

December 30, 2019

Keely Martin Bosler, Director
California Department of Finance
915 L Street
Sacramento, CA 95814

Dear Ms. Keely Martin Bosler,

In accordance with the State Leadership Accountability Act (Leadership Accountability), the California Institute for Regenerative Medicine submits this report on the review of our internal control and monitoring systems for the biennial period ending December 31, 2019.

Should you have any questions please contact Benjamin Huang, Associate General Counsel, at (510) 340-9138, Bhuang@cirm.ca.gov.

GOVERNANCE

Mission and Strategic Plan

In 2004, California voters approved Proposition 71, the California Stem Cell Research and Cures Initiative. The statewide ballot measure authorized issuance of \$3 billion in general obligation bonds to finance funding for stem cell and regenerative medicine research including dedicated research facilities at California universities and research institutions. Proposition 71 created CIRM as a new state agency to administer the funding. CIRM is a small agency now staffed by approximately 35 FTEs. In authorizing these funds, Californians expected to speed the delivery of stem cell treatments and cures to patients with unmet medical needs, including a priority for funding pluripotent and progenitor cell research that was not receiving timely or sufficient federal funding. Additional potential benefits to Californians include propelling California into a leadership position in regenerative medicine, establishing California as the premier international location to advance stem cell medicine, stimulating the economy, reducing health care costs by replacing chronic treatments with cures, and ensuring that the State has the opportunity to benefit from revenue-sharing originating from CIRM-funded treatments or technologies. CIRM is governed by the Independent Citizens' Oversight Committee (ICOC), a 29-member Board appointed by various state officials according to criteria specified in Proposition 71.

ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups, and the biotechnology industry. In addition to its fiduciary responsibility to the people of California, the Board is charged with: (1) adopting scientific, medical, ethical and intellectual property policies; (2) making final funding decisions on grant and loan awards; and (3) providing oversight of CIRM.

The mission of CIRM is to accelerate stem cell treatments to patients with unmet medical needs. CIRM does so pursuant to the highest ethical and medical standards, and seeks to discover and develop cures, therapies, diagnostics, and research technologies to relieve human suffering from chronic disease and injury. To date, CIRM has approved grants and loans totaling approximately \$2.7 billion. Of that amount, approximately \$2.4 billion has been disbursed to grantees as of the date of this report.

If CIRM is not renewed by a ballot measure next year in 2020, it will enter wind-down mode. There is a workplan in the event of a wind-down so that the remaining grants will receive disbursements through 2023. If CIRM is renewed by a ballot measure, it will need to generate a new strategic plan to reflect the requirements of the new Proposition.

Control Environment

CIRM establishes standards of conduct, by setting the tone at the top: The ICOC Board, the President and CEO, and management at all levels of the organization demonstrate through their directives, actions, and behavior, the importance of integrity and ethical values to support the functioning of the system of internal control; in CIRM's case, the mission to accelerate stem cell treatments to patients with unmet medical needs. These expectations are defined within the CIRM Employee Handbook under Conflict of Interest Policy, Incompatible Activities Statement, and Conflict of Interest Code, and are understood at all levels, including outsourced service providers and business partners. The Ethics class is taken every two years. Evaluations assessing performance, behavior, and integrity and ethical values, occur every 12 months or as needed should a deviation occur. If this is determined to be the case, the deviations are identified and remedied in a timely and consistent manner.

As noted earlier, CIRM is governed by the Independent Citizens' Oversight Committee (ICOC), a 29-member Board appointed by various state officials according to criteria specified in Proposition 71.

ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups, and the biotechnology industry. In addition to its fiduciary responsibility to the people of California, the Board is charged with: (1) adopting scientific, medical, ethical and intellectual property policies; (2) making final funding decisions on grant and loan awards; and (3) providing oversight of CIRM.

Through public ICOC meetings, the CIRM executive team assists the governing Board in performing its control function by updating it on the performance of individual units in the overall achievement of the strategic goals and efforts to mitigate any challenges identified.

