Empire State Stem Cell Board
Funding Committee Meeting Minutes
October 26, 2009

The Empire State Stem Cell Board Funding Committee held a meeting on Monday, October 26, 2009, at the Department of Health offices, 90 Church Street, New York, New York. Dr. David C. Hohn, M.D., presided as Chairperson.

Funding Committee Members Present:

Dr. David Hohn,* Acting Chairperson
Dr. Richard F. Daines**
Mr. Kenneth Adams
Dr. Bradford Berk*
Mr. Robin Elliott
Dr. Gerald Fischbach
Dr. Bruce Holm*
Dr. Hilda Hutcherson
Dr. Allen Spiegel
Dr. Michael Stocker
Ms. Madelyn Wils

*via video-conference ** via teleconference

Funding Committee Members Absent:

Dr. Richard Dutton

Department of Health Staff Present:

Mr. Marty Algaze
Dr. David Anders
Ms. Bonnie Brautigam
Ms. Judy Doesschate
Ms. Susie Han
Ms. Beth Roxland
Ms. Lakia Rucker
Dr. Lawrence Sturman
Ms. Carrie Zoubul

Observers Present:

Mr. David McKeon
Dr. Hongbao Ma
Ms. Caroline Marshall
Ms. Susan Solomon
Ms. Kelly Ryan

Opening Remarks and Introductions

Dr. Hohn called the meeting to order and welcomed Board members, staff and the public. He noted that Dr. Daines had asked him to chair the meeting and that Dr. Daines was participating in the meeting via telephone due to an illness.

Dr. Hohn advised members that Dr. Allen Spiegel had been appointed to the Funding Committee in June and officially welcomed Dr. Spiegel to the Funding Committee. He advised members that Dr. Spiegel is the Dean of the Albert Einstein College of Medicine of Yeshiva University and had previously worked at the National Institutes of Health (NIH) for 33 years, the last six as the Director of the National Institute of Diabetes, Digestive and Kidney Diseases. Dr. Hohn also noted that even before being appointed to the Funding Committee, the Board and NYSTEM program benefitted from Dr. Spiegel's expertise and dedication through his valuable contributions to the Board's Strategic Plan Workgroup and participation in NYSTEM's First Annual Scientific Meeting. Dr. Spiegel thanked Dr. Hohn

for his kind introduction and advised members that he looked forward to working with the distinguished members of the Board on its very important work.

Dr. Hohn also welcomed Dr. Berk back to his first Funding Committee meeting since his accident. Dr. Berk advised members that while he was at Kessler Institute for Rehabilitation, he gained a greater appreciation for the importance of stem cell biology research to people with chronic disease and rehabilitation needs. Dr. Berk stated that people with significant illnesses envision stem cells as the future hope for their recovery. He said he found it very moving to hear how important people with these kinds of diseases and disabilities view the work of the Board and other similar organizations. He advised members that he returned to the Board early to encourage translational programs and clinical trials to help others realize the benefits of stem cells as a potential therapy.

Dr. Hohn then asked members and staff to introduce themselves.

Approval of Minutes for the June 11, 2009, Funding Committee Meeting

Dr. Hohn directed members to the draft minutes for the June 11, 2009, meeting of the Funding Committee included in their agenda books and asked for a motion to approve the minutes. Dr. Stocker so moved and Dr. Holm seconded the motion. The motion passed unanimously.

Program Updates

Dr. Hohn turned the floor over to Dr. Sturman to provide members with the updates that are annexed to these minutes. Dr. Sturman also agreed to provide members with copies of the updates in writing.

Discussion of Funding Allocation for Pending RFAs

Dr. Hohn informed members that NYSTEM staff received 205 applications in response to the Investigator-Initiated Research Projects (IIRP) and Innovative, Developmental or Exploratory Activities (IDEA) in Stem Cell Research Requests for Applications (RFA) and that the $15 million allocated for this RFA would only fund only about 10 percent of the applications received. Dr. Hohn then turned the floor over to Dr. Sturman to provide the Committee with his recommendation for increasing the funding available for this round of applications.

