

**Empire State Stem Cell Board**  
**Ethics Committee Meeting Minutes**  
**January 26, 2009**

The Empire State Stem Cell Board Ethics Committee held a meeting on Monday, January 26, 2008, 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  
Ms. Brooke Ellison  
Dr. Samuel Gorovitz  
Dr. Robert Klitzman  
Rev. H. Hugh Maynard-Reid  
Dr. Samuel Packer  
Dr. Daniel Sulmasy  
Mr. Robert Swidler

**Ethics Committee Members Absent:**

Fr. Thomas Berg  
Ms. Nancy Neveloff Dubler  
Dr. David Hohn (*participating in part via telephone*)  
Dr. Vivian Lee

**Department of Health Staff Present:**

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

**Guest Presenter:**

Dr. Alan J. Friedman

**Observers Present:**

Ms. Katayoun Chamany  
Mr. Ed Ellison  
Ms. Jean Ellison  
Mr. Joseph Feldman  
Ms. Barbara Meara  
Ms. Ellen Murray  
Ms. Joyce Raskin  
Ms. Kelly Ryan  
Ms. Shelia Wusinich

## **Opening Remarks and Introductions**

Chairman Daines called the meeting to order and welcomed Board members, staff and the public. Dr. Daines advised Committee members that Msgr. Smith had passed away on Saturday, January 24, 2009, and that members would be provided with information regarding the wake and services. He noted that Msgr. Smith had made many valuable contributions during his service on the Board and expressed his condolences to the Monsignor's family, friends, colleagues and former students.

Dr. Daines also advised the Committee that Dr. Harold Varmus had resigned from the Funding Committee due to his appointment as Co-Chair of the President's Council of Advisors on Science and Technology and other commitments. Dr. Daines expressed his appreciation for Dr. Varmus' many contributions that helped get the Empire State Stem Cell Board and its programs off to a successful start.

Dr. Daines then asked Committee members and staff to briefly introduce themselves. Following the introductions, Dr. Daines noted that the agenda may need to be revised due to several unexpected absences and that he would discuss those changes with members after the Committee addressed the routine agenda items.

## **Approval of Minutes of the October 16, 2008 Meeting of the Ethics Committee**

Dr. Daines directed Committee members to the draft minutes for the October 16, 2008, meeting of the Ethics Committee included in their agenda books and inquired if members had a chance to review them.

Mr. Swidler asked that the minutes be revised to reflect the fact that the Ethics Committee had asked a workgroup to look at proposing model forms to be used in the informed consent process. Dr. Gorovitz recommended that the sentence at the top of page 6 be changed to reflect that Dr. Eggan was "a" 2006 recipient of the MacArthur Foundation Genius Award, rather than "the" 2006 recipient since more than one award is made each year. He also asked that the sentence on page 9 referring to the prohibition of valuable consideration be clarified. Dr. Sulmasy asked that the section of the minutes dealing with Dr. Eggan's presentation be revised to insert "while mammalian SCNT is currently very inefficient, eventually" before "maybe one or two donors would be required per patient." He also asked that the phrase stating that SCNT may become "more efficient" be stricken from the minutes since he did not recall Dr. Eggan making that statement. Ms. Doesschate noted that she had asked Dr. Eggan to review the draft of the minutes concerning his presentation and would check with Dr. Eggan and the transcript before making the suggested change. Dr. Sulmasy agreed that would be appropriate.

Dr. Gorovitz then moved to approve the minutes for the October 16, 2008, meeting of the Ethics Committee with the changes as noted. Dr. Sulmasy seconded the motion. The motion passed unanimously.

## **Report on Funding Committee Activities**

Dr. Daines advised members that the Funding Committee met on November 6<sup>th</sup> and voted to recommend approval of nine awards totaling \$32.4 million to support the establishment and operation of multi-institutional core facilities and specialized equipment to maximize the expertise, efficiency and quality of stem cell research in New York State. Dr. Daines reported that the Funding Committee also met on December 18<sup>th</sup> and voted to recommend approval of twenty awards totaling approximately \$14.9 million to support targeted research to investigate induced pluripotent stem cells and other derivation approaches and seventy-eight awards totaling approximately \$53.1 million to support investigator-initiated stem cell research projects.

