

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

**April 7, 2005 ICOC Meeting Minutes**

Metropolitan Water District of Southern California  
Board Room at Headquarters Building  
700 North Alameda Street  
Los Angeles, CA 90012-2944

**OPEN SESSION**

**Agenda Item #2**  
**Spotlight Presentation on Liver Disease**

***Presentations on Liver Disease and the experiences of liver disease and transplant patients were presented by the following speakers:***

- **Ronald W. Busuttil, MD, PhD**
- **Gerald Lipshutz, MD**
- **Nori Kasahara, MD, PhD**
- **Rhea Meshekow, Liver Patient**
- **Amy Wang, Liver Transplant Recipient**
- **Jackie Colleran, RN, Liver Transplant Recipient**

**Roll Call**

David Baltimore	Present
Robert Birgeneau <b>Surrogate: Dr. Mary Burnside</b>	Present
Keith L. Black	Present
Susan V. Bryant	Present
Michael A. Friedman	Present
Michael Goldberg	Absent
Brian E. Henderson	Present
Edward W. Holmes	Present
David A. Kessler	Present
Robert Klein	Present
Sherry Lansing	Absent
Gerald S. Levey	Present
Ted W. Love	Present

Richard A. Murphy	Present
Tina S. Nova	Absent
Ed Penhoet	Absent
Philip A. Pizzo	Present
Claire Pomeroy	Present
Phyllis Preciado	Present
Francisco J. Prieto	Present
John C. Reed <b>Surrogate: Jeanne Fontana</b>	Present
Joan Samuelson	Present
David Serrano Sewell	Present
Jeff Sheehy	Present
Jonathon Shestack	Present
Oswald Steward	Present
Leon J. Thal	Present
Gayle Wilson	Absent
Janet S. Wright	Present

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

**CONSENT ITEMS**

***Agenda Item # 5***

***Consideration of Per Diem Travel Expenses Reimbursement Policy for ICOC and CIRM Staff.***

***Agenda Item # 6***

***Approval of minutes from February 3, 2005 meeting.***

***Agenda Item # 7***

***Approval of minutes from March 1, 2005 meeting.***

- A letter received 4/6/05 from Jesse Reynolds/Center for Genetics and Society, regarding the CIRM response to the Halpern/Lee petition, was read aloud by Dr. Friedman.

**Motion**

- Motion to approve consent calendar items: Dr. Levey
- Second: Dr. Friedman

**Vote**

- All in favor
- No opposition
- Motion carries

***Agenda Item # 8***  
***President's Report***

- Dr. Zach Hall presented his report on activity inside the CIRM, including:
  - Developing an organizational chart
  - New hires and planned hires
  - Consultants found to help with grant processes, IT needs and more
  - Budget planning
- Immediate hiring needs identified include:
  - Scientific Program and Review personnel
  - Grants Management
  - Information Technology
  - Human Resources
  - Director, Office of Communications

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

- Dr. Arlene Chiu was hired as Director, Scientific Program and Review
  - Dr. Chiu is a developmental neurobiologist
  - She was an NIH funded researcher at City of Hope
  - She had served as the head of the NINDS Stem Cell and Spinal Cord Research Program
  - She received the 2004 NIH Director's award for outstanding contributions to development of stem cell research at NIH.
  - She was most recently serving as Deputy Director, Office of Research Administration, NIBIB
- Alexandra Campe was hired, on loan, from UCSF Human Resources
- Consultants identified to help the CIRM include:
  - Constance Atwell, PhD, to help with Scientific Program and Review
  - LMI, Government Consultants (non-profit), Ellen Angus and Diana Jaeger, to write CIRM Grants Management Policy
  - Diane Watson, to establish CIRM Grants Management Office
  - David Kingsbury, PhD, consultant to do pro-bono work on IT system for grants review; from Moore Foundation

**Question:** from Dr. Levey regarding Grants Management – where we're getting model, lots of institutions

**Answer:** HHMI, UC, with David Kingsbury and Grants Management team will assess an online system; thought about outsourcing but decided not to because:

1. Grants management must be closely tied to scientific programs
2. We have grave responsibility to spend funds well, they're accounted for and we manage them in the right way and I'm reluctant to give to 3<sup>rd</sup> party at this point. We need to be in charge of setting it up, know what's happening, be accountable, not having to ask someone else how something happened – we need to know ourselves.

**Question:** from Dr. Pizzo: What do you mean by awarding grants in Sept.? Training Grants?

**Answer:** Yes. Other cycles will follow with lag.

**Question:** from Dr. Preciado in 2 parts

1. What kind of outreach efforts are you doing with regard to diversity of the state?

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

**Answer:** Dr. Chiu was hired after a search that included exploring 11 candidates. 2 were interviewed and she was hired.

