Friday, August 5, 2005 ICOC Meeting Minutes

University of California, San Diego
Price Center
Ballrooms A & B
9500 Gilman Drive
La Jolla, CA 92093-0008

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

CONSENT ITEMS

Agenda Item #5
Approval of minutes from July 12, 2005 ICOC meeting.

Agenda Item #6
Designation of CIRM contact for filing regulations with the Office of Administrative Law.

Motion

- Ms. Wilson moved to approve consent items under agenda items 5, 6 and 7.
- Ms. Samuelson seconded the motion.

Vote

- All in favor; no opposition
- Motion carries

Agenda Item #7
Chairman's Report, including but not limited to:

- **Informational update on state and national legislation**
- **Consideration of ICOC letters in support of, or opposition to, federal stem cell research related legislation**
- **Informational presentation on bond funding**

Chairman Klein: We have some extremely important state and federal legislation to consider. Kirk Kleinschmidt will lead us through the status of the federal and state legislative issues.

Kirk Kleinschmidt: In your binders, you have a written summary of the active legislation on the state level. I won't go into much detail on that unless there are questions, but there are a number of measures we are still tracking and monitoring closely.

On the federal level, there are a number of issues we wanted to bring to you attention for discussion and hopefully consideration of a position on two measures that are particularly timely at this point.

Those two measures have been getting a lot of media interest, and this has to do, of course, with the history of this issue (stem cell research funding) going way back to 2001, but more recently, in May, when the House passed the Castle/DeGette measure, which would expand the existing lines eligible for federal funding. You may recall this board discussed this issue and took a position of support for the measure, which did subsequently pass in the House by substantial margins.

We hope there will be a Senate vote on that measure in the near future. Originally, we were told there would be a vote on it in the Senate before the August recess, but that did not happen. We are told we will get a vote on it in the fall, probably after the Supreme Court nomination process.

It's not quite as simple as an up-or-down vote on one measure. There are a number of competing measures having to do with stem cell research that are being considered as far as a package in the Senate. We do have some concerns over some of these measures.

Specifically, a measure by Senator Brownback of Kansas – Senate Bill 658 - would ban, no only human reproductive cloning, but also SCNT. A companion bill in the House is sponsored by Congressman Weldon.

A number of other pieces of legislation may go forward in a unanimous consent decree, and it's not clear at this point what that entire package would be. The measures I've been told would be considered in addition to the Castle/DeGette measure and the Brownback bill would be:

- A measure sponsored by Hatch and Dodd in Senate Bill 1317, this specific measure having to do with bone marrow and cord blood and creating a national infrastructure to support that kind of research.
- A new bill sponsored by Brownback and with no co-sponsors at the moment also is a possibility for the package. This bill would ban human chimera research. There is obviously some concern if that would go forward.
- Then recently – last week – Senators Feinstein and Hatch, together with 29 members of the Senate, introduced the Human Cloning Ban Act of 2005, Senate Bill 1520. This bill would ban only human reproductive cloning and remains silent on SCNT.

What's really important is that it is a very fluid situation and we're not completely clear on what will go forward for the final vote in the Senate, but were are optimistic there will be a vote. So the main thing to focus on is the Human Cloning Prohibition Act, the Brownback bill, as well as the Castle/DeGette measure. The Brownback bill would criminalize SCNT, which many of us know we need for disease-specific lines and for patient-specific treatments in the future. It is a much needed technique that would be put in jeopardy if this measure passed.

Chairman Klein: Let's do this incrementally. The issue in the Senate is that currently in the unanimous consent resolution being considered prior to Senator Frist's announcement of his change of position, there was no option for any Democrat or Republican who is against human reproductive cloning to vote against human reproductive cloning without voting against SCNT.

Beyond the obvious issue of confusing the subject and raising the risk that SCNT is prohibited through the Brownback bill, the Brownback bill and its House companion the Weldon bill used some artful legal coding to disguise the reach of their prohibition. In addition to criminalizing the research for doctors and scientists, if you look at the Brownback bill, you will find that it also reaches a prohibition against anyone who participates in the process, which for those of you from areas of chronic disease, as a spouse or as a parent or child caring for your ailing parent, it's really reaching beyond prohibiting it. It is reaching the point that in the future, we could not have this type of therapy in this country and then, if you took your family members to another country where the therapy is available and then brought them back to this country, you would be,

under this bill, a participant. You would be arrested upon return to this country and subject to up to ten years in prison.

