

Empire State Stem Cell Board
Full Board Committee Meeting Minutes
May 22, 2012

The Empire State Stem Cell Board held a Full Board meeting on Tuesday, May 22, 2012, 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 Chair.

Ethics Committee Members Present:

Dr. Nirav Shah, Chair

Ms. Jann Armantrout

Ms. Nancy Dubler

Ms. Brooke Ellison*

Dr. David Hohn, Vice Chair

(*participated by videoconference)

Dr. Samuel Gorovitz

Dr. Robert Klitzman

Rev. Hugh Maynard-Reid

Dr. Samuel Packer

Funding Committee Members Present:

Dr. Nirav R. Shah, Chairperson

Mr. Robin Elliott

Dr. Richard Gronostajski

Dr. David Hohn, Vice Chair

Dr. Hilda Hutcherson

Dr. Mario Loomis

Dr. Allen Spiegel

Dr. Michael Stocker

Funding Committee

Members Absent:

Dr. Bradford Berk

Ms. Madelyn Wils

Department of Health Staff Present:

Dr. David Anders

Ms. Janet Cohn

Dr. Kathy Chou

Ms. Susie Han

Ms. Valerie Koch

Dr. Matthew Kohn

Dr. Matthew Kohn

Ms. Beth Roxland

Ms. Lokia Rucker

Dr. Lawrence Sturman

Observers Present:

Mr. Lawrence Connolly

Mr. Robert Feldman

Ms. Julia Gelman

Mr. Ronald Goldman

Ms. Mary Greene

Mr. Ted Lawson

Mr. Scott Lipnick

Mr. Edward Reinfurt

Ms. Kristin Smith

Ms. Phoebe Stone

Welcome and Introductions

Dr. Shah called the meeting to order and welcomed Board members, staff and the public. He advised members that Fr. Berg had resigned from the Ethics Committee, that Dr. Fischbach had resigned from the Funding Committee, and that this meeting would be Dr. Hutcherson's last. He wished them all success in future endeavors and thanked them for their service. Dr. Shah then asked members and staff to introduce themselves and to provide their titles and affiliations.

Approval of Minutes for the November 14, 2011, Full Board Meeting

Dr. Shah directed members to the draft minutes of the November 14, 2011, meeting of the Empire State Stem Cell Board and asked for a motion to approve them. Dr. Spiegel so moved and Dr. Loomis seconded the motion. The motion passed unanimously.

Program Updates

Dr. Shah advised members that staff would now provide program updates. He turned the floor over to Dr. Chou.

Dr. Chou reported that on May 7, 2012, the Columbia Stem Cell Initiative hosted Columbia Stem Cell Day 2012. Noting that Columbia personnel engaged in aspects of stem cell work are based at locations and labs throughout the University, she stated that the Initiative provided a critical, strategic link between the Morningside and Medical School campuses, as well as coordination of efforts from undergraduate teaching to clinical trials. Dr. Chou mentioned that the highlights of the one-day event included plenary talks focused on using iPS technology to model neuro-degenerative diseases; engineering approaches for cartilage and cardiac regenerations; and the latest work by the Columbia Stem Cell Initiative and the Columbia Center for Translational Immunology (CCTI). She reported that NYSTEM support was enthusiastically acknowledged throughout the day.

Next, Dr. Sturman directed members to the current fiscal report in their materials, and noted that to date the Board had issued 12 Request for Applications (RFAs) and had entered contracts for approximately \$196 million. He reported that the program had released four additional RFAs, which consisted of round three of the IIRP and IDEA awards, Short Term Faculty Training Opportunities, Research Training for Medical, Dental and Veterinarians, and Consortia to Accelerate Therapeutic Applications of Stem Cells. The plan was to vote on the first three that afternoon and on Consortia at the September 14, 2012 meeting of the Funding Committee. Dr. Sturman noted that Requests for Proposals (RFPs) for Scientific Oversight of Consortia and for the second Merit Peer Review Services contract had also been issued and that procurements were in progress.

