

**Empire State Stem Cell Board
Ethics Committee Meeting Minutes
September 13, 2011**

The Ethics Committee of the Empire State Stem Cell Board held a meeting on Tuesday, September 13, 2011, at the offices of the Department of Health, 90 Church Street, New York, New York. David C. Hohn, M.D., presided as Chairperson.

Ethics Committee Members Present:

Ms. Jann Armantrout
Ms. Nancy Dubler
Ms. Brooke Ellison*
Dr. David Hohn, Vice Chair
(*participated by videoconference)

Dr. Samuel Gorovitz
Dr. Robert Klitzman
Rev. Maynard Hugh-Reid
Dr. Samuel Packer

Ethics Committee Members Absent:

Fr. Thomas Berg

Department of Health Staff Present:

Dr. David Anders
Ms. Janet Cohn
Ms. Susie Han
Ms. Valerie Koch

Ms. Beth Roxland
Ms. Lakia Rucker
Ms. Angela Star
Dr. Lawrence Sturman

Observers Present:

Ms. Katayoun Chamany
Ms. Caron Crummney
Ms. Ruth Fischbach
Mr. Daniel Kalderon

Mr. John D. Loike
Mr. Michael Pettinger
Ms. Julia Wargaski

Welcome and Introductions

Dr. Hohn called the meeting to order and welcomed board members, staff, and the public. He advised members that Dr. Shah would be unable to attend and had requested that Dr. Hohn chair the meeting in his place.

Dr. Hohn stated that vacancies on the Ethics Committee were causing quorum challenges. He noted that one committee member would be leaving early that afternoon and recommended re-ordering the agenda to achieve maximum participation.

Dr. Hohn reported that the agenda would include the continued discussion on model consent forms; the chimera research statement; a working lunch featuring a presentation by recipients of the Curriculum Development for Undergraduates awards; program updates; a report on federal and state litigation, and a discussion of possible future agendas.

Dr. Hohn requested a motion to amend the agenda as proposed. Dr. Klitzman so moved and Rev. Maynard-Reid seconded the motion. The motion passed unanimously.

Approval of Minutes for the May 23, 2011, Ethics Committee Meeting

Dr. Hohn directed members to the draft minutes for the May 23, 2011, meeting of the Ethics Committee. Members expressed concern that some comments did not appear in the minutes or were recorded inaccurately. Ms. Cohn advised members that staff endeavored to reflect the discussions correctly but that she would review their comments and make any needed changes.

Rev. Maynard-Reid asked whether Dr. Shah had researched the possible alternatives as to where in the donation process a donor could no longer withdraw their consent. Dr. Hohn suggested that the issue be deferred so that staff could look back through the minutes and reconcile them at a future meeting. He then asked for a motion to approve the minutes. Dr. Gorovitz so moved and Dr. Klitzman seconded the motion. The motion passed unanimously.

Committee Discussion: Model Informed Consent Forms

Ms. Roxland advised members of the public that the Committee had been working on its model informed consent forms since 2008, which were initially based on the International Society for Stem Cell Research's (ISSCR) model forms. She noted that the forms have been revised to conform to the needs and requirements of the NYSTEM program and to reflect ethical concerns of the Empire State Stem Cell Board members. Ms. Roxland then opened up the floor for discussion.

Ms. Dubler expressed her support of the current version of the forms and suggested that a one page summary precede each form to direct potential donors to critical sections. She mentioned that the purpose of the forms, and informed consent forms generally, is to protect human research subjects, as specified in 45 CFR 46. She later proposed that summaries be drafted at a later time, and that discussion of the summaries not preclude a vote going forward. Dr. Gorovitz suggested that the forms could be formatted to include reader-friendly font and graphics.

Ms. Ellison stated that in the Physical Risks section, the form cites ovarian hyper-stimulation syndrome (OHSS) as the most common risk of hormonal stimulation and asserted that that was not accurate. She noted that the most common physical risks were bloating, discomfort and other side effects similar to premenstrual syndrome. Ms. Ellison suggested an edit to reflect that OHSS is one of the more notable risks, but it is not the most common. She further suggested that the word "embryo," as used on occasion in the oocyte donation form, might not be accurate as it related to somatic cell nuclear transfer processes.