Dr. Daines advised members that the Funding Committee had also provided feedback on a draft Recurring Request for Applications (RFA) for Investigator-Initiated Research and other concept proposals. He stated staff would be presenting additional RFAs at the next Funding Committee meeting that would support investigator-initiated research, promising young scientists transitioning from fellow to faculty and additional shared research facilities.

Dr. Daines also reported that the Funding Committee was continuing its discussions regarding options for funding consortia or other collaborative work and had agreed that it would be good to find out what the recipients of the planning grants have been considering before moving forward with an RFA to support consortia.

## **Program Update**

Dr. Sturman provided more information regarding the applications received in response to the shared equipment and facilities, targeted research and investigator-initiated research RFAs and the status of the awards. He reported that staff is continuing to work on the June 12<sup>th</sup> grantees conference and the expansion of the NYSTEM website. He noted that the annual report has been posted on the website and some frequently asked questions (FAQs) will be posted in the near future.

In response to questions, Dr. Sturman advised members that the RFAs for undergraduate curriculum and summer intern projects were being reviewed at the Division of the Budget before issuance. He also advised members that there was substantial diversity in the investigator-initiated and targeted research applications submitted and funded from plant cells to human therapy related research, but that the majority involved non-human animal cells. He noted that few applications were directed at therapeutic applications or involved human embryonic stem cell (hESC) lines and that none involved the derivation of new stem cell lines, somatic cell nuclear transfer (SCNT) or parthenogenesis. Dr. Sturman also agreed to check into the feasibility of creating a mechanism that would allow members of the public to submit questions through the NYSTEM website.

In response to additional questions about the annual report, Ms. Doesschate advised members that individual color copies of the annual report could be made available to Board members, but that due to fiscal constraints, the Department would not be printing this document for mass distribution.

## **Federal Developments**

Dr. Daines noted that the Committee had requested an opportunity to discuss potential federal developments with the change in administration and then opened the floor to members to provide their thoughts.

Several members suggested that the Board and the Department should establish liaisons with appropriate federal entities to ensure that the Board's work is in alignment with any standards and incentives the federal government might develop. Dr. Daines noted that New York State is well positioned to take advantage of any potential increases in federal funding for scientific research and that the Department has been in touch with New York's Congressional delegation to help ensure New York can leverage its advance work in this area. Ms. Doesschate also noted that the Interstate Alliance on Stem Cell Research has collectively encouraged the new administration to keep in mind that several states have undertaken initiatives in this area and any standards that are developed should maintain flexibility to facilitate collaborative research and funding efforts.

Rev. Maynard-Reid noted that at a recent meeting of the National Academy of Science (NAS), the Food and Drug Administration stressed that safety will be of the utmost importance as they consider the approval of clinical trials. Dr. Packer suggested that with the anticipated easing of federal restrictions on stem cell research and the recent approval of Geron's clinical trial, the pharmaceutical and health care industries may become more interested in supporting research in this area and working with NYSTEM. Dr. Daines concluded, saying that Department staff will continue to monitor federal developments in this area and cultivate relationships to help position New York to take advantage of federal opportunities.

## **Informed Consent for Gamete Donors**

Dr. Daines noted that the Committee had scheduled three topics for discussion: respect of the embryos, payment of gamete donors and informed consent. He suggested that since several members were absent and Dr. Sulmasy needed to leave by 1:00 P.M., it would be best to take up the discussion of informed consent and then address one of the other issues, if time permits, after the lunchtime presentation on museums. With the Committee's concurrence, Dr. Daines turned the floor over to Ms. Roxland to address the issue of informed consent.

Ms. Roxland directed the Committee to the draft document entitled "Informed Consent Contract Clauses for Appendix A-2." She advised the Committee that she had drafted this document based upon the Committee's discussions at its last meeting. She noted the footnotes included the NAS or International Society for Stem Cell Research (ISSCR) language wherever it was referenced in the document. Ms. Roxland then reviewed each subsection of the document with the Committee to solicit comments and possible amendments.