2. What are you doing with regard to parallel efforts to educate the community, i.e. on "what is a stem cell" for community in addition to scientific/grants route?

**Answer:** We would like to see a very active campaign of education to the public and disease advocacy groups. Have ideas, premature, but want to make available as quickly as possible any research done, explained in lay terms. Explain what SCR is and help public understand the road to therapy is long and diff; won't happen over night.

An agenda setting conference is in the works for late summer, with a communications arm at end of each day – scientific and then lay. We need to move the science out front and talk about it in terms that lay people understand.

**Dr. Preciado:** I'd like to push for a box on the org chart, someone hired to do this.

**Chairman Klein:** We do need to help the public understand translational research, the open meeting process and more.

**Dr. Pomeroy:** With regard to the Org Chart, staff should report to President for HR and are assigned to board for activities

**Dr. Baltimore:** financial people reporting to Chairman...no indication on chart that financial people report to Chair; CFO would report to president?

**Answer:** The Chair is charged with sitting on the finance committee with the Director of Finance to work on bonds.

**Dr. Pomeroy:** Chair isn't an employee of Institute, correct? Is it a paid position?

**Chairman Klein:** I am an employee. I haven't yet asked for compensation.

**Dr. Hall:** Chair and Vice-Chair are employees of the Board, and elected by the board. They don't count against the 50 total staff count.

**Dr. Henderson:** Everyone should be hired by Pres. Office and then assigned to Chair and board. This way, you don't set up parallel employee operations.

**Chairman Klein:** we are following your procedure – ethics and HR are all done under the President's auspices.

**Dr. Pizzo:** This topic – staying on it is important because it will stand for years to come. There needs to be clear separation between staff and the board, which has fiduciary oversight. Making these things crystal clear is important.

**Dr. Baltimore:** The arrow coming down from ICOC doesn't capture the structure. The Chair should be shown as reporting to the board. Problem: don't know where to put the ICOC on this chart.

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

**Joan Samuelson:** candidates should understand – presidential – that they'll be able to shape the staff.

**Dr. Hall:** yes, but the CIRM also needs staff now to get things going. We have applications pouring in. The biggest question is where we will be. We need to know that before hire many more people. That's biggest constraint now.

**Joan Samuelson:** Out of fairness to hires, they should know there will be a new Pres. is coming in.

**Dr. Love:** We need to make sure we try to get a clear proposal for chart to you. I recommend we take ICOC off this chart, start with the President and staff. All employees should report to the President. Some staff have duties in support of Chair and Board, and will get assigned to that. We don't want 2 populations of people in the CIRM.

**Dr. Pizzo:** How about we modify this – it's OK to have more than 1 chart. Dr. Love is describing the CIRM. We need to have something showing the relationship of ICOC to the Institute as well, showing board having oversight.

**Chairman Klein:** to fulfill my functions, I need separate chart so I can set priorities – finance, board support, etc. Need to be able to manage their time and activities to fulfill my role.

**Dr. Murphy:** The relationship between the President and the Chairman is still not clear in my mind. Are we restricted by Prop 71? The ICOC should deal with both the Chair and President, but not as two co-equals. This sets up the wrong dynamic.

**Chairman Klein:** The President must give a report at every ICOC meeting; the President and the board must have direct relationship.

**Zach Hall:** The President should report to the board. The Chair is on the board. One of the people the President reports to in reporting to board is the Chair – along with all other members of ICOC.

**Dr. Thal:** Have the ICOC at the top of the Org Chart, then lines down for Chair and President – we are an active board.

**Chairman Klein:** We have great input. Let's bring this back specifically at next meeting, agendized.

**ACTION ITEM: RE-WORK ORG CHART. PUT ADDITIONAL INFORMATION BACK IN THERE. WE WILL BRING AN UPDATED ORG CHART BACK, AGENDIZED AT NEXT MEETING.**

**Question:** From Jeff Sheehy – do we have a strategic scientific plan and timeline for grants?

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

**Dr. Hall:** I'll address that at May meeting – we do have problem of having sense of urgency and also wanting to do things in the best way. We won't direct everyone's research, but there may be critical elements in the process – tech infrastructure., grant design to help move process along. None of these would be the only element in our program. We'd use it to adjust and modify and make portfolio more sophisticated. Need to have results of May 6 meeting. Want some more directed efforts as part of our portfolio. Let's discuss in May.

