Develop succession plans for the Chair and Vice Chair, document knowledge of individuals serving in leadership roles, and continue to identify potential highly qualified prospective ICOC members.

The ICOC officers' roles are broadly defined in Proposition 71. The ICOC should build on this framework to develop job descriptions for officer roles, with responsibilities and performance goals defined. In addition, CIRM staff should begin the process of documenting the knowledge of the Chair, Vice Chair, and other key members with expiring terms to ensure that their significant institutional knowledge is not lost.

If CIRM's funding is renewed, the ICOC should consider establishing "past officer" ex-officio positions, so the outgoing officers can serve as transition resources. The ICOC should also consider whether some officer duties, such as government relations and fundraising, will be performed by ICOC members in the future or if they should be delegated to staff.

If CIRM's funding is renewed, identifying potential new ICOC members will be increasingly important. When a vacancy occurs, Board leadership with the help of CIRM staff typically identifies a list of potential ICOC members for consideration by the Constitutional Officers, who may or may not appoint from the list. CIRM should develop a matrix of desired ICOC member attributes, such as geography, diversity, and professional expertise, and seek potential candidates based on current and future ICOC needs.

ENGAGEMENT

8. Finding: ICOC member expertise could be more effectively leveraged, especially since strong Board engagement will be particularly important during organizational transition.

The ICOC is a large, statewide governing board, with 29 members located across California. There are inherent challenges to this structure: Geography limits the ability of some members to participate in



person and interface with CIRM staff; individuals on a large board may feel less personally responsible and therefore less inclined to participate; and it is difficult for officers and committee chairs to meaningfully build relationships with and identify the best roles for such a large number of members. This is evident in committee participation; while CIRM leverages ICOC expertise through standing and ad-hoc committees, which is a best practice, some members serve on multiple committees while others serve on none.

In addition to these challenges, changes to CIRM's conflict of interest policy in 2013 eliminated the ability of institutional members to participate in grant funding votes. This has limited their overall participation, and several ICOC members reported a reluctance to participate in discussions. Both ICOC members and CIRM staff reported a decline in the engagement of institutional members in all discussions, not just those related to grants.

As funding winds down and the future of the agency is uncertain, it is important for the board to be fully engaged in critical decisions, and ensure they are leveraging the full potential of board members. When an organization has limited funding, stronger governance and prioritization is necessary to focus staff on the most important programs. For example, CIRM may in the near future be considering whether to limit or end certain types of funding to focus on key areas with the most impact.

Recommendation: Proactively engage more Board members in decision-making and policy development activities.

CIRM staff and the ICOC Governance Subcommittee should assess the engagement of all ICOC members and determine options for increased engagement. Board member engagement can take many forms, including committee membership, serving in leadership roles, active meeting participation, serving as a resource to staff, special projects, advocacy, and public relations. At least twice a year, CIRM should identify these and other opportunities for board engagement with target dates, resource needs, and time commitments, and provide it to the ICOC on a semi-annual basis.

CIRM should conduct an annual ICOC member survey to assess ICOC member engagement and satisfaction, and collect input on potential opportunities for increased engagement from members. At least once a year, the ICOC should discuss the roles and responsibilities of ICOC members in relation to CIRM's strategic plan and set clear expectations for member participation for the upcoming year. The Governance Subcommittee could lead this work.

The most effective boards have members who were intentionally recruited for their skills. As discussed in Recommendation 8, CIRM should assess the skills necessary for effective governance and seek potential candidates based on identified needs.

