Summary Minutes of the
Scientific and Medical Accountability Standards Working Group Search Subcommittee of the
Independent Citizens Oversight Committee (ICOC)

California Institute for Regenerative Medicine (CIRM)

Meeting on January 31, 2005

University of California, San Francisco

Regents' Room, Laurel Heights Conference Center

Roll Call

David Baltimore (ex officio)	
Ed Penhoet (ex-officio)	
David Kessler (Chair)	Present
David Serrano Sewell	Present
Jeff Sheehy	Present
Joan Samuelson	Present
Jonathon Shestack	Present
Oswald Stewart	Present

Agenda Item #3
Consideration of process, including criteria and timeline, used to select membership recommendations of the Scientific and Medical Accountability Standards Working Group to the ICOC.

David Kessler presented the proposed criteria for selecting working group members in the three categories of seats – ICOC members from the 10 patient advocacy groups (5 seats), scientist or clinician nationally recognized in the field of pluripotent and progenitor cell research (9 seats) and medical ethicists (4 seats) – and who will commit to the estimated 6 – 8 meetings in the first 12 months.

Comments from the members:

- Function #1 of the Standards working group "to recommend to the ICOC scientific, medical and ethical standards" may need to be clarified. For instance, does it include intellectual property (IP) (Samuelson)
- IP is part of the standards working group (Sheehy)
- Do not get into IP unless specifically charged to (Stewart)
- IP is too complicated to do in regular ICOC meetings – may need ad hoc group (Shestack)
- "Standards" broadly should include IP (Samuelson)

- Keep the charge of the standards working group "pure", i.e. concentrate on medical and scientific standards, as the focus of expertise articulated in Prop 71, is medical and scientific, not IP, Bayh-Dole, or economic issues (Kessler)
- Ethical issues are related to economic issues – similar to issues surrounding organ donation. Should set up ad hoc group that also looks at public benefit issues, like open source. The standards working group should have broad point of view (Sheehy)

Comments from the public:

- IP is not part of the standards working group (Mark Voelker)
- The standards working group needs to represent the public interest (Marcy Darnovsky)
- Expand definition of medical ethicist to include social scientists in humanities (Chris Ganchoff)

The Subcommittee Chairman facilitated a consensus summary that whatever group ultimately handles IP, needs to be broadly based and consider ethical, public interest, legal, and health economics issues in addition to IP. After further discussion, consensus was achieved that any IP ad hoc group should be linked to the standards working group.

Comments from the members:

- The ad hoc group on IP should meet under Bagley-Keene (Sheehy)
- Need more information on whether it should fall under Bagley-Keene (Samuelson)

Comments from the public:

- Look at the NIH's Genome Project's Ethical, Legal, and Social Implications (ELSI) as possible model (Chris Ganchoff)

The Chairman discussed eight further practical criteria for consideration and two qualities to look for in organizing the group:

A. For individual members:

1. Expertise with the Biomedical Ethics of Stem Cell Research
2. Experience with NIH guidelines for research
3. Experience with NAS guidelines for research (stem cell in particular)
4. Experience with informed consent issues
5. Experience with controls on research involving human subjects
6. Experience with patient privacy laws and regulations
7. Experience with medical standards compliance
8. Experience with medical regulatory agencies (such as the FDA)

B. Qualities to look for in organizing group outside of individual qualifying criteria

1. Diversity of experience in the subject areas listed above
2. Balance between scientists and clinicians

Comments from the members:

- Since many questions on the program focus on ethical and fiscal issues, should there be representation from theologians in the working group? (Samuelson)
- If have theologian, would still need to meet other criteria (Kessler)

- There should be a criterion on “resource banking” in public scientific areas like organ banking (Shestack)

Comments from the public:

- Add experience on healthcare disparities in underserved populations (Michelle McMurry)

A motion was made and seconded to accept the criteria, as presented, with two additional “desirable” criteria to the eight for individual members: experience in scientific resource creation and experience with healthcare disparities. The motion passed unanimously.

On the idea of including theologians as a criterion, the Chairman offered suggested language of “recognizing the separation of religious actions and government actions, including looking at potential members who bring a moral, theological perspective, assuming they meet other criteria,” while mentioning his own personal concern with this.

Comments from the members:

- Bring the issue of including a theologian to the ICOC (Stewart)
- Withdrew the request to include a theological perspective until counsel and the AG look into the issue and until appropriate language is drafted (Samuelson)

Comments from the public:

- Strong objection to including a religious perspective as it is unnecessary and brings up the question of what faith to include (Don Reed)
- Concern that this proposal equates moral person with religious person, and that this would bring up a practical problem of how to decide what faith is chosen (Mark Voelker)
- Additional desirable traits to include are experience with conflict of interest laws, representation from the public interest separate from the scientific community, experience with healthcare disparity, and experience with ethics surrounding women’s health, such as egg donation (Jesse Reynolds)

The Chairman asked the subcommittee members for their views on limiting the membership of the working group to Californians.

