

## MINUTES OF 8/8/07 ICOC MEETING

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

Ricardo Azziz <b>Alternate David Meyer</b>	Present
Robert Birgeneau & <b>Alternate Bob Price</b>	Present
David Brenner	Present
Susan V. Bryant <b>Alternate: Dennis Cunningham</b>	Present
Marcy Feit	Present
Michael A. Friedman	Present
Michael Goldberg	Present
Brian E. Henderson <b>Alternate Frank Markland</b>	Present
David A. Kessler	Present
Robert Klein	Present
Sherry Lansing	Present
Gerald S. Levey	Absent
Ted W. Love <b>Alternate: Michael Levy</b>	Present
Tina S. Nova	Present
Ed Penhoet	Present
Philip A. Pizzo	Present
Claire Pomeroy	Present
Francisco J. Prieto	Present
John C. Reed	Present
Duane Roth	Present
Joan Samuelson	Absent
David Serrano Sewell	Present
Jeff Sheehy	Absent
Jonathan Shestack	Absent
Oswald Steward	Present
Janet Wright	Present

**Agenda Items # 4, 5 & 6: Consent Calendar**

- **# 4: Consideration of minutes from the following ICOC meetings: April 10, 2007; May 2, 2007 and June 4-5, 2007.**
- **# 5: Consideration of regulation 100120: Medical and Ethical Standards, Record Keeping Regulation.**
- **# 6: Amendments to the CIRM Conflict of Interest Code. Approval will allow staff to initiate the regulatory amendment process with the OAL and the Fair Political Practices Commission, our code reviewing body.**

**Motion:**

- Dr. Wright moved for approval of the items on the Consent Calendar.
- Mr. Goldberg seconded the motion.

**Vote:**

- The ICOC unanimously approved the consent calendar.

To see the final, approved minutes, see these URLs:

<http://www.cirm.ca.gov/minutes/pdf/2007/04-10-07.pdf>

<http://www.cirm.ca.gov/minutes/pdf/2007/05-02-07.pdf>

<http://www.cirm.ca.gov/minutes/pdf/2007/06-04-07.pdf>

To see the language of regulation 100120 as approved, see this URL:

[http://www.cirm.ca.gov/meetings/pdf/2007/080807\\_item\\_5.pdf](http://www.cirm.ca.gov/meetings/pdf/2007/080807_item_5.pdf)

To see the CIRM Conflict of Interest Code amendment details, see these URLs:

[http://www.cirm.ca.gov/meetings/pdf/2007/080807\\_item\\_6a.pdf](http://www.cirm.ca.gov/meetings/pdf/2007/080807_item_6a.pdf)

[http://www.cirm.ca.gov/meetings/pdf/2007/080807\\_item\\_6b.pdf](http://www.cirm.ca.gov/meetings/pdf/2007/080807_item_6b.pdf)

[http://www.cirm.ca.gov/meetings/pdf/2007/080807\\_item\\_6c.pdf](http://www.cirm.ca.gov/meetings/pdf/2007/080807_item_6c.pdf)

## **II. Agenda Item # 7: Chairman's Report.**

Chairman Klein provided an update on recent travel by himself and various CIRM staff members, including travel by both Chairman Klein's team and the Science team to Australia for the annual meeting of the International Society for Stem Cell Research held out of the US for the first time this year, as well as travel by Zach Hall and Arlene Chiu to stem cell focused conferences in Singapore and the UK.

He pointed out that such travel by CIRM leaders and staff members is important to CIRM's mission and to the ongoing leadership the CIRM provides globally, serving as an acting force to get other nations and states to increase their budgets in the stem cell research area and driving the formation of new collaborations among researchers, benefiting patients in California, across the US and globally.

Chairman Klein stated that leveraging California's research assets and keeping California researchers at the leading edge of the global advancements in medical research and therapies, California has a unique role because of the vision of the public in California in approving Prop 71 in 2004.

He then provided details on CIRM's plan to host the International Stem Cell Forum in San Francisco next February, with a reminder that there are now 19 members including the CIRM, all nations with the exception of the CIRM. Zach Hall, attending the Forum in Singapore in early 2007, extended the invitation to host the next one in California.

