DRAFT MINUTES 2/10/06 ICOC MEETING

Stanford University
Arrillaga Alumni Center
McCaw Hall
326 Galvez Street
Stanford, CA 94305

David Baltimore **Designee: Paul Jennings**	Present
Robert Birgeneau (until 3:30 PM) **Designee: Robert Price (3:30 PM on)**	Present
Keith L. Black **Designee: David Meyer**	Present
Susan V. Bryant	Present
Marcy Feit	Present
Michael A. Friedman	Present
Michael Goldberg	Present
Brian E. Henderson **Designee: Francis Markland**	Present
Edward W. Holmes	Present
David A. Kessler	Present
Robert Klein	Present
Sherry Lansing	Present
Gerald S. Levey	Absent
Ted W. Love	Present
Richard A. Murphy	Absent
Tina S. Nova	Present
Ed Penhoet	Present
Philip A. Pizzo	Present
Claire Pomeroy	Present
Francisco J. Prieto	Present
John C. Reed	Present
Joan Samuelson	Present
David Serrano Sewell	Present
Jeff Sheehy	Present
Jonathan Shestack	Present
Oswald Steward	Present
Leon J. Thal	Present

CONSENT ITEMS

Agenda Item # 5: Approval of minutes from December 6, 2005 ICOC Meeting:

http://www.cirm.ca.gov/meetings/pdf/2006/02/021006_item_5.pdf

Motion:

- Mr. Goldberg moved approval of the minutes.
- Dr. Love seconded.

Vote:

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

REGULAR ITEMS

Agenda Item # 6: Chairman's Report

Chairman Klein gave an update on the formation of the Citizens Financial Accountability Oversight Committee, chaired by the State Controller, to oversee the CIRM's financial operations and performance, the first time in the history of the state of California that such a committee was created by an initiative forming a state agency.

Chairman Klein: *I would like to begin by saying that one of the great firsts of proposition 71 is that for the first time in the history of the state of California an Independent Citizens Committee has been created by an initiative to oversee the agency's financial operations and performance. This has not ever been true before in the history of the state. It's called the Citizens Financial Accountability Oversight Committee.*

This committee has appointments by the President Pro Tem of the Senate, the Speaker of the Assembly, by the Treasurer and Controller, I make an appointment as chairman of this board, and the Controller sits as the chairman of that committee. In the interim between the last board meeting, I have made the appointment for this board being Myrtle Potter, a person of great distinction with a career including years at the very top levels of Genentech.

Chairman Klein also provided an update on the bridge financing, moving forward well toward the $50 billion benchmark challenge announced at the November 2, 2005 ICOC meeting.

It is expected that the $50 million in bridge financing will be closed in increments, with the first increment dedicated to the Training Grant program. The Finance Committee, chaired by the State Treasurer, will hold a meeting to finalize the terms negotiated with participants, and then the Treasurer's office will set up the timeline for closing.

Chairman Klein: *The bridge financing effort is moving well. Achieving the $50 million benchmark challenge announced in the November meeting for the first time will require an additional noticed meeting of the Finance Committee of the state to finalize all the terms that have been negotiated*

with the participants with the help of the state treasurer's office. The State Treasurer's Office will set up the timeline for closing after that finance committee is held, which may take some five to six weeks from that time to funding. We expect that of the $50 million, it will be closed in increments, obviously with the first increment being dedicated to the fellowship program, which we need immediately. I'd like to particularly express my appreciation to those board members who have been very active in the last increment of time since the final board meeting. It takes a great effort of many of us together working together to accomplish our goals, and it's very important to realize that there's a lot of thanks to be spread around in this effort.

Agenda Item #7: President's Report

President Hall introduced staff members that either had not yet attended an ICOC meeting or were new to the CIRM. He gave a review of the accomplishments of the CIRM and ICOC during 2005, and pointed out that our efforts have not gone unrecognized on the international stage, with the CIRM having been invited to join the International Stem Cell Forum and to hold a joint scientific meeting with the Medical Research Council of the United Kingdom.

Dr. Hall provided thoughts on what 2006 will bring, including the continuation of the litigation with the trial starting February 27 and the likelihood that it will be roughly 15 months – due to the litigation – before we will be able to sell bonds and pursue stem cell research on the scale supported by California voters when Prop 71was passed in 2004. He detailed a model for how we will sustain our scientific vitality and momentum, and lay the groundwork to implement our program at full speed in the spring of 2007.

To view Dr. Hall's presentation, see this URL:

http://www.cirm.ca.gov/meetings/pdf/2006/02/021006_item_7.pdf

Dr. Hall: *Now, I want to begin by making a few remarks. This is the first meeting in this year, and I'd like to just look back briefly on where we've come during the past year and look forward to the coming year. We've had a somewhat tumultuous first year. We've had a number of challenges both locally and worldwide and I want to say that I think the ICOC and the CIRM staff have responded to these challenges superbly.*

The ICOC has been organized and has become a functioning unit, bringing together people from the world of academia and research, from patient advocacy, and from the private sector. The ICOC has established our Working Groups. All three of these working groups have met, and two of them, the Grants Group and Standards Group, have already done major substantive work. We've added critical new scientific and administrative personnel. We have chosen a site and designed new offices. We've issued our first RFA, reviewed the applications, and approved our first grants, all working in a new, more transparent format that has posed challenges for balancing our various priorities.

