

Empire State Stem Cell Board
Funding Committee Meeting Minutes
June 11, 2009

The Empire State Stem Cell Board Funding Committee held a meeting on Thursday, June 11, 2009, in Meeting Room 2, at the Empire State Plaza, Albany, New York. Commissioner Richard F. Daines, M.D., presided as Chairperson.

Funding Committee Members Present:

Dr. Richard F. Daines, Chairperson
Mr. Kenneth Adams
Dr. Richard Dutton
Mr. Robin Elliott
Dr. Gerald Fischbach

Dr. David Hohn
Dr. Hilda Hutcherson
Dr. Michael Stocker
Ms. Madelyn Wils

Ethics Committee Members Present:

Dr. Samuel Gorovitz
Dr. Robert Klitzman
Dr. Vivian Lee

Rev. H. Hugh Maynard-Reid
Dr. Samuel Packer
Mr. Robert Swidler

Ethics Committee Members Attending by Telephone:

Ms. Brooke Ellison

Ms. Nancy Neveloff-Dubler

Department of Health Staff Present:

Mr. Martin Algaze
Dr. David Anders
Ms. Bonnie Brautigam
Dr. Kathy Chou
Mr. Thomas Conway
Ms. Judy Doesschate
Ms. Gail Gardener
Dr. Matthew Kohn
Ms. Jeroo Kotval
Ms. Marti McHugh

Ms. Amy Nickson
Ms. Beth Roxland
Ms. Lakia Rucker
Dr. Stewart Sell
Ms. Phyllis Silver
Dr. Lawrence Sturman
Ms. Linda Tripoli
Ms. Carlene VanPatten
Dr. Ann Willey
Ms. Kathy Zdeb

Special Guest Present:

Dr. John Gearhart

Observers Present:

Ms. Caron Crummey
Mr. Michael Mangeniello
Ms. Caroline Marshall
Mr. David McKeon
Ms. Barbara Meara

Dr. Scott Noggle
Ms. Kelly Ryan
Ms. Susan Solomon
Mr. Steven Taylor

Approval of Minutes for the April 23, 2009, Funding Committee Meeting

Dr. Daines directed Committee members to the draft minutes for the April 23, 2009, meeting of the Funding Committee included in their agenda books under tab 2 and asked for a motion to approve the minutes. Dr. Stocker so moved, and Dr. Dutton seconded the motion. The motion passed unanimously.

Consideration of Requests for Applications to Support Training Opportunities

Dr. Daines then turned the floor over to Dr. Sturman to present two proposed Requests for Applications (RFAs) and two concept papers that would provide funding for training opportunities in stem cell research.

The first RFA Dr. Sturman presented would commit \$7.5 million to make approximately four five-year awards to support stem cell research training opportunities in institutions. Each award would provide up to \$350,000 for annual direct costs and eight percent modified total direct costs for facilities and administration. He noted that institutions could use the funds entirely for pre-doctoral traineeships or entirely for post-doctoral traineeships, or a combination, but that no individual trainee would be able to receive more than five years of support at a pre-doctoral level or three years at the post-doctoral level. Dr. Sturman also noted that the principal investigator serving as the training program director must be employed by the institution, but that the plan for recruiting trainees needed to specify recruitment of trainees from outside the institution as well as inside the institution. Dr. Sturman also noted that institutions would only be able to submit one application in response to the RFA.

Dr. Sturman explained that the second RFA would commit \$2.1 million to support fellowships for individual pre-doctoral or post-doctoral applicants for a period of up to three years. He noted the applicant would be the principal investigator and would be required to make a 100 percent commitment. He noted that the institution would also need to demonstrate a commitment to stem cell related research and have a proven track record in training and mentoring pre-doctoral and post-doctoral fellows in those areas. The RFA would also limit the number of fellows assigned to a particular mentor to a maximum of one pre-doctoral fellow and one post-doctoral fellow.

