

Empire State Stem Cell Board
Ethics Committee Meeting Minutes
September 24, 2009

The Empire State Stem Cell Board Ethics Committee held a meeting on Thursday, September 24, 2009, at the Department of Health offices, 90 Church Street, New York, New York. Commissioner Richard F. Daines, M.D., presided as Chairperson.

Ethics Committee Members Present:

Dr. Richard F. Daines, Chairperson
Fr. Thomas Berg
Ms. Nancy Neveloff Dubler
Ms. Brooke Ellison
Dr. Samuel Gorovitz
Dr. Robert Klitzman
Dr. Vivian Lee
Rev. H. Hugh Maynard-Reid
Dr. Samuel Packer
Mr. Robert Swidler

Ethics Committee Members Absent:

Dr. David Hohn

Department of Health Staff Present:

Mr. Thomas Conway
Ms. Judy Doeschate
Ms. Susie Han
Ms. Amy Nickson
Ms. Beth Roxland
Ms. Lokia Rucker
Ms. Angela Star
Dr. Lawrence Sturman

Observers Present:

Mr. Ed Ellison
Ms. Jean Ellison
Mr. Robert Feldman
Ms. Barbara Meara
Mr. Martin Strosberg

Opening Remarks and Introductions

Chairman Daines called the meeting to order and welcomed Board members, staff and the public. Dr. Daines reported that Governor Paterson had issued a proclamation declaring September 23, 2009, “Stem Cell Awareness Day” in New York. He advised members that the proclamation recognized the work of the Board, the State’s commitment to stem cell research and the prominent scientists within the State who are responsible for the scientific advances.

Dr. Daines then asked Committee members and staff to introduce themselves. Dr. Daines advised members that Fr. Berg was expected to arrive shortly.

Approval of Minutes of the June 11, 2009, Meeting of the Ethics Committee

Dr. Daines directed members to the draft minutes for the June 11, 2009, meeting of the Ethics Committee included in their agenda books and inquired if members had a chance to review them. Ms. Doesschate advised members that Fr. Berg had suggested the last paragraph on page 3 be amended to strike “enables it to develop into all cell types” and replace it with “enable it to reprogram a nucleus and enable the cell to develop into all cell types.” She advised members that staff agreed with the proposed change. Dr. Gorovitz then moved to approve the minutes for the June 11, 2009, meeting of the Ethics Committee with the proposed amendment. Dr. Lee seconded the motion. The motion passed unanimously.

Program Updates

Dr. Sturman provided the Committee with the following information regarding Requests for Applications (RFAs) and awards:

- *Institutional Development Grants:* 24 of the 25 contractors awarded grants have submitted reimbursement vouchers totaling \$12 million. The one institution that has not submitted a voucher for reimbursement is experiencing a delay with an equipment purchase. Several contractors have been granted no cost extensions. NYSTEM staff continues to conduct on-site visits.
- *Shared Equipment/Facilities Contracts:* The nine recipients of these awards have begun to submit vouchers for reimbursement.
- *Targeted iPS and Innovative Investigator Initiated Research Contracts:* Staff is continuing to process the 98 awards and is focusing on securing proof of all reviews required by the contract. Some vouchers have been submitted for reimbursement.
- *Summer Undergraduate Experience in Stem Cell Science and Undergraduate Curriculum Development:* The applications submitted have been reviewed and will be voted on by the Funding Committee at its October 26th meeting.
- *Targeted Projects in Human Embryonic Stem Cell (hESC) Research and Investigator-Initiated Research Projects:* NYSTEM received five applications targeted to the derivation and characterization of new lines and 205 applications in response to the RFA for investigator-initiated research projects. The applications are scheduled to be peer reviewed in early November. Since the funding allotted for this round would only

support 11 percent of the applications received, the Funding Committee may increase the amount of funding available in this round at its October 26th meeting.