It's recommended the board take a position against the Brownback bill and for the Feinstein/Hatch bill.

Ms. Samuelson: Perhaps the Standards Working Group can play a role in being like a truth patrol on some issues that are misunderstood in the way they characterize them and in the case of SCNT. We have to develop standards on all this, and in do doing, there could be some education. The public might shed some light on this in the Congressional setting – that's what advocates end up doing, every time they meet with a member of Congress, they have to reeducate them about the true facts, and maybe media coverage of our work or some direct communication could work in conjunction with our standards setting process.

Ms. Lansing: I think we must be active on this issue. We can't be passive. The Brownback and Weldon bills go to the very core of the work we're trying to do. The Feinstein/Hatch bill, which is a bipartisan bill, is supporting our work. For us not to be supportive of that bill would be a tragedy.

I think we have to do this as a board. We need to go to Congress, and we need to meet individually with people. We need to educate people because the biggest problem we're facing is not what we're doing, but an education of what we're doing because very educated people, our Congress members and our Senators, are not clear that we are definitely not doing human cloning. I think we have to come out actively in our communications and say that. And they don't know what SCNT is. It s big, scientific term. It's unfortunate the word "cloning" is part of it.

We have to be actively against the Brownback and Weldon bills, and not be shy about it. Equally important is when we have two distinguished Senators coming out with a bipartisan bill supporting our work, we have to give them the support they need. We also need to educate the public and educate our representatives – we're not doing human cloning.

Dr. Murphy: To reinforce what Sherry said, we as a board should use the term, and Paul Berg was one of the first to coin the term, of "patient-specific" or "disease-specific stem cells. By using the term "cloning", which no one is doing here, we are playing into the hands of the opposition. And I think we have to take a leadership position in using exactly what this is, which is cells that are specific to certain patients with diseases that those patients have.

Dr. Holmes: Assuming for the moment that we support the recommendation to oppose the Brownback and Weldon bills, Kirk, could you or someone tell us what does it look like in the Senate? How close is this bill to actually passing? And where should we focus our attention as far as members because I would think, along with Sherry, that one of the things we're going to have to do is make some personal contact with people we might influence in addition to saying we support something or don't support something.

Mr. Kleinschmidt: Both our senators are in support of Castle/DeGette and against Brownback, and they've gone on record for that. As far as Brownback, there are

currently 33 cosponsors for that measure in the Senate. But, again, there are a number of procedural votes that have to happen under the unanimous consent decree.

Chairman Klein: I think the most important contribution, given the leadership on this board, is by an outreach to the scientific leadership in other states. If the scientific leadership in other states will get out front and explain in the press what the position is and why stem cell therapy tools are critical here, it gives the Senators in those states the political cover to be able to vote conscience and be able to vote with science. Without an explanation in the press in those states, it is very difficult for them. Obviously, patient advocates and their activity in making clear in those states the importance of these scientific tools is very important.

Dr. Bryant: Perhaps it would be appropriate for our Working Group members, who are from all over the country and who are interested in seeing the research going forward, would be a good group to have help with this outreach effort.

Ms. Lansing: This is worthy of some serious thinking. I suggest we have Kirk draft a letter explaining we are opposed to these bills and why we're for other bills, and explaining that we don't do human cloning.

Mr. Kleinschmidt: We have drafted such a letter, Sherry, and we're hoping to have the board approve it and sign it today. We have a copy we can show on screen for your review and input.

Ms. Wilson: Going to Washington to visit various Senators and members of Congress made a big difference. Bob and I went to visit Mike Castle earlier this year, and he was so thrilled. This is the man with the Castle/DeGette bill, which passed with about 50 extra votes, not enough to overturn a veto. He was so thrilled to have is come and give him some cover.

Bob, also, who is so articulate on this issue, was able to give him some talking points, which we hear from Bob often, but that Mike Castle had not heard.

I'm not positive the Brownback bill is ever going to be brought to the Senate floor, but it's something we should worry about. They're so thrilled in Washington to have people from the CIRM come and give them some support because they are way out on a limb.