Ms. Roxland stated that subsection a. would require that informed consent be accomplished through a dynamic process that encourages the potential donor to ask questions and prompts the potential donor to confirm his or her understanding of the information being

disclosed. Members expressed strong support for this provision and emphasized the need for this requirement to be enforced because it is critical to ensuring that there is voluntary informed consent.

Subsection b. would require re-consent for the donation at the time gametes or embryos are transferred to the research team. Ms. Roxland advised members that this provision had remained unchanged since the last version of Appendix A-2 was adopted by the Funding Committee following the recommendations of the Ethics Committee. It requires the Embryonic Stem Cell Research Oversight (ESCRO) committee to apply the standards set forth in ISSCR 11.2, but would allow them to follow the stricter standards set forth in NAS guidelines 3.2. Ms. Roxland highlighted the fact that the NAS standards would prohibit the use of embryos created using sperm donated anonymously because re-consent would not be possible, but that the ISSCR provision could permit an anonymous sperm donor's initial consent for research to suffice if the ESCRO committee agreed after a rigorous review. Several members expressed concern that current informed consent documents for anonymous sperm donors may not include an authorization for use in research and suggested that staff should get sample copies of the forms currently in use to determine the extent to which this might be a barrier to using embryos created with anonymously donated sperm. Mr. Swidler also stated that he wondered whether there was a need to protect the sensitivities of an anonymous sperm donor.

The Committee then moved on to a discussion of subsection c. which read:

“Donors must be informed of the intended use of their biological materials and must be offered the opportunity to impose restrictions on the types of research in which the materials might be used, e.g. formation of chimeras or nuclear transfer. Donors should not, however, be allowed to impose such restrictions once cell lines using those materials have been created. Donors should be encouraged to provide their materials free of restrictions and use.”

Mr. Swidler suggested that the words “to the extent known” should be inserted after “use of biological materials.” In response to questions raised regarding the appropriateness of individuals being able to restrict the uses of donated gametes, Dr. Sulmasy suggested that “initial” be inserted before “use” to make it clear that any stated restrictions would only apply to the initial use of the donated gametes and not to subsequent uses of the stem cells derived from those gametes. Dr. Sulmasy noted that from a practical standpoint not all potential research uses can be envisioned at the time of donation and it would create an incredible imposition on researchers to require them to obtain re-consent every time a stem cell line is used in a new experiment. He explained that the purpose is to give potential donors a reasonable opportunity to object to initial uses from a moral point of view. In response to concerns raised by Ms. Ellison about the ability of a lay person to understand some of the terms being used and the restricted donations clause, Dr. Sulmasy pointed out that these issues should be addressed in the dynamic process envisioned by the Committee. He suggested that the ability to restrict the donations was a means of helping ensure that people have the opportunity to be fully informed of the potential uses of their gametes and that researchers should not assume that everyone will give a blanket consent. He suggested making an

assumption that donors would give blanket consent would be disrespectful to the variety of opinions held by individuals.

The Committee also discussed whether the language would allow donors to restrict the use of the materials to research conducted in the original laboratory. Dr. Sulmasy questioned whether such a restriction might rise to the level of a deep moral conviction anticipated by the provision. Dr. Gorovitz suggested that such a restriction could be consistent with a person's moral viewpoint because their agreement to donate could arise out of a sense of trust for that particular laboratory or researcher and they may be uncomfortable allowing the resulting stem cell line to be distributed to other states or countries. Ms. Doesschate reminded the Committee that the Funding Committee had adopted provisions that required funded researchers to make the results of research, including materials, available to other researchers and suggested the Committee should consider whether such a restriction would be appropriate for stem cell lines developed with government funds. Dr. Packer suggested that if a patient wants to impose such restrictions, it may be an indication that the person is not aligned with the purpose of the donation and the donation should be declined.

The Committee then moved on to subsection d., which would prohibit researchers from allowing an embryo to develop in culture for longer than 14 days. Mr. Swidler clarified that the inclusion of this provision in the informed consent requirements would require researchers to advise donors of this limitation. Committee members expressed agreement with this requirement.