- *Requests for Proposals (RFP) for Assessment of the Economic and Other Benefits of the NYSTEM Program:* This RFP was issued in April. Because only three responses were received and there were significant variations in the costs of the proposals, staff will be reviewing, revising and reissuing the RFP, focusing on clarification of the deliverables. A Request for Information (RFI) will also be published shortly.
- *Fellow to Faculty RFA:* This RFA was issued on August 27, 2009. Applications are due December 1, 2009, and the anticipated start date is November 1, 2010. This RFA will provide up to \$5.4 million for five awards that are intended to transition promising postdoctoral fellows to independent research careers.
- *Shared Facilities RFA:* This RFA was also issued on August 27, 2009, and has the same deadlines and start date as the Fellow to Faculty RFA. The RFA will make another \$15 million available for three awards to support shared research facilities.

Dr. Daines welcomed Fr. Berg who arrived during Dr. Sturman's presentation.

It was suggested that the Chronicle of Higher Education be contacted to increase interest in the RFP for the Assessment of Economic and Other Benefits of the NYSTEM Program. Dr. Gorovitz suggested waiting until the educational awards are made and then issuing a press release that might be published in the Chronicle of Higher Education.

Report on Consortia Planning Meeting

Dr. Sturman advised members that there were approximately 50 participants for the consortia planning meeting. He stated that an RFI was issued before the meeting that yielded 18 responses. Six responses were received from launch grant recipients, eight from planning grant recipients, and four from recipients of other awards.

Dr. Sturman advised members that Zack Hall, the first President of the California Institute of Regenerative Medicine (CIRM), delivered opening remarks and spoke about his experience that led to the creation of CIRM's "Disease Teams." He also provided comments and observations at the end of the meeting.

Dr. Sturman informed the Committee that the meeting was divided into five sessions of 40 minutes each and that each of the 18 awardees gave a brief five minute presentation. He noted that Board members Dr. David Hohn, Mr. Robin Elliott, Dr. Klitzman and Dr. Alan Spiegel each moderated group sessions of the meeting.

Dr. Sturman reported that the participants were interested in knowing what the consortia RFA would look like and the outcome of the meeting. He stated that the meeting was a way to get the recipients' views to develop one or more concept papers for the RFA.

Update on Activities of the California Institute for Regenerative Medicine (CIRM)

Dr. Daines advised the Committee that Dr. Klitzman attended a meeting of CIRM's Standards Workgroup and asked Dr. Klitzman to provide the Committee with information about that meeting.

Dr. Klitzman advised members that CIRM invited him to speak about the Board's decision to allow women to be compensated for donating oocytes solely for research purposes. They were particularly interested in what the Board's thoughts were at the start of the discussions, the process by which the decision was made and how the Board arrived at its decision.

Dr. Klitzman stated that several workgroup members expressed concerns about the exploitation of women and the commodification of oocytes. He stated that he thought that if CIRM was not constrained by California's Proposition 71, they would likely reach the same conclusions as the ESSCB. He also stated that CIRM appeared to be interested in finding a way to work with New York State's lines if possible.

Ms. Dubler noted that CIRM's interest in the Board's decision highlighted the importance of the Board's decision and the need to publish the Committee's decision in the medical literature or prominent journals. She suggested that Ms. Roxland draft a document and offered to assist Ms. Roxland in doing so. Dr. Klitzman concurred with Ms. Dubler's recommendation and offered to assist as well. He suggested that the document address the issue of exploitation and reflect the Board's view that its decision respects the autonomy of women to make their own decisions. Dr. Gorovitz suggested that the article should make it clear that the Board has not said that they are in favor of women donating oocytes for research, but that they also don't believe women should be prohibited from donating oocytes for research, as long as the informed consent and donation process is subject to an array of checks and balances. Dr. Packer expressed support for the idea of developing such a document. Fr. Berg suggested that the Board and staff also communicate information to the public regarding the first donation and how many women donate oocytes for research purposes each year thereafter. Mr. Swidler also supported the idea of publishing an article about the decision, but stressed that the article should also include information about the Committee's discussions and conclusions regarding the informed consent process because the development of rigorous informed consent standards served as the foundation for the decision to allow researchers to compensate women donating oocytes solely for research purposes.

