Wednesday, November 2, 2005 ICOC Meeting Minutes

Moscone Center South
747 Howard Street
Room 304
San Francisco, CA

David Baltimore	Present
Robert Birgeneau **Designee: Robert Price**	Present
Keith L. Black	Present
Susan V. Bryant	Present
Marcy Feit	Present
Michael A. Friedman	Present
Michael Goldberg	Present
Brian E. Henderson	Present
Edward W. Holmes	Absent
David A. Kessler	Present
Robert Klein	Present
Sherry Lansing	Present
Gerald S. Levey	Absent
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	Present
Joan Samuelson	Present
David Serrano Sewell	Present
Jeff Sheehy	Present
Jonathan Shestack	Absent
Oswald Steward	Present
Leon J. Thal	Present
Gayle Wilson	Absent
Janet S. Wright	Present

CONSENT ITEMS

Agenda Item #5: Approval of Minutes Sept.9th ICOC Meeting

Agenda Item #6: Approval of Marcy Feit as ICOC Member

Agenda Item #7: Approved revised CIRM Conflict of Interest Code

Motion:

- Mr. Serrano-Sewell moved for approval of consent items.
- Dr. Thal seconded.

Vote:

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

Agenda Item #8: Chairman's Report

Chairman Klein: I'd like to start with some formal thank-you resolutions addressing a number of the parties in the state who have recognized that the litigation against Prop 71 is a real intent to delay the implementation of an initiative that came with a major public mandate, 59 percent of the voters, who approved this a year ago today. We have 15 patients groups and 15 institutions across the state that have joined an amicus brief supporting our legal position on the constitutionality of Prop 71.

The firm of Munger, Tolles and Olson, which happens to be Warren Buffet's firm, a very famous law firm in the United States, has volunteered the work of five of its partners on the amicus brief, which is a huge benefit to this effort. The board resolutions are to thank the following attorneys: Mark Epstein, Ron Olson, O'Malley Miller, Michael Doyen and Paul Watford.

Motion:

- Dr. Os Steward moved approval of the resolution to thank the Munger, Tolles and Olson attorneys who worked on the amicus brief.
- Dr. Nova seconded

Vote:

- All in favor
- Motion carried

Chairman Klein: We would also like to thank Wareham Development and the City of Emeryville for so graciously hosting us in our temporary headquarters free of charge for the space, the utilities and the furniture, for their tremendous responsiveness, and the great facilities they provided for us during this past year. We would like to make sure that in a formal motion we send letters on behalf of the board to the individual principals as well as to the companies and to the members of the council and the chamber of commerce in Emeryville, in addition to the institutions themselves.

Motion:

- Dr. Henderson moved approval of the resolution to thank the individuals and institutions in the City of Emeryville as described by Chairman Klein.
- Dr. Wright seconded.

Vote:

- All in favor
- Motion carried

Chairman Klein: Finally, I'd like to have the board consider a formal thank-you resolution to the City and County of San Francisco and to the members of the board of supervisors and especially to Mayor Newsom and his principal staff assigned to the task of the facility and getting us into the facility. The staff members are Jessie Blout and Jennifer Mottes.

In addition to the mayor and the governmental entities, we should consider a letter of thanks to the Chamber of Commerce and the other parties and individuals who were participants in this effort.

We had a ribbon cutting ceremony yesterday. The space is phenomenal. The construction is on time. It is beautiful.

Mr. Serrano-Sewell: There are others on the mayor's staff, and also in the offices of the city attorney and in the planning department that were heavily involved as well.

Motion:

- Dr. Love moved approval of the resolution to thank the individuals and institutions in the City of San Francisco as described by Chairman Klein and Mr. Serrano-Sewell.
- Mr. Serrano-Sewell seconded.

Vote:

- All in favor
- Motion carried

Agenda Item #9: President's Report

President Hall: Alexandra Campe has come on board as our personnel officer. We were very fortunate in that she worked with us for about six months on loan from UCSF. When she went back to UCSF, we put the job up and had a variety of applicants for it. We were pleased to see that she was one of them, and felt she was the most qualified. She'll be joining us in about a week.