**Dr. Pomeroy:** What about Training Grants?

**Zach Hall:** I will present that later, it's on the agenda today.

***Agenda Item # 9***

**Consideration of Conflict of Interest Policy for ICOC Members**

The ICOC discussed point number one and footnote number one of the policy at length, working to develop the best possible language for this important part of the policy. After the initial discussion, a motion was made to approve the policy with a suggested amendment. Following the motion and second, the amendment was further discussed in great depth.

A recommendation was made to amend point number one to read "Members of the ICOC shall not apply for or receive salary support through grants, loans or contracts from the ICOC, nor shall they act as a Principal Investigator."

A recommendation was made to amend footnote number one to read "Senior Academic officers (including, but not limited to, presidents, deans, department chairs and executive officers of research institutions.)

**Motion**

- Motion to approve with amendment: Dr. Henderson
- Second: Dr. Friedman

**Dr. Prieto:** Can we have a restatement of sentence as it will read? Words are important. Public perception is important. The regular responsibilities of people on the ICOC put them in these positions.

**Dr. Pomeroy:** this is a conversation we started at last board meeting. It's tricky. Let's discuss further #1 on this Policy. The implication is that being Principal Investigator is precluded, but being paid co-investigator or otherwise involved is not precluded. No ICOC member should be listed as investigator or part of team submitting grant. You could get around not being able to be Principal Investigator by a putting junior person on the project and calling oneself co-investigator.

**Chairman Klein:** Points 2, 3, 4 and 5 of the draft policy address that issue. I'll ask Dr. Hall to address this concern.

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

**Dr. Hall:** We need to be very careful. The public doesn't share the amount of knowledge we have. The ICOC may have to make sacrifices to have a policy that makes the public comfortable. To have anyone on this committee materially assisting in prep of grant is not appropriate; association with a grant – have to be very careful about what it is, state in way there is no doubt.

**Dr. Pomeroy:** I want to reinforce what you're saying. I want to make sure we match up the language to what you just said.

**Dr. Bryant:** Why are we taking this position instead of the NIH position which is for recusal when necessary? The way we have this now is punitive for some of the people on this board. No connection to the funding can be made, but other way works at NIH.

**Dr. Hall:** We're a smaller community and we struggle every day with public perception of how we operate. We need to err on the side of being careful. Hardship to ICOC members is a relatively small price to pay in the name of perception.

We are not here to fund grants that anyone on ICOC can profit from financially or professionally.

**Dr. Levey:** I agree with Zach. The state gave us \$3 billion. We knew coming on board that CA has very strict rules. There are a lot of people very concerned about what we do. Just keep ICOC members out of the process, period. If you want to sit on this board, you're out of the process, period.

**Chairman Klein:** Quite correct, and we're trying to do it carefully so it's not mistaken that the normal duties of a Dean. – allocation of lab space, etc. – want them to be able to allocate space and help SCR in their institutions. That's not material participation in a grant. Those are functional in their institutions.

**Dr. Preciado:** appreciate what you said, Dr. Hall. I hope it gets into the language of the Policy. All of us on board have level of knowledge about what's going on that community can't. We know what's going on – we report it back to our Institutions. This is a benefit. We have a position of power. Needs to be acknowledged and recognized. We need to remain above board.

**Dr. Prieto:** I strongly endorse what Dr. Hall, Pomeroy and Preciado said. We're all getting benefits from being here, and are also making sacrifices to be here. We need to make it clear we will in now way personally benefit.

**Dr. Friedman:** I support this too. I'm not actively engaged in research now, though I know this would be a sacrifice for others who serve on this committee. Actual Conflicts of Interest would be very small or non-existent. It's public perception that is the problem. We can never completely get rid of the perception of there being a conflict of interest. This causes me some sadness because there are talented investigators on this committee that will be affected.

**Dr. Steward:** I support notion of not allowing ICOC to be listed as participant for grant. Where I have trouble is I that I am still an active researcher and will be collaborating with my colleagues. I hope this policy won't preclude me from participating in this science,

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

authoring papers, etc. Is there a way to modify the doc so it doesn't exclude me from this? Others on the board could be affected when we move into clinical investigation.

**Jeanne Fontana:** I'm a Representative of Burnham and surrogate here for Dr. Reed, who would be affected by this. Reed is a world renowned scientist.