Additional opportunities approved included the Stem Cell Research Experience for Pre-College Teachers RFA, a second RFA for Institutional Training Programs, the Stem Cell Science for Journalists RFA, the Public Education through Museums solicitation, the Stem Cell Graphic Novel RFP and an RFA for the third round of Shared Facilities. He said that there would be discussion later that afternoon of a fourth round of Investigator Initiated Research and IDEA awards. Together, these seven opportunities represented approximately \$63 million in future funding.

Dr. Sturman advised the Board that there are several state-wide initiatives underway that were designed to improve efficiency and transparency for state contractors, such as the new financial tracking system, and the development of a centralized contract management system aimed at streamlining the entire procurement process, which is expected to be implemented next year. He informed members that the Ethics Committee had recommended changes to Appendix A-2, which would be considered by the Funding Committee during the afternoon session. Dr. Sturman then turned the floor over to Dr. Anders to provide information regarding the 2012 annual NYSTEM meeting.

Dr. Anders stated that NYSTEM 2012, beginning the next day, would be a one and one-half day event featuring some of New York's leading stem cell researchers and educators. He informed members that Dr. Mahendra Rao, the keynote speaker, would provide an update on the efforts of the NIH Center for Regenerative Medicine to develop and disseminate standardized protocols and resources critical to advancing regenerative research. Other highlights would include plenary talks from Drs. John Schimenti, Fiona Doetsch, and Lorenz Studer; presentations by Empire State Scholar Fellow to Faculty awardees and 17 other speakers; and over 60 posters. He added that over 200 participants from almost 30 NYSTEM-funded state institutions were expected to participate.

Dr. Sturman then turned the floor over to Dr. Spiegel to discuss the report of the Associated Medical Schools of New York (AMSNY) on NYSTEM and steps taken on the next strategic plan. Dr. Spiegel advised members that AMSNY, an advocacy organization for 13 New York State medical schools, had issued a report on April 18, 2012, which assessed NYSTEM's success to date. He noted that the report focused on economic impact, job creation, leveraging of NYSTEM funding, cost savings, scientific innovation, medical advances, and cross institutional collaborations. With respect to the next ESSCB strategic plan, Dr. Spiegel reported that surveys had been sent to funded institutions and investigators, which included questions on recruitment of investigators from outside the state, creation of facilities, leveraging of funding, invention reports, and patent filing. Dr. Spiegel noted that assessing accomplishments to date was the starting point for strategic planning.

Rev. Maynard-Reid questioned whether potential patents would be owned by NYSTEM since they will be acquired through use of public funds. Dr. Spiegel responded that in general, patent ownership is with the university.

Dr. Sturman confirmed that NYSTEM policy follows Bayh-Dole, and that it is the institution that holds the rights in the patent. He reminded members that they did have discussions earlier on this issue. He also noted that because NYSTEM awards are relatively small, there would rarely be a case where the research leading to a patent was funded solely by NYSTEM money.

Policy and Legal Updates

Ms. Roxland gave a brief update on the *Sherley v. Sibelius* litigation. She reminded members that the status of the case when the Board met last had been that the trial court had rejected the plaintiffs' claims, including that the new guidelines violated the Dickey-Wicker Amendment. The case proceeded to Court of Appeals for the D.C. Circuit, which heard arguments on April 23, 2012, with a decision expected by October 2012. The key issue for decision remained whether the new NIH regulations violated Dickey-Wicker, but there were several additional claims, including whether NIH had violated its own rules by disregarding the many voices raised in opposition during the public comment period.

