

**Empire State Stem Cell Board
Full Board Committee Meeting Minutes
May 23, 2011**

The full board of the Empire State Stem Cell Board held a meeting on Monday, May 23, 2011, at the offices of the Department of Health, 90 Church Street, New York, New York. Commissioner Nirav R. Shah, M.D., M.P.H., presided as Chairperson.

Funding Committee Members Present:

Dr. Nirav R. Shah, Chairperson

Dr. Bradford Berk*

Mr. Robin Elliott

Dr. Gerald Fischbach

Dr. David Hohn, Vice Chair**

*via video-conference

**via teleconference

Dr. Mario Loomis

Dr. Allen Spiegel

Dr. Michael Stocker

Ms. Madelyn Wils

Funding Committee Members Absent:

Dr. Hilda Hutcherson

Ethics Committee Members Present:

Dr. Nirav R. Shah

Ms. Jann Armantrout

Fr. Thomas Berg

Ms. Brooke Ellison*

Dr. Samuel Gorovitz

*via video-conference

Dr. David Hohn, Vice Chair**

Dr. Robert Klitzman

Rev. Maynard Hugh-Reid

Dr. Samuel Packer

** via teleconference

Ethics Committee Members Absent:

Ms. Nancy Dubler

Department of Health Staff Present:

Dr. David Anders

Ms. Bonnie Brautigam

Dr. Kathy Chou

Ms. Janet Cohn

Dr. Matthew Kohn

Ms. Valerie Koch

Ms. Diane Mathis

Ms. Beth Roxland

Ms. Lakia Rucker

Dr. Lawrence Sturman

Ms. Carrie Zoubul

Observers Present:

Ms. Jennifer Becht

Dr. Stephen Chang

Mr. Robert Feldman

Ms. Elizabeth Misa

Ms. Caroline Marshall

Mr. David McKeon

Ms. Susan Solomon

Opening Remarks and Introductions

Dr. Shah called the meeting to order and welcomed Board members, staff and the public. He introduced himself and explained that he was formerly an internist at Bellevue Hospital in New York City, a researcher at the Geisinger Center for Health Research in Pennsylvania, and an advocate and a vocal proponent of scientific research to advance health care. Dr. Shah noted that he is well acquainted with the process of seeking funding for important research and that the focus of his work has been on improving the delivery of health care to vulnerable populations. He advised members that as commissioner he plans to maintain and improve the health of all New Yorkers and to help find new treatments and cures by bringing scientific research to the forefront of Department activities. Dr. Shah concluded by asking members to reintroduce themselves.

Approval of Minutes for the December 17, 2010, Full Board Meeting

Dr. Shah directed members to the draft minutes for the December 17, 2010, meeting of the Empire State Stem Cell Board and asked for a motion to approve them.

Dr. Spiegel noted that 1) Dr. Stocker, and not he, had led the first Strategic Plan work group; and 2) that a recent article published in *Nature* raised questions about the commonly held belief, repeated by Dr. Rossi in his presentation at the December meeting, that transplants of patient-specific induced pluripotent stem cell (iPSC) products would be unlikely to be rejected by the patient's immune system. In the article, mice rejected cell products derived from their own cells. Dr. Spiegel emphasized that we can no longer make the assumption that iPS cell products had the key attribute that Dr. Rossi had described.

Ms. Armantrout asked that Dr. Rossi's statement, that "scientists feared that human embryonic stem cell lines grown on mouse feeder layers could never be used clinically because of the possibility of contamination and the risk of animal disease transmittal into patients," be made part of the record for future chimera discussions. Dr. Spiegel responded that methods of growing human embryonic stem cells without those materials have been developed. Cells grown in that way would therefore pose no risk of contamination.

Dr. Fischbach urged that although clinical trials were still far in the future, NYSTEM should continue to encourage work with that goal in mind.

Dr. Shah stated that staff would verify Dr. Rossi's statement and enter the language he used, as well as the other corrections, into the minutes. He then asked for a motion to approve the minutes with the suggested edits. A motion was made and seconded. The motion passed unanimously.

Program Update

Dr. Sturman referred members to the chart showing the status of awards and contracts and highlighted the following points:

1. To date, NYSTEM has issued 12 Requests for Applications (RFAs) and funded 227 awards to 183 investigators at 37 institutions throughout New York State, totaling nearly \$200 million.
2. More than 150 of these awards are in direct support of individual investigators' initiated or targeted research projects.
3. Nearly \$60 million has also been committed to support 16 specialized stem cell facilities, expanding access to key technologies for hundreds of scientists across the state.
4. NYSTEM provided funding through two RFAs to support innovative educational programs, curriculum development and summer internship programs.

