

Empire State Stem Cell Board
Funding Committee Meeting Minutes
February 12, 2009

The Empire State Stem Cell Board Funding Committee held a meeting on Thursday, February 12, 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
Mr. Robin Elliott
Dr. Gerald Fischbach
Dr. Bruce Holm
Dr. Hilda Hutcherson
Dr. Michael Stocker

Funding Committee Members Absent:

Dr. Richard F. Daines
Dr. Richard Dutton
Ms. Madelyn Wils

Department of Health Staff Present:

Ms. Bonnie Brautigam
Mr. Thomas Conway
Ms. Judy Doeschate
Dr. Matthew Kohn
Ms. Amy Nickson
Ms. Beth Roxland
Ms. Lakia Rucker
Dr. Lawrence Sturman

Observers Present:

Mr. Robert Feldman
Ms. Sheila Gordon
Ms. Judith Hohn
Mr. Jung-Chi Liao
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. He advised members that Dr. Daines asked him to chair the meeting because he needed to travel to visit an ill family member.

Dr. Hohn advised members that Msgr. Smith had passed away in January and that Dr. Varmus had submitted his resignation due to his appointment as Co-Chair of the President's Council of Advisors on Science and Technology. He then asked members and staff to introduce themselves and provide their title and affiliation.

Following the introductions, Dr. Hohn noted that the program updates and report on the activities of the Ethics Committee were being moved to after lunch to help ensure that all members would be able to participate in the discussion on the Requests for Applications (RFAs) that were in the agenda books.

Approval of Minutes for the December 18, 2008 Meeting of the Funding Committee

Dr. Hohn directed members to the draft minutes for the December 18, 2008, meeting of the Funding Committee found under tab 1 in their agenda books. He then asked for a motion to approve the draft minutes. Dr. Holm so moved and Dr. Fischbach seconded the motion. The motion passed unanimously.

Consideration of Recurring Request for Applications for Support of Investigator-Initiated Research

Dr. Hohn directed members to the Recurring RFA for Investigator-Initiated Research that was included in their agenda books under tab 3 and turned the floor over to Dr. Sturman to highlight significant points for the Committee to consider.

Dr. Sturman advised members that the key components agreed upon by the Committee in prior discussions were now addressed in the revised RFA. The RFA included awards that would be the same amount as established in the last RFA for Investigator-Initiated Research Project (IIRP) awards, but the minimum professional effort for the Innovative, Developmental, and Exploratory (IDEA) awards would be reduced from 20 percent to 10 percent. He said that approximately \$15 million was being set aside for this RFA for an estimated 13 IIRP awards and 10 IDEA awards. Dr. Sturman advised members that he expected the RFA would be issued in the spring and then re-issued about every nine months. The RFA proposed that the scoring cut-off would be 2.5 and that any applications that receive a score of 1.5 or better would be processed without requiring a formal vote of the Committee. Dr. Sturman also noted that the evaluation criteria had been changed slightly to include "research environment" and "investigators" into the consideration of "feasibility." Dr. Sturman asked whether members might want to include some preference for early stage investigators and opened the floor up for discussion.

Dr. Stocker expressed a preference for the current process that provided a balance of having both the expert independent peer-review and the Committee review of applications.

He stated he would not want the Committee to give up their responsibility for making the final decision on awards. Dr. Sturman responded to questions from Committee members regarding how the provision might help expedite the contracting process and the start of research. The Committee also discussed other options for speeding up the approval process. The Committee then concurred with Dr. Sturman's suggestion to delete the provision that would have allowed any application with a score of 1.5 or better to proceed with just administrative approval.

Dr. Fischbach asked whether it was possible to provide an emphasis for funding research involving human embryonic stem cells (hESC) in the recurring RFA. He noted that if nothing was done in the current RFA, the Committee may not be able to do anything to encourage hESC research for six to twelve months. He stated that he thought that part of the mission of the Board was to stimulate research in this area since the federal government was not providing support for this type of research. In response to questions, Dr. Sturman suggested a number of ways the Committee could encourage hESC research, including providing for a special peer-review panel, including more hESC researchers on peer-review panels, giving points for hESC research, and setting aside funding to target hESC research.

Mr. Elliott stated that a benefit of the original legislation was that it was "method-neutral." He commented that it was an odd time to suggest a proposal to encourage hESC research in light of the changing federal environment. However, he also noted he had been surprised that there were so few applications in the last round that involved the derivation of new cell lines. Mr. Elliott suggested this raised a question about the state of the science.

