

Institute of Medicine (IOM) Review of the California Institute for Regenerative Medicine

CIRM's Governing Board commissioned the Institute of Medicine (IOM) to review CIRM over the next several months culminating with a report due in late 2012. The principal objective of this review is to ensure that all aspects of CIRM's operations are functioning at peak performance. The committee is tasked with providing recommendations regarding short, medium, and long-term actions that could improve the performance of CIRM. Specifically the IOM committee will review and address the following:

- **CIRM's initial processes** – What can be learned from the history and process of building consensus in the public and scientific communities to support the inception and work of CIRM?
- **CIRM's programmatic and scientific scope** - Does CIRM have the portfolio of projects and grant opportunities necessary to meet its scientific goals? How can CIRM improve upon its existing array of programs? What additional programs and initiatives are recommended to meet its goals? What impacts have been seen from international agreements? Does CIRM's scientific strategic plan address the range of relevant issues in regenerative medicine within CIRM's mandates scope of work?
- **CIRM's organizational and management systems** - Are the internal organizational and management systems (in particular the board and working group structures and operations, the peer review system, the conflict of interest guidelines, and the grants management system) effective in working toward the institute's scientific goals? Are the systems that are in place scientifically and ethically valid and rigorous? Do they achieve the level of transparency and the level of stakeholder and scientific community involvement needed to meet the institute's public responsibilities and scientific goals?
- **CIRM's funding model** - Has the funding model for CIRM had an impact on the work of the institute? What are the advantages of CIRM's model for covering long-term costs of medical research? Could aspects of this funding model serve as a paradigm for other states or countries? What has been the economic impact of CIRM's research and facilities awards and grants?
- **CIRM's intellectual property policies** - What are the strengths and weaknesses of CIRM's policy for sharing revenue generated by intellectual property? How does this model compare to the model governing federally-supported research?

Current Status:

- The IOM initiated its review in July 2011. The first stage of the review involved requesting nominations for members of the committee and empaneling a committee composed of 13 representatives from a variety of backgrounds, including individuals with expertise in science, medicine, management and economics. At the IOM committee's first meeting on October 19-20, 2011, CIRM leadership provided the charge to the committee and presented background information about the CIRM and its programs.
- Currently, CIRM is working with the IOM to respond to the IOM's request for comprehensive information in various areas, including CIRM's initial processes, grants and programs, grants management, governance and management, reviews and evaluations, financing, collaborations, economic impact, conflict of interest, and intellectual property. CIRM staff has worked diligently

to respond and to date has provided responses (satisfactory to the IOM) to approximately 75 percent of the more than 50 such requests. CIRM hopes to complete its response to the remaining requests in the near future. Additionally, CIRM is working with the IOM to facilitate site visits of CIRM's major facilities. CIRM expects to devote considerable time and attention to the IOM review in 2012.

- IOM Committee meetings/workshops in 2012 are currently scheduled for January 24-25, April 10-11, June, and August. The January 24th and April 10th workshop meetings, to be held in Northern and Southern California respectively, both include an open session component which will allow the public to attend and provide comment.
- Report – The IOM's report should be available in late 2012.