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Minutes of the Independent Citizen’s Oversight Committee (ICOC) to the California Institute for Regenerative Medicine (CIRM)

Meeting on February 3, 2005

The Neurosciences Institute
10640 John Jay Hopkins Drive
San Diego, California 92121

Roll Call

David Baltimore Surrogate: Paul Jennings	Present
Robert Birgeneau	Present
Keith L. Black	Present
Susan V. Bryant	Present
Michael A. Friedman	Present
Michael Goldberg	Present
Brian E. Henderson Surrogate: Francis Markland	Present
Edward W. Holmes	Present
David A. Kessler	Present
Robert Klein	Present
Sherry Lansing	Present
Gerald S. Levey	Present
Ted W. Love	Present

Richard A. Murphy	Present
Tina S. Nova	Present
Ed Penhoet	Absent
Philip A. Pizzo	Present
Claire Pomeroy	Present
Phyllis Preciado	Present
Francisco J. Prieto	Present
John C. Reed	Present
Joan Samuelson	Present
David Serrano Sewell	Present
Jeff Sheehy	Present
Jonathon Shestack	Present
Oswald Steward	Present
Leon J. Thal	Present
Gayle Wilson	Present
Janet S. Wright	Present

Agenda Item #4

Approval of minutes from January 6, 2005 ICOC meeting.

The draft 1-6-05 minutes had been circulated the preceding day and Chairman Klein gave board members the option of taking additional time to consider the minutes and approve them at the March meeting.

No comments from Board or Public

Motion made to approve the minutes. Motion seconded and approved by voice vote.

Comments from Board:

Question raised as to whether board member substitutes are voting members of the board.

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CIRM outside counsel James Harrison clarified that Health & Saf. Code Section 125290.20(A)(2)(d) permits an executive officer of a California University, nonprofit research institution or life science commercial entity who is appointed as a board member to delegate, from time to time, those duties to an executive officer of the entity or to the dean of the medical school, if applicable. In order for a member to designate an alternate under this section, the alternate would have to be sworn in and would be considered a public official subject to the requirements applicable to all other members of the board (including need to file Form 700 and recuse him or herself from a decision to award a grant in which he or she had any participation whatsoever.) Alternatively, a member may send a designee to audit the meeting. Patient advocates, under the Act, do not have the authority to appoint a voting alternate. They may designate individuals to attend the meeting to audit.

Question raised as to whether alternate needs to be a citizen of California.

Agenda Item #5

CIRM Interim Office space update.

Chairman Klein reported that the Institute staff would move into new, temporary space on February 11. This is a critical first step in the continuing development of staffing structure and overall functionality and effectiveness. The Department of General Services provided four specialists to assist with the logistics of this move.

Klein highlighted some of the terms of the space agreement: 7400 square feet ready for occupancy; nine private offices and one conference room; located close to two airports, Amtrak and BART; adequate space to expand to 30+ persons. The intended occupancy is for less than six months, and the lease provisions allows for free rent during up to seven months of a 12 month period. The lease can be terminated at any time with 30 days notice. Landlord also provided free tenant improvements and furnishings.

Comments form the Board:

Question raised as to whether facility would accommodate ICOC meetings. Chairman Klein responded that the space is not intended to accommodate ICOC meetings, but that permanent CIRM office space ideally will have greater meeting space.

Observation that the ICOC meetings will continue to move from site-to-site over the next six or seven months. Chairman Klein asked whether board members saw a benefit in continuing to rotate between sites. Observation that this is a good idea, particularly as it affords members of the public in different parts of the state the opportunity to attend a meeting. Specific suggestions made to hold meetings in Los Angeles, Fresno, and Irvine.

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Request made to enter name of company that is leasing the temporary space into the minutes. The company is called Wareham Development and has holdings in the east bay. Chairman Klein pointed out that there is no known connection between Wareham development and any beneficiary of any potential grant, and that no consideration is given in the interim lease for any consideration in the permanent location. Chairman Klein also asserted that there is no connection between Wareham Development and Klein Financial Corporation. The same clear representation will be made with respect to the permanent space.

Comments from the Public:

Jean Loring, Burnham Institute, asked what the lease terms would be for the final five months at the temporary space. Deputy ICOC Chair Amy DuRoss responded that the terms, which are still being negotiated, would be market rate.

