

**HUMAN SUBJECTS POLICY BOARD
MINUTES
1:00-2:30p.m. December 4, 2006
EE (Electrical Engineering) 303**

Members Present

Cheek, Jeff, **Chair**
Booth-LaForce, Cathryn
Brunzell, John
Buck, Steven
Handsfield, H. Hunter
Mason, Robert M.
Moe, Karen
Rimmele, Carl
Saxon, Andrew
Takeuchi, David
Wilensky, Alan
Zuiches, Carol

Members Absent

Barker, Theresa
Brown, Zane
Burke, Wylie
Chaney, Edmund
Crutchfield, Robert
Eaton, Dave
Patricia Kuszler
McCutchen, Deborah
Mitchell, Pamela
Rein, Rebekah
Sherrard, Donald J.
Slattery, John
Streidl, Gigi
Thummel, Kenneth

Introductions and approval of minutes from October 4 meeting:

Jeff Cheek called the meeting to order at 1:05 p.m. He reminded the Board that Mary Lidstrom asked that he assume the role of Chair of the Human Subjects Policy Board, although she may continue to attend meetings in the future, should there be a need for her participation on particular issues. He iterated the advisory responsibilities of the Board with regard to reviewing policies and procedures, and emphasized that one of the primary tasks for the Board is to liaison with investigators and other stakeholders. He said he was delighted to announce that Karen Moe is no longer *Acting* Director of the Human Subjects Division; as of last month, she is now the Director. The minutes from the October 4th meeting were approved and accepted.

Report on FDA audit:

Karen Moe briefed the Board on the recent not-for-cause FDA audit on devices (October 2006). Though the audit went generally well, there were two findings of non-compliance. The first was that HSD is not meeting a regulatory requirement that IRB minutes be shared within the institution. Jeff Cheek has since agreed to be the designated University official to receive the minutes from IRB meetings and thus satisfy the regulatory requirement. The second finding of non-compliance was that the IRB did not provide some required information to the sponsor of an emergency medicine study. Karen prepared a response that was forwarded to the national office, which included remedial actions taken on the non-compliant issues, and the FDA responded that the actions taken were sufficient.

Jeff expressed appreciation for all of the jobs done at HSD besides just reviewing applications. HSD also plays an important role in managing researcher conflict of interest and in serving as the HIPAA Research Board for review and oversight of the research use of Protected Health Information. HSD coordinates cooperative reviews with Institutional Review Boards at other

institutions, obtains prisoner certifications from the appropriate federal agencies, and certifies to funding agencies that research studies have IRB approval. Individual HSD staff members provide presentations and consultations to classes, individual researchers and research staff, and research groups on an almost daily basis.

Appeals policy and procedures for Policy Board review:

The federal OHRP audit in 2005 found that the current appeals policy is noncompliant with federal human subjects regulations. Karen is working on a revised policy that provides a mechanism for addressing communication problems between the IRB and a researcher but that still preserves the requirement that the ultimate decision rests with the IRB. Karen pointed out that the existing appeals policy is codified in the Faculty *Handbook*. Thus, the Handbook may need to be revised. Karen asked for suggestions about facilitating the revision process. One Board member described the laborious process to change the *Handbook*, citing the incredible level of detail required and the lengthy wait while revisions are channeled through the Secretary of the Faculty, and reviewed by appropriate Faculty Councils and administrative boards. One suggestion was to entirely remove the Human Subjects Manual from the Faculty Handbook. Karen said she would look into this possibility.

Proposed form for research using residual human tissues:

In introducing the topic, Jeff said that Karen is reviewing all of HSD's forms as part of the accreditation process.. Karen distributed a list of discussion issues related to this form and the research use of biological specimens. This form relies upon the decision-making tree that HSD uses to evaluate a protocol: (1) Is it research? (2) Does it involve human subjects? (3) Does the research qualify for exemptions? (4) Does the research qualify as minimum risk? Specifically, the sequence in which the questions are posed on the biological specimens form, and the citation of regulatory definitions provides more information to investigators about the review process and decision making tree.

Karen asked whether this form could also be used to pre-review protocols involving data acquisition, or if these should be on a separate form. Some Board members thought it would be too complicated to include data, and urged that the form be specifically for biological specimens.

The Board discussed the duration of reviews by the proposed process: how long should an approval last? It was noted that protocols that are deemed exempt from the federal regulations for human subjects research are authorized for five years. The Board decided that the biological specimens review process is a similar evaluation, so five years would also be the duration for these reviews as well. As mentioned at the last meeting, the Board may occasionally need to revisit the criteria especially with regard to genetics research. One Board member suggested that the form could specify five years, and stipulate that if the technology changes, the researcher would have to resubmit, but Jeff thought it problematic to put the burden on the researcher to determine whether the technology had changed to the point where her or his protocol should be re-reviewed. He suggested that one caveat could apply: that the Human Subjects Policy Board would be asked to reassess the appropriate duration on an annual basis.

HSD priorities for the next 3 months:

The probable focus of the coming three months will be to fill the new positions at HSD that have been authorized by the Provost, and to look at regulatory compliance on hot-button issues. Jeff said he had asked Karen to look at current practices and processes at HSD from a compliance point of view, to determine if there are any compliance issues that need to be addressed. Jeff noted that his priority is to address the often adversarial relationship between investigators and IRBs, and asked the Board for input as to how best address this issue. Jeff asked the Board for patience as we work on changing the culture at UW and strive to build a more collegial relationship between the investigator community and HSD. He said wants to establish an open dialogue with the IRBs and investigators, and wants to try to find common ground and bridge the gaps between them. He said he would welcome input at any time and plans to start by scheduling one-on-one meetings with IRB chairs.

Future agenda items:

Board members mentioned a couple of items for the February meeting: an update on the accreditation process, and what we can learn from those departments from which human subjects applications breeze through the process (even if such information is anecdotal). Jeff agreed that it would be helpful to look at trends and consistencies. Karen said she would present feedback on the proposed form at the next meeting after taking it to a focus group for review.

The meeting adjourned at 2:26. The next Human Subjects Policy Board meeting will be February 9, 2007, 9:00-10:30, in room 142 Gerberding.