

**Empire State Stem Cell Board
Ethics Committee Meeting Minutes
December 17, 2010**

The Ethics Committee of the Empire State Stem Cell Board held a meeting on Friday, December 17, 2010, at the offices of the Department of Health, 90 Church Street, New York, New York. Dr. David Hohn, M.D., presided as Vice Chair.

Ethics Committee Members Present:

Dr. David Hohn
Ms. Jann Armantrout
Fr. Thomas Berg
Ms. Brooke Ellison*
Dr. Samuel Gorovitz
*via videoconference

Dr. Robert Klitzman
Dr. Vivian Lee
Rev. Maynard Hugh-Reid
Dr. Samuel Packer
Mr. Robert Swidler

Ethics Committee Members Absent:

Dr. Richard F. Daines
Ms. Nancy Dubler

Department of Health Staff Present:

Dr. David Anders
Ms. Bonnie Brautigam
Dr. Kathy Chou
Ms. Janet Cohn
Ms. Susie Han

Dr. Matthew Kohn
Ms. Beth Roxland
Ms. Lakia Rucker
Dr. Lawrence Sturman

Observers Present:

Mr. Joe Feldman
Mr. Mike Jolin
Ms. Caroline Marshall
Mr. David McKeon

Ms. Elisabeth Misa
Ms. Kelly Ryan
Ms. Valeria Vavassori

Welcome and Introductions

Dr. Sturman called the meeting to order and welcomed Board members, staff, and the public. He advised members that Dr. Daines would be unable to attend and had asked Dr. Hohn, who had been delayed and was expected to arrive shortly, to chair the meeting. Dr. Sturman stated that he would preside until Dr. Hohn's arrival.

Dr. Sturman advised members that Mr. Robert Swidler would be resigning from the Ethics Committee effective December 18, 2010, in order to serve on the Task Force for Life and the Law. He thanked Mr. Swidler for his service, and noted that his energy and intelligence had contributed substantially to resolving the difficult issues faced by the Board.

Dr. Sturman reintroduced Ms. Janet Cohn, whose previous position was as the Department's Deputy General Counsel. He noted that she would now be taking on the former positions of both Ms. Judy Doesschate and Dr. Ann Wiley.

Dr. Sturman welcomed the newest board member, Ms. Jann Armantrout, and stated that she had been appointed by the Governor to the Ethics Committee upon the nomination of the Assembly Minority Leader. He advised members that Ms. Armantrout is the Diocesan Life Issues Coordinator for the Roman Catholic Dioceses of Rochester and that she received her certification in Catholic Health Care Ethics from the National Catholic Bioethics Center in Philadelphia. He then asked members and staff to introduce themselves and to provide their title and affiliation.

Approval of Minutes for the September 27, 2010 Ethics Committee Meeting

Dr. Sturman directed members to the draft minutes for the September 27, 2010, meeting of the Ethics Committee and asked for a motion to approve the minutes.

Fr. Berg stated that his comment on page 6 was inaccurate and should read, "The only way forward for advocates of human embryonic stem cell research would be the repeal of the Dickey-Wicker amendment" and he also suggested the changing the word "embryo" to "egg" on page 13.

Dr. Sturman then asked for a motion to approve the minutes with Fr. Berg's suggested edits. Dr. Packer so moved and Rev. Maynard-Reid seconded the motion. The motion passed unanimously.

Committee Discussion: Donor Consent Form

Dr. Sturman advised members that the next item on the agenda was a discussion of the model consent form for oocyte donation. He noted that the latest draft had been distributed before the meeting for review by Committee members and turned the floor over to Ms. Beth Roxland.

For the benefit of the new member and the public, Ms. Roxland briefly recounted the events that led to the drafting of model forms. She noted that the Committee had recommended standards pertaining to informed consent, which had been incorporated into NYSTEM contracts, and had agreed to prepare a model consent form to guide NYSTEM contractors.

A discussion followed in which members raised various concerns which Ms. Roxland agreed to address, including whether the results of genetic testing would in all cases be reported to the donor and whether specific consent need be separately obtained for that. Ms. Ellison suggested the language be clearer on the issue that donors were providing eggs, not embryos. She further noted that the language describing somatic cell nuclear transfer (SCNT) was not strictly correct and Ms. Roxland agreed to vet it with the NYSTEM scientists.

At that point Dr. Hohn arrived and assumed the duty of chairing the meeting.

Ms. Armantrout raised several concerns about the consent provisions, noting the need to remove any possibility of undue influence. She was concerned about the use of the passive voice as well as contingent type sentences. She noted the opening sentence under Informed Choice, which read “providing eggs for this research project *should be* completely voluntary...” (emphasis added) and pointed out that it should read “*is* completely voluntary.” Ms. Armantrout said that she had identified numerous such wording problems and that she would provide them separately to Ms. Roxland. Ms. Armantrout also expressed concern about the length of the document and its effect on voluntariness of consent. Dr. Klitzman recommended that introducing the form with an overview of its contents might assist the donor in understanding its provisions. Dr. Gorovitz commended the addition of a table of contents for the same purpose.

