

Empire State Stem Cell Board
Ethics Committee Meeting Minutes
November 10, 2009

The Empire State Stem Cell Board Ethics Committee held a meeting on Tuesday, November 10, 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. David Hohn

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

Department of Health Staff Present:

Ms. Judy Doesschate
Ms. Susie Han
Ms. Marti McHugh
Ms. Beth Roxland

Ms. Lakia Rucker
Dr. Lawrence Sturman
Ms. Linda Tripoli
Ms. Carrie Zoubul

Observers Present:

Mr. Ed Ellison
Ms. Jean Ellison

Mr. Robert Feldman
Ms. Barbara Meara

Opening Remarks and Introductions

Chairman Daines called the meeting to order and welcomed Board members, staff and the public. He then asked Committee members and staff to introduce themselves.

Approval of Minutes of the September 24, 2009 Meeting of the Ethics Committee

Dr. Daines directed members to the draft minutes for the September 24, 2009, meeting of the Ethics Committee and inquired if members had a chance to review them. Dr. Gorovitz identified two needed corrections. Dr. Daines then asked for a motion to accept the minutes for the September 24, 2009, meeting with those edits. Dr. Gorovitz so moved and Fr. Berg seconded the motion. The motion passed unanimously.

Program Updates

Dr. Daines advised members that Ms. Doesschate had sent the Ethics Committee the program updates for the October 26, 2009, meeting of the Funding Committee and that Dr. Sturman would be providing additional information regarding program activities. Dr. Daines then turned the floor over to Dr. Sturman.

Dr. Sturman advised members that there was a very positive response to the Request for Applications (RFA) for Investigator Initiated Research Projects and Innovative Developmental or Exploratory Activities awards. He stated that due to the large number of applications received, the Funding Committee voted to increase the available funding for this round of awards by \$20 million to enable them to fund as much as the top 25 percent of proposals. Dr. Sturman noted that peer reviews for these applications were conducted on November 3rd and 4th and that the results would be presented to the Funding Committee at its March 2010 meeting.

Dr. Sturman advised members that there was a limited response to the Summer Undergraduate Experience in Stem Cell Science and the Undergraduate Curriculum Development RFAs and that the number of awards recommended for approval for each of these RFAs were three and five respectively. Dr. Sturman advised members that the Funding Committee requested information about the possible obstacles to applicants applying for these awards and that staff would be researching this and providing feedback at a future meeting.

Dr. Sturman advised members that NYSTEM staff are in the process of planning the second annual scientific meeting which is expected to be held in New York City in May 2010.

Dr. Sturman then provided members with information on the work being done to develop additional educational funding mechanisms as a result of the feedback provided by the Committee. He advised members that Dr. Alan Friedman, a consultant in the areas of museum development and science communication and the Executive Director of the New York Hall of Science for 22 years, will be presenting information on “Learning Science in Informal Environments” at the December 11th Board meeting. Dr. Sturman advised members that due to the Board’s interest in funding programs to educate journalists, staff has begun to meet with leaders of graduate journalism programs. Dr. Nicholas Lemann, Dean of the Graduate School of Journalism at Columbia University, was consulted and meetings are scheduled with the faculty from the Newhouse School of Public Communications at Syracuse, the City University of New York’s Graduate School of Journalism and the Carter Journalism Institute at New York University. Dr. Sturman advised members that staff will be preparing a proposal to submit to the Committee once these meetings have occurred.

Dr. Klitzman questioned whether out-of-state and in-state collaborations could be used to increase the number of applications submitted for the curriculum development and internship RFAs. Dr. Sturman advised members that collaborations are encouraged in all NYSTEM RFAs, as long as the principal investigator is from within New York State. Dr. Gorovitz stated that the summer interns could be from anywhere but strongly suggested that principal investigators remain as the applicant to advance the State’s agenda.

Report on the Activities of the Funding Committee

Dr. Daines advised members that he was not present at the Funding Committee on October 26th due to an illness and that Dr. Hohn chaired the meeting. He said that in addition to making recommendations on the education awards mentioned by Dr. Sturman, the Funding Committee unanimously approved the Ethics Committee’s recommendations for the revisions to NYSTEM standards to make them more compatible with the recently issued National Institutes of Health (NIH) guidelines. He stated that the Funding Committee also discussed a

concept paper for accelerating stem cell research through funding consortia. He then turned the floor over to Dr. Hohn and Dr. Sturman for any additional comments about the meeting.