National Institutes of Health Guidelines for Human Stem Cell Research and Comparison to NYSTEM Contract Requirements

Dr. Daines noted that the National Institutes of Health (NIH) had issued revised guidelines that could impact the extent to which stem cell lines derived in New York State are able to be used in NIH-funded research. He then turned the floor over to Ms. Roxland to provide an overview of the new NIH guidelines and compare them to NYSTEM requirements.

Ms. Roxland directed members to the NIH guidelines adopted on July 6, 2009, included in their agenda binders. She noted that the guidelines were substantially changed from the draft that had been proposed by NIH in the spring, but that they still: 1. did not

require funded research to be reviewed by an Embryonic Stem Cell Research Oversight (ESCRO) Committee; 2. limit funding to research that only uses hESC lines derived from embryos in excess of clinical need; 3. only require re-consent to donation for research from the individual(s) who had sought reproductive treatment; and 4. did not grandfather in the “presidential lines.” She also advised members that NIH planned to create a registry of hESC lines that are acceptable for use in NIH-funded research and that hESC lines could qualify for entry in the registry by complying with NIH guidelines or by researchers providing adequate documentation that voluntary informed consent had been obtained in accordance with traditional scientific and ethical principles.

Ms. Roxland then directed the Committee’s attention to a chart she had prepared that highlighted the provisions in the NIH guidelines that were not specifically covered in the NYSTEM standards. She stated the Committee may want to consider recommending changes to the NYSTEM standards to increase the likelihood that lines derived with NYSTEM funding would be eligible for use in NIH-funded research. Committee members expressed support for the idea of revising NYSTEM standards to increase the likelihood that lines derived using NYSTEM funds would be eligible for use NIH-funded research to the extent practicable.

The Committee first discussed whether to bring existing NYSTEM standards into compliance with the NIH restriction that only permits the use of stem cell lines that were derived from embryos created for reproductive purposes, but were no longer needed for that purpose. Members noted that if New York did not adopt this restriction, some lines derived using NYSTEM funds may not be eligible for use in NIH-funded research. Members expressed support for continuing to allow NYSTEM funds to be used for the derivation of new stem cell lines from oocytes donated solely for research purposes, noting that the Committee had already decided that there was a need for research involving the donation of oocytes solely for research purposes and did not want to foreclose the opportunity to explore a line of research that could lead to viable treatments and cures. Fr. Berg questioned the impact of that decision and how much research would be done on cell lines derived from oocytes donated solely for research purposes using NYSTEM funds. Ms. Doesschate noted that the number of lines derived from oocytes donated solely for research using NYSTEM funds was likely to be very limited due to the complexities of deriving new hESC lines. She also noted that many of the lines currently used in research have not been eligible for use in NIH-funded research, but that research has been, and is likely to continue to be, supported with private and other government funding. Mr. Swidler suggested the Funding Committee should consider giving a preference to research that could leverage NIH dollars when looking at two equally valid scientific proposals.

The Committee then reviewed a series of standards that were highlighted by Ms. Roxland and decided that NYSTEM contract requirements should be amended to comply with NIH requirements to: 1. require donors to be advised of all options for disposition of unused embryos and explicitly mention embryo adoption as an option while recognizing it may not be a feasible option in all instances; 2. expressly require policies and procedures to be in place to advise potential donors that providing or declining to provide consent to donate biological materials for research will not affect the quality of care provided to the donor; 3. require ESCRO committees to review documentation to ensure there was a clear separation between the prospective donor’s decision to create human embryos for reproductive purposes while

also clarifying that a general authorization to donate for research at the time of providing consent for reproductive treatment does not violate this requirement; and 4. require donors to be informed that they have the right to withdraw consent for donation until the embryos are actually used in research or until information that could link the identity of the donors with the embryo is no longer retained.