Bradley Fikes, North County Times, asked for the exact address. The address is 5858 Horton Street in Emeryville, off the Powell exit. Chairman Klein offered to post the rent terms for the balance of the term on the website.

***Agenda Item #6
CIRM staffing update***

Introduced by Chairman Klein. (See staffing memo.) Two high level positions filled through interagency agreements. Intermediate term contracts signed for outside general counsel and communications. Deputy Vice Chair also hired.

Comments from the Board

- What process was used to make hires?
 - o Five individuals were hired who had gained a great deal of expertise while working for the Prop 71 effort and subsequent non-profit. These are Chairman and board support hires, not scientific-area hires. The CIRM has now adopted a policy of posting public notice of positions and taking applications for these.
- Expression of appreciation for work done by staff people and satisfaction with service provided.

Comments from the Public

Jesse Reynolds, Center for Genetics and Society: (1) How were salaries determined relative to other state agencies? (2) Some questions on job application could be characterized as intrusive.

- Salary structure is specifically addressed in the Initiative, and is indexed to the UC system and other research institutions represented on the ICOC.
- Application came from the Governor's office.

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Recent LA Times Article reported that \$1 million of Yes on 71 campaign debt is owed to Mr. Klein, who individually loaned money to the campaign. To avoid conflicts, Mr. Klein is encouraged to make the roles of leadership and staff at the Institute clear and separate from those of the CRCC nonprofit advocacy organization, the Yes on 71 campaign, and Mr. Klein's personal and business finances.

Chairman Klein responded that there are very clear lines between these institutions and that the amount of debt reported in the press did not take into account counterbalanced assets. He also emphasized that he is making no efforts to raise any money to deal with his long term debt.

Agenda Item #7

Consideration of Summary Minute Report of the Presidential Search Committee

Primary undertaking of the presidential search committee is to supervise the process for selecting candidates for President and Acting President of the CIRM. General criteria for selection of president were summarized and approved (called the "Lansing Proposal"):

1. Outstanding scientific and Biomedical Expertise
2. Proven Management Capacity
3. Sensitivity to Political Ramifications and Implications

Committee solicited proposals by RFP to executive search firms for engagement in search for eligible candidates for president. Authors of top three proposals will make individual presentations today before the board. List of ten criteria was approved by committee to be used in analyzing executive search firm proposals. (See 1-24-05 Presidential Search Subcommittee minutes for list.)

Comments from the Board:

Question raised as to whether it is necessary to have a staff member attend every teleconference subcommittee meeting site. Chairman Klein responded that as a best practice a staff member should be present to assure board members that someone is there to make an evidentiary record that all proper procedures were followed and that board members were not put in the position of not being able to verify with an independent person that the board member carried out all the necessary procedures. Staff members are also present to help accommodate members of the public.

Comment that background and expertise in effecting treatments and cures and not just in conducting biomedical research should also be reflected in the search firms' presentations.

Comment that an additional quality to consider in evaluating search firms is that they have a demonstrated commitment to working with under-represented

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communities and providing equal opportunity. Chairman Klein and other board members expressed support for this suggestion.

Search Process Timeline Presented

Chairman Klein presented the timeline for the search process:

- Reconvene presidential search subcommittee in four weeks from selection of firm to review long list of candidates;
- Review of long list of candidates by two-person interview teams to create short list;
- Present short list to full ICOC for comment and decision as to whether entire board wished to interview and rank top 2 or 3 candidates.
- ICOC then authorizes search subcommittee to make offer to highest ranked candidate, then second-ranked, etc.
- Process subject to amendment from input from executive search firm to board, or from board itself.
- If any candidate for permanent president was from an institution represented on the board, that board member would recuse him or herself from voting.

Comments from the Board:

Affirmation that the entire ICOC should interview short list. Comment that reference checks should be mentioned as a step in search timeline. Request that an equal employment opportunity report on long list of applicants be provided to the ICOC when short list is presented.

Chairman Klein reminded members of the public that they can submit candidates by email to the CIRM.

Question as to who decides what the salary structure will be for the president. Chairman Klein pointed out that the ICOC could discuss salary structure in executive session but the actual salary must be approved in public session.