Dr. Sturman noted that the Funding Committee expressed an interest in obtaining information from researchers relative to their distance from starting clinical trials and about the mechanisms available for monitoring consortia. He advised members that the information will be presented at the December Board meeting.

Report on the Activities of the Interstate Alliance on Stem Cell Research Committee

Dr. Daines advised members that the Interstate Alliance on Stem Cell Research (IASCR) held a meeting on October 7th and 8th that Ms. Doesschate, Dr. Willey and Ms. Roxland attended. He stated that Ms. Roxland would be providing information on the discussions about ethical standards and Ms. Doesschate would be providing information on funding partnerships.

Ms. Roxland advised members that she presented information about the Ethics Committee's deliberations leading to the vote on donor payments and the changes made to NYSYSTEM requirements to make them more compatible with the recently issued NIH guidelines. Ms. Roxland advised members that many states were supportive of the Board's vote on payments to donors. She informed members that some representatives liked the Board's provision preserving the authority of ESCROs to review the ethicality of NIH registry lines proposed to be used in funded research and indicated they would be considering a similar provision in their state programs.

Ms. Roxland informed members that since the revised NIH guidelines were produced, NIH has not awarded any grants for human embryonic stem cell (hESC) research because there are no lines on the registry. She advised members that President Obama issued a memorandum on July 30th that directs the heads of all federal government departments and agencies that support and conduct stem cell research to adopt the NIH guidelines. She noted that this was an interesting development since it would effectively apply the Dickey-Wicker Amendment restrictions against embryo-destructive research to all federal agencies, although the Dickey-Wicker Amendment only applies to funding provided through the Department of Health and Human Services. She then opened the floor for questions or comments.

Members suggested the attention given to their decision at IASCR highlighted the importance of the Committee educating the public about its decisions. They discussed the possibility of publishing an article in a peer-reviewed journal with the rationale for their decision.

Fr. Berg asked why there were no lines on the registry. Ms. Roxland explained that the new NIH requirements impose certain application documentation and review requirements that will take some time to implement, but that the process is under way. Fr. Berg asked whether the NIH registry would accept induced pluripotent stem (iPS) cell lines. Ms. Doesschate stated that NIH's guidelines are focused on research involving hESC research and does not specifically include provisions for the review and approval of iPS lines. Fr. Berg asked that the Committee be provided with regular updates on the status of the registry. Ms. Ellison pointed

out that NIH's delay in funding hESC research highlights the importance of NYSTEM's funding and increased flexibility.

Dr. Daines then turned the floor over to Ms. Doesschate to discuss the funding aspects of the meeting. Ms. Doesschate advised members that Ms. Nancy Koch, counsel at the California Institute for Regenerative Medicine (CIRM), gave two excellent presentations at the IASCR meeting about CIRM's disease team experience and provided recommendations on how to encourage collaborations across state lines and establish funding partnerships with for-profit companies, not-for-profit companies and government entities to accelerate stem cell research. She said that Ms. Koch made it clear that it requires an enormous effort to establish these kinds of partnerships.

Ms. Doesschate informed members that Ms. Koch recommended that any funding partnerships should start with an agreement at the highest levels of an organization to work towards an agreement, and then immediately identify any "deal breakers" or absolute barriers to partnering with the entity, as well as any natural unique synergies that make the partnership desirable. Ms. Doesschate stated that this requires an assessment of the strengths and weaknesses of the different partners or collaborators, the resources available to each entity and its researchers, barriers to collaboration, recent developments that present unique opportunities and consideration of what can be gained from the partnership. She noted that Ms. Koch also recommended that scientists from the different jurisdictions or entities should be brought together early in the process to have them help figure out if there are ways they can benefit from a partnership or a unique collaboration. Ms. Doesschate emphasized that it is important to make sure that there is a real interest in collaborations and that the whole will be greater than the sum of its parts or the amount of effort required will not be worth the result.

Ms. Doesschate advised members that in CIRM's partnership model, the funding entities determine the purpose of the RFA and basic parameters and that the goal is to have each entity issue a related RFA on the same day, with the same deadlines and award dates. She noted that each of the funding entities can have different award amounts and requirements, and that the intellectual, reporting and other requirements of a funding entity only apply to the researchers funded by that entity and not to the entire collaboration.

