December 21, 2017

Michael Cohen, Director
California Department of Finance
915 L Street
Sacramento, CA 95814

Dear Mr. Michael Cohen,

In accordance with the State Leadership Accountability Act (SLAA), 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, 2017.

Should you have any questions please contact C. Scott Tocher, Deputy General Counsel, at (510) 340-9159, stocher@cirm.ca.gov.

BACKGROUND

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 research and 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 50 FTE. 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 the potential receipt of royalty payments arising from CIRM-funded treatments or technologies. CIRM is governed by the Independent Citizen’s 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 $2.6 billion. Of that amount, approximately $1.57 billion has been disbursed to grantees as of the date of this report.

ONGOING MONITORING

As the head of California Institute for Regenerative Medicine, Maria T. Millan, M.D., President and CEO, is responsible for the overall establishment and maintenance of the internal control and monitoring systems.
Executive Monitoring Sponsor(s)
The executive monitoring sponsor responsibilities include facilitating and verifying that the California Institute for Regenerative Medicine internal control monitoring practices are implemented and functioning as intended. The responsibilities as the executive monitoring sponsor(s) have been given to:

C. Scott Tocher, General Counsel, 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 30, from 2006-2015. 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 year through fiscal year through June 30, 2014.

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 Code section 125290.30(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. (See http://www.sco.ca.gov/eco/cfaoc/index.shtml.)

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 2010–11. 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 of 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 is currently underway.

**Addressing Vulnerabilities**

CIRM holds 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 chiefs charged with implementation of the controls, each of which oversees implementation of various components of the controls and evaluates the control's performance.

**Communication**

Because of the relatively small size of the agency (50 employees), senior management is in daily close contact and communication with all units within the organization and receive real-time feedback on success or challenges of monitoring practices conducted and the overall monitoring performance within each team. 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. 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.

**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, and Staff.

**Risk Identification**

CIRM’s President and Leadership Team meet together and with the Board and team to review strategic goals and risks, including the issues identified by previous audits, to compile the items described herein. Identified Risks are prioritized using a risk impact/probability analysis, accounting for the prioritization indicated. Risks with a higher quantitative impact and probability are prioritized higher than risks with lower such characteristics. The entire CIRM team also meets quarterly to assess performance on metrics and identify areas of risk to the broader strategic goals of each unit, identify and discuss the appropriate response, and meet subsequently to report on the success of that response.

**Risk Ranking**

CIRM’s President and Leadership Team met together and with the Board and team to review strategic goals and risks, including the issues identified by previous audits, to compile the items described herein. Identified Risks are prioritized using a risk impact/probability analysis, accounting for the
prioritization indicated. Risks with a higher quantitative impact and probability are prioritized higher than risks with lower such characteristics.

RISKS AND CONTROLS

RISK: OPERATIONS - EXTERNAL - STAFF — RECRUITMENT, RETENTION, STAFFING LEVELS

Although Proposition 71 did not provide a sunset date for CIRM, the Institute’s life is limited by two related factors. First, Proposition 71 authorized CIRM to spend a total of $3 billion in bond proceeds. Second, of that $3 billion, CIRM may spend no more than six percent, or $180 million, plus donated funds and interest earned on its funds, for administrative purposes. In the absence of the authorization of additional funds or some alternative source of revenue, therefore, CIRM cannot continue to exist once its current funding expires. The uncertainty relating to CIRM’s longevity creates a challenge for CIRM in recruiting and retaining talented team members. This challenge is compounded by the fact that the State’s contribution towards an employee’s retirement benefits vests after five years of service. CIRM’s current funding budget, based on Proposition 71’s allocation, is forecast to last through the end of 2019. While CIRM forecasts maintaining current staffing levels to meet agency needs through the end of 2019, if alternative programmatic funds are not raised by then the agency must begin to reduce staffing levels to meet core award management functions.

As explained above, the agency’s drawdown of Proposition 71 bond funds will sunset operations.

As explained above, the possible winddown of CIRM operations may cause critical team members to find more longterm employment opportunities elsewhere in spite of CIRM’s continued need for such service.

CONTROL A

Per Proposition 71, CIRM has the authority to set compensation for its employees within the range of compensation provided to staff at UC medical schools and certain nonprofit academic and research institutions. Health & Saf. Code § 125290.45(b)(4). CIRM has the authority to set compensation for its employees within the range of compensation provided to staff at UC medical schools and certain nonprofit academic and research institutions. Health & Saf. Code § 125290.45(b)(4). To meet the hiring and retention challenge posed above, CIRM will survey the appropriate organizations and institutions set forth in Proposition 71 to identify and assess appropriate compensation and other types of measures to reward performance and incentivize continued service over the next several years.

