

**Empire State Stem Cell Board**  
**Ethics Committee Meeting Minutes**  
**June 11, 2009**

The Empire State Stem Cell Board Ethics Committee held a meeting on Thursday, June 11, 2009, in Concourse Meeting Room 2, at the Empire State Plaza, Albany, New York. Commissioner Richard F. Daines, M.D., presided as Chairperson.

**Ethics Committee Members Present:**

Dr. Richard F. Daines, Chairperson	Dr. Vivian Lee
Dr. Samuel Gorovitz	Rev. H. Hugh Maynard-Reid
Dr. David Hohn	Dr. Samuel Packer
Dr. Robert Klitzman	Mr. Robert Swidler

**Ethics Committee Members Participating Via Telephone:**

Fr. Thomas Berg  
Ms. Nancy Neveloff Dubler  
Ms. Brooke Ellison

**Funding Committee Members Present:**

Mr. Kenneth Adams  
Dr. Richard Dutton  
Mr. Robin Elliott  
Dr. Hilda Hutcherson  
Dr. Michael Stocker  
Ms. Madelyn Wils

**Funding Committee Members Absent:**

Dr. Bradford Berk  
Dr. Gerald Fischbach  
Dr. Bruce Holm

**Department of Health Staff Present:**

Mr. Martin Algase	Ms. Amy Nickson
Dr. David Anders	Ms. Beth Roxland
Ms. Bonnie Brautigam	Ms. Lakia Rucker
Dr. Kathy Chou	Dr. Sewart Sell
Mr. Thomas Conway	Ms. Phyllis Silver
Ms. Judy Doesschate	Dr. Lawrence Sturman
Ms. Gail Gardener	Ms. Linda Tripoli
Dr. Matthew Kohn	Ms. Carlene VanPatten
Ms. Jerroo Kotval	Dr. Ann Willey
Ms. Marti McHugh	Ms. Kathy Zdeb

**Special Guest Present:**

Dr. John Gearhart

**Observers Present:**

Ms. Caron Crummey  
Mr. Michael Mangeniello  
Ms. Caroline Marshall  
Mr. David McKeon  
Ms. Barbara Meara

Mr. Scott Noggle  
Ms. Kelly Ryan  
Ms. Susan Solomon  
Mr. Steven Taylor

**Opening Remarks and Introductions**

Chairman Daines called the meeting to order and welcomed Board members, staff and the public. He noted that Dr. Berk had been seriously injured in a bicycling accident on May 30th and that he knew that the entire Board joined him in wishing Dr. Berk a complete and speedy recovery.

Dr. Daines reminded members and the public that the first meeting of NYSTEM-funded scientists was being held on Friday, June 12, 2009, at the Desmond Hotel and Conference Center in Albany. He advised members that over 100 stem cell scientists from across the State would be attending the meeting and sharing information regarding the results of their research.

Dr. Daines noted that all members of the Board had been invited to attend the Ethics Committee meeting since the Funding Committee and full Board would be meeting later in the day.

Dr. Daines then asked Committee members and staff to briefly introduce themselves, starting with Fr. Berg, Ms. Dubler and Ms. Ellison who were participating in the meeting via telephone. Dr. Daines noted that under the Open Meetings Law, Fr. Berg, Ms. Dubler and Ms. Ellison would not be able to vote on any pending matters, but that they were otherwise able to fully participate in all Committee and Board discussions.

**Approval of Minutes for the May 12, 2009, Ethics Committee Meeting**

Dr. Daines directed members of the Ethics Committee to the draft minutes for the May 12, 2009, meeting of the Ethics Committee that were included in their agenda books and asked for a motion to approve the minutes. Dr. Klitzman so moved and Rev. Maynard-Reid seconded the motion. The motion passed unanimously.

**Gamete Donor Compensation**

Dr. Daines reminded members that the Ethics Committee had passed a resolution at its May 12, 2009 meeting recommending the Funding Committee adopt revised standards for NYSTEM-funded research that would allow researchers to use stem cell lines, or derive new stem cell lines, for which women donating oocytes solely for research purposes have been, or are being, reimbursed for out-of-pocket expenses and compensated for the time, inconvenience and burden associated with the donation in a manner consistent with the New York State standards applicable to women who donate oocytes for reproductive purposes. He noted that Committee members had asked for

additional time to discuss the issue of whether such payments to oocyte donors would be an allowable expense under NYSTEM contracts. Dr. Daines then turned the floor over to Ms. Roxland to facilitate the discussion on this topic.

Ms. Roxland advised Committee members that if they took no action on the issue, state funds could be used to compensate oocyte donors as an allowable expense under the existing contract language. She then opened the floor to discussion.

