Proprietary & Confidential

FINAL REPORT

California Institute for Regenerative Medicine

FY 2019–2020 PERFORMANCE AUDIT

October 13, 2021

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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.

CIRM is required to commission a performance audit every three years to examine the functions, operations, management systems, and policies and procedures of the agency, and to assess the 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.

This performance audit covers Fiscal Year 2019–2020. During our audit period, CIRM's initial funding via Proposition 71 was set to expire at the end of 2023, and the agency was experiencing a wind-down period. CIRM was at risk of closure in the event that Proposition 14: The California Stem Cell Research, Treatments, and Cure Initiative of 2020 was not approved by California voters. Additionally, the COVID-19 pandemic impacted CIRM operations beginning March 2020.

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, document review, process walkthroughs, and testing. Detailed methodologies are included in Appendix B.

B. SUMMARY OF FINDINGS AND RECOMMENDATIONS

The recommendations described in this report should be considered in context of the impact on the organization, new areas of focus for 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.

FINDINGS AND RECOMMENDATIONS		
Compliance		
1.	**Finding**	Of the 20 grant applications tested, two applications in the Grants Management System (GMS) included a "hasn't acted" status; however, these applications had been reviewed and scored by the Grants Working Group (GWG).
	Recommendation	The Grants Review Team, in collaboration with the IT Department, should consider improvements to the GMS to strengthen controls related to the review and scoring workflow and ensure that any review and scoring information is captured as part of the application status.

FINDINGS AND RECOMMENDATIONS		
2.	**Finding**	During testing of the grants management process, we identified three exceptions to the Grants Administration Policy Standard Operating Procedures (SOPs) in a sample of 20 grants in process, 23 new grants, and 20 closed grants.
	Recommendation	A. The Grants Management Team should reinforce the requirements of the Grants Administration Policy SOPs to ensure that all required information is documented and maintained to support grants received and managed by CIRM, including documentation to support changes or deviations from an executed agreement. B. Consider adding a requirement for a separate individual to review due dates entered into the GMS to ensure there are no data entry errors and to prevent late reports due to these errors.
3.	**Finding**	CIRM adopted regulations in 2018 outlining the technology disclosure requirements. While we found no exceptions, we noted that the ability for CIRM to monitor and determine compliance of the Grantees with the technology disclosure appeared challenging.
	Recommendation	Implement an IT control that allows for missing documentation or reports to be flagged and routed to the responsible CIRM team members.
Efficiency and Effectiveness		
4.	**Finding**	CIRM is undergoing a significant governance transition. The terms of the Independent Citizens' Oversight Committee (ICOC) Chair, Vice Chair, and most long-term members are expiring in the next year, creating a potential loss of institutional knowledge.
	Recommendation	Conduct succession planning for ICOC leadership and key contributors, document knowledge of long-serving individuals, and continue to take steps to support ICOC leadership transition.
5.	**Finding**	CIRM staff and ICOC members report a high level of engagement among ICOC members currently. However, as a large statewide governing board, there are inherent challenges in effective and consistent member engagement, particularly during organizational transition.
	Recommendation	Take steps to proactively engage more ICOC Board Members in decision-making and policy development activities.
6.	**Finding**	CIRM does not have an effective policy or proactive process for monitoring and enforcing awardee publication disclosures.
	Recommendation	A. Develop a policy to consistently monitor and enforce compliance with publication disclosure requirements. B. Consider options, such as implementing a Customer Relationship Management (CRM) system, to support automated proactive monitoring of awardee publication and press releases.

FINDINGS AND RECOMMENDATIONS		
7.	**Finding**	CIRM has historically relied on scientific experts and partners with a connection to the organization for grant review. As a public agency with the mission of cures for all, it is important for CIRM to diligently seek diverse perspectives and expertise and ensure the perception of independence in application review.
	Recommendation	Continue to implement recently adopted practices to actively seek more diverse members of the California scientific community to review and recommend grants, and monitor and evaluate the Grants Working Group (GWG) to promote a diversity of perspectives, backgrounds, and expertise.
8.	**Finding**	CIRM's Records Retention Schedule with the State of California expired in 2018. Staff continue to report confusion related to records retention requirements, which can negatively impact the organization's ability to respond to information requests.
	Recommendation	CIRM should update its Records Retention Schedule, establish policies and procedures for records management, and consider developing annual trainings to support a consistent understanding of records requirements.
9.	**Finding**	The use of three document management systems continued to present confusion to CIRM employees, resulting in inconsistent user adoption and records management practices.
	Recommendation	When implementing a new document management system, develop an adoption strategy that includes ample communication, policy and procedure guidance, and accountability practices to support consistent expectations and system utilization.
10.	**Finding**	CIRM has made significant improvement 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, centralize data, and enhance access.
11.	**Finding**	CIRM hosts a significant amount of scientific and business data but lacks a strategy or system to integrate information in an optimal way.
	Recommendation	Consider implementing an integrated database and Customer Relationship Management (CRM) system to collect and better analyze scientific and business data in support of CIRM's mission.

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 funds stem cell research at not-for-profit, government, and for-profit organizations throughout California. The mission of CIRM is to accelerate stem cell treatments to patients with unmet medical needs. According to Proposition 71, the purpose of CIRM is to:

- Make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and/or medical procedures that will result in, as speedily as possible, the cure for and/or substantial mitigation of major diseases, injuries, and orphan diseases
- Support all stages of the process of developing cures, from laboratory research and facilities development
- Establish the appropriate regulatory standards and oversight bodies for research and facilities development

CIRM first began funding awards in 2006. As of December 2019, the agency approved grants and loans totaling approximately $2.7 billion ($2.4 billion of which had already been disbursed). CIRM funding was set to expire at the end of 2023; however, in November 2020, California voters approved the continuation of funding through the passage of Proposition 14: The California Stem Cell Research, Treatments, and Cures Initiative of 2020.

