AGENDA ITEM #12 FOR 8/18-19/10 ICOC MEETING

M E M O R A N D U M

TO: **MEMBERS OF THE GOVERNING BOARD, CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE**

FROM: MELISSA KING

SUBJECT: IOM STUDY STATEMENT OF TASK & TIMELINE

DATE: 16 AUGUST 2010

Attached to this memo you will find a Draft Task and Work plan provided to CIRM by the Institute of Medicine (IOM) for a possible study of CIRM by the IOM. This document is for discussion purposes at the August 18-19, 2010 meeting of the Board, for item 12 on the Board agenda, as referred to the Board by the Science Subcommittee.

Based on internal discussions at CIRM, it has been proposed that the timeline for the IOM study be pushed out so the completion date would be 24 months following (pending) approval by the Board for this study to go forward. This would mean the completion date for the study would be approximately August/September of 2012, rather than the study being completed by the end of 2011, as proposed by the IOM in their Statement of Task. This CIRM-proposed extended timeline would either push the start date of the IOM study out, or would extend the timeline for work on the study from the IOM's proposed 15 months to a longer work period. The 24 month extended timeline has been proposed in order to accommodate staff time requirements for other studies and audits of CIRM, including the CIRM-commissioned audit required by SB 1064 / Alquist.

Institute of Medicine
Review of the California Institute for Regenerative Medicine

Draft Task and Workplan
7/20/10

Statement of Task

The California Institute for Regenerative Medicine (CIRM) has requested that the Institute of Medicine (IOM) provide an independent assessment of CIRM's programs, operations, strategies, and performance since its inception in 2005.

Specifically, the IOM committee will review and address the following questions:

- **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 mandated 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?

- **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?

The principal objective of this review is to ensure that all aspects of CIRM's operations are functioning at peak performance. The committee is asked to provide recommendations regarding short-, medium-, and long-term actions that could improve the performance of CIRM.

Workplan

An Institute of Medicine study committee of approximately 14 members will be assembled to review data, hold public workshops, develop findings and recommendations, and prepare a report. The committee will convene 4 times over the course of 14 months. Two public workshops will be planned and convened in California in conjunction with the committee's meetings to gather data and ensure that the committee hears the perspectives of relevant stakeholders.

The first committee meeting will be largely organizational and will include bias and conflict of interest discussions and plans for each of the future meetings. The sponsors will be asked to provide the charge to the committee and provide background and context for the study. The next two meetings will include public workshops and review of documentation and processes. Discussions with the sponsor and with grantees and other relevant stakeholders will be held during this time. During the last meeting the committee will finalize its recommendations and report. The report will then go through the National Research Council's peer review process and be subject to appropriate institutional review procedures. A prepublication copy of the report will be delivered to the sponsors after 12 to 13 months with the published books delivered after 14 months. The prepublication copy will be delivered to the sponsors within 10 days before the public release of the report. Dissemination activities will include briefings with the sponsor and other congressional or legislative briefings as determined.

The following is the proposed timeline:

Months	Action
0-2	Seek committee nominations, assemble committee, begin background research; contact stakeholders; initial discussions with sponsors
3	Hold first committee meeting; hold bias and conflict of interest discussion, discuss charge to the committee and context for the study, plan workshops – identify topics and potential speakers; identify information needs; develop plans for receiving stakeholder input
4-8	Hold second and third committee meetings with workshops; develop report outline and workplan; hold working group conference calls; seek and receive input from stakeholders; draft and revise the report; draft recommendations
9-10	Hold 4th committee meeting and finalize recommendations and report
10-12	Report review and response to review; finalize report
12-13	Deliver prepublication (uncorrected proof) to the sponsors; public release of the report; post report online; sponsor briefing; congressional and other briefings
13-14	Prepare report for publication and send to publishers; deliver final books to the sponsors; dissemination activities

Committee Expertise

A committee of approximately 12 to 14 members will be appointed with expertise in stem cell research, regenerative medicine, developmental biology, bioethics and law, research administration, program evaluation, finance, health economics, business administration, and intellectual property. Committee nominations will be solicited from a variety of sources, including the membership of the National Academies, relevant organizations and associations, federal agencies, and other experts in the areas to be addressed in the study.

Estimated Budget

The total estimated cost of this project is $615,000 for the period from November 1, 2010 to December 31, 2011.

In accordance with federal law and with few exceptions, information-gathering meetings of the committee are open to the sponsor and the public, and any written materials provided to the committee by individuals who are not officials, agents, or employees of the National Academies are maintained in a public access file. National Academies staff do their best to schedule committee meetings at times and places convenient to the sponsor and their colleagues, and will provide an agenda prior to the meetings. However, the sponsor does not control meeting plans and agendas.

The committee deliberates in meetings closed to the public and sponsors in order to develop draft findings and recommendations free from outside influence. Brief summaries of these meetings are made publicly available on the National Academies' Web site. All analyses and drafts of the report remain confidential.

Report Review

As a final check on the quality and objectivity of the study, all reports must undergo a rigorous external review by independent experts whose comments are provided anonymously to the committee members. The National Academies recruit independent experts with a range of views and perspectives to review and comment on the draft report. The draft report and review comments are not publicly disclosed.

The review process aims to ensure the report addresses its approved study charge and does not go beyond its statement of task, the findings are supported by the scientific evidence and arguments presented, the exposition and organization are effective, and the report is impartial and objective.

Each committee must respond to, but need not agree with, reviewer comments in a detailed "response to review" that is examined by one or two independent report review "monitors" responsible for ensuring that the report review criteria have been satisfied. The names and affiliations of the report reviewers are made public when the report is released.

If the sponsor does not seek to have a prepublication version of the report, only a final printed report is made publicly available and published a few months after final sign off.

