

**HUMAN SUBJECTS POLICY BOARD
MINUTES
9:30-11:00 a.m., October 4, 2006
EE (Electrical Engineering) 303**

Members Present

Lidstrom, Mary (Chair)
Booth-LaForce, Cathryn
Buck, Steven
Burke, Wylie (represented by Malia Fullerton, Medical History & Ethics)
Cheek, Jeff
Crutchfield, Robert
Handsfield, H. Hunter
Patricia Kuszler
Mason, Robert M.
McCutchen, Deborah
McGough, Helen
Mitchell, Pamela
Moe, Karen
Rimmele, Carl
Streidl, Gigi
Takeuchi, David
Wilensky, Alan
Zuiches, Carol

Members Absent

Barker, Theresa
Brown, Zane
Brunzell, John
Chaney, Edmund
Eaton, Dave
Rein, Rebekah
Saxon, Andrew
Sherrard, Donald J.
Slattery, John
Thummel, Kenneth

Welcome and reiteration of charge to the Board:

Mary Lidstrom called the meeting to order at 9:30 a.m. After Board members introduced themselves, she introduced Jeff Cheek, new Associate Vice Provost for Research Compliance and Operations, who came to UW on August 1 from Colorado where he held a similar position. She announced that Jeff would take over as chair of the Policy Board after today's meeting.

Mary announced that Helen McGough will be retiring as of Friday, October 6, and said that she wanted to officially thank Helen for her 22 years of service in the Human Subjects Division. Her remarks about Helen's contributions to the institution were met with a warm round of applause from the Board. Helen said that she would be staying on to work on special projects, and that she looked forward to continuing doing what she loves to do. Karen Moe, currently Assistant Director, will become Acting Director of HSD as of Saturday, October 7.

Mary mentioned the large number of recent changes in HSD, and indicated there would be more coming. She reminded the Board members that their role is advisory and that she would like them to provide input on policies, particularly as HSD works through the accreditation process. She cited the incredible expertise and commitment that members bring to the Board.

Request of HSPB to review proposed HSD policies pertinent to AAHRPP accreditation requirements:

Karen Moe provided a handout of the HSD website pages pertaining to accreditation and reviewed the changes in the process to review human subjects draft policies, procedures, and forms. She said that there's now a public website where one may access drafts for review (http://www.washington.edu/research/hsd/about_accr.html).

HSD accreditation staff will send email to HSPB members and others when policies become available for review. Comments may be emailed to the website, or entered by hand on downloaded copies and mailed to HSD. Round 1 of the review process will be an email notice to staff; round 2 will be a notice to IRB chairs and committee members; and round 3 will be a notice to the Policy Board and other interested parties. One may comment on any drafts that are of interest. Comments will be collated and distributed without attribution to individuals.

Karen also updated the Board on the accreditation timeline. The deadline to submit UW's application to AAHRPP (Association for Accreditation for Human Research Protection Programs) has been extended from March 2007 to early August 2007 because of the many changes in HSD, among them the director's retirement, the new Institutional Official (I.O.), and a new assistant director. A site visit is expected next October or November, which will probably last five days and will involve four or five visitors, followed by a report one to two months later. AAHRPP, a non-profit organization that Helen McGough helped to found, is the only national body accrediting human research programs. Jeff Cheek pointed out that accreditation by AAHRPP is voluntary and there is no assurance that a program wouldn't be audited by another agency. Karen said that accreditation is a driver for change and process improvement that will ultimately help researchers, IRB members, and HSD staff.

Proposed policy on research using residual human tissues:

Jeff said he had reviewed the Policy Board minutes of the 5/13/2006 meeting and could tell there had been a spirited discussion around the proposed policy on research using residual human tissue and data. The new proposed policy was not approved at that meeting. He said John Slattery, Vice Dean for Research and Graduate Education in the School of Medicine, asked him to participate in discussions at the School of Medicine on the use of existing data or residual human tissues that are anonymous or coded for research. We have also recently received guidance from the Attorney General's office as to which State laws actually apply to the use of data or human specimens that are coded or otherwise de-linked from identifiers; ultimately, it depends on what the researcher intends to do with the research.