Senator Hatch is picking them off one by one. I just think that if we can go and put a face for the CIRM in front of the Senators, it would be a good thing.

Vice-Chair Penhoet: To follow up on Sherry's point about a clear and unambiguous communication, I think to some degree whenever we discuss the various bills which are in play and how they interact with each other, we end up with a somewhat confusing message because it is a little hard to keep track of exactly how they overlap. So I make a plea for a clear and unambiguous statement on our part about what we support and don't support that's not directly linked to any piece of legislation precisely.

I think we should take a very clear and unambiguous position that we oppose human reproductive cloning, period. That we do support the generation of patient-specific cell lines or whatever it is for it. So it may be as a lead-in to a letter which has the

complexities of the legislative situation embedded in it, but that we don't lose the clear and pointed message about what we do support and what we don't support because I do think part of the ambiguity about what we support or don't support is that we sort of fail to lift those things out of the ambiguous nature of the political debate and make a clear statement about what we do and don't support.

Dr. Holmes: It would be nice to know which states to focus on with regard to us influencing, or at least calling colleagues at other universities. I think Kirk said there were swing senators in ten states. It would be helpful to know which those are so we can focus our attention and efforts.

Mr. Kleinschmidt: They are Arkansas, Indiana, Minnesota, Mississippi, New Mexico, Tennessee, Texas, Utah, Virginia and West Virginia.

Chairman Klein: the letter is up on the screen for review by the board, and thanks to Dr. Paul Berg being sworn in, we have a quorum. We'll have Kirk read the letter out loud.

(Letter read aloud)

Dr. Reed: There is just one phrase in the letter that's inaccurate in terms of the terminology that scientists use. We might want to correct that. It's the phrase that says "molecular therapies". It is usually "small-molecule therapies", a hyphenated term. You could probably just take out that clause of the sentence and it would be more impactful.

(Ms. King made changes in the letter while it was on screen, as per the comments of the board, including Dr. Reed's comments above and the following comments.)

Dr. Steward: Picking up on something Ed raised earlier, I wonder if we want to be a bit broader and make sure we're making a statement here that is in principle not necessarily linked to a particular bill. What I'm proposing is that in the first paragraph, we say we support the process of somatic cell nuclear transfer as a technology toward therapeutic applications. In other words, any bill that prohibits it, we oppose.

(Further suggestions and minor tweaks were made.)

Dr. Price: This letter doesn't yet do what Ed suggested, which is make a clear statement that CIRM and the ICOC oppose human cloning, and explains what SCNT is, why it isn't human cloning and why we support it. We could add a paragraph explaining this. As a layman here, I'm not a stem cell scientist, I think we have to at some point make clear what SCNT is and why it's not human cloning.

Chairman Klein: If it is the sense of the board, I suggest we follow the suggestions from Dr. Price, Sherry Lansing and others, work out the additions and bring the letter back for an individual vote at that point. We can vote right now on the Brownback and Feinstein bills separate from the letter.

Motion to oppose Brownback bill

- Ms. Samuelson moved to oppose the Brownback bill
- Dr. Holmes seconded this motion

Vote

- All in favor
- Motion Carries

Motion to support Feinstein/Hatch

- David Serrano Sewell moved for support of Feinstein/Hatch
- Sherry Lansing seconds

Vote

- All in favor
- Motion carries

Agenda Item #8
President's Report

Dr. Zach Hall:

- Provided a summary on the Grant Review Meeting, pointing out Dr. Arlene Chiu has been the center of the effort.
- Announced the appointment of Dr. Geoff Lomax as the Senior Staff Liaison to the Standards Working Group. Dr. Lomax has a PhD in Public Health and has recently staffed a legislatively mandated committee, complete with a panel of experts, to assess the impact of the environment on chronic disease. He essentially wrote the first draft of the report and received very high praise from those involved.
- Gave an update on the new office space for the CIRM along
- Updated the board on CIRM recruiting and its prioritization to focus on 5 critical hires kept on the front burner to achieve three short term objectives. First, to be able to give out money, we need to get the Grants Management Officer, the Grants Technical Assistant and the Director for Information Technology in place as soon as possible. Second, we will need to give the Chair all the support we can as he is engaged in raising bridge financing during the next months, so having an executive assistant is a priority for us. Finally, we have our plans for our new space complete. We need to start planning now for our move, and for that it is essential we have a facilities and procurement operations manager. This person would report to Walter Barnes.
- Provided an update on the Scientific Meeting and the plan to have a student rapporteur that will summarize each session for the lay audience.
- Informed the Board that that Standards Working Group will need some work, possibly by the Search Subcommittee led by Dr. Kessler. Working Group Co-Chair Harriet Rabb has resigned from the Working Group due to unexpected personal and professional responsibilities. We will need a Co-Chair, and also need 3 new members of the Working Group – a Scientist-Physician, an Ethicist and an ICOC patient representative.

