

Friday, September 9, 2005 ICOC Meeting Minutes

Sheraton Grand Sacramento
1230 J Street
Sacramento, CA 95814

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

Agenda item #5

Approval of minutes from August 5, 2005

Motion:

- Dr. Wright moved to approve the minutes.
- Dr. Levey seconded.

Vote:

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

Agenda item #6 Chairman's Report

Chairman Klein: In deference to the fact we have the historic opportunity today to advance the first round of grants, I'm going to make it very short. On a historic basis, if we look back at frontiers of medical research, I think we would be hard-pressed to find as a precedent a model with the scale of intellectual infrastructure and training program that is coming before us today. The scope of California's institutions and its universities, its research hospitals, and its research institutions is unprecedented. It is remarkable that California has assets of this intellectual quality and breadth, and we are the beneficiaries of those great institutions in the proposals we have before us.

Hopefully with a favorable approval of the program today, we will launch an intellectual training program that will be a model for the nation, that will be a model certainly for California, and for the study of new frontiers of medicine for the future.

With that, I would like to turn it over to Dr. Zach Hall for the President's Report and to advance our agenda.

Agenda item #7 President's Report including, but not to:

- **Informational update on the CIRM Scientific Meeting taking place Oct. 1-2**
- **Consideration of CIRM/ICOC Organizational charts**

Dr. Hall: We have defined our short-term priorities. And among those are, number one and most importantly, raising bridge funding, number two, putting our infrastructure together so that when the funding becomes available, we will be able to not only award the grants, but send grant money out, and number three, we have a very important move coming up in early November.

We have prioritized our personnel and hiring, and I want to announce the hiring of two new very important appointments: Julie Kaye, who is here, who is the senior executive assistant to the Chair and will provide help to Bob in his efforts to raise funding for us and in his other duties. And secondly, Mr. Ed Dorrington has just joined us as Director of Information Technology. This is extremely important because we are putting our systems for grants management into shape, and we will need to do that before we actually send out the money. I want to thank the Moore Foundation who have advised us and helped us find the best possible person for this position and who have given us very valuable advice in the meantime.

We are currently hiring two more people. One is a grants technical assistant who will help us with the grants management under Dr. Arlene Chiu and secondly, we're hiring a facilities procurement

and operations manager who will be able to help us with a very important part of our move coming up in November.

I wanted to remind you of our Scientific Meeting: "Stem Cell Research in California, Charting New Directions." It will be the first step in setting our scientific agenda October first and second in San Francisco. We have registration which is limited to 200 on-site and fortunately we are going to have web casting in real time, so it will be available to anybody who wants to follow the proceedings, and we will through that also have a record of the meeting. So we are excited about that and very much look forward to that as the first step in really establishing our scientific priorities for this huge venture.

Next I'll talk to you a little bit about the administrative structure for CIRM. We – Bob Klein, our Chair, Ed Penhoet, our Vice Chair and myself have worked very hard with a management consultant and have come up with a plan that we think will give us very effective internal management.

Basically, the fundamental concepts are that that personnel in CIRM will report to the President. There will be a Chair's office, and personnel in the Chair's office will report through the Chair and Vice-Chair to the President for personnel management, but will be responsible to the Chair and Vice-Chair internally for allocation of duties, reporting lines and time management. All other senior officers will report to the President, and the budget decisions will be made when possible by consensus within the executive committee with final decision by the President, as required by Proposition 71.

This slide shows the Chair and Vice-Chair, and the ICOC. The President then reports to the ICOC, and then CIRM underneath. And if we take the bottom part of that and just show that, what you see is here. I think you should have material in your folders that correspond to this and it just shows the various offices.

As we have already described to the Governance Subcommittee and you will hear later from Walter Barnes, we have divided the CIRM into four groups: an Administrative group, a Chair's group, a President's group and a Science group, and we are working to establish within each of those reporting lines and budget structures.

Two of our units do not at the moment have heads. These are Communications and Legal Affairs. We have deferred hiring those until our financial situation is more clear. For the moment, the people in those offices are reporting directly to the President. Information Technology reports directly to the President.

So this is the chart by which we will operate and carry out our function. The three of us are convinced that this will give us an effective and efficient organization and will allow us to have sound administration and to get our work done.