Training Grants

I also want to bring you up to date on the status of our Training Grants, approved for 16 institutions at our last meeting in early December. Arlene Chiu and her staff have been working very hard to go over the budgets and the approved grants to make sure that all is correct, and they now have a corrected figure of 12.1 million for the first year of the training grants. That will rise slightly in each successive year, and the total for the three years is roughly $38 million.

These grants will be ready to go out when the money comes in, but we will need to do two other things before we send them out. You will hear about both of those later today. One is we need to have interim regulations for our medical and ethical standards in place, and the other is we need to have an Interim Grants Administration Policy for Training Grants.

Strategic Plan

The next thing I wanted to discuss is what I see as a major challenge for us for the next six months or so. That is to put together a scientific strategic plan that will guide our programs. We are initiating a large and ambitious research program in a new area of research, a program which will go over probably more than ten years and will involve hundreds or perhaps thousands of grants over that period of time.

In order to have our program work as we want it to, that is, to succeed in our goal of using stem cell research to develop therapies, we need to engage in a large-scale process of strategic planning. We need to identify ideas for scientific and translational problems and opportunities to translate those ideas into a plan that is expressed through our grants-making process, and we need to accompany this with a financial plan that will give us some idea of how we will distribute funds among different projects and over time.

We envisage that the final product will be an overarching plan for action with a series of sequential phases with milestones by which we can measure our progress. We don't believe that this plan will be set in stone. It will need to be responsive to both the results that it produces and also to new scientific developments, and so it will need to be reviewed, updated and modified at periodic intervals.

In addition to the scientific agenda, we will also as a part of the plan seek to foster a scientific culture in which our ideas can succeed, testing new models of grant mechanisms that can promote interdisciplinary and interinstitutional collaboration and that can bring together basic and clinical researchers.

I see this as our next large and important task. As I told you when I spoke to the ICOC and the Presidential Search Subcommittee, I see this as my major responsibility and an effort that I personally plan to lead over that period of time. We will need to work closely between the CIRM and the ICOC, and I look forward to the appointment of an ICOC subcommittee for scientific strategic planning and look forward to working with the chair and co-chairs and members of that committee when they are appointed.

The first step in the plan will be a period of information gathering. This is a very large-scale and intensive and extensive process that we will be involved in over a period of time. We will not be able to really begin on this until we have the necessary resources. That is, we need additional scientific staff to help us carry this out, and we will also need a consultant, we think, to help us with many of the tasks. We have begun preliminary discussions with at least one possible consultant, and we are meeting with another later this month. We expect to ask these groups to make formal proposals to us.

Proposed Short Term Grants Plan

Innovation Grants:

While we are doing this, we also have some scientific needs that we can meet and seem to be immediate and urgent. We see two kinds of grants that are important at this stage. First are innovation grants, which would be relatively small grants of maybe a couple hundred thousand dollars for a couple of years. They would allow people to try out new ideas.

We hope they would attract scientists who are well established in other related fields who might wish to try out an idea in stem cell research, and we hope they would allow people to provide preliminary data for more substantial grant proposals later on. If we're able to attract $50 million in bridge funding, which is our first goal, then we would be able to issue an RFA for this.

Shared Space Grants:

- Bob pointed out this need to me, and in discussions around the state, I've found there is no question we need this
- Small scale space that would allow people to do ESCR outside federal guidelines
- 2-4K square feet plus staff, allowing people not engaged in SCR, or not equipped to do it outside fed guidelines, could do their work.

Agenda Item #10: Consideration of formation of Strategic Planning Subcommittee

Chairman Klein: A number of board members have ideas they've put forward informally individually on the Strategic Planning Subcommittee. What I would like to do here is get a sense of who is willing to volunteer for this subcommittee so we can see what kind of personnel power we have from the board, and come back for action at the December meeting with the full mission statement, the time frame, the process and have a very organized package to present.

VOLUNTEERS:

Baltimore
Bryant
Friedman
Henderson
Kessler
Lansing
Love
Pizzo
Pomeroy
Prieto
Reed
Samuelson
Serrano Sewell
Sheehy
Steward
Thal
Wright

Chairman Klein: After 50 public meetings, it is extraordinary, the commitment of this board. It is impressive and inspiring. When we lay out this process, if there is a part of this process that contemplates, as I expect it will, bringing the whole plan back to the board for real substantive matters and in-depth review, we may find that we don't need as many board members to actively be on the subcommittee. I think it's important to inform everyone of the number of meetings anticipated to see whether people's time will really permit this participation.

