

December 31, 2021

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

Dear Director 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, 2021.

Should you have any questions please contact Benjamin Huang, Associate General Counsel, at (510) 340-9138, [Bhuang@cirm.ca.gov](mailto: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. In 2020, California voters approved Proposition 14, which authorized an additional \$5 billion in general obligation bonds for CIRM to continue administering the funding. CIRM is a small agency now staffed by approximately 43 FTEs. In authorizing these funds, Californians expected to accelerate world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and the world.. 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 and gene therapy medicine, stimulating the economy, reducing health care costs by replacing chronic treatments with cures, and ensuring that the State has the opportunity to benefit via treatment accessibility to low income Californians from revenue-sharing originating from CIRM-funded treatments or technologies. CIRM is governed by the Independent Citizen's Oversight Committee (ICOC), a 35-member board appointed by various state officials according to criteria specified in Proposition 14. 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, nursing advocates, 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 world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and the world.. 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 \$3.0 billion. Of that amount, approximately \$2.6 billion has been disbursed to grantees as of the date of this report.

Since CIRM was renewed in 2020, it has developed a new strategic plan which has received final ICOC Board approval in December 2021.

## **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.

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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 Development team, which consists of Science Officers with Ph.D.

who establish the milestones and budgeting of translational and clinical grants as well as primary contact with the Principal Investigators, and finally a Scientific Programs Team, which consists of Science Officers who do the same for basic research and education grants. For the functioning of the agency, CIRM has a Finance team, HR team, 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.

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 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: 2ell 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. 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 43 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 CEO 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 Citizen's Oversight Committee, CIRM's governing board. Through its periodic 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. 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 dedicated human resources professionals who initially receive and manage 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: Pouneh Simpson, Director of Finance; and Maria T. Millan, M.D., President and CEO.

### Monitoring Activities

- A. Propositions 14 and 71 require 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 2006-2021. 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, 2021.
- C. CIRM's financial practices are also reviewed each year by the Citizen's Financial Accountability Oversight Committee. In addition to the annual independent financial audit and the annual SCO review of that audit, Health & Safety Cod section 125290(c) creates a Citizen's 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. The last performance audit for FYI 2019-2020 was completed recently in 2021 by Moss Adams with similar audit responsibilities.

#### Addressing Vulnerabilities

CIRM holds bi-weekly senior management meetings which now occur weekly during COVID-related work from home requirements. 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, ongoing monitoring activities, audit/review results, other/prior risk assessments, and performance metrics.

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

## **RISKS AND CONTROLS**

### **Risk: Lease ending 2022**

CIRM's current lease expires March 30, 2022. CIRM, using the Department of General Services has identified a new office space and has negotiated all the terms but finalizing the lease has taken much longer than expected.

#### **Control: Work from Home policy**

CIRM can also extend the duration of the work from home policy for the staff until the new space opens.

#### **Control: Furniture storage**

CIRM has entered into negotiations with its potential landlord to store furniture for any duration of time between the expiration of the old lease and the completion of the build out for the planned new lease.

#### **Control: Public meetings at hotel conference rooms**

In the event the Bagley Keane requirements for in-person ICOC Board meetings are reinstated (currently all public meetings are conducted via teleconference during the COVID pandemic), CIRM would plan for public meetings at hotel conference rooms which it has done previously.

### **Risk: Employee Recruiting and Retention**

Since CIRM's planned new office is in a different part of the Bay Area, there is a risk that employees may leave due to the increased commute times. The new location may also impact recruiting. The current Work from Home policy during COVID pandemic may impact retention once the pandemic is over and an office policy is reinstated

#### **Control: Employee Retention Planning**

In order to keep employees committed to CIRM, CIRM has offered more professional development opportunities to the staff though the COVID pandemic has impacted some of these offerings. The



new location has a variety of public transit options and free parking unlike the current location. Once the new office is open and the pandemic is over, the executive leadership may consider a hybrid office/work from home policy.

### **Risk: Incorporation of Diversity, Equity and Inclusion**

There has been an increased emphasis by the CIRM's ICOC Board of considering diversity, equity and inclusion issues in the review of the applications for CIRM funding. There is a risk that such consideration may conflict with Proposition 209, which amended the state constitution to prohibit state government institutions from considering race, sex or ethnicity, especially in the area of public contracting

#### **Control: Outside counsel and Board training**

In order to avoid any conflicts with Proposition 209, CIRM has engaged outside counsel to determine analysis procedures during an application review. Such procedures seek to focus review on DEI on the inclusion of the relevant clinical treatment population. Any criteria related to the application team should focus on socio-economic issues and not issues related to race, sex or ethnicity. In addition, CIRM will conduct Board training to ensure consistency among the ICOC Board who review such criteria in the applications

### **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