I would like to request approval from the ICOC for the organizational chart as presented. Mr. Chair, I turn it over to you for that.

Dr. Pizzo: First, I commend you and Bob and others for significant progress in the administrative structure. I think this is much clearer than it was at earlier times, so that's progress. I'm very pleased with the organizational chart for the CIRM.

I do have a question: under most nonprofits, whether it's universities or foundations, a board of directors is listed as the oversight group for the organization. Whether it's a university, like Stanford, or I assume it applies to state universities as well or any nonprofit, I've never seen an organizational chart in which a Chair and Vice-Chair were listed separately from the board and above the organizational entity of the board.

Unless there is a specific reason for that, I'd recommend conformance with the more standard approach.

I think it is self-evident that a chair of a board or a vice chair of a board are possessed of specific responsibilities that are concordant with their activities, but I think this creates an artificial image of hierarchy that doesn't need to be in place for what we're trying to achieve.

Dr. Hall: That's an ICOC internal matter, so I have no comment on that.

Chairman Klein: As I have stated previously, that is completely consistent with my view. I view myself as a peer with special responsibilities, and there are members of the board that have suggested the other representation. But as a matter of record, from my perspective, you've properly described how I see my function. Ed, how do you feel?

Vice-Chairman Penhoet: Same as you. On this issue.

Dr. Hall: Let me just say that the unusual feature here about the whole thing is one that actually our consultant pointed out to us was not so unusual, and that is that we have a Chair and Vice-Chair who are operationally active in the organization. He said the usual solution to that is then to have people assigned to them who report to the President through them. And in that role, they then report to the President in the personnel role.

Dr. Pizzo: And I think that's reflected in this exhibit and doesn't need to be presented in the first – if you go back to the first one, the earlier slide. My recommendation for this exhibit is that the portion that says Chairman and Vice-Chairman simply be eliminated, and the organizational structure be, in essence, the ICOC, which is the Board of Directors, of which the Chair and Vice-Chair have special responsibility and authority, and they collectively with the ICOC oversee the CIRM.

CONSIDERATION OF CIRM/ICOC ORG CHARTS

Motion:

- Chairman Klein moved to adopt Dr. Pizzo's recommendation.
- Second:

Dr. Wright: Zach, I thought I heard you mention an executive committee.

Dr. Hall: Internally, we have an executive committee that is myself, the Chair, the Vice-Chair and the Senior Administrative Officer, Walter Barnes, and we meet once a week. That is not reflected in the boxes on the chart because the boxes have more to do with reporting relationships.

Dr. Murphy: The issue of final decisions on budgets – it says that the budget decisions will be made with final decision by the President. That, of course, is subject to oversight by the ICOC and final approval by the ICOC.

Dr. Hall: We bring a budget to you. We've discussed this in the Governance Committee. Once the budget is approved, then we will not bring every budget decision to the Governance Committee or to the ICOC. So then within those frameworks, we will operate. And there's been some discussion about whether decisions involving a certain amount of money, we want to have specific approval or not. But all this is presumably within the operating budget that's approved by the ICOC. So, of course, the ICOC has final oversight.

But the point of that is when we are making decisions internally about how we spend dollars, then the aim is to try to work it out in executive committee and reach agreement there. And in the final

analysis, if we can't reach agreement, then as in agreement with Proposition 71, the President makes the final decision.

Chairman Klein: All budgets are approved by the ICOC, and there's discussion in the Governance Subcommittee that will be brought to this board for action that specifies that if there is a variance in that budget of more than X percent, that it would also be brought back either to the Governance Subcommittee, if it's a lower level, or to the board, if it's a higher level variance, but as long as it's within those variances and within the budget, then it is the President who will lead the organization in implementation of the budget.

Ms Samuelson: My question is about one of the charts with boxes, which has Scientific Program, Scientific Review, Grants Management, and Grants Working Group under the science office. Since the title is CIRM Administrative Structure, this may reflect those aspects that are within the CIRM exclusively, but I think it's important to point out that the Working Group is advisory to the ICOC and the committee itself plays an essential role in crafting the scientific program and then the criteria which will be applied.