Agenda Item #15 – MOVED UP AND DONE EARLY

Consideration of update from Grants Review Working Group, including appointment of a new scientist-member.

Dr. Hall: I'd also like to take an item out of order, if I might, to take advantage of our quorum while we have it. This is item number 15. Alan Trounson from Australia was originally selected to serve on the Grants Review Working Group. He developed a conflict of interest between the time he originally agreed to be on the Group and the time of the first meeting, in that he became engaged in active discussions about possibly collaborating and being on-site for experiments for some portion of the year with a California university.

That's a wonderful thing for stem cell research in California as he is an internationally recognized authority, but it clearly constituted a conflict of interest so he has resigned from the Working Group for that reason.

Our first alternate among the 15 reported from the Search Subcommittee was Wise Young. It was suggested by us and agreed to by you that he would be the first alternate, that is, the first person to fill any vacancy that occurred.

He is a professor at Rutgers, founding director of the W. M. Keck Center for Collaborative Neuroscience and is a well-known and well-recognized spinal cord injury expert. He is also a co-head, with Ira Black, who some of you may know, of the New Jersey Stem Cell Center centered around Rutgers. He will be a very important and good addition to our working group.

I would ask as an action item that the ICOC approve his appointment.

Motion

- Ms. Samuelson moved to approve Wise Young as a new member of the Grants Review Working Group.
- Dr. Holmes seconded the motion.

Vote

- All in favor; no opposition
- Motion carries

Agenda Item #12
Closed Session

a. Pending Litigation: People's Advocate v. Independent Citizens' Oversight Committee, Alameda County Superior Court, Case No. HG05206766; Mary Scott Doe v. Robert Klein, et al., U.S. District Court, Central District, Case No. ED CV 05-00438 (Government Code section 11126, subdivision (e)); California Family Bioethics Council v. California Institute for Regenerative Medicine, Sacramento County Superior Court, Case No. 05AS02927

b. Discussion of Personnel (Government Code section 11126, subdivision (a); Health & Safety Code section 125290.30(d)(3)(D)).

Agenda Item #13
Public report of any action taken, if necessary, during closed session.

Mr. Harrison: Provided a brief report back on litigation, including:

- The Alameda County Superior Court ruled August 4, 2005 on a motion filed by the ICOC and the other State defendants in the Alameda County Superior Court Action, the People's Advocate action, to transfer the action filed by the California Family Bioethics Council, which was filed in Sacramento, to Alameda County Superior Court so that it could be consolidated for the purposes of hearing at trial with the People's Advocate motion. The Court granted that motion, so the California Family Bioethics Council action will now be consolidated with the People's Advocate Action as of September 1, 2005. This is important, for several reasons. It saves the CIRM's resources as it permits the CIRM to deal with this litigation in a single court instead of having to fight it on two separate fronts. It also avoids the possibility of inconsistent rulings. Also, Alameda County Superior Court has a pilot single assignment project to which this action has been assigned, which means all matters pertaining to both actions will be heard by a single judge, Judge Bonnie Sabraw, which should also aid in terms of judicial efficiency and speed of the process.
    - It is important to note that in ruling on the motion, Judge Sabraw recognized that one of the purposes behind the validation procedures was to limit the extent to which delay due to litigation may impair a public agency's ability to operate financially. She wrote "this objective is met in part by assuring a speedy determination of the validity of financial transactions and of challenges that may affect the marketability of the public agency's bonds." So your courts have recognized the importance of resolving these issues as quickly as possible so the CIRM can get on with its business of funding stem cell research.
- An event that happened earlier this morning – the plaintiffs in the action which was filed in federal district court in Riverside by Mary Scott Doe, a fictional human embryo, have now served the members of the ICOC with a copy of the complaint so that case has now been served. We obviously haven't had a chance to review the complaint in detail having just received it, but as with all of this litigation, we take it very seriously and we will aggressively defend the ICOC and the CIRM in this litigation as well.

