

Empire State Stem Cell Board
Funding Committee
Minutes

December 13, 2007
10:00 AM - 12:45 PM

The Empire State Stem Cell Board Funding Committee held a meeting on Thursday, December 13, 2007 at the Department of Health's Offices at 90 Church Street in New York City. Commissioner Richard F. Daines, M.D., presided as Chairperson.

Funding Committee Members Present:

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

Ethics Committee Member(s) Present:

Dr. Robert Klitzman

Department of Health Staff Present:

Dr. David Anders
Ms. Bonnie Brautigam
Mr. Thomas Conway
Ms. Judy Doeschate
Ms. Kathleen Flowers
Mr. Mike Heeran
Ms. Marti McHugh
Ms. Amy Nickson
Dr. Tia Powell
Ms. Lani Rafferty
Ms. Beth Roxland
Dr. Lawrence Sturman
Dr. Ann Willey

Observers Present:

Dr. Michelle Cissell
Mr. Robert Cohen
Ms. Sunita D'Souza
Dr. Kevin Eggan
Mr. Robert Feldman
Ms. Sarah Fielding
Ms. Arlene Grame
Ms. Arana Hankin
Dr. Ihor Lemischka
Mr. Mark Leinung
Ms. Jordan Leslie
Ms. Kelly Ryan
Dr. Christoph Schaniel

Opening Remarks and Introductions

Chairman Daines called the meeting of the Funding Committee to order and welcomed members, staff and the public to the first separate meeting of the Funding Committee. Dr. Daines provided an update on the activities the Department has undertaken as a result of actions taken at the first meeting of the Board, including the issuance of an RFP to help arrange for independent scientific peer review of applications, and the issuance of an RFA designed to increase the capacity of New York State research institutions to conduct in stem cell research and encourage New York State scientists to join the elite group of investigators working in this promising area of research. He noted that the Committee would be continuing to build on those initiatives by approving standards to be applied to researchers using human embryonic stem cells in research to be funded under the initial RFA, considering refinement of intellectual property policies, discussing the Board's strategic planning process, considering the issuance of a revised consortia RFA proposal, and providing direction on potential additional funding initiatives. Dr. Daines then asked Committee members and staff to briefly introduce themselves.

Approval of Minutes of the October 22, 2007 Meeting of the Funding Committee

Following the introductions, Dr. Daines directed Committee members to the draft minutes under tab 1 of the agenda book and asked for a motion to approve the minutes for the regular and executive session meetings of the Funding Committee for October 22, 2007. Dr. Varmus so moved; Dr. Stocker seconded the motion. The motion passed unanimously.

Opportunity for Public Comment

Dr. Daines noted that time was included in the agenda for members of the public to speak before the Funding Committee considered the Ethics Committee's recommendations for standards to be applied to human embryonic stem cell (hESC) research funded under the first RFA. Dr. Daines noted that Dr. Kevin Eggan, Scientific Director of New York Stem Cell Foundation, was the only person who signed up to speak during the public comment period.

Dr. Eggan asked the Committee to support all forms of stem cell research because it is impossible to know which avenues of stem cell research will lead to new discoveries and particular viable treatments. He expressed support for the Ethics Committee's recommendation that existing hESC research be conducted in a manner that is consistent with either the International Society for Stem Cell Research (ISSCR) or the National Academy for Science (NAS) guidelines, but discouraged the Committee from adopting the Ethics Committee's recommended limitation on funding the derivation of new hESC lines. He noted this would result in New York State having one of the most regressive funding policies of all states currently funding stem cell research. He also asked the Committee to be cautious in its use of language as it adopts standards, to keep in mind that the questions that surround the moral status of the embryo at the blastocyst stage are a matter of faith and religion, and to avoid trying to bend others to their views or branding the beliefs of others or the science being conducted as unethical.

Consideration of Ethics Committee Recommendations

Dr. Daines noted that the Ethics Committee had approved two sets of recommendations for consideration by the Funding Committee. The first involved recommendations for standards to be applied to hESC research funded through the initial RFA for institutional development grants. The other involved a recommendation regarding the funding of educational, ethical, and other initiatives.

Dr. Daines first presented the Ethics Committee's recommendations for standards for hESC research to be funded under the initial institutional development grants. He noted that the initial RFA approved by the Funding Committee included a requirement that applicants proposing to use hESCs in funded research must comply with any additional standards for such research approved by the Funding Committee on or before December 31st and that such standards must reflect consideration of recommendations made by the Ethics Committee. He noted the Ethics Committee deliberated on this issue for over two and a half hours at its November 30th meeting, but felt that it could not give the issues involved in hESC research appropriate consideration in the timeframe allotted. Consequently, the Ethics Committee agreed the proposed standards should only apply to the first RFA, which limits funding to pre-existing research. Dr. Daines also noted that the Ethics Committee unanimously agreed to the interim recommendations forwarded to the Funding Committee.