Ms. Doesschate explained that the decisions about what will be funded remains with the individual boards or authorities within each jurisdiction so that the authority of the various boards is not diminished by these partnerships. Consequently, separate independent peer reviews may be conducted on behalf of each funding entity. She noted that CIRM's RFAs do not add or subtract extra points for the collaborative aspect of an RFA with another funding partner. However, whenever an applicant partners with a researcher in another jurisdiction who had applied for funding, the research proposal would be evaluated as a single, integrated project. She then opened the floor for questions.

Dr. Klitzman wanted to know whether these collaborations are driven by the need for additional research or for additional funds, whether staff was contemplating similar arrangements and if staff had information on the success rate of the partnerships. Ms. Doesschate stated that staff would be considering these issues further and noted that this may be an opportunity for the states to support clinical trials. Members also suggested that it may be beneficial to form international collaborations to help accelerate the research towards cures.

Dr. Hohn noted the Board would need to make sure that the science is compelling enough to pursue the initiation of a clinical trial and not just pursue funding partnerships for the purpose of starting a clinical trial. He emphasized the need to get advice from experienced clinical trial investigators on the policies and procedures applicable to clinical trials. Dr. Hohn also cautioned members against considering partnering with other countries as a way to go around ethical limitations since the members are stewards of ethical policies on behalf of the taxpayers.

Dr. Sturman informed members that CIRM had allocated \$230 million to twelve academic institutions and three not-for-profit companies, one of which is not located in California. He stated that the United Kingdom and Canada allocated \$8 million and \$35 million respectively to stem cell research. Fr. Berg inquired whether the depth of stem cell research being done in New York justifies the need for establishing such partnerships. Dr. Sturman advised members that NYSTEM is currently funding more stem cell research than the federal government and that he would provide more information at a future meeting.

Committee Discussion: Respect for the Embryo

Dr. Daines advised members that the Committee had agreed to follow up on its robust discussion of what is meant by respect for the embryo. He reminded members that they agreed that a work group should consider how to use the results of their prior discussions to structure the dialogue on this topic and possibly develop a statement for the Committee to consider. He then turned the floor over to Ms. Roxland to facilitate the discussion.

Ms. Roxland advised members that she did not convene a work group due to scheduling conflicts with the volunteers. She then reminded the Committee that they had begun their deliberations on this topic with a philosophical discussion and then moved on to consider the behavioral principles that showed respect for the embryo. She noted that those principles have included: using the fewest number of embryos reasonably necessary to attain research goals; limiting hESC research to evidence-based protocols that have been peer-reviewed and have a reasonable likelihood of resulting in important new data; prohibiting research involving in vitro culture of any intact human embryo for longer than 14 days or until formation of the primitive streak begins, whichever occurs first; prohibiting human reproductive cloning; protecting the autonomy of the embryo donor through informed consent requirements; promoting access to knowledge gained from hESC research; and forming policies on issues related to hESC research in a transparent, public forum.

Ms. Roxland reminded members that two additional issues that have been raised recently are the methods of embryo destruction and the use of respectful language around embryos. She suggested that with respect to the discussion on the destruction of embryos, the Committee should consider what the basis for distinguishing between the methods used for embryos donated research in NYSTEM funded projects and those donated for reproductive and other research purposes would be. Ms. Roxland then opened the floor for discussion.

Ms. Dubler stated that the principles that the Committee has developed to date are useful and that she would not object to promulgating them in a way that increases the integrity of the research and leads to a higher standard for review. She then stated that she is no longer willing to work on the subcommittee because she feels that stem cells, along with the issue of abortion, are presently being treated as a “political football” and she doesn’t want her words or

the work of the Committees to be used against the principles that she holds dear. Ms. Dubler stated that she is very committed to a woman's right to choose and that she felt that this has been severely undercut by the recent compromise in the House of Representatives. She said discussions about stem cells have the potential to be used in political arguments in ways that she does not support. Ms. Dubler also stated that she felt that the Committee has shown a great amount of respect for both the science and religious beliefs in articulating guidelines and standards thus far. She stated she was uncomfortable proceeding with any further dialogue on the respect for the embryo discussion because all roads in American bioethical discussions about the destruction of embryos lead to the issue of abortions. Ms. Dubler stated that she preferred to preclude this discussion from having that same outcome. She said she thought decisions regarding destruction methods should be discussed with those who created the embryo and made in line with their own beliefs. Ms. Dubler ended by stating that she is resigning from the subcommittee so that she won't "give ammunition to the other side," and that she hopes that the subcommittee achieves something very modest and not subject to abuse.