Members also discussed the possibility of amending the NYSTEM requirements to follow the NIH guidelines and only require re-consent at the time of the actual donation to research from the individual(s) who sought reproductive treatment, but opted to continue to require the re-consent of the gamete donors, except when the International Society for Stem Cell Research (ISSCR) guidelines might not require it.

The Committee then turned its attention to the question of whether researchers should be able to use stem cell lines listed on the NIH registry even though some of those lines may not meet all NYSTEM, National Academies of Science (NAS) or ISSCR standards. Ms. Roxland noted that the Committee had already decided to allow researchers to use lines derived in other jurisdictions that do not fully comply with all NYSTEM requirements applicable to the derivation of new stem cell lines, as long as the informed consent complied with the NAS or ISSCR guidelines, or if the lines were previously approved for use in NIH-funded research prior to the initiation of the NIH registry. She stated that recognizing the hESC lines included on the NIH registry as eligible for use in NYSTEM-funded research would make things easier for funded researchers and their institutions.

Dr. Daines expressed discomfort with the concept because it would mean the Board would be ceding control to NIH. He asked what would happen if the Board starts to see entries into the NIH registry that don't meet the Board's standards. He suggested that such recognition could act as a back door for researchers to avoid meeting particular NYSTEM standards.

Ms. Dubler stated that if the Committee were to second guess what NIH would include on its registry, ESCROs, the Board and the Department might need to investigate each of the lines that were included on the NIH registry. She stated that she thought it made sense for specific standards to be applied to NYSTEM-funded researchers who are deriving new stem cell lines using NYSTEM funds, but that it was appropriate to defer to NIH for other lines because the NIH standards are close enough to the NAS and ISSCR standards the Committee found acceptable. She expressed concerns about the "balkanization" of research by putting up barriers and carving out special rules that make collaboration across different jurisdictions more difficult. Dr. Daines acknowledged that recognizing lines appearing on the NIH registry for use in NYSTEM-funded research may make it easier for researchers and institutions, but expressed concern that the Ethics Committee might be ceding its authority and putting itself out of business if it deferred to NIH and its determinations.

Dr. Lee agreed with Ms. Dubler and said it was important to keep in mind that the goal is to advance the science. She suggested the Committee should be wary of imposing barriers when there may not be a significant difference in the respective standards. Dr. Klitzman also concurred with Ms. Dubler and asked Ms. Roxland what important ethical issues are covered by NYSTEM standards that are not addressed in the new NIH guidelines. Ms. Roxland responded saying that the NYSTEM requirement that informed consent be obtained through a "dynamic process" was the most significant difference. She noted that the NIH requirements

do not vary significantly from the NAS standards that the Committee had already recognized as being sufficient for lines derived without using NYSTEM funds.

Dr. Daines clarified that his concern is that the NIH standards could continue to change over time and potentially become too liberal or out of alignment with the standards the Committee had developed. He cautioned against using language in NYSTEM contracts that would defer to NIH standards in all cases, now and in the future. He advised members that he needed to leave, and that Mr. Swidler had agreed to Chair the meeting in his absence.

Ms. Roxland advised members that she had begun to draft changes to the NYSTEM contract language and would work on that further and present the Committee with specific recommended language later in the afternoon.

Formal and Informal Education Programs and Priorities

Mr. Swidler advised members that both the Funding and Ethics Committees had expressed an interest in funding formal and informal education programs, but that no decisions had been made about the specific types of programs to fund. He reminded members that Dr. Alan Friedman recommended that the Board identify what audience it wanted to target and the message it wanted to convey as part of an educational initiative. Mr. Swidler then turned the floor over to Ms. Doesschate to facilitate the Committee's discussion regarding potential educational programs and priorities.

Ms. Doesschate stated that staff had begun to discuss how to move different educational programming options forward, but that it needed further input from the Board on its goals and priorities before staff can develop concept papers and additional funding mechanisms. She advised members she would be engaging them in a brainstorming activity using a document that had been distributed that asked three essential questions: 1. What is the audience you want to reach? 2. What is the message you want to convey? and 3. What mechanisms do you want to use? She noted that some responses were already provided based upon prior discussions, but that she wanted Committee members to add to the list any other suggestions they would want to consider, and then have each member identify their highest priorities from the expanded list.

