MINUTES
HUMAN SUBJECTS POLICY BOARD
http://www.washington.edu/research/main.php?page=orAdvisory&group=hspb
9:00 – 10:30 AM
November 18, 2011
Gerberding 142

Members Present
Buck, Steven
Cheek, Jeff, Chair
Chronister, Lynne
Majeski, Steve
Moe, Karen, Acting Chair
Purell, Jeff
Slattery, John
Thomas, Karen
Whitney, Joie
Wilensky, Alan

Members Absent
Berggren, Elizabeth
Brown, Zane
Crutchfield, Robert
Korslund, Kathryn
Jones, William
McCutchten, Debrah
Melvin, Anne
Meisinger, Richard
Oberle, Mark
Rimmele, Carl
Spieker, Susan
Takeuchi, David
Thummele, Ken
Turns, Jennifer

Guests:
Ella Mae Kurashige

1. Approval of minutes from meetings of 9/9/2011 (Jeff Cheek)
The Board accepted the minutes of the 9/9/2011 meeting as submitted.

   Action Item: Post approved 9/9/2011 meeting minutes and final 11/18/2011 meeting agenda on HSPB website.

2. Standing Item: HSD/IRB Update (Karen Moe)
   - Karen provided an update on staffing at HSD. Back in the summer, one in five HSD staff positions was vacant although HSD managed to keep application turnover times stable at that time. Currently, all positions have been filled with only one vacant position present.
   - Yesterday’s Seattle PI published an article regarding individuals posing as researchers who are trying to recruit research subjects. One perpetrator left false research study advertisements in Odergaard library. UW campus police identified some of the victims who were recruited. The police and victims jointly went public with the information.

   Committee members provided some solutions on how to avoid this from happening again, which included:
   - Require that research staff involved with recruitment display legitimate UW IDs.
   - Presentation of a bona fide and previously approved recruitment flyer on a UW webpage.
   - Request that newspaper staff inform students to contact HSD if they have any concerns.
Standing Item: Regulatory Updates (Karen Moe)

- Karen provided the status of the Advanced Notice of Proposed Rulemaking on Human Subjects Protections. The public comment period ended October 26th, 2011 with over 1100 comments posted on the OHRP website. The assistant secretary of HHS has said they plan on implementing the proposed rules before January 2013. Regulations.gov contains an archive of the public comments.
- HIPAA issues: HSD has been experiencing push back from industry-sponsored clinical trial companies on UW Medicine’s policy that the HIPAA form be separate from the consent form. The companies also want HSD to revise the content of the UW HIPAA authorization form, which has been vetted heavily by UW Privacy Office. Karen has tasked Wendy Brown and Arna Elezovic in HSD to work with UW Medicine to introduce some flexibility in the form to respond to contract issues. They will also ask UW Medicine to provide a letter showing that they require that the HIPAA Authorization be separate from consent to mitigate these industry issues.

Standing Item: Process Improvement Efforts (Karen Moe)

Karen provided an update on HSD Metrics reflecting turn-around time for modifications. HSD is continuing to refine performance metrics for the Division’s workload. HSD has been publishing information on turnaround times for applications for about two years now. The next step will be to publish turnaround times on modifications, which are more challenging to extract because of the database infrastructure, however, the database manager has found a way. The next report will be provided to HSPB to review in January 2012


NIH and DHHS are very concerned about the type of research that allows exceptions to requiring informed consent in human subjects research. They convened a meeting sponsored by DHHS out of the Office of the Secretary of Preparedness and Response. Those present were concerned about emergent research mainly arising from some type of pandemic response, which must go through IRB review quickly and appropriately. The UW was only one of two academic institution attendees (with representation from UW faculty and UW compliance offices) asked to attend the meeting. The first day was focused on problem solving of IRB review processes and discussion of the possibility of having a single central IRB that reviews these emergency medicine studies. The second day focused on recommendations to federal agencies. UW and Harvard were the two institutions nominated to be the single central IRBs that review this type of research.


Karen was invited to provide testimony at the Commission because of the UW’s longstanding compensation program on human subjects research-related injuries. One of the charges to the Commission is to look at the state of human subjects protections, which was the focus of the meeting that Karen attended. Topics addressed included the Advanced Proposed Rule Making, accountability and transparency, and compensation for injury (for which Karen was invited to speak).

One of the Commission’s recommendations is to create a minimal national database that lists all human subjects research as a result of federal agencies not being able to list all the research studies they are funding. The purpose of the database would be to ensure transparency and accountability. They will also provide a detailed response to the proposed changes in rulemaking, first talking about what needs to be pruned in the regulations and then next, addressing recommended additional regulations to enhance human subjects’ protection.
5. **Researcher education about human subjects requirements, responsibilities, & processes (Karen Moe)**
   - The need for improving education to researchers on research compliance is growing. UW researchers are expected to be aware of and comply with regulations that govern their research. However, UW has a decentralized compliance structure, which challenges our ability to inform researchers and administrators on what they need to comply with. As a result, numerous noncompliance problems have arisen, discovered through multiple venues. Noncompliance poses real institutional risk, risk to researchers, and reputational risk. The questions are who is responsible for educating UW researchers, how should education be done, and what are the contributing factors?

   - How should the need be addressed? Committee suggestions include:
     - Create a high-quality online education with tracking system, since topics are complex and not everyone can get to the same central physical location.
     - Coordinate with Alison Wylie and her Biological Futures Project, which may incorporate in-person training in these areas.
     - Personalize in-person training by recruiting teaching faculty who students are familiar with and implement discipline-specific training in small groups.
     - Board member Wylie Burke, although unable to attend the HSPB meeting, would also like to commit effort towards improving education in the responsible conduct of research (RCR).

6. **Discussion item: New Administrative Policy Statements (APS) on privacy and security (Jeff Cheek)**
   HSPB has struggled with how to educate researchers on what privacy and database management issues researchers must be aware of. Jeff described several Administrative Policy Statements (APS) that govern policy and data management at the UW.

   - **APS 2.2.** “University Privacy Policy” http://www.washington.edu/admin/rules/policies/APS/02.02.html is the privacy policy.

**New business/future agenda items (Karen Moe)**
None at this time.

Meeting ended at 10:25 a.m.