Dr. Hall: Absolutely. But as I read Proposition 71, the Working Groups actually report to CIRM. They are part of the CIRM, and we have senior staff that are liaison to those committees and work with them, but they are under CIRM and not directly under ICOC. This is in contrast to the earlier subcommittees. James, is that correct?

Chairman Klein: I think the distinction that Joan may be drawing here is that for recommendations for policy, for grant award, etc., all of those recommendations from the Working Groups come directly to the board with the assistance of CIRM staff. But for administrative support and for implementation of the program processing for grants management, for all the operational purposes, they are under the CIRM. And certainly we look to the President and his staff to lead that process with the policy development to carry out the overall strategic plan and mission of the institute.

Mr. Harrison: That's a correct representation.

Chairman Klein: Since we've had a discussion on the scope of these, to make it clear for the record, I think it would be appropriate if the motion I made include not just the amendment of that chart, but, in fact, the approval of what's been proposed so we don't have to go through two separate processes. If that's acceptable to the maker of the second, the motion would include approval of the organizational charts that have been proposed. Is that acceptable to the maker of the second?

Ms. Wilson: Yes.

Chairman Klein: With that, is there anyone on the board who would object to that process? With that, I would ask if there is public comment. Mr. Halpern.

Mr. Halpern: I have two comments on the proposed administrative structure. First, in my judgment, based on 30 years of nonprofit management and ten years as president of a significant foundation in New York City, this structure is one that I've never seen before. I just want the ICOC to consider carefully whether this is really the structure that optimized the likelihood of successful operation of this important program. Having 20% of the staff under the Chairman's office poses a serious question in terms of administrative structure and the responsibility of the new president.

I think the diagram inaccurately describes the relationship that is conceived. This makes it appear that the President supervises the office of the Chairman, supervises, indeed, the Chairman himself. That's what the conventions of these boxes and arrows generally means. That is not what is intended, I believe. More accurately would be to move the Chair's box up on a parallel level with the President's office, to have a dotted line connect them to show that the people in his

office, who are reporting to him on all substantive matters or on personnel matters, are reporting to the President's office.

To show the chair reporting to the President is inappropriate, and secondly, to show the real authority that the Chair has over the people in his office, I think, is something that should be shown in the diagram.

Dr. Hall: I think we said it states on the chart, we said what this diagram was intended to show. And that is, that the personnel in the Chair's office ultimately report to the President, as required by Proposition 71. But they do so through the Chair and Vice-Chair, and that on personnel matters, that the Chair and Vice-Chair are responsible for people in that unit to the President. And that's exactly what we intend.

These people are assigned to the Chair's office, and it is then the Chair's prerogative to set up an internal organization chart and to assign duties and allocation of time as the Chair and Vice-Chair wish. And I will say, Mr. Halpern, in spite of what may be strange to your experience, it was suggested to us by a very experienced management consultant whom we met with several times and discussed this with. So he was, in fact, the one who suggested that this was perfectly normal, happened in many large organizations. And so I, for one, am quite comfortable with it and think it is the right organization to let us do our business.

Chairman Klein: Any additional comments from the board? Call the question.

Vote:

- All in favor
- Motion carries

Agenda item #8

Consideration of recommendations from Grants Working Group regarding:

- **Bylaws for Grants Working Group**
- **Procedures for considering grants**
- **Criteria for review of research grant applications**
- **Criteria for award of training grants**
- **Award of training grants**

Chairman Klein: We have before us the intellectual infrastructure grants, postdoctoral fellows, postdoctoral clinical fellows, and graduate students that will create tremendous intellectual framework for advancing science and medicine in the state in the embryonic and adult stem cell area.

We want to remind everyone in the public that any member of the board who represents an institution that may be a candidate will not be able to participate in the discussion, nor will that board member be able to vote on this item. Every board member that this affects has a list of items they cannot vote on. You will find that we have a CIRM staff member who is monitoring this process. The votes will be roll call votes to make certain there is not any accidental impact in addition to the oversight that is being conducted.

Because this is a public meeting and the public can see who is voting, and there's going to be a record of this, the board member does not need to leave the room during the discussion, merely not to participate in the discussion or the vote.