Agenda Item #10
Consideration of updated conflict of interest policies for the three CIRM Working Groups.

Dr. Hall: This is basically a continuation of a discussion we had last time where, as you recall, the Legislative Subcommittee had approved an enhancement of our policies. We brought that for conflict of interest and also for our funding recommendations to the ICOC. I'll deal with those in just a moment. Let's deal first with the Conflict of Interest (policies).

During that discussion, it was clear there were small discrepancies between the different conflict of interest policies, and we asked last time for interim authority because we had meetings going on. In that time, we also made the policies consistent with each other. It's not important to go through it point by point as we already have, but the two major things are that now the relevant financial interest is $5,000 under whatever category and is true for all three groups. And the other is the definition of family interest now. The relevant phrase is "spouses or others with whom a reviewer has a common financial interest." So that's been added to all of them, so they're now consistent. And if you find any other improvements, we are, of course, delighted to consider them. But I think the point was to finish that task and to make them commensurate across the board.

Chairman Klein: James Harrison, would it be appropriate to have a motion that encompasses all the reconciling changes to all three?

Dr. Hall: There is a technical point here. This is technically a change to our procedures. We have also previously passed the policies, so they have now been brought into consistency with each other. So let me ask that the motion encompass both the policies and the procedures so that those changes are reflected here represent a change in detail in both our conflict of interest policy statement and in the procedures in that it is part of a form that we send to our Working Groups to ask for disclosure.

Mr. Harrison: I think you should just make clear that what you are voting on pertains to the financial disclosure policy and procedures for the Working Group members.

Motion

- Dr. Murphy moved to approve the changes as outlined by Dr. Hall
- Dr. Steward seconded the motion.

Jessie Reynolds: I've stated numerous times in the past the importance of having public disclosure of the personal financial interests of the Working Group members in order for the public to have confidence in the objectivity of their decisions.

What I want to emphasize now is the exception clause that is in all three Conflict of Interest policies. For example, in the Grants Review Working Group policy, it says the President of the CIRM or a designee may decide that the need for special expertise of the reviewer outweighs any possible bias posed by a real or apparent conflict of interest.

I feel the result of this is something of a toothless policy because, in the end, not only will the public not know the person interests of the Working Group members, and when recusals did and did not occur on funding decisions, but they can't be assured with 100 percent confidence that the Institute staff has in every case reviewed and prevented any conflict of interest.

I urge you to reconsider this policy.

Dr. Hall: We can also take out word "designee" from end of graph, so it is just the CIRM President (not a designee) who can "decide that the need for special expertise of the reviewer outweighs any possible bias posted by a real or apparent conflict of interest."

We would expect to use this extremely rarely. It would be documented. I guess the situation we're thinking of is a case in which there is some highly specialized scientific area in which there are only a very small number of people who are expert and in which, in order to make a judgment about whether something is feasible or not, we need the opinion of that expert.

Vote on Policy with suggestion from Mr. Reynolds taken into account.

- All in favor; no opposition
- Motion carries

Agenda Item # 11
Consideration of format for funding recommendations to the ICOC.

Dr. Hall: Provided brief presentation on plans for presenting funding recommendation information to the ICOC.

Chairman Klein: consider exception: if only 2 instead of 3, and give range of scores, you've given scores of each…

Dr. Hall: yes, but we don't know which is which

Chairman Klein: I would hope we can give you more discretion.

Dr. Holmes: Who is going to prepare abstract? Applicant or staff?

Dr. Hall: Applicants will be asked to provide a lay summary, and this is what we will present as a summary – possibly tweaked a bit. They will know their lay summaries will possibly become public documents.

Dr. Pomeroy: Will there be any fourth category like the NIH has, called "unscored"?
Dr. Hall: These will be picked off before the review – our staff would take those out. These would go in Group III.

Ms. Samuelson: We don't want to disclose too much information…

Dr. Hall: That's exactly our intent with this recommended policy.

Dr. Holmes: Group I: you will know will know the amount of funds. There could be trade offs, such as knocking something out of Group 1. The likelihood of not having enough grants to fund is not likely.