Fr. Berg stated that he felt that the Committee has done well in keeping politics out of their discussions up until this point and that he felt uncomfortable with the idea of politics being a catalyst that halts the Committee's discussions. He asked members whether they thought there could be agreement on a statement, and if so, what would be the minimum they could live with in terms of an action item coming out of the Committee's discussion on respect for the embryo.

Ms. Dubler stated that the draft would need to say at the outset that different populations have different notions about the meaning and moral standing of the embryo to get her approval. She added that it should also state that the Committee respects those notions and that as a result the Committee has established scientific rules and that people who donate embryos should determine the disposition of their embryos. Ms. Ellison stated that she was in agreement with Ms. Dubler and that the Committee has been particularly mindful of people's differences of opinion in all of its discussions and in developing its policies.

Dr. Daines advised members that he has considered how the recent discussions on this topic would result in recommendations to the Funding Committee for standards that are different than what the Committee has already recommended to the Funding Committee. He reminded members that the principles that Ms. Roxland mentioned have been incorporated into NYSTEM contract requirements, the Board's strategic plan and the annual report. He suggested that any further recommendations or a statement from the Committee would go further than the Committee's charge regarding funded research. Dr. Daines also expressed uncertainty as to the benefits of issuing a separate statement that incorporates the standards already included in NYSTEM contracts. Dr. Daines then asked members what action, if any, should be taken by the Committee.

Ms. Dubler stated that she felt the Committee has reached a stopping point on this topic. Rev. Maynard-Reid stated that he felt Ms. Dubler had expressed her views in a profound manner and that she should remain on the Committee because the Committee has already stated their reasoning behind its decisions and that the difference of opinions and changes in the political landscape will continue. He also expressed his agreement with the idea there was no need to go any further on this topic at the moment. Dr. Hohn suggested that the Committee

should periodically revisit the issue of respect for the embryo to keep current and knowledgeable as the research progresses.

In response to suggestions that the Committee may want to submit an article to a peer-reviewed publication to inform the public of its deliberations, Dr. Daines suggested that interested members should address this individually and reminded members that the Board's position as a whole is already stated in both the annual report and the strategic plan.

Dr. Lee advised staff that she would be leaving the meeting during lunch due to other commitments. Ms. Dubler also advised staff that she needed to leave a half hour before the end of the meeting.

Presentation and Discussion of Key Issues and Policy Options: Chimeras

Dr. Daines reminded members that Dr. John Gearhart gave an excellent presentation on naturally occurring chimeras and hybrids and their value in research at the June Board meeting. He stated that the Committee has also expressed an interest in considering whether it should develop standards for chimeric research in addition to those set forth in the National Academies of Science (NAS) and International Society for Stem Cell Research (ISSCR) standards already incorporated into NYSTEM contracts. Dr. Daines noted that staff had provided members with the standards applicable to chimeras and a number of informative articles on the topic. He then turned the floor over to Ms. Roxland to review those standards and identify the key issues and policy options for the Committee to consider.

Ms. Roxland advised members that she would only be focusing on the ethical issues since Dr. Gearhart had provided an excellent presentation on the science at the June Board meeting. She stated that the literature on chimeras tends to focus on the effects of such research on humans and human society more than on the impact of such research on animals. She also noted that while some of the literature argues for not treating stem cell research involving chimeras differently from the other chimeric research, other literature raises significant arguments about the "unnaturalness" of stem cell research involving chimeras, the moral taboo, species integrity and human dignity.

Ms. Roxland reminded members that chimeric research is subject to review by several committees. She stated that the Institutional Review Board (IRB) focuses on human subject research and the issues of informed consent and vulnerable populations; the Institutional Animal Care and Use Committees (IACUCs) look at the animal protection aspects of the research; and the Embryonic Stem Cell Research Oversight (ESCRO) committees look at special ethical issues involved in stem cell research.

Ms. Roxland advised members that the NAS and ISSCR guidelines focus on three areas: 1. whether the hESC cells that are transplanted into an animal impact the germ line in any way because they could be carried into the next generation or could affect the brain or central nervous system and arguably transfer human capacity to animals; 2. whether cells are injected prenatally which could result in them being incorporated into the whole animal; and 3. how closely related the species is to humans.