I'd like to point out that in addition to the board member's own activities, the staff has looked at activities of the family of board members. If anyone is compensated by any institution, that

institution shows up as a recusal institution on the board member's list. So we have tried to be very thorough and look at both the primary responsibility and the primary opportunity to avoid conflict as well as any secondary opportunities to avoid conflicts.

The ICOC is the board of final decision, and I will remind the board members that the medical and scientific working group, while representing distinguished scientists and physicians, but it comes to this board as advice. The recommendations that are made on funding, on funding cuts from proposals, or on lack of funding will be looked at as individual matters and reviewed by this board for decisions by this board. The board can deviate by increasing or decreasing the funding or by any other action that the board feels is appropriate, including suspending the review of a particular item.

So we would like to begin this review of this historic initial grant program of the California Institute of Regenerative Medicine with an understanding that it is the tremendous knowledge, expertise and empathy represented in this board that will make those final decisions. Dr. Hall.

Dr. Hall: Let me add a note to that, really on a personal level. In my experience as director of an institute at the NIH and with various patient advocacy groups, what we are doing here is not only the first step in our grants awarding process, it also represents a new way of doing business. And I, for one, have been extremely pleased with the process so far.

We have a Working Group that consists not only of outstanding scientists, but also of patient advocates. And as we know, Joan Samuelson is the Co-Chair of that group, and we had a terrific review session. And I think the experience of scientists and patient advocates working together was extremely good. And we also here today are doing something that is rather different from any organization I've ever been in, and that is having in public session discussion of the awards of the grants. An so we are embarking on something new here.

We're going to walk you through the procedures as we see them. There may be some normal growing pains in our process, and we can change things for the better as we go along. But it is, I think, important for us not just as the first step in our scientific program, as I said, but it is the first step in a new way of doing business that I think will very much characterize the ICOC and CIRM as we look back in future years at it.

Before we can actually consider the grants, we have several items of business that we must do. The Working Group held its first meeting August 3rd and 4th in San Francisco, with a two part meeting: a public meeting to consider matters of procedure and policy, during which the Working Group received public comment on each of the issues that it considered. Several of these issues resulted in recommendations to the ICOC. The second part of the meeting was the confidential session in which the applications to our training grant program received scientific evaluation, and recommendations to the ICOC were decided upon.

BYLAWS FOR THE SCIENTIFIC AND MEDICAL RESEARCH FUNDING WORKING GROUP

Dr. Hall: A preliminary draft of the bylaws was developed by CIRM staff and was presented to the ICOC for informational purposes at its July meeting. The Working Group at its meeting in August made several modifications to the draft and now recommends the amended version to the ICOC for approval.

Ms. Samuelson: It seems to me that the procedural rules, criteria and so on should go back to the Working Group for evaluation and recommendations based on what we've learned at this very early stage in the process. I think it would be well if the bylaws were reviewed then as well because I think that discussion may inform more informed recommendations about the bylaws as well. I don't know that there is any reason we have to set them in stone now.

Dr. Hall: They certainly can be amended and changed later. They were recommended a month ago by the Working Group which considered them for approval by this committee. And actually you have seen them before because I presented them for informational purposes. So they have been considered. My suggestion would be that you vote on them as they are, and then if there are specific items that we need to amend or change later, we can do that.

Chairman Klein: A possible approach here would be a motion that we move to adopt with instructions to send them back for additional refinements. We are constantly in real time learning, and that is one of the beautiful things about this group is that they're adapting and constantly improving the model. Having the bylaws in place with the discussion by the Working Group, with the public input from prior meetings, with the staff work provides a very useful framework which we're probably going to be improving for some time.

Dr. Wright: I'd be happy to make that motion. I also have one other question. In article 6, meetings, section 4, I'm assuming that the emergency and special meetings are called by the Chair of the Working Group, not the Chair of the ICOC. And if that's the case, we probably ought to specify that.

Dr. Hall: Yes, and we will make that amendment.

Chairman Klein: Joan, are you comfortable with the suggested motion where we would adopt these so that we have a framework in place with specific instructions to send them back for additional refinements?

Ms. Samuelson: Sure, with the understanding that I expect there will be.

Motion:

- Dr. Wright moved to approve the Bylaws for the SMRFGW
- Dr. Prieto seconded.