Ms. Lansing: We don't have to spend all the money if we don't see sufficient grants, so there's a chance you could elevate something.

Dr. Hall: The ICOC is free to move things around as it sees fit. The Grant Review Working Group will report out what it does.

Dr. Murphy: Let's assume 10-15 grants approved for recommendation to ICOC, do you see ICOC going through all these grants publicly?

Dr. Hall: We will have to vote on each grant individually, publicly. Board members will be asked/expected to recuse themselves from voting on any grant application for which they have a conflict.

Dr. Holmes: Will we be able to gain access to the original proposal?

Dr. Hall: No, because then it becomes a public document.

Dr. Holmes: so we'll just have a lay summary? All respect to lay summaries, but we need more than that to judge a grant.

Chairman Klein: There will be a scientific summary prepared by scientific staff.

Dr. Holmes: But you won't have enough/the right information to rescue a potentially good grant from further down the list.

Dr. Hall: It's more a broad policy decision…may decide to increase budget to extend to more grants, for example, or 'looking over whole portfolio, we'd like to see more grants in a particular area, and there are some just below the line that we want to bump up, etc.

Chairman Klein: Advisory groups can only be advisory groups. The ICOC has to be the final decision maker, and if the ICOC wants to pull a grant up from lower on the list, it can do that, and if the ICOC feels it needs a more detailed scientific summary of a grant, it needs to ask for that. The ICOC must be the body that makes the final decision.

Paul Berg and Claire Pomeroy: Asked about availability of information in the application to the ICOC, and specifically, what about the fact that a scientific summary that would contain enough information on which to base a decision would be compromising the confidentiality.

Dr. Hall: We don't want to provide a detailed summary of the whole grant, but also, confidentiality – especially for grants that don't get funded – we have an obligation to protect people.

Dr. Berg: The NIH makes your grant available the DAY it is approved for funding.

Don Reed: Is person applying for grant the one that would draft the lay summary?

Dr. Hall: Yes, and "draft" is the right word. Staff will review and tweak as needed before presenting to ICOC.

Don Reed: I have some background in this, from the Roman Reed grants. I asked for a one page run down of what their goal was and how they would define success. It was tough to get them to do, but it was very valuable to have. The team works hard to help

get the lay summaries to be as clear and useful to the public as possible. We have 2 booklets, which I brought as examples. Have the scientists do the work, not CIRM staff – don't have Dr. Chiu and her team having to clarify.

This will have larger echoes than maybe it seems at first. If our scientists spend the time to make themselves clear, it will help the nation as well, i.e.

Dr. Hall: It will be part of their application and they know it will come to the ICOC and the ICOC will use it in making their decisions, so people will spend quite a bit of time on it.

Also, clarification in the text: "The general range of scientific scores of applications not recommended for funding…" will be changed.

Dr. Berg: Just have it say "scored below a certain score".

Chairman Klein: good suggestion from Dr. Berg.

Dr. Hall: The score below which Group III had to have scored to be below the line, and not get funding, will be the bottom of the range for Group II.

Chairman Klein: when people are recusing themselves, does the quorum adjust to be based on the number of ICOC members who can vote on a particular application?

Mr. Harrison: Yes.

Dr. Pomeroy: If you're just telling us which numbers on which to recuse ourselves from the vote, and not IDing the institution, how do we recuse ourselves from votes with which we have a personal COI?

Dr. Chiu: one way is we will be looking at whether an ICOC member has published with an applicant in the past 3 years.

Chairman Klein: Dr. Pomeroy, if you could write up a paragraph on the fact pattern you see, that would be helpful – I see your point and it's a good one. We need to work on this further.

Dr. Steward: There is tremendous cost from having to balance transparency with need to protect applicants.

Dr. Hall: no way to tell if something is at the dead bottom without saying exactly that, and we don't want to do that.

Dr. Bryant: middle group is the one you have to worry about not getting enough funding.

Dr. Hall: Grouping into I, II and III is a compromise. We are required by law to give you all the apps, but don't want to compromise confidentiality.

Ms. Samuelson: We may want to note that this dilemma is caused by Bagley-Keene, and I don't think this is what Senator Keene intended to have happen.