D. TECHNOLOGY

GMS

- 9. Finding: CIRM has made significant improvements to the Grants Management System (GMS) in recent years; however, 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:

- For certain reviews with higher volume, initial eligibility determinations are made on an internal eligibility spreadsheet. An internal discussion is held and, once finalized, determinations are recorded in the GMS. Although this process is reasonable, documentation does not exist to demonstrate the basis for changing this initial determination. Without this evidence, it is difficult for CIRM to demonstrate that all eligibility determinations are fair and reasonable.
- Documentation of payments requested and processed by the State Department of General Services (DGS) is not maintained within GMS. While significant improvements have been made to streamline CIRM's payment process and even more improvements are on the horizon, documentation of electronic payment requests and processed payments are not saved in the GMS.
- Paper checklists are still in use for the grant close-out review process and other review processes (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 in accordance with the GMS enhancement plan, which requires ongoing identification, evaluation, and prioritization of enhancement opportunities. Consideration should be given to potential organization wind down when decided which enhancements should be implemented.

SYSTEM UTILIZATION

10. Finding: CIRM utilizes multiple document management systems, which result in some inefficiencies.

CIRM utilizes a number of different systems for document management, particularly related to financial documents. Some of these documents are housed in multiple different systems, as shown in the table below. Not only is duplication of documentation inefficient and a cause for confusion, but CIRM may also unnecessarily be supporting additional secondary systems.

CIRM DOCUMENT MANAGEMENT SYSTEMS						
	Grant Payment Request	Grant Payment	TEC Payment	Invoice Payment	Honorarium Payment	CAPS Payment
DropBox	X		X	X	X	X
Alfresco			X	X	X	X
GMS	X	X				

For example, CIRM operates three document management systems, including DropBox, Alfresco, and its GMS system. Staff reported confusion regarding the discrete role of each system. As a result, employees may be using one or more of the document management systems in a manner that contradicts its intended purpose. For example, CIRM moved its document management system software from



DocuShare to Alfresco because Alfresco aligns with the State's records retention schedule. With multiple systems in place, it is unlikely that any of the systems are utilized to their fullest potential.

As CIRM potentially winds down and workload decreases, the usefulness of certain systems is likely to also decrease. For example, CIRM's internet speed and electronic storage space requirements are both likely to decrease, especially as documents transition to the State's archive system. As system requirements decrease, IT services will require right-sizing to continue utilizing CIRM's resources efficiently.

Recommendation: Regularly evaluate IT systems to eliminate duplication and ensure systems are adequately meeting CIRM's needs.

CIRM should regularly evaluate its selection of IT systems to reduce duplication and clarify the role of each system. Documents should ideally not be stored in multiple locations throughout the organization. If documents are stored in different systems for reasons outside CIRM's control, CIRM should develop document storage guidelines to ensure documents are retained appropriately in the systems.

Additionally, as CIRM's technology needs decrease over time, the IT Department should develop a policy to evaluate its current systems to ensure they are reasonably meeting the organization's needs. Systems should match the organization's requirements, and not supersede them in the name of efficiency or preference of certain employees. In light of a potential wind-down, the Department should plan for how to sunset or transition systems. The Department should consider, in alignment with the detailed transition plan developed by leadership, what systems and hardware are required at each phase of the organization and how to manage vendor relationships and inventory to provide the most cost-effective IT services to employees. This analysis should include an assessment of the number of employees expected to be working at CIRM, the functions and system requirements of those employees, and regulatory issues such as security and records retention. This plan will help the organization use its remaining funds in the most efficient and effective manner by potentially reducing spending on IT products and services.



APPENDIX A: PERFORMANCE AUDIT REQUIREMENTS

A. 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.

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.

B. MANAGEMENT RESPONSIBILITIES

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.



APPENDIX B: PERFORMANCE AUDIT METHODOLOGY

The performance audit conducted by Moss Adams had three areas of focus, including:

- Compliance of CIRM policies and procedures with applicable regulations and laws.
- Compliance of CIRM processes with its policies and procedures and testing key internal controls.
- Evaluation of 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.

Our audit approach for each function and project deliverables are described below. Areas of audit focus within each function were informed by a risk assessment that was developed through an iterative process of fact finding activities such as a kickoff meeting, interviews, document review, and walkthroughs. The risk assessment was updated after each fact finding activity.

