

DRAFT MINUTES OF 12/07/06 ICOC MEETING

**UCI University Club
University of California, Irvine
801 East Peltason Drive
Irvine, CA 92697**

Ricardo Azziz	Present
David Baltimore	Present
Alternate Paul Jennings	
Robert Birgeneau	Absent
Susan V. Bryant	Present
Marcy Feit	Present
Michael A. Friedman	Present
Michael Goldberg	Present
Brian E. Henderson	Present
Edward W. Holmes	Absent
David A. Kessler	Present
Robert Klein	Present
Sherry Lansing	Present
Gerald S. Levey	Present
Alternate Leonard Rome	
Ted W. Love	Absent
Richard A. Murphy	Present
Tina S. Nova	Present
Ed Penhoet	Present
Philip A. Pizzo	Absent
Claire Pomeroy	Present
Francisco J. Prieto	Absent
John C. Reed	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

Agenda Item # 4: Approval of minutes from October 11, 2006 ICOC meeting.

Motion:

- Dr. Steward moved for approval of the minutes
- Dr. Azziz seconded.

Vote:

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

The ICOC unanimously approved the minutes from the 10/11/06 ICOC meeting.

To see the final, approved minutes, see this URL:

<http://www.cirm.ca.gov/minutes/pdf/2006/10-11-06.pdf>

Agenda Item # 5: Chairman's Report.

Chairman Klein provided an update on the CIRM's first two years of existence, the many accomplishments of the board and agency in that time, the current landscape and the work ahead.

In a brief state-of-the-agency remarks, he summarized some of CIRM's achievements, including that we now have \$181 million in the bank, a set of Medical and Ethical Standards that are now serving as a model for others, an Intellectual Property Policies for non-profit organizations in the process of becoming state regulations and another close to finished for for-profit organizations and much more in place now, in contrast with two years ago at the first ICOC meeting on December 17, 2004.

With the new House and Senate compositions following the November elections, and global momentum for stem cell research at the federal government level, including in Australia, things are looking positive with regard to the global strategy to implement stem cell research. With all we have left to do here in California, we have much to celebrate and a lot of work to do.

Agenda Item # 6: President's Report.

Dr. Hall updated the board on recent personnel additions, coming departures and ongoing recruitments, the activity of the Science Team on the Scientific Strategic Plan, SEED Grant applications and review and Comprehensive Grants RFA. He also gave an update

Agenda Item # 4 A
6/4-5/07 ICOC Meeting

on the performance audit, on CIRM regulations in development and the possibility of working with a partner on a stem cell research journal. He also announced his plan to step down as President and Chief Scientific Officer of the CIRM sometime within the next six months.

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

http://www.cirm.ca.gov/meetings/pdf/2006/12/120706_item_6.pdf

Agenda Item # 7: Consideration of CIRM Scientific Strategic Plan

Motion:

- Mr. Serrano Sewell moved for approval of the Scientific Strategic Plan with the request that the CIRM President come back at a later board meeting with a feasibility study of the sabbatical program mentioned in the plan.
- Dr. Azziz seconded this motion.

Vote:

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

The ICOC unanimously approved the Scientific Strategic Plan with one request, which is for the President to come back at a later board meeting with a feasibility study of the Sabbatical Program covered briefly in the plan.

To view the final Strategic Plan, see this URL:

http://www.cirm.ca.gov/meetings/pdf/2006/12/120706_item_7.pdf

Agenda Item # 8: Consideration of interim CIRM Policy for For-Profit Organizations and submission to the Office of Administrative Law to begin Administrative Procedure Act review process.

Motion:

- Dr. Henderson moved for approval of the CIRM Policy for For-Profit Organizations.
- Dr. Wright seconded.
- One amendment was proposed by Mr. Sheehy and Dr. Kessler, to include the language "consistent with then existing industry standards" with regard to the access plans required of grantees at the time of commercialization of therapies

Agenda Item # 4 A
6/4-5/07 ICOC Meeting

- resulting from research funded by a CIRM grant. This amendment was accepted by the maker of and second for the original motion.
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Vote:

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

The ICOC approved the CIRM Policy for For-Profit Organizations with one change, which is to include the language “consistent with then existing industry standards” with regard to the access plans required of grantees at the time of commercialization of therapies resulting from research funded by a CIRM grant.