Ms. Roxland noted that subsection e. requires compliance with the financial disclosure provisions ISSCR 11.3 (8) and (9) regarding the potential commercial potential of any resulting cell lines and any potential financial benefits to the investigator and the institution.

Ms. Roxland then referred the Committee to subsection f. regarding potential disclosures of genetic and medical information. After some discussion clarifying the intent of the draft provisions, Mr. Swidler suggested that since both sets of guidelines require the researcher to advise the donor that genetic information will be retained and protected, this provision could be made simpler by only requiring the donor to be advised that the stem cell lines will retain their DNA. Members agreed this would help clarify this requirement.

The Committee then discussed subsection g., which would require grantees to reimburse donors for the costs of research-related injuries. Following a discussion of the phrase "directly and proximately" in this provision, it was agreed that it would be sufficiently clear to require that the costs of treating injuries just be "directly" linked to the act of donating. Ms. Roxland also noted that although the language makes it clear that the State would not be responsible for costs associated with injuries, she would be revising this to address circumstances when the grantee may be a State institution.

Ms. Roxland noted that subsection h. would require grantees to comply with the ISSCR guidelines 11.5(b) requirements for disclosing risks of donating oocytes, rather than the more permissive NAS guidelines 3.6 (l). Dr. Gorovitz asked that the provision be modified to clarify that donors must be informed of the both short-term and long-term risks to the extent they are known at the time of donation.

Mr. Swidler noted that the more difficult question that needs to be answered is whether these rules would apply to existing stem cell lines being used by grantees. He suggested that the Committee may want to accommodate ethically non-significant variations for already donated eggs, embryos and cell lines if the donations complied with NAS or ISSCR. Ms. Roxland agreed it would be appropriate to include something in the next draft. Mr. Swidler suggested that “Materials donated or cell lines created prior to the implementation of these rules would be an acceptable basis for research if they complied with either NAS or ISSCR.” Ms. Roxland agreed to add that language to the next draft.

Dr. Sulmasy noted that with the discussion of this topic coming to an end, he wanted to state for the record that while he had been participating in the discussion, he is morally opposed to almost all the uses that will be made of these donations, and that he did not want anyone to think that his participation in the discussion implies that he endorses these kinds of activities in any way. He stated he was participating in the discussion with the rest of the Committee members to help identify what can be done best ethically in light of the fact that people will be participating in something that he considers to be immoral.

Dr. Daines asked the Committee to return to the provisions in subsection c. because he was concerned that it was not clear what restrictions donors would be allowed to impose under the proposed subdivision. He suggested it be revised to state:

“Donors must be informed of the initial intended uses and potential dissemination to other institutions or researchers of their biological materials. Donors should be encouraged to provide materials free of restrictions. However, they must be offered the opportunity to impose restrictions on the types of research that the researchers or institutions seeking their consent will conduct and to prohibit transfer of their materials or cell lines derived, to other researchers, institutions or banks where such restrictions would not apply.”

It was noted that if donors were concerned about only being able to impose restrictions against the initial uses of their gametes, they may be more comfortable donating to a particular laboratory if they know the laboratory could not transfer the gametes or resulting stem cell lines to other laboratories.

Dr. Daines noted Dr. Friedman was ready to give his presentation and Ms. Roxland suggested the Committee take up the issue of the draft forms after lunch and Dr. Friedman’s presentation. Dr. Daines also noted that Dr. Sulmasy would need to leave before the end of Dr. Friedman’s presentation.

### **Working Lunch Presentation: Science Museum Programs by Dr. Alan J. Friedman**

Dr. Daines then introduced Dr. Alan J. Friedman, a museum consultant and former director of the New York Hall of Science. He reminded Committee members that they had expressed an interest in hearing from someone who is familiar with how to engage the public in learning about science and technology, especially with regard to the development of exhibits in museums.

Dr. Friedman briefly mentioned that the development of brochures, websites, school programs, public forums, museums, exhibits, advertising and celebrity messengers are all

ways to engage the public in learning more about science and technology. He also noted that no one channel of communication will reach everyone. Consequently, it is important to consider what audience you want to reach and what your purpose is when planning educational materials, programs and exhibits.