Dr. Klitzman questioned the practical impact of not allowing researchers to use state funds to compensate women for their oocyte donations. He noted that he had received a letter from Concerned Women of America (CWA) that stated that six billion human eggs would be needed to pursue stem cell therapy and asked for clarification on the number of oocytes researchers would need to conduct different types of research. Dr. Hohn commented that the CWA letter seemed to assume that all therapeutic applications would use only stem cells derived from oocytes donated solely for research purposes and stated that was extremely unlikely.

Fr. Berg agreed that the Committee should have a better understanding of the number of oocytes that would be needed and advised members that experiments involving the cloning of monkeys have needed about 150 eggs per phase to be successful. Fr. Berg stated that he thought that any statement issued by the Board on this topic should make it clear that researchers would be using the oocytes for somatic cell nuclear transfer (SCNT) and that the Board should use the term “human cloning” or “therapeutic cloning” to describe that use. He also stated that he thought the Board should have a much broader discussion of this issue with the general public and seriously consider the consequences of the action being considered.

Dr. Daines advised members that the Board’s guest speaker for the day, Dr. Gearhart, a well-known stem cell research expert, was willing to respond to some of the Committee’s questions. He then turned the floor over to Dr. Gearhart. Dr. Gearhart confirmed Fr. Berg’s estimates regarding the number of eggs required to successfully clone a mammal, but advised the Committee that since there is no data available for humans is it not clear whether the numbers needed would be higher or lower. He stated that although the number would be quite large, it would clearly not be in the billions.

Dr. Gearhart also clarified that oocytes donated solely for research purposes would not only be used for SCNT, but would also be used to expand upon the work being done in other animals to identify the unique properties in an oocyte that enable it to reprogram a nucleus and enable the cell to develop all cell types. He said the goal is to understand those properties and then use that information to make the same thing happen without using an oocyte. He noted there are thousands of molecules in each oocyte and researchers are using traditional biochemistry and molecular biology methods to determine which molecules are the key players so they can be used directly in a cell or exposed to a cell nucleus to reprogram the cell. He commented that researchers are in a tremendous learning curve and that he views the human oocyte as an invaluable research resource for studying human development. Dr. Gearhart also acknowledged that researchers would need to use SCNT to determine whether the human egg is capable of developing using that process and to assess its similarities to other mammalian eggs.

Dr. Klitzman stated he wanted to show respect for individuals who do not want taxpayer money used to compensate women for oocyte donations, but that he was also concerned that the Committee might block or impede the progress of science if it prevented researchers from using state funds to compensate oocyte donors. He noted this might be particularly true if researchers needed large numbers of oocytes. Dr. Klitzman also clarified that he thought the Committee's purpose is to balance the competing goals of advancing or improving the health and well-being of the public through science and respecting people's rights, which often involves practical considerations. Dr. Packer shared Dr. Klitzman's concerns and suggested that the Committee should consider the impact of its decision on support for the NYSTEM program.

Ms. Dubler pointed out that taxpayer money was already being used for the NYSTEM initiative and that allowing researchers to use those funds to compensate oocyte donors would not present any additional infringement on those who already oppose the State's support of human embryonic stem cell (hESC) research. She stated that given the protections the Board has put in place, she saw no reason to make a distinction between paying women for oocytes and paying for other parts of the research structure. She expressed the concern that the Committee might broadcast that it has some discomfort with its decision to allow oocyte donors to be compensated – a discomfort that she does not have.

Dr. Daines noted that the Committee's tendency to characterize the funds as "taxpayer funds" implied that taxpayers have a particular power over the use of these funds that they don't have over other state expenditures. He observed that it was not clear that there are individuals or groups that support hESC research, but oppose public support for egg donations for research. He stated that he thought it was too fine a distinction to make to withdraw NYSTEM funding for the compensation of oocyte donations that the Committee had otherwise determined was ethically acceptable and needed.

Dr. Gorovitz commented that he thought the Ethics Committee has an obligation to impede or obstruct research if it threatens to violate ethical principles the Committee endorses. He also expressed disagreement with the idea that if there are more dollars at issue, the Committee should be less influenced by the discomfort of people who oppose the State's support of it. He concluded if the Committee wants to respect the sensitivities of people who dissent, it shouldn't be based on how many dollars are at issue.

Mr. Swidler noted that the Committee had had a good and thorough discussion on the issue of the compensation of oocyte donors and that nearly all members were comfortable concluding that it should be allowed within certain limits with Embryonic Stem Cell Research Oversight (ESCRO) committee review. He stated he was not able to identify what additional ethical problem was raised by including such payments as a reimbursable expense under the NYSTEM program other than the argument that it is offensive to some portion of the public. He said that he thought the real dividing point was over embryo-destructive research and that allowing payments to oocyte donors as an allowable expense is an avenue that leads to that type of research. However, he noted that most of the Board supports that research as a way to advance the science and maximize the potential for finding cures.

