

Empire State Stem Cell Board
Ethics Committee Meeting Minutes
May 21, 2010

The Empire State Stem Cell Board Funding Committee held a meeting on Friday, May 21, 2010, 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	Dr. David Hohn, Vice Chair*
Fr. Thomas Berg	Dr. Robert Klitzman
Ms. Nancy Dubler	Rev. H. Hugh Maynard-Reid
Ms. Brooke Ellison*	Dr. Samuel Packer
Dr. Samuel Gorovitz	Mr. Robert Swidler
*via videoconference	

Ethics Committee Members Absent:

Dr. Vivian Lee

Funding Committee Members Present:

Mr. Kenneth Adams	Dr. Mario Loomis
Dr. Bradford Berk*	Dr. Allen Spiegel
Mr. Robin Elliott	Dr. Michael Stocker
Dr. Bruce Holm*	Ms. Madelyn Wils
Dr. Hilda Hutcherson	
*via videoconference	

Department of Health Staff Present:

Dr. David Anders	Dr. Matthew Kohn
Ms. Bonnie Brautigam	Ms. Beth Roxland
Dr. Kathy Chou	Ms. Lakia Rucker
Mr. Thomas Conway	Dr. Lawrence Sturman
Ms. Judy Doesschate	Dr. Ann Willey

Observers Present:

Ms. Laurel DeGeorge	Ms. Caroline Marshall
Ms. Ellen Ferranti	Mr. David McKeon
Dr. Samuel Gandy	Ms. Barbara Meara
Ms. Anna Granat	Ms. Kathleen Pickering
Ms. Susie Han	Ms. Kelly Ryan
Ms. Shauna Katz	Dr. Thomas Sakmar
Dr. David Levy	Ms. Carrie Zoubul

Welcome and Introductions

Dr. Daines called the meeting to order and welcomed Board members, staff and the public. Dr. Daines introduced Dr. Mario Loomis who was recently appointed to the Funding Committee by Governor Paterson upon the recommendation of the Assembly Minority Leader.

Approval of Minutes for the May 3, 2010, Ethics Committee Meeting

Dr. Daines directed members to the draft minutes for the May 3, 2010, meeting of the Ethics Committee and asked for a motion to approve the minutes. Dr. Packer so moved and Rev. Maynard-Reid seconded the motion. The motion passed.

Embryonic Stem Cell Research Oversight (ESCRO) Committee Issues and Experience

Dr. Daines reminded members that at the May 3rd meeting they agreed it would be beneficial to hear from ESCRO committee members to gain a better understanding of how ESCRO committees operate and apply the National Academies of Science's (NAS) and International Society for Stem Cell Research's (ISSCR) standards. Dr. Daines advised the Committee that Dr. Ann Willey had arranged for ESCRO committee members to come and speak, and turned the floor over to Dr. Willey.

Dr. Willey advised members that due to potential difficulties of making travel arrangements on such short notice she only sought speakers from New York City institutions that have ESCRO committees. She introduced Dr. David Levy, Chair of New York University (NYU) ESCRO Committee; Ms. Kathleen Pickering, Administrative Director of the Tri-Institutional Research Program; and Dr. Thomas Sakmar, Chair of the Tri-Institutional ESCRO Committee. Before turning the floor over to them, Dr. Willey provided the Committee with the following information regarding ESCRO committee review of NYSTEM-funded research: 1. of the initial 78 funded investigator-initiated research projects, only 9 projects required ESCRO registration and 3 required full ESCRO review; 2. 13 of the initial 20 targeted research projects required ESCRO notice or review; 3. 17 of the 52 recently approved investigator-initiated research projects required ESCRO review or notice; and 4. all 3 of the approved targeted research proposals involving the derivation of new stem cell lines required ESCRO review. She also advised members that the NYSTEM-funded projects that require ESCRO notice or review involved 15 New York State institutions. Dr. Willey then turned the floor over to Dr. Sakmar and Ms. Pickering to describe how the Tri-institutional ESCRO Committee operates and to provide information regarding the issues they have addressed.

Ms. Pickering advised members that the Tri- Institutional ESCRO Committee was developed in 2005, partially in response to private joint funding Weill-Cornell, Memorial Sloan-Kettering and Rockefeller University received for stem cell research. She noted the Committee's inception coincided with the issuance of the NAS guidelines and that those guidelines provided a good operational framework for the Committee.

Ms. Pickering advised members that the Tri-Institutional ESCRO Committee is comprised of 12 individuals: 6 scientists from the member institutions and 6 external members, 4 whom have special legal and ethical expertise and 2 who are representatives of the public. Although the appointments are for one-year terms, some members have served up to four years. She said members are not compensated, but they are indemnified by the organization. Ms. Pickering advised members that meetings have been held quarterly, but that the Committee had recently developed an expedited review process to allow some types of applications to be handled by the chair of the ESCRO Committee without a formal meeting. Ms. Pickering stated that she thought the multi-institutional ESCRO committee concept has worked well and that it

has been particularly beneficial in avoiding duplication of effort and facilitating the review of collaborative research projects that are conducted across the participating campuses.