Comments from the members:

- No reason to limit to persons outside California (unlike the grants working group) but make it heavily weighted to Californians (Shestack)
- Keep search open to Californians and non-Californians (Sheehy, Serrano Sewell, Samuelson)

Comments from the public:

- “Scientists” should be open to natural scientists (Marcy Darnovsky)

A motion was made and seconded that membership to the Scientific and Medical Accountability Standards Working Group is open to residents and nonresidents of California. The motion passed unanimously.

Next the Chairman reviewed a draft flowchart, based on the process that the grants search subcommittee is using for their selection process, that summarized the process used for making recommendations for membership on the standards working group. Two major mechanisms for seeking nominations are professional societies newsletters, listservs, and websites, like the American Journal of Bioethics, the American Society for Bioethics and the Humanities, and the International Society of Stem Cell Research, as well as public recommendations. After all of the initial nominations have been made, they will be screened for eligibility and distributed to three 2-person review teams for further recommendations. The three review teams will bring suggestions for selection to the next meeting of this search subcommittee, at which time the potential nominees will be discussed in an open meeting. Each review team will bring at least 8 names to the meeting, giving us a minimum of 24 for public discussion. The subcommittee will then select 13 nominees to be recommended to the ICOC for approval. The suggested timeline and draft job descriptions were introduced, and the Chairman noted that the subcommittee would need to finalize the due date for submitting nomination forms and suggested that date is February 22, 2005. The chairman noted that the grants search subcommittee made a 10-day due date. The information form will allow screening for qualifications, and provide additional information such as a self-rating of expertise in pertinent subject areas and a time commitment provision.

Comments from the members:

- Can the potential members be discussed in closed session? (Stewart) *Counsel clarified that the members of the working group are not employees and thus cannot be selected in executive session. (James Harrison)*
- Would like more time to review job description language (Samuelson)

A motion was made and seconded to endorse the process, as discussed, to select membership recommendations for the Scientific and Medical Accountability Standards Working Groups, with possible non-substantive stylistic changes to the wording of the job description to clarify certain words. The motion passed unanimously.

Agenda item #4
Consideration of subcommittee's recommendations on how to develop conflict of interest policy for potential members of the Scientific and Medical Research Funding Working Group, Scientific and Medical Accountability Standards Working Group, and Scientific and Medical Research Facilities Working Group to the ICOC.

The Chairman reminded that all three working groups created by Proposition 71 are advisory and have no final decision-making authority, and that members are not considered public officials, employees or consultants for the purposes of the Political Reform Act. However, Proposition 71 also states that the ICOC shall adopt conflict of interest rules based on standards applicable to members of scientific review committees of the National Institutes of Health to govern the participation of non-ICOC working group members.

The Chairman brought to the members' attention a copy of the relevant NIH guidelines, which are familiar to anyone who has participated in an NIH study section. The Chairman proposed that the subcommittee authorize an independent, non-NIH consultant who is familiar with the current NIH standards to develop specific conflict of interest guidelines governing working group members.

Comments from the members:

- Will this consultant also help with interpretation of guidelines? (Serrano Sewell) *No, just with devising guidelines.* (Kessler)
- Would these guidelines also cover grantees? (Stewart) *No, just working group members.* (Kessler)
- What conflict of interest vetting is taking place during the selection process? (Sheehy) *Potential members are notified that they would be subject to conflict of interest guidelines endorsed by the ICOC during the selection process.* (Kessler)

A motion was made and seconded to hire a consultant to make recommendations on adaptation of the NIH conflict of interest guidelines. The motion passed with a majority of 5 votes and one abstention (Sheehy).

Agenda item #5
Consideration of subcommittee's recommendations on two (2) members of the Independent Citizens' Oversight Committee for membership on the Assembly Concurrent Resolution 252-mandated committee to develop best practices for handling intellectual property when generated from state funding as authorized by the Act. Assembly Concurrent Resolution 252 requests the California Council on Science and Technology to create a special study group to develop recommendations on how the state should treat intellectual property created under state contracts, grants and agreements.

The Chairman brought to the members' attention two documents that were posted with the meeting agenda – actual language of Assembly Concurrent Resolution 252 and the letter from the California Council on Science and Technology to participate with their process to develop recommendations on intellectual property created with state funds.

The Chairman suggested that ICOC members with expertise in intellectual property issues be identified at the February 3rd meeting. He feels that the it is advisable to select one member with academic IP experience and another with industry IP experience to form the 2-member team representing the ICOC. As a point of information, he relayed that Susan Hackwood, executive director of the California Council on Science and Technology, supports ICOC members Susan Bryant and Michael Goldberg as representatives on this committee.

