

Empire State Stem Cell Board
Funding Committee Meeting Minutes
April 23, 2009

The Empire State Stem Cell Board Funding Committee held a meeting on Thursday, April 23, 2009, at the Department of Health offices, 90 Church Street, New York, New York. David C. Hohn, M.D., presided as Chairperson.

Funding Committee Members Present:

Dr. David C. Hohn, Vice Chair
Mr. Kenneth Adams
Dr. Bradford Berk
Dr. Richard Dutton
Mr. Robin Elliott
Dr. Gerald Fischbach
Dr. Bruce Holm
Dr. Hilda Hutcherson
Dr. Michael Stocker
Ms. Madelyn Wils

Funding Committee Members Absent:

Dr. Richard F. Daines

Ethics Committee Members Present:

Dr. Robert Klitzman

Department of Health Staff Present:

Dr. David Anders
Ms. Bonnie Brautigam
Dr. Kathy Chou
Mr. Thomas Conway
Ms. Judy Doeschate
Ms. Amy Nickson
Ms. Virginia Reyes
Ms. Beth Roxland
Ms. Lakia Rucker
Dr. Lawrence Sturman

Observers Present:

Ms. Margaret Close
Mr. Joseph Feldman
Mr. Eric Kriegstein
Ms. Caroline Marshall
Ms. Janet Paluh
Ms. Hannah Park

Opening Remarks and Introductions

Dr. Hohn called the meeting to order and welcomed Board members, staff and the public. Dr. Hohn advised members that Dr. Daines was unable to attend the meeting and asked him to chair the meeting. He also reported that Dr. Daniel Sulmasy had resigned from the Ethics Committee effective May 1, 2009. He then asked members and staff to introduce themselves.

Approval of Minutes for the February 12, 2009 Meeting of the Funding Committee

Dr. Hohn directed members to the draft minutes for the February 12, 2009, meeting of the Funding Committee found under tab 1 in their agenda books and asked for a motion to approve the draft minutes. Mr. Elliott so moved, and Dr. Holm seconded the motion. Mr. Elliott noted that “method-mutual” on page 3 should be “method-neutral.” Dr. Hohn suggested the last sentence in the first paragraph on page 3 should be amended to clarify that the provision suggested for deletion would have allowed administrative approval of some applications. With those changes, the motion passed unanimously.

Motion to Amend the Agenda to Consider Changes to the Request for Applications for Shared Facilities Approved on February 12, 2009

Dr. Stocker advised the Committee that in reviewing the minutes for the Funding Committee’s February 12, 2009, meeting he noticed that the Request for Applications (RFA) approved by the Funding Committee at that meeting had included a provision that would prohibit institutions funded under the prior shared facilities RFA from applying for additional shared facilities funding. He stated that while he did not dispute the accuracy of the minutes, he did not recall this provision being discussed at that meeting and would like the Committee to discuss the appropriateness of that provision. He then made a motion to amend the agenda to allow for discussion of that issue before additional business was considered. Dr. Hutcherson seconded the motion. The motion passed unanimously.

Consideration of Changes to the Request for Applications for Shared Facilities Approved on February 12, 2009

Dr. Stocker then suggested that the Committee should eliminate the provision in the shared facilities RFA approved on February 12, 2009 that would prohibit institutions that received funding under the prior shared facilities RFA from applying for additional shared facilities funding under that RFA. He noted that the Committee’s pre-eminent concern has been to fund the best science and that he thought that preventing some institutions from applying for subsequent funding ran contrary to that principle. He stated that he was not looking for any special treatment for any one facility, but that he thought the Committee should consider whether this restriction was appropriate in light of the Committee’s interest in funding the best science.

Dr. Holm noted that in the first round of funding many of the applications included fairly equivalent science, but some were funded and some were not. He agreed that funding

the best science was important, but commented that setting up infrastructure does not necessarily fit that paradigm because of the expense and need to make sure places that have done outstanding science have the facilities to support the science. He agreed that applications would need to meet the bar, but was not sure that there was enough funding to go around to apply that attitude towards infrastructure. He also noted that the scoring of the prior applications had little to do with “bad science” or “good science,” but with other factors such as budget and organizational focus.