And finally, we have held our first scientific conference, complete with a write-up of the conference which is almost complete. Most importantly, we have carried a major body of administrative and policy work that will reach culmination in this meeting today with the presentation of three documents to the ICOC that represent the foundation of our institute policies for research. They are the intellectual property policy, the Medical and Ethical Standards, and our Grants Administration Policy. I think you will find that with respect to each of these areas, CIRM, the ICOC, and California has gone above and beyond the national standards in each of these areas. We, I believe, are truly setting a new standard that the rest of the country and, indeed, the world can follow.

Our efforts have not gone unrecognized on the international scene. I want to tell you briefly about two recent invitations that highlight our standing. first, CIRM has received an invitation to join the international stem cell forum. the international forum, composed largely of national research organizations from different countries, was formed to promote international cooperation and collaboration in stem cell research through promoting compatible ethical and scientific standards among different countries. At the recent meeting, the International Forum invited representatives of Italy, China, and California to join their membership.

Agenda Item # 8: Consideration of report from IP Task Force Subcommittee including but not limited to consideration of proposed Interim IP Policy for Non-Profit Organizations.

Dr. Penhoet presented the working draft of the Interim IP Policy for Non-Profit Organizations, as developed over the past four months by the IP Task Force, with input from many parties at its 3 public meetings in that time frame.

James Harrison informed the board of Proposition 71's authorization for the ICOC to adopt Interim Regulations that are outside the scope of the Administrative Procedures Act, enabling the ICOC to adopt the IP Policy for Non-Profits at this meeting, after which they will remain in effect for 270 days during which time they will go through the formal Administrative Procedure Act Rulemaking Process, including public hearing and public comment – providing further opportunity for the public to provide input for this policy. After that 270 day period, the ICOC will adopt the policy as the Final IP Policy for Non-Profit Organizations, sending it to the Office of Administrative Law for review and approval. Once the OAL approves the policy, it will be considered final.

Mr. Harrison: *As we discussed previously, Proposition 71 authorizes you as a board to adopt interim regulations that are outside the scope of the Administrative Procedure Act. This enables you to adopt these guidelines for intellectual policy applied to nonprofit grant recipients today. They, the regulations you adopt, will remain in effect for 270 days during which time they will go through the formal administrative procedure act rulemaking process, including a public hearing and public comment. They will then be adopted as final regulations by you as a board at the close of the public comment period and go to the Office of Administrative Law for review. Once the office of administrative law approves them, they will become final regulations and replace the interim regulations you adopt today.*

Dr. Penhoet: *Since our last meeting -- at the last meeting we developed the five core principles collectively as a group in the last ICOC meeting. We provided an interim document, a long acronym there, the Intellectual Property Policy for Nonprofit Organizations, was provided to the Task Force and posted. The Task Force met again and discussed and approved really a maturation of the five principles into a more fleshed-out document, which you have in front of you today. We had that meeting here at Stanford, and we had lots of input to that meeting.*

The IP task force update was provided to the Standards Working Group, which by Prop 71 has a role of reviewing this material, and Jeff Sheehy presented that to that group. The document was revised, sent to all of you, and posted. And today I'm here to present to you the work of our entire group.

So to refresh your memory, these were the core questions that guided our IP discussions. Who should own any inventions that arise from the funding? How shall we as CIRM require the sharing of data tools, technology, and intellectual property? Three, should CIRM create a research

exemption for the use of IP for basic research purposes? Four, what licensing requirements should be adopted by our CIRM grantees? And then finally, should CIRM retain march-in rights?

Just to give you a quick overview answer to no. 1 is we believe the grantees should own the inventions. No. 2, that we are proposing to push the envelope of what's traditionally been done in the area of sharing of data tools, technology, and intellectual property. An important manifestation of that is that the answer to no. 3 is, yes, we should create a research exemption for the use of intellectual property. In recommending this, we have taken into account the fact that such an exemption may have a consequence of decreasing the commercial opportunity for research tools, etc., and we should talk about that as one of the items as we go through this today.

We have a fairly extensive section in your document about licensing requirements on commercial organizations. The work of our committee was really to balance return to the state, the issues of sharing of data and information, the widespread use of our technology, at the same time trying to ensure that we don't go so far down that path, that we really discourage the commercialization of the technology because there is an awareness on all of our parts that diagnostics, therapies, etc., will only reach patients if they are taken up by the private sector. So we worked hard to achieve what we think is an appropriate balance in that regard. and finally, we believe that CIRM should retain march-in rights to protect the interests of the citizens of California under certain circumstances.