Mr. Sheehy: I had a questions on article 4, section 6. I think the language in section 5 and section 6 should be fairly similar in terms of selection of those members, and the ad hoc and the alternates. I think that in that they both have voting privileges – haven't we been voting on ad hoc and alternate members? I think we've approved ad hoc and alternate members. In section 5, we stipulate an ICOC approval process for the alternates. We don't have similar language in article 6, but I think we've voted to appoint ad hoc and alternate members. Since they have voting privileges and I think we need to have them approved by us if they're going to vote, so the language should be the same for both sections.

Dr. Hall: All these have been voted on by the ICOC, but the difference is that ad hocs were often some of our most distinguished people, who said they would be happy to help, happy to serve, but they could not do so on a regular basis. So they are not meant to replace members when members step down, but they are available to come in at a special time. Because they've been approved by the ICOC, then we thought they should have voting privileges.

Now, the differences are in specialists in the next category, who we invite in because they have special knowledge on a particular topic, and they don't have voting privileges and don't count toward a quorum. They're there to provide expert advice.

With regard to Jeff's suggestion, yes, that is consistent with the intent and everything that's happened, so let's put that in section 6 – specifying that ad hoc members have been previously approved by the ICOC.

Chairman Klein: Does the maker of the motion accept the improvements and clarifications discussed? And then we'll have public comment on this item.

Dr. Wright: Yes.

Dr. Prieto: Yes.

Mr. Halpern: I know the effort is to adapt and constantly improve the model, but I want to remind you that Prop 71 has some very specific and concrete limitations, and it cannot be amended for three years. So with regard to ad hoc members and special members who are given voting rights in these bylaws, I want to remind you that neither of those categories exists in Prop 71. Prop 71 states how many members shall be appointed, and there's only one class of members in Prop 71. This kind of innovation is, I think, prohibited by law.

Chairman Klein: Mr. Harrison is specifically focusing on those issues, and the exact nature of an ad hoc member. We are going to have a specific procedure to confirm the legal status of an ad hoc member before those ad hoc members actually serve.

Dr. Hall: So counsel is looking at that question and, if necessary, the bylaws may be modified later to accommodate counsel's opinion.

Chairman Klein: Seeing no other comment, I'll call for the question.

Vote:

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

PROCEDURES FOR CONSIDERING GRANTS

Dr. Hall: The next item is just a matter of how the grant applications are to be reviewed. Although we've been through this before, we went through it with the Working Group, and they recommended that we get the approval of the ICOC for this process. And this was done in the public session of the Working Group meeting.

Let me remind you that our way of proceeding is that the ICOC approves a concept of an RFA and a specified budget for that RFA. The CIRM staff issues the RFA and applications. These applications are then evaluated by the Working Group, which makes recommendations to the ICOC for funding, within the budget. And then the ICOC makes the final decisions about which applications are then funded.

The review within the Working Group, then, consists of two parts as specified by Proposition 71. The first stage is an initial scientific review in which the 15 scientific members evaluate the scientific merit and give each grant a score. In the second stage of the review, presided over by the Vice Chair, the full Working Group considers how the grants should be recommended to the ICOC, and they are in three categories: Highly Meritorious, recommend funding; Meritorious, could fund if funds are available; Not Sufficiently Meritorious to recommend funding at this time.

Now, as described in Proposition 71, any grant application recommended for funding by at least 35 percent of the members of the Working Group can be submitted at the ICOC meeting as a minority recommendation for funding. The recommendations are then conveyed to the ICOC. Mr. Chair, I recommend these procedures, which have been approved by the Working Group, to the ICOC for approval.

Joan Samuelson: It was an incredible, wonderful, fascinating process. And that's coming from someone who had not had experience in the peer review process, so it is very much a work in progress for the group. And I'm very proud of the work product to date.

I do think that, to the extent that any of these recommended procedures would be used beyond the training grant process that we will be approving today, that we defer them for further review and recommendations by the Working Group because it was truly a work in progress and evolving during that session. So to the extent we approved any procedures at the outset, they're not necessarily the ones that with more reflection we would want to use in the future.

