

**Tuesday, July 12, 2005 ICOC Meeting Minutes**

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

David Baltimore <b>Surrogate: Paul Jennings</b>	Present
Robert Birgeneau <b>Surrogate: Robert Price</b>	Present
Keith L. Black <b>Surrogate: David Meyer</b>	Present
Susan V. Bryant	Present
Michael A. Friedman	Present
Michael Goldberg	Absent
Brian E. Henderson	Present
Edward W. Holmes	Absent
David A. Kessler	Present
Robert Klein	Present
Sherry Lansing	Present
Gerald S. Levey <b>Surrogate: Leonard Rome</b>	Present
Ted W. Love	Present
Richard A. Murphy	Absent
Tina S. Nova	Present
Ed Penhoet	Present
Philip A. Pizzo	Present
Claire Pomeroy	Present
Francisco J. Prieto	Present
John C. Reed <b>Surrogate: Jeanne Fontana</b>	Present
Joan Samuelson	Absent
David Serrano Sewell	Present
Jeff Sheehy	Present
Jonathan Shestack	Absent
Oswald Steward	Present
Leon J. Thal	Absent
Gayle Wilson	Absent
Janet S. Wright	Present

CONSENT ITEMS

**Agenda Item #5**

**Approval of minutes from May 23, 2005 ICOC meeting**

**Agenda Item #6**

**Approval of minutes from June 6, 2005 ICOC meeting**

**Agenda Item #7**

**Consideration of amendments to enhance conflict of interest code categories to reflect new hires and current staff responsibilities**

**Motion**

- Dr. Pizzo moved to approve consent items under agenda items 5, 6 and 7.
- Dr. Bryant seconded the motion.

**Vote**

- All in favor; no opposition
- Motion carries

**Agenda Item #8**

**Consideration of update on financial issues including but not limited to bridge financing.**

**Chairman Klein:** The bridge financing is structured around Bond Anticipation Notes, the terms of which state that if we are not successful in litigation, the Notes would become grants. Bridge financing has proceeded in a task force of the Institute, the Treasurer's Office, and the Controller's Office as authorized by the Finance Committee in May.

The key objective is to work with major philanthropic foundations and individuals to fund sufficient portions of the Bond Anticipation Notes so that, at the September board meeting when we are prepared, we hope to approve the Training Grants, we have sufficient funding for those Training Grants.

There is no action needed at this time. This is an update item.

**Agenda Item # 9**

**Consideration of creating a joint CIRM/California State Legislature Task Force on Intellectual Property**

**Chairman Klein:** The intent here would be to carry forward the intellectual process that has been proceeding vigorously beginning with Assembly Concurrent Resolution 252 by Assemblyman Gene Mullin, also passed by the Senate, directing the California Council on Science and Technology to come back to the state with an Intellectual Property Policy. That was augmented this year by Assembly Concurrent Resolution 24 specifically guiding the CCST to create a policy in biotech area on Intellectual Property.

Both our own Dr. Susan Bryant and Michael Goldberg from our board are serving on the CCST Task Force, as approved by the ICOC at our January meeting.

This is a challenging issue, and will take several months, probably ending in October with some final recommendation back to this board, or sooner if the Task Force were able to perform miracles along the way.

**Dr. Bryant:** The CCST Task Force dealing with this issue as it relates specifically to Proposition 71 is about to issue a final report.

There have been a lot of discussions with the members of that committee about how to make a recommendation that would be suitable for ICOC, given, first of all, some of the language in the Proposition and so forth, but also bearing in mind the long experience with IP issues through Bayh-Dole and with NIH funding, which, of course, even though the \$3 billion that's coming our way for stem cell research here is a huge amount of money, it is dwarfed by the amount of money that goes into research by the NIH.

So there's a great deal of history to be looked at here in terms of what works and what doesn't work in terms of IP because it's not just getting the research done. It's getting companies to come in and pick up the results of that research and spend even more money in developing products.