Dr. Sturman suggested that the funds committed to the pending RFA should be increased to enable the Committee to fund up to the best 25 percent of the applications submitted. He advised members that $70 million had been allocated for the 329 applications received in the last round of funding, which resulted in 26 percent of the applicants being funded. Dr. Sturman suggested that the allocation for the current round be increased by an additional $20 million.

Mr. Elliott inquired how much funding would remain if the allocation for the RFA was increased as recommended. Dr. Sturman stated that the funding committed for research thus far was not close to the amount projected in the Board's Strategic Plan and reminded

members that the Committee had agreed to issue this type of RFA on a regular basis. He stated that the alternative would be to re-issue the RFA and have the unfunded applicants start the process over again. Ms. Doesschate clarified that the proposed increase would merely make the additional funding available for this round of awards, but that it would not obligate the Funding Committee to use the entire allocation. She stated it would provide the Funding Committee with added flexibility in case the peer reviews reveal a large number of quality applications that the Committee wants to fund.

Dr. Fischbach inquired whether the Board could bring together a group of investigators to help understand why there were so few applications submitted in response to the RFA targeted to the derivation of new human embryonic stem cell (hESC) lines. Dr. Sturman noted that there had also been a low response to the prior targeted RFA relating to the derivation of induced pluripotent stem cells and agreed that it may be appropriate to establish a work group to understand the barriers to furthering the derivation of new stem cell lines. Dr. Hohn suggested that a work group should also explore strategies for moving funded work towards clinical applications.

Dr. Hohn then asked for a motion to increase the amount of funding to be made available through the IIRP and IDEA RFA issued on July 8, 2009, from $15 million to $35 million and to allow any funds left over from the targeted research RFA issued in June to also be used for awards approved under this IIRP and IDEA RFA. Dr. Stocker so moved and Dr. Berk seconded the motion. The motion passed unanimously.

Results of Consortia Planning Meeting and Discussion of Funding Concept Papers

Dr. Hohn then turned the floor over to Dr. Sturman to provide members with information about the September 8th meeting of the awardees of the Planning Grants for Emerging Opportunities and Consortia Development for Stem Cell Research and to present a concept paper for a potential RFA.

Dr. Sturman advised members that a Request for Information (RFI) was issued to collect information to develop a consortia funding proposal. He advised members that it yielded 18 responses from recipients of various NYSTEM awards.

Dr. Sturman advised members that Dr. Zack Hall, the first President of the California Institute of Regenerative Medicine (CIRM), delivered opening remarks and spoke about his experience that led to the creation of CIRM's "disease teams." He also chaired one of the group sessions and led off the discussion at the end of the meeting. Dr. Sturman advised members that the meeting was divided into five sessions of 40 minutes each and that each of the 18 awardees gave a five minute presentation. He noted that Dr. Hohn, Mr. Elliott, Dr. Klitzman and Dr. Spiegel each moderated a group session.

Dr. Sturman reported that staff followed Dr. Hall's suggestion to develop a taxonomy of the different proposals or ideas that were presented at the September 8th meeting and in the RFI responses. Staff identified two primary groupings for the presentations and ideas; one oriented towards the development of platforms and the other oriented towards translational research or the pathway from basic through therapeutic development to clinical trials. He

advised members that the Committee's prior comments, responses to the RFI and program staff's analysis led to the development of the concept paper distributed to members.

Dr. Sturman explained that the concept paper proposes a two-part RFA, entitled *Accelerating Stem Cell Research through Consortia.* He advised members that the purpose of the proposed RFA would be to support disease-focused translational research, or the development of new platforms and technologies that will accelerate translation of stem cell research for prevention, treatment and diagnosis of diseases. The concept paper proposes two disease team awards of three million dollars each per year for five years, and two platform awards of two million dollars each per year for four years duration. He advised members that the total amount committed for these awards over five years would be $46 million, including indirect costs. He noted that based upon his discussions with Dr. Hall and input from others, the proposal requires a project management component. Dr. Sturman then opened up the floor for discussion.