Comment: Dr. Preciado did not see in the minutes her comment about sending emails to organizations that are reflective of communities of color. Ms. DuRoss commented that the proposal had been sent out to the organizations enumerated by Dr. Preciado and that the minutes would be amended.

Comment: The president's job description is taken wholesale from the initiative itself, but will be further developed with the assistance of the search firm.

Suggestion that transcripts be posted on the CIRM website.

Motion made to approve the minutes with amplification of need to focus on equal opportunity employment. Motion seconded and approved by voice vote.

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Agenda Item #8

Consideration of qualifications for candidates for president and procedures for appointment, including role of Presidential Search Committee.

Procedural item: During the executive session (agenda item #10) board will discuss candidates for interim president. In order to arrive at a salary that a candidate would accept, it is important that there be discussion with Interim candidate selected by board, to take place after a salary range is set in executive session.

Board was asked for support in delegating to Chair and Vice Chair ability to discuss salary, within range set in executive session, with selected Interim Presidential candidate.

Salary would then be brought back to full board at next meeting so it can be discussed and adopted in a public session.

Motion made to delegate ability to discuss Interim President's salary to Chair and Vice Chair. Motion seconded and unanimously approved by voice vote.

Agenda item #9

Consideration of selection of Executive Search firm to assist in search for President, including presentations from three Executive Search firms whose proposals were recommended by the ICOC Presidential Search Committee.

Presentations made by A.T. Kearney, Isaacson Miller and Spencer Stuart.

Suggestion made by Chairman Klein for ICOC members to vote for the number one choice, then hold a subsequent vote for the number two choice.

Question from Joan Samuelson: Is this the hiring of a firm or of a search professional?

Good point: while we're hiring a firm, we want to be clear on who will be the responsible principal and what the time commitment of that responsible principal will be. If one, two or three team leaders will all commit substantial time, please make that clear as well.

Question from Dr. Thal (unrelated to search firms) can members of the ICOC apply for grants? Or are we prohibited from applying for grants? Is there language in the act?

Chairman Klein: The Grants Working Group Search Subcommittee needs to provide policy recommendations. There is no language in the act.

A.T. KEARNEY

Alberto Pimentel, Vice President in charge of western region for education non-profit practice.

Terry Scherck, life science practice.

Basic assets: superior intellectual capital and research, very experienced consultants, and substantial interface with our management consulting firm, parent A.T. Kearney, Inc. with very well developed and robust pharma and healthcare practice.

Questions/Comments from the Board:

Dr. Birgeneau: Can you tell us what searches you are currently carrying out and what percentage of your time either or both of you will devote to this search?

A.T. Kearney answer: From our perspective, this is the premiere search to conduct. Part of it because it's groundbreaking. Part of it because it is going to set a trend for the rest of the United States and the rest of the world to follow.

We would do what we did with other large searches, such as the UC Presidency. Terry and I would be the team. You would have two senior vice presidents conducting the search. This is a large search in terms of reach and scope. We think the best way to address it is to have a team that does nothing else.

Dr. Levey: What kind of timeline could we expect before receiving your short list?

A.T. Kearney answer: Short answer: we could pull together a short list in eight to ten weeks. Longer answer: it will really depend on how broad you want to go.

Dr. Pizzo: Can you describe your working relationship together?

A.T. Kearney answer: The two of us have worked together extensively.

Dr. Pizzo: How would your firm handle candidates who may arise from institutions where you have previously placed individuals?

A.T. Kearney answer: First, there would be a limited number of off limits individuals, which would cause a problem here. Second, we would work with you hand in hand. If you identified individuals we could not pursue due to obligations to clients, we would notify you immediately and instruct you to contact the individual directly.

Claire Pomeroy: For this particular search, what are your proposed fees?

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A.T. Kearney answer: Could suggest flat fee, fixed fee. Keen on accountability. I suggest doing it based on milestones. Four payment structure, first payment at initiation of search, second after you see first slate of candidates. Third – after you're satisfied with interviewing the candidates. Last payment once search is concluded and you are happy with the outcome.

Flat fee: \$150,000.

