

California Institute for Regenerative Medicine

Summary Minutes of the Independent Citizens Oversight Committee (ICOC) of the California Institute for Regenerative Medicine (CIRM)

Meeting on January 25, 2005

University of California, San Diego

Pepper Canyon Hall, Director's Conference Room

Roll Call

<i>David Baltimore (ex officio)</i>	
Ed Penhoet (ex-officio)	Present
Keith Black	Present
Brian Henderson	Present
Ed Holmes (Chair)	Present
Sherry Lansing	Present
Gerald Levey	Present
<i>Ted Love</i>	<i>Absent</i>
<i>Phil Pizzo</i>	<i>Absent</i>
John Reed	Present
Jeff Sheehy	Present
John Shestack	Present
Leon Thal	Present
Janet Wright	Present

Agenda Item #4

Consideration of criteria for Selecting Scientific and Medical Research Funding Working Group members, both scientists and patient advocates

Ed Holmes presented the proposed criteria for selecting scientific reviewers making clear that the charge of the scientist reviewers is to do initial ranking of the scientific merit of the grant submissions; the entire Grants Working Group, including seven appointed patient advocates, will then vote on which grants to recommend to the ICOC for funding.

Item B (b)-Geographic diversity, majority from out-of-state with some in-state experts in fields subsumed by and related to stem cell research.

General consensus of the search sub committee is that eligibility be limited to out-of-state reviewers. Ed Holmes points out that the ultimate goal is having the best candidates serve on the grants working group and suggests that limiting the pool may be problematic.

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Gerald Levey proposed to amend the language of the proposed criteria for selecting working group members to read:

- a) "Must have a mix of basic scientists and physician scientists *from institutions outside of California*"
- b) "Scientists who are not doing stem cell research, but are considered experts in biomedical research subsumed by and related to stem cell research are eligible for membership."

Comments from the Sub Committee Members:

- There are areas outside of stem cell research that have adept investigators; these areas should not be ignored (Dr. Leon Thal)
- We need to ensure that we get the best and the brightest; there is no reason to suspect that we will not have some conflict of interest concerns to address even if we pool scientists only from out of state; selecting out of state reviewers will not eliminate all concerns over conflicts (Dr. Ed Holmes)
- There should be a diversity of experience represented on the Committee (Dr. Keith Black)
 - This is largely satisfied by our ability to bring in ad hoc members as necessary (Dr. John Reed)

Comments from the Public:

- There should be a statistician on the working group (Dr. Phil Posner)

The question of whether diversity in discipline needs to be stated as an explicit criterion for the working group selection process. It was agreed upon that this is not necessary given that the working group has latitude to select ad hoc reviewers from broad sources of expertise outside the working group depending on the needs of the grant under review.

Item E (i) They will be paid

Chairman Klein clarified that it is within the discretionary powers of the grants working group, when deemed necessary, to authorize a consulting compensation as well as reimbursing for staff that are supporting the reviewer in reviewing the grants.

The search sub committee requested that the language be formalized to read "honoraria".

Motion to approve the proposed criteria for selection of members was passed by majority vote of 9 affirmative votes. There was one abstention on this vote and 2 absentee members who did not vote.

Item E: Time commitment

The initiative proposes a six-year term for grant working group members. The general belief among the members was that this term is too long and could be a disincentive for top quality reviewers.

Chairman Klein pointed out that the term commitment is flexible and should be read as “up to” six years. The search sub committee recognized the need for a mechanism for dealing with terms of service, e.g., staggering the terms of service would be a benefit in avoiding a complete turnover after the initial six-year term.

Chairman Klein presented the following scenario: The initiative provides that at the end of the initial six-year period, the staggered terms start. What could happen here is that if someone served two years and someone has a replacement term for four years, then the third appointment would fall into the staggered term category. Because many reviewers may only serve part of a six year term, a natural staggering of terms will probably begin on or about the third year.

Informational Note:

A complete turnover after the initial six years can be avoided by reappointing a portion of the reviewers prior to that time.

John Reed questioned whether the time burden on individual reviewers could be modified by having fewer than the proposed 4 grant periods per year. Chairman Klein clarified that, while the legislation does specify 4 grant cycles per year, one or more of the grant cycles could be very limited (such as focused on intellectual infrastructure such as scholarships for post docs) so as to pose little demand on the reviewers.) In this way, flexibility is built into the initiative.

Agenda Item #5. Invitation to members of the public and the ICOC to submit the names of candidates and any background information for appointment to the Scientific and Medical Research Funding Group

Ed Holmes reviewed the proposed process of gathering nominees for the committee to review. The following sources were suggested:

- NAS & UC list of leaders in stem cell research
- Nominations from professional societies' e.g., Society for Neuroscientists, American Society for Cell Biology. The committee agreed that these should not be solicited as a general broadcast to members but rather a request to the societies themselves to nominate individuals
- Solicitation from ICOC members to submit nominations
- Solicitation through the CIRM website to the public
- Foreign investigators are also eligible

**All nominations should be sent c/o Amy Daly to the CIRM website at info@cirm.gov
The deadline proposed for all submissions: Monday, February 14.**

There was concern among some search sub committee members that the working group would be selected without input from the incoming President. Chairman Klein suggested that, while this may be the case for the initial period, there would be turnover among reviewers, and in the case of the chairmanship of the working group, the sub committee could recommend that the initial grant working group Chairperson's term be limited to six months and the replacement chair be selected with the advice and consent of the President.

There is general agreement among search sub committee members that NIH standards should serve as the base guidelines for dealing with conflicts of interest.