Motion:
- Ed Penhoet moved approval of format and content of Funding Recommendations with amended language (deleting "The general range…" to say "below threshold of Group II)
- Dr. Thal seconded

Vote
- All in favor
- Motion carried

Agenda Item #9
Consideration of report from Governance Subcommittee

Ms. Lansing: Provided overview of first meeting of Governance Subcommittee and what it is reporting back to the ICOC today, asking for approval on some policies, procedures and contracts on which Walter Barnes will present the details.

PROPOSED POLICY AND PROCEDURES FOR CONTRACTING

Mr. Barnes: Presented on Attachment A: Proposed Policy and Procedures for contracting and made recommendation that board adopt these.

Motion
- Everyone moved
- Everyone seconded

Vote
- All in favor
- Motion carries

PROPOSED POLICY FOR APPROVAL OF CONTRACTS AND INTERAGENCY AGREEMENTS

Mr. Barnes: Presented on Attachment B: Proposed Policy for Approval of Contracts and Interagency Agreements – with regard to delegation of authority to approve contracts and interagency agreements.

Recommendation made starting at bottom of page 1 in Attachment B.

This is an evolving process. These limits are kind of low. Over time, as you get comfortable and understand and feel good about what we're doing with the contracts policy, we'll come back and get some broader recommendations.

Ms. Lansing: Right, if we have to come to the board for every contract over $100,000, we would have a dysfunctional organization. We've moved it to the Subcommittee, a

smaller group. What I'm hopeful for is that when we have our budget in place, it will become self-evident what we're spending.

Chairman Klein: I'd like to make a motion to approve recommended policy with complete recognition of your statement about review once budget is in place.

Mr. Serrano-Sewell: Can we delegate authority completely to a Subcommittee, or does it have to come back to the board?

Mr. Harrison: The board does have the power to delegate authority to a Subcommittee.

Chairman Klein:

Motion

- Everyone moved
- Everyone seconded

Vote

- All in favor
- Motion carries

REMCHO CONTRACT

Mr. Barnes: Remcho contract

Gayle Wilson: What is the contract with the Attorney General's office?

Mr. Barnes: The Attorney General will get involved in litigation matters. You need lawyers that are experts on your particular topic/field.

Ms. Lansing: Also, isn't the Attorney General's office charge us, and isn't it actually cheaper to work with Remcho?

Mr. Barnes: It is competitive, and also, Remcho is more accessible. The Attorney General's office is a bureaucracy.

Chairman Klein: We greatly appreciate the work of the Attorney General's office. James Harrison defended Prop 10. The Attorney General's office works in teams, they send 2 or 3 people to every meeting. James Harrison's knowledge is sufficient, this way we can just have one person who can answer all the questions that come up.

Ms. Lansing: I just wanted to stress how competitive the Remcho fees are with the Attorney General's office.

Ms. Samuelson: I've been impressed with the work we've gotten from Remcho and particular from James.

Motion

- Mr. Serrano Sewell moved approval of the Remcho contract
- Second?

Vote

- All in favor
- Motion carries

EDELMAN CONTRACT

Mr. Barnes: Provided comment on Edelman contract origins and details. The CIRM has figured out what the bare minimum services are that we would like to have every month, and negotiated down to the amount we now have per month – no more than $27,500. I recommend that the ICOC approve this contract.

Ms. Lansing: I am pleased with Walter's presentation and with Edelman, who forgave some overages. We have a clear need for communications and education. As we hire our own people, the need will change.

Dr. Pomeroy: I would like to congratulate Sherry and the committee on a job well done. I was one of the people who wanted to see all this discussed in depth and openly, and the Subcommittee has done that.

Don Reed: Our education need is huge – we're talking about things that are microscopic. We should do what the English do and give brochures out to the public, in schools.

Jessie Reynolds: There was no competitive bidding process, and there was no written agreement at first – it seems to have been an oral agreement for the first 4 months. I hope it was an oversight and acting in haste rather than a cavalier attitude about spending the state's money.

Chairman Klein: There were written terms during the whole period when the contract was being written. They knew they were at risk of not being paid until a contract was agreed upon, and would be giving us their work if the board did not decide to execute a contract with them. There were written terms the whole time, as well as a pro bono component.