Report Release and Dissemination

The plans for release and dissemination of the approved report will be discussed with the sponsor. Sponsors are provided with copies of the report and offered the opportunity for a briefing in advance of the public release of the report. Prerelease briefings may also be provided to other key executive and legislative branch members. In instances in which there is great interest in the report and careful coordination of its release is necessary to be fair to all concerned, the time between delivery to the sponsor and public release may be short, as little as a day. In no case will sponsors receive reports more than two weeks in advance of their public release. Sponsors may make recommendations regarding dissemination strategies for the report, but ultimately the National Academies are responsible for the final products and their release.

Studies are published as printed books by the National Academies Press and are posted on the National Academies Web site for public dissemination. Often a prepublication version of the report is given to the sponsor and posted on the National Academies Web site soon after sign off by the committee and National Academies and in advance of the final printed report. This is to provide the information contained in the report as quickly as possible, even as final editing, layout, and publishing are proceeding. In other cases, only the final printed report will be published. In either case, printing of the final report generally takes a few months after final sign off.

For studies with broad interest, the National Academies may prepare separate report briefs or other derivative materials that are widely circulated. Also, committee members and project staff may testify or make public presentations about the content of the reports, once they have been released. Staff and committee members may assist in disseminating the report, such as by providing copies of the report or report briefs and making presentations. Sponsors should be aware that the time and resources needed for dissemination of the report will often be included in the project timeline and budget. Therefore, National Academies staff may recommend that contracts extend several months beyond the expected delivery of the report to allow for anticipated dissemination activities.

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A Guide for Prospective Study Sponsors

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THE NATIONAL ACADEMIES
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For more than 140 years, the National Academies have been advising the nation on issues of science, technology, and medicine. An 1863 Congressional charter signed by President Lincoln authorized this non-governmental institution to honor top scientists with membership and to serve the nation whenever called upon. Today the National Academies—**National Academy of Sciences, National Academy of Engineering, Institute of Medicine,** and **National Research Council**—continue that dual mission.

Like no other organization, the National Academies can enlist the nation's foremost scientists, engineers, health professionals, and other experts to address the scientific and technical aspects of society's most pressing problems. Each year, more than 6,000 of these experts are selected to serve on hundreds of study committees that are convened to answer specific sets of questions. All serve without pay.

The National Academies are a unique resource. Their reports are viewed as being valuable and credible because of their reputation for providing advice with high standards of scientific and technical quality and independence. National Academies staff will work with potential sponsors to develop a specific set of questions to be answered by a committee of experts.

This guide is intended for prospective sponsors interested in requesting studies from the National Academies. It describes the process for producing these reports—from funding to report dissemination—and explains the sponsors' involvement at each stage. This approach ensures that sponsors receive the best product possible. Checks and balances are applied at every step in the study process to protect the integrity of the reports and to maintain public confidence in them.

Defining and Initiating the Study

Before a contract or grant is signed, National Academies staff and board members work with the sponsor to determine the specific set of questions to be addressed. A formal "statement of task" is developed that defines the scope of the study and serves as the basis for determining the expertise and the balance of perspectives needed on the committee.

Typically, the following steps are taken to ensure that the project is clearly defined and that both the National Academies and the sponsor understand what is expected throughout the study process:

1. Sponsor and National Academies staff meet to discuss task, schedule, and likely costs.

2. When the staff and sponsor have come to a general agreement, staff prepares a prospectus for approval by the Executive Committee of the National Research Council Governing Board. This step ensures the appropriateness of the topic and the scope of the study before a formal proposal is sent to the sponsor.

Most studies are funded by those requesting the advice. Consistent with the congressional charter, experts serving on study committees volunteer their time without compensation. The cost of consensus studies can range from about $200,000 to more than $1 million, depending on the breadth and complexity of the issues being addressed and the length of time needed to produce the desired report. The costs include the expenses of committee meetings, professional staff supporting the committee, report publication, and public dissemination.

Several funding options are available to sponsors. These include contracts, grants, cooperative agreements, and purchase orders. A project may have one or several sponsors. Studies typically take from 9 to 18 months to complete, although some urgent studies may be completed in a shorter time and some broader or more complex studies may take a longer time.

Because of their unique origins and status, federal sponsors interested in having the National Academies conduct a study can obtain their services on a sole source basis. The National Academies do not compete for federal contracts. Grants, contracts, and gifts can also be received from states, foundations, and other sources.

A project begins after formal commitments have been received for sufficient funds to complete the study.

Committee Selection and Approval

Selection of appropriate committee members, individually and collectively, is essential for the success of every study. All committee members serve as individual experts, not as representatives of organizations or interest groups. Each member is expected to contribute to the project on the basis of his or her own expertise and good judgment.

Once a project is funded, the National Academies seek nominees for members of consensus study committees from many sources, including the sponsors. However, the president of the National Academy of Sciences (who also serves as chair of the National Research Council) has the sole authority for appointing all members of study committees. Before a committee can be approved, a thorough balance and conflict of interest discussion is held in closed session during the first meeting, and any issues raised in that discussion or during the public comment period are investigated and addressed. Committee members are considered prospective until after this process is completed.

Committee Meetings, Deliberations, and Drafting Report

Study committees typically gather information through: 1) meetings that are open to the public and announced in advance through the National Academies' Web site, 2) submission of information by outside parties, 3) reviews of scientific literature, and 4) investigations by the committee members and staff. In all cases, efforts are made to solicit input from individuals who have been directly involved in, or who have special knowledge of, the topic under consideration. Sponsors are typically invited to make presentations to the committee at its first couple of meetings to discuss the sponsors' expectations for the study. Also, the sponsor is asked to provide as much information relevant to the study as possible.