

Empire State Stem Cell Board
Full Board Meeting Minutes
May 13, 2008

The Empire State Stem Cell Board held a meeting on Tuesday, May 13, 2008, in Concourse Meeting Rooms 2 and 3 in the Empire State Plaza in Albany, New York. Commissioner Richard F. Daines, M.D., presided as Chairperson.

Board Members Present:

Dr. Richard F. Daines, Chairperson
Mr. Kenneth Adams
Fr. Thomas Vincent Berg
Dr. Bradford Berk
Dr. Richard Dutton
Mr. Robin Elliott
Ms. Brooke Ellison
Dr. Gerald Fischbach
Dr. Samuel Gorovitz
Dr. David Hohn, Vice Chair
Dr. Bruce Holm
Dr. Hilda Hutcherson
Dr. Robert Klitzman
Rev. H. Hugh Maynard-Reid
Dr. Michael Stocker
Dr. Daniel Sulmasy
Mr. Robert Swidler
Ms. Madelyn Wils

Department of Health Staff Present:

Dr. David Anders
Ms. Bonnie Brautigam
Mr. Thomas Conway
Ms. Judy Doeschate
Ms. Connie Gardner
Mr. Michael Heeran
Ms. Sharon Johnson
Mr. Robert Keefe
Dr. Jerro Kotval
Ms. Susan Mantica
Ms. Marti McHugh
Ms. Amy Nickson
Mr. Kenneth Peek
Dr. Tia Powell
Ms. Beth Roxland

Dr. Lawrence Sturman
Ms. Mary Szesnat

Observers Present:

Ms. Kyle Alexy
Dr. Michelle Cissell
Mr. Ed Ellison
Ms. Jean Ellison
Ms. Kathleen Gallagher
Mr. Thomas Irwin
Ms. Summer Johnson
Mr. Richard Marlin
Ms. Barbara Meara
Dr. Janet Paluh
Dr. Glenn Monastersky
Ms. Kelly Ryan

Introductions

Chairman Daines called the meeting of the full Board to order and asked Committee members and staff to briefly introduce themselves.

Approval of Minutes for the October 22, 2007 Full Board Meeting

Dr. Daines directed Committee members to the draft minutes for the October 22, 2007, full Board meeting that were included in their agenda books under tab 2. Dr. Daines explained that the minutes for the full Board meeting held on October 22, 2007, had not been approved yet because the full Board had not met since then. Dr. Daines then asked for a motion to approve the minutes for the October 22, 2007, meeting of the full Board. Dr. Klitzman so moved. Mr. Swidler seconded the motion. The motion passed unanimously.

Update on Requests for Applications

Dr. Daines advised Board members that the Department had recently issued four requests for applications (RFAs) that are designed to encourage collaborations among stem cell research scientists, facilitate the acquisition and development of specialized stem cell equipment and facilities, and support researcher-initiated and targeted stem cell research. He noted that the four RFAs will make almost \$109 million available. He further noted that the RFAs provide flexibility to reallocate the funds, as deemed appropriate, among the four RFAs to permit the best applications to be funded.

Report on the Interstate Alliance on Stem Cell Research

Dr. Daines then turned the floor over to Ms. Doeschate to provide members with an update on the activities of the Interstate Alliance on Stem Cell Research (IASCR). Ms.

Doesschate reminded members that IASCR is an organization of representatives from states that support stem cell research and are interested in increasing opportunities for interstate collaboration and decreasing obstacles to collaborative research across state lines. Ms. Doesschate provided updates on the activities of the different states and organizations represented at the April 2008 meeting of IASCR and highlighted several areas where discussions and activities occurring in other states overlap with issues discussed during Empire State Stem Cell Board committee meetings. She noted that the California Institute of Regenerative Medicine (CIRM) and the National Academy of Sciences (NAS) have both been examining issues related to the use of somatic cells to derive new stem cell lines and that NAS is expected to issue guidance in this area by the end of 2008. She advised members that CIRM has concluded that research involving the use of somatic cells to derive new stem cell lines should comply with the existing guidance from the federal Office of Human Research Protections for research involving biological materials.