Those are the questions. This is what we decided last time, all of you have this in your book. I've just gone through this verbally. We do support a broad sharing policy, we will create a research exemption, that we will have a return to the state, and that a direct financial return to the state in addition to all of the other returns which we've talked about which are not directly financial, but obviously have financial implications. And finally, that we will have march-in rights as part of this.

So as I said, there are three sections. We're going to focus now in this discussion on section II because this is the part which will eventually have the force of law in the state of California. Within section ii, there are three parts: section G, invention reporting requirements; H, sharing of CIRM-funded intellectual property; and, I, march-in rights. I propose actually that we attempt to approve these sections each individually because the whole package is a very large package. So I would like to proceed by analyzing each of these sections on its own.

The ICOC discussed the working draft of the Policy at length, making changes to the document live and on screen during the meeting. Public comments were also heard and the changes made reflected the board's consideration of the public comments.

The ICOC approved the Interim IP Policy for Non-Profit Organizations, section by section, with changes and additions as discussed, and made on screen, during the meeting.

To view the Interim IP Policy for Non-Profit Organizations as approved, with updates based on the 2/10/06 ICOC discussion, see this URL:

http://www.cirm.ca.gov/policies/pdf/IPPNPO.pdf

Agenda Item #9: Consideration of proposed Draft CIRM Medical and Ethical Standards/Regulations for Human Stem Cell Research.

Dr. Bernard Lo, Co-Chair of the Standards Working Group, presented the Draft CIRM Medical and Ethical Standards Regulations for Human Stem Cell Research, as developed by the Working Group over the past six months, at its five public meetings and three public workshops. The ICOC had approved Interim Regulations, as recommended by the Standards Working Group, at the November 2, 2005 ICOC meeting, and this final draft represented further development and revisions on the part of the Working Group since that time.

Dr. Lo: *Let me just start by saying I'm very proud of the work the SWG has done. I really think that we have gone substantially beyond the current standards set by the national academy of sciences. And I think I'm very happy to be able to present these to you. The Standards Working Group had 19 members and, as you know, we come from a variety of backgrounds. There are scientists and clinicians, there are people with background in law or research ethics, and that was specifically in the language of Prop 71 to make sure that our Working Group had expertise in those areas. We had a number of patient advocates, and there was, I think, very good diversity in terms of geography, people from out of state, gender, and ethnic background.*

The members of the committee have had really extensive experience going back quite a long time serving on national and state panels dealing with human research and with stem cell research in particular. I was very fortunate to be able to have such expertise on our panel.

We also sent out the penultimate version of the draft guidelines to external reviewers, and we were very fortunate that the co-chairs of the National Academy of Sciences committee, which made guidelines for human embryonic stem cell research that were promulgated in May of 2005, Richard Hynes from MIT and Jonathan Moreno from the University of Virginia, both reviewed the manuscript. It was reviewed by the individuals from the Harvard Department of Molecular and Cellular biology, and Harriet Rabb, who's Vice President and General Counsel of Rockefeller and previously served as General Counsel for HHS, also was gracious enough to review these, and they all offered their wisdom.

To summarize the process by which we developed these regulations: we had a series of meetings, five meetings altogether, all of which were open to the public. And I just would like to personally say that I think the public was wonderful. They participated actively. I think we had a good back-and-forth dialogue where we learned a lot from members of the public. They really brought up issues that really deserved our attention, fresh ideas, and I think in large measure the strength of these guidelines is a result of this very open public process.

We also had three public sessions for the interim guidelines where we specifically scheduled them at several locations to get additional input from people who might not be able to attend our regular meetings. We also held a one-day workshop co-sponsored by the university of California, Office of the President, and Gladstone Institute was gracious enough to host us where we invited research institutions in California who are interested in stem cell research, basically all the institutions that applied for training grants, to come and give us their perspective.

So we heard from a lot of different stakeholders in the state and really tried our best to consider, think deeply about the issues they raised. So today we're here to present these to you for your consideration. And I'm going to ask, if I may, James Harrison to just quickly remind us of sort of where we go from here because there are a number of additional steps in terms of the administrative law process and opportunities for more public comment and further ICOC consideration.

James Harrison informed the board that we are at a different stage in the development of these Regulations than we are with the IP Policy. The ICOC adopted Interim Regulations in November, as Dr. Lo explained, and the ICOC was now being asked to adopt the final Draft CIRM Medical

and Ethical Standards Regulations as proposed regulations which will then go through the process set forth in the Administrative Procedures Act.