The result of this vote is that the policy would then be converted into regulatory language, by CIRM staff, and then submitted to the OAL to initiate the process of getting the regulations finalized and approved. The vote also put the policy in place as interim regulations, so as of the time of this vote, the CIRM can now make grants to for-profit organizations.

To view the plan as it was approved, see this URL:

<http://www.cirm.ca.gov/meetings/pdf/2007/For-Profit%20DraftICOC120706.pdf>

Agenda Item # 9: Consideration of Intellectual Property Regulations for Non-Profit Organizations, including but not limited to permanent adoption of Proposed Regulations 100306 regarding "Licensing CIRM-Funded Inventions" and 100309 regarding "Press Releases."

Motion:

- Dr. Murphy moved for approval of regulation 100309.
- Dr. Jennings seconded this motion.

Vote:

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

The ICOC approved regulation 100309, part of the Intellectual Property Regulations for Non-Profit Organizations, to reflect the desire of the ICOC to strike one sentence with regard to joint press releases with the CIRM. This edited regulation will now be submitted to the OAL for finalization and approval as a regulation.

Motion:

- Mr. Roth moved for approval of regulation 100306.
- Dr. Reed seconded this motion.

Vote:

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

The ICOC approved regulation 100306, part of the Intellectual Property Regulations for Non-Profit Organizations, with regard to licensing requirements for CIRM-funded patented inventions. This regulation will now also be submitted to the OAL.

Agenda Item # 10: Consideration of permanent adoption of Grants Administration Policy for Academic and Non-Profit Institutions Regulations.

Motion:

- Dr. Steward moved for approval of the Grants Administration Policy for Academic and Non-profit Institutions Regulations.
- Dr. Rome seconded.

Vote:

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

The ICOC approved the Grants Administration Policy Regulations for submission to the OAL for the final 30-day review before it becomes an official regulation.

Agenda Item # 11: Consideration of recommendations for CIRM Medical and Ethical Standards regulations:

- a. **Consideration of final Standards Working Group recommended language for section 100085 – use of human tissue in CIRM-funded research. For this regulation to be submitted to the OAL to begin the adoptions process, the ICOC must approve regulatory language.**
- b. **Consideration of final Standards Working Group recommended language for section 100120 – record keeping requirements. Recommended language has been drafted to address comments from OAL. For this regulation to be submitted to OAL for final adoption, the ICOC must approve regulatory language.**

- c. Consider Standards Working Group recommended withdrawal of section 100130 – materials sharing. Materials sharing is addressed in the CIRM intellectual property regulations. For this regulation to be withdrawn, the ICOC must approve deletion.**

Motion:

- Ms. Lansing moved to authorize extension by emergency adoption of existing interim regulations.
- Dr. Azziz seconded.

Vote:

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

The ICOC authorized extension by emergency adoption of the existing interim regulations, so they remain in place during the finalization of the adoption process with the OAL.

Motion:

- Dr. Pomeroy moved for approval of language for section 10085.
- Ms. Lansing seconded.

Vote:

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

The ICOC approved the proposed language for section 100085, for submission to the OAL to initiate the regulatory process.

Motion:

- Dr. Pomeroy moved for approval of the revised language for section 100120.
- Dr. Bryant seconded.

Vote:

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

The ICOC approved the revised language for section 100120 so it could be resubmitted to

the OAL for final adoption.

Motion:

- Dr. Henderson moved for withdrawal of section 100130.
- Mr. Roth seconded.

Vote:

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

The ICOC approved the withdrawal of section 100130, with regard to materials sharing, as it has been superseded by the Intellectual Property regulations now in the adoption process.

Agenda Items # 12 and 13: Closed Session and Public Report From Closed Session:

In closed session, the ICOC approved a salary of \$158,000 for Rick Keller, joining the CIRM as Senior Officer to the Facilities Working Group, from UC Davis where he was Assistant Vice Chancellor for Capital Planning and Resource Management. This salary approval was announced in the public session of the meeting immediately following the closed session, and a formal public vote was taken on this matter.

Motion:

- Dr. Pomeroy moved for approval of this salary.
- Dr. Henderson seconded.