**Dr. Pomeroy:** I can't vote on it the way #1 is written now. It isn't adequate. I won't vote on it.

**Dr. Hall:** what wording would cover your concerns?

**Dr. Pomeroy:** "nor shall they act as key personnel..." or something like that.

**Dr. Pizzo:** The public wants to know "is this person funded or not?"

**Dr. Baltimore:** this organization is taking a stance in direct opposition to NIH. I was willing to let that happen. If I reach the point where I wanted to be involved in a grant, I would leave the committee. But for the moment I don't have to worry about it. Fundamental change with #1: to a view that non-peers make decision about funding (as opposed to having peers – people doing the science – making the decisions). The value of having people actually involved in the science is huge for this ICOC. I am philosophically not in tune with what #1 says, in my view of how scientific community should work.

**Dr. Henderson:** I support what Dr. Baltimore just said. The tone of the comments may be such that I would have to resign from the committee as well. My work in scientific investigation – would have to be so careful no to cross. And then it becomes "moral" – if it becomes a discussion about a moral issue, that makes me very uncomfortable.

I accept we should not be funded investigators. Beyond that, it's going to far.

**Dr. Baltimore:** Could we say funded or salaried? Funded – your pipettes? Or are we talking about salary. Let's use "salary".

**Dr. Black:** We're talking about conflicts of interest for individual research grants. Another part of the initiative is to build facilities. This could lead to conflict of interest as well. What will be our policy when we award grants to various centers, to avoid public perception of conflict of interest?

**Chairman Klein:** Individuals have to recuse themselves from grants from their own institutions. The also can't actively influence board on behalf of their institution.

**Dr. Levey:** We are not serving any particular institution, we're serving the state. This has nothing to do with our roles at our universities or institutions. We need to be squeaky clean. I discussed with my Chancellor before coming on...we're establishing a stem cell group at UCLA, and I can't be on it.

Bob Klein: We need a strong starting point. We will have public hearings, including on this topic. But we need a strong starting point.

Insert "SALARIED INVESTIGATOR" for "PRINCIPAL INVESTIGATOR"

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

**Motion**

- Dr. Pizzo to vote on it as amended
- Second: Dr. Friedman

**Vote**

- All in favor
- No opposition
- Motion carries

***Agenda Item # 10***

***Consideration of Conflict of Interest Policy for CIRM Staff***

It is important we have strong Conflict of Interest policies in place.

We need to go beyond the Incompatible Activities statement passed at last ICOC meeting. We are therefore adding to that this proposed Conflict of Interest policy for CIRM staff.

**Dr. Prieto:** Exception regarding single talks or presentations – can we put that in the document? Would be good to have it in there.

**ACTION ITEM: ADD EXCEPTION REGARDING SINGLE TALKS OR PRESENTATIONS**

Dr. Baltimore: one part of this bothers me – “is or has been a professional associate” – in #3.

**Question:** What does in mean to participate in a review?

**Answer/Dr. Hall:** Staff will be present at Working Group meetings – won’t “participate” but will take comments of WG and summarize them for ICOC. Won’t be people with long careers in labs – will have moved mid-career into Admin. Or have done brief post-docs.

Prieto: Does this apply to direct collaborators?

**Dr. Hall:** Yes, refers to direct collaborators. I would not want to review a grant from a former student of mine.

Presidential Candidate would have to be advised

**Motion**

- Motion: Dr. Friedman
- Second: Dr. Wright

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

**Public Comment**

**Charles Halpern:** I want to comment on how many appropriate standards are in this. Your suggestion, Mr. Chairman, of a small committee to work on this and bring a stronger document back to the next meeting. Not a huge delay, just bring a stronger doc to next meeting.

Unnecessary Restrictions: employees may not participate in grant or facilities review for any inst. – should also apply to after grant awarded, the monitoring of the grant recipients.

**Dr. Hall:** Let me explain how policy would work in practice. Right, employees wouldn't know who replied unless involved with review.

**Dr. Phil Posner:** Item #6, you state "for any institution engaged in stem cell research" – maybe want to say just engaged in state of CA b/c they would be a resource for other states and countries. Financial Perspective: grandfathered, put in holding accounts. Also, if have name on patent, can't divest from having name on patent.

**Dr. Hall:** Putting it in blind trust would be an acceptable amendment. So is "in the state of CA". We also need to add "contracts". We can ask people if they have patents. It's a Q of who holds the patents...would have to give that some thought.

**Chairman Klein:** we can address PATENT issue in public hearing, specifically agendized.

**Dr. Hall:** Other suggestion by Mr. Halpern – can put that in, need help with wording

**Charles Halpern:** suggestion applied to monitoring, but was illustrative only...

**Dr. Hall:** Maybe we want to take that up later.

**Chairman Klein:** dynamic tension: need to illustrate to public clearly which direction we're going. Create good standards immediately, BUT these are interim standards. We will have public hearings on them to improve them.