## **Agenda Item # 8: Reports from Acting President's and Interim Chief Scientific Officer.**

### **Acting President:**

Lori Hoffman gave a report on the progress made by the Facilities Working Group, holding four successful public meetings to get input for the Major Facilities Program, as well as a Facilities Working Group meeting to discuss the input from the public meetings. These public meetings are the ones recommended to the ICOC by the Facilities Working Group members on April 13th, based on a suggestion from Vice-Chair David Serrano Sewell. The ICOC approved in May the plan to hold these meetings, and the CIRM Facilities Working Group staff and the Group itself went on to hold the meetings and develop the concept plan for the Major Facilities RFA.

Ms. Hoffman also reported on the progress of the Shared Research Lab Awards, for which the first check had been issued. Notices of Grant Awards were in progress, to be followed by more checks to grantees.

Ms. Hoffman also updated the ICOC on staffing matters, including the resignations of Kirk Kleinschmidt, Director of Legislation and Research Policy and Scott Tocher, Interim Associate General Counsel. She then walked the ICOC through the proposed '07-'08 administrative budget.

**Interim Chief Scientific Officer:**

Dr. Chiu provided a report to the ICOC on personnel changes in the Science Office and an update on current and upcoming scientific activities.

She announced three new appointments, as follows:

- Bettina Steffen, Scientific Officer
- Mario Garcia, Grants Management Specialist
- Susan Marton, Grants Technical Assistant

She also announced the departure of Dr. Ruth Globus, who planned to return to her lab at NASA. Along with these three additions and one departure, Dr. Chiu and her team continue to recruit scientific staff, particularly scientific officers and grants management specialists, to take on the ongoing and upcoming initiatives.

Dr. Chiu informed the board that her team was working on a compilation of all grant applications that have been approved by the ICOC to date, so the ICOC and the public can see in one document all the grants to date. This document is planned for publication in time for the October 2007 ICOC meeting.

She walked the ICOC through the CIRM New Faculty Award Program, the Letters of Intent due August 9<sup>th</sup> and applications due August 30<sup>th</sup>, for review by the Grants Working Group October 23<sup>rd</sup>-24<sup>th</sup>.

She detailed the Disease Team Initiative, one of the special programs planned to jump start translational research. There are three components, a workshop and two RFAs. The first RFA will be for planning grants for disease teams, short term grants so groups can gather and write proposals. The second RFA is for large, multi-year grants that target specific diseases and usher treatments to clinical trials. The team embarked on the first step in July, holding a workshop organized by Dr. Ruth Globus and Dr. Bettina Steffen and including ICOC members, patient advocates, basic and clinical researchers, representatives from industry, the FDA and other funding agencies.

Dr. Chiu also provided details on the Annual CIRM Scholar meetings being planned by Gil Sambrano, and the annual meeting of the International Stem Cell Forum, mentioned earlier by Chairman Klein, which will be theme organized and led by Pat Olson, Interim Director of Scientific Activities.

**Consideration of Proposed Additional Agenda Item for addition to the agenda:  
“Consideration of authorization for negotiation and execution of personal services contract.”**

**Motion:**

- Mr. Serrano Sewell moved for approval of the item for consideration during the meeting.
- Dr. Wright seconded the motion.

**Vote:**

- The ICOC approved this motion with one “no” vote, from Mr. Sheehy.

To view the proposed additional agenda item as approved for addition to the agenda, see this URL:

[http://www.cirm.ca.gov/meetings/pdf/2007/080807\\_addition.pdf](http://www.cirm.ca.gov/meetings/pdf/2007/080807_addition.pdf)

**Agenda Item # 9: Consideration of update from IP Task Force and proposal to modify the payback requirement for products licensed by for-profit entities.**

Dr. Penhoet sought the ICOC’s approval of changing the payback provision for the non-profit entities if they license technology to third parties.

The existing version of the IP policy said that when a for-profit entity uses CIRM funds to create intellectual property and licensed that property to a third party, sharing of the royalties or any other payments that ensue as a result of that license would involve 17% of those payments being returned to the state, and the for-profit would keep 83% of the payments.