Mr. Harrison: *We are at a different stage in the development of these regulations than we are with respect to the IP policy. You as a board in November adopted interim regulations to govern the research. What you were doing -- what you are being asked to do today is to adopt these as proposed regulations, which will then go through the processes set forth in the Administrative Procedure Act, which means that the Office of Administrative Law will publish the proposed regulations, there will be a public comment period, and we anticipate a public hearing at which the public will have a further opportunity to comment followed by an opportunity, again, for you to review the final regulations and any proposed changes that come out of the public comments. And then the Office of Administrative Law will have 30 working days to review those regulations. And at that point in time, they will become final and replace the interim regulations that are now in place.*

Chairman Klein: *James, to make it clear for the public and the members of this board, you say an opportunity for you to review. The ICOC would review those comments in a public meeting and take action in a public meeting?*

Mr. Harrison: *That's correct.*

Ms. Lansing: *Even at that point, and I think our whole committee is reemphasizing it, even at that point after all of that, we view this as a living document, a document that as the science changes is an ongoing process that we're always going to readdress and readdress and readdress. And we sort of made a commitment to this, life commitment to this.*

Dr. Lo: *The guiding principles our working group used were, first, to use the NAS guidelines, which you approved as interim guidelines, but to recognize that we really needed to go beyond those. First, the NAS only addressed embryonic stem cells. That was their charge, and obviously CIRM may be funding other types of stem cell research. And NAS really meant to give guidelines that are applicable throughout the country regardless of source of funding. And we interpreted our charge really strictly and narrowly, which was to write regulations, not just guidelines, but regulations for CIRM-funded research. And we had to make sure that we weren't putting things in that were really going to extend beyond our appropriate reach.*

We decided to incorporate all pertinent existing state and federal laws and regulations. There are federal regulations governing all research with human beings. California has additional laws and regulations applying within the state and additional laws for stem cell research. We wanted to incorporate all of those protections in these guidelines, but we also wanted to go beyond the existing standards because we thought that there were a few places where we could make an improvement.

SCRO membership, the stem cell review organization membership, as you recall from your November deliberations, each institution receiving CIRM funding has to set up this body, which was also recommended by the NAS report, to provide oversight and review of stem cell research. The current interim regulations require expertise in all sort of pertinent and multiple disciplines. The Proposed Draft Regulations make two what we think are important additions. One, that every SCRO needs to have at least one representative of the public, and we define that carefully in the regulations, and in addition at least one patient advocate. And we think these two additional requirements for membership will increase transparency, and, we think, build public trust in this very, very important research enterprise.

We also wanted to make sure that we build in flexibility, that stem cell research is new,

the SCRO's are new, and we didn't want to be overly prescriptive in telling institutions how to work things out within their own institutional arrangement. So in response to several queries, we state explicitly that if several institutions want to join together to create one ESCRO, that's permitted. We leave open the possibility of a possible CIRM-funded SCRO for part of the state, and we do not -- we had a lot of questions about the timing of review by the SCRO versus other bodies such as the existing IRB's, and we want to leave that up to the institution as to how to work out the timing. We think that will depend tremendously on local factors and also, frankly, that people as they get more experience with this research and multiple reviews will figure out ways to do it better. We didn't want to prescribe too much at the beginning.

The next big topic is acceptable stem cell lines. So we wanted to set standards for stem cell lines that CIRM-funded researchers could work with. And we had two different ways that a stem cell line could qualify for research under CIRM. One is that if it had been approved or deposited by a number of national bodies that have already quite a bit of experience reviewing stem cell research. A second way a stem cell line could be acceptable for CIRM-funded research would be if the stem cell line met these four criteria. And we think in a sense these are core ethical standards that any stem cell line that CIRM researchers work with, whether it's derived outside of the state or without CIRM funding, should meet these criteria. First, that the donors gave free and informed consent; that the donors received no valuable consideration except reimbursement for expenses. This tracks the Prop 71 language, and we felt that this is such a sensitive issue, that we thought at least at this time that we should not allow donors who were paid beyond their expenses.

We also require that there be no payment for storage of materials before the decision to donate. So that's another way that people might get consideration for payment of storage fees, for example, for frozen embryos. And that stem cell line derivation process be overseen by an IRB. So the core protections we give in all human subjects research, requirement of consent and IRB oversight, we want any stem cell line that CIRM researchers are funded to use to have gone through those oversight processes. And we don't also want necessarily -- we don't need that to be redone a second time by the CIRM investigator if this has already been done.

It may also be likely that CIRM will fund researchers to derive new stem cell lines with CIRM funding. And for that research done within California with CIRM funds, we thought there should be even higher standards. We were reluctant to impose standards outside of California, particularly in countries where they may not be needed, but we thought in California we should go beyond this. And we want to have heightened informed consent requirements for CIRM-funded derivation of new stem cell -- CIRM-funded research. And also, if there's derivation of new stem cell lines, additional protection for oocyte donors and very meticulous recordkeeping so that all gametes, embryos, or products of SCNT there be a tracking of each cell. The reason we wanted to include both more heightened informed consent and additional protections for oocyte donors is that with the recent news, there's been a lot of concern about could there be misconduct in this publicly funded research. And we wanted to make sure that we had reasonable, but not burdensome protections to reassure the public that all work being done with CIRM funding would, in fact, be done to very high ethical standards.