Dr. Hall thinks it's important to have these adopted now.

We have a motion to approve and a second.

**Susan Fogel:** wanted to draw attention to fact this is only limited to stem cell therapy. The Initiative says "other vital research"...

Dr. Hall: It's clear we will be focusing on stem cell research for the immediate future. If a grant application comes in for something else, then we'll address that at that time.

**Also, we need to add to amendment: GIVING TALKS, ONE TIME**

**Dr. Steward:** trying to work here on the fly...that's the way we have to work b/c we need rules. The only time we can discuss it in open meetings.

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

**Chairman Klein:** The public markup of the document, right here in the meeting, shows the public the entire process. That's the intent of Bagley-Keene.

**Vote to approve policy as amended**

- All in favor
- No opposition
- Motion carries

***Agenda Item # 11***

***Consideration of policies for Working Groups, including confidentiality, meeting format, conflict of interest, compensation and chair positions.***

Presentation made by Dr. Zach Hall, including the following:

- CIRM recommends to ICOC to keep Grant Working Groups meetings CLOSED.
- Standards Working Group is a little different. Proposition called for closed meetings. Halpern and Lee want these to be open. This is a possible choice for the ICOC.
- Middle Ground: combination of open and closed meetings, like what NAS does. Do this for POLICY ISSUES. Committee formulating standards for stem cell research at NAS. Richards Hynes and Jonathan Moreno are co-chairs. I included letter from them in the information you have.
- Reasoning behind closed meetings: sometimes people change their minds on these issues once they hear from colleagues – it's part of the discourse. This is harder to do when initial conversation is done in public.
- One possibility is to have public sessions, then have closed, deliberative sessions. Hold open sessions, which are data collecting sessions. Then the group goes into a closed session.

Chairman Klein: We could merge the two like the NAS model – public hearings then closed sessions. Under our initiative, after we have interim standards, we have to publish everything and adopt everything at a public meeting.

- Conflict of Interest for Grants Review WG: before any review, WG members asked to look at list of grants and identify any with which they have a conflict, and recuse themselves from those discussions.
- Conflict of Interest for Standards WG: if have conflict, will be discussed with CIRM staff members and they will be asked to DQ themselves from service on the WG.

Recommendations for Working Group Chairs are very important. The Working Group chairs will work with CIRM staff to organize everything, will run the meetings, etc. These people need to be in place before the first meetings of the Working Groups. We ask the

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

Subcommittees to propose Chairs when they propose their slates for the Working Groups.

**5 Resolutions:**

1. Confidentiality
2. Meeting Format
3. Conflict of Interest for WG Members
4. Consulting Rate/ Payment
5. Chairs

**Dr. Levey:** I agree with Henderson, great job on all this. Will all the meetings be in CA? This came up at least twice on teleconferences, with regard to subcommittee meetings.

**Dr. Hall:** we will give geographical relief to our East Coast colleagues. We really need participation of the very best people in the country on these working groups. None of them are eligible for funding. We're trying to persuade them to participate, and we'll do everything we can to attract them and be respectful on their time. We can have regional meetings and do teleconferences if necessary.

**Dr. Levey:** Could we pay them \$1000 day Consulting Fee? They have no stake in this...

**Dr. Hall:** Have to balance it – it's complicated -- \$500/day seemed adequate, but I'm open to suggestions.

**CONFIDENTIALITY**

**Dr. Kessler:** There is no question regarding confidentiality with Grants Working Group – the argument is compelling. For Standards Working Group, I don't see compelling case to have any of the meetings closed, so I'm not sure a combo works. Please expound.

**Dr. Hall:** I talked to Richard Hynes; they dealt with same issues. They felt discussion out of public limelight was essential.

**Dr. Murphy:** NIH study groups, have sanctions in place. Do we have to worry about plagiarism? NIH mechanism: if someone takes idea from process, the NIH could sanction them.

**Dr. Hall:** We can add this language in. It's a good, but minor, addition.

**Dr. Prieto:** Would the committee consider and mixed model of open meetings for the Grants committee as well?

**Dr. Hall:** This would be covered in the context of the open ICOC meetings at which grants were discussed. We do not need a second public meeting (Although the Disease Advocates on the Working Group can bring some of the same public point of view

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

**Chairman Klein:** We have a responsibility to protect intellectual property—it is the intent to discuss policy issues at the Board level.

**Dr. Prieto:** Only qualified grants would come to the ICOC level of review?

**Dr. Hall:** If we had a round of funding (40M) the Grants Working Group would bring to the ICOC 50-60M in grant proposals — it would be up to the ICOC of what to ultimately fund.