B. SCOPE AND METHODOLOGY

CIRM is required to commission a performance audit every three years to examine the functions, operations, management systems, and policies and procedures of CIRM, and 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.

This performance audit covers Fiscal Year 2019–2020 and has 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 methodology for each section of this performance audit are included in Appendix B.

C. STATEMENT OF COMPLIANCE WITH GAGAS

We conducted this performance audit in accordance with Generally Accepted Government Auditing Standards (GAGAS). 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

Based on the results of interviews and document review, it is evident that CIRM has many commendable attributes. Some of these attributes are noted below.

- **Mission-driven employees and organizational culture:** Managers, Board Members, and staff cited CIRM's mission and organizational culture as the reason many employees stayed with the agency through the uncertainty of the potential wind-down phase.
- **Focus on goal setting and monitoring:** As a continuation of CIRM 2.0 (the second phase of the CIRM program), CIRM applied ongoing focus on setting ambitious goals and continually monitoring targets in quarterly all-hands meetings.
- **Organizational agility and dedication to fund COVID-19 research:** CIRM quickly shifted to funding COVID-19-specific research/therapies at the onset of the pandemic, which required significant dedication and additional work on the part of both staff and Board Members. The entire agency, which lost several members during this uncertain year, took on the challenge of an accelerated, rolling two-week cycle to expedite the funding process.
- **Forward-looking planning:** Even during the potential wind-down, CIRM leadership dedicated resources to begin developing a strategic plan for the next five years to enable the organization to scale up and initiate work expeditiously if Proposition 14 was approved by voters in November 2020.
- **Clear, proactive communication:** The strategic wind-down plan developed by leadership was regularly communicated to staff in the event that California voters did not approve Proposition 14. Staff report that the transition plan was well communicated with clear timelines and staffing requirements.
- **Ability to complete high volumes of work despite attrition:** Over the course of FY2019–20, seven employees left the organization, as noted in the following table. Given the uncertainty related to the agency's future and in the interest of fiscal prudence, CIRM distributed work among remaining employees or contracted out tasks rather than replacing employees. Although these staff reductions were impactful to teams—particularly IT and Grants Management—all departures were voluntary and the remaining employees continued to complete significant additional work.

POSITION	UNIT IMPACTED	ACTION TAKEN
Executive Secretary	Office of the President	Work redirected to existing staff
Grants Management Specialist	General Counsel	Work redirected to existing staff
VP of Grants Management	General Counsel	Internal promotion
General Counsel	General Counsel	Internal promotion
IT Lead Architect	Administration	Work redirected to existing staff
Systems Engineer	Administration	Contracted services out
Procurement/Contract Officer	Finance	Work redirected to existing staff

- **Implementation of Electronic Funds Transfer (EFT):** In collaboration with the State Controller's Office, CIRM implemented a major process improvement initiative by implementing EFT for grant and loan payments. This cross-functional effort achieved significant efficiency benefits for CIRM. In addition, grantees now quickly receive payments directly in their accounts.
- **GMS flexibility and responsiveness:** The internal IT team consistently sends system updates and provides in-house support for the homegrown Grants Management System (GMS).
- **Transition to remote work:** Staff report that the transition to remote work as a result of Shelter-in-Place orders beginning March 2020 was seamless. Employees were able to continue working without technology or connectivity hurdles, and most processes were already automated prior to the pandemic.

IV. COMPLIANCE FINDINGS AND RECOMMENDATIONS

A. GRANTS APPLICATION AND REVIEW

1.	Finding	Of the 20 grant applications tested, two applications in the Grants Management System (GMS) included a "hasn't acted" status; however, these applications had been reviewed and scored by the Grants Working Group (GWG).
	Recommendation	The Grants Review Team, in collaboration with the IT Department, should consider improvements to the GMS to strengthen controls related to the review and scoring workflow and ensure that any review and scoring information is captured as part of the application status.

We tested documentation for the GWG and ICOC scores for 20 applications. Of the 20 applications tested, we identified two instances in which the status in GMS indicated the application had not been acted on (i.e., had a status of "hasn't acted") by the GWG; however, in both instances, the GWG had reviewed and scored the application.

The Grants Review Team, in collaboration with the IT Department, should consider implementing improvements to the GMS to strengthen controls related to the review and scoring workflow to ensure that any review and scoring information is captured as part of the application status.

B. GRANTS MANAGEMENT

2.	Finding	During testing of the grants management process, we identified three exceptions to the Grants Administration Policy Standard Operating Procedures (SOPs) in a sample of 20 grants in process, 23 new grants, and 20 closed grants.
	Recommendation	A. The Grants Management Team should reinforce the requirements of the Grants Administration Policy SOPs to ensure that all required information is documented and maintained to support grants received and managed by CIRM, including documentation to support changes or deviations from an executed agreement. B. Consider adding a requirement for a separate individual to review due dates in the GMS to ensure there were no data entry errors and to prevent late reports due to these errors.

As part of our testing, we selected 63 grants (20 grants in process, 23 new grants, and 20 closed grants) and tested select internal controls and compliance components of the grants management processes outlined in the Grants Administration Policy SOPs. We identified the following findings:

- For the 23 new grants we tested, we observed three instances related to two grants for which certain events did not adhere to internal controls and/or compliance requirements for 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
        - Evidence of Notice of Grant Award executive review and approval prior to NGA issuance
        - Evidence that payments issued by the State Controller's Office to grantees were monitored and reconciled by CIRM
        - Progress reports appropriately reviewed
        - Grant modifications and/or amendments appropriately reviewed and approved
    - For one grant tested, there was no evidence of the Grant Manager's review of the annual progress report.
    - For two grants, we found that there was no Progress Report or Financial Report submitted and that the due dates for these reports were incorrectly keyed into the GMS.