Now, let me try and walk you through the heightened informed consent process for CIRM-funded research. First, we wanted to have extensive disclosure during the informed consent process, and we adopted California laws as well as federal laws and regulations that spell out in really some detail what consent -- what must be disclosed particularly to women donating oocytes. We also put in a set of provisions really having to do with future uses of stem cell lines.

One of the exciting things, obviously, about stem cell research is that these lines can be propagated for quite a period of time in the laboratory. If they're shared with other researchers

under these provisions, the IP provisions that you discussed this morning, other scientists will take them, manipulate them, work with them, do new research, and it's quite possible that if you donate materials to derive new stem cell lines, months or years down the road, a researcher will want to use those cell lines for projects that were not conceived of at the time of the original donation. And the real question is how can people give consent for research that will take place years in the future that no one perhaps even thought of at the time. We tried to approach that in the following way.

One, we think that researchers should not violate any documented preferences that donors have. So if a donor says I'm a supporter of stem cell research, but I don't want my research used for this particular type of research down the road, we think that should be honored as a matter of respecting the autonomy -- the informed wishes of the donor. We also think it's important that the donors be given an opportunity to document their preferences. All the time when you go into a hospital, you're asked to sign a blanket consent that any material left over from your clinical care, you give Dr. Lo and his associates permission to use it for teaching and research. You don't really know what that means, and we felt uncomfortable having that kind of blanket consent. We wanted the donors to really think about this. On the other hand, we also wanted to explicitly allow researchers to include as donors for new stem cell lines only people who would agree to all future uses of their stem cell lines derived from their materials provided, of course, it was reviewed, approved by an IRB and SCRO, and also that it was approved for scientific merit.

Basically what we think needs to happen here is someone donating materials for a new stem cell line under CIRM funding in California, most of the time they're going to have to put their trust in this entire CIRM enterprise to say I can't predict exactly and neither can you scientists tell me exactly what will be done with my cells by other scientists; but as long as it undergoes scientific review and ethical review, I give my permission. We think that's kind of the spirit in which new stem cell lines should be derived. This goes quite a bit beyond, we think, what is required in regulations and guidelines elsewhere in the country.

Now, we also added some additional provisions for oocyte donors. And, again, just to sort of give you a little bit of background, oocyte donation is obviously very sensitive given the nature of these reproductive cells. People have very strong feelings about them, and there have been concerns raised in the public and by senator Ortiz and others in the legislature about what are the risks of oocyte retrieval as it's now currently done? For CIRM-funded research using oocyte donors, we specify additional disclosure regarding risks, particularly the short-term risks of the oocyte retrieval process. We also went beyond that to ask researchers to ascertain that the donor understands essential aspects of the research.

So we think -- I take very much to heart the discussion you had earlier about writing regulations that break new ground, not wanting to overstep and put things in that either won't work or are unduly burdensome or have unanticipated adverse effects. We think this is a situation where there's some precedent for what we're doing, but we're requiring it, and we're also extending it to a discrete segment of research.

Another protection we want to put in is that there be adequate time for the oocyte donor to deliberate about what's a pretty involved process. And we don't want these decisions to be made without adequate deliberation.

In addition, we have yet several more protections for oocyte donors. Again, this breaks new ground, and I'll try and explain the background for this. There's no question that there is a risk, albeit a small risk, of short-term complications of the oocyte retrieval process. There's a hyperovulation syndrome which can cause pain, peritoneal signs, you can have bleeding, you can have infection, you can have complications of anesthesia, you can become pregnant because not all the mature oocytes may have been retrieved. There may be medical

costs associated with taking care of those short-term complications. And we thought, as a matter of fairness or reciprocity, that women who aren't being paid, who are volunteering, who are only being reimbursed for expenses should not have to shoulder the costs of medical care. You say a lot of these people will be insured. Well, that's true, but there may be co-payments, there may be deductibles. And given our healthcare insurance system in this state, a woman may need to apply as an individual and be subject to having a records review. We thought for many reasons it would be desirable not to have the woman have to pay the cost of those short-term immediate risks. We put it on the institution to assume that cost of care, leave it to the institution to figure that out.

Now, we realize this is a complicated process. There are some institutions that are trying to do that. I know the UC system is trying to think about how to do it. It's very complicated. We tried to make it easier by saying there's no long tail here. We're really talking about the short-term immediate consequences which should be fairly easy to calculate on an actuarial basis. At our last meeting we were told that there actually is commercially available insurance for exactly these kinds of complications in the oocyte donation context of an infertility clinic. So we think this is an important step. We don't think it's unreasonable. We don't think it's going to be unduly burdensome to try and implement, but we think it will go a long way towards not asking too much of oocyte donors.