Mr. Elliott questioned whether the purpose of the RFAs was to cultivate leadership in the field in New York State or to develop praiseworthy training programs. He suggested that the proposed RFAs may not cultivate future leadership in the field in New York State, which he believes is a significant purpose of the law. He suggested that the RFAs should be revised to include provisions that require or encourage individuals to stay in New York State following the training. Dr. Sturman responded, noting that the Committee had approved the issuance of a fellow-to-faculty RFA that would address some of the issues Mr. Elliott raised, and that it would be difficult to include provisions that would realistically increase the likelihood of individuals staying in New York State. He also noted that if the money that has been entrusted to this program is well spent, it will build a robust community and provide opportunities that will make people want to stay in New York State and come back if they've left. He suggested that the sum total of

the NYSTEM program and its emphasis on young investigators should attract leaders in the field and encourage them remain or to come back if they leave. Drs. Dutton and Hohn both agreed that the development of strong programs within New York State institutions will attract promising young scientists and leaders in the field to come to the State of New York and remain. Dr. Hohn also noted that people who leave the State may still bring major benefits back to New York State through contacts and collaborations that they have made and through future discoveries that we will all benefit from.

Committee members also expressed concerns about the delay in the estimated contract start date of October 1, 2010. Dr. Sturman explained that the start date is only an estimate and noted that the extended time frames for the posting of RFAs, the awarding of contracts and the reviews and approvals required for the execution of contracts was something the Board and NYSTEM staff would not be able to resolve. He acknowledged that the time frames were a deterrent to individuals applying for fellowships and that part of the advantage of the training programs is that institutions are able to use them more easily whenever a contract starts. Dr. Hohn also noted that there is an additional challenge in linking the start of fellowships to the start of the academic calendar.

Dr. Dutton then moved to approve the RFA for Empire State Stem Cell Research Fellowships and Dr. Stocker seconded the motion. The motion passed unanimously.

Dr. Hohn then moved to approve the RFA for Empire State Training Program in Stem Cell Research for Pre-doctoral and Postdoctoral Trainees, and Mr. Adams seconded the motion. The motion passed unanimously.

Dr. Sturman then presented two concept papers. The first proposed to create a program that would award Empire State Medical, Dental and Veterinary Stem Cell Research Fellowships to students beyond their second year of training. Dr. Sturman noted that Dr. Fischbach had suggested these at the last meeting and that these fellowships would provide valuable experience to medical, dental and veterinary students and may attract them to the field. He advised members that the structure of the fellowships would be similar to the other fellowships and would provide support for nine months to a year. The proposal would allow institutions to provide training for up to two students over a three-year period. He noted that students could choose a mentor anywhere in the U.S. or Canada, similar to the Howard Hughes program for medical students.

Dr. Sturman explained that the second concept paper proposed to make funding available for sabbaticals or mini-sabbaticals for researchers to work with researchers in the stem cell field, gain experience and potentially move into the field. He noted that an institution could apply for up to six months of total support for up to \$5,000 per month, to be used by one to six individuals at the institution, to go anywhere outside of the immediate geographic area for periods of up to three months. The contract would be a three-year contract to the institution and the applicants would be selected by the institution.

Dr. Dutton commented that these types of awards are extremely effective mechanisms and suggested the Funding Committee should consider increasing the proposed amount of the investment.

In response to questions about academic qualifications of the individuals eligible for the sabbaticals, Ms. Brautigam explained that staff had considered imposing qualifications but decided to provide institutions with as much flexibility as possible to decide the process for identifying participants, their location and what their experience will be.

Following a brief discussion regarding where applicants might be able to go, the Committee agreed that the RFA would be written without geographical limitations as to where individuals could train.

Dr. Daines concluded the discussion noting that the proposals would be turned into RFAs and presented to the Committee at a future meeting.

Consideration of Ethics Committee Recommendations for Gamete Donor Compensation

Dr. Daines then turned the floor over to Ethics Committee member Robert Swidler to present the Ethics Committee recommendations on the compensation of gamete donors to the Funding Committee.

Mr. Swidler started by clarifying that the Ethics Committee's recommendations pertain only to the compensation of women who are donating their eggs solely for research purposes. He advised members that the Committee had been provided extensive information on this topic, including laws, policy guidelines and numerous articles expressing different perspectives and had discussed this issue extensively over the course of the past year. He advised members that the Ethics Committee had agreed in March to recommend that researchers be allowed to pay donors for at least out-of-pocket expenses, and continued to discuss the issue of additional compensation at subsequent meetings.