ISAACSON MILLER

Dr. Susan Shurin, Vice President and Director, Pediatric Oncologist

David Bellshaw, Vice President and Director, Executive Search Consultant

Basic assets: Experience working with public entities; focused on nonprofits and strengthening civic infrastructure. Hallmark search components: early scoping to determine nature/challenges of search; use of common set of metrics to judge all candidates; transparent process on rigorous timeline; extensive candidate referencing; emphasis on diversity.

Questions/Comments from the Board:

Isaacson Miller response to Pizzo off limits question: It is IM policy not to approach person who is currently in position in which IM placed that person. Will not approach an IM placement or placement's direct reports for one year following placement. These restrictions do not apply if person approaches IM.

Dr. Pizzo: What degree of commitment can you offer this search effort?

IM response: We currently have freedom to take on this search. We haven't worked together as a team before, but our communications systems are very good. Communicating with one of us would be communicating with both.

Dr. Levey: What is your estimated time frame for assembling a short list and what are your fees?

IM response: Time frame: six to nine-month process. Fee structure: fixed fee negotiated with the search committee. This would be a function of what the target salary is. We recognize that this is a public institution.

Chairman Klein: When would you have a short list?

IM response: Three months.

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Chairman Klein: Fee would be set in payment increments related to performance milestones. Is that approach acceptable?

IM response: Yes, subject to negotiation as to what those milestones are.

IM: Our fee would probably not be above \$150,000.

Dr. Thal: What are examples of other high level individuals placed by IM?

IM: President searches, specifically President of Oregon State University, Presidents of liberal arts colleges; high level dean searches; working with Kaufman foundation and their national commission for entrepreneurship.

Dr. Black: What is your estimated salary range for this position?

IM: Something comparable to medical school deans: \$300,000 to \$600,000.

SPENCER STUART

Dr. Mimi Hancock, PhD, Genetics and Cell Biology

Dr. Lisa Pieper, MD

(Dr. Ira Isaacson, MD, MBA, not present, will be third key member of SS core team.)

Ben Holzemer, search consultant, to serve as project manager.

Basic Assets: Global offices; conduct searches across many industry sectors; multidisciplinary partners available for this search: life sciences, non-profit, higher education, diversity; oriented towards higher level searches; commitment of many firm partners to this particular search.

Understanding of the search: Necessary to carefully elaborate job description to expand on three basic elements: scientific and medical credibility, ability to lead and manage the organization, need for diplomatic skills to manage organization and liaise effectively with stakeholders. (See transcript for elaboration on each element.)

Diversity: We affirmatively assert diversity focus in every contract.

Time line and process: Meet within four weeks to discuss long list. Time line will depend on level of involvement vs. delegation of ICOC members.

Off limits: Placed candidate is off limits in perpetuity. Hiring manager and direct reports are off limits for one year. Exception when individual approaches SS, but

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requirement that supervisor at institution be aware of individual's desire to change positions.

Fees: Fixed fee of \$150,000.

Questions/Comments from the Board:

Chairman Klein: Will this search be your number one priority?

SS response: Yes, we need to be uniquely prepared to do an excellent job.

Dr. Prieto: How many active searches are you currently working on?

SS response: Dr. Hancock, five or six (mostly later stage); Drs. Pieper and Isaacson, eight to ten (but other peers are involved in these as well.)

Ms. Lansing: Explain fee and overhead.

SS response: \$150,000 professional fee plus 10 percent administrative overhead fee and expenses.

Ms. Lansing requested clarification as to whether other firms charge equivalent amount.

- *Isaacson Miller charges 9 percent overhead; AT Kearny charges 15% overhead.*

Dr. Kessler: Candidate profile?

SS response: Derives from position description (see transcript for details.)

Dr. Levey: How will other ICOC decisions (i.e. picking grant reviewers, etc.) impact ability to attract President?

SS response: Location and compensation will be key factors. Other aspects will impact different candidates in different manners.

END PRESENTATIONS

Chairman Klein asked board members to rank the executive search firms.

Comments from the Board:

Support for Spencer Stuart:

- Spencer Stuart was very well prepared and gave an excellent presentation (Love)
- Impressive depth and breadth in Spencer Stuart team.