Ms. Armantrout voiced concern that: (1) the forms did not adequately explain the protocol that potential donors would use for future research-related injuries; (2) that program funds be allocated to track donors; and (3) that institutional contact information should be added so that participants would know whom to contact in the event of a future injury. To the first point, Ms. Roxland replied that all NYSTEM contracts mandated that any costs associated with a potential injury would be covered by the institution. Ms. Roxland also stated that the section describing potential risks and injuries had been substantially edited from earlier drafts to reflect Ms. Armantrout's concerns. To Ms. Armantrout's second point, Ms. Roxland explained that the Committee had discussed that option before Ms. Armantrout's membership and they could speak

about it separately.

Members also discussed a number of outstanding issues in the revised model forms, including language regarding financial and non-financial conflicts of interest, information on whom to contact in the event of any psychological effects of participation, and clarification of the phrase “when the research has begun” as it pertains to when a donor may still withdraw her consent. Dr. Sturman advised the Committee that staff researched the question and found that the prevailing standard, formalized by the ISSCR, permits donors to withdraw consent up until the materials are actually used in research. Ms. Armantrout suggested that the right to withdraw consent should end as soon as eggs were retrieved. Ms. Roxland noted that such a policy would conflict with the recommendations and policies of the National Academies of Science (NAS) and those of other states, in addition to the ISSCR’s.

The Committee also decided not to require a witness signature, as this could have privacy implications.

Dr. Hohn then asked for a motion to approve the Empire State Stem Cell Board (ESSCB) Model Research Informed Consent Form for Egg Donation for Human Embryonic Stem Cell Research (eggs provided directly and solely for stem cell research). Dr. Klitzman so moved, Dr. Gorovitz seconded the motion. The motion passed seven to one, with Ms. Armantrout opposing.

Ms. Roxland then directed members to the informed consent form for somatic cell donation for human embryonic stem cell research. She noted that the form was drafted solely for the purpose of human embryonic stem cell research and not iPS.

Ms. Armantrout inquired what the discussion box on page six regarding reimbursement referred to. Ms. Roxland explained that the language mirrored the ISSCR’s forms, which state that reimbursement related to the informed consent process is feasible but not for the donation process. Several members stated that without some form of reimbursement, there would not be many donors. Nonetheless, the Committee chose to move forward without addressing reimbursement at this time.

Ms. Armantrout then stated that she felt the Committee’s decision to comply in its contracts with section 11.3a(viii) of the ISSCR guidelines, which states that donors will not receive financial benefits from any future commercial development, was a travesty and a social injustice. Ms. Roxland noted that the Board conducted a robust discussion of issues surrounding future commercial potential of stem cells collected from resulting embryos before Ms. Armantrout joined the Board.

Dr. Hohn asked for a motion to approve the ESSCB Model Research Informed Consent Form for Somatic Cell Donation for Human Embryonic Stem Cell Research. Ms. Dubler so moved, Dr. Gorovitz seconded the motion. The motion passed by a vote of seven to one. Ms. Armantrout opposed.

Ms. Roxland directed members to the sperm donation consent form and stated that the only additional revisions to this form were to the privacy language, the definition of

androgenesis, and the conflict of interest language, all of which were similarly revised in the other model forms. She advised that the only outstanding issue related to compensation of sperm donation and that the ISSCR leaves the decision to the Embryonic Stem Cell Research Oversight Committees (ESCROs). At the Board's request, Ms. Roxland then addressed the form for donating eggs collected in the course of fertility treatment in excess of clinical need, during which time Ms. Armantrout and Dr. Packer were out of the meeting room. She advised members that the form is similar to those previously discussed except that it only contains the psychological risks associated with donations for research of eggs in excess of those used for fertility and does not address risks associated with the fertility treatment itself, which would be previously addressed by the donor's fertility provider.

Upon Ms. Armantrout's return, Ms. Roxland discussed the consent form for embryos created for fertility purposes and in excess of clinical need. Ms. Roxland stated that the form began with a warning to donors that only those risks associated with donating to research would be discussed as risks associated with the fertility treatment should have been addressed by the donor's physician. She advised that all of the applicable changes discussed previously had also been made to this form and noted that compensation for embryos is prohibited. Ms. Roxland then opened up the floor for discussion of the three forms.

Several members suggested voting on all of the remaining model forms at one time. Dr. Hohn then asked for a motion to approve the Model Consent Forms for Sperm Donation for Human Embryonic Stem Cell Research, Eggs Created for Fertility Purposes and in Excess of Clinical Need, and Embryos Created for Fertility Purposes and in Excess of Clinical Need. Dr. Klitzman so moved, Dr. Packer seconded. The motion passed, with Ms. Armantrout opposing.