A. GRANTS APPLICATION AND REVIEW

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

- *The grants application, review, and approval processes are in accordance with CIRM's stated policies; and*
- *Conflicts of interest are considered for all reviewers, ICOC members, and CIRM staff.*

During on-site fieldwork, we interviewed the Grants Review Team including the Vice President of Portfolio Development and Review, Project Manager, and Senior Science Officers. We performed walkthroughs of several grant programs, applications, GWG Reviews, and ICOC Reviews. Interviews and walkthroughs ensured we understood workflow processes for the entire application, review, and approval cycle, 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.

Key controls were identified during the walkthrough process and tested using a sample of the 320 applications received during Fiscal Year 2016-2017. Key controls that were tested using samples are as follows:

- ICOC approved the written concept.



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

In addition to testing key internal controls, we tested compliance with the grants application, review, and approval processes. Compliance requirements that were tested using samples are as follows:

- Program announcement was issued by CIRM based on the approved concept plan.
- Application was submitted by applicant.
- Reviewers disclosed financial interests to CIRM by completing confidential disclosure forms.
- CIRM retained documentation to substantiate the positive selection review and selection process.
- CIRM retained documentation to substantiate scoring of applications and recommendations of the GWG.
- CIRM retained documentation to substantiate ICOC's selection of applicants.

Throughout the audit process, we analyzed whether CIRM is achieving economy, efficiency, and effectiveness in the employment of available resources as they relate to the grants application, review, and approval processes. This was performed by comparing current practices to documented standard operating procedures, as well as comparing current practices to other criteria such as best practices and/or National Institutes of Health's Grants Policy Statement.

B. GRANTS MANAGEMENT

We reviewed the grants management process as guided by CIRM's Grants Administration Policy and internally documented policies and procedures for new, active, and closing grants during Fiscal Year 2016-2017. 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 on-site 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. 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 the aforementioned guidance.



During on-site fieldwork, we interviewed the Director of Portfolio Operations and Performance and the Grants Management Officers. We performed walkthroughs of the processes related to review and approval of pre-funding administrative checklists, NGAs, payments, scientific progress reports, financial and administrative reports, award modifications, and grant close-outs. Interviews and walkthroughs helped ensure 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 the aforementioned guidance.

Key controls were identified during the walkthrough process and tested using a sample of the 63 new grants, 256 grants in progress, and 91 grants closed out during Fiscal Year 2016-2017. Key controls that were tested using samples are as follows:

- The Grants Management Officer and a Science Officer approved the pre-funding administrative review (PFAR) checklist.
- The NGA was reviewed, approved, and signed by the appropriate members of the Executive, Scientific, Legal, and Financial teams.
- 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 the 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 that were tested using samples are 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.

Samples were selected prior to our on-site arrival, and a list of documents required for each sample was provided.

Throughout the audit process, we analyzed whether CIRM is achieving economy, efficiency, and effectiveness in the employment of available resources as they relate to the grants application, review, and approval processes. This was performed by comparing current practices to documented standard



operating procedures, as well as comparing current practices to other criteria such as best practices and/or the National Institutes of Health's Grants Policy Statement.

C. LOANS

Since the loan process is similar to the grant process, many aspects of our methodology were similar to the grants management process. As part of the testing performed for grants management, we tested loans. 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.*
- *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 was 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.

It is important to note that no loans were started or closed during the audit period, Fiscal Year 2016-17. Instead, we tested the only two loans that were active during this period.

Throughout the audit process, we analyzed whether CIRM is achieving economy, efficiency, and effectiveness in the employment of available resources. This was performed by comparing current practices to documented standard operating procedures, as well as comparing current practices to other criteria, such as best practices.

D. INTELLECTUAL PROPERTY

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

During on-site fieldwork, we interviewed the General Counsel, Grants Management Officer, Contract Administrator, and Associate General Counsel. 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 plans for IP process improvements. Interviews and walkthroughs ensured we understood workflow processes for IP, as well as the key controls employed to ensure adherence to the



aforementioned guidance. Based on the interviews and walkthroughs, we documented the processes employed by CIRM, as well as the key internal controls utilized to ensure compliance with IP policies.

