

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

The Ethics Committee of the Empire State Stem Cell Board held a meeting on Tuesday, May 22, 2012, at the offices of the Department of Health, 90 Church Street, New York, New York. Nirav R. Shah, M.D., M.P.H., presided as Chair.

Ethics Committee Members Present:

Ms. Jann Armantrout	Dr. Robert Klitzman
Ms. Nancy Dubler	Rev. Maynard Hugh-Reid
Ms. Brooke Ellison*	Dr. Samuel Packer
Dr. David Hohn, Vice Chair	Dr. Nirav Shah, Chair
Dr. Samuel Gorovitz	

(*participated by videoconference)

Department of Health Staff Present:

Dr. David Anders	Dr. Matthew Kohn
Ms. Janet Cohn	Ms. Beth Roxland
Dr. Kathy Chou	Ms. Lakia Rucker
Ms. Susie Han	Dr. Lawrence Sturman
Ms. Valerie Koch	

Observers Present:

Mr. Lawrence Connolly	Mr. Ted Lawson
Mr. Robert Feldman	Mr. Scott Lipnick
Ms. Julia Gelman	Mr. Edward Reinfurt
Mr. Ronald Goldman	Ms. Kristin Smith
Ms. Mary Greene	Ms. Phoebe Stone

Welcome and Introductions

Dr. Shah called the meeting to order and welcomed board members, staff, and the public. He and board members congratulated Dr. Klitzman on the recent publication of his new book, *Am I My Genes: Confronting Fate and Family Secrets in the Age of Genetic Testing*; Ms. Roxland on the publication of her article entitled “New York State's Landmark Policies on Oversight and Compensation for Egg Donation to Stem Cell Research;” and Dr. Ellison on receiving her doctoral degree.

Dr. Shah also advised members that Fr. Thomas Berg, who consistently worked hard and provided intelligent analysis of the issues before the Ethics Committee, had resigned his position on the Board after five years of dedicated service. He then asked members and staff to introduce themselves.

Approval of Minutes for the September 13, 2011, Ethics Committee Meeting

Dr. Shah directed members to the draft minutes for the September 13, 2011, meeting of the Ethics Committee and asked if there were any comments. Ms. Armantrout asked that the following statement be included at the bottom of page four: “Ms. Armantrout reiterated that the placement of embryos into artificial gestational devices remains unaddressed by this Committee.”

Dr. Shah then asked for a motion to approve the minutes. Dr. Gorovitz so moved and Rev. Maynard-Reid seconded the motion, which passed unanimously.

Committee Discussion and Possible Approval of Revisions to Appendix A-2

Ms. Brautigam stated that staff decided to take another look at Appendix A-2 to see if further refinements, based on recent experience, should be made. She advised members that they were recommending several changes, most of which would serve to consolidate issues, laws and regulations addressed in different parts of the document, sometimes with outdated legislative citations or references. Ms. Brautigam stated that Sections A, B, C, F, and G were consolidated and rearranged in the proposed new version; Section D had been amended to clarify the responsibilities of the contractor; and changes to section E were made to improve clarity. She concluded by stating that staff values the extensive work that the Board has put into Appendix A-2 and took many measures to ensure that its original intentions remained in the document.

Rev. Maynard-Reid, referring to Section A, asked to whom an individual at an organization should refer problems. Ms. Brautigam responded that they should contact NYSTEM as well as a designated institutional contact person.

Ms. Dubler noted that the changes all appeared technical and asked if there were any ethical issues affected. Ms. Roxland stated that the vulnerable population section was removed because it had been based on law that has been overturned.

Ms. Armantrout requested an explanation of the paragraph that said: “the escrow committee should review information where available regarding the payment of donors who provide gametes originally for reproductive purposes to ensure compliance with ISSCR guideline 11.5. Where no such information is reasonably available, the escrow committee need not ensure that payment history complies with NAS or ISSCR.” Ms. Roxland explained that Committee determined that when an egg harvested for reproductive purposes has been left over and payment history is not available, it should still be available for research. She noted, however, where the information is available; it must be reviewed for compliance with the other guidelines.

Dr. Shah then asked for a motion to approve Appendix A-2 as amended. Dr. Packer so moved and Ms. Dubler seconded. The motion passed, with Ms. Armantrout abstaining.

Committee Discussion: NYSTEM Support of Scholarly Research and Topics for Future Ethics Committee Consideration

Dr. Shah reminded members that at the November 2011 board meeting, Ms. Dubler raised the idea of an RFA for scholarly research. He stated that staff was seeking more specific guidance from Ethics Committee members to help develop a concept paper and to identify topics for future meetings. Dr. Shah turned the floor over to Ms. Dubler to lead the discussion.

Ms. Dubler had four specific suggestions: 1) respect and dignity in debating contentious issues, such as the status of the embryo, which tend to be fueled by religious disagreement; 2) justice in the distribution of new drugs and treatments; 3) property law, as it affects unused embryos and related issues; and 4) permissible limits on patent protection to benefit patients in need.

Dr. Klitzman stated that releasing an RFA may result in respondents opting to address small pieces of major issues instead of adopting a comprehensive approach. He suggested that the Committee take up these issues themselves and develop white papers as does the Task Force on Life and the Law. He suggested the possibility of dedicating funds to an additional staff member to lead these efforts.

Dr. Ellison agreed with Dr. Klitzman, noting that conceptualizing these questions from an RFA perspective could be very difficult. She suggested that the Committee address the complex questions which will continue to arise in different contexts itself, such as clinical trials, commenting that it was uniquely equipped to analyze these issues in an open and academic way.

Dr. Shah responded that it was also important for the Committee to focus on areas in which the Board could promulgate standards, and that its purview should be action-oriented, as well as intellectual.

Dr. Packer added to the praise of Ms. Dubler's rubric and stated that trying to find a medium among religious groups is a problem that could be prohibitively difficult. He noted that the Board had examined patent issues and the tension between greater and lesser restrictions, and noted that they had not gone on to link it to the impact on health. He too liked the idea of handling some of these issues in-house, with visits by experts. He also thought doing something about Bayh-Doyle would be worthwhile.

Agreeing with Dr. Packer, Dr. Gorovitz stated that the Committee should address the question of whether the public investment of funds in research should alter policies with respect to access and affordability. But he expressed discomfort with the idea of following the model of the Task Force, which is aided by high level staff and spends two years on a single subject before going public with its views. Additionally, the Task Force can discuss issues in private, which cannot be done by the ESSCB. Without questioning the value of transparency, he noted that the effect is a less efficient and forthright handling of contested issues. For those reasons, Dr. Gorovitz stated that he favored an RFA which is quite limited in scope. Like Dr. Packer, he would like to address the issue of public access to publicly funded development.

Dr. Hohn added his support to the Commissioner's view that their goal should be to generate light rather than heat. He would like to see internal work on a specific project, with assistance from outside experts, but the form of the project would require deep thought and planning.

Dr. Klitzman again stated his preference for a model along the lines of Ms. Roxland's paper rather than an RFA.

Ms. Dubler suggested finding a way to combine the idea of a very targeted RFA with an internally managed product that both explores important moral issues and provides real guidance moving forward.

Adjourn

Dr. Shah asked members to spend some time thinking about these ideas and email suggestions to staff. He'd like to get as many as possible before narrowing the choices.

He then asked for a motion to adjourn the Ethics Committee meeting; it was moved and seconded. The motion passed unanimously.

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