Committee Discussion: Standards for Research Involving Chimeras

Ms. Roxland reminded committee members that they had had several discussions on chimera research developments, and had heard from Drs. John Gearhart and Willie Lensch, and had decided to allow NYSTEM researchers to follow either the standards of the ISSCR and/ or the NAS. She explained that staff had drafted a brief statement to capture the Committee's discussions and analysis and that the goal was to post the statement on the NYSTEM website if the Funding Committee approved it.

Ms. Armantrout inquired whether there was a way to convey the minority opinion to the Funding Committee for its deliberations. Ms. Roxland informed Ms. Armantrout that she could attend the next Funding Committee and express her opinion there or draft a statement for distribution to Funding Committee members beforehand. Ms. Armantrout then expressed concerns that the risks of disease transmission and of placing embryos in artificial gestational devices had not been adequately addressed. Ms. Roxland responded: (1) that the purpose of the chimeric research statement was to alert reviewing institutional review boards (IRBs) and ESCROs to these issues; and (2) that placing chimeric embryos into human and non-human primate uteruses is strictly prohibited by both the NAS and ISSCR.

Ms. Dubler stated for the record that she would not be present during the afternoon session and suggested that the committee consider an RFA for scholarly work on under-addressed ethical, legal, societal and educational issues.

Dr. Hohn then asked for a motion to move the statement on chimera research to the Funding Committee for posting on the NYSTEM website. Rev. Maynard-Reid so moved, Dr. Gorovitz seconded and Ms. Armantrout opposed. The motion passed.

Presentation: NYSTEM Funded Educational Initiatives for Undergraduates

Dr. Hohn informed members that Drs. Daniel Kalderon, John Loike and Ruth Fischbach from Columbia University and Katayoun Chamany, Michael Pettinger and Ms. Julia Wargaski from The New School were there to discuss their Curriculum Development award projects. He turned the floor over to Dr. Chamany.

Dr. Chamany stated that the New School project, “Stem Cells across the Curriculum,” was designed so that it could be taken by any undergraduate, whether a science student or not. In the class entitled “Stem Cells and Social Justice,” students were taught to question normative assumptions that often accompany biomedical research while exploring the biology of stem cells. She noted that among the topics covered by the course are the ethics of embryo research, oocyte payment and procurement, clinical trials and regulation, disability discrimination, commercialization and patenting of stem cell reagent tools and products, bio-banking and stem cell registries. She reported that the learning environment combined traditional learning, such as labs and exams, with student-centered approaches, such as case studies and independent projects.

Dr. Chamany reported that because statistics indicate that students learn and retain best when personally involved, case studies are the principal teaching mechanism in the curriculum. Dr. Chamany then guided members through the case study process over the course of the semester, which proceeds from basic biology to analytical thinking. Topics covered include the story of HeLa cells, the development of pure science research to therapeutic applications, and the use of public funds to support controversial research. She concluded by demonstrating infographics developed for the curriculum with Ms. Wargaski that map four “timelines” of stem cells consisting of ethics, policy, technology and science.

Rev. Maynard-Reid inquired about the comprehensiveness of the religious and philosophical issues presented to the students. Dr. Pettinger responded that the effort was to balance religion and ethics into the coursework, and to help students to examine preconceived notions on these issues.

Dr. Kalderon advised members that Columbia’s project was composed of two parts, a standard course that covered the biology, ethics and applications of stem cells; and an online course which Dr. Fischbach would discuss later. He then reported that their course: 1) was designed to be a high level biology course for students seeking to become researchers, medical students or PhDs; 2) examined biology, ethics and regulatory issues; and 3) included hands-on learning in place of passive lectures. Dr. Kalderon stated that the biology portion of the course had two components, pluripotent stem cells and adult stem cells (specifically hematopoietic stem cells) and that the course also covered legal, ethical and regulatory aspects. The class made a site visit to Dr. Scott Noggle’s lab at the New York Stem Cell Foundation and attended two public seminars, one by Dr. Christopher Henderson on translating stem cell research into therapies, and the second by Dr. Judith Shizuru on the future of blood stem cell transplantations

and the ethics raised by related research. Dr. Kalderon stated that the course was undersubscribed and that next semester they would try to attract more liberal arts students and add topics such as animal research ethics, research regulation, and reproductive cloning ethics.