Compliance requirements that were tested for IP processes using samples are as follows:

- Evaluated a sample from the 37 Invention Disclosure Forms that were received during Fiscal Year 2016-2017. These forms identify the grant, the inventor(s), and PI. We evaluated whether any of the grants triggered the IP policy revenue sharing requirement through:
 - Documentation of sufficient technical detail to convey disclosure, nature, purpose, operation, and physical, chemical, or electrical characteristics. If the invention had been submitted for publication or presentation, then documentation of publication and date of abstract or manuscript.
 - Documentation that Grantee reported all Exclusive License Agreements, Non-Exclusive License Agreements, Material Transfer Agreements, or Collaborative Agreements conveying rights in CIRM-funded inventions or CIRM-funded technology.
 - Documentation that each grantee, or the exclusive licensee of the grantee, submitted a plan to CIRM to afford access to any drug that is, in whole or in part, the result of research funded by CIRM to Californians who have no other means to purchase the drug.
- Evaluated a sample from the 216 Publication Disclosure Forms that were filed for CIRM-funded projects during Fiscal Year 2016-2017 to determine conformance with the Invention and Licensing Reporting requirements (Section 1000602), which specify that the following information be captured:
 - Identification of the publication, including abstract and statement of the PI's biographical credentials.
 - Date of the abstract, manuscript, or presentation.
 - Submission date and, if relevant, any publication dates, including publications via the internet.
- Evaluated a sample from the 29 Invention Utilization Reports that were submitted to CIRM during Fiscal Year 2016-2017, as specified under the Invention and Licensing Reporting requirements (Section 1000602), for the following information:
 - Patent applications filed, including countries in which applications were filed, application serial numbers, status, and detailed description of CIRM-funded inventions.
 - Reporting on the total funding from all sources that directly contributed to CIRM-funded inventions disclosed or claimed in the patent application.
 - Reporting on the execution of all Exclusive License Agreements, Non-Exclusive License Agreements, Material Transfer Agreements, or Collaborative Agreements conveying rights to CIRM-funded inventions.
 - For CIRM-funded inventions/technology that generate revenue, reviewed whether revenue has been received during the 12-month period prior or subsequent to the last report that was filed.
 - For CIRM-funded inventions that triggered licensing activities, determined if the following information is captured: initiation of clinical testing, initiation of pivotal studies, and application for marketing approval.

Samples were selected prior to our on-site arrival, and a list of documents required for each sample was provided.

Throughout the audit process, we analyzed whether CIRM is achieving economy, efficiency, and effectiveness in the employment of available resources. This was performed by comparing current



practices to documented standard operating procedures, as well as comparing current practices to other criteria, such as best practices.

E. CONTRACTS

We reviewed key provisions of the 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 was 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 on-site fieldwork we interviewed the Supervising Finance Officer, Contracts Administrator and Director of Finance and performed walkthroughs of several procurement transactions to ensure we understood workflow processes of the procurement cycle. Key controls were identified during the walkthrough process and tested using a sample of the 103 contracts issued during Fiscal Year 2016-2017. Key controls that were tested using samples are 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 ICOC. 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.

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

- CIRM documented the justification for sole source utilizations for agreements over \$100,000 or more and competitive proposals were not submitted.
- Prior to preparation of request for proposals, the requestor at CIRM submitted a written presentation on 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 ICOC.

Samples were selected prior to our on-site arrival, and a list of documents required for each sample was provided.

Throughout the audit process, we analyzed whether CIRM is achieving economy, efficiency, and effectiveness in the employment of available resources. This was performed by comparing current practices to documented standard operating procedures, as well as comparing current practices to other criteria, such as best practices.