**Dr. Steward:** To what extent would the WG discussion be available to the ICOC?

**Dr. Hall:** In order to protect confidentiality, we would have summaries of the comments.

**Dr. Pomeroy:** It may not be clear to the patient advocates of what their role will be in the Working Groups. Many feel uncomfortable covering the science. What is the point of having Advocates in the Review meetings if they can't speak to scientific merit

**Dr. Hall:** There will be a technical discussion of grants among the scientists (referenced model of the Defense Department grants) In my experience the Advocates serve to speak to the impact of the science on disease mitigation. This all needs to be worked out but the question before us is will these meeting be open or closed.

**Dr. Levey:** This Board cannot consider grants item by item

**Dr. Hall:** This is complex and will be dealt with later.

**Dr. Preciado:** As a patient advocate, I am in the trenches and do have a perspective that can contribute to the review process

**Chairman Klein:** There are many national examples of disease advocate contribution to review committees.

**Dr. Hall:** Getting back to whether these committees should operate in open or closed meetings. There is value to both models for the Standards Working Groups (The Grants Review Committee should definitively be closed)

**Joan Samuelson:** Two considerations. One is Bagley-Keene obstacle that serves to impair the work of this committee, such as not being able to talk to each other freely without the burden of travel etc. This is a strong argument for closed meetings to optimize the talent on this committee. The second argument in favor of closed meeting is that each member feels free to speak freely without the embarrassment or confusion of making public announcements.

**Dr. Bryant:** I would tend toward open meetings

**Dr. Friedman:** I would recommend entirely public meetings. Because of the intense public interest in these issues

**Dr. Steward:** Regarding informed consent: one can imagine a situation in which detailed medical procedures might be discussed—this raises the concern of preserving patient

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

privacy in these discussion. To, at least, have the option of having private meetings would be valuable.

**Chairman Klein:** When you get to clinical trials where there is private company involvement—private meetings would insulate reviewers from the influence of private lobbying

**Jeff Sheehy:** I feel strongly that the standards working group be conducted in public. As someone who has worked in open meetings, believe we could capture for the public everything that is discussed and is given a summary statement as long as people are given a clear opportunity to give public comment. We should look at some of the model that exist and create a hybrid model (not the NAS model which “slaps the public in the face”) and come back with a workable model.

**David Serrano-Sewell:** There are various requirements of Bagley-Keene. For the Standards Working Group, we can find a hybrid that gives a weight towards public access BUT those issues that the Working Group wants flexibility on, I think it is very relevant to have members have the opportunity to work from home if they wish to which is not allowable per Bagley-Keene.

Chairman Klein: Once the advisory group has its recommendations, the Public meeting act is put into play, and the ICOC then votes on final standards.

Dr. Kessler: Agree with Sheehy and Serrano Sewell. The presumption should be that the meetings are open Some exceptions that have been mentioned: patient protections, competition, and efficiency may be exceptions to the rule of having an open meeting exclusively. The spirit of this committee should be to have open meeting with the understanding that there will be exceptions.

#### **Motion**

- Motion to endorse this model: Dr. Kessler.
- Second: Dr. Wright

**Jon Shestack:** This is an onerous Working Group. Having consistent public comments is an added burden. There should be some period of insulated time for this Working Group to work—there could be some scenario where interim drafts of the Working Group are provided to the ICOC and the public.

**Dr. Hall:** The position here is clear—we want neither exclusively open or closed meetings. The hybrid model will be discussed with counsel and staff and will be considered

#### **CONSULTING RATE**

**Dr. Steward:** second Levey's comment about having rate be \$1000/day. We're asking a lot of them. Really need to get the very best people. To get highest quality reviewers, this would help.

**Chairman Klein:** if we pay them for travel, does that solve the issue?

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

**Dr. Hall:** Individuals may be called on to be Primary or Secondary reviewer on 10 grants. Takes 5 days per grant to review, consider and come up with type written comments.

**Jon Shestack:** plus they have responsibility to review all the grants, not just ones for which they're primary or secondary reviewer.

Dr. Prieto: what is the going rate at NIH, Hughes, etc.?

Answer: NIH = \$150/day; Hughes: \$500/day? But they can qualify for NIH grants.

**Dr. Baltimore:** reviewers at Howard Hughes are people not entitled to get money from Hughes. People don't complain about how much they get for this work. \$500 a day may even seem like a windfall, excessive. To really pay people for their time, you'd have to have a lot of money – a consulting fee that Bristol-Myers would pay someone. You're doing just fine at \$500. The scientific community is quite comfortable to help each other out.