The corresponding feature in the not-for-profit IP proposal is that 25% of the remuneration to the not-for-profit entity as a result of licensing would be returned to the state. The difference, 25 vs. 17, arose from the fact the 25% is of the net proceeds to the not-for-profit after that not-for-profit has paid its inventor’s share to the inventors. The sense of parity was seen to be that in the case of for-profits, those entities paid their employees, and the employees did not get any share of the royalties, and therefore the employer should be rewarded for the inventor’s share. This looks like the for-profits are getting a better deal, even though they are not – they are sending 17% of gross revenues to the state rather than net after inventor’s share.

Though there was parity the way the two policies were written, the optics weren’t good. Industry seemed to be willing to accept retaining 75% of the licensing revenue rather than 83%. Therefore, the proposal was made to change the for-profit policy to reflect that the 25% would be the same for for-profit and not-for-profit.

**Motion:**

- Mr. Roth moved for approval of the proposal to change the for-profit IP policy so the share returned to the state of licensing is 25% rather than 17%.
- Dr. Wright seconded the motion.

**Vote:**

- The ICOC unanimously approved this motion.

**Agenda Item # 10: Report from and possible consideration of study of proposal from the California State University system.**

Representatives from the California State University system and the California Community College system presented their joint proposal to the ICOC. Presenters included Dr. Charles Reed, Chancellor of the CSU system, Dr. Rollin Richmond, President of Humboldt State University, Dr. Susan Baxter, Executive Director California State University Program for Education and Research in Biotechnology (CSUPERB), Dr. Mary Pat Huxley, Director of Biotechnology Initiatives for the CCC system, Dr. Elizabeth Ambrose, Assistant Vice Chancellor for Research Initiatives for the CSU system and Dr. Jeff Thompson, Associate Provost for Research at CSU San Bernardino.

Following an informative presentation on the two systems and how they can help provide the science infrastructure and prepare the future workforce for biotechnology in California, the speakers answered several questions from the ICOC. With a clear desire by the ICOC to further explore working with the CSU and CCC systems, a two-member ICOC team was formed to work with CIRM staff members and the two systems to develop a path for achieving the desired outcomes. ICOC members Marcy Feit and David Serrano Sewell volunteered to serve on this team.

**Motion:**

- Dr. Prieto moved for approval of the plan to have ICOC members Feit and Serrano Sewell work with CIRM staff and the CSU and CCC systems to further explore the possibilities of the CIRM working with the two academic systems.
- Dr. Wright seconded the motion.

**Vote:**

- The ICOC unanimously approved this motion.

**Agenda Item # 11: Consideration of Standards Working Group items from 7/27/07 meeting including:**

- **Use of cell lines derived under Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells;**
- **Limitations on payment for cells; and**
- **Requirements for use of somatic cells and human tissue**

Dr. Bernard Lo, Chair of the Standards Working Group, presented the three components of this item to the ICOC for approval as recommended by the Standards Working Group.

To view the details of these three components, please see this URL:

[http://www.cirm.ca.gov/meetings/pdf/2007/080807\\_item\\_11.pdf](http://www.cirm.ca.gov/meetings/pdf/2007/080807_item_11.pdf)

**Motion:**

- Dr. Reed moved for approval of the recommendation to deem lines derived in Japan under the Japanese guidelines for derivation and utilization of human embryonic stem cells as acceptable for CIRM researchers to use.
- Mr. Roth seconded the motion.

**Vote:**

- The ICOC unanimously approved this motion.

**Motion:**

- Dr. Prieto moved for approval of the recommended language on limitations of payments for stem cells, clarifying that these are payments not to the people who donate cells or materials, but to third parties who process the cells and make them available.
- Dr. Friedman seconded the motion.

**Vote:**

- The ICOC unanimously approved this motion.

**Motion:**

- Dr. Reed moved for approval of the modifications to the requirements for the use of somatic cells and human tissue for derivation of new stem cell lines
- Ms. Lansing seconded the motion.

**Vote:**

- The ICOC unanimously approved this motion.

**Agenda Item # 12: Consideration of appointment of new scientific members of the Grants Review Working Group.**

Dr. Chiu presented this item, requesting approval of a new sitting member to the Grants Working Group from among the current alternates, and the naming of one current alternate as the first alternate. Additionally, she requested approval of five new scientists and clinicians to serve as new alternate members.