Mr. Elliott commented that people involved in patient advocacy would welcome this proposal. He noted that past proposals have only required one New York State institution and inquired whether that was still an option. Dr. Sturman acknowledged it could be, but that staff had previously considered requiring a minimum of three institutions, two of which would need to be New York State institutions. Mr. Elliott also suggested that for-profit commercial entities would need to be involved to create strong translational proposals.

Dr. Fischbach suggested that the proposal include something about human subject research to make it clear that the Board is eager to hear proposals that involve human subject research. Dr. Berk expressed support for Dr. Fischbach's suggestion and noted that this RFA would be one of the best opportunities for researchers moving towards human clinical trials to access funding for them. He agreed that the RFA should clearly speak to individuals who are interested in doing clinical trials in patients and should include language referring to patient-focused research and human trials.

In response to comments from members about the association between human clinical trials and for-profit companies, Dr. Sturman noted that under the unique features of the disease teams, the proposal states, "…the participation of co-investigators, with clinical and commercial experience must be included in any aspects of the project that relate to products or services, as appropriate." He also noted that the proposal included an Investigative New Drug (IND) application as an example of a milestone to be included in the submissions. He stated that the intent is for the consortia to yield a product or treatment and that applicants would be expected to partner with clinicians and companies. He also noted that partners do not need to be located in New York State.

Dr. Fischbach suggested the RFA should be very explicit that there could be platforms for patient-oriented research, potentially using Clinical and Translational Science Centers (CTSCs). He also suggested that the platforms be used to invite out-of-state investigators to work in New York State institutions if there is no expertise in New York State for clinical human subject research. Ms. Wils commented that the Board should do everything possible to encourage collaborations with New York State researchers and companies and invest the funding in New York State.

Dr. Berk expressed concerns about the amount of time it takes to enroll patients in clinical trials and inquired if the Committee would have the flexibility to make additional awards if the awarded money is not spent in a timely manner. He noted that the amounts of the awards recommended by staff were higher than those recently approved for the Heart, Lung and Blood Institution consortia. Dr. Sturman responded, saying that the Board has a contractual process that must be followed, but that members may be able to build milestones into the RFA that would need to be met within a stated time frame or the award will be terminated. He also suggested that the Board could issue a two-stage RFA. The first stage could gauge the quantity and quality of responses and then have the Committee decide who can apply for the second round. Several members expressed a preference for this method. Ms. Wils suggested that the Committee might use a Request for Qualifications for the initial evaluation stage.

Dr. Spiegel expressed some concerns and confusion about the Committee's discussions. He confirmed his recollection that none of the presenters at the September 8th meeting of planning grant recipients indicated that they were ready to proceed to human clinical trials. He also advised members that he had heard Dr. Steven Goldman's excellent presentation at the recent New York Stem Cell Foundation meeting on the work he had been doing in preparation for human clinical trials on the Vanishing White Matter disease using glial precursors, but noted that the work he reported on involved a mouse model. Dr. Spiegel also noted that the Geron Phase I trial for spinal cord injury using hESCs raised many questions and that anyone doing human clinical trials with hESCs would need to address major safety issues and provide the federal Food and Drug Administration with stacks of pre-clinical data to get approval to conduct a clinical trial.

Dr. Spiegel said he was reminded of the gene therapy field where people were excited about the progress being made going into human trials and then had a significant setback when some subjects wound up with leukemia. He noted that the focus of the Heart, Lung and Blood Institute consortia referred to earlier is a multi-center clinical trial network. Upon Dr. Spiegel's request, Dr. Sturman clarified that the stated goal of those consortia are to identify and characterize progenitor cell lines, direct the differentiation of stem and progenitor cells to desired cell phase and develop new clinical strategies to address the unique challenges presented by the transplantation of these cells. Dr. Sturman also confirmed that these projects are at a much earlier stage. Dr. Spiegel suggested that the Heart, Lung and Blood Institute leadership have decided to take a step back and stem the tide of arguably useless human clinical trials in which huge amounts of money and patient time have been invested.