So we have to make sure whatever comes out of this is that the ultimate goal of getting cures to people is not compromised by anything that we do along the way. There are going to be a lot of interesting conversations that have to take place before we will have a policy in this area to recommend.

**Chairman Klein:** Michael Goldberg and Dr. Bryant will hopefully participate on this task Force on behalf of the board so we have an integrated knowledge of the CCST Task Force's recommendations. Hopefully the task force can also formally interface with the council efforts with the legislature so you have a tri-party interface.

Vice-Chairman Ed Penhoet has had leadership on this issue here for some months here on Intellectual Property issues. And he has the distinguished advantage of having looked at this as dean from the public health side at Berkeley to roles in venture capital and roles in the biotech sector. So he has a three sided vision of this very complicated challenge.

It is important to motivate members from the ICOC who are from the patient advocacy side to participate along with the biotech side and the academic side because all three components have to work together in any intellectual property policy that's going to be effective in some balanced way.

**Dr. Nova:** This issue of IP is probably the most critical and one of the most complex and Important decisions we're going to be making as a committee, and there are many ways

to approach intellectual property. It is going to be incredibly important that we vet all of the different ways of looking at IP.

I think the recommendations from the CCST are going to be incredibly helpful and certainly serve as a foundation for this whole important area.

I think this task force is critical, and it is critical that we have representation from life sciences, academics and patient advocates, to follow up on what was just said. I hope that members of the board will step forward so we can accomplish this with equal representation.

### **Motion**

- Dr. Prieto moved to approve creation of IP Task Force with Dr. Penhoet as Chair.
- Dr. Friedman seconded the motion.

**Vice Chairman Penhoet:** Clarification: What we're doing is forming a Subcommittee of our ICOC to be the IP Task Force on our side. It is up to the legislature to decide how they're going to respond to us. So I think our motion is limited to us forming a Subcommittee to deal with IP issues, hopefully with the legislature.

**Chairman Klein:** Right, we are following up on a leadership recommendation of the legislature. They would like to have a group to relate to in this ongoing process. If we have a specific committee formed, then there will be continuity of this discussion and intellectual depth to this discussion. So we're trying to bring the resources together, but the legislature will really define how they constitute their part of this discussion.

**Dr. Steward:** If this is a Subcommittee, does it have to operate under Bagley-Keene rules? And if so, would the legislature be willing to participate?

**Dr. Pomeroy:** This goes back to comments I've made previously about the committees that we form, committees and task forces. I strongly urge us to specifically write out charges, deliverables and etc. for each of these committees. I'm not sure I have clarity about on exactly what this committee will be doing.

I'm happy to support the motion as long as it comes with a second motion about a specific written charge.

**Mr. Serrano Sewell:** The public, the legislature and we ourselves are looking to the ICOC for some leadership and discussion on this point. It is a good faith step that will show the public that we take this issue seriously and we're going to give it the time it deserves.

**Vice Chairman Penhoet:** We have a set of IP issues in which the legislature has a real interest. We have another set of IP issues in which they may have no interest. Still we have to develop these policies for our own internal purposes in working with our grantees, working with licensees, etc.

So I want to be clear we're authorizing a committee to be formed to deal with IP issues

broadly for ICOC and bring back recommendations to the whole board. A subset of those activities will be to deal with the legislature's interest, but this committee won't be limited to that in its activities.

**Vote**

- All in favor; no opposition
- Motion carries

The following members volunteered to participate on this Subcommittee:

Susan Bryant  
Sherry Lansing  
Ted Love  
Tina Nova  
Phil Pizzo  
Jeannie Fontana for John Reed  
Jeff Sheehy  
Os Steward  
Francisco Prieto  
Janet Wright

It was suggested, in his absence, that Michael Goldberg be part of this Subcommittee.