AGENDA ITEM #6 for 4/7/05 ICOC Meeting

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- Positive first-hand experience working with Spencer Stuart.
- Scientific background of presenters made great impression.
- Willingness to make this their number one priority, enthusiasm and promised speed.

Support for AT Kearny

- Alberto Pimental is an excellent recruiter.
- Very familiar with appropriate candidates due to Chancellor and President searches they have carried out.

NO Comments from the Public

MOTION made and seconded to proceed with negotiation to conclusion with Spencer Stuart. Motion passed by voice vote. Opposed by Holmes.

MOTION made and seconded to select AT Kearney as backup firm. Motion passed by voice vote. Opposed by Samuelson.

Next steps: Intent to delegate ability to move to a contract to Presidential Search Committee.

Comment regarding grant applications by ICOC members:

Chairman Klein formally referred to Standards Committee question as to whether a member of the ICOC would qualify for a research grant. Stated that it was not originally conceived that a member of the board would qualify for a grant, recusal provisions notwithstanding. This would create harmful perception of conflict of interest that could interfere with goal of reaching highest standards in the country for setting a model for awarding grants.

Board members expressed agreement.

Question regarding alternates

Dr. Reed asked for board members' opinion as to whether alternates should be non-active scientists, i.e. not grant applicants.

Comment and clarification: Board members who are in leadership roles at institutions will continue to encourage people at those institutions to apply for grants.

Agreement that a conflict of interest discussion would be agendaized for the March meeting.

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Agenda Item # 10

Closed Session

Personnel: (Government Code section 11126, subdivision (a); Health & Safety Code section 125290.30(d)(3)(D).) Consideration of Candidates for Acting President for the California Institute for Regenerative Medicine.

Board adjourned to closed session.

Agenda Item # 11

Consideration of Request for Proposal Drafts for Executive Search Firms in connection with search for Chief Operating Officer, Chief Financial Officer, and General Counsel.

Tabled.

Agenda Item # 12

Consideration of summary minute reports for the following:

a. Site Search Committee

Tabled.

b. Working Groups Subcommittees:

i. Standards

ii. Facilities

iii. Grants

#12.b.i. Consideration of Standards Subcommittee summary minutes report.

Introduced by Dr. Kessler. Group met on January 31, 2005. All members attended in person.

- Committee unanimously approved criteria and process for selection and evaluation of members to serve on Standards Working Group.
- Time line and job description created
- February 22 deadline for submission of completed information form
- Plan to select 13 nominees as slate to be recommended to entire ICOC for approval.

Item 1: Dr. Kessler asked for board member volunteers to serve in five Standards Working Group slots allotted to disease advocate members of the ICOC. (No immediate action would be taken on this item, since it had not been agendized.)

Volunteers: Phyllis Preciado, Jon Shestack, Jon Sheehy, Francisco Prieto, Joan Samuelson.

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The subcommittee will take these 5 volunteers names into consideration at its next meeting.

Item 2: Development of Conflict of Interest Standards. The subcommittee suggests that the ICOC authorize the Institute to retain an independent, non-NIH conflict of interest consultant to advise the ICOC on how to develop conflicts guidelines governing working group members. A consultant, familiar with NIH policy, could recommend how closely the Institute should follow NIH guidelines.

Item 3: (1) Development of Intellectual Property standards and (2) ICOC cooperation with Committee on IP created by Assembly Concurrent Resolution 252 (ACR 252).

(1) Subcommittee reached consensus that Standards Working Group, as outlined in Prop 71, does not have adequate technical expertise to handle IP matters alone. Subcommittee felt strongly that IP group should be broadly based and have expertise to consider ethical, public interest, legal and economics issues in addition to IP expertise. Consensus that IP advisory group should be linked to standards working group in some fashion. Subcommittee suggested that an independent IP evaluation process be developed by ICOC, in addition to ACR 252 recommendations.

(2) Request has been made for nomination of two ICOC members to serve on ACR 252 committee. Subcommittee suggestion that one nominee have industry IP experience and one have academic IP experience. Dr. Kessler asked for volunteers. Michael Goldberg and Sue Bryant volunteered. No official action taken, as item had not been agendized.