Ms. Doesschate reported that several states, as well as the International Society for Stem Cell Research (ISSCR), were considering activities to facilitate translational research and provide guidance on appropriate ethical, medical and scientific standards. She noted that Maryland requires all grant applications to include a translational plan or evidence of the translational potential of the proposed research. Ms. Doesschate also advised members that CIRM had commissioned the Institute of Medicine and the National Research Council to study the medical risks of human oocyte donation for stem cell research and develop recommendations to reduce medical risks for donors. CIRM had also sponsored a workshop on stem cells and environmental health research to consider how human stem cells can provide fast and less expensive test systems for environmental toxicants and to explore the relationship between environmental exposure and disease.

Ms. Doesschate also reported that members of patient advocacy and other interested groups attended the meeting. She noted that speakers encouraged the organization to:

1. facilitate collaboration of researchers across states lines by adopting standards that follow the NAS and ISSCR models;
2. communicate what the states are doing to build support for stem cell research;
- and 3. focus the dialogue on patients who are suffering with potentially curable diseases because they are the reason underlying the public's support for funding stem cell research.

She also advised members that Robert Goldstein of the Juvenile Diabetes Foundation had offered to work with states to fund collaborative research by picking up the costs for the out-of-state portion of an interstate collaborative research project when a state is funding the in-state effort.

Ms. Doesschate advised members that IASCR will be compiling information regarding state efforts to develop umbilical cord blood banks and other registries; examining issues unique to funding for the private sector; keeping abreast of developments at the federal and state levels; and updating its website (www.iascr.org) with information to help scientists and the public understand the similarities and differences between the various state funding programs. Ms. Doesschate commented that this type of communication and collaboration among the state programs is very beneficial, especially since the ESSCB can rely on the work being done in other states on the same or similar issues to avoid duplication of efforts and encourage collaboration.

Ms. Doesschate responded to questions from Board members regarding IASCR activities and discussions. Board members also discussed the potential for including a translational component, similar to Maryland's, in the Board's funding mechanisms. It was pointed out that the significance of including such a requirement would depend on how "translational" is defined and that most research has translational implications. A few members expressed concern that including such a requirement in funded research could undermine the Board's ability to fund basic stem cell research, which is an important first step in the development of discoveries that can lead to new therapeutic applications. Rev. Maynard-Reid encouraged staff to provide the Board with regular reports on IASCR meetings and activities.

Consideration of Draft Strategic Plan and Next Steps

Dr. Daines advised members that the draft strategic plan included in their agenda books had been revised to incorporate comments and suggestions made at the last meetings of the Ethics and Funding Committees. The draft had also been revised to add an Executive Summary, an introductory letter from Dr. Stocker as Chair of the Strategic Planning Coordinating Committee, and more fully developed appendices. He pointed out that staff had provided a copy of the fully formatted document to every member at the start of the meeting. Dr. Daines thanked Dr. Stocker for the work, time and energy he had put into helping ensure the process moved along swiftly and that every member of the Board had an opportunity to provide meaningful input into the development of the document.

Dr. Daines reminded members that the Ethics and Funding Committees had agreed to discuss the potential for additional review or input at the May meeting of the full Board. Before opening the floor up for discussion, Dr. Daines asked Drs. Stocker and Sturman if they had any additional comments. Dr. Stocker clarified that the document before members had changed little since the April 1 meeting of the Ethics Committee and that the primary changes were the addition of an executive summary, changes to the appendices, and the addition of his letter. Dr. Sturman advised members that if the Board wanted to make the document available for public comment, staff was prepared to post the draft plan on the NYSTEM website and provide a form for the submission of public comments. He noted staff could send a notice to the over 200 individuals who have signed up to receive e-alerts and could develop a press release announcing its availability for review and public comment. He offered to have staff summarize any comments for the Board and potentially develop revisions for the Board to consider at its next meeting on June 27, 2008. Dr. Daines then asked if there were any additional comments on the plan itself, before the Board considered the issue of the distribution for public review and comment.

Dr. Gorovitz noted an error and an omission and asked that the document be reviewed and proofed to ensure it is up-to-date and accurate before posting. Dr. Sturman acknowledged that there were a few omissions and some edits that had not been incorporated into the formatted version of the draft plan and that those would be addressed prior to posting the draft plan on the internet.