Dr. Daines summarized the four standards the Ethics Committee recommended be applied to hESC research funded through the first RFA as follows: 1. ESCRO committees should adhere to either NAS or ISSCR standards, including those guidelines' recommendations regarding the composition and proper scope of review of ESCRO committees; 2. consent to donate gametes or embryos to research must be obtained prior to donation, but for re-consent, ESCROs should apply the standards set forth in ISSCR 11.2, but may choose to use the stricter guidelines provided in NAS 3.2; 3. ESCROs should review information, where available, regarding the payment of donors who produced gametes originally for reproductive purposes to ensure compliance with ISSCR 11.5(a), but that where no such information is reasonably available, ESCROs need not ensure that payment history complies with either NAS or ISSCR guidelines; and 4. funds from the initial RFA should not be used for the creation of new hESC lines, for research directed towards human somatic cell nuclear transfer or human parthenogenesis, for research involving the introduction of non-human cells into human embryos, or for research involving the introduction of hESC into non-human animals at any stage of embryonic, fetal, or postnatal development.

Dr. Daines asked Dr. Hohn, who is also a member of the Ethics Committee, if he had any additional comments. Dr. Hohn noted he was encouraged by the positive spirit and attitude of cooperation that prevailed at the meeting. He also noted that the Ethics Committee raised the potential for assisting organizations with the formation of ESCROs in the future, possibly through consortia, and that there were discussions regarding the need for a carefully thought out communications plan.

Dr. Daines asked for a motion to adopt the interim standards for hESC research funded under the current institutional development RFA as recommended by the Ethics Committee. Dr. Varmus motioned to accept the first three recommendations of the Ethics Committee. Dr. Stocker seconded the motion. The motion passed unanimously.

Dr. Daines then asked for a motion to accept the fourth recommendation of the Ethics Committee. No such motion was forthcoming. Dr. Daines then asked if there was a motion to not accept the fourth recommendation of the Ethics Committee. Dr. Fischbach so moved, and Dr. Dutton seconded the motion.

Dr. Fischbach clarified that he could not support the restrictions contained in the fourth recommendation because they are likely to be enormously influential and color the thinking of the community of scientists with regard to the goals of the New York State initiative. He suggested that rather than restricting the research in the manner suggested without further deliberation, the presumption should be to follow the recommendations of the National Academy of Sciences and other states and organizations that have debated these issues extensively. He also noted that the limitations contained in the fourth recommendation are overly broad in that they prohibit the introduction of hESCs into all animals, not just into primates, and that the determination of whether a particular cell type is truly a pluripotent stem cell requires the cell to be introduced into mice. He concluded that

these limitations would tie the hands of funded researchers and prevent them from moving in new directions.

Dr. Varmus expressed concern at the prospect of New York State establishing limitations similar to what the federal government has done and suggested that was not the intent of the authorizing legislation. Dr. Varmus also shared Dr. Fischbach's concern that the adoption of the fourth recommendation would delay progress in this area and send an unfortunate signal as to how New York State will support stem cell research.

Some members expressed concern that the recommendations did not contain a time limit, and that it was not clear how long it would take the Ethics Committee to further develop recommendations in this area. Dr. Daines stated that although no specific time frame had been set, members of the Ethics Committee had expressed a desire to move forward expeditiously with their deliberations. Several members of the Funding Committee expressed the view that while they were not inclined to adopt the fourth recommendation of the Ethics Committee at this time, that would not preclude further discussion on the issues raised, nor the Funding Committee's consideration of additional or refined recommendations from the Ethics Committee for future RFAs.

Following the discussion, Dr. Daines asked for the vote on the motion to decline the fourth recommendation of the Ethics Committee. Mr. Adams, Dr. Berk, Dr. Dutton, Mr. Elliot, Dr. Fischbach, Dr. Hohn, Dr. Hutcherson, Dr. Stocker and Dr. Varmus voted in favor of the motion; Dr. Daines voted against. The motion passed 9 to 1, with no abstentions.