Dr. Hohn questioned whether it was appropriate to exclude different researchers at the same institution from submitting an application for a different project. Dr. Stocker pointed out that his intention was not to allow additional funding for a previously funded project, but funding for a different project.

Mr. Elliott noted that one of the goals of the Board’s Strategic Plan was to build a strong stem cell research community and that it would be appropriate to not encourage others who have already received funding to apply, but to spread the support through the community further. He questioned how many institutions might be eligible for this funding and whether there was a gap in the scoring of the previously submitted applications. In response, Ms. Brautigam noted that twenty facilities applied in the first round and eight received funding for shared facilities. Ms. Doesschate advised members that the shared facilities applications that received a score of 1.9 or higher were funded, and that most other applications were between 2.3 and 2.9. However, she noted some had a larger standard deviation in their scores.

Dr. Berk stated that he thought it was too soon for institutions to reapply for funding and that he agreed that one of the Committee’s charges is to spread funding through the stem cell community. He also thought that this type of funding could be used to encourage cores and would be a more cost-effective way to develop infrastructure.

Dr. Hutcherson asked if it would be appropriate to compromise by allowing all institutions to apply, but give more weight to institutions that were not awarded funding previously. Dr. Fischbach expressed support for Dr. Hutcherson’s suggestion and asked whether the Committee could exert that kind of control and use its discretion to facilitate the spread of the technology. Ms. Brautigam agreed that the Committee can have that kind of latitude either by agreeing to weight the evaluation criteria or by considering those factors as part of the post-evaluation discussion of the applications. Dr. Berk suggested that the RFA include language to require institutions that have already received shared-facilities funding to explain why and how they expect the funding to expand stem cell research, to make it clear that will be a consideration.

Dr. Stocker then made a motion to amend the shared facilities RFA approved by the Funding Committee on February 12, 2009, to: 1. eliminate the restriction that would prohibit institutions that had been awarded funding under the prior shared facilities RFA from applying for support for new projects (but not to obtain additional funding for previously funded shared facilities projects); 2. provide that when making awards the Funding Committee will take into consideration factors such as the novelty of the proposal and need for researchers to have access to the proposed type of facility; and 3. require applicants that received funding under the prior shared facilities RFA to provide justification for the

institution to receive additional funding. The motion was seconded by Dr. Dutton and passed unanimously.

Program Updates

Dr. Hohn then turned the floor over to Dr. Sturman to provide program updates. Dr. Sturman referred members to the chart that had been handed out at the start of the meeting that included all RFAs and RFPs approved by the Funding Committee to date and provided an update on each of the RFAs and RFPs listed. He noted that the Committee would later discuss the charts and commitments made to date when it takes up future funding priorities. Dr. Sturman also noted that significant progress had been made in the development of the grantees conference scheduled for June 12, 2009.

Intellectual Property and Economic Development Workgroup Update

Dr. Hohn noted that the Board had expressed an interest in the Strategic Plan in exploring potential intellectual property and economic development policies that might further the purposes of the program and that Dr. Sturman had assembled a workgroup to study these issues. He then turned the floor over to Dr. Sturman and Mr. Adams, Chair of the workgroup, to provide an update on the workgroup's activities.

Dr. Sturman advised the Committee that the workgroup was in the process of finalizing plans for two forums. The first forum is scheduled for May 5th in Albany at the David Axelrod Institute and will gather information on economic development issues. The second forum is scheduled for May 15th at the Department of Health's offices at 90 Church Street and will focus on intellectual property issues. He advised members that the workgroup expects to report its findings to the full Board at its June 11th meeting.