A second protection we wanted to put in has to do with a very particular situation. And that's when a woman is donating oocytes both to CIRM-funded researchers and to a woman who's undergoing treatment in an assisted reproduction clinic. She may be trying to get pregnant herself, or she may be donating oocytes to an infertile woman. It seems to me we were concerned of the complexity of that ethical situation where the woman who's infertile and is trying to get pregnant, she may need every oocyte that can be retrieved. And to give some to researchers may actually harm her reproductive goals. So we wanted to say if that situation occurs, that the way the donor is handled should not compromise the optimal reproductive success of the woman in infertility treatment.

Finally, we wanted to be sensitive to potential conflicts of interest or potential conflicts of interest on the part of the physician who's actually managing the oocyte retrieval process for these research oocytes. We didn't want that attending physician to be the principal investigator on the CIRM grant because he/she might be pulled in two different directions. There's an amendment in your sheets to also say that the attending physician needs to disclose his relationship to the research team and funding, and the attending physician in the oocyte donation may not have a financial stake in the outcome of the research. We think these were protections that needed to be put in place, again, to protect against even the appearance of a conflict of interest. And, again, this is not unlike what's done, for example, in the transplantation context where there's a separation of roles.

We very much view our recommendations as being part of a package together with the IP recommendations and with the grants management policy that you will hear about later, and that there are a lot of issues having to do with compliance, enforcement which we put in some to our regulations, but we really are deferring to the much more sort of detailed regulations that the Grants Working Group will present you with. And also in terms of the materials sharing, we just want to highlight for you that sharing materials is good for many, many reasons. And an additional reason is that we think it serves as a safeguard against misconduct. To the extent that you share your materials with other scientists to try and replicate your work, build upon it, it really serves as a big disincentive to try and commit the kinds of science misconduct that we've seen in South Korea.

Let me try to conclude by saying I'm pleased to present to you, the ICOC, for your

consideration these draft regulations. We ask you to take the next step in this regulatory process of approving these regulations so they can be sent to the office of administrative law and begin this formal public commentary period to which we will then have to respond to those public comments, and have the ICOC deal with them as well.
I just want to add on a personal note by saying I'm tremendously proud of the work this panel has done. I'm very proud of those regulations. I think it's a really big step forward in making sure this research is on a very firm ethical footing. I think it's something that the people of California can be very proud of. Thank you.

We're asking you to approve with the attachment that you got in your briefing book, there are four omissions or misstatements that actually were called to our attention by our very helpful members of the public and the ICOC, and we want you to approve those as well as the thick stapled document with the pretty box that looks like that.

Motion:

- Dr. Pizzo moved for approval of the Regulations with the revisions included on the amendment document.
- Dr. Thal seconded.

Vote:

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

Following Dr. Lo's presentation, comments from members of the public including Shannon Smith-Crowley/American College of Obstetricians and Gynecologists, Charis Thompson/UC Berkeley and Jesse Reynolds/Center for Genetics and Society, Ellen Auriti/UCOP and patient advocate Don Reed, along with questions and comments from ICOC members, **the ICOC approved the CIRM Medical and Ethical Standards Regulations, thereby entering them into the APA process.**

To view the Proposed Medical and Ethical Standard Regulations as approved with revisions by the ICOC on 2/10/06, see this URL:

http://www.cirm.ca.gov/laws/pdf/Regulations.pdf

Agenda Item # 10: Consideration of report from Governance Subcommittee, including but not limited to consideration of policy for removal of Working Group members.

Scott Tocher and Dr. Hall presented the draft Policy for Removal of Working Group members, as reviewed by the Governance Subcommittee at its meeting on January 27, 2006.

Mr. Tocher: *Proposition 71 establishes basic rules governing the appointment of working group members. However, the act is silent as to the circumstances and procedures for their removal. However, the act allows the ICOC to establish guidelines for the operations of these Working Groups. And to that end, the following proposal is designed to address the issue of the removal of Working Group members for cause.*

Section I describes the circumstances for removal for cause of working group members. These were inspired by provisions in other state laws and policies governing other local and state bodies. And it is really, I think, if you look at it, sort of a common-sense list of circumstances that would allow removal. They are delineated in section I, numbers 1 through 7. And they include intentional or grossly negligent violations of the conflict of interest policy, a series of unexcused absences, violation of professional medical or ethical standards, professional employment that would result in an unavoidable conflict; and, finally, a catchall for felonies or other serious misconduct. The second portion describes the initial procedures for suspension of the working group member, and that is accomplished when the president of CIRM gives written notice of the suspension and the grounds for doing so that are delineated above in section I. That suspension remains in effect until any one of three circumstances: One, it is terminated by the president; second, there is a resignation of the member; or, 3, upon consideration of the ICOC.

Section III is sort of a relief valve which allows the CIRM president or the working group chair to allow for excused absences up to six months for good cause.

Finally, section IV of the policy describes the conclusion of the removal process, which is accomplished when the president notifies the ICOC, which then conducts a hearing at its meeting where the working group member can address the board either in person or in writing, after which time a vote is taken by the board.