Dr. Fischbach suggested the few applications in this area raised questions about the need to stimulate the science and that while a change in federal policy is anticipated, he questioned whether there would be federal funding for this kind of research within the next year. He stated that he felt that there is a need for a special emphasis on hESC research precisely because the Board did not get many applications before. He suggested this may have been because scientists are concerned they would not receive high enough scores to be funded because of a lack of experience in this area. Dr. Stocker concurred stating that the intent of the legislation included funding research involving new hESC lines. He asked staff whether it would be possible to approve such a project at this meeting.

Dr. Sturman suggested a few ways the Committee might approve support for hESC research without waiting for the next meeting, such as modifying the proposed recurring RFA to set aside some funds for hESC research. Dr. Berk suggested that the IDEA awards in the proposed RFA could be used to encourage new investigators to derive or use new hESC lines and that a separate RFA that targeted funds to new hESC lines could be created using the proposed RFA as a template.

Dr. Sturman asked Committee members whether they wanted to provide some special consideration for early stage investigators. Committee members expressed an interest in providing some additional encouragement or consideration of early stage investigators, including having them evaluated separately, adding points to their scores, having them evaluated together within the appropriate peer-review panel, increasing the pay line for young investigators, creating a separate RFA for young investigators, and allowing

post-evaluation comparisons across all peer review panels. Dr. Fischbach expressed support for a “back end” approach to considering support for early stage investigators and also reiterated his strong preference for creating a selected targeted RFA for hESC lines at the meeting, rather than waiting several more months. Some members questioned whether it was wise to split the funds up into too many separate pots. Staff also noted that increasing the number of RFAs could make it more difficult for the peer-review contractor to arrange for peer-reviews of all of the applications. The Committee agreed that it would be sufficient to have two RFAs: one using the draft recurring RFA contained in the agenda book, modified to encourage hESC research and allow the Committee to give special consideration to early stage investigators to the extent permitted under State guidelines; and the other to target funds to support research to improve methods for deriving new stem cell lines. Ms. Brautigam also recommended setting the cut-off for the Committee’s review of applications at 3.0 to increase the flexibility of the Committee.

Dr. Fischbach then made a motion to authorize staff to issue the Recurring RFA for Investigator-Initiated Research contained in the Committee’s agenda books with modifications that would: 1. delete the authorization for automatic processing of applications receiving scores of between 1.0 and 1.5; 2. add language to encourage the submission of research proposals involving the derivation of new hESC lines; 3. add language to allow the Committee to give special consideration to applications submitted by investigators in the early stages of their careers; and 4. reduce the score cut-off for Committee consideration to 3.0. Dr. Stocker seconded the motion. The motion passed unanimously.

Mr. Elliott then asked for clarification on the scoring criteria for “innovativeness” that included consideration of “the extent to which successful completion will advance ESSCB’s mission.” Ms. Brautigam stated that the provision was added to address the questions of peer-reviewers regarding some research proposals that seemed to include stem cells, although the use of stem cells might be unnecessary or not central to the research. Mr. Elliott suggested that the criteria for evaluation should be amended to include a reference to the therapeutic relevance of the research. Dr. Hohn suggested that could be done by adding “and have potential therapeutic significance” to the end of the phrase referenced by Mr. Elliott in both the criteria for the IIRP and IDEA awards.

Mr. Elliott then moved to add the phrase “and have potential therapeutic significance” to the phrase “[t]he extent to which successful completion of the project will advance ESSCB’s mission” where that phrase appears in the previously approved RFA. Dr. Berk seconded the motion. The motion passed unanimously.

Dr. Fischbach then moved to authorize staff to issue another RFA similar to the recurring RFA included in the agenda book, as modified by the prior motions, that would make \$6.5 million available for awards targeted to support research related to the characterization, standardization and optimization of the derivation of new hESC lines. Ms. Brautigam clarified that the proposed amount of funding would likely result in approximately five IIRP and four IDEA awards. Dr. Stocker seconded the motion. The motion passed unanimously.