Dr. Sturman emphasized that the fruit of these investments is evident in more than 125 publications reporting NYSTEM support, many in the most high impact journals.

5. The contracts under the first two RFAs, for Institutional Development and Planning, have officially ended.
6. Of the \$32.4 million for Shared Equipment or Facilities contracts, \$14.8 has been requested through reimbursement vouchers. Seven continue to run through the end of 2012.
7. Approximately half of the \$69.7 million allocated in 2008 to Investigator-Initiated Research (IIRP) and Targeted iPS contracts has been requested through reimbursement vouchers.
8. \$34.75 million was approved to fund the 2009 round IIRP and IDEA awards. All of the 52 contracts awarded were executed late and work has only begun recently.
9. All three Targeted Human Embryonic Stem Cell Research contracts were executed in September and only a small amount has been requested through vouchers so far.
10. The first progress reports have been received from the three Summer Undergraduate Internship awards and the five Undergraduate Curriculum Development awardees.
11. The three Fellow-to-Faculty contracts were executed late, but are now underway and the three appear to be progressing nicely toward independence.
12. The second round of seven Shared Facility applications were recommended for funding one year ago in the amount of \$27.3 million. The start date has been moved to August 1, 2011.
13. Four Institutional Training applications were recommended to receive \$7.4 million in funding at the September 17, 2010 meeting of the Funding Committee, and award announcements will be issued shortly so that the contracting process can begin.

In summary, to date, through 12 RFAs, we have conferred \$196 million of which \$66 million has been paid out – about a third.

14. NYSTEM staff expects to receive approval to issue three procurements very soon, which include: round three of the Investigator Initiated Research and IDEAS were written for a maximum of \$25 million; the Consortia to Accelerate Therapeutic Applications of Stem Cells with a maximum allocation of \$80 million; and a RFP

for Scientific Oversight Of Consortia which will mandate the selected contractor to engage teams of expert advisors to provide ongoing guidance to NYSTEM on the progress and success of Consortia contracts.

15. Five additional RFAs have been approved by the Funding Committee which includes Short Term Faculty Training Opportunities; Research Training for Medical, Dental, and Veterinary Students; Stem Cell Research Experience for Pre-College Teachers, Stem Cell Science Experience for Journalists and another round of the Institutional Training programs, all of which represent an additional \$16.7 million in funding earmarked for training and education.

Dr. Sturman then turned the floor over to Dr. Anders to provide information regarding the NYSTEM annual conference.

Dr. Anders informed members that the conference was being held May 24-25, 2011, and would feature workshops, plenary and poster sessions, and a keynote address by Elaine Fuchs, the current president of the International Society for Stem Cell Research (ISSCR). He stated that the program would feature an education workshop convened by the Curriculum Development and Summer Undergraduate Internship awardees; a Shared Facilities session in which the new awardees would describe their projects; and a translation panel discussion by regulators, researchers and private industry. Dr. Anders noted that the program included 19 NYSTEM-funded speakers, including Viviane Tabar from Memorial Sloan Kettering Cancer Center, Gordana Vunjak-Novakovic from Columbia University, Shahin Rafii from Weill Cornell Medical College, and Ihor Lemischka from Mt. Sinai School of Medicine.

Update of State and Federal Litigation

Dr. Shah then turned the floor over to Ms. Roxland to describe recent developments in the state and federal stem cell litigation.

Ms. Roxland reminded members that the Board had been sued by Feminists Choosing Life of New York and a number of individually named taxpayers, who alleged that compensating oocyte donors, who provide eggs to be utilized in somatic cell nuclear transfer (SCNT), violated the authorizing statute prohibiting funding of research involving human reproductive cloning. She recounted that in July of 2010 the New York State Supreme Court ruled in favor of the Board on the grounds that 1) Feminist Choosing Life lacked standing to sue but the individuals did as taxpayers; 2) the term 'human reproductive cloning' was ambiguous and that since the legislature had not spoken on the issue, the court would defer to the Board's interpretation as experts in the field; 3) that the funds were not being used to fund human reproductive cloning directly and that the claim of indirect support was too tenuous.