Ms. Roxland noted that members had questioned whether the use of the word “donation” was appropriate, given that there would be some payment made to the woman, though she reminded them that there was no payment for eggs *per se*, but for the time and burden of the process.

Fr. Berg questioned the intellectual honesty of the term “donation” when there was an exchange of a substantial amount of money, and suggested using another term such as exchange, bestowal, or transference. Dr. Gorovitz stated that a more neutral term could be used so long as it did not suggest a sale. Dr. Packer cautioned against removing the charitable connotation, which might well be a large part of the woman’s motivation to donate, even if she was receiving a payment. Dr. Klitzman suggested the word “provision.” Rev. Maynard-Reid suggested “contributor,” which another member noted had all the challenges of the term “donor.”

Ms. Armantrout favored “provision” because she did not believe that a purpose of the form was to give value to a woman’s decision to “provide” her eggs, and that she objected to what she saw as an effort to validate that choice throughout the form. She noted that there are a myriad of reasons that could motivate a person to take this step.

Ms. Roxland noted that the word “donor” is used for women who give their eggs for *in vitro* fertilization (IVF) purposes and Fr. Berg noted that he would object equally to the usage in that setting. Dr. Packer urged that the form be kept simple and use terms that are already recognized. He cautioned against elevating the language of the form above the important conversation that must take place among the participants.

Fr. Berg suggested as a matter of accuracy that the word “human” be inserted into the second paragraph so that it read, “*human* embryonic stem cells can be found in *human* embryos.” Dr. Hohn suggested using the word “human” once, to modify “embryos,” so that the line would read, “embryonic stem cells can be found in human embryos.” Several members voiced support for Dr. Hohn’s suggestion.

Ms. Roxland advised members that the next comment concerned the line, “beyond 14 days. . . ,” which referred to the primitive streak. Dr. Klitzman expressed that he was in favor of leaving the wording as it stood but to add some background information in the beginning of the document.

Ms. Armantrout expressed concern that in several places, for example, the second paragraph on page seven (“[f]or this reason, embryonic stem cells can be used to study and possibly one day treat...”), sounded like a sales pitch to induce consent. Fr. Berg agreed and added that in the phrase, “the eggs donated to this project will advance the important research goals discussed above...,” “will” should be replaced with “could.”

Dr. Klitzman stated that it was both legitimate and necessary to include the goals of the research in the informed consent form. Mr. Swidler agreed and stated that the goals mentioned in the form are part of the risk-benefit analysis and therefore an essential component. He agreed, however, that in the sentence Fr. Berg had identified, the word “could” would be more accurate than “will.”

Dr. Hohn advised members that, because of time constraints, the Committee would continue its discussion of informed consent and postpone to a subsequent meeting the discussion of the proposed chimera research statement.

Dr. Packer raised the issue of the interplay between the consent needed to donate oocytes and the consent needed for genetic testing, and whether the contractor could obtain consent for genetic testing and/or provide results. Ms. Roxland noted that the requirements for consent for genetic testing were laid out in the Civil Rights Law and were quite exacting and difficult to understand. Dr. Sturman advised members that the topic would need to be deferred until he could consult with Dr. Jeanne Linden, Director of the Blood and Tissue Resources Program, and Dr. Michele Caggana, Director of the Human Genetics Division.

Ms. Roxland advised members that the next issue was the withdrawal of a potential donor’s consent to use her eggs for research. She stated that the form provides that the potential donor has the right to withdraw consent until the egg has been used in research or upon the creation of an embryo.

Fr. Berg presented a scenario in which an embryo was created with donor sperm and frozen, with no further steps taken. He questioned whether the egg donor would be able to withdraw consent at that point.

Dr. Packer stated that ideally a donor would be allowed to withdraw consent at any stage, but that on the scientific methods employed it may not be possible. Mr. Swidler stated that human subject research has recognized the option to drop out at any stage as a basic human right. He noted that generally, however, once the donor gives informed consent and signs the papers, the decision has been made. Mr. Swidler stated that the Committee could recognize the rights of a donor by advising her that informed consent could be withdrawn so long as the donation is still an egg; once it is an embryo it is no longer what she donated.

Ms. Roxland described the 1998 decision in the New York State matrimonial case of *Cass vs. Cass*. The couple had earlier preserved frozen embryos and had agreed that any remaining would be donated for research. The wife now wanted to use the embryos to conceive a child, while the husband sought enforcement of the original agreement. The court, relying on basic contract law, held for the husband.

Most members expressed the view that the proposed language clearly offered the opportunity for the donor to withdraw her consent up to the time that the research began.

Adjourn

Dr. Hohn then asked for a motion to adjourn the Ethics Committee meeting. Dr. Packer so moved and Dr. Klitzman seconded the motion, which passed unanimously.

*s/ Janet Cohn
Executive Secretary to the
Empire State Stem Cell Board
Approved: May 23, 2011*