Mr. Adams added that a number of experts, recommended by workgroup members, had been invited and are being confirmed. He suggested members speak to Dr. Sturman as soon as possible if they had speakers to recommend. Mr. Adams also encouraged members to attend both meetings and to encourage others to attend both meetings. Dr. Sturman also noted that members of the public are also invited to submit comments on these issues.

Report on Activities of the Ethics Committee and Consideration of Recommendations on Informed Consent

Dr. Hohn advised members that he would be turning the floor over to Ms. Roxland to provide a report on the activities of the Ethics Committee and then to Dr. Klitzman to present some formal recommendations of the Ethics Committee for standards relating to the informed consent of donors of biological materials.

Ms. Roxland first provided members with a brief overview of the recently-issued draft National Institutes of Health (NIH) Guidelines for Human Stem Cell Research, which were also distributed to Committee members. Ms. Roxland noted that the draft guidelines would limit federal funding to research using only human embryonic stem cell (hESC) lines

derived from embryos that were created for reproductive purposes and met the standards in the guidelines. She identified several provisions that could present problems for researchers seeking federal funding for research using existing stem cell lines, such as the requirement for a clear separation between the decision to create the embryos and the decision to donate the embryos for research, the requirement for re-consent of all gamete donors, the prohibition against inducements being offered “for the donation,” which could be read as requiring that stem cell lines derived from embryos created for IVF purposes using paid donors would be ineligible for funding, and the ambiguities in the document. She also noted that the guidelines do not require review by an Embryonic Stem Cell Research Oversight (ESCRO) committee and do not contain “grandfathering” provisions. Members then discussed some of the provisions of the draft guidelines and possible alternative interpretations. Ms. Roxland acknowledged that different interpretations were possible and noted that this highlighted the need for clarification of some of the provisions in the draft guidelines.

Ms. Roxland then advised members that in addition to the recommendations Dr. Klitzman would be presenting, the Ethics Committee had discussed the issue of respect for the embryo and payments for gamete donors at its last meeting. She stated that although the Committee had extensive conversations regarding the moral and philosophical bases for respecting the embryos and the ways respect might be shown to an embryo, the Committee did not reach a consensus on this issue.

Ms. Roxland advised the Committee that several members of the Ethics Committee have expressed support for the idea of compensating donors for time and burden and noted that New York would be the first state to do so. Dr. Stocker pointed out that most states have not taken a position on the issue of payments for gamete donors and presumably would allow payments for gamete donors unless they took formal action to prohibit it. He also noted that unless a state had taken formal action one way or the other, we may not know whether a state had considered imposing a restriction and decided not to. Ms. Roxland then turned the floor over to Dr. Klitzman to present the recommendations of the Ethics Committee for informed consent standards to be applied to the procurement of biological materials for human stem cell research.

Dr. Klitzman referred members to the draft standards included in their agenda books and briefly reviewed each of the provisions contained in the recommended standards. Ms. Roxland then highlighted the few provisions that had been significantly altered since the draft standards had been presented to the Committee at its last meeting. Specifically, she noted that the standards no longer included a provision that would allow a donor to impose restrictions on the transfer of stem cell lines derived from donated materials and that the standards now included “grandfathering” provisions that would allow researchers to use stem cell lines derived without NYSTEM funding as long as the procurement complied with the National Academy of Science (NAS) or International Society for Stem Cell Research (ISSCR) guidelines.

Dr. Fischbach moved to approve the recommendations of the Ethics Committee for standards for informed consent of donors of biological materials to be applied to research funded through the Empire State Stem Cell Fund. Dr. Stocker seconded the motion. Ms. Doesschate clarified that the standards would be incorporated into Appendix A-2 of the

contracts approved by the Funding Committee and would apply to the RFAs approved by the Funding Committee at its February 12, 2009, meeting and thereafter.

Dr. Berk inquired how institutions would be assisted in meeting the guidelines when they responded to the RFAs. Ms. Brautigam noted that staff has been conducting outreach with institutions regarding their ESCRO committee structure and offering technical assistance as needed. Ms. Doesschate pointed out that the “grandfathering” provisions in the proposed standards would limit the application of the standards to entities that are deriving new human stem cell lines. Dr. Fischbach suggested that the guidelines be publicized widely and provided to private clinics, a significant potential source of embryos for research. Dr. Hohn then called for the vote and the motion passed unanimously.