The Grants Management Team should reinforce the requirements of the Grants Administration Policy SOPs to ensure that all required information is documented and maintained to support grants received and managed by CIRM. In addition, consider adding a requirement for a separate individual to review due dates entered into the GMS to ensure there were no data entry errors and to prevent late reports due to these errors. Finally, any time a change or deviation from an executed agreement is made, such as those related to grant payments, adequate documentation should be maintained to support the change.

C. LOANS

No findings. Based on testing of the one loan in process in Fiscal Year 2019–2020, we did not identify any non-compliance with policy or internal controls.

D. CONTRACTS

No findings. Based on testing a sample of 35 contracts out of 181 total contracts in Fiscal Year 2019–20, we did not identify any non-compliance with policy or internal controls.

The rollout of the State's FI$Cal system has unified the procurement, payment, and budget systems. Now that CIRM is using FI$Cal, 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% of the payments initiated by CIRM through the FI$Cal system before payments are made to the payee or grantee.

E. INTELLECTUAL PROPERTY

3.	Finding	CIRM adopted regulations in 2018 outlining the technology disclosure requirements. While we found no exceptions, we noted that the ability for CIRM to monitor and determine compliance of the Grantees with the technology disclosure appeared challenging.
	Recommendation	Implement an IT control that allows for missing documentation or reports to be flagged and routed to the responsible CIRM team members.

Technology Disclosures

Based on testing nine technology disclosures of 84 total disclosures made in Fiscal Year 2019–20, there were no exceptions. However, there are opportunities to improve processes around technology disclosures for more efficient and effective compliance monitoring. CIRM personnel have a process for following up with Grantees to confirm the existence of technology disclosures; however, certain Grantees are not pro-active in voluntarily complying with CIRM regulations and do require such follow-up from CIRM. To enable more effective monitoring of technology disclosures, CIRM should implement an IT control that flags missing documentation and alerts responsible CIRM staff.

Invention Disclosures

No findings. Based on testing eight invention disclosures of 51 total disclosures made in Fiscal Year 2019–20, we did not identify any non-compliance with policy or internal controls.

CIRM's intellectual property (IP) regulations are designed to protect the IP developed using CIRM funding by requiring initial invention disclosures as well as 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 1. 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 sends email 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.

Publication Disclosures

No findings. Based on testing 17 publication disclosures made in FY 2019, we did not identify any non-compliance with policy or internal controls. In accordance with California Code of Regulations (CCR) Section 100603 – Publication Requirements, a Grantee must provide public access to any

publication of a CIRM-Funded Technology. For any manuscript that is peer-reviewed and accepted for publication in a scientific journal, the Grantee must ensure that an electronic version of the final peer-reviewed manuscript is submitted to PubMed Central or to CIRM to be made publicly available no later than 12 months after the official date of publication. The Grantee shall make reasonable efforts to comply with this requirement through submission to PubMed Central, including notifying CIRM of the PubMed Central identification number. If the Grantee is unable to submit the manuscript to PubMed Central, the Grantee may comply by providing the manuscript to CIRM no later than 12 months after the official date of publication.

V. EFFICIENCY AND EFFECTIVENESS FINDINGS AND RECOMMENDATIONS

A. GOVERNANCE

Governance Transition

4.	**Finding**	**CIRM is undergoing a significant governance transition. The terms of the Independent Citizens' Oversight Committee (ICOC) Chair, Vice Chair, and most long-term members are expiring in the next year, creating a potential loss of institutional knowledge.**
	Recommendation	**Conduct succession planning for ICOC leadership and key contributors, document knowledge of long-serving individuals, and continue to take steps to support ICOC leadership transition.**

During the audit period, the ICOC was comprised of 29 members from across California, including representatives from patient advocate groups, researchers, academia, and the biotechnology industry. Members are appointed by Constitutional Officers for the State of California and may serve a maximum of two eight-year terms. CIRM's two ICOC officers, the Chair and Vice Chair, have served in their roles on the ICOC since nearly CIRM's founding; their terms are set to expire simultaneously in 2022, along with several other long-term members of the ICOC who have served in key committee leadership roles for many years. In addition, eight patient advocates' terms expired in 2021. With the passage of Proposition 14, the ICOC is required to expand to 35 members.

The agency is taking steps to support the significant transition in ICOC membership. Internally, staff is beginning to plan for the Chair and Vice Chair appointment process and develop timelines for the appointments. To support knowledge transfer and develop future leadership, CIRM has streamlined and restructured ICOC subcommittees, appointing experienced chairs and newer vice-chairs. In addition, the Governance Subcommittee is in the process of updating the ICOC's bylaws to support more effective governance. CIRM has dedicated staff resources to support the ICOC, including the Vice President of Public Outreach and Board Governance, who directly supports ICOC members and committees.

With respect to the Chair and Vice Chair roles, CIRM has benefitted from long-term governance stability, but as a result, the agency lacks experience transitioning ICOC leadership. CIRM should develop succession plans and intentionally transition knowledge and stakeholder relationships to staff and other members of the ICOC to support governance and, in some key areas like government relations, to ensure operational continuity. This will support the current leadership transition as well as mitigate risk in the case of an unplanned transition. Succession planning should include documenting key knowledge, defining roles and responsibilities, ensuring job descriptions are up to date, and identifying potential ICOC members and staff to whom the Chair and Vice Chair can work with to ensure institutional knowledge is not lost. CIRM's Chair and Vice Chair are working officers who provide leadership in key areas, including government relations and fundraising, which CIRM staff do not currently provide.

CIRM leadership is currently deliberating whether the vacated Chair and Vice Chair positions should be filled by existing or newly appointed members of the ICOC. The table below summarizes the relative benefits of each potential choice.