**Agenda Item # 10**

**Consideration of update from Legislative Subcommittee, including policy enhancements recommended to the ICOC by the Subcommittee and general policies on Subcommittee composition and structure**

**Chairman Klein:** At our June 6 meeting, there were policy suggestions that had come from a meeting that Senator Perata's staff had chaired on June 3<sup>rd</sup> in his office with the leadership of the state senate. In that meeting, our Interim President Zach Hall, counsel James Harrison and I worked with Senator Perata's staff, Senator Ortiz' staff and senior consultants of a number of committees of the Senate to come to a conclusion on conceptual items that could be advanced. This meeting was an attempt to find more core items on which we could make real progress in enhancing the policies for transparency, accountability, and for further raising that we believe are already the highest standards in the country.

Dr. Zach Hall with staff developed a number of specific recommendations from the conceptual points that we brought to the June 6<sup>th</sup> meeting, at which we also formed the Legislative Subcommittee. These were brought to the Legislative Subcommittee at its first meeting on June 20<sup>th</sup>.

**Dr. Hall:** On June 20<sup>th</sup>, the Legislative Subcommittee agreed on policy enhancements to recommend to the ICOC, which will meet several concerns addressed by the legislature. And with respect to these policies, the Subcommittee recommended that that ICOC require notice to the legislature and the public and a vote of 70 percent of quorum of

ICOC members to amend these enhanced policies once they are adopted.

The policies involve conflict of interest issues of the ICOC and of members of the Working Groups as well as meeting procedures and other matters. Since the Subcommittee meeting, we have had ongoing discussions with members of the ICOC and with members of the legislative staff about further improvements to the enhancements.

The enhancements that were passed on June 20 need some further work. On the other hand, we have our Working Groups already meeting, and we need some policy in place in order to deal with those meetings. So I suggest that we ask the ICOC to pass the enhancements recommended by the Legislative Subcommittee as interim enhancements so we can use them for the activities that are now in progress. Staff will amend these enhancements based on our discussions here and with legislative staff and bring back the suitably amended final enhancements, and pass those at the August meeting.

Changes we contemplate are as follows:

First of all, there are some inconsistencies with respect to both form and financial threshold among the different Working Groups with respect to their disclosure and conflict of interest. We would like to make those consistent, applying a \$5000 financial threshold of \$5,000 interest to all three Working Groups.

Second, With respect to companies that are privately held, if a Working Group member has a substantial position in equity or options in a privately held company, these may have a low or difficult to determine dollar value, but nevertheless may represent substantial conflict of interest.

Third, with regard to funding recommendations to the ICOC, what we need to decide on is exactly what information will be given about each grant application that comes. We need to try and balance the traditional and widespread policy of confidentiality of grant applications with our desire to be transparent.

Essentially, almost all granting agencies identify grants that are chosen for funding, but don't identify the ones not chosen for funding. Decisions are made in confidential sessions. In the case of the ICOC, the decisions are made by you, and it's done in a public session. This means it is not possible for us to maintain confidentiality of the applications, but we do not wish to have the full text of the applications made public in order to preserve confidentiality.

So we are working on exactly how to get you the information that you need in a way that preserves that confidentiality and in a way that also respects our desire not to embarrass people unnecessarily and not to identify the losers in ways that would be inappropriate.

I recommend we deal with these in separate pieces, starting with discussion on all the enhancements except conflict of interest for the ICOC and for Intellectual Property, which should be considered as separate items.

## **Motion**

- Dr. Henderson moved to adopt interim policy enhancements for the Working Groups.
- Dr. Friedman seconded the motion.

There was extensive board discussion and public comment made on this matter, including many suggestions taken by Dr. Hall with the plan to incorporate these in to the Enhancements following this meeting.

