

DRAFT MINUTES 8/2/06 ICOC MEETING

Mission Bay Conference Center at UCSF
Robertson Auditorium
1675 Owens St.
San Francisco, CA 94158

David Baltimore	Present
Robert Birgeneau	Absent
Susan V. Bryant	Absent
Marcy Feit	Present
Michael A. Friedman	Present
Michael Goldberg	Present
Brian E. Henderson	Absent
Edward W. Holmes Designee: Jack Dixon	Present
David A. Kessler	Absent
Robert Klein	Present
Sherry Lansing	Present
Gerald S. Levey	Present
Ted W. Love	Present
Richard A. Murphy	Present
Tina S. Nova	Present
Ed Penhoet	Present
Philip A. Pizzo Designee: Paul Berg	Present
Claire Pomeroy	Present
Francisco J. Prieto	Present
John C. Reed Designee: Jeannie Fontana	Present
Duane Roth	Present
Joan Samuelson	Present
David Serrano Sewell	Present
Jeff Sheehy	Present
Jonathan Shestack	Absent
Oswald Steward	Present
Leon J. Thal	Present
Janet Wright	Present

CONSENT ITEMS

Agenda Item # 5: Approval of minutes from June 2, 2006 ICOC Meeting:

To view the minutes as approved, with the approved update, see this URL:

<http://www.cirm.ca.gov/minutes/pdf/2006/06-01-06.pdf>

Motion:

- Dr. Baltimore moved for approval of the minutes
- Dr. Love seconded.

Vote:

- All in favor; no opposition.
- Motion carried; minutes approved.

REGULAR ITEMS

Agenda Item # 6: Chairman's Report

Chairman Klein gave an update on several items of good news, including:

- We have the nation's first comprehensive intellectual property program, developed under the leadership of Ed Penhoet and Mary Maxon.
- The first stage of our strategic plan is under way.
- Our validation in the court system was a remarkable achievement that has served as a catalyst for other good news.
- We have conducted the most cost-effective and transparent agency start-up in state history, holding more than 80 public meetings in 18 months and attracting donors from around the state, including the City of San Francisco related to our headquarters and meetings held in San Francisco.
- BANs purchasers put private dollars behind their belief in everything we are doing, validated by the court decision.
- Now we are focused on readiness to proceed with our program.

With thanks to the Governor and his staff, and to Sherry Lansing and James Harrison for their help, Chairman Klein provided details on the \$150 million state loan to the CIRM as directed by Governor Schwarzenegger. Sherry Lansing expressed her appreciation for

the Governor's courageous decision to make the loan available and thanked his staff for their hard work in making the loan possible.

Chairman Klein also praised national leaders for the tremendous courage shown in the US Senate with the 63 to 37 vote passing HR 810 on July 18th, a bipartisan showing of support for stem cell research with senators from both sides of the aisle standing up for what they feel is critical for the future of medical research in this country.

Agenda Item #7: President's Report

President Hall provided an update on personnel changes and current recruitment efforts, including the departures of Jennifer Rosaia and Nicole Pagano, and the active recruitment of a Chief Communications Officer, Chief Finance and Administration Officer, a Scientific Review Officer and a Grants Technical Assistant.

In an update on the scientific strategic planning, Dr. Hall gave details on interviews conducted and meetings held to date. He also updated the board on other scientific activities, including the Assessment of Medical Risk for Egg Donors conference planned for September 28th (note: date may change) and the California/UK stem cell meeting planned for November 13-14.

Dr. Hall informed the board that the CIRM Stem Cell Training Program is moving ahead, with a meeting of Directors at the CIRM having taken place on June 20th and trainee recruitment well under way at the 16 grantee institutions.

To view Dr. Hall's presentation, see this URL:

http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_7.pdf

Agenda Item # 8: Consideration of Standards Working Group report, including but not limited to:

- a. Update on APA process and timeline with respect to the CIRM Medical and Ethical Standards Regulations for Human Stem Cell Research.**
- b. Consideration of recommended changes to the CIRM Medical and Ethical Standards Regulations for Human Stem Cell Research for submission to the Office of Administrative Law.**
- c. Consideration of final language for the CIRM Medical and Ethical Standards Regulations and supporting documentation for submission to the Office of Administrative Law.**

Dr. Bernard Lo, Co-Chair of the Standards Working Group, gave a presentation on the process of developing and revising the CIRM Medical and Ethical Standards Regulations, through the most recent public comment period. He then provided details on the latest revisions and requested board consideration for approval of several items.