He stated that after a very thorough and rich discussion in May, the Ethics Committee passed a resolution that would allow researchers to provide compensation to donors for out-of-pocket expenses plus time, inconvenience and burden, consistent with the New York State Department of Health's standards on the compensation of women donating oocytes for reproductive purposes, up to the amounts allowed by the guidelines for the American Society for Reproductive Medicine (ASRM). He noted that ASRM guidelines make it clear that total payments to donors in excess of \$5,000 require justification, and sums above \$10,000 are not appropriate.

Mr. Swidler explained that in discussing the issue, the Committee could not identify any rationale for allowing payments to women who donate oocytes for reproductive purposes, but prohibiting similar payments when women donated oocytes for research purposes. He stated there appeared to be a stronger rationale for allowing the payment for research purposes because the donation benefits the public generally while donations for reproductive purposes only benefits a private individual. Mr. Swidler noted that the Committee discussed the legitimate concerns of exploitation and the risk to women when their eggs are retrieved, but that the Ethics Committee felt that those could be reduced by the informed consent process and the ESCRO review process. He advised

members that the Ethics Committee also considered the fact that there are risks for participation in other kinds of research and that individuals are allowed to participate in that research and be compensated in a manner similar to what the Ethics Committee was recommending for women who choose to donate their oocytes for research purposes.

Mr. Swidler then summarized the discussion of the Ethics Committee earlier in the day pertaining to whether such payments made to women should be an allowable expense under NYSTEM contracts. He noted that a significant argument made against including this as an allowable expense in NYSTEM contracts was that many people would be offended by having their tax dollars used to support these types of payments. He noted that Fr. Berg also suggested that the Board would be complicit in inducing women to do something that is dangerous to them. Members had also considered whether it may be unnecessary to include this as an allowable expense because it was such a small amount that researchers would be able to make these payments using other funding sources.

Mr. Swidler then summarized the factors the Ethics Committee had considered in favor of allowing such payments to be supported with NYSTEM funds. He advised members that most Ethics Committee members felt that since they had concluded that it is ethical for researchers to compensate women in this way, it is ethical for NYSTEM to also support those payments. He noted that the Ethics Committee recognized that human embryonic stem cell research is offensive to some people whether or not payments are made to women and that the Committee felt that it should not base its recommendations solely on the fact some will oppose their decisions. He noted that the Committee felt the objective was a worthwhile objective and reiterated Dr. Hohn's observation that public funds are used to compensate research subjects in other kinds of high-risk research.

Ms. Roxland advised members that as a result of the recommendation made by the Ethics Committee earlier in the day, the resolution in their agenda books would be modified by adding the sentence "Payments made to oocyte donors in accordance with the provision of this section are an allowable expense under this contract" in the first paragraph of the contract language after the phrase "Guidelines of the American Society for Reproductive Medicine."

Mr. Elliott asked whether information was available on how many people have volunteered to donate oocytes and under what circumstances, including the amount of compensation. Dr. Daines responded, noting that exact numbers are not available, but that women have been donating for reproductive purposes at the proposed level of compensation in New York State, and that in the absence of payments at these levels, voluntary donations for research purposes have been almost entirely non-existent. He stated that the Committee has reason to believe that this will make oocytes available for research by drawing a parallel to reproductive uses.

Several members suggested including more facts and justification in the resolution to explain the rationale to the public, but Ms. Roxland and Dr. Daines advised members that a statement had been drafted for the full Board's consideration when both Committees meet jointly.

Mr. Adams moved to approve the Ethics Committee's recommendations for gamete donor compensation and the changes to the language contained in Section E of Appendix A-2. Dr. Dutton seconded the motion. The motion passed unanimously.

Adjourn and Break

Dr. Daines noted the Funding Committee would be taking a break for lunch and that the full Board would reconvene at 12:45 P.M. Dr. Daines then asked for a motion to adjourn the meeting of Funding Committee. Ms. Wils so moved. Dr. Stocker seconded the motion. The motion passed unanimously.

*s/ Judy L. Doesschate, Esq.
Executive Secretary to the
Empire State Stem Cell Board*

Approved: October 26, 2009