Consideration of Requests for Applications for Support for Fellow-to-Faculty Awards and Shared Facilities

Dr. Sturman then directed members to the other two RFAs contained in their agenda books. He advised members that the proposed fellow-to-faculty awards would provide funding at a maximum of \$100,000 for two years of post-doctoral training and then up to three years of funding at a maximum of \$250,000 for independent research at the faculty level. He noted the indirect costs would be 8 percent for the first two years and 15 percent after the faculty position is established. He stated the RFA would be able to fund approximately five awards. He noted there is also a requirement that the institution provide a minimum of \$400,000 in start-up funds in addition to a salary commensurate with what a new investigator is typically paid. Dr. Sturman stated that the RFA restricts institutions to recommending a maximum of two post-doctoral fellows and the proposed score cut-off is set at 2.0 to ensure the Committee is only funding the very best applicants.

Dr. Fischbach expressed strong support for the proposal, but suggested that applicants be limited to only having three prior years of post-doctoral training. He also questioned whether it was appropriate to rule out individuals who have a commitment from an institution. Dr. Sturman clarified that the intent was not to rule out individuals recruited by institutions, but to make sure candidates do not have a faculty appointment at the time of the application. After discussing the institutional variations, it was agreed that the provision prohibiting tenured faculty from applying would be changed to require the applicant to be “employed as a post-doctoral fellow at an applicant institution.” Members also agreed that it would be good to give the program a name, such as “New York State Scholars” or “Empire Stem Cell Scholars.”

Dr. Fischbach then moved to approve the Fellow-to-Faculty RFA included in the Committee agenda binders, modified by reducing the number of years a candidate could have been a post-doctoral fellow from five to three and requiring the candidate to be employed as a post-doctoral fellow at the time of application, rather than as a professor. Mr. Adams seconded the motion. The motion passed unanimously.

The Committee then considered the proposed RFA for additional support for shared facilities included in their agenda books under tab 5. Dr. Sturman noted that the RFA was similar to the last one for funding shared facilities that resulted in nine awards totaling \$32 million. He note that only \$15 million was being set aside for this round of applications and that institutions that had been awarded funding for shared facilities under the prior RFA would not be eligible for funding. Dr. Sturman noted that the review criteria had been modified to increase the weight for design considerations from 10 percent to 20 percent.

Dr. Holm moved to authorize the Department to issue the RFA for shared facilities. Dr. Fischbach seconded the motion. The motion passed unanimously.

Program Updates

Dr. Sturman advised members that institutions have been submitting progress reports and vouchers for the Institutional Development Grants. He noted that NYSTEM staff has been encouraging funded institutions to submit vouchers for payment in a timely manner to

ensure the full amount of available funding is distributed prior to the end of the contract period. Dr. Sturman also reported that all recipients of the Planning Grants for Emerging Opportunities and Consortia Development have submitted the necessary information to complete processing of their contracts and that 18 contracts were currently being reviewed by the Office of the State Comptroller and Office of the Attorney General. He also reported on the progress of the shared equipment and facilities, targeted and generic research awards. Dr. Sturman also provided a brief update on plans for the June NYSTEM Grantees Conference.

Dr. Sturman advised members that Dr. Alan Friedman, former Director of the New York State Hall of Science, spoke at the last Ethics Committee meeting about museum programs and other ways of engaging the public. He stated that Dr. Friedman offered valuable insight that he would also like to have the Funding Committee members hear and suggested that Dr. Friedman could address the Committee at its next meeting.

Report on Activities of the Ethics Committee

Ms. Roxland advised members that the Ethics Committee focused solely on the informed consent issue at its January meeting to attempt to close out discussions on this topic and forward recommendations to the Funding Committee in the near future. She said that the Ethics Committee was interested in getting some feedback from the Funding Committee on its discussions before it finalizes its recommendations.

Ms. Roxland advised members that on the issue of payments to gamete donors, the Ethics Committee had decided it was ethically permissible to reimburse donors for out-of-pocket expenses and would be discussing the issue of allowing payments for time and burden at its next meeting. She then encouraged members to provide their thoughts on this topic.

Dr. Fischbach advised the Committee that he would be leaving early, but wanted to point out that in Massachusetts there are no egg donors due to the fact that they do not currently allow donor payments. He stated that he favored donor compensation that is reasonable and will attract and encourage donor participation. Dr. Stocker suggested that in vitro fertilization donations have evolved in a market environment that allows for payment for time and burden. He expressed support for allowing compensation for time and burden for donations for research if there is adequate informed consent. He also expressed support for a cap on such compensation. Dr. Berk suggested that staff should identify who will be dealing with this issue on the federal level so that the State can be consistent with any changes in federal policies. Dr. Hohn suggested it would be easier to come up with an appropriate number for reimbursement than it would be to address the details of how to implement it in a way that doesn't "checkmate" the Board and researchers in New York State. Mr. Elliott suggested that it might be beneficial for the Ethics Committee to get direct input from women's and minority advocacy groups. Ms. Roxland concluded saying she had attempted to capture the various advocacy groups in the materials provided to the Committee, but would give further thought to the comments to ensure all viewpoints are covered.