**Dr. Love:** #1 reason people will want to be involved is because of commitment to stem cell research and what it can bring. Whatever we give them is a token to acknowledge their participation.

**Dr. Thal:** not a single person has asked how much they'll get paid. They ask how much TIME it will take. 10 grants per individual for Training Grants. May be hundreds when we get to other types of grant proposals – scientific grant proposals.

**Dr. Pomeroy:** \$500 for clerical support is important – I'm glad it's in there. Can we reimburse ICOC members of Working Groups for clerical support?

**Answer:** Yes, we can provide clerical support to ICOC members.

## WORKING GROUP CHAIRS

**Jeff Sheehy:** Advocate decided not appropriate for ICOC; came up with hybrid - Advocate Chair, Scientist Vice-Chair.

We don't have rules or procedures; Working Group Chair won't fill out Form 700. Should have someone from ICOC serve as Co-Chair for each WG – a patient advocate.

**Dr. Murphy:** We really run the risk of this committee getting involved in operations rather than overseeing. Having ICOC in that strong a role on WG would change dynamic of what ICOC does.

**David Serrano-Sewell:** If we don't have Co-Chair, we'd have a non-Californian Chair for the Grants Working Group.

**Dr. Hall:** The Chair presides. The Chair helps choose primary and secondary reviewers. CIRM staff can advise who published on a particular COI issue. Jeff's idea is an excellent one. Co-Chair to help work out procedures – no to deal with primary and secondary reviewers, etc.

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

Mentioned to NIH review team member that there would be patient advocates on Working Groups and they said well then there won't be two separate levels. Co-Chair as patient advocate to help organize WG and have a sense of participation, I'd support.

**Chairman Klein:** Question for Dr. Hall: do we have the ability to take a proposal and have certain parts of the Chair function involve a Co-Chair? Two step review: best science, then review involving Patient Advocates – already a 2 part review that goes on.

### **PUBLIC COMMENT**

**Diane Winokur:** ALS advocate; one suggestion re. Scientific Review WG. Could Advocacy membership revolve? Several illnesses are unrepresented for as long as these advocates are on it. Could advocates for each particular grant be illness-appropriate? Concern: some individuals and orgs that could not defeat Prop 71 at the polls and are attempting to now by nitpicking and grandstanding. Those of us who supported the Prop and support you now will NOT continue to be silent.

**Janitors Union:** please improve area standards for janitors.

**Chairman Klein:** please keep to issue at hand, about to lose quorum.

**Jessie Reynolds:** ask you to reconsider policy for Grants Working Group. 4 of the 7 responsibilities to not involve Peer Review of grants but instead policies.

**Susan Fogel:** support suggestion to have shorter terms for some of the Working Groups. Also emphasize those of us who are involved b/c this is the democratic process. Suggestion: could be some subcommittees looking at some of these issues, and we'd be happy to participate.

Charles Halpern: comments re. Appendix E, Prop 59 giving high prior to open meetings, open meetings of Standards WG.

### **MOTIONS AND VOTES ON WORKING GROUP ISSUES**

#### **1. Confidentiality for Peer Review Process – approval of policies presented**

- Motion – Dr. Friedman
- Seconded – Dr. Baltimore
- Approved

#### **2. Closed Format for Grants**

- Motion: Dr. Baltimore
- Second: David Serrano Sewell
- Approved

#### **3. Meeting Format**

- Not voting on this now.
- Committee members to give suggestions, limited to conform with B-K are:

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

- Sheehy
- Prieto
- Steward
- Samuelson

**4. Approval of Conflict of Interest policies for Grants Review**

- Motion: Dr. Baltimore
- Second: Dr. Levey
- Approved.

**5. Conflict of Interest Policy for Standards Working Group**

- Motion: Dr. Love
- Second: Dr. Levey
- Approved.

**6. Consulting Rate – per diem of \$500**

- Motion: Joan Samuelson
- Second: Phyllis Preciado
- Approved.

**7. Request nominees for Chairs – need to rethink Co-Chairs.**

- Motion to consider Chairs: Joan Samuelson.
- Second: Dr. Steward
- Approved.

**ACTION ITEM: MAY 6 ICOC MEETING: PLAN TO DISCUSS ISSUE OF HAVING PATIENT ADVOCATE SERVE AS CO-CHAIR OF EACH WORKING GROUP.**

***Agenda Item # 12***

***Consideration of Proposal for CIRM Training Grants Program for future stem cell researchers.***

Briefly touched on then tabled until 5/6 ICOC meeting.