CIRM is divided into a number of functional teams, those that relate to the grant functions and separate teams related to agency function. For the grant functions, CIRM has a Review team, which handles incoming applications and the review process, a Grants Management team, which handles the disbursement of funds and tracking the milestones and progress of the Grants in CIRM's Grants Management System, a Therapeutics team, which consists of Science Officers with PhDs who establish the milestones and budgeting of clinical grants as well as serve as primary contact with the Principal Investigators, and finally a Translational Team, which consists of Science Officers who do the same for translational grants. For the functioning of the agency, CIRM has a Finance team, HR, Legal, IT, Communications and administrative staff. These teams (or combination of teams) have team leaders who serve on the leadership team with the CIRM President & CEO.

The CIRM Grants Management System (GMS) is the control system for managing all grant related documentation, such as applications, reviews, grant reporting, intellectual property, licensing etc.

Employees have access only to those portions of the GMS related to their duties. All documentation about the GMS is maintained on an internally accessible Redmine Wiki. Git is used for source code control.

As part of the employee control system, CIRM has implemented and documented the ongoing monitoring processes as outlined in the monitoring requirements of California Government Code

sections 13400-13407. These processes include reviews, evaluations, training, and improvements to CIRM's systems of controls and monitoring.

In establishing a competent workforce, CIRM's hiring practice is extensive and targeted. Job descriptions are specific to duties and necessary skill set. Leadership team members and functional team members are included in the interview process, with final sign off from the President & CEO. Once a hire is made, the onboarding process includes meetings with all departments within the organization with a special emphasis on those with which the individual will most work. In addition there is often the opportunity to cross train with other relevant job functions if there is a desire. In addition to internal knowledge gathering, CIRM also provides the opportunity to take classes and get training outside the organization to improve internal job performance, including science specific classes (e.g., regulatory processes), leadership classes, management training, and program management.

CIRM has committed to increase administrative controls which include: Well developed onboarding processes; management approved procedural manual (Employee Handbook) for all staff; cross-training of staff; opportunities for training classes; ongoing Leadership mentoring and training and; Analyst Certification Program, offered by the California Department of Human Resources, and other offered training courses. Staff are offered flexible work schedules. Teamwork strategies and promotional opportunities to create long-term incentives for retention and skills development are ongoing. When possible, CIRM creates hiring incentives for new staff in order to draw more qualified applicants for posted positions. The Employee Assistance Program is available to all staff and staff are aware of this assistance

Information and Communication

As a funding agency for life sciences grants, CIRM and its Applicant/Grantees communicate and record documentation via a customized Grants Management System portal. This software system serves as a repository of all the reporting requirements on the part of Applicants and Grantees as well as allowing CIRM to update with the Grantees via automated reminders. During the application phase, the applications are vetted by out-of-state peer reviewers with expertise in the science and methodology of the applicants. During the Grantee phase, the Grantees are assigned CIRM Science Officers, all with PhDs, with the knowledge base to interact deeply with the Grantee at that particular stage of scientific/ Drug development. Any research which gets published via a CIRM-funded grant has to be credited to CIRM and such publication citations are provided to CIRM for CIRM's records. In addition, CIRM has a public website and a dedicated communications staff keeping the website up to date. The website provides the public with information regarding the grants and grantees, the dates of CIRM public meetings and the transcripts of those meetings. Part of the website also serves an education aspect as various talks with scientific experts on various disease topics are sponsored by CIRM.

As a small state agency with 35 FTE situated in an open office space environment, CIRM has a fairly informal communication process among individuals in the agency where individuals can easily walk up to discuss items with other individuals in the agency with various conference rooms for private calls and team conferences. In addition, the various teams in CIRM are all represented by team leaders who participate in a biweekly senior management team meeting with the CIRM President which has interactive elements for team leaders to provide updates on progress and issues within their teams. Team leaders have an open door policy with their team members. CIRM encourages all members of the CIRM team to communicate to the rest of the team if they identify an opportunity that should be

considered to better assist CIRM with fulfilling its mission and goals.