Ms. Roxland then directed the Committee to the draft document entitled “Informed Consent Contract Clauses for Appendix A-2.” She advised the Committee that she had drafted this document based upon the Ethic Committee’s discussions at its last meeting. She noted that the precise language from the National Academy of Science (NAS) or International Society for Stem Cell Research (ISSCR) guidelines was included in the footnotes wherever it was referred to in the document. Ms. Roxland then reviewed each of the subsections with the Committee to solicit comments and possible amendments.

Ms. Roxland noted that subsection a. would require that informed consent be accomplished through a dynamic process that encourages the potential donor to ask questions and prompts the potential donor to confirm his or her understanding of the information being disclosed. She noted that the second provision relating to re-consent at the time the gamete or embryo is transferred to the research team was the same as the informed consent provision adopted by the Funding Committee in March of 2008.

Ms. Roxland advised the Committee that the next provision addressed the issue of donor restrictions on both initial uses and on transfers to other laboratories. She noted that the first provision only allowed donors to impose restrictions on initial uses because the Ethics Committee felt it was too burdensome and unrealistic to expect restrictions on subsequent uses to be followed. On the other hand, some members of the Ethics Committee thought letting donors prohibit transfers to other institutions might encourage more people to donate if they trusted a particular institution and had concerns about other institutions, states, or countries using their donated materials. Consequently, a second paragraph had been added to allow a donor to prohibit transfers of donated materials to other institutions.

Dr. Berk stated that he felt allowing donors to impose restrictions on transfers to other institutions would be particularly damaging to the goals of the stem cell research process in that confirmation of research results in other environments is essential to translating stem cells to clinical care. He said there are also significant rules on transfers of biological materials and suggested the Committee should take a strong stand on this provision. Dr. Holm concurred with Dr. Berk’s statements.

Ms. Roxland then explained the next provisions were similar to requirements contained in the ISSCR and/or NAS guidelines and would require researchers to advise potential donors: that the embryo would not be allowed to develop in culture for longer than 14 days; that the resulting cell lines could have potential commercial value; that the stem cell lines will retain the donor’s DNA and could identify the donor in the future; and that the investigator and institution may benefit financially from any resulting cell lines.

Ms. Roxland then referred the Committee to subsection g., which would require grantees to reimburse donors for the costs of research-related injuries. Ms. Roxland also noted that she would be revising this language to address circumstances when the grantee may be a State institution. Dr. Berk mentioned that institutions are legally prevented from passing on the costs of medical research to commercial, federal, or state insurers and that it has to be borne by the research project. He also noted that the responsible organization is usually the grantor, not the grantee. He suggested that Ms. Roxland consult with medical center attorneys regarding their indemnification clauses and look at the New York State

Spinal Cord Injury Program's indemnification provisions. He also noted that indemnification issues are one of the biggest hurdles to hESC research.

Ms. Roxland noted that subsection h. would require grantees to comply with section 11.5(b) of the ISSCR guidelines when disclosing the risks of donating oocytes. She noted that the Ethics Committee modified this provision to clarify that donors must be informed of both the short-term and long-term risks to the extent they are known at the time of donation.

Ms. Roxland stated that the final provision clarified that the proposed ESSCB informed consent rules should apply going forward to newly solicited biological materials, but that all previously solicited biological materials would have to adhere to NAS or ISSCR guidelines. She advised members that she would be adding a provision to grandfather in the lines approved for use in research funded by the National Institutes of Health (NIH).

Ms. Roxland then turned the Committee's attention to the draft model informed consent forms. She stated that the purpose of the forms was to inform the donor of what will happen to her eggs and the risks associated with undergoing the egg donation process. She noted that the Ethics Committee had used the ISSCR model informed consent form, but had reworded a lot of the definitions to make them more easily understood.