Mr. Serrano-Sewell: Can we permit the ICOC members that cannot appoint an alternate do so for this strategic planning committee only? I have a preference that for this planning committee, I have the option to appoint a representative, a delegate.

Chairman Klein: Counsel agrees to look into this over the next two weeks so we have this information before the December 6 ICOC meeting.

Agenda Item #11: Consideration of report from IP Task Force

Dr. Penhoet: The Task Force is at work. We have a short-term timeline for what we hope to accomplish by December 6. We had a meeting on October 25 to hear three things:

- A description of the CCST report, and an opportunity to ask questions
- A presentation by Fred Dorey, an attorney who's a long time observer and participant in many ways in the biotechnology industry, on the importance of intellectual property and the private relationships between universities and the private sector in building California's biotechnology industry.
- Comments from a number of members of the audience

On October 31, there was a legislative hearing in San Francisco, which turned out to be quite useful and took up most of the day on Monday hearing a variety of different views about intellectual property and advice from a number of people to us and to the legislature about how we should handle these issues.

There is an expectation that on November 17th, a very important study will be introduced by the National Research Council. This is a study which ha been going on for some time relating to the patenting and use of patents in the field of genes and proteins. Stem cells were not a specific part of the report, but I believe the principles which will be articulated in that report are likely to be easily extended to stem cells.

November 22 we will have a second IP task force meeting at Stanford to further consider what we've heard in these various meetings and in the NRC report with an intention of coming to a conclusion about a recommendation to the ICOC for an interim policy on our meeting of December 6th. The Interim Policy would apply only to Training Grants, so it's a limited objective. And the primary purpose of training grants is not to generate intellectual property or to do research, but to train people. So we hope to have a simple proposal in place by the December 6 meeting.

The long term goals of the group remain to define a final policy, which we hope to have in place by the February board meeting so that that can be applied to the research grants that we'll make going forward. So we will have a lot of work in front of us.

Dr. Prieto: Given the importance of this and to get past the litigation and our issuing bonds, is it appropriate that we ask IRS officially for ruling on taxable vs. non-taxable?

Dr. Penhoet: There was a discussion at the hearing on Monday by bond counsel who pointed out the IRS does not like to opine on a menu that you bring them and where they pick and choose. It's very hard to get a ruling from them unless you have a specific proposal. At the moment, we have a lot of variables. As soon as we are able to articulate a policy which is clear about what we want to do, they're prepared to go ahead and do that.

Chairman Klein: In that regard, I would say that from a patient perspective in terms of benefit to the state, if funds were going into a nonprofit benefit model, for example, a portion of the royalties were going to benefit model access for new therapies for patients in California, so that we could show to the state that it was in the state's huge economic interest to intervene early with new therapies so that in spinal cord damage, for example, where you intervene at acute injury stage and don't have someone spending a life with huge medical cost in a wheelchair or in diabetes you don't have blindness or kidney loss. If you can avoid massive downstream cost for the state, the state is better off using some of this royalty money up front for a model access program to show that these new therapies are beneficial to the state economically as well as reducing suffering.

In terms of that model, it is my expectation we can get an IRS letter ruling for tax-exempt bond use, which is very important if we're going to address that area. So that area of bonds, which could be a very substantial area of bonds that benefited from that royalty policy could be tax-exempt bonds, for example.

Dr. Murphy: Those of us who have worked with Bayh-Dole know what a powerful act it has been and how it's been a stimulus to research and also to the economy. My concerns and questions about this are:

1. That whatever we do could have ramifications in other states as they develop the same kind of technology.
2. It could stimulate a re-look or rethinking about Bayh-Dole federally because I can understand the reaction would be, "well, look, if California is going to keep it for themselves, why we are, NIH, and the feds putting money into California and not benefiting that way.
3. Do we have any report available to us that looks at the effect of Bayh-Dole through NIH money on the California economy?

I can't imagine that the numbers would be any less than startling, and that we could use those numbers to bring back to government. We all realize that government has got a political hurdle here, to show how many companies have started, what the effect of Bayh-Dole has been on the California economy, I think we should have that information in our back pocket.