The first step is to in collaboration and advice to the ICOC to be involved in the actual plan for what that scientific program is going to be and what its several parts in terms of different kinds of grant applications are going to be. The second step, which is establishment of the criteria which will be used to evaluate the grant applications that result in issuance of an RFA in review of the applications. That was something we were really doing as we were evaluating. And I think the process will need more reflection and criteria to be established before issuing the RFAs. The third is the review for the scientific merit.

Dr. Hall: Right now, we're talking about the training grants exclusively. We are doing this so we can move into considering the recommendations that were made. We will discuss this afternoon the research grant criteria, and I'd like to hold that for the moment if we could.

We brought to the ICOC the concept for the RFA. It was the ICOC who participates in that first step, and it was approved. In fact, in this particular case, the specific RFA was approved. That RFA included criteria for the training grants, as we will discuss, and then we brought them back to the ICOC on July 12. They were then considered by the Working Group and so forth.

What we have before us here is simply the structure by which the group operates. The first part is stipulated by Prop 71, and the second part simply describes the categories for recommendation. Beyond that, I will consider the criteria for training grants in just a moment – as the next item. But this is just a general framework by which we operate, and I think it would be very helpful if we could reach a decision on this. Again, it's not written in stone. We can come back and modify it later, but I think if we're going to be able to move ahead, then I think we need to agree now that this is sufficient for how the Working Group will operate. I think we can't hold everything in suspension for this. We need to decide and go ahead with the understanding that we can come back in this case and modify these.

Dr. Baltimore: I am going to largely support what Zach just said, which is that these are procedures for evaluation. They're not procedures for determining what grants are to be made or to be proposed under an RFA process. I think that is the responsibility of the ICOC and of the CIRM staff – to decide that an appropriate RFA will take us in a given direction with a given kind of proposal. The Working Group's job is to take the direction from that RFA and use their scientific knowledge to evaluate the grants that have come in response to that RFA.

Now, these are very smart people. They have a wide range of experience. I think we should take advantage of their experience to get advice, but I don't think we should write into our procedures that they are responsible for the RFA process. We really need to maintain that separation.

I do think this group may want to ask for advice from scientific peers, and some of those might, in fact, be the same people, but I think that needs to be a separate process.

Mr. Sheehy: I'd like to move to adopt these as an interim process. And I think we're kind of missing the point that Joan was trying to make. We have a novel process, and it hasn't even been reviewed by the people who are participating in the process to see how well it worked. They're our brain trust. And if they think that the process is not working to take the best advantage of their

skills, we ought to know that rather than put in cement a process without having had any feedback from them on whether or not it works well for them.

Dr. Hall: Jeff, in answer to that, I'm quite happy to do that. We can call them to get their feedback. While we didn't ask formally for their feedback, the informal feedback I got was highly positive about the process. One of the Working Group members who had chaired study sections before at the NIH came up afterwards and said "I have never seen a group work so well together after one meeting as this group did."

So our general sense, I don't think there is anything seriously awry here, but I'm happy to go back to the group after our first meeting and say if you have any suggestions you want to make in these procedures, let us know.

But just in our own ways of operating, I would like to have some sort of stable guidelines that we can use about how we're going to do our procedures, so if we could just pass these, if you wish, on an interim basis or just pass them with the understanding that, again, these are not regulations. They're internal matters of the organization, so they come under the APA, so it's a different matter and we can amend them without difficulty. Is that correct, James?

Mr. Harrison: I believe that is correct. We'll take a look.

Chairman Klein: I think that the goal here is that, as we've said, we're learning in real time. We have tremendous assets in these groups. The feedback can be quite helpful.

Dr. Baltimore: It says applications will be defined into two or three groups, but it should just say three – even if one is empty.

Dr. Hall: Let's take out two then.

Chairman Klein: As a friendly amendment, do the maker and second accept it? Yes.

Dr. Baltimore: I have another point: nowhere in here does it talk about the review groups changing the budgets or changing the recommended budgets. And yet the review groups seem to have recommended changing the budgets. I think this question ought to be dealt with. I don't think we ought to try to craft that language today.

Dr. Hall: So you're saying we should draft language that would allow that to happen?

Dr. Baltimore: Yes. I'm perfectly happy with it happening, and I think, in fact, it ought to happen.

Chairman Klein: Any other board comments? Public comments?