Dr. Ruth Fischbach explained that the online distance learning course was originally intended to support students enrolled in the classroom course, but turned out to be much more comprehensive. She stated that the course takes a multidisciplinary approach which includes modules on the biology and history of stem cells, an introduction to stem cell bioethics, cellular differentiation and epigenetics, somatic cell nuclear transfer, induced pluripotent cells, human hematopoietic systems, human-animal chimeras, and applications of stem cell science. Dr. Fischbach reported that the course provides a large list of supplemental readings, along with enhancements such as a text-linked glossary feature, case studies, biographies, challenge questions, videos, self-evaluation questions and additional resources. She concluded that the intent is to make the course available to a wider audience and not just to Columbia undergraduates.

Dr. Loike added that to avoid the static nature of some online courses, Columbia had partnered with Microsoft to offer interactive chat rooms focused on specific modules, teacher-student live dialogue, and video clips.

Program Updates

Dr. Sturman advised members that approximately \$50 million had been awarded in 2008, which funded 78 Innovative, Developmental or Exploratory Activities (IDEA) contracts, of which \$32 million has been requested through reimbursement vouchers. He stated that the second competition for IDEA contracts was held in 2009, for approximately \$35 million. Because of delays, the 50 resulting contracts were not executed until April 2011, and are just getting underway.

Dr. Sturman reported that in August 2011, NYSTEM issued two new Requests for Applications (RFAs) which included: the third round of Investigator Initiated Research Projects (IIRP) and IDEA contracts, for a maximum of \$25 million, and the Consortia to Accelerate Therapeutic Applications of Stem Cells, with a maximum allocation of \$80 million, and that a Request for Proposals (RFP) for Scientific Oversight of Stem Cell Consortia was released simultaneously. He then stated that NYSTEM would be issuing the Institutional Awards for Short Term Faculty Training and Collaborative Opportunities and the Empire State Medical, Dental and Veterinary Student Stem Cell Research Training Program within the next few weeks.

Dr. Sturman advised members that Dr. Spiegel has been assisting staff in drafting the next strategic plan and suggested gathering information on the program's impact both on funded institutions and on the state economy, a topic to be discussed in greater detail at the Full Board meeting in November. He then stated that three vacancies have led to quorum issues, but that two nominations are presently being reviewed by the governor's office and that appointments would hopefully be forthcoming. Dr. Sturman informed members that although seven of ten members have outserved their terms, they were authorized to continue serving until their reappointments. He concluded by mentioning that Dr. Mahendra Rao, the newly appointed

Director of the Center for Regenerative Medicine of the National Institutes of Health, will be speaking at the Board meeting in November.

Federal and State Stem Cell Litigation

Dr. Hohn then turned the floor back to Ms. Roxland to recount recent developments in the state and federal stem cell litigation.

Ms. Roxland reported that the trial court had granted summary judgment to defendants in *Sherley v. Sebelius*. It rejected all of the plaintiffs' claims, including the claim that the new guidelines had violated the Dickey Wicker Amendment. NIH has resumed funding the research at issue.

Ms. Roxland next reported that the state intermediate court had upheld the lower court decision in *Feminists Choosing Life v. Empire State Stem Cell Board*, finding specifically that *compensation* for oocyte donation does not violate the Board's authorizing statute prohibiting funding for human reproductive cloning. She stated that the court deferred to the Board's interpretation of "human reproductive cloning" and found that "human reproductive cloning" does not include "therapeutic cloning," in which SCNT is used to produce stem cells for research or therapeutic purposes. The court further found that the donor compensation program does not improperly make grant funds available to be "indirectly utilized" for human reproductive cloning. Ms. Roxland informed members that should the plaintiffs file a notice of appeal by the September 30, 2011 deadline, the Court of Appeals would not necessarily agree to review the case.

Development of Future Agendas

Dr. Hohn advised members that the final agenda item was the discussion of future meetings and agenda items. He advised the committee members that the number of meetings to be held in 2012 may be reduced as they had accomplished most of the major goals they had set for themselves.

As to future agenda items, members stated that the topics for future meetings would be dictated by research developments; ethical and legal developments; and the development or issuance of future RFAs and RFPs. They suggested a number of topics, including presentations on new developments in science as well as clinical trials; intellectual property; donor registries; the development of scholarly research initiatives as raised earlier that day by Ms. Dubler, and reports on interstate meetings.

Adjourn

Dr. Hohn 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: May 22, 2012*