After the last Policy Board meeting and further discussions, a new draft revision of the form "Research Use of Existing Data, Information, or Specimens from Humans that are Anonymous or Coded" was created by Helen McGough and provided to Board members for comments. Helpful feedback was received from Dave Eaton and Ken Thummel, both of whom suggested a similar approach to the concern about question 6, "Will you use the data or specimens to conduct genetic research?" Dave expressed concern that unless "genetic research" is defined, it would trigger questions about what actually constitutes genetic research and could possibly trigger full review of an application when "in fact the genetic research proposed in no way would reveal any identifying information." He iterated that, at the very least, the term "genetic research" should be defined. He recommended the following wording for Question 6: "Will detailed genetic data or analyses, such as genetic fingerprinting, microsattelite analysis, or whole genome analyses, that could be unique to an individual or family be obtained from the data or specimens?" He said "if the answer to this is 'yes,' then it should go for review. If the answer is no, I believe that 'genetic research' could still be conducted on the samples without compromising anonymity." Ken Thummel and the Board agreed with this revision of Question 6.

Concerns were expressed about potential future technologies that would be permit personal identification via human tissues (especially DNA). A member recommended that Question 5 be amended to include the

phrase “based on current technology.” The Board decided that this issue should be reassessed annually as technologies develop.

Helen McGough commented that the policy refers to any kind of data or specimens collected, as long as they are de-identified, and that the implications cross all disciplines at UW. A whole new category has been created because federal agencies don’t consider these data or specimens human subjects, but the policy satisfies both an ethical issue legal obligations. Helen emphasized that this category does NOT apply if the original specimens or data were collected for research purposes. This new category of review is intended to be a clear, fast, process that isn’t burdensome. Since this is a public institution, there is an obligation and responsibility to the citizens of the state to treat specimens with the utmost respect and to make the process as transparent as possible. There is a great promise in the use of these specimens and data for education and public health and it would be a loss to society if the specimens and data aren’t available for research.

Proposed FDA changes to waiver of consent in emergency medical procedures:

Board members were provided with a handout describing proposed FDA guidance for Emergency Research. The URL for the proposed guidance is: <http://www.fda.gov/ohrms/dockets/98fr/06d-0331-gd10001.pdf>. Comments are due at FDA by October 30, 2006.

As background, Helen described the current regulations for conducting emergency research under waiver of consent. A lengthy set of criteria must be met before such research can be approved, including (but not limited to) the following: the research cannot include a placebo, the research needs to be registered with FDA, consent prior to the conduct of the research is not possible, the approval process must include community consultation and disclosure, and the research intervention must offer a strong hope of benefit. Approximately nine emergency research projects have been conducted at the UW under FDA’s waiver of consent regulations since 1996. Helen said there are numerous research studies conducted in emergency situations at the UW; however, most are not approved under the waiver of consent regulations.

Helen said that for the most part, the proposed guidance ratifies current UW practice; however, there are some implications for the UW for revised practices if the guidance is adopted. (1), The UW does do some emergency research with a waiver of consent that is not FDA-regulated. If OHRP adopts the guidelines there may be inconsistencies between the FDA guidance and OHRP regulations about the definition of a human subject, and the criteria used to assess whether study risks are minimal or not. (2), The UW would probably want to keep review of research involving emergency waivers at the UW rather than outsourcing review to Western IRB. (3), Reporting requirements under the new guidance will place more burden on the IRBs and HSD staff. (5), FDA should be asked to provide more guidance on when a site is engaged in research.

The UW hasn’t drafted a response yet. Sue Clausen, Associate Vice President for Medical Affairs Compliance in the School of Medicine, is collecting comments from the School of Medicine. Board members and researchers may send comments to Jeff Cheek who will in turn forward them to Sue Clausen to be included in a UW response. All comments should be collected by no later than October 24, 2006. Helen suggested that the UW response should include a statement that the UW supports this type of research.

Other issues:

Mary Lidstrom asked the Board to identify issues they would like to see addressed at future meetings. One Board member asked if the Board could look at public health surveillance and create guidelines for determining when surveillance is research. Helen said the School of Public Health has drafted policies on

this issue. Karen added that a policy decision on the definition of research would address this issue. Suggestions were made about the need to change the relationship between HSD and the campus community, which at times has been adversarial; to identify problematic departments that need help; and to track service levels and establish accountability metrics that can be communicated to the community. Mary reminded the Board that, given the limitations of the current HSD database, metrics have to be tracked manually now and that it will be 2-4 months until the new database is completed. She also said that there is a lag of 1-2 years for faculty and staff to recognize that the additional resources allocated to HSD are leading to improved turnaround. A member emphasized that the research community and the Human Subjects Division need to work together to improve the review process and that it would help to know what departments are doing well and where improvements are needed. Setting expectations, following through with those expectations, and advertising that improvements have been made will be important. The Board agreed that accountability metrics would be an appropriate topic to take on. Helen said that she, Mary, Jeff and Karen have been working to establish metric points.

Mary said the Board would continue to schedule regular meetings every other month; however, some special meetings will be scheduled as needed. One immediate topic needing a philosophical discussion is: "What is research?"

The meeting adjourned at 10:50.