

Empire State Stem Cell Board
Funding Committee Meeting Minutes
November 6, 2008

The Empire State Stem Cell Board Funding Committee held a meeting on Thursday, November 6, 2008, at the Department of Health offices, 90 Church Street, New York, New York. Commissioner Richard F. Daines, M.D., presided as Chairperson.

Funding Committee Members Present:

Dr. Richard F. Daines, Chairperson
Mr. Kenneth Adams
Dr. Bradford Berk
Dr. Richard Dutton
Mr. Robin Elliott
Dr. Gerald Fischbach
Dr. Michael Stocker
Dr. Harold Varmus

Funding Committee Members Absent:

Dr. David Hohn
Dr. Bruce Holm
Dr. Hilda Hutcherson
Ms. Madelyn Wils

Department of Health Staff Present:

Dr. David Anders
Ms. Bonnie Brautigam
Dr. Kathy Chou
Mr. Thomas Conway
Ms. Judy Doeschate
Ms. Amy Nickson
Ms. Beth Roxland
Ms. Laker Rucker
Dr. Lawrence Sturman
Ms. Mary Szesnat

Observers Present:

Mr. Robert Feldman
Ms. Janusz Frackowiak
Ms. Elaine Marchi
Ms. Bozena Mazur-Kolecka
Ms. Elizabeth Misa
Ms. Janet Paluh

Opening Remarks and Introductions

Chairman Daines called the meeting to order and welcomed Board members, staff, and the public. He then asked members and staff to introduce themselves.

Approval of Minutes for the September 19, 2008 Meeting of the Funding Committee

Dr. Daines directed members to the draft minutes for the September 19, 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. Mr. Elliot so moved, and Mr. Adams seconded the motion. The motion passed, with Dr. Varmus abstaining.

Program Updates

Dr. Sturman advised Committee members that the institutional development grants are now eligible for first and second quarter reimbursements and that 15 of the 25 awardees have already submitted reimbursement vouchers totaling a little over one million dollars. He noted that six of the 25 awardees have already submitted progress reports that will be reviewed by staff to determine and assess the progress and stated objectives of the NYSTEM-funded projects.

Dr. Sturman stated that the targeted research and investigator-initiated research applications were reviewed October 15th – 17th and that he anticipated that they will be considered at the Funding Committee's December 18, 2008, meeting. He noted that the two educational Requests for Applications (RFAs) for undergraduate curricular development and undergraduate summer research experience were completed and are being reviewed by Department of Health fiscal staff.

Dr. Sturman announced that the Program Committee for the 2009 Grantees' Conference held its first meeting to begin planning for the conference which, is scheduled for June 12, 2009, in Albany. Save-the-date announcements have been sent to NYSTEM grantees and a notice has also been posted on the NYSTEM website. Dr. Sturman advised members that the Program Committee members include Dr. Elaine Fuchs from Rockefeller University, Dr. Steven Goldman from the University of Rochester Medical Center, Dr. Ruth Lehman from New York University Medical Center, Dr. Ihor Lemischka from Mt. Sinai School of Medicine, Dr. Lorenz Studer from Memorial Sloan Kettering and Dr. Gordana Vunjak-Novakovic from Columbia University.

Dr. Sturman informed the Committee that the NYSTEM website has launched a searchable database of stem cell scientists in New York State. The database contains investigators who were included in the report, "Stem Cell Research in New York State: A Snapshot," as well as additional scientists who have been identified subsequently. Users will be able to search the database by full text, keywords and institution, or browse using the full list or categories. Additional investigators will be added as they are identified and their information becomes available.

Dr. Sturman noted that the final version of the Strategic Plan has been posted on the website and the print version is underway. He also stated that the Annual Report is in the final design stage.

