

**Empire State Stem Cell Board**  
**Funding Committee**  
**Minutes**  
**March 28, 2008**

The Empire State Stem Cell Board Funding Committee held a meeting on Friday, March 28, 2008, at the New York Network Studios in the Empire State Plaza in Albany, New York. Dr. Hohn presided as Chairperson while Commissioner Daines was detained for other Department business.

**Funding Committee Members Present:**

Dr. Richard F. Daines, Chairperson  
Mr. Kenneth Adams  
Dr. Bradford Berk  
Mr. Robin Elliott  
Dr. Gerald Fischbach  
Dr. David Hohn, Vice Chair  
Dr. Hilda Hutcherson  
Dr. Michael Stocker  
Dr. Harold Varmus  
Ms. Madelyn Wils

**Funding Committee Member Participating Via Telephone:**

Dr. Richard Dutton

**Funding Committee Nominee Present:**

Dr. Bruce Holm

**Ethics Committee Member Present:**

Mr. Robert Swidler

**Department of Health Staff Present:**

Ms. Bonnie Brautigam  
Mr. Thomas Conway  
Ms. Judy Doeschate  
Mr. Mike Heeran  
Ms. Lalitha Iyer  
Ms. Marti McHugh  
Ms. Amy Nickson  
Dr. Lawrence Sturman  
Ms. Nicole Garner  
Dr. Ann Willey  
Ms. Katherine Zdeb

**Observers Present:**

Dr. Michelle Cissell  
Mr. Mark Leinung  
Ms. Sarah Lewis  
Mr. Michael Manganiello  
Dr. Janet Paluh  
Mr. Kenneth Pokalsky  
Ms. Kelly Ryan

**Opening and Introductions**

Dr. Hohn called the meeting of the Funding Committee to order and welcomed members, staff, and the public. He advised Committee members that Ms. Madelyn Wils, Executive Vice President of the New York City Economic Development Corporation, had recently been appointed to serve on the Funding Committee and welcomed her to the Board.

Dr. Hohn reminded members that Dr. Rudolf Jaenisch, a pioneering stem cell investigator, had accepted Wadsworth Center's invitation to deliver the 2008 Brown-Hazen Award Lectures on April 3<sup>rd</sup> and 4<sup>th</sup> in Albany and invited everyone to attend the lectures.

Dr. Hohn then asked Committee members and staff to briefly introduce themselves for the benefit of the public attending the open session and those tuning in to the webcast.

**Approval of Minutes of the February 15, 2008 Meeting of the Funding Committee**

Following the introductions, Dr. Hohn directed Committee members to the draft minutes under tab 1 of the agenda book and asked for a motion to approve the minutes for the regular and executive session meetings of the Funding Committee held on February 15, 2008. Mr. Elliott so moved; Mr. Adams seconded the motion. The motion passed unanimously.

**Department Update on Requests for Applications**

Dr. Sturman advised Committee members that all Requests for Applications (RFA) approved by the Funding Committee are expected to be issued within the next month. In response to several questions, Dr. Sturman provided clarification on the anticipated start dates of the contracts to be awarded for the next round of grants. Dr. Varmus asked for information on the timing of the submission of applications, the completion of reviews, and the execution of contracts. Committee members urged the Department to expedite the process to permit the supported research to be undertaken as soon as possible.

**Ethics Committee Report and Consideration of Recommendations**

Dr. Hohn reported on the recent activities of the Ethics Committee and noted that Mr. Robert Swidler, a member of the Ethics Committee, was present to discuss the latest recommendations of the Ethics Committee. Dr. Hohn reminded Funding Committee members that it had approved revisions to Appendix A-2 for the next round of grants that

would require grantees to comply with additional standards adopted by the Funding Committee for human embryonic stem cell research after consideration of any recommendations made by the Ethics Committee.