Chairman Klein: *Thank you very much, Scott. Questions from the board members? But first a clarification from counsel. We're addressing here working group members who wouldn't otherwise be covered by the ICOC conflict provisions and other provisions, so it's non-ICOC members; is that correct?*

Mr. Harrison: *That's correct. This policy applies only to non-ICOC members in the working groups.*

Dr. Steward: *So as they're written, the policy seems well-thought out and fine. I raise the question, though. It's my understanding that it's the ICOC that appoints members of the working groups and, therefore, I'm curious why it is the President of CIRM who's listed in several points there as making decisions. I'm a little concerned about that in terms of the duties of the ICOC.*

Mr. Tocher: *Because the president of CIRM oversees the day-to-day operations and because CIRM -- because the ICOC board is sort of an oversight of that function, that the initial sort of procedure seemed proper to vest it with the day-to-day operations of the working groups and with CIRM to sort of take an initial take on the circumstances that might give rise to the suspension or ultimate removal.*

Dr. Hall: *Let me just say that part of it is the procedure for suspension. With the ICOC meeting every two months, we sometimes need to meet more quickly than that. And if there is a real problem, we need to be very responsive so it. So it's meant to be worded so that we suspend, and then we bring it to the ICOC for consideration either to void the suspension or consider the permanent removal. And also it's our duty actually, I believe, to bring to your attention any misconduct that we believe -- or reason for disqualification that we believe goes on. So I'm meant to act as your day-to-day agent and bring these matters to your attention, but not to supersede your authority.*

Chairman Klein: *So very clearly, the President is acting to suspend and make sure we have immediate action, but it's the ICOC which will remove if appropriate.*

Motion:

- Dr. Nova moved for approval of the policy.

- Dr. Pizzo seconded.

Vote:

- All in favor; no opposition.
- Motion carried; the ICOC approved the Policy for Removal of Working Group Members.

To view the policy as approved, see this URL:
http://www.cirm.ca.gov/meetings/pdf/2006/02/021006_item_10.pdf

Agenda item #13: Consideration of naming opportunity for CIRM training grant program

Chairman Klein: *It has arisen during our bridge financing effort that individuals may be interested in a naming opportunity to benefit the CIRM based upon a preference to give a grant rather than buying the bond anticipation notes. There are obvious very substantial benefits to the people of California of a grant.*

At our August 31st Governance Subcommittee meeting, we first discussed this potential for naming opportunities. It was recommended that the Executive Committee, that is, the Chairman, the Vice Chairman, and the President, make a determination for a naming opportunity for BAN purchases to fund the training grant and or the seed money innovation grant program of 10 million or more.

If the person made very clear as an intention that after one year they would either make it an outright grant or donate their bond anticipation notes, so that we would permanently have the benefit of at least $10 million. There would be a permanent naming of the fellowship program, the CIRM scholars program. It was discussed in the committee that this would be subject to consideration here at the board and approval by the board. As a part of this motion, the program would be delegated to the Executive Committee for implementation to be brought back to this board for acceptance of the final determination and acceptance of the grant.

So this is an implementation step, but you will see the final approval coming back to you. It is important to notice these three elements as summarized in the proposed resolution if it's the sense of this committee. Notice, again, the actual grant or gift will be brought back to the board at a future meeting for final approval. It is a significant item to realize that the gift of funds could be used for any of the purposes of the CIRM, including the ramp-up that dr. Hall referenced and

Dr. Arlene Chiu has addressed before in the scientific staff to give us the internal capacity to reach the level of scientific staff necessary to process our next round of grants, which we may have substantially and hopefully substantially at greater volume.

Ms. Lansing: *I just want to remind those of us on the governance Subcommittee, and then to kind of explain why we came to this. And I think we all felt that if we were so lucky that someone wished to give us, during this time of lawsuits, $10 million with no restrictions on it, that they could have their name in perpetuity. And I think I feel that that's a reasonable thing to say. $10 million is a great deal of money. It could be used for a great deal of grants. We know that we're trying to get BAN's. Those are going to be reimbursed. This naming proposal is for something that's an outright gift. And I think it would be unreasonable to not have an outright gift go with a naming opportunity.*

Dr. Friedman: *I too would like to speak in support of this for a slightly different reason, which*

is, not only at this moment when we need money to do the research, but at any time. I think the fundamental question is what's in this for the citizens of the state? And any way in which we can leverage…people talk about public-private partnerships. This is a real demonstration of that. With the understanding that there are no restrictions, it can be used at the discretion consistent with our strategic plan and our processes, I think this is a perfectly legitimate thing.

One can imagine difficulties that certain individuals who might be unsavory characters or something, you might not want to have a name associated with it. It comes back to this group for a decision, and we can make that decision at the time. And so I think this is a perfectly reasonable thing to do and would be strongly supportive. I don't want to get into the details. We may want to have an individual or a foundation's name hyphenated with CIRM so that the public knows this is a collaboration, but I'll leave that to other people to discuss when we actually have a candidate to focus on.