To view the memo about the recommended changes discussed, please see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_8b1.pdf

To view the final compiled regulations, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_8b2.pdf

To view the language options for Section 100095, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_8b2.pdf

To view the Summary and Response to Public Comment, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_8c.pdf

To view the Summary of Original Basis for the regulations, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_8ci.pdf

There were five items voted on related to this agenda item. The votes took place as follows:

1. Motion to approve Option 3 for section 100095/Additional Requirements for CIRM-Funded Research Involving Oocytes.

- Dr. Prieto moved for adoption of Option 3.
- Mr. Sheehy seconded.

Vote:

- All in favor; no opposition.
- Motion carried.

2. Motion to approve entire set of MES Regulations with 3 changes: 1) append a glossary 2) make a change to the section regarding payment covering care for the direct and proximate complications at no cost, to make antecedent clear and 3) modify section 100130 to read “stem cell lines and biomedical materials developed

with CIRM funding shall be disseminated in accordance with CIRM intellectual property regulations.”

- Dr. Love moved for approval
- Mr. Sheehy seconded.

Vote:

- All in favor; no opposition.
- Motion carried.

3. Motion to adopt the Summary and Response to Public Comment.

- Dr. Murphy moved for adoption
- Dr. Wright seconded.

Vote:

- All in favor; no opposition.
- Motion carried.

4. Motion to approve Summary of Original Basis.

- Dr. Baltimore moved for approval
- Dr. Levey seconded.

Vote:

- All in favor; no opposition.
- Motion carried.

5. Motion to repeal the regulations in place once these final regulations are approved by the OAL.

- Dr. Nova moved for repeal of existing regulations.
- Dr. Thal seconded.

Vote:

- All in favor; no opposition.
- Motion carried.

Agenda Item #9: Consideration of Intellectual Property Task Force report, including but not limited to:

- a. Consideration of CIRM Intellectual Property Policy for Non-Profit Organizations regulations.**
- b. Consideration of whether and how to address the issue of open access to published CIRM-funded research results.**
- c. Consideration of referring state technology transfer issues review to Legislative Subcommittee.**

Ed Penhoet provided an update on IP Task Force activities, including the approval at the meeting on July 14th of the Intellectual Property Policy for Non-Profit Organizations for submission to the OAL. The Task Force is now continuing work on developing a policy for for-profit organizations.

Dr. Penhoet expressed the recommendation from the Task Force that the following two topics be further addressed, either by the Task Force or another ICOC subcommittee:

- Technology transfer, as a larger issue that should be dealt with at the level of the state Legislature rather than by the CIRM
- Open access to published research results

Sense of the ICOC: It was the sense of the ICOC that technology transfer issues should be dealt with at the level of the state Legislature, and should be tracked by the ICOC Legislative Subcommittee.

Sense of the ICOC: It was the sense of the ICOC that the topic of open access to published CIRM-funded research results is one the IP Task Force will continue to look at and on which it will seek to gain further input from the public.

Agenda Item # 12: Consideration of interim debt, including but not limited to General Fund loan to CIRM and delegation to Chair to take all actions necessary to complete transactions including but not limited to negotiation and execution of all documents related to interim debt.

Chairman Klein introduced a resolution for approval by the ICOC to authorize the Chairman to take all actions necessary to secure the general fund loan to the CIRM authorized by Governor Schwarzenegger.

Chief Deputy Director of Finance Anne Sheehan addressed the ICOC, bringing compliments from the Governor to the ICOC, Bob Klein and the CIRM staff. She informed the ICOC that the Finance Committee will have a public meeting, hopefully in the next couple weeks, and then will be able to execute the loan. She informed us that the resolution before the ICOC would help them with this work.

Dr. Baltimore presented a resolution to thank the Governor and his staff for their courage in making the \$150 million loan to the CIRM possible.

Motion:

- Dr. Baltimore moved for approval of his resolution thanking the Governor and his staff
- Ms. Lansing seconded.