Report on the Ethics Committee

Ms. Roxland advised members that the Ethics Committee met on Thursday, October 16, 2008. She reported that the Committee heard two presentations. The first was by Dr. Jennifer Schneider, whose daughter donated eggs for in vitro fertilization and later died of colon cancer at the age of 31. Dr. Schneider asserted that the risks of undergoing ovarian stimulation are unknown and potentially very high. She strongly recommended that the Empire State Stem Cell Board support the development of an egg donor registry so that donor health can be followed for long periods of time and more information can be acquired about any risks. Dr. Schneider also asserted that high monetary payments can have a very coercive effect on young women and that the Committee should take that into account when assessing what and how much to pay egg donors. The second presentation was by Dr. Kevin Eggan, a principal investigator and faculty member at the Harvard Stem Cell Institute. Dr. Eggan presented information about the need for oocytes in scientific research, particularly in the area of Somatic Cell Nuclear Transfer.

Ms. Roxland advised members that the Ethics Committee primarily discussed the issues of informed consent and donor payment. She noted that the Committee was using the National Academies of Science guidelines, the International Society for Stem Cell Research guidelines and other relevant guidelines as a starting point and then deciding whether any alterations were appropriate. The Committee's informed consent discussions focused on re-consent, donor restrictions on uses, conflicts of interest and disclosures concerning risks of ovarian stimulation. The Committee's discussions on the payment of gamete donors focused on the three basic payment options: no payments or reimbursement; reimbursement for out-of-pocket expenses only; and reimbursement for out-of-pocket expenses and for time, risk and burden. Ms. Roxland informed members that the Committee decided it was ethically permissible to reimburse donors for out-of-pocket expenses, and that the Committee would be discussing whether to allow for time and burden payments at its next meeting. She noted that the Ethics Committee invited Funding Committee members to attend this meeting if they want to be involved in this discussion or listen to the Committee's deliberations.

Executive Session

Dr. Daines advised the Committee and members of the public that the Committee would be moving into Executive Session to discuss the applications submitted in response to the RFA for funding of shared equipment and facilities that was issued in May. He asked for a motion to go into Executive Session. Dr. Stocker so moved and Dr. Dutton seconded the motion. The motion passed unanimously.

Dr. Daines then asked members of the public and non-essential staff to leave the room. He advised them that they were welcome to return when the Committee was expected to reconvene in public session at about 12:45 p.m.

Executive Session Discussion of Evaluations of Planning Grants for Shared Equipment and Facilities

Dr. Daines advised the Committee that several members would need to be recused for discussion of various applications, but that he would first turn the floor over to Dr. Sturman to provide members with information about the applications received and the evaluation process.

Dr. Sturman and Ms. Brautigam reminded members of the evaluation criteria they approved for inclusion in the RFA and provided members with information about the peer review evaluation process. The Committee was then provided with specific information relating to the applications, while members who were identified as having a potential conflict of interest left the room during consideration of those applications.

Upon completion of the discussion of the applications, Dr. Daines asked for a motion to adjourn the executive session and reconvene in public session. Dr. Stocker so moved and Mr. Adams seconded the motion. The motion passed unanimously.

Approval of Shared Equipment and Facilities Grant Awards

Dr. Daines advised the Committee and the public that the next item on the agenda was the approval of the grant awards to applicants who responded to the RFA for funding of shared equipment and facilities. He stated that the Department received and reviewed 22 of the 23 applications that were submitted in response to this RFA. He noted that the purpose of this funding is to support the establishment and operation of shared core facilities and specialized equipment to maximize the expertise, efficiency and quality of stem cell research in New York State. Approximately \$31.5 million dollars was earmarked for this effort. Dr. Daines noted that the applications were reviewed by a panel of independent experts from outside of New York State and that summaries of the panel's reviews were shared with the Funding Committee and discussed in Executive Session.

Dr. Sturman and Ms. Brautigam provided a brief overview of the evaluation criteria and the evaluation process. Dr. Daines then advised members that they would first act on the applications for which Committee members had not declared a conflict of interest. They would then take up the applications for which members of the Committee had identified a conflict of interest individually, so that members with a conflict would be able to recuse themselves during consideration of those applications. Dr. Daines then asked Dr. Sturman to read the list of applicants for which no conflicts of interest exist, the amount of the recommended award and whether staff recommended the award be subject to additional contingencies.