The first question that Dr. Friedman had suggested the Board address was "What is the audience you want to reach?" After Committee members added to the list and identified their priorities, the potential audiences were prioritized as follows: teachers (7); journalists (5); secondary school students (3); public attentive to science and health issues (3); government officials/staff (3); undergraduate students interested in science (2); graduate students interested in science (2); public attentive to public policy (2); scientists (2); and people who may benefit from the research (1). Other categories that were mentioned, but were not selected as a priorities included: key decision makers/leaders in their field; business people; health care professionals; elementary school students; and general adult population with no special interest in science.

Ms. Doesschate then moved the discussion on to the next question "What is the message you want to convey?" Ms. Doesschate noted that Dr. Friedman had suggested another way of crystallizing the issue would be to ask: "What is the single most important thing you want people to know about stem cell research?" Ms. Doesschate noted that based

upon the comments of Board members in prior meetings and discussions, she prepared the following list: 1. stem cell research has tremendous promise; 2. stem cell research will go forward in the public interest; 3. it will take much time and effort to get clinically useful applications; 4. this work raises many important ethical issues - few of which pertain to embryos, but most do not – which require sustained, respectful discussion by reasonable people with good will.

Members then suggested that the following messages be added to this list: 1. the state of the science, including specific information about the science performed, current progress and recent developments; 2. information about scientific mechanisms and the state of the art; 3. facts about the science presented in a objective, complete and balanced manner; 4. an equal, honest presentation of the ethical and moral arguments; 5. explanations or clarifications of the common misconceptions or misrepresentations of the research; 6. complex ethical issues need to be weighed; and 7. stem cell research is a promising and viable career. Fr. Berg also suggested that the fourth item in the listing provided by Ms. Doesschate be changed to read, “This work presents many important ethical issues - some of which pertain to embryos, but most do not - which require sustained, respectful discussion by reasonable people with good will.”

Dr. Sturman stated that it is very likely the results of this discussion will lead to more than one message and more than one RFA or RFP. He noted that each category of audience might have a different message. Dr. Sturman suggested that the most favored audiences should be grouped into subsets and then the appropriate messages for each group or subset should be identified. Ms. Doesschate agreed and noted that the goal of the activity was to get additional input from the Board for staff to use in additional planning and to develop concept papers.

Ms. Dubler stated that the message will be determined by the setting and the consumer and that categories of people should not be thought about separate from the messages and methodologies. She suggested science competitions for monetary awards as an addition to the list of mechanisms on page three of the handout.

Dr. Klitzman stated that two objectives of education should be advancing the science and building public support for it. Ms. Dubler stated that the goal of education is to create a “buzz” and get people informed and thinking. She also reiterated the idea of creating a set of competitions for journalists, teachers, high school students and graduate students as a way to educate New York residents. Ms. Ellison expressed disagreement with the idea of competitions and suggested more modern approaches, such as “You Tube.”

Dr. Sturman stated that the discussion required more time than was available and that he didn’t want to rush the process. He advised members that staff would consider options for the top four categories and bring additional information back at the next Committee meeting.

Committee Recommendations on Revisions to NYSTEM Contract Requirements Relating to NIH Guidelines

Mr. Swidler then turned the floor over to Ms. Roxland to present the Committee with the proposed changes to the NYSTEM contract based upon the Committee’s discussions earlier in the day. Ms. Roxland distributed copies of the draft amendments to section E of

Appendix A-2 of the NYSTEM contract and identified the specific provisions she had revised. She advised members that:

1. She addressed the requirement for a clear separation between the clinical decision and the research decision in paragraph b by revising it to read: “ESCRO committees should review available documentation to ensure there’s a clear separation between prospective donors’ decisions, the decision to create human embryos for reproductive purposes and the prospective donors’ decision to donate the embryos for research purposes. Providing a general authorization for research donation when providing consent for reproductive treatment does not violate this provision, so long as a specific consent to the research donation is obtained at the time of donation.” She advised members that the last sentence was intended to address Dr. Klitzman’s concern that an initial general consent to research would not violate the revised requirement.
2. In paragraph d she inserted the requirement that an institution must have policies and procedures in effect that require donors to be advised that the decision to donate or decline to donate will not affect the quality of care.
3. Paragraph e was revised to read: “Donors should be informed they retain the right to withdraw consent until the biological materials are actually used in research in compliance with ISSCR guideline 11.2, or until information that links the identity of the donors with the biological material is no longer retained.”
4. Paragraph g, dealing with the options for disposition, was revised to read: “Donors shall be advised that there are alternatives to donating their biological materials to research and shall be provided with an explanation of what the alternatives are, including, but not limited to, all of the options available at the health care facility where the reproductive treatment was sought, embryo adoption, donation for fertility treatment and discarding.”
5. The provisions addressing the application of the requirements are now found in paragraph m, which was revised to include a new sentence that reads: “In addition, grantees may use cell lines registered on the National Institutes of Health registry, subject to ESCRO review.” She advised members that this was to incorporate usage of the lines in the NIH registry and to take care of the Commissioner’s concern that the revision would abdicate the Board’s duties, she made such use subject to non-specific ESCRO review that will let the ESCRO use their discretion.

Ms. Roxland confirmed that these changes were consistent with the Committee’s discussions and thoughts on the matter. Mr. Swidler then asked for a motion to recommend the Funding Committee adopt these changes to Appendix A-2 of the NYSTEM contracts. Dr. Packer so moved and Dr. Klitzman seconded the motion. The motion passed unanimously.

Committee Discussion: Respect for the Embryo

Mr. Swidler reminded members that the Committee had agreed to follow up on its robust discussion last spring about sources of stem cells with a discussion of what is meant by “respect for the embryo.” He then turned the floor over to Ms. Roxland to facilitate the discussion.

Ms. Roxland briefly reminded members of some of the significant points made in prior discussions about the source of stem cells and that the Committee agreed to form a work group to discuss how the issue may be moved forward in subsequent meetings. Ms. Roxland advised members that she did not convene a work group because only two members volunteered. She then opened the floor up to the Committee to identify what respect for the embryo would actually entail and inquired if the Committee might want to make policy recommendations going forward.

Dr. Gorovitz commented that he was struck by the seriousness and mutual respectfulness of the prior discussions on this topic as reflected in the minutes. He suggested that the Committee should have two foci of attention: 1. how to understand the concept of respect in all of its variety and particularly in relationship to embryos; and 2. what follows from that in terms of what is allowable, prohibited and required to be done with respect to the embryo. He noted that the Committee had spent some time in prior discussions focusing on the diversity of things people respect and the different things people do when they respect various things, some of which are based upon how we think we and others relate to embryos. He noted that the way scientists relate to embryos is different from the way the donors or the couple that aspires to use the embryo for reproductive purposes relates to it. He noted that what is appropriate to do with respect to an embryo might depend upon the particular context of the relationship pertaining to that embryo. He suggested that a possible methodological approach would be to think about the different situations in which the question might arise, and then consider why we should respect the embryo in a particular situation and what follows in that particular situation.

Dr. Sturman inquired whether what Dr. Gorovitz was talking about was what was meant by “situational ethics.” Dr. Gorovitz responded in the negative and stated that “situational ethics” is a kind of term of denigration in the vernacular that means “no standards.” He noted that he didn’t think that anyone would support the position that you should withdraw life support from all dying patients and that virtually everyone would agree that you need to know more about the particulars of the situation. He then provided several examples of how different circumstances may call for different reactions, including examples of how different people may reach different conclusions about appropriate treatment of pain or the treatment of a rare book based upon the individual, the circumstances and their relation to the situation. He said good ethics needs to be grounded in good facts with a clear sense of what facts are relevant and what facts are not. He said the right thing to do in a particular situation depends a lot on the features of that particular situation. He concluded, suggesting that the Committee should be sensitive to different fact patterns that would lead to different conclusions about what should be done with respect to an embryo.