To see the bios of the proposed new alternate members, see this URL:

[http://www.cirm.ca.gov/meetings/pdf/2007/080807\\_item\\_12.pdf](http://www.cirm.ca.gov/meetings/pdf/2007/080807_item_12.pdf)

**Motion:**

- Dr. Prieto moved for approval of Dr. Csete as the new sitting member and Ian Duncan as the First Alternate.
- Mr. Serrano-Sewell seconded the motion.

**Vote:**

- The ICOC unanimously approved this motion.

**Motion:**

- Dr. Penhoet moved for approval of the five new alternate members.
- Dr. Pizzo seconded the motion.

**Vote:**

- The ICOC unanimously approved the

**Agenda Item # 13: Consideration of concept plan for RFA 07-03.**

Rick Keller and Lori Hoffman presented the concept plan for the Major Facilities RFA, number 07-03. To read the details of the concept plan, see this URL:

[http://www.cirm.ca.gov/meetings/pdf/2007/080807\\_item\\_13.pdf](http://www.cirm.ca.gov/meetings/pdf/2007/080807_item_13.pdf)

**Motion:**

- Dr. Pizzo moved for approval of the plan to use a two-step approval process.
- Dr. Wright seconded the motion.

**Vote:**

- This motion carried with a voice vote.



**Motion:**

- Dr. Penhoet moved to raise the \$40 million cap in the top category to \$50 million. This motion was amended to include making the middle range cap \$25 million.
- Mr. Klein seconded the motion.

**Vote:**

- The ICOC approved this motion with one “no” vote from Dr. Pomeroy.

**Motion:**

- Dr. Reed moved to have equal weighting across the board, 20% in each category.
- Mr. Roth seconded the motion.

**Vote:**

- This motion failed with a roll call vote.

**Motion:**

- Mr. Serrano Sewell moved for adoption of the criteria as noted in the concept plan, including: Value/25 points; Leverage/25 points; Urgency/20 points; Shared Resources/15 points and Functionality/15 points. The motion was amended as follows: passage subject to a discussion of definitions.”
- Dr. Pizzo seconded the motion.

**Vote:**

- The ICOC unanimously approved this motion.

**Motion:**

- Dr. Pizzo moved to weight the criteria such that the first two categories, Z and Y, are 40% and Z is 20%, based on his belief that the Z portion, the Clinical Research element should not have the same weight as the other two.
- Dr. Penhoet seconded the motion.

**Vote:**

- This motion was withdrawn for further consideration at a later meeting.

**Motion:**

- Dr. Pizzo moved for approval of the proposed scientific evaluation of the applications.

- Dr. Price seconded the motion.

**Vote:**

- The ICOC unanimously approved this motion.

**Motion:**

- Dr. Reed moved for approval of the total dollar amount available for this RFA, \$227 million, and also the dollar ranges as amended by Dr. Penhoet's earlier motion to raise the caps so the ranges would now be: \$25-50 million; \$10-20 million and \$5-10 million.
- Dr. Meyer seconded the motion.

**Vote:**

- The ICOC unanimously approved this motion.

**Motion:**

- Mr. Roth moved for staff to provide greater clarity to definitions in the RFA, removing his condition from a previous motion and now just asking for more clarity in the RFA.
- Dr. Penhoet seconded the motion.

**Vote:**

- This motion carried.

**Agenda Item # 14: CLOSED SESSION**

**Agenda Item # 15: Public report of any action taken, if necessary, during closed session.**

**Motion:**

- Dr. Pizzo moved that the ICOC appoint an Interim President for the CIRM.
- Mr. Goldberg seconded the motion.

**Vote:**

- This motion passed with one "no" vote.

Following the discussion of the concept plan, General Counsel Tamar Pachter presented

to the ICOC the voting procedures for the Major Facilities RFA 07-03.

**Additional Agenda Item as Previously Approved for Consideration: “Consideration of authorization for negotiation and execution of personal services contract.”**

**Motion:**

- Dr. Pizzo moved for approval of Dr. Richard Murphy as Interim President, including providing authorization to negotiate and execute a personal services contract with Dr. Murphy to have him serve as Interim President of the CIRM.
- Ms. Lansing seconded the motion.

**Vote:**

- The ICOC approved this motion by voice vote, with one “no” vote.

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