	PROS	CONS
Internal Candidates	• Institutional knowledge is kept within the organization • Decreased time to hire and onboard new positions • Could potentially strengthen Board engagement and relationships	• Potential for more frequent turnover in Chair or Vice Chair role when existing members' terms expire
External Candidates	• New, outside perspective • Broader, potentially more diverse pool of applicants	• Less familiarity with CIRM operations

The Governance Committee will begin the nomination process in March 2022. Regardless of whether the Chair and Vice Chair positions are filled by internal or external candidates, actions to support leadership transition should continue on the part of both ICOC members and staff to ensure a successful organizational change. While the Chair and Vice Chair are ultimately appointed by CIRM's constitutional officers, CIRM should deliberately plan for ICOC leadership succession.

Succession planning is best practice in the event of planned and unplanned vacancies. As part of the nomination process, CIRM and the ICOC Governance Committee will reevaluate the Chair and Vice Chair responsibilities and should consider whether some duties, such as government relations and fundraising, should continue to be performed by ICOC members or if they would be best performed by staff. Meanwhile, the Chair and Vice Chair should actively seek to introduce newer ICOC members and appropriate staff to key stakeholders to ensure the agency does not weaken valuable relationships.

Board Engagement

5.	**Finding**	**CIRM staff and ICOC members report a high level of engagement among ICOC members currently. However, as a large statewide governing board, there are inherent challenges in effective and consistent member engagement, particularly during organizational transition.**
	Recommendation	**Take steps to proactively engage more ICOC Board Members in decision-making and policy development activities.**

The ICOC is a large statewide governing board, with 29 members located across California; under the newly approved Proposition 14, the ICOC will be expanded to 35 members. 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. Although CIRM leverages ICOC expertise through standing and

ad-hoc committees—which is best practice—some members serve on multiple committees while others serve on none.

Despite these challenges, the Board was very engaged during this last fiscal year because of the potential wind-down plans and the COVID pandemic. ICOC members reported feeling a strong sense of engagement currently and a desire to leverage this engagement more effectively, especially with members representing academic institutions who are unable to vote on grants. It is important to keep the ICOC fully engaged in critical decisions and leverage the full potential of Board Members.

As the ICOC transitions many long-serving Board Members and onboards new members, it is particularly important to retain current, high levels of engagement and strengthen the Board's culture. CIRM has acknowledged the need to support a larger ICOC with more dedicated staff capacity, which should enable the agency to support a more engaged and active Board. Board Members have governance and fiduciary responsibility for the agency, and also bear leadership responsibility for CIRM's culture, strategic outcomes, and effectiveness; as well as a duty to serve as ambassadors and advocates for CIRM and its mission.

The Governance Subcommittee, with support from CIRM staff, should conduct an annual self-assessment 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 collaborate with staff to identify 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. To increase Board engagement, CIRM should identify specific opportunities with target dates, resource needs, and time commitments, and provide it to the ICOC on a semi-annual basis. To enable more effective statewide participation post-pandemic, CIRM should consider strategies to support effective hybrid meetings allowing for both virtual and in-person attendance.

B. PROCESSES

Grantee Publication Monitoring and Enforcement

6.	**Finding**	**CIRM does not have an effective policy or proactive process for monitoring and enforcing awardee publication disclosures.**
	Recommendation	**A. Develop a policy to consistently monitor and enforce compliance with publication disclosure requirements.** **B. Consider options, such as implementing a Customer Relationship Management (CRM) system, to support automated proactive monitoring of awardee publication and press releases.**

As CIRM awardees advance and complete scientific research, the following disclosures are required to be made per the NGA and contract:

- Disclosure of scientific publication to CIRM
- Disclosure of CIRM funding in white papers or other published research articles
- Disclosure of CIRM funding to media for press releases

Compliance with publication disclosure requirements is monitored by the Grants Manager and Science Officer per the periodic reporting requirements and at the close-out phase of the grant. For example, awardees must indicate on the latest Progress Report if a publication was made, and are sent reminders to report disclosures annually. Despite these initiatives, some awardees may still not comply, or third parties (like a newspaper) may not disclose that research was CIRM-funded even at the direction of an awardee. In order to demonstrate how CIRM funding has been used in relevant current research, it is imperative that all associated research publications appropriately disclose the organization's financial contributions.

CIRM staff report challenges in efficiently and effectively monitoring awardee disclosures of CIRM-funded research, as well as understanding the appropriate consequences of non-compliance. Although the SOP outlines publication disclosure responsibilities, effective processes for monitoring and enforcement are missing. Staff report that most monitoring efforts are completed on an ad-hoc basis, either through a scan of relevant research regularly completed by employees or Google alerts. When CIRM-funded research publications or press releases do not mention CIRM, the appropriate Science Officer sends an email to the grantee reminding them of these requirements and may request a correction be made to the publication. However, there is not a defined approach to enforcement or potential consequences for non-compliance.

As CIRM continues to fund new and innovative research across several key disease areas, it is imperative that the organization's reputation is upheld and awardees acknowledge the agency as a funding source. Therefore, CIRM should revise its policies to explicitly define publication disclosure monitoring and enforcement activities and expectations, including progressive consequences for contract violations. As this policy is developed and implemented, it will be important to reinforce the notification language to all applicable awardees to ensure this language is being communicated properly and consistently.

Additionally, CIRM should explore automated options to support systematized publication and press release monitoring. For example, a Customer Relationship Management (CRM) system could be leveraged to pull and send relevant articles from media outlets to the assigned Science Officer to support proactive publication monitoring. See Recommendation #12 for more information on the potential benefits of a CRM system.