Dr. Sturman stated that SUNY Upstate (\$5,136,655), New York Stem Cell Foundation (\$5,861,451), Cornell University (\$1,629,645), Albert Einstein College of Medicine (\$5,993,889), Mount Sinai School of Medicine (\$3,812,528), Regenerative Research Foundation (\$1,923,629) and Cold Spring Harbor Laboratory (\$481,738) were being recommended for awards and that staff had recommended that all applicants, except for Regenerative Research Foundation, should satisfy the specified contingencies before being funded. He then presented members with information about the applications,

contingencies and amounts recommended by staff. Dr. Daines then asked for a motion to recommend approval of the awards for these institutions in the amounts and with the contingencies recommended by staff. Dr. Fischbach so moved and Dr. Dutton seconded the motion. The motion passed unanimously.

Dr. Daines then advised the Committee they would be considering the application for Memorial Sloan Kettering and noted that Dr. Varmus had advised the members of a conflict with the application and was leaving the room. Dr. Sturman provided the Committee with information about the application and noted that the application was being recommended for funding without contingencies. Dr. Stocker moved to recommend approval of the award to Memorial Sloan Kettering in the amount of \$2,707,911 as recommended by Department staff. Mr. Adams seconded the motion. The motion passed unanimously.

Dr. Varmus returned to the room and Dr. Fischbach left the room due to a conflict of interest while the Committee considered the application for Rockefeller University. Dr. Sturman provided the Committee with information about the application and noted that the application was being recommended for funding subject to the identified contingencies. Dr. Dutton moved to recommend approval of the award to Rockefeller University in the amount of \$4,864,705 as recommended by Department staff. Dr. Stocker seconded the motion. The motion passed unanimously. Dr. Fischbach then returned to the room.

Discussion of Review and Approval Process for Future Awards

Ms. Brautigam started the discussion by stating that she needed guidance from the Committee members on how they would like to handle large volumes of applications submitted in response to RFAs, especially those being considered at the December 18th meeting. She asked the members how much detail they would like to receive, if they would prefer to have different amounts of information on the applications depending on where they fall in the funding range and whether they preferred the information on paper or electronically.

Ms. Brautigam proposed to provide members with different levels of information for applications in the “funding range,” which she suggested would include the highest ranked applications up to the amount of the total funds committed to the particular RFA plus another 10%. She suggested that she would provide three pages of essential information for all applicants within the top two-thirds of the total funding range, which would include the cover summary sheet, the scores and the investigator’s abstract. She proposed that for the bottom third of applicants she would provide members with the type of full critiques they received for shared equipment and facilities applications, to ensure members had all relevant information at their disposal. Ms. Brautigam assured members that even though they wouldn’t necessarily discuss all submitted applications, they would be given a full listing of all applicants, including their institutions, dollar amounts, the principal investigator’s name, the application number and the scores for any applications receiving a score of 3.0 or lower.

Dr. Varmus stated that he would prefer less verbiage from the reviewers and that the summary of the critique would be satisfactory. He also felt that a summary budget of personnel, equipment, supplies and construction expenses would be appropriate in case they felt that a reduction was needed to make the funding go further. Dr. Fischbach suggested

that it would also be helpful to have the budget justifications to help make award amount decisions. Members discussed whether it would be possible for them to review that level of detail and Ms. Brautigam noted that the peer reviewers took a careful look at the budgets and made recommendations in many cases for reductions or additional justification. Mr. Adams suggested that staff might be able to include the budget comments made by the reviewers for all of the applications to address this concern.

Several members suggested that it would be helpful to have the applications on CDs or the web in case it was necessary for members to refer to the entire application. Ms. Brautigam advised members that she would not be able to arrange for the type of web set-up being suggested, but that she could provide members with all of the applications on several CDs if they wanted them.

Dr. Berk suggested the Committee should also be provided with information about the categories of research on submitted and funded applications so that the Committee could play a strategic role in funding decisions and communicating with the stem cell community. Ms. Brautigam acknowledged that some of that kind of information could be provided.