Ms. Roxland directed members to the chart she provided that compared the NAS and ISSCR guidelines and stated that she would initially be focusing only on the portion that deals with research involving hESCs. She noted both NAS and ISSCR break research into three categories: 1. research that is required to be reviewed by the IRB and IACUC and subjected to an expedited ESCRO review; 2. research that is reviewed and possibly approved after a full ESCRO review; and 3. research that is prohibited. Ms. Roxland reviewed the NAS and ISSCR guidelines in each of the three categories and then highlighted the areas where there are differences between the NAS and the ISSCR guidelines.

Ms. Roxland advised members that the ISSCR guidelines allow expedited review for experiments with pre-existing hESC lines where the experiment is routine and standard, but that NAS subjects such research to a full ESCRO review. Ms. Roxland then stated that ISSCR allows hESCs to be mixed with pre-implantation nonhuman primate embryos, as long as the embryo is less than 14 days old, whereas NAS prohibits this. ISSCR also allows embryonic stem cells to be mixed with human blastocysts as long as the embryo is not allowed to be developed for more than 14 days, but NAS also prohibits this. She then stated that ISSCR allows the breeding of one animal in which the implanted cells might have contributed to the germ line, but prohibits the breeding of two such chimeric animals to each other, whereas NAS would prohibits the breeding of any chimeric animals in which the hESC could have contributed to the germ line. Ms. Roxland concluded by stating that ISSCR allows a lot of experiments as long as they are terminated within 14 days and the results are not implanted into a human or non-human primate uterus, whereas NAS usually prohibits the experiments in the first instance. Ms. Roxland then opened up the floor for discussion.

Dr. Daines noted that ISSCR's guidelines made an odd distinction by allowing an animal in which an implanted hESC might have contributed to the germ cells to breed with another animal as long as the other animal wasn't derived that way because scientists wouldn't know what they would end up with in either case. After discussion of the language in section 10.3c of the ISSCR guidelines it was agreed that clarification on this issue and the underlying rationale for the provision was needed.

Ms. Dubler confirmed her understanding with staff that all NYSTEM-funded scientists conducting research involving chimeras are currently required to comply with either the NAS or ISSCR guidelines and other applicable laws and regulations, including compliance with IRB and IACUC review. Ms. Dubler also commented that the chart provided did not seem to have a logical progression and she was struggling to identify a logical way to organize discussions on this topic and understand the fundamental logic behind the guidelines. For example, she could not identify the ethical objection to the introduction of hESCs into a nonhuman primate blastocyst if the development would be halted at 14 days.

Other members concurred and suggested ways to approach the topic. Fr. Berg suggested that the Committee might start with a broader discussion of how Committee members feel about cross-species and chimeric research to get a bearing on where people stand and then address specific issues. Dr. Klitzman noted that some of the concerns raised are just hypothetical at this point because no one is doing or contemplating doing this type of research. He also noted that some of the same issues arise outside of the area of hESC research with human genomic research and adult stem cell research. He suggested the Committee may want

to divide the issues into socially constructed concerns, moral or ethical concerns and scientific concerns.

Dr. Gorovitz commented that he thought that American culture seems to have a unique concern about the notion of the closeness between human beings and other primates that is fundamentally unsettling to people in a way that the closeness to humans and other species is not so distressing. He suggested that the distinctions being made in the guidelines may be a backwash from the old battle between evolution and species essentialism. Ms. Ellison noted that when NAS developed its guidelines they tended to take a conservative approach to protect against some of the inaccurate and inflammatory rhetoric that was being espoused by opponents to hESC research. Ms. Dubler suggested that the distinctions do not go back to central speciesism, but to Leslie Fiedler's work on "freaks." She noted that there is a repulsion factor and concern about the danger of science to the integrity of the species. She suggested that NAS may have drawn its boundaries more widely around the central concerns to provide greater protection to those core concerns. She noted that genetically engineered farm animals and corn and its impact on the environment and species over time raise similar concerns and that it is often difficult to figure out where the line is between irrational fears and fears that require the development of careful guidelines.

Members expressed concerns about the complexity of the science and indicated that they would like to receive more information on: 1. the types of experiments that have been approved and those that have been prohibited involving chimera; 2. clarification on which types of research present a scientific danger, versus a significant moral or ethical concern, versus a public perception concern; 3. what scientific and policy considerations led to the differences between NAS and ISSCR; and 4. whether the NAS prohibitions against introducing hESC cells into a nonhuman primate blastocysts applies to introducing nonhuman embryonic stem cells into a human blastocyst. Dr. Hohn also noted that he would like to be provided with a copy of Dr. Gearhart's very informative presentation. Members also suggested it may be good to have Dr. Gearhart come back or be available by conference call.