Comments from the members:

- The participation of the ICOC does not bind us to any of the recommendations that come out of the ACR 252 process (Shestack)
- Suggest sending out a request regarding interest in serving on the ACR 252 process (Stewart)

The consensus of the subcommittee was to discuss this at the next ICOC meeting and to survey ICOC members ahead of time regarding their experience and interest in serving. ICOC members should let the Chairman know about their interest.

Agenda item #6
Report on status of Senate Bill 322 and discussion of subcommittee's cooperation and consideration of actions. Senate Bill 322 requires the State Department of Health Services to develop guidelines for research involving the derivation or use of human embryonic stem cells in the state through the creation of a Human Stem Cell Research Advisory Committee.

The Chairman introduced the agenda item with a brief background on Senate Bill 322. SB 322 requires the California Department of Health Services to develop guidelines for research involving the derivation or use of human embryonic stem cells in the state. These guidelines are to be developed by an appointed 13-member task force. SB 322 was passed when there were no guidelines for embryonic stem cell research. We now know that the National Academies is scheduled to release standards in April of this year. Senator Deborah Ortiz, a strong proponent and champion of stem cell research, sponsored this bill in the 2003 legislative session. After passing the Legislature, it was signed into law by then-Governor Gray Davis in September 2003. The bill required that guidelines be issued by January 1, 2005. However, at the time the bill was signed into law, no new funding was included for staffing the effort. In last year's legislative session, money for staffing the created task force was included in the state budget. Since last summer, DHS staff have been identifying potential members, but at this time, none of the 13-members has been named, nor has the task force met. Needless to say, the January 2005 deadline was not met.

The Chairman recommended that the ICOC and the Standards Working Group should fully cooperate with the SB 322 task force, and that a letter should be sent to the Governor to get a formal progress report on the SB 322 task force, as until we know this information, it is unclear how to proceed to cooperate. At a minimum, the Chairman recommended that the appropriate Institute staff attend the meetings of the SB 322 task force and report back to the ICOC.

The Chairman then introduced Dr. George Cunningham of the California Department of Health Services who gave a brief update. He has submitted 14 names to the DHS Director for consideration, but to date, none has been formally appointed. He is searching for two positions to staff this process and to date has hired one of them. Tentative meetings are scheduled for February and March. Dr. Cunningham explained that the difference between the SB 322 task force and the Proposition 71 Scientific and Medical Accountability Standards Working Group is that the guidelines created under SB 322 would cover stem cell research that is privately or federally funded, as Proposition 71 is exempt, other than the prohibition on payment for the donation of embryos.

<u>Comments from the members:</u>

- The letter should focus on cooperating with the SB 322 process (Shestack)

A motion was made and seconded to send a letter to the Governor that the ICOC would like to cooperate with the SB 322 process but cannot fully cooperate until the appointments are made. The motion passed unanimously.

Agenda item #7
Invitation to members of the public and the ICOC to submit the names and contact information of candidates and any background information for consideration for membership on the Scientific and Medical Accountability Standards Working Group to info@cirm.ca.gov or by mail to P.O. Box 942850, Sacramento, CA 94250-5872.

The Chairman reminded everyone that any interested party who wishes to either apply for membership to the standards working group or to nominate a qualified candidate for membership must do so by February 22, 2005.

Agenda item #8

The Chairman asked for any final member or public comments.

- Raymond Barglow of the Stem Cell Action Network said that he thought this was a very productive meeting. Rather than read a statement that he prepared, he asked that it be included in the minutes. The Chairman accepted this request.

The meeting was adjourned at 6:20 PM.

Action items:

- Report on subcommittee's selection process at February 3, 2005 ICOC meeting
- Survey ICOC members on their interest in serving on the ACR 252 committee
- Send a letter to the Governor on cooperating with the SB 322 task force

Stem Cell Action Network Statement Presented to the
Accountability Standards Working Group Search Subcommittee
January 31, 2005

My name is Raymond Barglow and I am here this afternoon representing the Stem Cell Action Network, a nationwide grassroots organization consisting of patients, their families, and other advocates. I have a personal interest in finding a cure for devastating illnesses, since my mother died of Alzheimer's disease. I would like others not to have to go through what our family experienced as my mother gradually lost her mental capacities and eventually her life. The following remarks take up three matters:

1. Oversight Implementation. Many of the ethical and regulative concerns regarding stem cell research are already addressed by federal and California state policies governing biomedical research. These policies have been established by such federal agencies as the NIH, FDA, and the Recombinant DNA Advisory Committee (RAC). These agencies, along with California regulatory and advisory bodies already in place, should continue to work with the California Institute for Regenerative Medicine (CIRM) to ensure establishment of appropriate oversight.