Dr. Hohn advised members that the Ethics Committee had examined a number of issues, including the standards for Embryonic Stem Cell Review Oversight (ESCRO) committees, and concluded that ESCRO committees should be subject to additional standards for membership, conflicts of interest, and recordkeeping, similar to the standards applicable to Institutional Review Boards (IRBs). The Ethics Committee also agreed that the scope of research subject to ESCRO-like review should include research involving pluripotent stem cells, but that research involving pluripotent stem cells limited in tissue potential would be exempt from the heightened ESCRO review, except for research involving gonadal and neural progenitor cells, which are ethically sensitive. He noted that this expanded scope of review is similar to the scope of review recommended by the International Society for Stem Cell Research (ISSCR), and therefore, it also includes an exemption for purely *in vitro* research that does not involve the derivation of new stem cell lines.

Dr. Hohn advised the Committee that the Ethics Committee's recommendations were included in their agenda books as a revised section E of Appendix A-2. He also noted that staff had prepared a comparison chart showing the proposed standards alongside the National Academies' of Science (NAS) and ISSCR guidelines that was also included in their agenda binders.

Dr. Hohn then turned the floor over to Mr. Swidler to present more information on the Ethics Committee's recommendations. Mr. Swidler noted that although little is known about the operation of ESCRO committees, the NAS and ISSCR standards rely extensively on them. He stated that staff had gathered some information from New York State institutions and the Ethics Committee had learned a great deal from Dr. Greely of Stanford University, an expert on California's standards and practices regarding ESCROs. Mr. Swidler then addressed the suggested changes in the sequence in which they appeared in the recommended revised section E of Appendix A-2.

Mr. Swidler advised members that the first recommended revision would expand the scope of review of ESCRO committees to include research using certain pluripotent stem cells. Dr. Varmus expressed support for the extension of ESCRO committee review, but suggested ESCRO committees might be unnecessarily overburdened if research that is not ethically sensitive, such as purely *in vitro* research, is submitted to these committees for review. Mr. Swidler advised Dr. Varmus that *in vitro* research not involving the derivation of new stem cell lines would be exempted by the incorporation of the referenced NAS and ISSCR exemptions.

Members suggested that the standards being considered should be re-evaluated annually. Ms. Doeschate noted that the standards had been incorporated into an appendix that would be annexed to contracts for grants awarded in the next round of funding and that the appendix could be revised for future rounds of grants if the Committee decides that different standards are appropriate at that time. Mr. Swidler added that because the standards would be annexed to contracts, they would automatically "sunset."

Dr. Varmus suggested that the word “pluripotent” be deleted from the phrase “human pluripotent stem cell research” because it could cause confusion and seemed under-inclusive and unnecessary. Dr. Varmus also suggested that the actual language of the ISSCR and NAS exemptions referenced in section E of Appendix A-2 should be incorporated into the document itself to help ensure that ESCRO committees and researchers are aware of those exemptions.

Mr. Swidler suggested that language be inserted to clarify that the ESCRO committee itself is subject to NAS and ISSCR guidelines, as well as the research being reviewed by the ESCRO committee. He advised members that this had been omitted unintentionally and that the change is consistent with the Ethics Committee’s intent. Mr. Swidler also mentioned that the Ethics Committee had suggested changing the name of the ESCRO committee to a Pluripotent Stem Cell Research Oversight (PSCRO) committee, but had not spent much time discussing that issue.

Some members questioned the language requiring the ESCRO committee to conduct ethical and scientific oversight of the research. After further discussion, the Committee concluded the wording should be changed to reflect the Ethics Committee’s intention that the ESCRO committee conduct initial and ongoing oversight of stem cell research.

Mr. Swidler then addressed the specific additional requirements that would apply to ESCRO committees regarding membership, conflict of interest, and recordkeeping requirements. Dr. Hutcherson inquired why the revisions included a requirement that membership on the ESCRO committee should not be made solely on the basis of gender. She noted that while such language might have been needed when the IRB regulations were adopted decades ago, it should not be necessary in this day and age. It was agreed that this phrase would be deleted from the document.

Dr. Daines joined the meeting at this point, but asked Dr. Hohn to continue chairing the meeting.

In anticipation of a motion to adopt the Ethics Committee’s recommendations, Dr. Hohn then confirmed that the additional changes recommended by members would: 1. clarify that ESCRO committees are subject to ISSCR or NAS guidelines; 2. clarify that ESCRO committees will conduct ongoing review of research; 3. delete the phrase stating that membership on an ESCRO committee shall not be based solely on gender; 4. delete “pluripotent” from the phrase “human pluripotent stem cell research” from the title and the introductory sentence; and 5. include the actual language from the NAS and ISSCR guidelines that exempts certain types of research from ESCRO committee review in the document. The Committee then discussed retaining “ESCRO” in the name of the review committee, rather than changing it to “PSCRO,” and concluded “ESCRO” should be retained since neither the NAS nor the ISSCR guidelines currently use “PSCRO” and the change may cause unnecessary confusion.