RISK: OPERATIONS - EXTERNAL - FUNDING — SOURCES, LEVELS

CIRM could run out of administrative funds to manage final awards necessary through 2023.

Proposition 71 provided CIRM with $3 billion in bond proceeds. The proposition authorized CIRM to utilize no more than six percent, or $180 million, plus donated funds and interest earned on its funds, for administrative purposes. At the beginning of the 17/18 FY, CIRM had a total $48 million for administrative expenses. Because final awards may not terminate until 2023, and without extra administrative funds made available to CIRM, the agency could run out of administrative funds if adjustments are not made during a wind-down phase.

Insufficient administrative funding would have to be resolved either by conventional state government funding allocations from the general fund or via absorbtion of critical functions by other state entities.

CONTROL A

To ensure that CIRM has sufficient administrative funds to manage its grant portfolio through their
term, and to identify strategies for securing additional funds to keep CIRM and its programs running beyond Proposition 71 funds, CIRM convened a transition committee to explore various options. The CIRM leadership team was tasked with developing a plan to ensure sufficient administrative funds to manage Proposition 71 funds should no additional funding become available.

The CIRM leadership team developed a transition plan, which was approved by its governing board in December 2017, that will support delivery on its 5-year strategic plan. The plan provides for the granting of new awards through 2019, and ensure key staff are retained to manage CIRM’s portfolios 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 through the end.

**Risk: Operations - External - Oversight of or Program Coordination with Others**

CIRM-funded programs fail to identify and partner with commercial-stage product developers to bring programs from early clinical-stage research to final therapy development.

Insufficient investor interest in cell therapy.

CIRM-funded research programs will stall before reaching the market and patients with unmet medical needs.

**Control A**

In an effort to achieve CIRM’s mission, CIRM proposes to establish the Industry Alliance Program (“IAP”), a unique opportunity to partner with CIRM to bring the most promising clinical and translational stage stem cell, gene therapy, and regenerative medicine programs to market. The goal of the IAP is to provide the Collaborator with access to CIRM’s large and growing portfolio and facilitate introductions to CIRM-funded investigators.

The IAP is designed to provide portfolio insight and engagement opportunities for the Collaborator. In addition, CIRM endeavours to streamline the diligence process through template legal agreements, such as non-disclosure agreements and licensing templates, and robust data rooms.

CIRM would use the program to help partner CIRM-funded programs with commercial partners to propel CIRM projects through the final stages of therapy development.

**Risk: Operations - Internal - Fi$Cal Implementation, Maintenance, or Functionality**

Because of challenges in implementing the the State’s new Fi$Cal system, the utility of the program has not yet been optimized, which presents challenges to CIRM staff in utilizing the system.

Two areas that have not been fully addressed by Fi$Cal include user training and reporting functionality. At times, Fi$Cal will implement system enhancements/revisions, however, the job aides are not immediately revised to reflect the enhancement/changes, causing challenges for those relying on these aides. Because the Fi$Cal system is module based, obtaining reports from the system that reflect all expenditures can be challenging, and can require multiple report runs to secure the necessary data.

CIRM is not able to obtain timely or accurate financial data. Additionally, CIRM has experienced operational inefficiency as a result of system issues, such as conversion, preparation of invoices for processing in both systems and training, for example.
Control A
To address this risk, CIRM hired an employee that was part of the FI$Cal implementation team and is extremely knowledgeable of the system. This has enabled CIRM to learn and use new tools to navigate the system and secure the needed data. This greatly improved CIRM’s reliability of FI$Cal. Additionally, CIRM is part of a super user group that provides input to FI$Cal. However, as FI$Cal continues to implement system enhances/changes, and transition new users onto the system, users will continue to experience system challenges. CIRM will continue to work with the FI$Cal partners to address these issues until the system is fully functional and remaining glitches have been addressed.

Risk: Operations - Internal - Workplace Environment
CIRM relocated its headquarters in 2015 from San Francisco to Oakland. Because of the limited availability of affordable office space CIRM’s relocation to Oakland required it to separate operations across two floors in one office building.

Limited affordable office space of such a size as to accommodate all of CIRM’s operations across one floor.

Separation of the team results in logistical difficulties and inefficiencies in achievement cost-unit functions. The separation impacts employee morale by separating CIRM’s core programmatic units from some support functions.

Control A
CIRM will explore subleasing its smaller space and consolidate operations on the main floor.

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 controls to prevent those risks from happening. 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