Fr. Berg expressed concern that the Executive Summary seemed to give prominence to human embryonic stem cell (hESC) research, specifically, leading off with a reference to hESC research in the second paragraph of the Executive Summary. He noted that the body of the

report had been modified to use the term “pluripotent” in most cases and to recognize the amount of research being conducted using adult stem cells. Other members concurred that it is appropriate to reflect the different types of stem cell research and suggested that since portions of the first and second paragraphs of the Executive Summary mention adult stem cell research, the second paragraph should be modified to add a lead-in sentence that would recognize all types of stem cell research. Fr. Berg concurred with that recommendation.

Mr. Elliott encouraged the Board to consider adding language to require RFAs to focus on research with therapeutic implications. Some members expressed concern about adding such a requirement for all funding because it could lead to rote recitations of potential therapeutic applications and preclude funding of basic science that may yield discoveries and understanding that may serve as the foundation for therapeutic applications. Fr. Berg noted that there is a tension in the draft plan between supporting basic stem cell science and supporting translational research and encouraged the Board to discuss how funding decisions would be made in light of the possible unstated bias toward funding basic science and hESC research over potentially immediately translatable research. Dr. Fischbach commented that members should be cautious in labeling anything “immediate” and observed that we are at a very promising beginning with induced pluripotent stem cells, but there is a lot we do not know. He stated he preferred to continue to leave the door wide open for all types of research especially in the first year of funding. Dr. Dutton concurred, commenting that current translational research is integrally based on past basic undertakings. Dr. Hohn emphasized that applications will be reviewed by a panel of outside experts and opined that he thought the mandate of the Board is to fund the best and most promising research consistent with the broad legislative mandate. Dr. Daines stated that he also supported that approach. He noted that the draft plan is constitutional in nature, rather than very specific, because we don’t know enough about where the advances will be made and the plan keeps all of the possibilities open.

Mr. Swidler suggested that Chapter 5 of the draft plan be modified to clarify that the Board has required “most,” rather than “all,” pluripotent stem cell research be reviewed and approved by Embryonic Stem Cell Research Oversight committees, and that the section on informed consent issues is intended to address individuals providing gametes for research, as well as, participants in clinical trials. Members also suggested that the plan should emphasize the sense that there is flexibility in the timing of funding mechanisms and that the date of issuance should be included since the plan will be reviewed and modified over time.

Dr. Daines then asked for a motion to approve the process for public comment that had been discussed. He summarized that process stating that the draft Strategic Plan would be posted on the website for four weeks to collect public comments on the draft, that staff would categorize and summarize the public comments received, and that staff would bring the summary of public comments back to the full Board at its June 27 meeting, along with viable suggestions for actual modifications to the plan with an eye to final adoption of the plan at the June 27 meeting. Mr. Adams so moved; Mr. Swidler seconded the motion. In response to a question, Dr. Daines confirmed that Board members could also continue to comment on the plan by submitting comments to Ms. Doesschate. Dr. Daines then called for the vote. The motion passed unanimously with no abstentions.

Development of Board Annual Report

Dr. Daines noted the Board is required by statute to issue an annual report. He turned the floor over to Dr. Sturman to advise the Board about the statutory requirements for the annual report and solicit the Board's input into the development of the annual report. Dr. Sturman distributed copies of the relevant statutory provisions and a broad outline for the annual report. He noted the annual report would include information about the Board, its activities, approved funding mechanisms and grants, a summary of the strategic plan, information about stem cell research activities in New York State, and administrative costs. He welcomed comments from Board members.

Members suggested that the annual report also include: 1. information on future plans; 2. public reaction and commentary to Board and program activities; 3. a "dashboard" to report on the financial and scientific accomplishments of five or six key goals or elements supported financially by the Board; 4. information on the state of the stem cell research field globally; and 5. an evaluation of the items in Chapter 7 of the draft Strategic Plan to the extent it is feasible to include that type of information in this year's report.