Agenda Item #6: Create interview teams to begin evaluating potential members based on criteria

Ed Holmes presented the proposed process for selecting working group members. This process follows:

- The search sub committee would be divided into 6, two-member interview teams
- Qualifying nominees would be divided equally among the 6 interview teams
- Each interview team would rank their nominees based on criteria set forth by the search sub committee and begin interviewing candidates to arrive at 5 top candidates.
- The result would be 30 candidates which would be narrowed to 20 by the search sub committee as a whole in context of an open meeting.
- These 20 candidates will be recommended to the ICOC and reviewed for final approval; the ICOC has the ability to select candidates, other than those recommended, and or modify the criteria or process, along with the option of selecting from the candidates recommended
- This process was developed not only to limit the individual workload of the search sub committee members but also limit the number of nominees whose reviews would be subject to public discussion. This is in the interest of preserving unnecessary breaches of privacy of those being considered for the working group.

Comments from the Sub Committee Members

John Shestack: Is there a way to arrange the process so that the incoming President is given the opportunity to provide input on working group members? How is this possible if the President will be coming on after the working group members have been formed and will presumably serve for a terms of up to six years?

While the search for a president is ongoing, he/she will not be in place for several months; this would significantly delay the process

Chairman Klein suggested the President would have input into the selection of the Chairman of the working group. The Chairman would have influence over policy decisions of the working group. Klein proposed that there might be an annual selection process for the Chairman which would directly involve input from the President.

Comments from the Public

Michelle McManus: there needs to be a mechanism in place so that we ensure overlap and there is not a complete turnover in six years

Comments from the Sub Committee Members

Brian Henderson: There needs to be established criteria for replacing reviewers who vacate their posts as well as develop the selection process/criteria for selecting ad hoc reviewers

Sherry Lansing: expressed concern about the fact that the nominees will be publicly vetted and explored ways in which to preserve the privacy of nominees. Can this meeting be held in closed session?

Chairman Klein responded that this meeting of the search sub committee cannot be held in closed session b/c executive sessions are only permitted for employees of the state; the working group members do not fall under this personnel exception because they are not considered employees of the state. There is no way to insulate the serious candidates from public review. This consideration must be done through public meetings.

Brian Henderson: The question was raised as to whether there can be a broad "reviewer pool" from which to select reviewers rather than have a static 15-member scientific review working group.

Sherry Lansing, to shield the nominees from any type of public humiliation from not being selected, proposed that the search sub committee recommend 30 candidates; 15 of whom would be chosen as full members of the working group, the remaining would serve as "ad hoc experts." In this way, those not selected to the full working group would not be considered "rejected." Furthermore, this would mitigate the potentially negative aspect of public vetting of nominees; individuals might be more willing to be considered under such an approach.

The amended process proposed by Lansing and supported by other members of the search sub committee follows:

- The search sub committee would be divided into 6, two-member interview teams (same as original proposal)
- Qualifying nominees would be divided equally among the 6 interview teams (same as original proposal)
- Each interview team would rank their nominees based on criteria set forth by the committee and begin interviewing candidates to arrive at 5 top candidates. (same as original proposal)
- The 30 recommendations of the 6 two member interview teams would be reviewed by the entire 12-member search sub committee in the context of an OPEN meeting. (same as original proposal)
- At this open meeting the search sub committee would select among the 30 recommended scientists, 15 who would serve as "full members" and 15 who would serve as "ad hoc experts" on the working group. *[The working group will also reserve the ability to draw expertise from a larger pool of ad hoc experts depending on the nature of the grants being considered.]*
- These 30 recommendations will be forwarded to the ICOC as a slate of 15 full members and a slate of 15 ad hoc members for review and final approval.

Motion to approve the proposed process for selection of working group members was passed by consensus vote of 10 affirmative votes. There were and 2 absentee members who did not vote.

It was noted that this process was exclusively to select scientific reviewers who will be responsible for reviewing grants for scientific merit. Importantly, there will also be seven patient advocates who will serve on this working group. Patient advocate members on the working group will not participate in the initial ranking. Ranking would be done by the scientific members, after which time the entire working group, including the patient advocates, would vote on what is forwarded to the ICOC.

Agenda Item #3: Consideration of the format of grants we expect the Scientific and Medical Research Funding Working Group to review.

Ed Holmes presented the proposed categories of grants. This was presented as an information item, only for preliminary discussion.

These grants refer to the first cycle of grant funding only; the type of grants will be evolving. The current proposed grants are:

- Intellectual infrastructure (training)
- Seed
- Centers of Excellence
- The initial grant period will not fund for-profit organizations or clinical research trials
 - Particularly since the Standards Working Group is not in place to make recommendations on standards that will guide the Institute

Grant proposals will be solicited covering embryonic stem cell research, and Other Vital Research Opportunities.

Note: In order to be recommended to the ICOC for funding, the Initiative requires that the Scientific and Medical Research Funding Group approve embryonic stem cell research grant proposals by a simple (50%) majority vote and approve adult stem cell research [or other Vital Research Opportunities] proposals by a 2/3 majority vote. It is at the recommendation level that there is a structural preference to deal with the complete lack of effective funding at the NIH for embryonic stem cell research.

Co-Chairman Penhoet made the point that this is by no means a comprehensive list of grants the Center will fund.

Action Items for 2/3

- Establish nominating procedure and post nomination form/information at info@cirm.ca.gov
- Modify criteria and nomination process

For Future Consideration:

- Establish procedure for staggering Working Group members terms of service
- Clarify allocation of money for grants (which will be included in RFA, other contracts?)