**Vote**

- All in favor; no opposition
- Motion carries

**Dr. Hall:** Now on the conflict of interest policy for the ICOC. We have a suggestion from David Baltimore that is to require board members and the CIRM President to divest themselves of or to place in a blind trust any investment of real property interest of \$2,000 or more in any publicly traded business organization that receives funding from or research contracts with the CIRM, and any publicly traded business organization that allocates more than 5 percent of the business organization's current annual budget in embryonic stem cell therapy. We wanted to bring these suggestions to the attention of the ICOC.

**Motion**

- Dr. Love moved that the ICOC advance the proposal Dr. Baltimore made and Dr. Hall put into language.
- Dr. Bryant seconded the motion.

There was board discussion, including:

- Concern about how it would work, the expense of making a blind trusts for surrogate members seeming excessive since they only participate occasionally, the seemingly low \$2,000 threshold and the fact that since funding from a research contract could include purchases of equipment, you don't know where the equipment is going to come from, it could include subcontracts and you don't know where the subcontracts come from.
- The need for recusal actually needing to take place after a decision to make a grant is made, putting something in a blind trust needing to happen after you know which grants get funded.
- Specifying "Human Embryonic Stem Cell" seeming to go against the intent.
- Adding a degree of complexity with regard to conflict of interest that's not going to have a real dividend.

**Dr. Hall:** I just want to make the comment that the CIRM did not participate in putting this together. It did come from the legislature. The CIRM is responsible for the Working Groups, but the ICOC speaks for itself. Curiously, it appears to be based on the policy that we put in place for CIRM staff.

There is no immediate need for this since we're not going to in the next month have grants from private industry before us, and in fact will not for several months. We could

take no action on this today and come back with something taking into account the discussion here.

There was some public comment made, followed by further discussion of tabling this matter.

**Motion**

- Dr. Steward moved to table the discussion of the ICOC Conflict of Interest Policy
- Dr. Prieto seconded the motion.

**Vote**

- All in favor; no opposition
- Motion to table the ICOC Conflict of Interest policy carries

**Dr. Hall:** The final issue on these enhancements has to do with IP. This was not addressed by the Legislative Subcommittee because of time, but the ICOC and CIRM remain concerned about it. We suggest the ICOC continue its good faith discussions and negotiations with the legislature and, in fact, would suggest adoption of this statement.

Dr. Hall read the statement.

**Motion**

- Ms. Lansing moved to approve statement.
- Dr. Wright seconded the motion.

**Vote**

- All in favor; no opposition
- Motion carries

**Agenda Item #11**

**President's Report, including:**

- **Consideration of meeting policy and procedures for Facilities Working Group.**
- **Consideration of bylaws for Grants Working Group.**
- **Consideration of bylaws for Standards Working Group.**
- **Consideration of CIRM Training Grant criteria.**
- **Consideration of development of Research Grant criteria.**

**Dr. Hall:** Dr. Hall provided a presentation including an update on the Standards Working Group meeting that took place on June 6, hiring the CIRM has done and the Scientific Meeting planned for October.

Also discussed were the Facilities Working Group meeting procedures, which were adopted as follows:

**Motion**

- Dr. Friedman moved to approve the Facilities Working Group meeting policy and procedures.
- Dr. Bryant seconded the motion.

**Vote**

- All in favor; no opposition
- Motion carries

**Additional Agenda Item:**

The Standards Working Group requested that the ICOC request that staff prepare for the next Standards Working Group meeting on August 30<sup>th</sup> an appropriate text for these guidelines that would put the guidelines into regulatory language and amend them as appropriate for the CIRM. They would then recommend the ICOC amend its previous motion by adopting the revised text. This would give the Working Group a starting document.

**Motion**

- Dr. Prieto moved that the ICOC consider this item.
- Mr. Sheehy seconded the motion.

**Vote**

- All roll call vote was taken to ensure there was a 2/3 vote to consider this item.
- Motion carries

The vote by the board to consider this item was followed by further discussion. It was then moved that the ICOC amend its previously adopted motion with respect to the NAS guidelines to now direct staff to prepare regulatory language in conformance with California Law to present to the Standards Working Group for its consideration and recommendation to the ICOC at its meeting in September.