Dr. Spiegel suggested that human clinical trials may not be the real focus of the consortia proposal. He noted that the platforms are not clinical trials and that the idea of the disease-focus teams is to advance the state of the art and the science with pre-clinical work to be able to get to an IND. He noted that such work could result in potentially valuable outcomes that would generate industry partners or spin-off companies in New York.

Dr. Spiegel concluded by commenting on the essential common features of the consortia proposal. He expressed a concern that the proposal should fund meaningful working partnerships which justify the term "consortia" and not just agglomerations of excellent investigators. He stated he would like to see the RFA explicitly require applicants to justify each and every component investigator as bringing a critical, absolutely essential,

ingredient driving toward the goal of the consortia; to demonstrate why each of the members of the team receiving funding are essential and supply complimentary, important strengths to the consortia.

Dr. Sturman and Dr. Fischbach agreed with Dr. Spiegel's comments. Dr. Fischbach especially empathized with Dr. Spiegel's frustration about tremendous amounts of money spent for marginal gain or questionable hypotheses. However, Dr. Fischbach also noted that the consortia RFA can push the Committee to see what investigators will do if they're given the challenge to do this type of work. He suggested that if the Committee let investigators know that translational work and clinical trials are among the highest priorities for the program, investigators may bring in needed people from out of state and may figure out ways to rise to the challenge.

Dr. Fischbach then inquired how the program would follow-up to ensure that the consortia function in the way the Committee envisions. Dr. Sturman said that the appropriate interface among the consortia, an external oversight group and NYSTEM's program staff needs to be addressed. Dr. Fischbach asked that this issue be added to the next meeting's agenda and expressed an interest in knowing who will be conducting the oversight, what their relationship will be to the program and the Board and how the oversight and assessments will be conducted.

Dr. Sturman then asked if there were any other questions members would like staff to look into. Dr. Hohn asked if, based upon experiences with other programs, the Committee or an external advisory group could have some flexibility on milestones. He suggested that it would be better to have a mechanism to alter milestones without terminating an award or contract. Dr. Spiegel asked for information on other investigators in New York State who may be poised to do a human clinical trials and what disease(s) would be involved.

Dr. Sturman concluded this portion of the discussion, saying staff would look into these issues and put the issues on the agenda for further discussion at the next meeting. He then advised members he would like Ms. Doesschate to provide the Committee with information about the last Interstate Alliance on Stem Cell Research (IASCR) meeting because of its relevance to the discussion. He advised members that following her presentation he wanted to discuss the issue of collaborations or partnerships in a broader context.

Ms. Doesschate advised members that Ms. Nancy Koch, counsel at CIRM, gave two excellent presentations at the IASCR meeting about CIRM's disease team experience with the Canada Cancer Stem Cell Consortia and recommendations on how to encourage interstate collaborations and establish funding partnerships with for-profit companies, not-for-profit companies and government entities to accelerate stem cell research. She said that Ms. Koch made it clear that it requires an enormous effort to establish these kinds of partnerships.

Ms. Koch recommended that any funding partnerships start with an agreement at the highest levels of an organization to work towards an agreement and then immediately identify any "deal breakers" or absolute barriers to partnering with the entity, as well as natural unique synergies that make the partnership desirable. This requires an assessment of the strengths and weaknesses of the different partners or collaborators; the resources available to each entity and its researchers; barriers to collaboration; recent developments that present unique

opportunities; and consideration of what can be gained from the partnership. Ms. Koch also recommended that scientists from the different jurisdictions or entities be brought together early in the process to figure out if there are ways they can benefit from a partnership or a unique collaboration to ensure there is sufficient benefit to pursuing the collaborations. She noted that Ms. Koch emphasized that it is important to make sure that there is a real interest in a collaboration and that the whole is greater than the sum of its parts; otherwise the effort that goes into establishing these kinds of arrangements will not be worth it.