A major stakeholder is the Independent Citizens' Oversight Committee, CIRM's governing Board. Through its monthly telephonic and quarterly in person governing Board meetings, the CIRM executive team updates the governing Board on the performance of individual units in the overall achievement of the strategic goals and efforts to mitigate challenges identified in this report. In addition, the Chairman and the Vice Chairman of the Board have offices at CIRM to aid communication with the CIRM employees. The Board also has subcommittees governing various items of interest to CIRM. Other stakeholders are the Grantees receiving CIRM funding who can and often do contact their CIRM Science Officers directly. The staffing at CIRM is fairly lean with very few administrative staff so direct calls are allowed and encouraged.

CIRM has a dedicated human resources professional in a private office who initially receives and manages any reports of inefficiencies and inappropriate actions. CIRM HR has an open door policy for any employee to report inappropriate actions. CIRM HR has provided sexual harassment training and provides guidelines, resources and other assistance to employees on an as-needed basis.

MONITORING

The information included here discusses the entity-wide, continuous process to ensure internal control systems are working as intended. The role of the executive monitoring sponsor includes facilitating and verifying that the California Institute for Regenerative Medicine monitoring practices are implemented and functioning. The responsibilities as the executive monitoring sponsor(s) have been given to: Chila Silva-Martin, Director of Finance; and Maria T. Millan, M.D., President and CEO.

Monitoring Activities

A. Proposition 71 requires an annual independent financial audit of CIRM. Health & Safety Code section 125290.30, subdivision (b), requires CIRM to commission an annual independent audit by a certified public accounting firm: "The institute shall annually commission an independent financial audit of its activities from a certified public accounting firm, which shall be provided to the State Controller, who shall review the audit and annually issue a public report of that review." Gilbert Associates, Inc. performed CIRM's audit for the period from inception to June 30, 2005. Macias, Gini & O'Connell LLP (MGO) performed CIRM's audit for each fiscal year ending June 30th, from 2006-2019. All of the audit reports previously released may be found on the SCO website.

B. The annual independent financial audit is also reviewed separately by the State Controller. As required by Section 125290.30(b), the annual independent financial audit of CIRM is provided to the State Controller, who then reviews the audit and issues a public report of that review. The SCO has reviewed and reported favorably on the independent financial audits of CIRM for every fiscal year through June 30, 2018.

C. CIRM's financial practices are also reviewed each year by the Citizens' Financial Accountability Oversight Committee. In addition to the annual independent financial audit and the annual SCO review of that audit, Health & Safety Code section 125290(c) creates a Citizens' Financial Accountability Oversight Committee (CFAOC): "There shall be a CFAOC chaired by the State Controller. This

committee shall review the annual financial audit, the State Controller's report and evaluation of that audit, and the financial practices of the institute." The CFAOC is a six-member board chaired by the State Controller. The committee meets annually to review the financial practices and performance of CIRM. The SCO's website has a page dedicated to the CFAOC's proceedings. CFAOC meeting transcripts, annual reports, and other resources can be found there.

D. CIRM is also subject to a triennial performance audit to ensure it is achieving economy, efficiency, and effectiveness in its use of resources. In addition to the multiple levels of oversight described above, Health & Safety Code Section 125290.30(c) requires that CIRM commission a performance audit every 3 years beginning fy 2010-211. The performance audit, which is conducted in accordance with government auditing standards, examines 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. This includes a review of whether CIRM is complying with ICOC policies and procedures. The first performance audit was presented to the ICOC in May 2012 and included a review of, among other things: (1) CIRM's 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; and (2) CIRM's policies and procedures relating to the protection or treatment of IP rights associated with research funded or commissioned by CIRM. The second performance audit conducted by Moss Adams LLP commenced in late 2014 and covered CIRM's operations in the fiscal year (July 1, 2013-June 30,2014). The FY 2013-2014 Performance Audit included, but was not limited to, a review of all the following: Policies and procedures for the issuance of contracts and a review of a representative sample of contracts; policies and procedures for the issuance of grants and loans and a review of a representative sample of grants and loans; and policies and procedures relating to the protection or treatment of IP rights associated with research funded or commissioned by CIRM. The third performance audit for FYI 2016-2017 was completed on March 1, 2018 by Moss Adams LLP. This audit assessed the compliance with policies and procedures for the core functions of grant applications, review, oversight, loans, contracts and intellectual property.