Dr. Klitzman then suggested the Committee take some time to consider whether to submit comments on the draft NIH guidelines. Ms. Roxland offered to draft a response for the Committee’s consideration. Mr. Adams and Mr. Conway suggested that any letter offering comments on the draft guidelines should come from the entire Board. Dr. Fischbach suggested it may be better for individuals to comment because a letter from the Board would only be a single letter amongst many. Several members expressed support for the Board submitting comments on the guidelines as a whole because of New York’s status as one of top funders of stem cell research in the country.

Dr. Klitzman suggested that the Board should advocate for allowing NIH funds to be used to conduct research on lines created with private or state funding, including those created via somatic cell nuclear transfer (SCNT); reversing the Dickey-Wicker amendment restrictions; and eliminating the requirement for the separation of consent for donation of gametes for reproductive and research purposes. Mr. Adams commented that the letter should also address ambiguities in the guidelines. Dr. Klitzman also noted the need to “grandfather” in the twenty-one approved lines. Ms. Doesschate pointed out that there are likely to be other lines that would need to be “grandfathered” in because they may not meet some of the specific requirements of the draft NIH guidelines, but may be considered to be useful in advancing stem cell research.

Dr. Hohn suggested that the Committee take some time to consider this issue and return to it after lunch.

Discussion of Draft Annual Report

Dr. Hohn then turned the floor over to Dr. Sturman to address the draft 2008-09 annual report that was distributed to members. Dr. Sturman noted the draft annual report followed the general format used in the prior year’s annual report, with a few additions. He noted that this year’s annual report would have information regarding publications, patents and updates of the abstracts. Dr. Sturman mentioned that the report would contain an overview of highlights of research from stem cell researchers in New York State, although not necessarily research supported with Board funding. He noted that staff was also providing other highlights in the field of stem cell research.

Dr. Sturman advised members that the Board is expected to adopt the annual report at its June 11th meeting and opened the floor for comment. Mr. Elliott stated he was very

impressed with the references to the national and state science included in the draft report and thought the report provides information that the public needs to know.

Dr. Sturman and Dr. Hohn encouraged members to provide any additional comments to Dr. Sturman or Ms. Doesschate during lunch or in the coming weeks.

Working Lunch

A video of Dr. Alan Friedman's January 26th presentation to the Ethics Committee on potential public outreach and education initiatives was shown during lunch. Due to difficulties with the audio, the presentation was terminated early and Ms. Doesschate encouraged members to review the summary of Dr. Friedman's presentation included in the January 26, 2009, Ethics Committee meeting minutes contained in their agenda books.

Comments on the Draft NIH Guidelines for Human Stem Cell Research

Following lunch, the Committee returned to its discussion of the NIH Draft Guidelines for Human Stem Cell Research and a potential response from the Board. Dr. Hohn suggested that the Committee identify three or four key bullets that are important to include in a letter for consideration by the Commissioner and the Ethics Committee. Dr. Hohn then asked Ms. Roxland for her suggestions.

Ms. Roxland suggested the Board comment on: 1. eliminating the restriction that limits funding to research involving only stem cell lines derived from embryos that were in excess of clinical need; 2. the need to clarify some ambiguities, such as the separation of consents for research and clinical need and the prohibition on payment of gamete donors; and 3. the need to "grandfather" in the twenty-one lines previously approved for NIH research and possibly other lines that adhered to the NAS or ISSCR guidelines.