(3) ICOC cooperation with Committee on Stem Cell Research Guidelines, created by Senate Bill 322. Members of committee not yet appointed, therefore process of developing guidelines has not begun. Subcommittee moved to send letter to Governor indicating ICOC willingness to cooperate with SB 322 process, and requesting progress report.

Comments from the Board

Major points:

- Regarding the SB 322 committee: a single Senate appointment has held up the process for a number of months and it's urgent that the work proceed.
- Scope of jurisdiction of working groups: some principal tasks such as IP and strategic planning are not encompassed by any working group and need a "home"

Chairman Klein agreed that strategic planning is an important area, and that IP will be particularly challenging because of the existence of WARF patents and complicated legal situations. The board could create a technical committee that

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incorporates the experience of lawyers represented at nonprofit institutions on the board. This would provide a base of information from which the board committee could launch a thoughtful examination of issues: financial, ethical and others.

Dr. Murphy emphasized distinction between two kinds of IP: (1) IP related to the commercial sector; (2) IP related to the nonprofit sector. He also pointed out that all California organizations have a strong IP component and that an effort should be made to use that expertise effectively, rather than rediscovering the wheel.

Comments from the Public:

Jesse Reynolds, Center for Genetics and Society. Mr. Reynolds wished to reiterate points made in a letter that he had sent to the board. On the subject of conflicts of interest, openness, and transparency, Mr. Reynolds pointed to the disconnects between CIRM policies and the spirit captured in new NIH conflicts of interest standards, which he feels arise from the exemption of the working groups from a number of state laws.

Mr. Reynolds' recommendations: (1) Adopt ICOC policy that members would divest themselves of all biomedical stocks and other investments which may benefit from the activities of the CIRM; (2) Have conflict of interest standards in place before you start to fill working group memberships; (3) Consider basing standards on new, rather than old, NIH standards; (4) Adopt policy that working group members and meeting be subject to Bagley-Keene, the Political Reform Act, and the Public Records Act, with a few explicit and understandable exceptions.

Dr. Kessler drew attention to the fact that information sheets created for working group nominees clearly state that working group members would be subject to applicable conflict of interest guidelines, which are in the process of being developed.

MOTION made and seconded to approve report and recommendations of subcommittee. Motion passed by unanimous voice vote.

Chairman Klein called attention to the fact that the Grants subcommittee report would suggest a standard that exceeds NIH and California state standards, by recommending that scientific and physician membership on grant review committee be limited to individuals from out of state.

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#12.b.ii. Consideration of Facilities Subcommittee summary minutes report.

Introduced by Dr. Friedman. The facilities working group subcommittee had not yet held its first meeting. It expected to meet later in February.

#12.b.iii. Consideration of Grants Subcommittee summary minutes report.

Introduced by Dr. Holmes. The subcommittee held a teleconference meeting on January 25.

Selection criteria for working group members. The subcommittee members reached consensus on the following criteria (see meeting minutes for details):

- A. Outstanding, highly recognized experts in the field of stem cell research.
- B. Balanced representation: basic scientists and physician scientists from out of state.
3 envisioned categories of grants in first round (center-based grants, seed grants, and intellectual infrastructure grants) would call for broad expertise in reviewers.
- C. Time commitment = 4 meetings per year, although attempts would be made to minimize reviewer time commitment by limiting scope of grants to make review cycles less burdensome.

Next phase: Soliciting names and talking with individuals. Make known that there will be an honoraria for participating in process and funds for support staff. Committee would have opportunity to add expertise by bringing in ad hoc reviewers in some areas, as necessary.

Conflicts of Interest: This issue needs to be decided by standards working group, but assume that grants working group members would be expected to disclose their conflicts of interest and recuse themselves from any consideration of grants, as necessary.

Nomination Process. Desire to solicit as broadly as possible to obtain list of qualified candidates. Nominations would come from: professional societies, members of the public, ICOC members, National Academy of Sciences, University of California planning group, "Who's Who in Stem Cell Research" database, and other sources.

Nomination Deadline: February 14, 2005. (Evaluation of candidates will take far longer than identification of candidates.)