Dr. Penhoet: I would like to ask Mary to get copies of the Fred Dorey presentation from our 10/25 meeting for the entire board before they here because a lot of that information is contained within that document. So we'd be happy to share it. I think it's been circulated among the task force, but we can get copies for everybody today.

Dr. Bryant: I'd just like to say, having served on the working group for the CCST, that I feel like anything less than consistency with Bayh-Dole would be a total gamble. We would be endangering the $3 billion that the state has given us, not serving the state. So I think all the evidence shows that experiments that have been done to try and alter Bayh-Dole have been unsuccessful. I think it would be irresponsible to gamble with the money that we've been given.

Mr. Sheehy: I understand the concern about Bayh-Dole from a royalties issue, but I don't think we should be so unreceptive to other ideas because it does seem that where Bayh-Dole has had a negative side effect is in terms of excessive patenting. We should, in order to advance the science, be willing to look at alternative models that lead to more sharing of knowledge and resources. The scientists, people actually doing the science, seem to be asking this, I think, to look at those types of models.

Dr. Penhoet: The issue of compatibility with Bayh-Dole and how Bayh-Dole is actually carried out in practice are two different issues, and we have to be careful to distinguish between the two. To follow up on Jeff's comment, we could have a policy which says the heart of Bayh-Dole is ownership of the technology by the grantee institution. You could have a policy which says that in doing so, the universities would make, for example, the results of their work freely accessible on a research-only basis to all other institutions participating in CIRM or within the state or anywhere that's compatible with Bayh-Dole, but not identical to how Bayh-Dole has been implemented.

John Reed: With respect to concerns about patents blocking the ability to use technology for research purposes, the Supreme Court ruled on that issue and provided a reinterpretation of those statutes to the extent that it liberalized access to technology for the purpose of developing new therapies. So I think some of those concerns that may have existed in the past have been ameliorated to a large extent by this recent Supreme Court ruling.

Chairman Klein: A non-profit program for model access for low income and moderate income patients to new therapies could be viewed as an extension of the research program. Certainly

during research, Medical and Medicare provide that very low income individuals have access to participation in clinical trials on these new therapy areas. But if a portion of the royalties went to providing model access after clinical trials, I think it would be viewed as an extension of the research applications, if you're creative.

As a historical statement, we need to have in context the fact that during the campaign, the economic projections were that 92 to 98 percent of the economic benefit to the state, the real payback, the driving force is the potential that this knowledge would enhance existing therapies and we at least reduce the cost of six of 70 conditions by one to two percent, and secondly that we would create new jobs and new tax revenues. We need to keep in mind the limited range of benefit we're talking about here.

The projections in the campaign made it clear that there will be no IP revenues for about 14 years. You have to develop all these things. You have to go through applied science, translational medicine, clinical trials, and get a drug into the market. So there's no therapy IP revenue projected for 14 years, and the average collection is 24 years out.

Dr. Penhoet: The CCST report is not proscriptive for us – it's a recommendation to us, not a mandate. We're open minded and will hear lots of different points of view.

Dr. Love: With regard to the concept of financial benefit to the state: there are a lot of ways the state could derive financial benefit. One of those ways relates to the very specific issue of royalties coming directly back to the state. The question is, when we get this feedback about benefit to the state, are people almost always talking about at least inclusions of some minimal amount of royalties? And more specifically, as an ICOC, should we feel there is an obligation to, in fact, come up with a structure that pays royalties because of commitments during the campaign? Or should we feel that if we decide that structure is not, in fact, in the best interest of advancing what we're primarily here to do, which is stem cell therapies, that we have the freedom to come up with a structure that provides benefit, but does not include direct royalties?

Chairman Klein: From a patient advocate position and from 70 different patient advocacy organizations that endorsed this initiative, it appears very clearly to be a direct benefit to the state. If we use our royalties to benefit a nonprofit program affiliated with different institutions or even regionalized, that provides access to new therapies that come out of this research.

If this is done in an area where you're going to provide patient benefit and access, low and moderate income access, which has been a tradition in California under various programs of our health department, it appears to be an area where you can definitely creatively, with IRS approval, create a program that is consistent with Bayh-Dole and minimally modifies the concept where you use tax-exempt bonds.

That said, it is for the board to decide what is in the best interest of the state.