Dr. Friedman provided the Committee with information about the effectiveness of “free choice learning,” i.e., learning that takes place outside of the classroom. He advised members that the National Academy of Science recently issued a report on the effectiveness of learning outside the classroom that clearly demonstrates that informal learning experiences are “cost-effective.” He noted that 61 percent of adults visit a science museum, aquarium or zoo each year, and an even higher percentage of children visit such locations each year. On the other hand, studies have shown that only about 20 percent of adults are “attentive to science,” i.e., they will pay attention to information about science available in newspapers and other media.

Dr. Friedman advised members that museum exhibits can be developed in a few months, but can also take up to two years to develop. The process begins with front-end evaluation of what your audience already knows, or thinks they know, and an assessment of what information should be conveyed to your audience. This phase is followed by a design and testing phase that involves the development of prototypes that are tested on focus groups. The developers use this “formative evaluation” phase to assess whether different portions of the exhibit will engage the public, hold their interest and accurately communicate content. Various aspects of the exhibit are then revised and improved through an iterative process. A “remedial evaluation” is also performed as the exhibit is being assembled to address any final aspects of the exhibit that are not working optimally. Finally, a “summative evaluation” is performed to assess what visitors actually learned. This assessment is used to prepare a report to the sponsors of the project about the effectiveness of the exhibit.

In his presentation, Dr. Friedman provided the Committee with extensive information about the Human Body Gallery of The Science Museum of Minnesota and the Maryland Science Center’s plans for an exhibit called “Cells: The Universe Inside Us.” He stated that both are well-done, inquiry-based exhibits that cover cell biology, stem cells and health-related research. Dr. Friedman advised members that the Maryland Science Center is building a smaller traveling exhibit that could travel to museums in New York State at a cost of approximately \$100,000 per museum. He suggested the Board may want to subsidize these types of activities. He noted that Maryland is starting to schedule the exhibit, and museums tend to book three years in advance. He suggested an alternative could be to ask Maryland to build a copy of the exhibit that could travel to science museums and possibly other venues in the State. Dr. Friedman noted that such exhibits often include staff to set up the exhibit and promotional materials, such as brochures and teacher packets that can be individualized to each museum. He advised members that one problem with purchasing an exhibit for New York State is that museums often want “exclusivity” clauses in their contracts so the interest in the exhibit will not be dissipated by the time it appears in their museum. Consequently, exhibits rarely go to more than two museums in the same state.

In response to questions, Dr. Friedman noted that the placement of educational exhibits in other venues, such as college, airports, hospitals and other public buildings, presents challenges. Rather than having a location that is set up to provide space and staff

support for exhibits, the sponsor of the exhibit would need to negotiate everything with the owner of the venue or provide it themselves. Exhibits also usually have to be modified to be less interactive in such locations, which tends to make them less engaging.

Dr. Packer noted that if you put an exhibit in twenty-five museums, you might miss the opportunity to provide educational programs and materials in a thousand hospitals and other health care locations. He suggested that funding should support opportunities where the public is, such as in emergency rooms and waiting areas where people spend a lot of idle time. Dr. Friedman agreed and noted that he had helped develop a series of science exhibits for Montefiore Children's Hospital.

In response to questions about who he thought was most in need of this type of education, Dr. Friedman suggested the Committee would need to retain a pollster to ask questions and then choose appropriate targets. He noted that the Board needs to know its goals and consider what fits best with the New York stem cell initiative.

Dr. Daines thanked Dr. Friedman for his very informative presentation.

### **Informed Consent for Gamete Donors (*continued*)**

Following Dr. Friedman's presentation, the Committee returned to its discussion of informed consent for gamete donors and the draft model forms that had been distributed to Committee members. Mr. Swidler reminded members that the Committee had asked the work group to develop forms that incorporate the informed consent principles agreed to by the Committee. He noted that the forms were intended to provide researchers with a model they could use and be assured that they were complying with the proposed requirements. The process of drafting the forms also helps vet and illuminate the ethical issues the Committee had been discussing and potentially identify other issues that need to be addressed. Mr. Swidler advised the Committee that the workgroup decided to use the forms developed by the ISSCR as a starting point.