Ms. Roxland then stated that the plaintiffs appealed that decision and three amicus briefs were filed in support of plaintiffs' position, including one by Theresa Deisher, a plaintiff in the federal stem cell litigation. The case was argued before the Appellate Division on April 27, 2011. Ms. Roxland noted that both sides provided articulate arguments to a well prepared five judge panel, but that it had not yet issued its decision.

Dr. Klitzman questioned what recourse would be available to the plaintiffs if the lower court decision were upheld. Ms. Roxland responded that there would likely be another appeal, regardless of the decision, and that the remaining action would be to petition the highest court to hear the case.

Ms. Roxland then provided an update on the *Sherley v. Sebelius* case. She gave a brief history of the litigation to date, reminding board members that after the District Court had dismissed the suit for lack of standing, the Court of Appeals had reinstated as to a limited class of adult stem cell researchers, based on their claim that the change in NIH policy harmed them by subjecting them to increased competition for funding. Ms. Roxland stated that the District Court then issued a preliminary injunction suspending funding of the challenged research.

The Court of Appeals stayed the injunction and heard argument. Ms. Roxland explained that a preliminary injunction was an extraordinary remedy, which required plaintiffs to show that: (1) there was a substantial likelihood of success on the merits; (2) they would suffer an irreparable injury if the injunction was not put in place; (3) the injunction would not substantially injure other parties; and (4) that the injunction was in the public interest. Ms. Roxland stated that the district court found that there was a substantial likelihood that plaintiffs would prevail on the ground that the NIH guidelines violated the Dickey Wicker amendment, and found that the balance of harms favored the adult stem cell researchers.

Ms. Roxland stated that the case then went to the Court of Appeals, which overturned the District Court's decision. She stated that on April 29, 2011, the Court found that 1) there was no likelihood of success on the merits; 2) the language in the Dickey Wicker Amendment was ambiguous and it deferred to the NIH's interpretation as reasonable; and 3) the balance was in favor of those human embryonic stem cell researchers who already had funding and would lose it midstream should the injunction be upheld, outweighing the plaintiffs' claim of harm from increased competition.

Ms. Roxland noted that the case will now be briefed and argued before the district court and that some significant issues remained. Supplemental briefs are due on June 24, 2011.

Interim Report on Educational Initiatives Workgroup

Dr. Shah then turned the floor over to Mr. Robin Elliott, Chair of the Educational Initiative Workgroup, to update the Board on that group's activities.

Mr. Elliott welcomed Commissioner Shah to his new position and then advised members that the two concept papers to be discussed today were intended to advance an original goal of the Board, namely, to educate the public on the benefits and challenges of stem cell research. He stated that the first proposal was to fund science museums to create and implement informal educational programs on stem cell science directed at a variety of target groups. Mr. Elliott noted that the funding, which would total up to \$1.95 million, would be made available at two levels, according to whether and in what amounts the applicant had received funding in the past three years for science educational programs from the National Science Foundation (NSF) and/or the National Institutes of Health (NIH). Those that have received in excess of \$400,000 would be eligible for up to 10% of the total amount received previously, to a maximum of \$250,000. Museums which have not received such funding, or have received an aggregate amount of

\$400,000 or less, would be eligible to receive an award of up to \$40,000. He then turned the floor over to Dr. Gorovitz to present the second proposal.

Dr. Gorovitz informed members that the second concept proposal was to solicit applications for the development of a graphic arts design product describing the history, fundamentals and societal and ethical issues of stem cell research, to be disseminated to high school students and staff, along with a teachers' guide. Following distribution, the awardees would conduct a state-wide contest among high school students to create their own graphic art books about stem cell science. Dr. Gorovitz stated that the contract(s) would be for two years and the total cost would be a maximum of \$200,000, consisting of up to two awards ranging from \$50,000 to \$100,000.

Members suggested that the RFAs be drafted to strongly encourage applications for programs that would be made available through the internet and social media.

Presentation: Translational Stem Cell Research: Bridging the Valley of Death

Dr. Shah introduced Ms. Susan Solomon, Chief Executive Officer and co-founder of the New York State Stem Cell Foundation (NYSCF). He stated that Ms. Solomon is a longtime health care advocate and a founding member of New Yorkers for the Advancement of Medical Research (NYAMR), which she currently chairs. He added that Ms. Solomon serves on the Government Affairs Committee for the International Society for Stem Cell Research (ISSCR); on the New York Council for the Joslin Diabetes Foundation; and served on the first Strategic Planning work group for the Empire State Stem Cell Board. He concluded by saying that in 2008, Ms. Solomon received a New York State Woman of Excellence Award from Governor Paterson and the Triumph Award from the Brooke Ellison Foundation.