We note the ICOC's cooperation with California state government to implement Proposition 71 safely and ethically. Specifically, the ICOC has indicated its interest in working with the California Council on Science and Technology, which was established by California state government to advise the state on scientific policy issues. This Council, a not-for-profit organization whose members include California's universities and community colleges, works closely with the National Academies and is well suited to working with the Accountability Standards Working Group in developing appropriate policies. We appreciate as well the ICOC's cooperation with California Senate Bill SB 322, which authorizes the State Department of Health Services to develop guidelines for stem cell research.

The CIRM's collaborative approach to addressing oversight matters is evident as well in the Institute's participation in the National Academies Best Practices Workshop on Stem Cell Research recently held in Irvine, California. The documents discussed in this Workshop provide excellent policy guidelines and merit careful scrutiny.

2. The Educational Mission of the CIRM. California citizens need to be informed about the science and the therapeutic implications of stem cell research, and also about oversight policy issues. In fact, policy issues cannot be adequately reflected upon in the absence of at least a basic scientific understanding. The American Association for the Advancement of Science expresses this well:

> "It is essential that there be a public that is educated and informed about the ethical and policy issues raised by stem cell research and its applications. Informed public discussion of these issues should be based on an understanding of the science associated with stem cell research, and it should involve a broad cross-section of society."

Hence the CIRM, including its working groups, have the responsibility for interacting with and educating the public on policy matters. This responsibility should be considered one of the Institute's high priorities, and sufficient resources should be devoted to carrying it out with the same diligence that has characterized CIRM proceedings in other domains.

The newly established and independent non-profit organization, California Research and Cures Coalition, can play a role in facilitating communications between the CIRM and the public. We applaud the recent selection of patient advocate Nicole Friedland as President of the CRCC.

The CRCC's four public forums held up and down the state of California this month (January 2005), in which stem cell research and policy issues were discussed, were valuable efforts. While the content of these meetings

was of a high quality, only two transcripts for the meetings have been posted to the CRCC website. These transcripts are poorly formatted, lack clear separations between the presentations, and omit the powerpoint graphics that help to explain what the speaker is talking about.

While we welcome the educational activities of the CRCC, its existence is independent of the CIRM and does not relieve the CIRM of its own responsibility to inform the public.

3. The Importance of Promoting Research in the Public Domain. We in the Stem Cell Action Network would like to emphasize as well the importance of keeping stem cell research centered in the public domain. We recognize that the private sector has a vital role to play in the initiative that California is taking, especially in the final stage of therapy development: bringing new therapies to the marketplace. However, we concur with the view of the American Association for the Advancement of Science that:

> "The private sector makes determinations about investments on the basis of potential profitability. This has several implications. The private sector will not invest resources in potential applications that they consider lacking in commercial value, but that may have considerable therapeutic promise. Commercial considerations will also affect the pricing of stem cell products. Here again, market concerns could raise prices, making stem cell therapies more expensive."

Indeed it is science done in California universities and non-profit institutes that will be the most likely source of remedies that are widely and affordably accessible to the public.

Intellectual property considerations will be among the most challenging considerations that the ICOC, and more specifically the Accountability Standards Working Group will face. In keeping with the CIRM mandate to advance stem cell research in the public interest, the granting of intellectual property rights and compensations ought not to impede scientific research or therapy development. While recognizing legitimate rights of authorship and discovery, the CIRM should ensure that these rights serve the public interest. Researchers whose work is funded by the CIRM should be not only permitted but encouraged to interact and share their methodologies and discoveries with one another and with the larger scientific community.

Bruce Alberts, President of the National Academy of Sciences, pointed out during the Irvine workshop on Prop. 71 implementation that California has a chance to set a new model for scientific research. Accessibility to research results is currently under review within the scientific community. Increasingly, publicly-minded scientists, supported by patient advocates and other stakeholders, are calling for free and open communications and the sharing of discoveries and data. Such openness is as essential to the advance of stem cell research as to progress in any other scientific domain, and we request that the CIRM participate in current initiatives to improve and ensure effective information-sharing and collaboration. Cooperation of this kind will be essential to move stem cell science forward and fulfill its therapeutic promise.

Conclusion. The work of the Institute for Regenerative Medicine will serve the interests not only of Californians but of millions of Americans nationwide who hold out hopes for the development of new, effective therapies. And California will serve as a model for other states in our nation that are considering undertaking a similar effort. We in the Stem Cell Action Network encourage and support these additional state funding initiatives, and look forward to working with the Accountability Standards Working Group to realize the humanitarian potential of stem cell research.

Raymond Barglow, Ph.D.
Advisory Board, Stem Cell Action Network