MINUTES
HUMAN SUBJECTS POLICY BOARD
http://www.washington.edu/research/main.php?page=orAdvisory&group=hspb
9:00 – 10:30 AM
November 16, 2012
Electrical Engineering 303

Members Present: Elizabeth Berggren, Zane Brown, Steve Buck, Jeff Cheek, Chair, William Jones, Steve Majeski, Ann Melvin, Karen Moe, Jeff Purcell, Carol Rhodes, Karen Thomas, Kenneth Thummel, Jennifer Turns, Karina Walters

Members Absent: Wylie Burke, Robert Crutchfield, Kathryn Korslund, Deborah McCutchen, Mark Oberle, Carl Rimmele, John Slattery, Susan Spieker, JoAnne Whitney, Alan Wilensky

Guests: Shannon Sowards

1. Approval of minutes from meetings of 9/21/2012 (Jeff Cheek)
The Board accepted the minutes of the 9/21/2012 meeting as submitted.

Action Item: Post approved 9/21/2012 meeting minutes and final 11/16/2012 meeting agenda on HSPB website.

Jeff announced that candidates have been hired for the Director of OSP and the Associate Vice Provost of Research Compliance. Both will start at the beginning of next year.

2. Standing Items: HSD/IRB Update (Karen Moe)
Regulatory Updates: The PRIM&R (national IRB) meeting will occur the first week of December. OHRP will have a heavy presence there and may discuss the status of the final proposed rule changes. Karen will likely have more information at the January HSPB meeting.

HSD received the final letter from the FDA regarding its recent audit. They accepted the plan HSD provided and now the audit is closed. Karen will provide more information at the January and March HSPB meetings.

Process Improvement Updates: HSD just posted their 16th metrics report, tweaked slightly to call out minimal risk applications involving only medical records review. The report shows a dramatic decrease in the turnaround time of a new application requiring full IRB review. Karen will confirm this trend in the next metrics report.
HSD will replace the medical records review form with a new form *Use of biological specimens and data*, effective at the end of November. This new form is intended to broaden the applicability of the previous form.

There has been some major staff turnover of staff that support Committee J and the subcommittee that review J minimal risk applications.

HSD has hired a new trainer and new minimal risk reviewer. Additionally, HSD is continuing to convert old forms into PDF smart forms.

3. **HSD and Research Roadmap: progress toward an e-submission system (Karen Moe)**
   The Office of Research hired a Business Analyst (BA) to map HSD and IRB processes, and manage the e-submission project. The BA has been working with to conduct a needs assessment of HSD, partner offices, IRB and researcher perspectives. When the needs assessment is completed, HSD will compare the advantages and disadvantages of buying a system versus building their own electronic system. It will likely take approximately two years before an active electronic system is in place.

HSD will also do a formal assessment of peer institutions similar to UW to identify systems they use and what their experiences have been.

4. **Publication of PASS Council’s “Social Media Guidelines (Jeff Cheek)**
   The Chief Information Security Office (headed by Kirk Bailey) led an effort to establish guidelines and training to remind the UW community that the use of online tools in the conduct of University business contain risks particularly involving privacy. For example, what are the risks related to collected subject data using a web-based tool? These guidelines are available online: [http://passcouncil.washington.edu/social-media-guidelines/](http://passcouncil.washington.edu/social-media-guidelines/) as well as a brief training module: [http://ciso.washington.edu/resources/online-training/](http://ciso.washington.edu/resources/online-training/)

5. **Financial conflicts of interest for non-UW researchers and IRB review (Jeff Cheek)**
   There are occasionally Key Personnel who are not UW employees who are listed on an IRB protocol. The IRB has no authority over non-UW personnel to disclose a financial conflict of interest. GIM-10 only applies to UW personnel. Jeff will ask the Attorney General’s office their legal perspective on when the UW IRB has the authority to impose restrictions on non-UW personnel.

6. **ORI’s invitation for UW to participate in an IRB – Research Integrity Officer (RIO) meeting in January 2013 (Jeff Cheek)**
   The Office of Scholarly Integrity (OSI) invited the UW to participate in a meeting in mid-January to discuss the inherent conflict of federal regulations governing confidentiality in investigations of allegations of scientific misconduct and the IRB’s need to know if subjects are at risk. Since scientific misconduct investigations are some of the most sensitive and invasive, ORI wants input from institutions on how and when these investigations may impact research subjects. HSD has inconsistently been informed about ongoing alleged scientific misconduct investigations, which has put HSD in the awkward position of not knowing what to do with the information.

7. **New Business/Future agenda items (Board Members)**
   None

Meeting ended at 10:09 a.m.