Dr. Love: As member of Task Force, at the 10/25 meeting in Sacramento, I felt an enormous weight of pressure around a variety of points – political and prior commitment, trying to advance these therapies, which I think is the fundamental task here, and trying to make things affordable. My biggest concern is that if we take on too many of these things, all of which are wonderful things to take on, we may end up not accomplishing our central mission.

Dr. Baltimore: There is a very important distinction from a university's point of view, from any entity's point of view. That is that you don't want to interfere with the internal processes of research and research funding by an IP policy. Therefore, saying we should re-think Bayh-Dole would isolate all California funded research from federally funded research in a totally unproductive way and would be an incentive for scientists at the university not to look to the California initiative for funding and to not get involved in human stem cell research because of the confusion of IP policy.

Asking the universities or the research institutes of California to return a certain fraction of the royalties or licensing income, and I point out that licensing income is a lot more important than royalties generally, is a relatively clean situation.

As long as the amount does not, again, make it counterproductive for individual research scientists to be involved, that is, allows the institutions to continue with their standard practice of return to the investigator or return to the institution, but takes some cut of that for the state, I think we can live with it. And we can live with it partly because it doesn't interfere with our internal processes and allows us to continue to see the funding of university research as a total entity, not as something which we have to compartmentalize the rules in order to satisfy.

Dr. Penhoet: All of us on the IP task force welcome input over the next 30 days with the limited goal of providing a framework for IP for the Training Grants, but especially over the 90-day period which will get us to the February meeting. This is a complex issue. It's entirely possible and probably desirable for us to develop a policy which is our own. The only consistent message we've gotten is just make sure it's not incompatible with Bayh-Dole, but it doesn't have to be Bayh-Dole per se. That's the framework most of us on the Task Force are embracing as we go forward in our work. We're glad to hear any other input that you might have.

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**
- **Consideration of Bylaws for Standards Working Group**
- **Consideration of Standards Working Group Meeting Procedures**
- **Consideration of recommended new members**

Dr. Hall: Before the CIRM can award any grants, we must have in place regulations that govern research on human embryonic stem cells. We adopted the national academy guidelines in May, shortly after they came out. Our Standards Working Group met in early July and pointed out that the guidelines had several versions of what they recommended, and that what we needed was precise and regulatory language. The guidelines were rewritten into regulations by James Harrison and by our staff. Then they were presented to the Standards Working Group, who made a few small changes and then approved them on August 30th. These regulations were discussed at the September 9 ICOC meeting and it was moved at that time that they be considered at this meeting for action.

This is subject to the Administrative Procedures Act, so there is a long process we must go through to come up with final regulations. It is these draft regulations that the Standards Working Group is now working on. According to the timetable, these will be presented to the ICOC for approval in early February, and then submitted to the office of administrative law. After a period of public comment and possible modification, these would then become final regulations.

So the only issue on the table right now is the interim regulations which will be in force until the Standards Working Group has done its work and the regulations have gone through the Office of Administrative Law. The clock for the OAL procedure starts with the adoption of the interim regulations by the ICOC. We also need to have these guidelines in place to do our work.

Motion:

- Dr. Henderson moved approval of the interim guidelines as interim regulations.
- Dr. Wright seconded.

Vote:

- All in favor
- Motion carried

APPROVAL OF PROCEDURES AND BYLAWS

PROCEDURES:

Motion:

- Dr. Baltimore moved approval of the Standards Working Group Procedures
- Mr. Sheehy seconded.

Vote:

- All in favor
- Motion carried

BYLAWS

Motion:

- Dr. Pizzo moved approval of the Standards Working Group Bylaws.
- Dr. Reed seconded.

Vote:

- All in favor
- Motion carried

APPROVAL OF NEW MEMBERS OF STANDARDS WORKING GROUP

Motion:

- Mr. Serrano Sewell moved approval of the new members of the Standards Working Group.
- Dr. Prieto seconded.

Vote:

- All in favor
- Motion carried

Agenda Item #15: Consideration of report from Facilities Working Group

Dr. Hall provided an updated on the Facilities Working Group and its first meeting, held Friday, October 28. The main item on the agenda for the Working Group was to discuss the grant programs of the CIRM and talk about how the Working Group would function and coordinate for facilities grant reviews with the Scientific and Medical Research Funding Working Group (previously referred to in shorthand as the Grants Working Group).