Search Committee Process: Nominees will be equally divided among six two-person interview teams, who review each on established criteria, then interview subset by phone, and come forward with recommendation of five candidates per team. These 30 candidates would be reviewed by the grants subcommittee in an

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open meeting. 15 would be nominated to serve as full members of the grants working group and 15 to serve as an ad hoc committee. This slate would be presented to the ICOC for consideration by the full group. Seven patient advocates from the ICOC will also serve on the grants working group, providing critical input to the grants review process after the scientists have made an initial review of the grants for scientific merit.

Comments from the Board

- February 14th seems like a hasty deadline for nominations.
 - o Holmes: 600 nominations have already been collected via preliminary submissions by the National Academy of Sciences, UC, patient advocacy groups, as well as database names. Subcommittee felt the deadline was adequate.
- Has there been any discussion of whether there's a separate body of research involved in translation of stem cell discoveries into effective therapies and cures and what expertise evaluation of such research requires?
 - o Subcommittee recognizes that it will need a diversity of expertise to review grant applications, including scientists and clinicians.
- Would a separate group look at translation of research?
 - o Translational research may mean different things to different people and merit a longer discussion.
 - o An advisory group could potentially be created to address strategic gaps in research that need to be addressed, or translational medicine specifically.
- Should a couple of working group member slots be left unspecified in anticipation of identification of nontraditional areas of research?
 - o Subcommittee chose to be inclusive and target the best scientists, rather than exclusive, targeting specific areas of research.
 - o Chairman Klein reminded the committee that four medical ethicists will sit on the standards working group and that the working groups should interface.
- Reminder that being a superb scientist does not necessarily predict ability to review grants in an excellent and rigorous way. The best measure of grant review ability is probably experience on NIH-like study sessions.
- Four reviews scheduled annually. Will you burn out the committee in one year unless you have overlapping committees?
- Translational research is very different from bench research. CDC has worked hard in this area. Board needs to think about the public's education and how to translate research and communicate it to patients. There must be some sort of environment created in the community that allows you to go in and give a new treatment to people. This piece is not focused on in medical school and fellowship training, and it is more difficult and time consuming than it appears. The issue is to ask people: what is it about your illness that you do or do not understand? At the same time as

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we do bench research, we should institute a committee to look at the dissemination and translation of this information.

- This is important and a good category to raise in discussion of grant programs.
- 15 member scientific review group can serve as initial nodal point for review, but will need to involve a large cadre of expertise. The ICOC will potentially receive thousands or tens of thousands of grant proposals.
- Suggestion to organize a board seminar to discuss translational medicine.
 - Discuss infrastructure required for effective translational research.
 - Dr. Holmes offered to provide a report from an Institute of Medicine committee which he co-chairs, which planned to address the topic of translational medicine.
 - Suggestion that CIRM support a program of board members attending specialized educational forums.

Comments from the Public

Mr. Posner: The ICOC will be awarding multiyear grants. Have you thought about how you are going to handle the grants management second, third, fourth, fifth year?

Dr. Holmes: That was not the purview of our subcommittee. We believe the president will take on the grant management task.

Jesse Reynolds: The Human Genome Project can serve as an analogy for your enterprise. It had a similar budget and time scale, and earmarked 3 percent of its research budget for the ELSI program: Ethical, Legal and Social Implications of their work. Urged the ICOC to consider a special section with a degree of autonomy and an earmarked budget.

George Burrows, Regenerative Medicine Awareness Program: Irv Weissman and the ISSCR have embedded ethicists into their board structure and conferences. Perhaps two of the 30 slots could be considered for ethicists like Laurie Zoloff.

MOTION made and seconded to approve report and recommendations of subcommittee. Motion passed by unanimous voice vote.

Agenda Item #13

Consideration of strategy regarding the award of scientific and medical research grants, including categories of grants and types of recipients.

Tabled.

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Agenda Item #14

Consideration of creation of Intellectual Property Advisory Council to make recommendations to the ICOC re: standards for IP agreements.

Tabled.

Agenda Item #15

Scheduling of Subsequent Meeting(s) of the ICOC.

Tabled.

Agenda Item #16

Public comment. The Committee will accept public testimony on any matter under its jurisdiction that is not on the agenda, but the Committee cannot act on any such matter at this meeting.