Mr. Swidler also expressed concern that if the Board excluded reimbursement of these expenses under NYSTEM contracts, researchers may need to engage in the same kinds of bookkeeping practices and oversight as the Bush administration limits required for hESC research. He concluded saying that while it might be tempting to not take a stand on this issue and allow reimbursement of these expenses by default, he thought the Ethics Committee should be transparent about what it is doing and why.

Dr. Gearhart suggested the Ethics Committee not use the term “therapeutic cloning.” He noted this has been debated and discussed in many venues and that he regretted being one of the people who introduced the term many years ago because it is so misunderstood. He suggested the Committee should instead define the procedure. He also advised the Committee that the ability of scientists to derive stem cell lines from embryos has improved so that they can get more than one line out of a single embryo. Finally, he noted that this kind of technology is not only a skill, but an art that requires a great deal of expertise and experience and suggested the Board should consider using state funds to develop core centers that are capable of deriving new stem cell lines.

Fr. Berg expressed concern that the Ethics Committee was moving ahead on this issue so quickly. He disagreed with Mr. Swidler’s suggestion that there is not a significant distinction between a person’s objection to hESC research and the idea of directly compensating women for egg donation for research. He asked members to think about parents who may find out that their daughter received \$5,000 for donating her eggs to help pay for college. He suggested the Ethics Committee was “bracketing” the unknown, foreseeable and unforeseeable health and issues and would be abdicating its ethical responsibility if it took action on the issue at the current meeting.

Ms. Dubler disagreed with Fr. Berg and noted that much of the egg donation process has been determined through the practices employed for the donation of oocytes for in vitro fertilization. She noted that the Committee had seriously considered the language in the standards, the risks to be discussed with donors and the donor protections that would be put in place. She also noted that the Committee has been assured by scientists that experience in this area could be important for the future of stem cell research, and therefore, women who choose to do this will be acting in the interest of the public. She stated that when this is determined to be a necessary part of a peer-reviewed research protocol it should be funded as laboratory tests tubes are funded and that there is no basis for making a distinction in funding it.

Ms. Ellison also disagreed with Fr. Berg and pointed out that the Committee had discussed this issue diligently and comprehensively for over a year. She suggested that the Committee would lose some of its moral status by saying that it supports the compensation of oocyte donors and that it is ethically acceptable, but then refuses to fund it.

Dr. Lee observed that the Committee has considered this issue very thoughtfully and very effectively over the last year, relied on both on internal opinions and external advice, and considered all sides of the issue in a very thoughtful and detailed manner. She also noted that by being explicit in its support of the payments, the Committee could

provide additional protections by limiting the amounts of the payments and by expressly requiring detailed ESCRO and Institution Review Board review.

Dr. Hohn noted that payments for research of this type and this degree of risk are well-precedented in many other areas of medicine. He noted that the Committee looked very carefully at the risks, at questions of informed consent and other issues raised in the CWA article, and that the Committee's determinations are clearly within acceptable bounds as compared to other aspects of medical research. He noted that what makes this different is the fact that it's an embryo donation.

Dr. Klitzman suggested the Committee should include something in the document that would make it clear that researchers are encouraged to assess socio-demographic and other characteristics of donors to ensure that exploitation of vulnerable groups does not occur as a result of the payment. However, Ms. Dubler cautioned against it, noting that some people consider it discrimination when certain people are barred from certain activities and others consider it exploitation. She reminded members that there is a great deal of literature on both sides arguing for protectionism or paternalism on the one hand, and for support of individual choice on the other, and they have been characterized as either preventing exploitation or engaging in discrimination. She concluded saying that she did not think the Committee was the proper forum to review all of that literature. Ms. Ellison concurred noting that it implies that women of lower socio-economic means are less able to make this kind of determination or give informed consent.

Dr. Klitzman then moved to recommend that the Ethics Committee's prior recommendations for changes to section E of appendix A-2 of the NYSTEM contract be amended to include the sentence "Payments made to oocyte donors in accordance with the provisions of this section are an allowable expense under this contract." Dr. Lee seconded the motion. The motion passed unanimously. Although she was unable to vote formally, Ms. Ellison asked the record to reflect her support of the motion. Fr. Berg asked his opposition to be reflected as well, and Dr. Daines noted that Ms. Dubler's support for the motion would also be set forth in the minutes.

### **Adjourn and Break**

Dr. Daines advised members and the public that the Ethics Committee would be taking a break and that the Funding Committee would reconvene at 11:20 A.M. Dr. Daines then asked for a motion to adjourn the meeting of Ethics Committee. Dr. Packer so moved. Dr. Lee seconded the motion. The motion passed unanimously.

*s/ Judy L. Doesschate, Esq.  
Executive Secretary to the  
Empire State Stem Cell Board*

*Approved: September 24, 2009*