

Institute of Medicine Report Praises Stem Cell Agency as a “Bold Social Innovation”

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Report highlights options for making the agency even more effective

San Francisco, CA – An in-depth report by the Institute of Medicine (IOM) praised California's stem cell agency, the California Institute for Regenerative Medicine (CIRM) for its ground breaking work in helping advance the science of stem cell research, and helping researchers, scientists and biotech companies accelerate the most promising research from the lab into clinical trials.

In the report the IOM highlighted a number of key areas in which the stem cell agency has helped advance the field of regenerative medicine, calling it “a creative supplement to the more traditional sources of biomedical research funding in the United States and an innovative initiative designed to further strengthen California's biotechnology efforts.”

Among the areas the IOM singled out for praise are:

- CIRM's collaborations with funders in the US and around the world saying this “substantially enhanced California's position as one of the key international hubs of activity in regenerative medicine.”
- Science and research - “CIRM has been highly effective in building an impressive research portfolio.”
- Global impact - “the work of CIRM-sponsored researchers continues to enrich regenerative medicine everywhere,” and that “CIRM and those it has funded have set in motion a significant scientific enterprise.”
- Grants management - “Given the complexity of this endeavor....the overall success of the grant management infrastructure is impressive.”
- Industry engagement – “CIRM has created an exemplary training program and seeded a pipeline of intellectual property and translational projects that are primed for industry involvement, outside funding, and unique therapy delivery mechanisms.”

“We thank Dr. Shapiro and the rest of the IOM panel for all the hard work they have put into this report,” says Jonathan Thomas, PhD, JD, Chairman of the Independent Citizens Oversight Committee (ICOC), the governing board of the stem cell agency and the group that commissioned the report. “Throughout the process we were impressed with the level of detail they went into to try and understand how we do our work, highlighting areas where we do very well, and coming up with recommendations on how we can be even more effective.”

The stem cell agency commissioned the review in 2011, asking the IOM to put together a panel to make an independent assessment of our programs, operations, strategies and performance. The goal of the review was to ensure that all aspects of CIRM's operations are functioning at peak performance, and to make recommendations on short/medium/long-term actions to improve the agency's performance.

The IOM committee, chaired by Harold Shapiro, PhD, the former President of Princeton University, consisted of 13 members including experts in stem cell research, developmental biology, bioethics and law, research administration, as well as finance and business administration. The IOM held three public meetings, requested data, reports and information from CIRM, solicited input from our governing board, and conducted interviews with independent scientists and industry experts.

The main questions to be answered were:

- Is CIRM's portfolio of projects and grants sufficient to meet its scientific goals – how can these be improved
- Does CIRM's strategic plan meet the challenges facing Regenerative Medicine
- Is CIRM's organizational and management system effective
- Is CIRM's funding model working well, and could it serve as a model for similar programs in the US and internationally
- What are the strengths and weaknesses of CIRM's intellectual property policies and how do they compare to the NIH model

“We are a unique organization, the first agency in the US created by voters to invest significant state money into basic and applied medical research in a particular field of study,” says Alan Trounson, PhD, President of the stem cell agency. “Because of our unique nature, and the challenges we face in fulfilling our mission, we felt it was appropriate to seek the assessment of experts from the peak body in medicine – the IOM – and ask them to help guide us in identifying what we do well and where we can improve. It's all about making us a better, more effective organization with the best practices expected of such an organization and living up to the trust placed

in us by the voters of California.”

The report recommends we consider changes in a number of areas including:

- Changes to the composition and structure of our governing board, the ICOC
- Changes in the roles board members play in the grant application review process
- Revisions to our Conflict of Interest policies
- Sponsor training programs on ethical issues and stem cells
- Establish a Scientific Advisory Board
- Develop a sustainability platform
- Increase industry representation on the ICOC and other key working groups

“As a public agency we have a duty to be as open and transparent as possible,” says Ellen Feigal, MD, Senior Vice President for Research and Development. “This report demonstrates our commitment to that goal. It includes opinions from a wide variety of perspectives, both scientific and non-scientific, and these will help guide us in the next phase of our work.”

Members of the IOM committee will present their findings to the ICOC at its next meeting on December 12th in Los Angeles. The ICOC commissioned the report and donor funds covered the almost \$700,000 cost of the study.

“We take this report very seriously,” says Dr. Thomas. “We look forward to hearing the IOM presentation at our next board meeting and we will then work on establishing a process to enable us to consider how best to proceed with reviewing the recommendations.”

About CIRM: CIRM was established in November 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research opportunities.

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