Fr. Berg asked for clarification as to whether the Committee will be devoting more time to this topic and whether the Committee was gravitating towards policy recommendations. Ms. Roxland said that she was willing to convene a work group in between meetings and asked members for their thoughts.

Ms. Dubler suggested the Committee should work on a core explanation that might be published in an article, and that Dr. Sulmasy had convinced her that the Committee should also move towards a policy recommendation. She stated that since the Committee had developed a policy that allows the destruction of embryos in certain circumstances with certain guidelines, there should be a policy to address how the others are handled. She noted

that the vast majority of embryos are not used in research and that it might be appropriate to have a policy that requires burial. She observed that there may be some fallout from such a suggestion in the clinical context. She noted that the underlying disagreement on the moral status of the embryo permits some to be comfortable with the destruction of embryos under certain circumstances and suggested that one way to narrow that space between people of different beliefs may be to have specific guidelines that would guide and constrain how embryos are treated.

Fr. Berg noted that the President's Council on Bioethics discussed the dignity of the human embryo and inquired if respect towards the embryo didn't presuppose the notion of the dignity of the human embryo. He asked if there was a reason why the Committee was not speaking about the dignity of the human embryo. Fr. Berg suggested that if the Committee were to publish something on this topic, using that term would grab people's attention.

Ms. Dubler stated that the President's Council on Bioethics used its discussions to oppose the destruction of the human embryo and that discussions that focus on the dignity and moral status of the embryo tend to undergird certain kinds of conclusions. She said the focus on respect permits actions that "dignity" and "moral status" categories do not.

Dr. Gorovitz commented that the notion of respect is very clearly linked to questions of behavior and how people act towards something, whereas dignity linguistically functions in a different way. He said that if an object has dignity it does not compel a result or an action, but presumably means you would show respect in some way. He suggested by discussing "respect," the Committee is starting its discussions in second gear, rather than in first gear.

Dr. Klitzman noted that "dignity" is a loaded term and that "dignity" and "morality" are much more closely allied with theology, whereas respect is more secularized.

Ms. Roxland noted the Committee is not likely to reach a consensus on the moral status of the embryo or the basis for showing respect to embryos, but that it may be able to reach a consensus on behaviors with respect to an embryo. She suggested that the Committee focus on the principles, such as research should not be conducted unless it has demonstrated scientific merit, that the research has been peer-reviewed, and possibly, that it would use the fewest number of embryos possible. She also noted that the standards already prohibit the use of an embryo beyond 14 days of development or after formation of the primitive streak. She suggested it would be helpful if the Committee discussed specifics that it might vote on.

Mr. Swidler commented that he thought that there should be a compelling purpose for the research, not just that the research has scientific merit. He noted that while research on cosmetics could have scientific merit, the fact that stem cell research could lead to cures meets his criteria of being for a compelling purpose. He said that the closest analogy that comes to his mind when considering how to treat embryos is the disposition of human remains. He noted it is not acceptable for people to desecrate a human body for frivolous reasons, and that it raises questions of how it is transported, stored and treated and how you act and what kinds of language you use around it. He acknowledged it was not a perfect analogy, but it was closer than others he had heard suggested. With respect to Fr. Berg's question of where the Committee was going with its discussions, Mr. Swidler stated that he thought the Committee might want to issue a statement if it reached agreement on how people should act, but that he did not want to develop a long set of regulations on language researchers can use with respect to embryos or the disposition.

Dr. Klitzman suggested that it may be appropriate to substitute “social benefit” rather than saying research needs to be for a “compelling purpose.” Mr. Swidler acknowledged that Dr. Klitzman’s suggestion captured the concept of social welfare that he had in mind.

Ms. Dubler stated that she thought it would be beneficial if the group could agree on processes and procedures. She agreed with Mr. Swidler that an expectation of respectful language was important. She also stated that she thought that flushing embryos down a toilet was incompatible with the notion of respect.