Dr. Fischbach expressed support for expanding the grandfathering concept to include other stem cell lines that were ethically derived, but may not have fully complied with the specific requirements contained in the draft NIH guidelines. He noted that other lines that have been developed are more likely to be approved for clinical use by the FDA because they have never been in contact with mouse feeder layers. Mr. Elliott also noted that the other lines should not be required to comply with a higher level of standards than the twenty-one approved lines. Ms. Doesschate noted that one way of addressing this issue would be to recommend that pre-existing lines conform to the NAS guidelines, since those guidelines "grandfather" in the previously-approved twenty-one lines and allow lines that "substantially complied" with the NAS criteria to be used. Mr. Adams noted that the term "grandfathering" is confusing because the concern is actually about controlling for the potential detrimental effect of the retroactive application of the standards. He noted that controlling for retroactivity of the guidelines is broader than the concept of grandfathering specific lines.

After further discussion, Mr. Elliott made a motion that the Funding Committee authorize the Ethics Committee to draft a letter from the full Board to NIH regarding the NIH Draft Guidelines for Human Stem Cell Research that would address the primary

concerns raised, i.e., 1. that federal funding should be available to support research involving stem cell lines derived using embryos created for research purposes; 2. the guidelines should permit funded researchers to use previously derived stem cell lines that meet NAS or ISSCR guidelines, including the twenty-one lines previously approved for use in NIH funded research, even if such lines do not meet every detail contained in the new NIH guidelines; and 3. the need to address ambiguities in the draft guidelines. Dr. Fischbach seconded the motion. The motion passed unanimously.

Discussion of Funding Options, Priorities, Leveraging Opportunities and Strategic Plan Updates

Dr. Hohn turned the floor over to Dr. Sturman to provide the Committee with information about potential additional funding proposals and strategic priorities.

Discussion of Training Proposals

Dr. Sturman noted that he first wanted to solicit the input of members on the two concept papers that had been distributed. The first concept paper would provide funding for institutional training grants. He noted that the proposed seven million dollar commitment was based upon approximately four awards being made that would each support three pre-doctoral trainees at about \$46,500 per trainee per year and three post-doctoral trainees at about \$70,000 per trainee per year for five years. He explained that the concept paper for the RFA for individual fellowship awards would fund approximately six pre-doctoral and six post-doctoral fellows at similar amounts for a maximum of three years each. He noted that the Board could fund three funding cycles of the individual awards for a little less than seven million dollars. Dr. Sturman also pointed out that the Committee had only committed some funding for training through the initial institutional development awards and a portion of the recently approved fellow-to-faculty RFA. Dr. Stocker noted that the Strategic Plan estimates that four to ten percent of the total funds should be spent on scientific training, but that the Board had only committed about one percent to training thus far.

Dr. Fischbach expressed strong support for the individual fellowship program because the institutional training awards would likely only support training at four institutions. He also suggested the Committee include support for medical students to take a year or two off to engage in medical applications of stem cell research. Dr. Berk also expressed support for both institutional training grants and individual fellowship programs and stated that he thought the “year-out” support for medical students would be an incredibly good investment to encourage medical students to expand into this type of activity. Dr. Berk also recommended the RFA for the institutional training grants should have a lot of flexibility so that institutions can move people on and off of the traineeship depending upon other funding that may be available to support trainees.

Mr. Elliott inquired whether it would be possible to ask people who receive funding for training to spend some time in the State after their training. Several members expressed the concern that such a requirement would have a negative impact on the program. Dr. Sturman also noted that it is difficult to assess the benefit based upon one point in time since

scientists may move in and out of the State and may return based upon the contacts they develop within the State during their training.

In response to questions about the estimated costs, Ms. Brautigam noted that the amount of support is similar to that provided by NIH. Dr. Anders also noted the amount for the fellowships was in line with what the New York Stem Cell Foundation provides to support its fellows.

Members also expressed support for including an ethical training requirement within the grants, preferably as part of existing ethical training programs, and for making the funding available to support non-US citizens.

Dr. Sturman advised members that staff would be developing the two proposals more fully, as well as one to provide support for medical students. He said he hoped to present the proposals to the Committee for consideration at the June 11th meeting.