Scientific Advisors Diversity

7.	**Finding**	**CIRM has historically relied on scientific experts and partners with a connection to the organization for grant review. As a public agency with the mission of cures for all, it is important for CIRM to diligently seek diverse perspectives and expertise and ensure the perception of independence in application review.**
	Recommendation	**Continue to implement recently adopted practices to actively seek more diverse members of the California scientific community to review and recommend grants, and monitor and evaluate the Grants Working Group (GWG) to promote a diversity of perspectives, backgrounds, and expertise.**

CIRM maintains a pool of approximately 250 scientific members to review grants through its Grants Working Group (GWG). GWG members are appointed by the ICOC for a six-year term and may be reappointed for a second two-, four-, or six-year term under Proposition 71. Appointments of GWG members have historically been based on filling knowledge gaps and ensuring an adequate number of experts are on hand to address the volume of applications received by CIRM. Each GWG panel must be comprised of seven patient advocate members from the ICOC, the Chair of the ICOC (ex-officio), and 15 scientific members with varied perspectives and relevant expertise for each review. Depending on the nature of the application, panelists with specific subject matter expertise in a particular disease area or technology may be recruited for a review.

Maintaining a large pool of qualified potential GWG members with varied backgrounds, perspectives, industry knowledge, and expertise can be challenging due to the time commitment involved in participation and limited availability of individuals with specialized expertise. Although interest in the work may be high, scientific advisors sometimes struggle with the time commitment required to participate in grant reviews and GWG panel meetings due to other obligations. Additionally, the availability of scientific members with specific knowledge in the grants awarded is often limited due to the innovative nature of many applications. However, as a public agency with the mission of cures for all, it is important for CIRM to diligently seek diverse perspectives and expertise and ensure the perception of independence in application review.

CIRM previously recruited scientific experts primarily from its network (including institutions conducting research, medical professionals, industry resources, and patient advocates), but recently developed a recruitment process to identify and evaluate members with the goal of increasing the diversity of the member pool. Key elements of this plan include outreach and partnerships with other key stakeholders, such as the National Academy of Science and National Institute of Health, to identify experts that may not be familiar with CIRM and willing to participate in grant review. In order to promote diversity among this group, CIRM started evaluating factors such as increasing the number of women and racial/ethnic minorities, seeking representation from both veteran and newer investigators, and targeting specific areas of expertise such as manufacturing, data science, and regulatory. CIRM plans to track progress on each of these areas by surveying GWG members to understand the evolving diversity of the group and identifying additional targeted recruitment efforts that may be warranted over time.

CIRM should continue the process of evaluating the composition of GWG, creating clear policies and procedures for members, and focusing on increasing diversity, equity, and inclusion throughout its operations.

C. DATA AND SYSTEMS

Records Retention

8.	**Finding**	**CIRM's Records Retention Schedule with the State of California expired in 2018. Staff continue to report confusion related to records retention requirements, which can negatively impact the organization's ability to respond to information requests.**
	Recommendation	**CIRM should update its Records Retention Schedule, establish policies and procedures for records management, and consider developing**

annual trainings to support a consistent understanding of records requirements.

As a state agency, it is imperative that CIRM adhere to records retention requirements to support transparency of its operations. The ability to quickly and reliably provide requested information, particularly historical information, is key to ongoing support for the organization, confidence in its operations, and demonstrated accountability to California voters. It is best practice to have a clear records retention schedule, regular training on records management, and a system that can be leveraged to store information for the appropriate periods of time.

CIRM's Records Retention Schedule was developed in 2013 and according to the State Records Management Manual, record retention schedules expire every five years. Therefore, the agency's recent Records Management Schedule expired at the end of 2018. Due to the uncertain nature of CIRM in FY2019–2020, the Schedule was not updated. In interviews, CIRM staff reported uncertainty related to retention and archiving requirements for different types of records. Historically, records retention was primarily managed through the document management system, Alfresco; however, this system was not consistently utilized by all teams and was discontinued during the audit period (see Recommendation #10).

Since Proposition 14 was approved by California voters, CIRM will need to update and submit a new Records Retention Schedule to the State in order to support compliance with this requirement. Additionally, the State Administrative Manual (SAM) Section 1612 requires State entities to inventory their records once every five years. This practice is to ensure better understanding of what records are generated and utilized and where these documents are stored. This records inventory is also past due and should be completed as CIRM updates its Records Retention Schedule and implements a refreshed document management system.

To ensure proper records management, CIRM should assign responsibility to a leader within the organization to review the state Records Management Implementation Checklist from the Records Management Manual, which describes best practices in implementing and monitoring a records retention schedule[1]. Some of these best practices include:

- Define roles and responsibilities around records management and the responsibilities of each employee
- Develop standard file nomenclature to ensure files are organized consistently and records can be easily located
- Consider notating which files must be communicated to the State per the retention schedule
- Periodically monitor records to ensure proper retention deadlines and archive notifications are compliant

These best practices should be incorporated in CIRM's records management policy guidance. Additionally, to reduce confusion among staff and ensure that the appropriate records are appropriately accounted for and stored, CIRM should consider developing annual trainings on records

[1] https://archives.cdn.sos.ca.gov/calrim/handbook/2018-12-records-management-manual.pdf

management. Ultimately, CIRM's ability to satisfy public records requirements and fulfill incoming requests is reliant on a consistent understanding and adoption of records management policies.

System Adoption

9.	Finding	**The use of three document management systems continued to present confusion to CIRM employees, resulting in inconsistent user adoption and records management practices.**
	Recommendation	**When implementing a new document management system, develop an adoption strategy that includes ample communication, policy and procedure guidance, and accountability practices to support consistent expectations and system utilization.**

At the onset of the audit period, CIRM used three primary document management systems: the GMS, Dropbox, and Alfresco. In the 2016–17 Performance Audit, we noted that staff reported confusion regarding the discrete role of each system and therefore it was likely that each system was not optimally utilized. One of these systems, Alfresco, was discontinued during the wind-down phase due to ongoing costs associated with the system and the uncertainty of the organization's future prior to the 2020 election. All documents housed in Alfresco were extracted and uploaded to Dropbox, which is typically used for active work across the organization. If used appropriately, Alfresco required users to categorize the type of information stored and would automatically apply State records requirements to the artifact. While Dropbox served the organization cost-effectively in the short-term, CIRM's renewed funding and purpose require a robust document management system to support records management (see Recommendation #9).