Ms. Roxland then addressed Mr. Elliott's earlier question regarding the process of restricted donations. She pointed out that there was a check box for donors if they wanted to limit the research uses of their gametes. Mr. Elliott expressed concern that the term "chimera" was not defined and emphasized the need for the language to be impartial.

Ms. Roxland then asked for the Committee's thoughts on whether the form should ask the donor if they want to be contacted if either medical or genetic information leads to some conclusion regarding inherited risks in their system. She noted this could be a benefit to the donor, but that it might also lead some donors to conclude there are no problems if they are not contacted. She also noted that this requirement could be very burdensome to researchers.

Dr. Berk expressed concern over the overlap of genetic and privacy issues in two different sections of the form. He suggested that these should be consolidated into a single comprehensive section addressing privacy and genetic information issues. He stated staff should ensure compliance with the Genetic Information Non-Discrimination Act. He also noted that some cell lines would have utility over time and may be used in numerous trials that would require genetic analysis in a licensed clinical laboratory. Dr. Berk suggested that genetic counselors should be used in the informed consent discussion with donors to fully explain the processes, risks, and re-contact issues. He also suggested that donors be provided with concrete, practical examples of how their genetic information may be used when cell lines are used clinically.

Dr. Hohn agreed with Dr. Berk's concern that researchers should not be contacting donors with potential relevant medical information. He also stated that information cannot be provided to the donor's physician without the donor's consent and the likelihood that the research will not be done in a licensed clinical laboratory would hamper the ability of researchers to report the results. He suggested donors should be encouraged to go for genetic testing in a licensed laboratory if they have concerns.

Dr. Holm expressed concern that including the option for donors to be re-contacted in the form would raise a donor's expectations and add to existing liability concerns.

Dr. Berk stated that of all the clinical trials he has reviewed, none had a re-contact clause because that would leave the institution responsible for finding the donor or research participant. He also noted that an isolated genetic factor only changes a person's risk; it doesn't necessarily translate into a true disease event. He said the dominant rationale for not including a re-contact provision in genetic research is that having the materials be "de-identified" provides a greater assurance of privacy, which outweighs the theoretical benefit of being re-contacted if something is found.

Mr. Adams suggested that the forms should support a system for donation and obtaining informed consent from an ideal donor in a way that helps advance the science. He commented that the goal should be to protect the person's rights in a way that actually encourages donation. He also expressed support for allowing payments for donations that are capped.

Ms. Roxland closed by asking members to contact her with any additional thoughts.

Discussion of Annual Report Development

Dr. Sturman noted that members were provided with a copy of the 2007-08 Annual Report and the proposed outline for the next annual report. He noted that the report is expected to include highlights of developments in the stem cell research field, accomplishments from NYSTEM-funded research, a report of the grants in progress, the Strategic Plan's goals, Board's activities, expenses, publications, and patents. He then opened up the floor to Committee members for their comments and suggestions.

Mr. Elliott stated that he was very pleased with the current report, but would like to see pie charts and other appropriate graphics included in the next report to show where the money went. He also suggested that the report should highlight things that the program has accomplished that are of the same scientific caliber as established programs such as NIH. He also suggested that the report focus on progress in translational and disease-centered research.

Dr. Stocker suggested that the description and relevance of some of the funded research should be made clearer and more understandable to legislators, reporters, and others reading the report.

Dr. Berk suggested the report should include testimonials from people who have received the grants and discuss why they decided to stay in New York State, the difference the grants made in their research, and the additional jobs they were able to create. He also suggested that the report include information and comments showing how funds have been leveraged to increase the economic benefit of the program to the State.

Mr. Adams agreed that testimonials would be a great addition. He suggested that the Annual Report should be comparable to the goals and achievements set out in the Strategic Plan, so that people can see what the Board set out to accomplish and what it has

accomplished. He suggested the Annual Report and Strategic Plan were great ways to get exposure for the program throughout New York and raise curiosity so that people will want to learn more.

Dr. Hohn concurred that the report should focus on the fact that New York is leveraging some of its strengths and should tout the progress being made. Dr. Hohn concluded by recommending members contact Dr. Sturman and NYSTEM staff with any further suggestions or comments regarding the draft of the next report.

Mr. Adams asked whether the Department had asked for federal stimulus aid for the program and encouraged staff to do so.

Adjourn

Dr. Hohn then asked for a motion to adjourn the Funding Committee meeting. Dr. Stocker so moved and Dr. Holm seconded the motion. The motion passed unanimously.

Approved: April 23, 2009