The Committee first discussed the draft form for informed consent to the donation of eggs collected in excess of clinical need. Mr. Swidler noted that the document had been revised to clarify that the form should not be used if donors had been given extra hormones to increase the number of eggs available to research beyond what would normally be needed for fertility treatment. Changes were also made to clarify and simplify the potential uses of the eggs and what restrictions the donor may impose on the initial potential uses of the eggs.

Several members expressed concerns about the way the different uses were described. Dr. Gorovitz noted that the word "parthenogenesis" is not sufficiently connected to the content to make it readily understandable to ordinary people who have no prior connection with the subject matter. He suggested adding "this technique is called parthenogenesis" to the third line of that paragraph. Mr. Swidler agreed that amendment would be appropriate.

Ms. Ellison expressed concerns about the ability of anyone to understand the definition of parthenogenesis and reiterated her concern about the ability of donors to restrict donations. She stated that allowing these kinds of restrictions would present researchers with logistical challenges that are similar to those caused by the current federal restrictions. She also questioned who would be keeping track of the restrictions. Mr. Swidler suggested it

would be helpful to get feedback from researchers on this issue, but also noted that if researchers do not intend to use gametes in parthenogenesis they would not have difficulty honoring that restriction. Dr. Klitzman also noted that he was not sure if the primary problem with getting egg donors was because of moral qualms or the lack of adequate remuneration. He suggested that if the purpose of allowing restrictions to be imposed on donations was to increase donations, the Committee should consider other ways to accomplish that.

Dr. Sturman suggested that the Committee may also want to clarify what is meant by “clone.” He stated that from a scientific perspective, SCNT does not create a clone because it does not contain the same mitochondrial genes as the individual from which the nucleus was obtained. He noted that this difference is not trivial because it could be the explanation for why some couples are infertile. He pointed out that this was something that Dr. Friedman had raised in his presentation; i.e. that most people don’t know what they think they know about a field and that the use of certain terms such as “clone” and “parthenogenesis” are often used to reflect what the person thinks they mean, as opposed to what it means scientifically. He concluded by suggesting the Committee focus on what the Committee wants people to know and understand from the language because the choice of words, such as the word “clone” will evoke different kinds of feelings from different people.

Dr. Daines agreed that the use of the term “clone” in the description of SCNT may be misleading because of what people understand “clone” to mean from the movies, articles about “Dolly” and other discussions. Mr. Swidler suggested that since the intent of the disclosure statement is to be accurate, concise, intelligent and neutral, and the use of the term “clone” normally refers to the creation of an organism in connection with a pregnancy, it would be appropriate to delete the parenthetical using that term and insert the word “largely” before “genetically matched.”

Ms. Ellison commented that the Committee’s discussion about these definitions underscores her concerns about the use of these terms causing more confusion, rather than less. Dr. Packer also expressed concern that the informed consent document could be very destructive and that it might be better to eliminate the definitions. He stated that a poorly done informed consent could have a very chilling effect by making everyone afraid to be involved in the creation of new stem cell lines. Mr. Swidler noted that the definitions had been in the original ISSCR document and that the work group had merely attempted to reword some of them to make them more comprehensible. He also reminded members that the form was intended to be used as part of a dynamic process to ensure the donor understood sufficiently to provide informed consent. He stated he would not want to eliminate parts of the informed consent form because they addressed complex issues.

Dr. Daines reminded members that it will be difficult to come up with language that institutions will not feel the need to word-smith, but that the Committee had felt it would be helpful to provide institutions with a template as a foundation for them to work from. Dr. Hohn agreed that most institutions would only use it as a guide and would feel the need to revise the forms to address their specific research and institutional concerns regarding consent and potential liabilities. Ms. Roxland suggested it might help if the discussion of parthenogenesis were moved back in the form to after discussion of the purpose of the form. The Committee agreed that would help and that the parenthetical reference to “clone” would

be removed. Ms. Roxland also asked members to send her an email with any other specific wording suggestions they might have.