Currently, CIRM leadership is in the process of defining business requirements and selecting a document management solution. Given the historical challenges related to document management system use, clarity of requirements, and inconsistent accountability practices, change management will be critical for full adoption to the new system. As part of this change management, staff need to understand when to use each system, what information is stored where, and leadership expectations related to accountability. A key challenge with any technological change is managing how people adopt and use the system. Without staff buy-in, commitment, mitigated resistance, elimination of fear, and consistent adoption across the organization, CIRM may not realize the full benefit of the new system.

To improve rollout of new systems and processes, CIRM should develop an adoption strategy and process to support consistent implementation across the organization. The following are key elements for implementing successful change management:

- **Commit to and communicate the need for change:** Excellent communication is critical to change management and implementation of new systems. Leaders across the organization should support the appropriate use of the new system through both their words and actions.
- **Plan for and understand the ramifications of the change:** Change should occur in a multi-step, well-communicated process that includes ample training. Key communication messages should be developed and disseminated to ensure staff are aware of progress toward

implementation and reminded of benefits they can expect to derive from the new system and process.

- **Consider and design a method for staff education:** Throughout system implementation, build staff knowledge and abilities through training opportunities. Following implementation, provide reinforcement and allow employees to provide feedback on the system and their user experience. Ensure consistency by providing policies, procedures, and performance measures that reflect the change and can serve as staff resources.
- **Define accountability:** Leaders should explain the importance of effectively leveraging the system and coach employees on appropriate usage. Over time, employees and leaders should be held accountable to using the correct system.

Through ample communication, policy and procedure guidance, and accountability practices, CIRM can support improved adoption of a new document management system.

GMS System Utilization

10.	Finding	**CIRM has made significant improvement 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, centralize data, and enhance access.**

CIRM continues to update the GMS system as new challenges are presented or additional functions are needed. During FY2019–20, few modifications to the GMS were made since the focus of the organization shifted to either winding down or ramping up with a new suite of research areas. While most staff members report GMS is working appropriately and is relatively user-friendly, there are additional capabilities the system could offer to improve functionality, efficiency, and effectiveness. Some of these examples include:

- **Consistent documentation within the system:** During system walkthroughs, we noted that some staff members document more information in GMS than others. This inconsistency in documentation can perpetuate confusion regarding where information related to grants is located, and creates an incomplete picture of a grant in the system.
- **Data warehousing:** In addition, some data that comes into the organization is not currently included in GMS. For example, some clinical trial data currently comes in on spreadsheets but is not entered or stored in GMS. Incorporating this data into the system would increase accessibility to the data and maintain data as people come and go from the organization.
- **Pre-Applications:** Another useful additional capability for GMS is incorporating pre-applications. Currently, some pre-applications are still done on paper, not in GMS. Incorporating an online form for pre-applications would reduce the amount of paper used and would improve the process with the use of searchable forms' ability to better track data.

As more time and resources are available after the passage of Proposition 14, IT should continue to research and develop new system enhancement opportunities to improve the system's operational effectiveness and efficiency.

Data Collection and Knowledge Management

11.		
	Finding	**CIRM hosts a significant amount of scientific and business data but lacks a strategy or system to integrate information in an optimal way.**
	Recommendation	**Consider implementing an integrated database and Customer Relationship Management (CRM) system to collect and better analyze scientific and business data in support of CIRM's mission.**

CIRM houses a variety of scientific and business-related data from grantees but has not yet developed a strategy to house or leverage that data to support its operations. Staff report that data is not collected or stored in a consistent place and there is often a disconnect between some of the business relationships and grantee relationships. For example, one employee at CIRM may have recruited a grantee to apply as a result of promising research, while another is supporting the grantee in establishing industry relationships to manufacture testing products. However, these interactions are not consistently tracked over the lifecycle of CIRM's relationship with the grantee.

While most grantee information is kept in GMS or by grants management staff, business development information is largely managed on spreadsheets or maintained through individual relationships. Therefore, knowledge and communications on activities like industry research are not always documented, or not documented in a central location that all CIRM employees can access or draw upon to support achievement of the organization's mission. In addition, staff noted that reports can be lost or shared with only a select group of people and thus are sometimes recreated year after year. Although CIRM leadership noted a need for improved data storage and management, administrative resources in FY 2019–20 were very limited and therefore the team opted to delay the creation or incorporation of an integrated system until after the 2020 election.

As CIRM expands under Proposition 14, it should consider establishing a Customer Relationship Management (CRM) system that can help track industry interactions, partner interactions, communications with grantees, and industry knowledge from different departments to help build relationships and expand CIRM's reach. Publicly available information as well as institutional knowledge of grants and grantees can be integrated with industry knowledge to better equip grant managers in supporting and maintaining relationships with grantees. A CRM system could also be leveraged by grant managers to proactively monitor publication disclosures (see Recommendation #10). Overall, a CRM system would assist Business Development and the Therapeutics and Strategic Infrastructure team in recruiting efforts as there is sometime overlap in the grantees or business partners recruited.

Additionally, CIRM should consider integrating scientific data from grantees in its Grants Management System (GMS) if feasible. This could be an opportunity for CIRM to proactively leverage available information to help support research and innovative ideas in pursuit of its mission.

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 2019–2020 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
- 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 approaches for each function and project deliverable 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.
- Conflicts of interest are considered for all reviewers, Independent Citizens' Oversight Committee (ICOC) members, and CIRM staff.