Lynne Balleu: Given that ALS is a fast-acting and fatal disease, can the ICOC require a clause in all grant awards agreeing to some degree of collaboration, while still respecting the need for proprietary information?

Chairman Klein: This very important issue is embedded in the Intellectual Property discussion as well as in the publication policy and the incentives to publish early and share information early, which the committee could decide to incorporate into its grants policy.

Mr. Shestack: These issues are also important for the standards working group.

Dr. Reed: The mandate for this committee is going to be to reward the types of behaviors we'd like to see incorporated into this research program by putting the financial reward where we want the behaviors rewarded.

Dr. Steward: Scientists do, in fact, like to collaborate, but there's currently no incentive or structure that fosters collaboration.

Jean Loring, Burnham Institute. Has eight years of experience on study sections. NIH grants are structured with only one principal investigator (PI). More and more it is inappropriate to have only one PI. Ms. Loring proposed a structure that has joint principal investigators of equal status. This would be a very serious change from NIH policy.

David Shatto. I'm an ordinary guy who took a day off work to come to this meeting because I really think that what you are doing here is historically important. We may not have another chance like this in our lifetimes to influence decisions of this magnitude. I urge you to put the public interest first, particularly as you consider models for handling intellectual property. Formation of an ad

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hoc committee of a subcommittee does not absolve you of your responsibility to do some independent consideration of this issue. You have the opportunity to establish a new scientific model by finding and adopting a viable open source model.

Coach Casey, San Diego. My mother died of Bulbar and it took 15 doctors to come to any type of conclusion. The ALS patient has no time. It's lethal. ALS doesn't need just a normal scientific project, it needs a Manhattan Project.

Question from the Board

What is the current timeline for making grant awards, are we still shooting for May or June?

Chairman Klein: The May timeline is still on the table, but we have to make sure that we have quality standards before we start any program.

17. "A Spotlight Presentation" on Amyotrophic Lateral Sclerosis

Introduced by Dr. Fontana. Spoke about ALS from the perspective of a particular patient. His mother's slurred speech led to tests that revealed she had ALS, a neurodegenerative disease that takes the life of nearly all of its victims within a few years of diagnosis. No treatment exists, although one drug prolongs life a few months. ALS can strike at any age, but is most common in fifth and sixth decade of life. Men are targeted more frequently than women until menopause, when rates become equal. 20 percent of cases are linked to SOD-1 gene mutation. Majority of cases have no known cause.

ALS presents in two ways. Vast majority present with skeletal form. Ten percent present with Bulbar form, which attacks muscles involved with speech, swallowing and breathing. This form has a more rapid course. Dr. Fontana's mother went from very active to wheelchair bound in a year. Through her physical degeneration, her active mind remained intact.

Mechanical ventilation is a choice that most ALS patient confront early on and which brings a huge financial and emotional cost with it.

The incidence of ALS is five times higher than that of Huntington's disease, slightly less than Parkinson's disease, and about equal to multiple sclerosis, but the number of people living with ALS is much less because of the rapid course of this illness.

The financial market potential for an ALS therapy ranges between \$500 million and a billion dollars.

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A major impediment to the advancement of drug development is the apparent complexity involved in a mechanism in neuronal cell death. ALS and many other diseases lack an accurate model with which to study the disease.

Stem cell research offers ALS research four areas of potentially great impact:

- (1) Using stem cells from diseased embryos or following nuclear transfer to develop models of ALS;
- (2) Using this model in conjunction with high throughput screening, potential pharmacological therapies may be identified more readily, along with a better understanding of the fundamental molecular mechanisms underlying cell death.
- (3) Stem cells may be used efficiently with site directed drug and/or gene therapy delivery systems.
- (4) Longer prospects are for replacement of neurons and their connections in the damaged nervous system for healthier functioning neurons.

Dr. Fontana advised the ICOC to take the best from the NIH and to improve upon it with special attention to transparency in intellectual property, mandate collaboration locally, nationally, and internationally, while maintaining a healthy sense of competition. Rewarding those that develop programs involving interdisciplinary teams, requiring the publication of both positive and negative results, and streamlining the review process are just a few ways to improve this system.

Chairman Klein raised the possibility of establishing a patient advocate portion of the CIRM website, featuring presentations like that made before the board.