Vote:

- All in favor; no opposition.
- Motion carried; resolution approved. To view this resolution as approved, see this URL: <http://www.cirm.ca.gov/icoc/pdf/Resolution2006-02baltimorefin.pdf>

Motion:

- Dr. Murphy moved for approval of the resolution authorizing the ICOC Chair to take all actions necessary to secure the general fund loan to the CIRM from the State of California.
- Dr. Thal seconded.

Vote:

- All in favor; no opposition.
- Motion carried; resolution approved. To view this resolution as approved, see this URL: <http://www.cirm.ca.gov/icoc/pdf/Resolution2006-01fin.pdf>

Agenda item #13: Consideration of approval for an RFA for innovation grants.

Dr. Hall presented to the ICOC the *Proposed CIRM Grants Program: Innovation in hESCResearch* as prepared by the CIRM staff.

To view Dr. Hall's presentation, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_13a.pdf

To view a summary document of the Grants Program, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_13.pdf

Motion:

- Ms. Samuelson moved for approval of the program.
- Mr. Sheehy seconded.

Vote:

- All in favor; no opposition.
- Motion carried; program approved.

Agenda item #14: Consideration of update on governance issues, including but not limited to:

- a. Consideration of the proposed full year administrative budget for 2006-07.**
- b. Consideration of the updated contracts/agreements reports.**
- c. Consideration of the proposed Gift Policy.**
- d. Consideration of acceptance of gifts.**

The ICOC approved the budget for 2006-2007.

Motion:

- Dr. Penhoet moved for approval of the budget
- Dr. Dixon seconded.

Vote:

- All in favor; no opposition.
- Motion carried; budget approved.

To view the budget as approved, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_14a.pdf

The ICOC approved the extension of the CIRM's contracts with the Spiegel and Remcho firms.

Motion:

- Mr. Roth moved for approval of the contract extensions.

- Dr. Murphy seconded.

Vote:

- All in favor; no opposition.
- Motion carried; contract extensions approved.

To view the Remcho contract extension approval form, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_14bii.pdf

To view the Spiegel contract extension approval form, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_14bii.pdf

The ICOC approved the CIRM Gift Policy and Letter of Commitment as updated with guidance from the ICOC at the April 6, 2006 ICOC meeting, and with one addition as follows: add “Working Group Members” to item number five under TERMS in the letter of commitment.

Motion:

- Mr. Roth moved for approval of the Gift Policy and Letter of Commitment.
- Dr. Prieto seconded.

Vote:

- All in favor; no opposition.
- Motion carried; Gift Policy and Letter of Commitment approved.

To view the background document on the gift policy, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_14c.pdf

To view the gift policy with tracked changes, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_14ci.pdf

To view the letter of commitment with tracked changes, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_14cii.pdf

Agenda Item #15: Consideration of values for the CIRM Scientific Strategic Plan, and further consideration of mission statement and objectives, to provide direction for the Scientific Strategic Planning team.

The ICOC discussed the items that had been considered the night before, on 8/1, by a smaller group of ICOC members, and further massaged the lists of Values and Strategic Principles suggested for use by the scientific strategic planning team.

The sense of the ICOC was that the slogan identified as the best by the 8/1 evening group is the one we should go with. Please note this slogan was suggested by a member of the public present at the 8/1 meeting: Roman Reed, stem cell research supporter and patient advocate for individuals with spinal cord injuries. The slogan is:

“Turning stem cells into cures.”

To view the updated slides, based on the ICOC discussions during the 8/1 evening meeting and the 8/2 full-day ICOC meeting, see this URL:

http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_15.pdf

Agenda Item #16: Consideration of adoption of conflict of interest regulations for CIRM Working Groups.

The ICOC approved the Conflict of Interest regulations for CIRM Working Groups, for send back to the OAL for final review and approval as regulations.

Motion:

- Dr. Baltimore moved for approval of the Conflict of Interest Regulations for CIRM Working Groups.
- XYZ seconded.

Vote:

- All in favor; no opposition.
- Motion carried; regulations approved.

To view the background memo on the COI regulations for CIRM Working Groups, see this URL:

http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_16a.pdf

To view the Standards Working Group COI regs, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_16c.pdf

To view the Grants Working Group COI regs, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_16d.pdf

To view the Facilities Working Group COI regs, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/08/080206_item_16e.pdf