During fieldwork, we interviewed several Science Officers for Review and the Project Manager for Review and performed walkthroughs of several Requests for Applications (RFAs), applications, GWG Reviews, and ICOC Reviews. Interviews and walkthroughs ensured we understood the workflow processes of the entire application, review, and approval processes, as well as the key controls employed at each stage to ensure adherence to the aforementioned guidance. Walkthroughs were also utilized to establish the reliability of procedures by observing processes, as well as discussing the procedures with key personnel.

Key controls were identified during the walkthrough process and tested using a sample of the 20 applications received during Fiscal Year 2019–2020. Key controls that were anticipated to be tested using samples are as follows:

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

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

- RFA was issued by CIRM.
- Pre-application and/or application was submitted by the applicant.
- Reviewers disclosed financial interests to CIRM by completing confidential disclosure forms.
- 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 grant 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, best practices, and/or the 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. 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 fieldwork, we interviewed the Director of Grants Management and Operations, the Associate Director of Grants Management, Finance Team members, and Grants Management Specialists, as well as some Science Officers. We performed walkthroughs of the processes related to review and approval of pre-funding administrative checklists, Notices of Awards (NOA), 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 were identified during the walkthrough process and tested using a sample of the 32 new grants, 543 grants in progress, and 221 grants closed out during Fiscal Year 2019–2020. 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 Notice of Award (NOA) was reviewed and approved, when applicable, by Legal, Finance, and a Scientific Executive, and the Scientific Executive signed the NOA.
- Payments issued by the State Controller's Office to grantees were reconciled to the NOA and payment request by CIRM staff.
- Progress reports were reviewed by Grants Management and Scientific Officers and follow-up was initiated, if required.
- Grant modifications were approved by Grants Management and applicable Science Officer.
- Final reports were reviewed by Grants Management and the appropriate Science Officer. The Grant Close-Out Checklist was completed.

In addition to testing key internal controls, we tested compliance with the grant 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 NOAs and compliance requirements for awards to each grantee.
- CIRM prepared an electronic funds transfer claim schedule request for each grantee and sent it to the State Controller’s Office for payment. The amount of the warrant issued to the grantee matched the amount and terms of the NOA.
- 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 fieldwork, 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 grant 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, 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 the audit plan for loans were similar to those for grants management. 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 borrowers' ability to repay the loan
- CIRM obtained, and appropriate personnel reviewed, information required to determine borrowers' compliance with the loan agreement

During the audit period, one grant was converted to a loan and the loan was repaid. Key controls that were tested are as follows:

- Documentation was sent to CIRM exercising the option to convert to a loan
- The entire loan payment was calculated correctly and repaid in full

In addition to testing key internal controls, we tested compliance with the loan management process. Compliance requirements that were tested include:

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

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 criteria, such as best practices.

D. INTELLECTUAL PROPERTY

We reviewed the intellectual property (IP) process as guided by CIRM's grants administration policy, intellectual property and revenue sharing requirements, and internally documented policies and procedures. Key audit objectives included evaluating whether:

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

During fieldwork, we interviewed the Associate General Counsel, Grants Management Officer, and Deputy Grants Management Officer. We performed walkthroughs of the processes related to IP regulations, including examples of follow-up communications with grantees, subsequent process changes to the IP process, and plan for IP process improvement. Interviews and walkthroughs confirmed that we understood workflow processes for IP, as well as the key controls employed to establish adherence to aforementioned guidance. Based on the interviews and walkthroughs, we documented the processes employed by CIRM, as well as the key internal controls utilized to verify compliance with IP policies.

IP processes were tested for adherence to compliance requirements using sampling as follows:

- Evaluated a sample from the 51 Invention Disclosure Forms that were received during FY 2019–2020. These forms identify the grant, the inventor(s), and principal investigator. We evaluated whether any of the grants triggered the IP policy revenue sharing requirement by examining the following:
    - Documentation of sufficient technical detail to convey the disclosure, nature, purpose, and operation, and physical, chemical, or electrical characteristics; if the invention has been submitted for publication or presentation, documentation of publication and date of abstract or manuscript
    - Documentation that the 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 153 Publication Disclosure Forms that were filed for CIRM-funded projects during FY 2019–2020 to determine conformance with the invention and licensing reporting requirements (CCR Section 1000602), which specify that the following information must be captured:
    - Identification of the publication, including abstract and statement of the IP'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 20 Invention Utilization Reports that were submitted to CIRM during FY 2019–2020, as specified under the invention and licensing reporting requirements (CCR 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, whether revenue was received during the 12-month period prior or subsequent to the last report that was filed
    - For CIRM-funded inventions (seven during the audit period) that triggered licensing activities, whether the following information was captured: initiation of clinical testing, initiation of pivotal studies, and application for marketing approval

Due to COVID-19, our audit was conducted remotely. Samples were selected 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 procurement policies contained in California Public Contract Code Chapter 2.1 – University of California Competitive Bidding, University of California Business and Finance Bulletin 34, and CIRM's Policy on Contracting and Services of Independent Consultants. The University of California competitive bidding requirements were reviewed, since Proposition 71 stipulates that CIRM shall be governed by these requirements.

Key audit objectives included evaluating whether:

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

During fieldwork we interviewed the Interim Contracts Administrator and various Finance Office staff 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 181 contracts issued during Fiscal Year 2019–2020. 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 Governing Board. The report included a statement indicating compliance with the provisions of CIRM's policy and listed all agreements and amendments executed in the reporting period that were for amounts above $20,000. These reports were reviewed by the Subcommittee/Board.

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 the reason why competitive proposals were not submitted.
- Prior to preparation of Request for Proposals, the requestor at CIRM submitted a written presentation for the need for an independent consultant to the Responsible Administrative Official.
- Proposals for independent consultants were obtained in writing in accordance with CIRM's thresholds for solicitations.
- Selection of independent consultants 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 agreements using the standard CIRM Independent Consultant Agreement form.
- Contractors 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 independent consultants were in accordance with the signed agreement.
- The Responsible Administrative Official submitted a report on procurement transactions to the Governance Subcommittee two times per year and submitted an annual report to the Governing Board.