Dr. Sturman advised members that he would look into the scientific literature to provide information about chimeric research currently being conducted and Ms. Roxland stated she would research the ethical issues discussed and provide responses at a future discussion.

Fr. Berg suggested that the Committee may want to consider a specific example, such as the work being done in Britain using a cow oocyte for somatic cell nuclear transfer research, as a vehicle for understanding the issues. He said it included several factors that the Committee was discussing: it involved chimeric work actually being done; it involved embryonic stem cells issues; and it has the "yuck" factor that provoked a public outcry. It was noted that this example does not involve a chimera, but a cybrid.

Dr. Packer noted that the scientists don't even know the answers to some of the questions the Committee is asking. He reminded members that the definition of research is that you don't know the answer. He suggested that members of the Committee are not going to be able to understand everything that someone like Dr. Gearhart understands and conveyed in his presentation and that there needs to be some deference given to the needs of researchers and their expertise.

Dr. Hohn agreed and also addressed the need to find a framework for understanding what really matters and examining the issues. He noted that some of it was old territory that the Committee did not need to be concerned about, but that some of it may be the kind of work that is being done in New York that the Committee needs to pay attention to. He suggested that required discussions with people in the field.

Ms. Doesschate pointed out that a lot of the gray areas involving chimeras and interspecies research are required to be reviewed and approved by ESCRO committees under the existing standards. She said those committees are responsible for looking at the details of a scientific proposal and addressing some of the types of issues the Committee has been grappling with. She noted that the experts who wrote the NAS and ISSCR guidelines recognized that they cannot understand and anticipate every research scenario that might raise ethical concerns and that was why they recommended the establishment of independent review panels to examine the ethics and safety issues on a case by case basis. As a result, she suggested that the Committee might want to start by focusing only on what is absolutely prohibited by the guidelines and especially where the two sets of guidelines differ; what the rationale is behind each specific prohibition; and then consider whether they think an absolute prohibition is appropriate or whether they think it may be appropriate to defer to the appropriate ESCRO committee to review on a case by case basis. She noted that members tended to be leaning in the direction of focusing on the distinctions between the guidelines in the areas of absolute prohibitions, making that a natural starting point.

Ms. Roxland agreed that may be a good approach and advised members that she would be attempting to line up a speaker for the next Committee meeting to address some of the questions members had about the science and the policies and their rationale.

Discussion of Future Agendas

Dr. Daines clarified that the next meeting of the Ethics Committee would be part of the full Board meeting, which would limit the amount of time available for Committee business. He noted that chimeras should be on the agenda for the next couple of meetings and opened the floor to other suggestions.

Members suggested that staff bring in a speaker to provide information on the types of research involving chimeras that are being undertaken. Ms. Ellison suggested Dr. William Lensch at the Harvard Stem Cell Institute as a speaker. Dr. Gorovitz stated he would like to hear more information on Dr. Sturman's discussions regarding educational programs for journalists. Dr. Klitzman suggested that balancing intellectual property and justice issues would be a good topic to address. Dr. Klitzman and Dr. Hohn both expressed an interest in starting preparatory work on understanding the ethical and fiscal issues involved in clinical trials. Fr. Berg suggested a videoconference with an NIH staff member to give members an update on the registry and provide clarity on the process for accepting new lines. Mr. Swidler also asked Ms. Roxland to include citations to the guideline provisions included on the chart that she provided so members could refer to the specific provisions when discussing chimeras.

Dr. Daines concluded that staff would be including a further discussion of educational initiatives and chimeras on the next agenda; hopefully with an expert to engage in a dialogue on

the topic, and that the issues of international standards and cooperation, clinical trials and intellectual property would be included on future agendas. After further discussion Dr. Daines agreed that staff would also attempt to prepare something on international standards and potential barriers to collaboration for the next meeting. Fr. Berg also asked that Board members be kept informed on a regular basis of the amount of funding that has been made available for hESC research and the status of oocyte donation in NYSTEM-funded projects.

Adjourn

Dr. Daines thanked the Committee for a productive meeting and then asked for a motion to adjourn the meeting of the Ethics Committee. Dr. Hohn so moved and Mr. Swidler seconded the motion. The motion passed unanimously.

*s/ Judy L. Doesschate, Esq.
Executive Secretary to the
Empire State Stem Cell Board
Approved: December 11, 2009*