Mr. Swidler then asked for input on the language the workgroup added to the draft consent form that would allow a donor to consent to having a researcher contact them if the research reveals information about a significant risk to the donor's health or to the health of their current or future children. Dr. Klitzman stated that Institutional Review Boards generally don't require this for genetics research because of the difficulty of locating people many years later. He stated it also raised questions of whether the tests need to be performed in an approved laboratory and whether it is appropriate to report results when the test is only predictive of a condition or disease. Dr. Daines suggested that some donors might view this as a potential benefit of participating in the research and others might want an "opt-out" box. He also pointed out that since stem cells lines contain genetic materials combined from two different individuals, it is unlikely that researchers would be able to identify significant health risks specific to one of the donors. He also noted that if this provision were not included in the model form, researchers could still agree to notify them of these kinds of results.

Ms. Doesschate advised members that any clinical laboratory tests performed at the time of donation requires informed consent for those tests and that the results of those tests would need to go to a medical provider who is qualified to interpret those results. She noted that the tissue banking regulations also provide guidance on this issue. Dr. Packer stated that eye banks are required to report any positive results for communicable diseases to the patients and other regulatory entities. Mr. Swidler suggested that there should be literature covering this issue in the ethics literature since it has been a big issue in the genetics field. He recommended that the language be pulled from the form for now and asked staff to provide additional information and literature on this topic for the Committee to consider.

Mr. Swidler then advised the Committee that the workgroup had deleted all references in the form to the egg retrieval process and its risks because consent for the actual egg retrieval for in vitro fertilization would occur separately from the donation of eggs for research purposes.

Mr. Swidler then directed members to the draft form that would be used to obtain informed consent for egg procurement specifically for research purposes. He stated that since the form tracked much of the language in the prior form, it would require changes similar to those discussed for the first form. He advised members that the main difference is that the consent document dealing with retrieval solely for research would require a thorough explanation of the nature of the procedure, the risks, benefits and alternatives to the procedure. He advised members that the workgroup suggested that an expert be retained to advise the Committee on this issue.

Dr. Daines suggested that it might be appropriate to have two separate forms: one for the process of egg retrieval and the other for the use of the gametes in research. He noted that institutions would likely need to have two different teams of experts to obtain informed consent. One team would need to discuss the process and risks associated with ovarian stimulation and egg retrieval, and the other would need to advise the donor of the anticipated research uses of the gametes. Mr. Swidler agreed that the separation of the forms and the process may make it more comprehensible and digestible. He also suggested that the Board

may have a greater responsibility for ensuring that the informed consent process is carried out properly when the State is financing research that will involve the recruitment of women to donate eggs for research.

Mr. Swidler directed Committee members to the last form that would be used when obtaining consent for the donation of embryos for research purposes. He noted that the form would need to be changed to be consistent with the changes made to the other forms discussed. He also noted that a unique issue raised by the form is who is required to consent to such donations. He suggested that the consent of the egg donor and the sperm donors would be sufficient. Dr. Klitzman suggested that the form could be improved to be more readable from a lay person's point of view. Mr. Swidler stated that the work group was trying to stay fairly close to the ISSCR forms and they fought off the temptation to tinker with the language in many places.

### **Discussion of Future Agendas**

Dr. Daines suggested that the two remaining topics for payment of gamete donors and respect for the embryo be deferred to the next meeting. He noted that staff has already contacted Dr. John Gearhart, a stem cell researcher at the University of Pennsylvania, to present information to the Committee on chimeras at its March 16<sup>th</sup> meeting. He suggested the Committee should also review the next iteration of the informed consent contract language and forms. The Committee agreed that it would be appropriate to share the revised documents with the Funding Committee to get their thoughts at this point.

In response to a question from Dr. Gorovitz, Dr. Daines assured the Committee that the Department would be in touch with the Governor's office and the Legislature about filling the recently created vacancies.

### **Adjourn**

Dr. Daines asked for a motion to adjourn the meeting of the Ethics Committee. Dr. Gorovitz so moved. Rev. Maynard-Reid seconded the motion. The motion passed unanimously.

*Approved: March 16, 2009*