Ms. Solomon stated that her talk today would focus on what is referred to as the "Valley of Death," which is what separates us from having medications and cures we need. She then provided a brief overview of adult stem cells, cord blood stem cells and embryonic stem cells, which remain the gold standard for research.

Ms. Solomon mentioned that iPS cells are great mechanisms to model disease and will play a significant role in future drug discovery. She also stated that there are many challenges for iPS cells such as 1) their instability as seen through an increased number of mutations, base changes in the DNA, rearrangements, and chromosome number differences; 2) the lack of standards for derivation; and 3) the length of time required to derive, differentiate and perform necessary quality controls, which hinders their use in acute applications such as spinal cord injuries. She referred to the *Nature* article discussed at the meeting earlier and noted that there was no consensus on these issues at this time and that it is still "early days" for iPSCs.

Ms. Solomon informed members that the researchers at NYSCF work on iPSCs, human embryonic stem cells (hESCs), and somatic cell nuclear transfer (SCNT). She noted that SCNT fell out of favor with the advent of iPSCs but that many researchers may turn back to it now. The issue for SCNT is the difficulty obtaining donors without compensation as evidenced by the experience of Drs. Eggen and Melton from Harvard University. She stated that the Board's

decision to compensate oocyte donations for research was discussed and hailed at the last International Society for Stem Cell Research (ISSCR) meeting.

Ms. Solomon briefly described the problems inherent in each of the three types of stem cell research and noted the difficulty posed to the FDA by the lack of clear standards for iPSC derivation. She emphasized the value and potential of iPSCs for testing new drugs and treatments, potentially saving lives and resources by understanding toxic side effects much earlier in the production process.

She stated that the mission of NYSCF is to 1) foster an environment where researchers can focus on high-risk, high-return translational projects to advance the science through its research laboratory, external grants program, the innovators program for fellows, postdoctoral fellows and early career investigators; 2) educate the public on stem cell science by holding lecture series and a translational research conference and symposia; and 3) host an annual conference to ensure that scientists within their respective fields know the latest research developments. This year's conference will focus on specific diseases.

Ms. Solomon described NYSCF's strategy for bridging the "Valley of Death." She reported that NYSCF has partnered with Lee Rubin at the Harvard Stem Cell Institute to use his large, high through-put drug screening facility; that it is building a large bank of fibroblasts and stem cell lines which will be made available to all researchers; and it is creating stem cell lines that will represent 97% of the population's genetics (it is currently at 87%) and the entire process has been automated, directly addressing the FDA's concerns about research standards; and it is forming research agreements with biotechnology and pharmaceutical companies to help de-risk potential treatments and bring them to the public more quickly.

Dr. Klitzman stated that drug companies should be encouraged to do more research and development at a basic level, rather than to pursue more versions of an already well known and successful treatment, such as statins. Dr. Shah stated that the drug discovery model is broken as evidenced in the last decade within the drug market and praised NYSCF's approach.

Dr. Sturman inquired about the number of institutions/researchers NYSCF interacts with and whether any of its scientists work with adult stem cells. Ms. Solomon responded that NYSCF has collaborations with almost all of the large New York State institutions, Harvard's Stem Cell Institute, and a few international projects. She stated that most of its adult stem cell work is directed at turning them into pluripotent cells, but that some funded researchers in its postdoc program are working with mesenchymal cells.

Fr. Berg asked if NYSCF owned patents on unique lines of human embryonic stem cells. Ms. Solomon responded that they do not. Fr. Berg then asked how many oocyte donors they have successfully recruited in recent years. Ms. Solomon said they do not directly recruit but rather work with local in-vitro fertilization (IVF) clinics which offer women the choice to donate for stem cell research purposes.

Adjourn

Dr. Shah then asked for a motion to adjourn the meeting of the full Board. Dr. Gorovitz so moved. Dr. Klitzman seconded the motion. The motion passed.

*s/
Janet Cohn
Executive Secretary to the
Empire State Stem Cell Board
Approved: November 14, 2011*