F. SUPPORTING FUNCTIONS

Since CIRM was established in early 2005, and it has a limited timeframe within which to utilize bond proceeds to award grants and loans, it faces the unique challenges of an organization that has to deal with both business ramp-up and ramp-down/transition in a relatively short time period. This facet of the performance audit will provide insights regarding how CIRM can more efficiently and effectively manage and operate. Functions of the organization that were addressed in this audit included administrative support, communications, executive leadership, finance, human resources, legal, office management, and planning.

Key audit objectives include:

- *Assess how CIRM can more efficiently utilize its resources (i.e., minimize time and effort) to conduct its business.*



- *Assess 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 scientific performance (e.g., the impact of the grants and loans). Areas of focus for this assessment included:

- Correlation of activities to strategic plan
- Tracking strategic plan implementation
- Organizational structure
- Span of control and chain of command
- Staffing levels and capacity
- Staff experience
- Outsourcing and insourcing
- Operational and technology resources
- Maximizing technology systems
- Performance measurement
- Resource planning
- Internal and external customer satisfaction
- Succession plan
- Transition plan
- Recruiting and retention

Efficiency and effectiveness was assessed through conventional fact finding and analytical activities, which are described below.

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 possible small group interviews were conducted:

Function	Positions
ICOC	Chair, Vice Chairs, and selected other members
Executive Team	All members
Grants Management	Director of Grants Management, Grants Management Officer, Grants Management Specialists
Finance, Administration, & Legal	Office Manager, Supervising Financial Services Officer, Senior Director of Communications, Associate General Counsel, Contract Administrator, Human Resources Officer, IT Director

We observed operations and reviewed additional documents associated with priority areas of focus. The purpose of these activities was 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 written up 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.

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 may 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. An 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 any 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.

We also determined the extent to which CIRM has responded to the outstanding recommendations from the Fiscal Year 2010-2011 Performance Audit and recommendations included in the Fiscal Year 2013-14 Performance Audit.

G. 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 will deliver 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.

The estimated timing of each deliverable is identified in the project schedule that is provided in Appendix II of this Audit Plan.



APPENDIX C: PROGRESS TOWARD PERFORMANCE AUDIT RECOMMENDATIONS

A. FISCAL YEAR 2013-2014 PERFORMANCE AUDIT RECOMMENDATIONS

RECOMMENDATION	STATUS	VALIDATION	BASIS OF VALIDATION
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.	Significant GMS enhancements made	Complete	Interviews and SOPs
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.	Significant GMS enhancements made	Complete	Interviews and SOPs
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.	Implemented significant process improvements	Complete	Interviews and SOPs
4. Implement procedures to ensure adherence to the Grants Administration Policy.	Implemented significant process improvements	Complete	Interviews and SOPs
5. Implement enhancements to the GMS to support increased accountability for, and enforcement of, Annual Utilization Report Requirements.	Significant GMS enhancements made	Complete	Interviews and GMS reports
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.	Significant GMS enhancements made	Complete	Interviews and testing of Invention Utilization Reports
7. Develop a slate of operational performance measures aligned with CIRM's strategic plan and report regularly to the ICOC.	Developed a strategic plan including operational performance measures	Complete	Strategic plan and annual report
8. Continue to proactively focus on improving employee engagement through effective employee outreach, team building, and communication.	Regular goal setting is inclusive of employees and fosters communication and collaboration among employees	Complete	Interviews and goal setting documents



RECOMMENDATION	STATUS	VALIDATION	BASIS OF VALIDATION
9. Ensure performance evaluation and merit increases occur in a timely manner.	Performance evaluations occur each January	Complete	Interviews and evaluation documents
10. Continue to monitor current trends in web application development to determine the best development applications to support the GMS moving forward.	Continued monitoring trends in web application development to support the GMS	Complete	Interviews
11. Continue to identify and pursue opportunities to enhance GMS capabilities to automate processes, reduce paperwork, and enhance information access.	Continued assessing and pursuing opportunities to enhance GMS functions	Complete	Interviews and applied process improvement
12. Continue implementation of FY 2010-11 performance audit recommendations.	Continued implementing recommendations	In progress	See Section B below

B. FISCAL YEAR 2010-2011 PERFORMANCE AUDIT RECOMMENDATIONS

Recommendations from the Fiscal Year 2010-2011 Performance Audit that were not fully complete were also revisited to evaluate progress in implementation.