Mr. Barnes: It is our expectation and goal to have contracts written before people start. The fact we were not able to do that this time is a reflection of the fact there was too much going on for us to get it done. This does not detract from the fact we are receiving excellent service and work from Edelman.

Ms. Lansing: Mr. Reynolds, I understand and appreciate your point and it was heard. I hope you heard the answer, but I want you to know I share your concern. In this case, it really was just that there was too much going on.

Motion

- David Serrano Sewell approval of the Edelman contract
- Ms. Wilson seconded the motion.

Vote
- All in favor
- Motion carries

Agenda Item #14
Consideration of update from Presidential Search Subcommittee.

Chairman Klein: SF General/Gladstone lab space: advice from Facilities Working Group to the Presidential Search Subcommittee was that we don't have time or the funds to vet and seismically retrofit the space, or to consider whether or not to offer lab space to a CIRM President candidate before the deadline on taking the option for the space. We don't have the money to put at risk.

There is a motion to accept the recommendation from the Presidential Search Subcommittee that we pass on the San Francisco General space.

Motion:
- Moved
- Seconded

Vote:
- All in favor
- Motion carries
-

Agenda Item #16
Informational update on CCST IP Task Force study.

Vice-Chair Penhoet: This will be a very quick report. We don't have the CCST report. It is expected early next week. Our Subcommittee has not met yet, and that is deliberate. We are waiting for the CCST report.

Dr. Bryant: Michael Goldberg and I will be receiving copies today, as members of the CCST Task Force. It will then be released next week.

Vice-Chair Penhoet: We're also planning another meeting with Perata, August 17th, for information purposes only. Going forward, developing a final IP policy for this group, we have to take into account IP policy recommendations broadly and also the concerns of the legislature.

Chairman Klein: Thanks to Susan Bryant and Michael Goldberg for their service on the CCST Task Force.

Agenda Item #17
Informational update on CIRM Headquarters progress.

Walter Barnes: Since the ICOC made decision to select San Francisco at May 6 meeting, we've taken several actions.

- Chairman Klein and Mayor Gavin Newsom signed the CIRM City Agreement as called for in the RFP. This commits the city to deliver all the benefits promised in its bid, including free rent and utilities, which also means the lease itself has been executed with free rent and utilities for a ten-year period beginning with the date of occupancy.
- Representatives from the CIRM, San Francisco, Stockbridge, the building owner Gensler, who is the architect, Hathaway Dinwiddie, the contractor, the DGS and Haworth, the furniture contractor, have held several meetings over the last two months to develop a plan for building out the space.
- We've developed a final budget for the tenant improvements on both the third floor and the lobby build out. The last budget is about $30-40 thousand under the $1.6 million. Anything that's left comes over to us, so we have a real incentive to try to make sure that this gets done, not only on time, but on budget and preferably under budget.

Chairman Klein: We cooperated and teamed up with the Mayor to increase the dollar amount, negotiating up from $1.2 million to $1.6 million. In that exchange, we go the benefit that if we could negotiate savings, they would help pay for furniture and other equipment for the offices.

Also, our intent is to have a November 2nd anniversary celebration in this space.

Dr. Penhoet: I'd like to comment on the role two of our board members played in bringing the first therapy for Multiple Sclerosis to patients. Michael Goldberg was a significant member of the management team at Cetus Corporation, which developed this product for 17 years before it came to market. Sherry Lansing was a director of that company for many of those years. So two of our board members were involved.

I think it is also a good example of the technology which is very controversial. Recombinant DNA technology eventually led to a very important therapeutic. So I would just like to recognize the contributions that both Michael and Sherry made to bringing the first Interferon to patients with Multiple Sclerosis.

Michael Goldberg: Thanks, Paul Berg.

Dr. Murphy: Just one question: once we are set up in San Francisco, do we expect the ICOC will still move around the state for its meetings, or will we be gravitating more to San Francisco to reduce travel cost?

Chairman Klein: I think this is a board level decision we need to get to.

Ms. Lansing: I had a great time everywhere we've been. We are a state agency, and I think we should go around the state. I think its very important to give the public the

opportunity to be present. It's not easy for people to travel. I think it's wonderful to go around the state.

Chairman Klein: With that enthusiasm, I think it would be a great not to adjourn the meeting unless the board or public has some further critical comment to make.

Adjournment.