Addressing Vulnerabilities

CIRM holds bi-weekly senior management meetings. Meeting topics include discussion of current and potential challenges to achievement of strategic goals, as well as updates on control activities and an assessment of the success of mitigation activities. The senior management meetings consist of individual unit leaders charged with implementation of the controls, each of which oversees implementation of various components of the controls and evaluates the control's performance.

Ongoing Monitoring Compliance

The California Institute for Regenerative Medicine has implemented and documented the ongoing monitoring processes as outlined in the monitoring requirements of California Government Code sections 13400-13407. These processes include reviews, evaluations, and improvements to the California Institute for Regenerative Medicine systems of controls and monitoring.

RISK ASSESSMENT PROCESS

The following personnel were involved in the California Institute for Regenerative Medicine risk assessment process: executive management.

The following methods were used to identify risks: brainstorming meetings, audit/review results, other/prior risk assessments, consideration of potential fraud, and performance metrics.

The following criteria were used to rank risks: likelihood of occurrence, potential impact to mission/goals/objectives, and timing of potential event.

RISKS AND CONTROLS

Risk: Funding through 2023 if CIRM is not renewed

Since the bond proceeds supporting CIRM are nearly fully allocated, CIRM could run out of administrative funds necessary to manage the final awards through 2023.

Control: Transition Planning

To ensure that CIRM has sufficient administrative funds to manage active grants through their term, CIRM convened a transition committee to explore various options. The CIRM leadership team developed a transition plan to ensure sufficient administrative funds to manage Proposition 71 funds should no additional funding become available. The transition plan was approved by the governing Board in December 2017, which allows granting of new awards through 2019 and ensures key staff are retained to manage the CIRM portfolio through 2023.

To address this risk, CIRM's Leadership and Finance teams are responsible for implementing, monitoring, and reporting the transition plan. Adjustments to the plan, as necessary, will be made by the leadership team to ensure CIRM maintains sufficient funds to manage its portfolio to the end.

Risk: Managing office space

In late 2020, a ballot measure, if the measure gets on the ballot, will determine if CIRM will be renewed or not renewed. This inflection point will either resort in a downsizing or upsizing of CIRM and CIRM current office location will not be appropriate in either circumstance. Identifying a new space and the movement of staff and office materials to a new space will take longer than CIRM's current lease expiration of April 2021.

Control: Lease extension

CIRM has entered into negotiations with its landlord for a lease extension to give CIRM an adequate amount of time to either upsize or downsize. If upsizing, CIRM would have to spend time to determine the size of a new staff, search for a new location, handle office construction (if needed) and move. If downsizing, CIRM would have to search for a new location which can handle the existing server room, handle office construction (if needed) and move.

A lease extension would give CIRM the time to handle the options above properly. Any such lease extension is already budgeted for.

Risk: Employee Retention

Since CIRM's continued existence is dependent on a ballot measure passing in the November 2020 elections, there is a risk that critical employees may leave for concrete job opportunities.

Control: Employee Retention Planning

In order to keep employees committed to CIRM in 2020, CIRM has offered more professional development opportunities to the staff. If this is not sufficient to ensure sufficient employees retention, CIRM may contemplate certain retention incentives as needed. In addition, CIRM has cross-trained more employees so as to fill any gaps till the election if the staffing level decreases.

CONCLUSION

The California Institute for Regenerative Medicine strives to reduce the risks inherent in our work and accepts the responsibility to continuously improve by addressing newly recognized risks and revising risk mitigation strategies as appropriate. I certify our internal control and monitoring systems are adequate to identify and address current and potential risks facing the organization.

Maria T. Millan, M.D., President and CEO

CC: California Legislature [Senate (2), Assembly (1)]
California State Auditor
California State Library
California State Controller
Director of California Department of Finance
Secretary of California Government Operations Agency