RECOMMENDATIONS	2013-2014 VALIDATION	2016-2017 STATUS	2016-2017 VALIDATION	2016-2017 BASIS OF VALIDATION
Tier 1				
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.	Partially Complete	Implemented significant process improvements and used enforcement mechanism	Completed	Interviews and testing of Invention Utilization Reports
III.E.1 Ensure the GMS IP Module specifications for Phase 1 include specific questions about commercial activity.	Partially complete	Significant GMS enhancements made	Completed	Interviews and testing of Invention Utilization Reports
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 indicators.	Partially complete	Annual report and quarterly performance reporting	Completed	Annual Report



RECOMMENDATIONS	2013-2014 VALIDATION	2016-2017 STATUS	2016-2017 VALIDATION	2016-2017 BASIS OF VALIDATION
IV.B Develop a communication plan and comprehensive, results-based annual report, and use the annual report as a cornerstone for external communications.	Completed	N/A	N/A	N/A
IV.C Amend policies to make completion of the grant outcome a survey a requirement of the grant closeout process.	Completed	N/A	N/A	N/A
VII.B Develop a detailed plan for completing development of the GMS, and provide ongoing project oversight.	Completed	N/A	N/A	N/A
VII.D Implement a document management system.	Completed	N/A	N/A	N/A
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.	Completed	N/A	N/A	N/A
VI.A Acquire and implement human resource forecasting software.	Completed	N/A	N/A	N/A
VI.B Reevaluate staffing levels if administrative and implementation costs are forecasted to exceed 6% of bond proceeds.	Completed	N/A	N/A	N/A
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.	Partially complete	Implemented significant process improvements	Completed	Interviews and SOPs
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.	Completed	N/A	N/A	N/A
Tier 2				
V.A Develop and implement a relational database to enable more efficient financial analysis and reporting of non-grant contracts and purchase order payments.	Completed	N/A	N/A	N/A
V.B Request authorization to access the State Controller's Office's fiscal system.	Completed	N/A	N/A	N/A
V.C Create and implement a comprehensive, formal business development plan.	Completed	N/A	N/A	N/A



RECOMMENDATIONS	2013-2014 VALIDATION	2016-2017 STATUS	2016-2017 VALIDATION	2016-2017 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.	Completed	N/A	N/A	N/A
V.F Incorporate performance metrics reporting into a structured meeting rhythm process and streamline weekly meetings	Partially complete	Quarterly meeting to report progress on goals	Completed	Interviews and goal setting documents
V.G Continue efforts to identify and implement efficiency improvements and strive to quantify efficiency gains.	Partially complete	Quarterly goal setting and evaluation of opportunities to increase efficiency	Completed	Interviews and goal setting documents
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.	Completed	N/A	N/A	N/A
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.	Completed	N/A	N/A	N/A
V.H Develop a formal onboarding process and incorporate it into the overall new employee orientation program.	Completed	N/A	N/A	N/A
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.	Partially complete	Transition subcommittee developed transition plan and communicated to employees	Completed	Interviews and transition plan
VI.D Adopt a Board Code of Conduct.	Completed	N/A	N/A	N/A
III.A.2 Review processes related to conflict of interest forms to assess whether there are redundancies the in process and, if so, there is a logical reason for the redundancy.	Completed	N/A	N/A	N/A



APPENDIX D: MANAGEMENT RESPONSE

CIRM would like to thank Moss Adams for their work on the Performance Audit. Moss Adams took time to learn about the improvements and operational excellence that came about due to CIRM 2.0 and to highlight these improvements in the audit. CIRM will consider the proposed recommendations, along with other options, all geared to improve the efficiency of the agency's operations. We will report back to the board at a later time with our plan and will continue to update the board as we progress.