Vote:

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

Agenda Item # 14: Consideration of recommendations from the Governance Subcommittee, including the following:

- a. **Consideration of all proposed amendments to the Policy for Contracting and Services of Independent Consultants.**
- b. **Consideration of amendments to the 2006-07 CIRM Administrative Operating Budget.**
- c. **Consideration of proposed amendments to the Policy and Regulations Governing Travel for CIRM staff and Working Group members.**

d. Consideration of modification of Governance Subcommittee Mission Statement to include delegation of authority for future CIRM travel policy amendments.

Motion:

- Dr Henderson moved for approval of the amended budget.
- Dr. Wright seconded.

Vote:

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

The ICOC approved the amended budget, which you can view at this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/12/120706_item_14b.pdf

Motion:

- Dr. Friedman moved for approval of the amended policy on contracting and services of independent consultants.
- Dr. Rome seconded.

Vote:

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

The ICOC approved the amended policy on contracting and services of independent consultants, which you can view at this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/12/120706_item_14a.pdf

Motion:

- Dr Pomeroy moved for approval or the amended policy governing travel for CIRM staff and Working Group members.
- Dr. Azziz seconded.

Vote:

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

The ICOC approved the amended policy governing travel for CIRM staff and Working Group members. You can view the amended policy, as approved, at this URL: http://www.cirm.ca.gov/meetings/pdf/2006/12/120706_item_14c.pdf

Motion:

- Mr. Klein moved for approval of the delegation of authority for the policy governing travel for CIRM staff and Working Group members to the Governance Subcommittee. This motion was made while Sherry Lansing, Chair of the Governance Subcommittee, was chairing the ICOC meeting for consideration of this agenda item.
- Dr. Henderson seconded.

Vote:

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

The ICOC approved the delegation of authority for the policy governing travel for CIRM staff and Working Group members to the Governance Subcommittee.

Agenda Item # 15: Consideration of Confidentiality Policy and Conflict of Interest Forms for Use as Part of Facilities Working Group Grant Review Process, and Proposed Amendments to Regulation 100004 Regarding Facilities Working Group Conflict of Interest Policy.

Motion:

- Mr. Serrano Sewell moved for approval of an amendment to the Facilities Working Group Conflict of Interest Policy.
- Dr. Azziz seconded the motion.

Vote:

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

The ICOC approved an amendment to the Facilities Working Group Conflict of Interest Policy, now in process with the OAL as regulation 100004. The change is with regard to professional conflicts of interest, making it consistent with the Grants Review Working Group policy. The added language is: “or have been engaged in during the last three years.”

Motion:

- Mr. Roth moved for approval of amending regulation 100004.
- Dr. Pomeroy seconded the motion.

Motion:

Agenda Item # 4 A
6/4-5/07 ICOC Meeting

- Dr. Azziz moved for an additional amendment, to add the word “employee” to the regulation.
- Dr. Penhoet seconded the motion.

Both Votes:

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

The ICOC approved the amendment to the actual regulation, 100004, for submission to the OAL in order to move forward with the adoption process. This motion passed following the approval of one amendment, which is to add the word “employee” with regard to conflicts of interest that arise when immediate family members are associated with applicant institutions.

It was clarified that this Conflict of Interest Policy applies only to non-ICOC members of the Working Group. ICOC members adhere to the Conflict of Interest Policy for ICOC members in all their work for CIRM.

It was also agreed that this policy would be revisited to consider the level of confidentiality needed for facilities grant reviews by the Facilities Working Group. This reconsideration of the policy will take place before any facilities grants are considered by the Facilities Working Group beyond the Shared Lab Space RFA in early 2007.

Agenda Item # 16: Consideration of update from Facilities Working Group including but not limited to:

a. Consideration of the definition of "capital equipment" under Proposition 71.

Motion:

- Dr. Henderson moved for approval of the definition of “capital equipment” as presented.
- Dr. Bryant seconded.

Vote:

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

Agenda Item # 4 A
6/4-5/07 ICOC Meeting

The ICOC approved the definition of “capital equipment”, developed in order to clarify that capital equipment, or fixed equipment, will be covered by facilities grants while “research equipment” will be covered by research grants.

Agenda item #'s 17, 18 and 19: These items were not addressed at this meeting. They may be added to future agendas when and if necessary.

Agenda Item # 20: Presentation on allocation of funds available for CIRM grant making.

To view the presentation, see this URL:

http://www.cirm.ca.gov/meetings/pdf/2006/12/120706_item_20.pdf

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