Discussion: Coordination of Committee Activities

Dr. Daines advised members the next agenda topic was the coordination of activities between the Ethics and Funding Committees. He noted that the statute anticipates that the majority of the work of the Board will occur in its two committees and that this framework has created some challenges. He noted that in the first six months of operation, the Board had accomplished a great deal within this framework, including the issuance of seven RFAs, the development of interim ethical guidelines and a strategic plan, the selection of a contractor to assist with independent peer reviews of applications, and the consideration of important ethical, scientific and policy issues underlying the research. Dr. Daines noted that the Board and staff have addressed these challenges over the past six months and taken several steps to help fine-tune communication and collaboration between the two committees. These include encouraging members to attend the meetings of the other committee; having additional members of the Ethics committee attend meetings of the Funding Committee to present the Ethics Committee's recommendations; providing members of each committee with the minutes of the other committee; including presentations by experts; and to the extent possible without violating New York State procurement laws, providing members of the Ethics Committee with documents developed by the Funding Committee. Dr. Daines noted that since members of both committees were present at the meeting, it was a good opportunity to discuss additional ways to enhance inter-committee communication and collaboration. Since Dr. Klitzman had suggested this topic be added to the agenda, Dr. Daines asked Dr. Klitzman if he would provide his thoughts on the topic.

Dr. Klitzman suggested there may be ways to streamline the processes between the two committees and suggested that it would be beneficial to have scientific expertise available to the Ethics Committee during meetings, possibly via telephone. He also suggested that it would be helpful to have the Funding Committee identify their needs as research moves forward. As an example, he suggested if the Funding Committee plans to fund clinical trials, it may want the Ethics Committee to study and develop recommendations on informed consent for clinical

trials and the numerous issues that raises. Dr. Daines suggested the Funding Committee agenda could include time for discussion of issues on which it would like the Ethics Committee to work on. Dr. Klitzman also suggested that the annual conferences for funded scientists could include discussions of ethical issues.

Dr. Sulmasy commented that some of the difficulty is that the Funding Committee has either accepted or rejected Ethics Committee recommendations without the Ethics Committee having an opportunity for feedback before actually voting on a final product. He suggested that kind of feedback should be built into the process to avoid either rejections of Ethics Committee recommendations or modifications without further Ethics Committee input. Dr. Sulmasy asked if it is possible to get that kind of feedback outside the setting of a meeting. Dr. Daines responded saying staff would look at how much of that could be done properly outside a formal meeting. Mr. Swidler commented that the adjustments made to facilitate inter-committee communications have been positive. He noted that having a member of the Ethics Committee present Ethics Committee recommendations to the Funding Committee has the added benefit of allowing the Funding Committee to be guided as to whether changes being considered by the Funding Committee are technical in nature and would be welcomed by the Ethics Committee or whether they might be contrary to the Ethics Committee's discussions and intent. He suggested the Board should look for the right balance between the need for feedback and self-correction and efficiency. He also suggested staff should attempt to add more of a social dimension to establish good relations between the Committees, such as a holiday party.

Mr. Elliott suggested that the Board could address some of the difficulties of the dual committee structure by having more joint meetings of the Board. Dr. Klitzman agreed with that recommendation. Dr. Fischbach agreed with the need for more communication and suggested the initial temporary disagreements have turned out to be very productive, helped the Committees work out a wonderful compromise and stimulated a lot of good discussion. However, he suggested the Board needs to be mindful of the time commitments already required of Board members and noted that scheduling additional meetings may be difficult for Board members.

Rev. Maynard-Reid suggested that it would be helpful to have staff provide all members with a summary of what is happening across the country and around the world in advance of meetings. He would also like annual meetings to include information about where stem cell research stands and where the research is going, to help inform a larger audience and the Board so members could make decisions in that context. Dr. Gorovitz suggested that communication from the staff to the Board should also be increased. He noted that he was not sure what the status of the educational funding proposals were and would like to keep better track of where things stood. Dr. Sturman responded by providing an update on those funding proposals and advised members that he expected they would be issued the following month.

Adjourn and Break

Dr. Daines noted that the Board would be taking a break before reconvening the Funding Committee at 2:30 P.M. Dr. Daines then asked for a motion to adjourn the meeting of the full Board. Dr. Hohn so moved; Mr. Swidler seconded the motion. The motion passed unanimously.

Approved: June 27, 2008