Ms. Brautigam requested clarification about the number of applications on which the Committee wanted to receive full critiques. Committee members expressed an interest in expanding the “funding range” to include an amount equal to an additional 20% of the total funds committed so that the Committee would be casting a broader net in its initial reviews. Dr. Daines suggested that this would be the minimum range and that there is likely to be some sort of natural breakpoint based upon the scores. Ms. Brautigam then clarified that members agreed that they only needed the essential application information, scores and summary for the applications in the top two-thirds of the funding range and full critiques for the applications in the bottom third of the funding range. Ms. Brautigam also assured members that she would have all of the applications and critiques available at the meeting if members wanted to review them and that she would attempt to provide individual members with any additional information they might need.

It was agreed that discussions regarding the handling of future RFAs would be scheduled for a future meeting.

Discussion and Possible Action on a Recurring Request for Applications for Investigator-Initiated Research Awards

Dr. Daines noted that Committee members had expressed an interest in issuing more RFAs to support investigator-initiated and innovative research and directed members to the draft RFA under tab 3 in their agenda book. He then turned the floor over to Dr. Sturman.

Dr. Sturman advised members that the draft RFA was similar to the investigator-initiated and innovative research RFA that was issued in May of 2008. He suggested that the RFA could be issued approximately every nine months with the next issuance having a May 2009 deadline and a January 2010 start date. He advised members that based upon the Department’s experience with the RFA issued in May and comments made by peer reviewers, staff had suggested a number of changes to the RFA about which he wanted the Committee’s input before they acted on the RFA.

He noted that the proposed amount of the R01-type awards had been reduced in the draft RFA from \$300,000 per year to \$250,000 in direct costs with the possibility of \$300,000 if the research involves larger animal models or the development of new stem cell lines. Ms. Brautigam advised members that peer reviewers had noted that the National Institutes of Health R01 awards are \$250,000 per year and had questioned whether some researchers were inflating their budgets to receive the full sum. Members suggested that the higher amount was needed to operate many labs and may encourage higher quality applications.

Dr. Sturman asked members whether they thought the 20% commitment of time currently required in the RFA was appropriate for both the R01 and R21-type awards. He advised members that some applicants had been disqualified because the Principal Investigator had not made a time commitment of 20% in the application. Ms. Brautigam noted that peer reviewers had suggested that they may be seeing fewer investigators apply for the smaller R21-type awards because they feel the amount of money was insufficient for the 20% time commitment requested. Board members suggested that the time commitment for the smaller awards should be reduced to 10%, but that for the R01-type awards the 20% time commitment was appropriate with a \$300,000 annual funding limit.

Dr. Sturman then sought the Committee's thoughts on a number of scoring penalties that had been suggested for not following the format and content requirements and failure to appropriately address Institutional Review Board, Institutional Animal Care & Use Committee and Embryonic Stem Cell Research Oversight considerations at the time of submission of the application. In response to a question, Ms. Brautigam clarified that researchers would be required to comply with the IRB, IACUC and ESCRO review requirements, but sometimes the applications raise questions as to whether the researcher has adequately considered whether the research plan is appropriate and is likely to be approved by those bodies.

Dr. Sturman advised members that the length of the research plan in the draft RFA has been changed to 12 pages for the R01 and 10 pages for the R21. Staff also suggested that the scoring cut-off for Funding Committee review be changed from 3 to 2.5 due to the volume of higher scoring applications that have been received. He asked Committee members whether they want to provide consideration for new or young investigators, such as raising the final score by two-tenths of a point. He noted that NIH is considering a change that would provide some type of consideration for newer investigators-tentatively identified as those within 10 years of their terminal degree. Ms. Brautigam noted that another change would take the environment into consideration as part of the relative feasibility of the project.

Dr. Sturman suggested that the Committee was not going to be able to make decisions in the time remaining. He noted that another issue the Committee should consider at its next meeting is whether high scoring applications should be fast tracked without requiring formal Committee approval. Dr. Daines suggested the Committee would be in a better position to assess that issue after it has had an opportunity to review the large number of applications scheduled for the December 18th meeting.

Division of Budget Review

Dr. Daines advised members that before proceeding to the next topic, staff had asked him to remind members and the public that because of the State's fiscal circumstances and the Governor's recent directive, the award recommendations made earlier in the meeting will undergo review by the Division of the Budget and the Office of the Director of State Operations before the awards can be finalized. He noted that nearly all State expenditures are now subject to this additional review.