Dr. Daines then presented the second recommendation of the Ethics Committee. He noted that the Ethics Committee has made a formal recommendation to the Funding Committee that they work together to develop an RFA to fund educational, ethical, legal and social implications of stem cell research. Specific topics suggested by Ethics Committee members include public education on the stem cell research initiative, curriculum development for undergraduate programs, education of the media, and research on societal attitudes. In response to Dr. Daines' request for input on this recommendation, several committee members expressed strong support for the initiative, especially with regard to funding educational initiatives.

Dr. Hutcherson and Mr. Elliott volunteered to work with members of the Ethics Committee in developing one or more RFAs to bring back to both Committees for their further consideration.

Intellectual Property: Issues and Approaches

Dr. Daines noted that at the first meeting of the Board, members asked to be provided with the intellectual property policies used by other state stem cell research funding programs and other New York State research initiatives. Dr. Daines directed Committee members to tabs 4 and 5 of their agenda binders, which included this information. He then turned the floor over to Dr. Ann Willey, Director of Policy and

Planning for Wadsworth Center, to provide the Committee with an overview on intellectual property issues as they pertain to government funding of research.

Dr. Willey provided a brief overview of what constitutes intellectual property, the various means of protecting such property interests, and the intellectual property issues the Committee might want to consider. Dr. Willey referred members to tab 4 of their agenda binders for the policies compiled from other states, including California, Connecticut, Illinois, Maryland and New Jersey. She noted that the California Institute for Regenerative Medicine (CIRM) has developed the most prescriptive intellectual property policies and adopted those requirements as regulations. These include disclosure by the funded entities of any perfected property interests, tracking of the revenue generated from such discoveries, and payment of specified percentages of revenues in excess of defined threshold to CIRM. The commercial developer of any therapeutics is also required to make such therapies available to uninsured or state insured patients at a predetermined favorable cost. Dr. Willey noted that substantial skepticism has been expressed regarding implementation of these provisions. Dr. Willey noted that Maryland has the least restrictive policy of all state funding programs, leaving all property interest protections and revenue distribution to the discretion of the grantee.

Dr. Willey then directed Committee members to the information provided under tab 5, which included intellectual property policies from the Department of Health (DOH), the State University of New York (SUNY), NYSTAR and NYSERDA, as well as to a hand-out that included recently published revised policies for DOH. DOH and SUNY policies, which apply to the discoveries of agency employees, generally call for disclosure of all discoveries that may involve intellectual property interests and for the sharing of revenues generated between the inventor-employee and the state operated institution. She noted that rather than seeking a direct return on the investment from grantees, NYSTAR measures the economic return of its investment in research by calculating the impact of newly created jobs and product sales or revenues as an overall impact to New York State economy. On the other hand, NYSERDA requires fund recipients who experience substantial cost savings or increased revenue to negotiate repayments to the authority.

Committee members expressed a particular interest in ensuring access to the information and materials generated from research funded by the State. Dr. Willey pointed out that the terms of the current institutional development RFA specifies that all information acquired in the course of research funded through the program should be published and made readily available to the research community. Some Committee members expressed support for extending this access to the general public through a digital library. It was agreed future RFAs would include such a requirement. Dr. Willey also noted that the current RFA requires grantees to provide the State of New York with access to all materials, including cell lines or reagents that might be developed in the course of the funded projects. However, it was agreed that future RFA language would be developed to be more specific as to the expectation for sharing of materials. Dr. Fischbach noted that the development of any intellectual property policies should take into consideration the potential impact on other funding sources and collaborations to ensure policies do not adversely affect such

arrangements. Committee members were asked to contact staff with any additional thoughts they had for revising the intellectual property policies contained in the RFAs.

Strategic Planning Process and Progress

Dr. Daines asked Dr. Sturman to provide an update with regard to his activities and discussions with Board members regarding strategic planning since the October 22nd meeting of the Board.

Dr. Sturman reported that he has met with most members of both Committees of the Board, and expects to meet with the remainder of Board members by the end of the year. He stated there were a number of actions that are an outgrowth of those meetings. First, a coordinating workgroup has been formed to provide guidance and act as a sounding board in the development of the plan. Dr. Stocker is the Chair of that group, and Dr. Varmus has agreed to serve as Vice Chair. There is agreement that all members of the Board should be involved in the development of the strategic plan, and that the product must reflect the special circumstances in New York State, which is different from the circumstances in other states. Dr. Sturman stated that the Ethics Committee and the Funding Committee would be engaged in parallel processes in drafting sections of the report that would identify the topics to be addressed, issues, objectives and obstacles. Dr. Klitzman has agreed to develop the first draft for the Ethics Committee, and Dr. Fischbach has agreed to do likewise for the Funding Committee. Each draft will be commented on by members of the respective committees before being merged into a single report. Dr. Sturman noted that the Department has solicited assistance in compiling and writing the report and expected to be contracting with a qualified person in the near future. After the initial draft is developed, Dr. Sturman will be consulting with the coordinating committee and the rest of the Board with regard to additional outreach before the plan is finalized.