Dr. Hohn then asked if there was a motion to amend Appendix A-2 to include section E as recommended by the Ethics Committee, with the additional suggested revisions, to apply to the next round of RFAs. Dr. Varmus so moved. Dr. Fischbach seconded the motion. The motion passed unanimously.

## **Discussion of Proposed Annual Meeting**

Dr. Daines turned the floor over to Dr. Sturman to engage the Committee in a discussion about an annual meeting of funded scientists. Dr. Sturman suggested such a meeting be held in the fall of 2008 and asked members for their thoughts on the timing, duration, and format of such a meeting.

Dr. Fischbach favored the idea, but thought the meeting should be held no earlier than the spring of 2009. He recommended that it include a couple key lectures, some plenary sessions, a panel discussion, and a poster session for students and post doctoral fellows. He suggested that the Department invite a public figure.

Dr. Varmus noted that a virtue of conducting a meeting for scientists funded in the first round was that the first round of awards were very inclusive and stem cell scientists from all of the state's leading research institutions would be attending. He stated that the Board needed to hold these types of meetings if it wanted to build a stem cell research community in New York State. He suggested the meeting be a two-day event in the spring of 2009 and include informational sessions on state oversight, state-based funding, and ethical issues. He also thought poster sessions were critical. Dr. Varmus encouraged the Department to keep the cost of attendance as low as possible. Drs. Berk and Hohn also expressed a preference for a meeting in the spring or later. Dr. Hohn suggested that depending on the timing, the Board may want institutions to discuss their progress on the collaborative planning grant process.

Dr. Sturman inquired whether members thought the event should include exhibitors. Dr. Varmus noted that the inclusion of exhibitors would change the nature of the meeting and require a larger space. He favored an academic setting for the meeting without exhibitors for this first meeting.

Dr. Sturman thanked the Committee for their input and stated he would be coming back to them as plans for the meeting develop.

## **Discussion of Draft Strategic Plan and Next Steps**

Dr. Daines reconvened the meeting following lunch and turned the floor over to Dr. Sturman and Dr. Stocker, Chair of the Strategic Planning Coordinating Committee (SPCC), to present the draft strategic plan and solicit the Committee's input.

Dr. Stocker provided a brief overview of the activities of the SPCC and noted the SPCC had met seven times to discuss and direct the development of the strategic plan. Dr. Stocker noted that the Ethics Committee had discussed the draft strategic plan at its March 13<sup>th</sup> meeting which resulted in the formation of a workgroup that developed specific edits, especially to Chapter 5, that were incorporated into the document sent to members electronically earlier in the week. Dr. Stocker noted that a hard copy of the most recent version had been distributed at the start of the meeting along with comments from a group convened by Mr. Adams. Dr. Stocker then asked the members for their thoughts on the current product.

Dr. Varmus stated that he thought that Chapter 5 could be reduced in length. He also noted that some of the ethical issues the plan raises are not unique to research in New York State and that attempts should be made to ensure New York does not fund initiatives that unnecessarily duplicate efforts in other states. Dr. Stocker, Dr. Hohn, and Mr. Swidler all agreed that funding should not be used to support duplicative research and noted that members of the Ethics Committee were familiar with a great deal of the research that had been conducted and have been consulting others on appropriate standards.

Mr. Adams noted that flexibility is important and asked Dr. Stocker how the SPCC decided on the 5 year time frame and annual reviews for the plan. Dr. Stocker stated the SPCC felt that since this is a rapidly evolving area, an 11 year plan seemed too long and that five years was used because it was roughly half of the initial funding time period. He advised members that since the Board is required to prepare an annual report, SPCC members thought an annual review of the strategic plan as part of that was appropriate.