Ms. Doesschate advised members that in CIRM's model, the funding entities determine the purpose of the RFA and basic parameters leading to the issuance of RFAs on the same dates with the same deadlines and award dates, but that each of the funding entities might have different requirements and award amounts. The intellectual, reporting and other requirements of a funding entity only apply to the researchers funded by that entity and not to the entire collaboration. For example, funding awarded for CIRM awards can only be used in California and they would be subject to CIRM's IP requirements, but "disease team" researchers funded through Canada's not-for-profit partner would not be subject to those requirements.

Ms. Doesschate explained that the decisions about what will be funded remains with the individual awarding authorities within each jurisdiction and the authority of the various boards are not diminished by these partnerships. Consequently, separate independent peer reviews are conducted on behalf of each funding entity. She noted that CIRM's RFAs do not add or subtract extra points for the collaborative aspect of an RFA with another funding partner. However, if an applicant has partnered with a researcher in another jurisdiction who had applied for funding, the research proposal would be evaluated as a single, integrated project. Ms. Doesschate then turned the floor back over to Dr. Sturman.

Dr. Sturman advised members that he wanted to open the concept of some innovative partnerships that the Committee may want to consider. He advised members that he attended a meeting that Robin Elliot had arranged with a number of advocacy foundations and disease foundations, and that Mr. Elliott had provided him with some examples of funding partnerships they have set up. He also advised members that CIRM has reached out to NYSTEM to consider a funding partnership and that staff is considering a number of other possibilities of innovative partnerships. He noted that it is important to consider why we would we want to do this, i.e., what is the advantage or reason for doing these types of partnerships? He suggested that the different varieties of partnerships could offer opportunities to conduct clinical research. He stated that the Committee should be aware of these partnerships and opportunities and may want to look into them further.

Motion to Convene in Executive Session

Dr. Hohn stated that the Committee needed to move into executive session to discuss the evaluations of the applications submitted in response to the two RFAs that were issued in the spring to support Undergraduate Curriculum Development and Summer Undergraduate Experience in Stem Cell Research. He then asked for a motion to move into executive session. Dr. Stocker so moved and Dr. Spiegel seconded the motion. The motion passed unanimously.

Dr. Hohn then asked members of the public and non-essential staff to leave the room and advised them that the Committee would reconvene in public session in approximately thirty minutes.

Executive Session

Dr. Hohn advised the Committee that several members of the Committee would need to be recused for the discussion of various applications, but that Dr. Sturman would be providing members with information about the evaluation process and applications for which there were no conflicts of interest first.

Dr. Sturman and Ms. Brautigam reminded members of the evaluation criteria they approved for inclusion in the two RFAs and provided members with information about the peer review evaluation process. The Committee was then provided with specific information relating to the applications for Development and Implementation of College and University Curricula Concerning Stem Cell Science and Related Ethical, Legal and Societal Implications, while members who were identified as having a potential conflict of interest left the room during consideration of those applications. The Committee then took up discussion of the applications submitted for funding of Summer Undergraduate Experience in Stem Cell Research Awards, while members who were identified as having a potential conflict of interest left the room during discussion of those applications.

Motion to Adjourn Executive Session

Upon completion of the discussion of the applications, Dr. Hohn asked for a motion to adjourn the executive session and reconvene in public session. Dr. Berk so moved and Dr. Holm seconded the motion. The motion passed unanimously.

Recommendations for Approval of Undergraduate Curriculum Development and Summer Undergraduate Experience in Stem Cell Research Awards

Dr. Hohn welcomed the public back and advised the Committee that the next item on the agenda was the recommendation of awards for applicants who responded to the RFAs for funding of Implementation of College and University Curricula Concerning Stem Cell Science and Related Ethical, Legal and Societal Implications and Summer Undergraduate Experience in Stem Cell Research. Dr. Hohn noted that due to the current fiscal crisis and in keeping with Governor Paterson's budget bulletin, no awards will be final until approved by the State Division of the Budget and the Office of the Director of State Operations. Dr. Hohn also noted that the applications were reviewed by a panel of independent experts from outside New York State and that summaries of the 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. Hohn then advised members that they would first act on recommendations for the Implementation of College and University Curricula Concerning Stem Cell Science and Related Ethical, Legal and Societal Implications Awards 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. Hohn then asked Dr. Sturman to read the list of applicants for which no conflicts of interest exist, the amount of the recommended awards and whether staff recommended that the awards be subject to additional contingencies. Dr. Sturman noted that there were no contingencies for any of the applications submitted in response to this RFA and read the recommended awards as follows:

PI	Sponsoring Institution	Application #	Proposal Title	Recommended Funding
Russell, John, PhD	Syracuse University	NO9C-007	Development of an Interdisciplinary Portable Course on Stem Cells	$324,000
Chamany, Katayoun, PhD	Eugene Lang College The New School for Liberal Arts	NO9C-001	The Development, Implementation, and Assessment of an Interdisciplinary Stem Cell Curriculum for Non-Majors	$212,914
Van Buskirk, Robert, PhD	State University of New York - Binghamton	NO9C-009	The Business and Biology of Stem Cells in Cell Therapy	$287,823

Dr. Berk then moved to recommend approval of these awards in the amounts recommended by staff. Dr. Spiegel seconded the motion. The motion passed unanimously.

The Committee then considered the following application while Drs. Fischbach and Hutcherson recused themselves and left the room:

PI	Sponsoring Institution	Application #	Proposal Title	Recommended Funding
Kalderon, Daniel, PhD	Columbia University - Morningside	N09C-002	Implementation of a New Undergraduate Course, "Stem Cells: Biology, Applications and Ethics"	$336,998

Dr. Stocker then moved to recommend approval of the award in the amount recommended by staff. Dr. Berk seconded the motion. The motion passed unanimously. Drs. Hutcherson and Fischbach returned to the room.

The Committee then considered the following application while Dr. Berk recused himself and left the room:

PI	Sponsoring Institution	Application #	Proposal Title	Recommended Funding
Markowitz, Dina PhD	University of Rochester	N09C-005	The Science and Ethics of Stem Cells: A Case Study Based for Undergraduates	$272,448

Dr. Holm then moved to recommend approval of the award in the amount recommended by staff. Dr. Stocker seconded the motion. The motion passed unanimously. Dr. Berk then returned to the room.

Dr. Hohn then advised members that they would be acting on the applications for the Summer Undergraduate Experience in Stem Cell Research Awards RFA for which Committee members had not declared a conflict of interest and then take up the applications for which members of the Committee had identified a conflict of interest, so members could recuse themselves as needed. Dr. Hohn then asked Dr. Sturman to read the list of applicants for which no conflicts of interest exist and the amounts of the recommended awards. Dr. Sturman provided the following information on the recommended awards:

PI	Sponsoring Institution	Application #	Proposal Title	Recommended Funding
Southard, Laurel, MS	Cornell University	NO9I-007	Cornell Undergraduate Stem Cell Science Program	$234,576
Bynum, David PhD	Stony Brook University	NO9I-001	Summer Undergraduate Experience in Stem Cell Research	$229,471

Dr. Berk moved to recommend approval of these awards in the amounts recommended by staff. Mr. Elliott seconded the motion. The motion passed unanimously.

The Committee then considered the following application, while Drs. Fischbach and Hutcherson recused themselves and left the room:

PI	Sponsoring Institution	Application #	Proposal Title	Recommended Funding
Heicklen, Alice PhD	Columbia University	N09I-008	Summer Graduate Research Experience in Stem Cell Science	$243,000

Dr. Spiegel moved to recommend approval of the award in the amount recommended by staff. Dr. Stocker seconded the motion. The motion passed unanimously. Drs. Hutcherson and Fischbach returned to the room.

Drs. Hutcherson and Stocker had other commitments and excused themselves before consideration of the next item.

Report on Activities of the Ethics Committee and Consideration of Recommendations for Revisions to the NYSTEM Contract Standards

Dr. Hohn then turned the floor over to Ms. Roxland to report on the activities of the Ethics Committee and the Ethics Committee's recommendations for amendments to the standards contained in the NYSTEM contracts as a result of the guidelines for hESC research adopted by the National Institutes of Health (NIH).