Motion:

- Dr. Nova moved for approval of the minutes.
- Dr. Pizzo seconded.

Vote:

- All in favor; no opposition.
- Motion carried; the ICOC approved the naming opportunity for a donor to the CIRM, specifically with respect to the potential naming of the Training Grants with the name of a potential donor's choice.

Agenda item #15: Consideration of scientific meeting: Assessing the Medical Risks of Human Oocyte Donation.

Dr. Hall: *I need your help on two items, one fairly short, I hope, and the other a little more lengthy. So if I could take item number 15 first and then go to item no. 14.*

I have talked on a number of occasions about our interest in having a meeting on assessment of medical risk to egg donors, and the intent of this meeting is to focus on the science and ask what do we know based on available data? What do we need to know? And are there practices that we could undertake or recommend that would mitigate or reduce risk for egg donors?

We have in our discussions evoked interest from the Society for Gynecologic Investigation, which, as I indicated before, is the leading scientific society in gynecologic research, a very prestigious group. They wish to co-sponsor with us, and we together would then invite the Institute of Medicine and the National Academy of Life Sciences board to organize and run the meeting, which would meet in California.

We would ask them to do it. They would choose an organizing committee. The organizing committee would choose the speakers. So the meeting would not be run by us in any sense, but would be done at our request, so this would give us, we hope, the very best information under the most objective possible circumstances. We have great interest, I think, in having this information. It is part of our obligation, in terms of what we've just been talking about to women who donate eggs to understand as best as we can what the risks are and what practices there are.

Furthermore, as far as we can tell, there has not been a national meeting on this topic, and we think this will be of national and even international importance. We think it is important. And,

furthermore, we think we should get to it as quickly as possible.

So I would like to request your authority to commit, when the money becomes available, and I'll come to that in a moment, but to commit up to $200,000 to have such a meeting. The meeting would be in California. The institute of medicine and the national academies' life sciences board, their services do not come cheaply, so we would work with them to have the meeting in as economical a way as possible, and I simply point to our previous experience in which we budgeted for our previous meeting $215,000, and we ended up actually doing it for how much, Arlene? 145 or something, 130.

But I want the freedom to be able to do this meeting without further delay and to get it going. institute of medicine will not do anything until we sign a contract with them. So I ask for your approval, if we can raise a $200,000 gift that would go to this, for your approval to go ahead and commit that money toward a contract with the institute of medicine and the national academies to begin work on this meeting. If we were to start today, it would probably take -- we could do it sometime in may, but as we wait longer, that date gets put off. I'm optimistic about us being able to raise that money, and so that's why I come to you in advance to ask for that authority.

Chairman Klein: I think this is an outstanding example of the leadership that we can provide, and in the fact that we're doing it in a time period that's concurrent with the administrative procedures act with the medical and ethical standards is highly relevant to our due diligence and the contribution of the public and the professional societies to this debate and the standards that we move forward with.

Motion:

- Dr. Friedman moved for approval of Dr. Hall's request for the authority to spend up to $200,000, to be raised for this purpose, for a contract with the IOM to plan and put on the a conference on Assessing the Medical Risks of Human Oocyte Donation.
- Dr. Pizzo seconded.

Vote:

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

The board approved, at the request of Dr. Hall, the plan for the CIRM to commit up to $200, 000, given as a gift to the CIRM, toward a contract with the Institute of Medicine and the National Academies to begin planning a scientific meeting on Assessing the Medical Risks of Human Oocyte Donation. Dr. Hall and Dr. Penhoet are working on raising the $200,000 in funds for this purpose.

Agenda item #14: Informational report on plan/process for development of Scientific Strategic Plan

Dr. Hall presented his "plan for a plan" with regard to the development of the Scientific Strategic Plan, and requested board approval to commit up to $500,000 for this purpose, to be paid in fees to Price Waterhouse Coopers who Dr. Hall and a team at the CIRM selected as the best potential firm to hire for development of the plan.

The board discussed the fee amount – not overly high for such an endeavor – and also the plan to work with a consulting firm as opposed to doing the work all in-house or working with one person as a consultant as opposed to a consulting firm.

There was not a quorum present to vote on whether or not to approve the commitment of funds to consulting fees for development of the Scientific Strategic Plan. The ICOC will continue discussion on this topic at a future meeting. It was suggested this be developed further and then considered at the April 6, 2006 ICOC meeting.

Agenda Item #17: Informational report on proposed Interim Grant Administration Policy

Dr. Arlene Chiu reminded the board that at its last meeting, on November 2, 2005, the ICOC approved the Interim Grants Administration Policy for Training Grants, and thanks to that approval, the CIRM can move forward as soon as funds become available for the Training Grants. She informed the board that the Interim Grant Administration Policy on the agenda for this February 2, 2006 ICOC meeting is a draft of the Interim Grant Administration Policy for all CIRM grants.

She requested that the ICOC review this document between now and the April 6, 2006 ICOC Meeting, at which she will request approval by the ICOC of this policy.

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