Ms. Fogel: In the bylaws and in the criteria, the framework, rather in the criteria for the framework for evaluation, we talk about vital research options. In other words, things that could be funded because of their very special need, etc., but the bylaws do not reflect Prop 71's requirement that those funding choices need a two-thirds of a quorum, not a majority of a quorum. So the bylaws ignores this other category of research that requires a two-thirds vote of a quorum.

My second comment is that there is nothing either in the bylaws or in these criteria, procedures that talk about the content of what comes to the ICOC in terms of the recommendation. It uses just scoring and evaluation. But if you are truly decision makers, then there needs to be some clarity about what information comes to you so that you can make good decisions. If you don't know who the applicants are, how are you going to abide by the criteria that require you to vote based on the overall quality of the training program, the qualifications of the program leadership – I'm reading from your criteria – the research and training strength of the proposed mentors, the

quality of existing training programs, and the strength of stem cell research at the institution? How will you vote on that if you don't have any information about the applicant?

If you have no independent knowledge on which to make a decision, that makes you a rubber stamp. You are here because you are all experts, and you're supposed to be bringing your independent knowledge to decision making. If you then are just going to read what they said and say, fine, we vote yes, then you are not decision makers. You are not fulfilling your obligations to the people of California, and you're rubber stamping a Working Group.

Chairman Klein: With regard to Susan's first point, James, I think it's subsection D, and I think she's correct with her recommendation, that we should incorporate the two-thirds vote at the Working Group level. Do you concur with that?

Mr. Harrison: Yes, that's accurate.

Chairman Klein: While it doesn't affect this specific round of grants, going forward we might as well incorporate this because it is straight from Prop 71.

Dr. Hall: Absolutely.

Dr. Baltimore: I think the problem is that you get buzz words and then you try to have a discussion about buzz words. The buzz word in this case was rubber stamp. We're not rubber stamping, but we're not reevaluating. We're in a different position. We're looking at the process, we're making sure the right criteria were taken into account. We may find an inconsistency in the description of the process of evaluation that would lead us to ask a question, but we're not substituting our own knowledge of those institutions for the knowledge that was presented to the Working Group and which they used for their evaluation.

And we really need to understand that. The public needs to understand that because otherwise we'd have to re-spend the time that was spent, and we would have to have much broader knowledge of what was in the applications than we have.

Dr. Pizzo: I affirm the points being made by Dr. Baltimore. Our primary responsibility was to appropriately charge and have oversight over the selection of the individuals who are on the review committee. And if we were going to, indeed, be able to make judgments about all of the areas of substance of any grant, we would have to, if we're really doing appropriate due diligence, review each of those grants ourselves in addition. And that is a process that makes no sense. I don't know of any other organization that would do that.

So in a way, although I don't think it's rubber stamping, we have delegated the intensity of scientific review to a group of nationally and internationally renown experts, and now we are going to utilize their recommendations to formulate our decisions. It's an iterative process, and I think the critical oversight that we'll make is about the overall quality, the nature of the proposals.

Motion:

- Jeff Sheehy moved to approve the review procedures as an interim process.
- Ms. Samuelson seconded.

Vote:

- All in favor
- Motion carries

CRITERIA FOR AWARD OF TRAINING GRANTS

Dr. Hall: In the case of the training grants, we have a set of criteria which should be familiar to you by now. They were part of the text of the training grant RFA, which was presented to you on May 6th and which you approved. Then on July 12 these same criteria were presented as an information item to the ICOC and to the public with requests for modification before presentation to the Working Group. There were no modifications at that time.

The Working Group then had its meeting and considered the criteria in public session, then recommended them at that time to the ICOC for approval. We present them here and request approval for them as interim criteria. And let me remind you of what they are.

They concern the ones that Susan Fogel just mentioned, the overall quality of the training programs, the qualification of the program leadership, the research and training strength of the proposed mentors, the quality of the existing training programs, and the strength of stem cell research at the institution.

We would like to propose these are criteria for our consideration of training grants now and in the future. These, because they affect our public decisions, would become a regulation under the administrative procedures act. And so the adoption here would be the first step in the procedure of adopting them as a permanent CIRM regulation.