Dr. Klitzman stated that he agreed in principle with the concept of treating embryos with respect in terms of language, process and disposal, but was uncertain how that would translate into action. He asked members to clarify what a burial would look like and whether embryos would need to go to a cemetery.

Dr. Gorovitz suggested that a middle ground might be to provide examples of situations in which respectful behavior is described, and other examples of situations in which behavior is insensitive, crude, disrespectful, inappropriate and potentially offensive. He stated that he favored going beyond simply saying “be respectful,” but would stop far short of anything that even remotely sounded like regulations. He suggested the Committee should have more information about what currently goes on so that the examples they provide have some plausibility to the people who are in the business.

Ms. Roxland then asked members to focus on whether they preferred focusing on examples of situations or actual principles.

Fr. Berg offered to consult with Dr. Arthur Caplan who had done some research on the disposition of embryos.

Rev. Maynard-Reid commented that the Committee should be mindful of cultural diversity and that some religions might require burial of body parts, while others do not.

Dr. Lee inquired who the custodian of the embryos are and whether it would be appropriate to expend additional resources for the disposal of embryos if the donor would be okay with the researchers disposing of it as they do now. She asked if the disposal is within the discretion of the donors or if it is the Committee’s responsibility to determine the method of disposal regardless of what a woman might want. Ms. Dubler then asked if members or staff knew what the usual procedure was for disposing of embryos and what time frames applied.

Dr. Sturman stated that his experience is mostly with laboratories and that usually specimens are autoclaved, disinfected or decontaminated depending upon the circumstance. He also noted that a woman may have a miscarriage at home well beyond 14 days of development and that the embryo is often disposed of in the toilet. He noted there are cultural differences and it would be difficult to legislate or regulate this issue. He suggested that the best way to address this may be through the courses for researchers that address what is and is not responsible conduct.

Dr. Packer noted that tissue banks are heavily regulated and there are concerns about endangering the public in any way. He stated that he was not certain what the Committee’s

product should be, but that he could see attaching an expectation statement to the funding that conveys the types of expectations the Committee had been discussing.

Dr. Klitzman said that he is less concerned about the language used in a laboratory because the offensive language used in the clinical setting is usually the result of some anger at the patient or other frustrations. He suggested that the Committee may want to look at considerations of how animals are treated in research.

Ms. Dubler suggested that this could be dealt with via a one page honest framing of the issues and concerns that recognizes the differences of opinion on the status of the embryo and then sets forth the Committee's way of trying to accommodate to the greatest degree possible the sensibilities of people who hold differing points of view. Ms. Roxland suggested the Committee could use the language in the Board's Strategic Plan that has already been agreed upon as a foundation for such a statement. Dr. Gorovitz expressed support for the idea of a one page explanation of expectations, but suggested that the title needs to be carefully chosen. He stated that such a document should also avoid characterizing people and their attitudes.

Ms. Roxland asked for volunteers to work with her on drafting a statement to present to the Committee at its next meeting. She noted that Fr. Berg had already volunteered. Dr. Klitzman volunteered and Ms. Roxland asked others to consider it and get in touch with her.

Discussion of Future Agendas

Mr. Swidler stated that the Committee needs to discuss other items for the next agenda and noted that chimeras need to be on the agenda since it had been pushed off the agenda. Ms. Dubler expressed an interest in addressing the issue of distributive justice as a component of respect for the embryo. Dr. Sturman noted that funding for educational purposes should also be included on the agenda. Dr. Klitzman suggested that balancing intellectual property and justice issues would be a good topic to address.

Dr. Gorovitz suggested that the agenda not be fully saturated because respect for the embryo and chimeras will involve lengthy discussions and the Committee had been having difficulty getting through all items included on its agendas.

Adjourn

Mr. Swidler asked for a motion to adjourn the meeting of the Ethics Committee. Dr. Gorovitz so moved and Dr. Lee seconded the motion. The motion passed unanimously.

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

Approved: November 10, 2009