The Facilities Working Group is developing a set of procedures and bylaws, like the other two working groups have done, and these will be addressed at a future ICOC meeting.

The Working Group is also considering how to go about carrying out the facilities inventory project and its many components, as discussed over the past several months.

Dr. Henderson: The timeline to getting new facilities up for this sort of an effort is pretty substantial. So you are going to take an inventory of what?

Dr. Hall: There's some confusion about this, and I think the subcommittee of the Working Group appointed to handle this is going to sort that out. On the one hand, there was talk about an inventory of available space in the state for human stem cell research. On the other hand, there was discussion in some of the minutes both of ICOC meetings and of the Facilities Subcommittee of an inventory of concepts or ideas for facilities that might be contemplated at various institutions around the state. And it would be a way or sort of giving the Facilities Working Group a heads-up about possibilities that were out there. Then, as I understand it, certain ones of these concepts would be turned into case studies by the facilities working group of how a facility actually like this might be funded and might work.

Dr. Henderson: To some extent this will be part of strategic planning process on the whole, I would think. We can't do it without facilities to work in.

Dr. Hall: Right, and you could regard this as part of the information gathering for the strategic planning process.

Dr. Pizzo: Facilities is going to be the rate limiting step for making progress going forward for sure. It is already certainly impacting us in terms of activities at hand, recruitment and the like.

One of the things I think will be very important to do is, as we identify what we're looking at, is on the one hand, one can envision advantages for separate space. The disadvantage of isolating the space is that we run the risk of not having other disciplines beyond the biology of stem cell research impact on its future. One of the key successes going forward is to really enhance research environments. The real payoff is going to be not just by what happens in our schools of medicine, but what happens because of the interactions with our schools of engineering and physical sciences and the like.

So I hope that we'll think quite broadly about the way we consider space – space that really enhances the creativity that will emanate from our universities in ways that I think will make us really the future leaders.

Dr. Hall: I agree that is an urgent need, we have to get on it right away. It is also complicated, it seems to me, by some of the institutional constraints.

Need to be aware of constraints every university has.

Whole process on how to do it requires a lot of thought.

Dr. Pizzo: because it is so complicated, only underscores the importance of starting that process now. It may take a few years before money is available, but we can't delay it.

Agenda Item #16: Consideration of interim grants administration policy for training grants

Dr. Chiu: The CIRM staff has been working on a guiding statement that gives applicants and grantees the information about our processes and procedures and also a statement that tells them what we expect from them if they accept a CIRM award.

Our goal is to provide you for your review and approval a comprehensive CIRM Grants Administration Policy, but we're not there yet. Today what I'd like to do is update you on our progress in crafting this document.

The draft policy has been provided for your review, and we will be coming back for your approval of an updated version of this document at the December ICOC meeting.

BACKGROUND
Before funding can take place:

- Determine final, actual budgets
- Develop process for transfer of funds
- Communicate roles and responsibilities to grantee

PURPOSE OF GRANTS ADMINISTRATION POLICY

- Sets terms and conditions of grant awards
- Provides guidance to CIRM grantees on their responsibilities
- Directed to both recipient institutions and to PI's

CONTENTS

- Roles of CIRM staff members with whom grantees will interact
- Eligibility requirements for institutions and PIs
- Procedures for submitting apps for review and approval
- Terms and conditions of award:
    - Payment schedule
    - Allowable and unallowable costs
    - Indirect costs
    - IP
    - Sharing research data
    - Scientific and budgetary reporting requirements
- CIRM requirements:
    - Use of human stem cells
    - Use of vertebrate animals
    - Use of biohazardous materials
    - Human subjects

Dr. Baltimore: I read this thing through because we got it beforehand, and it seemed actually very thoughtful and very complete. So my question is, is there any particular part of it that you would like to see discussed further, or is there a reason it couldn't be moved now?

Dr. Hall: There is one issue, and that is the question of IP policy.

Dr. Penhoet: We won't have a recommendation on IP until the next board meeting. You can approve the rest of this policy with the exception of the IP piece.

These guidelines would not be used for any purpose whatever between now and December 6th, so in one sense there is no urgency to approve them today.

The more discussion we can have today, the more points we can get in the open today, the more feedback Arlene and her team can have to refine the document.