Ms. Roxland directed members to the proposed amendments to section E of Appendix A-2 of the NYSTEM contract found under tab 4 of their agenda binders and a chart comparing certain provisions contained in the guidelines and standards adopted by NIH, the National Academies of Science, the International Society for Stem Cell Research and the ESSCB found under tab 3. Ms. Roxland informed members that the Ethics Committee had recommended amendments to the NYSTEM contract provisions to conform them to the

recently issued NIH guidelines in certain ways to make it easier for awardees to comply with both NYSTEM and NIH standards to the extent practicable.

Ms. Roxland first advised members that the Ethics Committee had decided to not recommend changes to the NYSTEM contract provisions that would conform them to the NIH guidelines with regard to: 1. only allowing research to be conducted with stem cell lines derived from embryos that are in excess of clinical need; and 2. not requiring review of hESC research by Embryonic Stem Cell Oversight (ESCRO) committees. She also advised them that the NIH guidelines call for the development of a registry of lines that are approved for use in NIH-funded research.

Ms. Roxland then advised members that the Ethics Committee recommended the following amendments be made to Section E of Appendix A-2 of the NYSTEM contract standards:

1. Revise paragraph b to address the NIH requirement for a separation between consent to donate gametes for reproductive purposes and the decision to donate embryos in excess of clinical need to research so it would read: "ESCRO committees should review available documentation to ensure there's a clear separation between prospective donors' decisions, the decision to create human embryos for reproductive purposes and the prospective donors' decision to donate the embryos for research purposes. Providing a general authorization for research donation when providing consent for reproductive treatment does not violate this provision, so long as a specific consent to the research donation is obtained at the time of donation."
2. In paragraph d, insert a requirement that an institution must have policies and procedures in effect that require donors to be advised that the decision to donate or decline to donate will not affect the quality of care.
3. Revise paragraph e to read: "Donors should be informed they retain the right to withdraw consent until the biological materials are actually used in research in compliance with ISSCR guideline 11.2, or until information that links the identity of the donors with the biological material is no longer retained." Ms. Roxland noted the current NYSTEM requirement does not address the fact that donors cannot withdraw consent after the biological materials associated with that donor can no longer be identified.
4. Revise paragraph g to read: "Donors shall be advised that there are alternatives to donating their biological materials to research and shall be provided with an explanation of what the alternatives are, including, but not limited to, all of the options available at the health care facility where the reproductive treatment was sought, embryo adoption, donation for fertility treatment and discarding." Ms. Roxland noted that the NIH guidelines only require providers to advise potential donors of all disposition options at the facility, whereas the Ethics Committee thought that the provision should require disclosure of all disposition options even if they are not available at the particular facility.
5. Revise paragraph m, which now contains the provisions relating to the application of the requirements, to include a new sentence that reads: "In addition, grantees may use cell lines registered on the National Institutes of Health registry, subject to ESCRO

review." She advised members that this would permit the usage of the lines in the NIH registry without review for adherence to other NYSTEM requirements, but still allow ESCRO committees to review the use of such lines at their discretion.

Dr. Hohn asked if there were any questions. Hearing none, he asked for a motion to approve the incorporation of the Ethics Committee's recommendations into Appendix A-2 of the NYSTEM contracts. Mr. Adams so moved and Dr. Berk seconded the motion. The motion passed unanimously.

Adjourn

Dr. Hohn then asked for a motion to adjourn the Funding Committee meeting. Dr. Berk so moved. Mr. Elliott seconded the motion. The motion passed unanimously.

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

Program Updates
EMPIRE STATE STEM CELL BOARD
Funding Committee Meeting
October 26, 2009

Status of Awards:

- **Institutional Development Awards:** Of the $14.5 million awarded to 25 contractors we have received reimbursement vouchers totaling $12 million. The outstanding reimbursement request is related to a delay with an equipment purchase.