Ms. Pickering advised members that the Tri-Institutional ESCRO Committee has reviewed 63 protocols since its inception, 12 of which have involved induced pluripotent stem cell research. The Committee has also reviewed seven protocols that involved the derivation of new human embryonic stem cells (hESC), but that most of the protocols have either used registry lines or non-registry lines that have been approved for entry in their local hESC registry. Ms. Pickering noted that all investigators are required to go through an on-line training course and post-test before their protocols are reviewed by the ESCRO Committee.

In response to questions, Ms. Pickering advised members that the Tri-Institutional ESCRO Committee has a gender balance and has recruited persons of color, but has not been successful yet in recruiting individuals from the Hispanic community. She noted that the Committee is conscious of the need to do that. She also advised members that she had examined the standards contained in Appendix A-2 of the NYSTEM contract and felt the only inconsistency with the Tri-Institutional ESCRO Committee policies is that the NYSTEM contract provisions require ESCRO review of a broader range of research. She noted, however, that the Tri-Institutional ESCRO Committee routinely accommodates any reviews that might be required by a granting agency.

In response to questions regarding public access to the Committee's work and decisions, Ms. Pickering stated that research protocols, follow-up annual reports and minutes are maintained, but that those records are not posted on the web. Dr. Sakmar added that members are encouraged to actively discuss all aspects of the research proposal, but the minutes do not attribute specific comments to individual members.

Dr. Sakmar then responded to the Ethics Committee's request for information about xenotransplantation and other cross-species research. He advised members that the Tri-Institutional ESCRO Committee reviewed large amounts of literature on the topic, including the NAS guidelines, and engaged in extensive discussions over a two-year period before reaching a consensus. These discussions resulted in the Committee agreeing to employ the following ethical principles and boundaries for studies involving introduction of hESCs into animals or animal embryos: 1. the experiment must be designed to explore a fundamentally important scientific question and be conducted in compliance with existing rules and regulations pertaining to animal experimentation; 2. experiments must follow a graded approach where the results of initial experiments and controls are used to guide subsequent experimental design and reevaluate ethical considerations; 3. experiments in which human stem cell lines are introduced into animal embryos must be designed to ensure that the modified embryos are initially studied in vitro, if at all practical, and that if the modified embryos are implanted into animals, the embryos shall not be allowed to mature beyond the stage of early organogenesis and will be terminated at the earliest point feasible; 4. any subsequent experiments designed to proceed beyond early organogenesis, allowing observation of cell function or physiology in the cross-species hybrid, must be justified by a careful evaluation of the scientific significance of the proposed research and by careful attention to the ethical issues such research may raise; 5. experiments involving the introduction of stem cell lines derived from adult somatic cells into animals or animal embryos are bound by these same principles; and 6. experiments designed to fuse human and non-human embryos directly are prohibited.

In response to questions, Dr. Sakmar clarified that these guiding principles are consistent with NAS's guidelines, but that they are slightly more restrictive in that they create a graded system. He noted that the ESCRO Committee's experience with actual protocols has helped guide the Committee's consideration of subsequent protocols and that they have found it beneficial to use their own experiences to modify their policies and processes without having to wait for the information to be distilled through a national organization or committee.

Dr. Sakmar advised members that the issue of xenotransplantation and the creation of cross-species hybrids has been among the most challenging issues the ESCRO Committee has addressed. He advised members that the ESCRO Committee has also recently been considering the issue of compensation of oocyte donors and has found the minutes of the ESSCB meetings instructive. He stated that Committee has used everything available when considering different issues and that Ms. Pickering and her staff have provided the ESCRO Committee with all needed or requested materials and have been exceptional in their support of the Committee.

Dr. Sakmar stated that he thought the ESCRO committee concept is a sound one, but that it requires a lot of effort to make it work well because of the need to educate community lay members, ethicists and legal scholars about the scientific aspects of the different research proposals. He noted that the continuity of membership and the care that the scientific members from the three institutions have taken to explain the proposals to both the lay members and the scientists at the other institutions have been important in helping the lay members participate in a meaningful way. He also stated that he thought it is extremely important to have the kind of strong staff support that has been provided to the Tri-Institutional ESCRO Committee to make it work well.