Discussion of Consortia Funding Options

Dr. Daines then turned the floor over to Dr. Sturman to continue the Committee's discussion of consortia funding options.

Dr. Sturman advised members that he had solicited comments from Committee members on consortia funding options using a document that identified the key issues for the Committee's consideration. A copy of that document was distributed. Dr. Sturman noted that a basic question that needs to be answered is how much the Committee wants to devote to consortia funding and provided examples of variations based upon the number of awards, annual funding and duration. Other considerations include whether the consortia should be disease-based or platform-based and whether they should include training and outreach.

Dr. Sturman reminded members of the two primary models they have been considering. The glue grant model facilitates interactions and is for investigators who have projects that are already funded to build a network of collaborations. It provides strong funding for administrative cores, data sharing, meetings and possibly modest bridging projects. He noted these are fluid and could involve investigators throughout the country or throughout the world, but they do not provide sustained R01-type funding.

On the other hand, the program project model is intended to provide significant amounts of funding to a core group of investigators for projects that would be peer reviewed at the time the application is reviewed. These provide larger amounts of funding for research in a more self-contained way with a smaller number of investigators and institutions. Dr. Sturman noted that some members have questioned whether this is just another vehicle for funding a lot of R01s and wondered what would be gained by the program project model. Dr. Sturman advised members that Dr. Berk had expressed support for both models in different percentages and Dr. Hohn had favored the program project model.

Dr. Dutton expressed a strong preference for the program project model and for the awards to be \$2 million a year. He suggested that amount could support four principal investigators, a post doctoral fellow, a technician and some cores to make a very viable unit.

Dr. Varmus stated that he had hoped that the Committee would learn something about how to award consortia grants from the planning grant awardees, but that without that information, he favored the program project model with some built-in assurance that multiple institutions are involved. He suggested that could be done through requiring

collaborative work and having a scientific review board that brings people together. He also expressed support for requiring the involvement of a minimum of three institutions and awards of about \$2 million per year depending upon whether the Committee would be issuing additional consortia awards. Dr. Varmus also suggested it would be a mistake to make the awards less than three years. He said he would prefer to see them be for four years to make sure the funding nurtures interactions among institutions. Dr. Varmus concurred with Dr. Sturman's assessment that glue grants can work very well when there are strong leaders.

Dr. Dutton expressed a preference for the consortia awards to run for five years. Dr. Fischbach expressed concerns about making the awards five year grants in light of the Board's overall budget. Several members questioned whether \$50 million should be committed to the RFA over the course of five years. Dr. Varmus suggested it would be a mistake to commit more than 25% of the budget for this category. Dr. Sturman noted that would limit the Committee to four consortia awards for a single RFA.

Members then discussed whether it was better to wait to make decisions until after the planning process for the planning grants matured. Dr. Sturman advised members that if the Committee waits to issue an RFA for consortia until after the planning process is complete there will be a funding gap. Dr. Sturman asked members whether they were comfortable with a gap and if so, how much of a gap. Ms. Brautigam advised members that she has been advising planning grant recipients to not look at their planning function as a means to provide a grant application, but as a means to investigate ways to collaborate scientifically with others in the field and to develop and design opportunities that might be appropriate for an R21, an R01, a P01 or some other award from NYSTEM or other programs. Dr. Daines noted that once an RFA was issued, it would drive the planning process in that direction. Mr. Elliott suggested that the Committee may want to issue a consortia RFA with the minimum possible specifications without committing to details to give the Committee a lot of flexibility to learn from the experience of the planning grant year.

Dr. Sturman suggested that it may be appropriate to hold some sort of open session to hear from planning grant awardees. Dr. Varmus agreed that it would be appropriate to get one or two participants from each planning grant group together in a few months after they've been thinking to let them talk about the ideas they have on the table and then be guided by that. Dr. Sturman concluded that staff will attempt to bring the awardees together in a few months to find out their thoughts at that point. He expressed his appreciation for the Committee's thoughts on this issue.

Adjourn

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

Approved: December 18, 2008