Dr. Steward: One of the things of concern to me is the training period. Just to put this in context, one has to balance between how long a trainee needs to spend in the activity to have it be useful, and that is always a good criterion. I think the appointment to 12 consecutive months is a good solution to that. Where one runs into trouble is in recruiting M.D. trainees and trying to integrate into, for example, residency programs. At times one needs to have situations where a resident, for example, might work four months, six months residency, go back to a residency training program, come back in, back out again.

Dr. Hall: That bears some thought. The last thing we want is to have people supporting summer students or people using it as a patchwork. We want continuity. I think it's the case that the stipend can be for one year, but we want them associated with a training program for at least two years so that it's not a question of moving funds around, but of having people who are really identified with the effort. That's really the thing we're trying to do.

We can make an amendment to say that with prior approval from our staff, training grant funds could be used flexibly to work in M.D. trainees, for example.

Mr. Harrison: These will go through the APA process and become regulations. This does not allow ad hoc exceptions, if you will, unless a procedure is built into the regulations themselves.

Dr. Penhoet: The general cases in each of these regulations where we do anticipate some need for flexibility, that anticipation has to be built into the language. Otherwise you won't have any flexibility.

Agenda Item #17: Consideration of interim criteria for review of research grant applications

Dr. Hall: The Grant Review Working Group met August 3rd and 4th, with the first part being a public meeting at which this document was presented and discussed, and it was approved with slight modifications made that day. We then brought it to the September ICOC meeting, and there was some discussion about having a name change for the Working Group. It was decided not to do that.

So we now have the original full name of the Working Group in the document, which as been revised. The document as revised as you suggested last time is the document that was passed by the Working Group in early August and recommended to you for approval.

Dr. Black: Is the Working Group going to be given some guidance as to weighting of these various criteria?

Dr. Hall: The criteria are meant to serve for a variety of grant types. In each case in the RFA w would state, for example, for an innovation RFA, you would want to weight the criteria of innovation rather heavily, and feasibility not so heavily, as opposed to a grant where you are giving somebody a several million dollar grant over five years.

The point is that rather than having to do each time a different one, what we'd like is a framework within which we'll say in the RFA particular emphasis will be given, it will be judged on the following criteria.

Chairman Klein: Dr. Hall, is it appropriate to say, as a clarification for Dr. Black, that if when you do an RFA for innovation, it will come back to this board? The board will look at the criteria,

decide if they have suggestions or changes, and the RFA will be approved here before it is issued?

Dr. Hall: What I would like to have is if we could get a conceptual approval with all the important points for each RFA and not have to bring the fundamental document back to the ICOC to go over. It slows us down, and I would hope that we would have your confidence in being able to draft the RFA based on the elements that we would present to you and receive your direction on.

Chairman Klein: At the time of a conceptual approval on something like criteria, it seems the board would be very interested in reviewing those criteria as part of this conceptual approval.

Dr. Pomeroy: This is a great start. Recognizing it's a living document, I'd like to make three specific suggestions for you all to consider as it lives and evolves.

1. A reference to responsivity of the application to RFA might be a nice specific criterion to have in there since there is such a broad range.
2. The importance of collaboration – encouraging more team science and looking at new ways and outreach – some recognition of that value that we attributed to multidisciplinary, to collaboration could be incorporated.
3. Require that the research must meet the highest ethical standards. There is no reference here to ethical considerations as part of the criteria.

Dr. Hall: We can add sentence at the beginning saying "we seek to fund research that advances stem cell research, that advances toward therapies under the highest possible medical and ethical standards." If you trust us to put that language in, we can start it with that.

Motion:

- Dr. Pomeroy: motion to amend interim draft with addition of sentence Dr. Hall suggested.
- Dr. Prieto seconds

Vote:

- All in favor
- Motion carries

Motion:

- Dr. Steward moved to add "are there identifiable milestones that can be used to assess progress towards a goal" or something along those lines.
- Dr. Pomeroy seconded.

Vote:

- All in favor
- Motion carries

VOTING ON DOCUMENT WITH AMENDMENTS

Motion:

- Dr. Penhoet moves to approve the document as amended.
- Dr. Murphy seconded.

Vote:

- All in favor

- Motion carries

Following public comment, the meeting was adjourned.