Ms. Dubler advised Dr. Sakmar that the Ethics Committee had devoted a substantial amount of time and effort to develop model informed consent forms and inquired if ESCRO committees might want to see model policies and informed consent documents. Dr. Sakmar stated that the Tri-Institutional ESCRO Committee members opted to start from scratch in the development of the Committee's policies and forms and had decided that it was important for them to engage in careful consideration of the issues rather than just adopting the policy statements of other groups. Ms. Dubler noted that the Ethics Committee was not planning on imposing model forms on ESCRO committees, but felt that ESCRO committees might find them helpful in sorting through the issues and may want to use the portions that made sense to them. Mr. Swidler also noted that the forms were intended to serve as a resource to researchers attempting to comply with NYSTEM standards. Mr. Swidler and Ms. Dubler both expressed an interest in having the Ethics Committee finalize the model informed consent forms and in having them provided to researchers and ESCRO committees for their consideration and potential use. Ms. Roxland agreed to work on revising the draft forms for the Ethics Committee's further review. Dr. Sakmar reiterated that Tri-Institutional ESCRO Committee members have found the work of the ESSCB Ethics Committee very valuable in its own deliberations, but preferred to review all available materials and make their own assessments.

Dr. Willey then asked Dr. Levy to provide information about NYU's experiences. Dr. Levy advised members that NYU's ESCRO Committee has existed for only about a year and that the vast majority of stem cell research being conducted at NYU has been basic science using model organisms. He informed the Committee that NYU's ESCRO Committee has only

received one registration document thus far and that the protocol did not require full ESCRO Committee review. He noted, however, that NYU has been recruiting stem cell researchers and that the ESCRO Committee would likely need to address some significant issues as the stem cell research program at NYU expands.

Dr. Levy advised the Committee that NYU's ESCRO Committee has six members, all of whom are scientists, including a leading expert on medical ethics. Although the ESCRO Committee has been attempting to recruit a lay community member, it has not done so yet. He said the Committee is staffed by NYU's Chief Compliance Officer and a member of NYU's Counsel's Office. Dr. Levy said the ESCRO Committee has been using the ISSCR and NAS hESC guidelines as well as NYSTEM contract requirements. He said he thought it was important to draw on the experience of other committees, such as the Institutional Animal Care and Use Committee (IACUC) that he chaired, and other ESCRO committees. He commented that the research protocols are usually much better after being reviewed by an IACUC. He advised members that IACUCs have mechanisms in place to communicate with one another and develop common standards and that has reduced regional variations. He said that he was not sure whether regional ESCRO committees were a good idea or not, but suggested regular communication amongst ESCRO committees, similar to what IACUCs do, would be helpful.

Mr. Swidler asked for clarification on the types of materials ESCRO committees review and what they look for when reviewing proposals, especially with regard to research involving chimeras. Dr. Sakmar reiterated the Tri-Institutional ESCRO Committee's requirement for a graded approach and the need to be provided with in vitro information, and then early information prior to organogenesis, before allowing a protocol that would progress beyond each stage.

Ms. Dubler observed that the evolution of ESCRO committees is similar to that of Institutional Review Boards (IRBs) in the 1970s, intellectually, methodologically, legally and ethically, and wondered if it is possible to begin to develop a common law of the review process and analysis. She suggested it would be valuable to have an open discussion of the review process for research protocols so that researchers, ethicists and others could learn from one another and thought that New York State might be able to play a useful role in bringing that about. Dr. Klitzman concurred, and suggested that it would be good to establish an interstate dialogue on ESCRO committee policies and implementation issues to help address some of the uncertainties in this area. He expressed an interest in having the Ethics Committee learn more from people in the field about the challenges of setting up an ESCRO committee and having established committees share the lessons they have learned. Ms. Pickering noted that both NAS and the World Stem Cell Summit have provided ESCRO committee members with opportunities to share information at different forums and discuss what has been working and what has not been working as ESCRO committees evolve and gain experience.

In response to a question about the interplay between the Tri-Institutional ESCRO Committee and the IRB, Ms. Pickering stated that the Tri-Institutional ESCRO Committee does not look at any protocol until it has been reviewed and approved by an IRB or IACUC, whenever such review is required. She said there has been some dialogue between the ESCRO Committee and the IRB at times and that the panels share information regarding the monitoring of proposals. She noted that this is one of the benefits of having members of the

Tri-Institutional Administrators Group on both committees and serving as a local resource on proposals that impact both panels.

Dr. Daines thanked Ms. Pickering, Dr. Sakmar and Dr. Levy for coming to the meeting and sharing their experiences and valuable insights with the Committee.

Adjourn

Dr. Daines then asked for a motion to adjourn the Ethics Committee meeting. Dr. Klitzman so moved. Fr. Berg seconded the motion. The motion passed.

*s/ Judy L. Doesschate, Esq.
Executive Secretary to the
Empire State Stem Cell Board
Approved: September 27, 2010*

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