  NYSTEM scientific officers have completed 21 on-site visits to learn about the research related to the awards. Their report indicates that the Institutional Development Awards had tangible value and facilitated interactions among the New York investigators. Additionally, it was reported that the supplemental and bridge funding provided through the awards allowed investigators to secure other sources of funding. Our scientific staff anticipates completing the visits by the end of this year and plans to develop a briefing document for the Board that will provide data about the funded research, research findings and resulting publications and patents.

- **Consortia Planning Awards:** Eighteen awards were made, totaling approximately $2 million. The start date of these contracts was November 1, 2008. We received a total of $400,000 in reimbursement vouchers to date.

  Information about the funded consortia planning activities was solicited from the contractors at a meeting held September 8th, as well as from a Request for Information, which was issued in July. This information gathering provided the basis for designing RFA concepts for the Board's consideration. RFA concepts were presented in the meeting.

- **Shared Equipment/Facilities Contracts:** Nine awards were made totaling $32.4 million with a start date of January 1, 2009; $31.9 million was awarded for shared facilities and $480,000 was awarded for shared equipment. Contractors are beginning to submit vouchers for reimbursement.

- **Targeted iPS/Innovative Investigator Initiated Research:** Staff continue to work with awardees on these contracts. Ninety-four of the 98 contracts (totaling $69.7 million) have been executed. Reimbursement vouchers are beginning to come in. NYSTEM scientific staff plan to begin conducting on-site visits and interviews related to both the Shared Facilities and the Targeted Research awards early next year and will report on their activities and funded research to the Board.

Status of RFAs and RFPs:

- **Summer Undergraduate Experience in Stem Cell Science (Internships):** $2.7 million was available, it was anticipated the program could fund 10 awards each for a maximum of $243,000; five applications were received and peer reviewed by AIBS on September 4th. The Committee voted on these during the meeting.

- **Undergraduate Curriculum Development:** $2.5 million was available; six applications were received and peer reviewed by AIBS on September 4th. The Committee voted on these at this meeting.

- **Investigator Initiated Research(IIRP or R01 model)/Innovative Development or Exploratory Activities(IDEA or R21 model)/Targeted Projects in hESC Research:**
  These two RFAs were issued on July 8th; peer review is scheduled for November 2009 and the anticipated start date for these contracts is September 1, 2010.

  We're very pleased with the response to these RFAs. Five applications were received in response to the Targeted RFA and 205 were received in response to the Generic research RFA. Approximately half of these applications were IDEAs (the R21 variety) and half were IIRPs (the R01 variety). More detailed information on funding levels for this RFA for the Committee's consideration was presented at this meeting.

- Two additional RFAs were issued on August 27, 2009; applications for both are due December 1, 2009 and the anticipated start date for both is November 1, 2010. The **Fellow to Faculty** RFA provides up to $5.4 million for five awards to transition promising postdoctoral fellows to independent research careers and the **Shared Facilities** RFA makes $15 million available for three awards.

- **Assessment of the Economic and Other Benefits of the NYSTEM Program:** This RFP was issued in April 2009; proposals were due at the end of June. Unfortunately, only three proposals were received. These proposals reflected a significant discrepancy in cost. Under the guidance of the Department's Fiscal Management Group, we are reviewing the RFP with the intent of revising and reissuing it. In the interim, we are drafting a Request for Information, which will be published shortly.

- **2010 NYSTEM Annual Scientific Meeting:** The RFP for a multi-year contract to plan and arrange NYSTEM's annual scientific meeting has not cleared all of the necessary administrative/fiscal approvals. As a result, it is in the program's best interest to have our staff begin planning for a scientific meeting of our funded investigators. This would be similar to last year's meeting with a few alterations; specifically, it is recommended that the venue be New York City. Due to fiscal constraints, we may want to consider an academic setting versus a hotel. The meeting could be held over one or two days, however there should be sufficient opportunities for networking and interaction. There is a full Board meeting currently scheduled for May 21st, so we are targeting May 19th and 20th for the scientific meeting. The Board's input is welcomed on this.