Samples were selected prior to fieldwork, 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.

Conclusion: Based on the testing performed, no items rise to the level of a finding in the report. Our testing did not identify any non-compliance with policy and/or internal control significant deficiencies or material weaknesses.

F. SUPPORTING FUNCTIONS

Since CIRM was established in early 2005, and it had a limited timeframe within which to utilize bond proceeds to award grants and loans, it faced the unique challenges of an organization that had to deal with both business ramp-up and ramp-down/transition in a relatively short time period. During the performance audit year, CIRM was preparing to wind down operations with the potential for renewal, which is a very unique position. Since the passage of Proposition 14 in November 2020, CIRM faces newly unique challenges of scaling up, expanding the ICOC, filling the term-limited seats of long-term ICOC members, and expanding the agency's mission. CIRM's Board and leadership are currently beginning a strategic planning process to identify the strategies and actions necessary to implement the goals and requirements identified in Proposition 14.

This facet of the performance audit provided insights regarding how CIRM can more efficiently and effectively manage and operate. Functions of the organization that were addressed include, but are not limited to, administrative support, communications, executive leadership, finance, human resources, legal, office management, and planning.

Key audit objectives included:

- Assess whether CIRM efficiently utilized its resources (i.e., minimized time and effort) to conduct its business during the audit period.
- Assess whether CIRM effectively utilized its resources (i.e., maximize achievement of intended purpose) to conduct its business during the audit period.

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 the assessment included, but were not limited to:

- 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
- Governance

Efficiency and effectiveness were 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 small group interviews were conducted:

FUNCTION	POSITIONS
ICOC	Chair, Vice Chair, and selected other members
Executive Team	All members
Grants Management	Director of Grants Management, Deputy Grants Management Officer, Grants Management Specialists
Finance, Administration, & Legal	Finance Officer, Senior Director of Communications, Associate General Counsel, Interim 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.

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. Alternatives ranged from minimal action to wholesale 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. Alternative solutions were presented with considerations for CIRM's upcoming strategic planning process.

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 verify facts and test the practicality of our recommendations.

We have also determine the extent to which CIRM has responded to the outstanding recommendations in FY 2010–2011, FY 2013–14, and FY 2016–17 Performance Audits (see Appendix C).

APPENDIX C: PROGRESS TOWARD PERFORMANCE AUDIT RECOMMENDATIONS

A. FISCAL YEAR 2016–2017 PERFORMANCE AUDIT RECOMMENDATIONS

RECOMMENDATION	STATUS	VALIDATION	BASIS OF VALIDATION
1. Increase controls to ensure that any scoring changes are accurately reflected in the Grants Management System (GMS) database.	Scoring controls improved	Complete	SOPs and detailed grants compliance testing
2. Implement procedures to ensure adherence to the grants management standard operating procedures and completion of the grant closeout checklist.	Ongoing improvement of the GMS, review and management processes	In progress	Interview and detailed grant compliance testing
3. 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.	Development funds secured	Complete	Interviews and Board meeting minutes
4. Develop communications and public education metrics that are integrated into CIRM's quarterly reporting.	Communications and public education metrics developed and incorporated into quarterly reporting	Complete	Interviews, performance metrics, quarterly performance reports
5. Continue to revise job descriptions to ensure alignment with current duties, roles, and authorities.	Continued revising of job descriptions	Complete	Interviews and updated job descriptions
6. 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.	Continued communication of transition plans to staff	Complete	Interviews, transition plan, and cross-training efforts
7. 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.	Streamlined subcommittees and changed subcommittee leadership roles	In progress	Interviews and Board and committee meeting minutes

RECOMMENDATION	STATUS	VALIDATION	BASIS OF VALIDATION
8. Proactively engage more Board members in decision-making and policy development activities.	High levels of Board engagement to support COVID-19 related research	Complete	Interviews and Board meeting minutes
9. Continue to identify and pursue opportunities to enhance GMS capabilities to automate processes, reduce paperwork, and enhance information access.	Continued assessment of GMS functionality	In progress	Interviews, walkthroughs, and SOPs
10. 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.	Ongoing evaluation of IT systems to support operations	In progress	Interviews, transition plan, system functionality

B. 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's use in recording 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

RECOMMENDATION	STATUS	VALIDATION	BASIS OF VALIDATION
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
9. Ensure performance evaluations 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 of 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 assessment and pursuit of 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 C below

C. FISCAL YEAR 2010–2011 PERFORMANCE AUDIT RECOMMENDATIONS

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
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 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

RECOMMENDATIONS	2013–2014 VALIDATION	2016–2017 STATUS	2016–2017 VALIDATION	2016–2017 BASIS OF VALIDATION
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 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
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

RECOMMENDATIONS	2013–2014 VALIDATION	2016–2017 STATUS	2016–2017 VALIDATION	2016–2017 BASIS OF VALIDATION
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 in the process and, if so, there is a logical reason for the redundancy.	Completed	N/A	N/A	N/A

APPENDIX D: MANAGEMENT RESPONSE

After a competitive RFP process, Moss Adams was chosen to conduct the CIRM performance audit for the FY 19/20. CIRM would like to thank Moss Adams for their hard work and feedback. Moss Adams acknowledged the challenges CIRM faced during the 2019/2020 audit year: a global pandemic and an uncertain funding future. Despite the challenges, CIRM was at peak performance. CIRM's systems were in place to allow for remote work and the CIRM team remained dedicated to the organization. CIRM will consider Moss Adam's recommendations to improve CIRM's operational efficiencies, many of which had already been identified and are currently underway.

We will report back to the board in January with our plan and will continue to update the board as we progress.


MOSSADAMS