**Motion**

- Dr. Prieto moved to approve consent items under agenda items 5, 6 and 7.
- Mr. Sheehy seconded the motion.

**Vote**

- All in favor; no opposition
- Motion carries

This vote was followed by informational discussions on bylaws for the Working Groups, which will be voted on by the Working Groups ahead of the ICCO, and also on criteria for Training Grants and Research Grants.

**Agenda Item #15**

**Consideration of establishing ICOC Governance Subcommittee to discuss**

**And advise the ICOC on items including:**

- **CIRM budget**
- **CIRM consulting contracts**
- **CIRM intergovernmental agency agreements**
- **CIRM organizational chart**
- **CIRM general financial and operating policies and issues.**

**Motion**

- Mr. Sheehy moved that the ICOC create a Governance Subcommittee including in its mission a review of outside third-party contracts. An amendment was added to have Sherry Lansing be the Chair of this Subcommittee, which was accepted by Mr. Sheehy.
- Dr. Wright seconded the motion.

**Vote**

- All in favor; no opposition
- Motion carries

**VOLUNTEERS:**

Sherry Lansing (CHAIR)

Phil Pizzo

Brian Henderson

Os Steward

Claire Pomeroy

David Meyer for Keith Black

Jeannie Fontana for John Reed

**Mr. Serrano Sewell:** keep composition of this Subcommittee as small as possible – 7 is a good number. Keep it small and focused.

**Agenda Item #14**

**Informational update on CIRM budget and consideration of Intergovernmental agreements and contracts policy.**

**Mr. Barnes** made a presentation on several budget related items, including the following that were voted on by the ICOC:

**Motion**

- Chairman Klein made a motion for adoption of Mr. Barnes' recommended policy with regard to Transportation Service with modification that if there is not airport you can access as closest distance, for sites in between major cities with airport transport, we allow this service to board members in those locations.

- Dr. Bryant seconded the motion.

**Vote**

- All in favor with the exception of Dr Pomeroy.
- Motion carries

The board also voted to approve reimbursement for meal expenditures beyond our Travel Policies in instances that require it, and as pre-approved by the CIRM Chief Administrative Officer.

This was followed by a presentation by Mr. Barnes on the CIRM budget and contracts, which included a healthy discussion by the board of expenditures and contracts currently in place.

Mr. Sheehy inquired as to the threshold for a contract approved by CIRM staff versus needing ICOC approval. A \$100,000 limit was discussed.

**Motion**

- Dr. Meyer made a motion that until the Governance Subcommittee is up and running, that the ICOC leave budget and contract decisions to Zach Hall and his staff.
- Chairman Klein seconded the motion.
- It was agreed to include that there is a \$100,000 ceiling for contracts, prospective from 7/12/05 so contracts already in place are not affected by this threshold.

**Vote**

- All in favor
- Motion carries

**Mr. Barnes** then made a presentation on the Operating Budget and fielding informational questions from the board.

**Dr. Hall:** We are about to engage in an IT contract. Labor charge of about \$2400; there will be over \$100,000 in equipment. We need to have our own IT system up and running, and want to do it before we make the move. It's mostly equipment, but in the name of transparency, I'd like to put it before the board.

**Motion**

- Dr. Meyer moved to change the past motion, with the \$100,00 contract cap, so Dr. Hall would not be limited in dealing with the IT contract. The specific suggestion was to remove the restriction, just deferring until the Governance Subcommittee can meet and work on this.
- It was suggested by Chairman Klein that there be a friendly amendment stating the \$100,000 applies to service contracts and that amounts for equipment, for example, not be subject to the limit.
- Dr. Wright seconded the motion as amended.

**Vote**

- All in favor with the exception of Mr. Sheehy.
- Motion carries