Mr. Adams noted that he and Mr. Elliott had agreed to look at the appropriate focus on economic development issues in the plan. He advised members that they had consulted with others interested in economic development initiatives and attempted to address the question of how to ensure that the Board is supporting the transition of this work from bench to bedside. He noted this would also require facilitating moving scientific discoveries into the private sector. He cautioned the Committee about setting specific numbers for jobs that would be created, but that it would be appropriate to look at how these funds trigger other funding. He suggested the leveraging of other funding should be increased as a priority in the strategic plan.

Mr. Elliott observed that there are several “engines” that would drive the funding towards cures, with the first being academic institutions. The other “engines” are business and disease advocacy groups that are interested in the translation of this work into treatments. He encouraged a greater focus on translational work in the plan. Mr. Elliott stated that two ideas that came out of discussions were the inclusion of disease advocacy scientists in the strategic planning process before the plan is finalized; and changes to the plan to focus on “venture philanthropy” where disease advocacy groups and others partner with business. He noted this type of partnership can help “de-risk” investments in bringing treatments to the market place, which may accelerate the move from bench to bedside.

Dr. Varmus asked for specific suggestions since the text of the plan already makes it clear that the goal is to conduct the science that is needed to find new ways to treat and prevent disease. He also noted that Dr. Fischbach has been involved in the development of the plan and is a disease advocacy scientist as Scientific Director of the Simons Foundation Autism Research Initiative. Dr. Hohn also noted that the last chapter includes the type of metrics suggested and that the plan has been revised to include funding for phase 1 clinical trials. Dr. Stocker noted that Chapter 2 includes a goal to “facilitate the evaluation of stem cell based therapies in early phase clinical trials” and asked if that could be modified to include the wording Mr. Adams had suggested in the comments he circulated. Mr. Adams agreed with Dr. Stocker’s suggestion. Mr. Elliott and Dr. Hohn urged that the revision include mention of early phase clinical trials. It was then agreed that the goal would be changed to read: “translate basic research discoveries into new therapies and diagnostic methods for testing in early phase clinical trials.”

Dr. Stocker then asked Mr. Adams to explain the written comments he provided regarding Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) grants. Mr. Adams explained that these are grants made to private entities by the National Institutes of Health and he was suggesting that the number of such grants received for stem cell research in New York could be another measure of the initiative's economic impact. It was suggested that SBIR and STTR be added to the Chapter 7 list of items to be evaluated in assessing the potential economic impact of the initiative. Members then discussed whether the factors assessed should be broadened to include all types of additional investments toward private stem cell ventures, not just SBIRs and STTRs. It was agreed that the list in Chapter 7 would be revised to include "new funding from any public or private source obtained as a result of NYSTEM-funded research." Mr. Adams thanked Dr. Stocker for helping to address these issues in the plan.

Ms. Wils then asked if Chapter 4 on infrastructure was going to be revised to support funding the development of resources and outreach to potential investors and foundations to encourage partnerships for commercialization of discoveries. She thought this was an important concept and suggested it might be included in Chapter 7 or Chapter 4. In response to questions, she clarified that she thought this was an educational, communication, and outreach function. Dr. Berk suggested that the plans might also encourage providing expertise to funded investigators on commercialization issues. Dr. Varmus suggested there should also be an evaluation about what should be in the public domain for the public good. Dr. Berk concurred that it was important to assist researchers in conducting that evaluation and making an informed decision. Mr. Swidler suggested that funding training or educational material for attorneys regarding intellectual property issues would likely be a more appropriate use of public funds than paying for attorneys who may have competing interests. After further discussion, it was agreed that since this issue involved educational, legal, and social justice components, it would be appropriate to address this issue in Chapter 5, which deals with educational, social, ethical, and legal issues.

Dr. Stocker confirmed that members thought the document was ready for sharing with the public following these changes. Dr. Daines advised members the revised document would go to the Ethics Committee for their further consideration and then the full Board would address the issue of additional outside input at its May 13<sup>th</sup> meeting. In response to questions, Dr. Daines advised members that although they have been asked not to distribute the document, it was expected that members will have discussed parts of it with people who have knowledge of the area and interest in the plan.

Dr. Daines then entertained a motion to adjourn. Dr. Fischbach so moved; Dr. Hutcherson seconded. The motion passed unanimously.

*Approved: May 13, 2008*