Dr. Daines thanked Dr. Sturman for his report and the individuals who have agreed to serve on the coordinating committee.

Potential Grant Initiatives

Dr. Daines noted that the Committee was ahead of schedule on its agenda. He suggested that the Committee undertake the last major agenda item before going into executive session and breaking for lunch so that members of the public could view the rest of the public session without having to return after lunch. Hearing no objection, Dr. Daines proceeded to the agenda item on potential grant initiatives.

Dr. Daines noted that at its first meeting, the Committee expressed a strong interest in continuing to make use of the available funds through the issuance of additional funding proposals while the Board developed its strategic plan. He turned the floor over to Dr.

Sturman to present several concept papers for funding proposals for the Committee's consideration.

The first was a proposal to provide grants to recognize and support outstanding investigators in New York State, and possibly recruit new outstanding investigators to New York State. The proposal would fund up to three outstanding investigators in an amount up to \$5 million dollars over the course of five years. Several Committee members expressed support for the concept, but some questioned whether the amounts should be reduced to fund more outstanding researchers and whether the proposal should be considered a high priority for funding prior to the issuance of the strategic plan. Several Committee members also favored increasing the indirect cost component of the proposal. Committee members also expressed an interest in understanding how much all of the proposed RFAs would commit prior to the development of the strategic plan, and suggested revisiting this proposal after discussion of the others.

The second proposal would provide grants for shared research facilities. Dr. Sturman provided several examples, including specialized laboratories for isolation, derivation and maintenance of pluripotent stem cells and their derivatives; high-throughput facilities for screening and development of therapeutics; and facilities that meet good manufacturing practices. The proposal would include grants for the repair and renovation of existing laboratory equipment and the purchase of new equipment to be provided over a five year period with direct costs capped at \$5 million. Some members expressed strong support for the proposal and, considering the lead time needed to develop facilities, felt it was appropriate to move forward with this proposal prior to finalization of the strategic plan. Some members expressed support for considering alternatives that would allow for the purchase of additional equipment, without necessarily involving the renovation and development of a separate facility. It was also noted that some consortia may seek funding for shared facilities.

The third proposal Dr. Sturman presented to the Committee would provide support for targeted investigation of various pluripotent stem cells, including induced pluripotent stem cells. The proposal reflected recent developments in stem cell science and the timely need for comparing the methods for obtaining of the various types of pluripotent stem cells and their characteristics. Several members expressed strong support for the proposal as written. A couple Committee members noted the risks indentified for induced pluripotent stem cells and questioned whether the State should be prioritizing this type of research over other types of stem cell research that could be equally promising. Other members indicated that because of the revolutionary nature of the discovery and the need to characterize the reprogrammed cells and compare them to other types of stem cells, New York should move forward expeditiously with funding this type of research. Dr. Fischbach suggested that the grants for this targeted RFA be limited to three years to reevaluate progress in light of evolving developments in the field. Noting general support for this proposal, Dr. Daines advised the Committee that staff would develop this concept into an RFA to be presented to the Committee at its January 7, 2008 meeting.

Dr. Daines asked the Committee for further direction on the other proposals discussed. Members expressed support for developing the shared research facilities proposal further, but favored limiting it to funding of specialized laboratories for stem cell research and high throughput facilities and eliminating support for good manufacturing practices facilities for now. Support was also expressed for modifying the proposal to include shared equipment and other shared resources.

Several members also expressed support for the development of “R01” type awards. Committee members expressed a variety of views on the merits of “R01” investigator driven awards, discovery awards, and outstanding investigator awards. Committee members felt it would be helpful for staff to develop the concepts discussed further and provide information on the brackets of awards and amount of funds committed through the variety of proposals discussed in the meeting to help them prioritize the types of activities and research to be funded. It was agreed that that kind of information would be developed and brought back to the Committee at its next meeting.

Executive Session – Consideration of Consortium Planning Grant

Dr. Daines noted that New York State procurement laws require the details of pending RFAs to be kept confidential, and therefore, the Consortia Planning Grant RFA would need to be discussed in executive session. Dr. Daines asked for a motion to go into executive session to discuss the proposed Consortia Planning RFA. Dr. Fischbach so moved; Dr. Stocker seconded the motion. The motion passed unanimously.

Approved: January 7, 2008