Discussion of Additional Priorities, Leveraging and Strategic Plan Updates

Dr. Sturman then directed members to the pie charts that had been handed out that show the amounts of funding commitments made to date broken down into the five funding categories set out in the Board's Strategic Plan. He noted that the charts showed the minimum and maximum recommended funding ranges for each category as established in the Board's Strategic Plan, as well as the percentage of actual funding committed in each category to date. He noted that the training and ELSIE categories had not been fully developed yet and that the Board had been considering potential additional funding for formal and informal education plans, such as secondary school education programs and museum exhibits. He also noted that additional funding should be made available to research to reach the projected funding goals and that staff expects to gather further information for the Committee's consideration of consortia funding at a meeting of the funded institutions scheduled for September 8, 2009. Dr. Sturman also directed the Committee's attention to a chart of potential additional funding opportunities that would support groundbreaking research and potential partnerships and leveraging opportunities.

Mr. Adams thanked Dr. Sturman for his presentation, the charts and their clarity. He stated that he thought the Committee should not deviate from the Strategic Plan in its initial five years so that the Board can evaluate the results of its initial plans better. He also suggested another chart be developed that shows what the Committee needs to do to reach its goals in each category for the first five years.

Dr. Dutton noted that money committed for training is also supporting research. Dr. Fischbach complimented Dr. Sturman for the terrific job he has done in getting \$175 million committed in such a short period of time. Both Dr. Sturman and Ms. Doeschate noted that credit also goes to the Board for its valuable input, time and commitment to helping ensure the program is a success.

Mr. Elliott noted that some of the funding disparities will "self-correct" because infrastructure was "front-loaded" and training and research projects are already anticipated. He also complimented staff on its willingness to look at novel ways of funding research to help leverage funding to increase investments in New York. He also inquired whether the

Committee is at a point where it could be creating an initiative to support more translational research and possibly clinical trials. Dr. Berk responded by noting that according to the charts, the Board is expected to spend another approximately \$111 million on research and suggested it would be appropriate to begin to have a dialogue with investigators in New York State to let them know funds may be available for translational research and get their input. Dr. Fischbach noted the phrase “translational” is often treated as a catch-all and the Committee should work with others to identify an appropriate focus for funding, such as drug discovery or disease mechanisms. He also commented the Board will need to develop partnerships with other groups if it wants to support clinical research. Dr. Fischbach also expressed an interest in the Board supporting the recruitment of stem cell scientists to New York State.

Dr. Hohn asked whether there were other ways to disseminate information about the Board’s progress than in the Annual Report. Ms. Wils commented that she thought a press briefing would be appropriate. Mr. Adams suggested the Board proceed with caution because not much of the Board’s money has actually been distributed yet and reporters need very concrete results and an angle. He suggested it would be appropriate to wait and let the scientists and grantees tell the story of the impact of the funding on their programs and research. Mr. Elliott and Ms. Wils suggested that it would be good to educate the science writers because they will be more inclined to write about a story when there is one if they the background history and knowledge.

Ms. Doesschate noted that the Board’s Annual Report is required to include the Board’s Strategic Plan and asked members whether they wanted the Board’s Annual Report to reflect any changes to the Strategic Plan. She noted that members had been provided with another copy of the Strategic Plan in advance of the meeting and asked to consider whether any changes are needed.

Dr. Holm noted that the types of new initiatives the Funding Committee had been discussing fit within the existing funding categories and objectives already set out in the Strategic Plan. Drs. Hohn and Holm both stated that they thought it was too early to alter the Strategic Plan to provide a greater emphasis on clinical trials and translational work. Members indicated their continuing support for the Strategic Plan as written and saw no reason to alter the document at this time.

Adjourn

Dr. Hohn then asked for a motion to adjourn the Funding Committee meeting. Dr. Fischbach so moved; Dr. Dutton seconded the motion. The motion passed unanimously.

*Approved: June 11, 2009
s/ Judy L. Doesschate, Esq.
Executive Secretary to the
Empire State Stem Cell Board*