***Agenda Item #13***

***Consideration of charging Institute staff with developing a proposal for CIRM Research Grants Program to be considered at the 5/6 ICOC meeting.***

Tabled.

***Agenda Item # 14***

Closed Session

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

***Agenda Item # 15***

***Report back from closed session if needed.***

No report required.

***Agenda Item # 16***

**Consideration of resolution: requesting the California Stem Cell Research and Cures Finance Committee to approve the issuance of bonds, in an amount not to exceed \$3 billion, pursuant to the California Stem Cell Research and Cures Bond Act of 2004 (Proposition 71); authorizing application to the Pooled Money Investment Board for interim financing in relation to such bonds; and delegating duties to the Chairman in relation thereto.**

**Tamar Pachter/AG's office:** This is a preliminary request to issue bonds is from Finance Committee.

**Public Comment/Questions**

Question: Litigation - if it is to slow down process, why was it first filed in Supreme Court on expedited basis?

Answer: They knew the Supreme Court rarely heard such cases. Now it's in Superior Court. They likely know we'll use Validation Action next.

**Motion**

- Motion to have process move forward: Dr. Henderson
- Second: Dr. Friedman

**Vote**

- All in favor
- No opposition
- Motion carries

***Agenda Item # 17***

***Consideration of status report from Standards Working Group Subcommittee***

Tabled.

***Agenda Item # 18***

***Consideration of status report from Grants Working Group Subcommittee***

Tabled.

***Agenda Item # 19***

***Consideration of status report from Facilities Working Group Search Subcommittee***

Tabled.

***Agenda Item # 20***  
***Consideration of status report from Site Search Subcommittee***

*Report from Rebecca*

*CO, WB and ADR worked with DGS team – not Chairman, Pres or Vice-Chair.*

*Bob: thanks to DGS for leadership in this process.*

We are grateful for leadership in major cities and regions for putting forth tremendous proposals, including some with free rent.

Subcommittee meeting on 4/13 – report made public prior to meeting with regard to evaluations.

Centers of Excellence can bring forth great collaboration. Cooperation of cities for site should be taken into consideration by this board. Initiative calls for priority to move proposals through quickly since policies at federal level have been inconsistent.

Pomeroy: we will do site visits very quickly. 2 weeks. Will each site get 2 site visits by teams of 2?

Bob: need to abide by B-K. If cities take over responsibility of coordinating with board members this allows more flexibility for subcommittee members.

Jane/San Diego: submitted a list of Q's, know process is going fast, just want to effectively address what you need IDd and done.

Bob: they were excellent Q's.

Process is 2 fold: DGS to respond to Q's they can; Site Search Subcommittee will have to respond to the others, and that will be done on 4/13.

Q: will you be making Q's public and the answers? Freedom of Information Act.

**A: Q's referred to by San Diego letter – on web site with answers DGS provides, then after meeting, answers from Subcomm will go up too.**

AGENDA ITEM # 4 for May 6, 2005 ICOC Meeting  
**DRAFT**

Making proposals public: made avail. to Sac Bee, available by request. DGS makes all decisions CONFIDENTIALLY. They are modifying their protocol for US to make it as open as possible.

We've asked cities to make their apps available to the press and the public.

At meeting on 4/13, will be full list of all cities and a full staff report.

We're in a specific process with DGS. We're not in a position to know which proposals remain on the list and which were DQ'd.

**Question:** Dr. Pomeroy, for Dr. Hall: Conflicts of Interest for Facilities – when will we have it?

**Dr. Hall:** We're still figuring out how Grants and Facilities Working Groups will work together. The CIRM won't give facilities grants without evaluating the science. We need to define task of the Facilities Working Group, and can then do Conflicts of Interest. It likely will resemble most closely the Grants Working Group Conflicts of Interest policy.

**MAY 6 MEETING: ZACH HALL WILL BRING BACK PROPOSAL FOR SEED MONEY GRANTS/INFRASTRUCTURE/TRAINING GRANTS. AGENDIZE.**

***Agenda Item # 21***

***Consideration of status report from Presidential Search Subcommittee.***

Tabled.

**PUBLIC COMMENTS**

**Statement from Janitors Union:** Some companies have striven to meet needs, to give basic healthcare and fair wages, not hide behind subcontractor. This includes Genentech. Public money should not go to subcontractor who does not treat its employees well.

**Susan Fogel:** Is there an operating budget? If not, will this be addressed in the content of an overall operating budget?

**Chairman Klein:** Yes, that is the intention.

###