Discussion on Recent Research on the Incidence of Borderline Tumors Following Ovarian Stimulation

Dr. Shah reminded members that Ms. Armantrout had circulated an article about the effects of ovarian stimulation on the development of borderline tumors, which the Board had considered earlier when assessing the health consequences of oocyte donation, before he and Ms. Armantrout had joined the Board. He said that staff had decided to schedule a brief presentation on the study described in the article, but that previously adopted policies would not be revisited at this time. Dr. Shah turned the floor over to Funding Committee member Dr. Hutcherson, a clinical professor of Obstetrics and Gynecology at Columbia University College of Physicians and Surgeons, and a practicing OB/GYN.

Dr. Hutcherson began by stating that her career commitments would not permit her to continue serving as a member, but that she was honored to have served on the Board. She then advised members that the study, which was conducted between 1983 and 1995 in the Netherlands, followed approximately 25,000 women over the course of fifteen years. The results showed an increased risk of borderline tumors among the in-vitro fertilization (IVF) group in comparison to the non-IVF group, especially in the year following fertility treatment. This timing raised the possibility that tumor cells were already present and that the medications had stimulated the tumors to grow. Dr. Hutcherson stated that there was no significant increase in risk of invasive ovarian cancer after IVF.

Dr. Hutcherson advised members that long-term studies were needed. She explained that borderline tumors are of low malignancy potential, are very slow growing, and that the survival rate is almost 100% after ten years. Increased number of IVF cycles or increased egg retrieval did not increase the incidence of tumors.

Dr. Hutcherson pointed to problems with the study, including missing data due to the poor response to the questionnaire from the women who chose not to receive IVF treatment; the high number of women with pre-existing risk factors for cancer, such as endometriosis and no pregnancies, etc. She concluded by stating that the Board has to determine the validity of this

data and whether it could be applied to healthy women with no fertility issues, especially since there have been significant changes to the fertility drug protocols since 1995, such as greatly reduced doses.

Ms. Armantrout expressed her concern over the lack of adequate mechanisms for monitoring oocyte donors and again requested the creation of a long term state registry, noting that it was an obligation to the women who donate to research.

Dr. Klitzman noted that there were differing results in previous studies and asked whether there was a consensus in the field. Dr. Hutcherson responded that it had gone back and forth over the years, but that when they look at the totality of available literature, most specialists believe that there is no significant increased risk in ovarian cancer in women who undergo ovarian stimulation.

Dr. Spiegel stated that the unique feature of this study was the length of follow-up. He suggested that the informed consent process should include a balanced statement describing the statistical possibility of a very small risk to women who were being treated for infertility.

Dr. Ellison reminded members that they had agreed to keep abreast of relevant literature and potential risks and thanked Dr. Hutcherson for her presentation. But she cautioned members that they need to be wary of looking at data that's available as opposed to data that is relevant. She also disputed Ms. Armantrout's characterization of compensation to donors as an incentive to donate. Ms. Armantrout replied that Harvard and other leading research institutions had found that pure donation of eggs to research occurred infrequently without some form of financial compensation. As such, the compensation is a financial incentive.

Dr. Hohn advised members that to determine the longitudinal risk of ovarian tumors in the very small numbers of women who choose to donate eggs to research would be extremely difficult. To get enough data a national or even international database would be required and the study would have to be conducted over a very long period of time. He stated that although it would be ideal to have such data, it would be unrealistic for the Board to attempt it.

Ms. Armantrout explained that her concern was for the woman who sustains an injury years from now as a result of egg donation and asked what her recourse would be. She questioned how we would even identify or find such people. She questioned a failure to take advantage of the ability to gather good statistics.

Ms. Roxland responded that the consent form acknowledges that all risks are not known at this time but that any direct injury, regardless of time, would be compensable. She also stated that a request had been made earlier by the Board start such a registry, but that it was decided that the numbers would be too small. Ms. Armantrout reiterated her concern for the woman who is injured in the distant future, and the lack of a mechanism for her to get compensated, noting that it was a separate issue from the registry.

Adjourn

Dr. Shah then asked for a motion to adjourn the meeting of the Full Board. Dr. Spiegel so moved and Dr. Stocker seconded the motion. The motion passed.

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