Dr. Pomeroy: One of the suggested criteria that we discussed the first time we saw these was the quality and diversity of the applicant pool that was available. The applicants themselves don't appear on this list, and I thought we had talked about that just being an oversight and we were going to incorporate it. So I would like to include the quality and the diversity of the applicant pool.

Chairman Klein: It was actually part of the RFA. The RFS included diversity.

Dr. Hall: So diversity was mentioned in the RFA, and that was one of the requirements, that they tell us their plans for diversity. We can certainly add that here.

Chairman Klein: It was discussed in the public hearing as well of the Working Group itself, and it was also one of the things discussed through the process. So it's consistent with what the process actually carried out.

Dr. Hall: Right. We ask in the RFA about this and it was used by the Working Group, so putting it in is not a problem. I'm happy to put it in. You want to state it.

Dr. Bryant: I have a suggestion for amending it which would say "overall quality and diversity of existing training programs", which would cover what you're saying.

Dr. Pomeroy: That would fix it for me.

Dr. Bryant: I propose we change bullet number 4 to read "quality and diversity of the existing training programs".

Dr. Pomeroy: Second.

Chairman Klein: We'll also change item one to read "overall quality of the proposed training program.

Motion:

- Dr. Bryant moved to make changes to bullets 1 and 4 as per Dr. Pomeroy and Chairman Klein, and approve these criteria.

- Dr. Pomeroy seconded.

Vote:

- All in favor
- Motion carries

AWARD OF TRAINING GRANTS

The ICOC heard presentations on and discussed all 26 training grant applications. A roll-call vote was taken on each application, with board members recusing themselves from discussions and votes as needed based on their institutional affiliations.

The final results included the ICOC awarding 16 training grants, as listed below. The total awards for the 16 Training Grants will be approximately \$12.5 million for the first year, and will provide funds for training approximately 170 pre-doc, post-doc and/or clinical trainees at the 16 institutions.

Burnham Institute
California Institute of Technology
Children's Hospital Los Angeles
Scripps Research Institute
Stanford University
The J. Gladstone Institutes
The Salk Institute for Biological Studies
University of California, Berkeley
University of California, Davis
University of California, Irvine
University of California, Los Angeles
University of California, San Diego
University of California, San Francisco
University of California, Santa Barbara
University of California, Santa Cruz
University of Southern California

Agenda Item #12/Consideration of report from Standards Working Group, including but not limited to:

- **Consideration of CIRM interim guidelines for human embryonic stem cell research**
- **Appointment of Co-Chair**
- **Consideration of Bylaws for Standards Working Group – *tabled***
- **Consideration of Standards Working Group Meeting Procedures – *tabled***

Dr. Hall: I present for your consideration the interim standards for human stem cell research. The Standards Working Group met toward the end of last month and considered the revised standards, put into regulatory language and made appropriate for the CIRM and the State of California, as requested by the Working Group and approved as a process by the ICOC. The revised standards were discussed and changed further at the recent Standards Working Group meeting. The document under your tab for agenda item #12 is the revised guidelines with the changes made by the Working Group.

Motion:

- Dr. Prieto made a motion to move this item to the November 2 meeting.
- Mr. Serrano Sewell seconded.

Vote:

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

APPOINTMENT OF CO-CHAIR

Dr. Hall: As you know, Dr. Harriet Rabb stepped down and had to resign from the Standards Working Group for unexpected personal and professional developments. Bernie Lo has agreed to Co-Chair the group. We'd like to get that approved here if necessary.

Motion:

- Ms. Samuelson moved approval as Dr. Lo as Co-Chair.
- Dr. Bryant seconded.

Vote:

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

Agenda Item # 13/Consideration of report from Governance Subcommittee

Walter Barnes gave an informational progress report from the Governance Subcommittee including detailing the three potential CIRM budget scenarios based on having no further funding beyond what we already have, an additional \$21.5 million in proceeds from the sale of bond anticipation notes, or an additional \$100 million in proceeds from the sale of either bonds or bond anticipation notes.

Chairman Klein introduced to the ICOC for feedback the potential for naming grant programs as requested by philanthropic donors. Board concerns were raised including possible problems with pharmaceutical company donors requesting programs be named after their companies, and the board seemed in general to feel the need for caution with regard to such a naming program.