MINUTES
HUMAN SUBJECTS POLICY BOARD
http://www.washington.edu/research/main.php?page=orAdvisory&group=hspb
9:00 – 10:30 AM
March 9, 2012
Gerberding 142

Members Present    Members Absent
Buck, Steven    Berggren, Elizabeth
Cheek, Jeff, Chair    Brown, Zane
Crutchfield, Robert    Burke, Wylie
Jones, William    Chronister, Lynne
Korslund, Kathryn    McCutchen, Deborah
Majeski, Steve    Oberle, Mark
Meisinger, Richard    Slattery, John
Melvin, Anne    Spieler, Susan
Moe, Karen, Acting Chair
Purcell, Jeff
Rimmele, Carl
Takeuchi, David
Thomas, Karen
Thummel, Ken
Whitney, Joie
Wilensky, Alan

Guests:
Shannon Sewards
Ella Mae Kurashige

1. **Approval of minutes from meetings of 11/18/2011 (Jeff Cheek)**
   The Board accepted the minutes of the 11/18/2011 meeting as submitted.

   **Action Item:** Post approved 11/18/2011 meeting minutes and final 3/8/2012 meeting agenda on HSPB website.

2. **Standing Items: HSD/IRB Update (Karen Moe)**

   **Regulatory Updates**
   The compliance team will begin preparing an annual compliance report which will reflect HSD observed patterns and trends; this will be provided to the Board yearly.

   Post-approval monitor position status: The first round of interviews with the top three candidates has occurred and the next round of interviews will occur in two weeks. The position will likely be filled in the next two months. Karen will ask HSPB members to help develop a post-approval monitoring program.

   Internal Audit update: HSD went through an internal audit in January 2010 with the final report just being completed yesterday. The primary findings include the need for a post-approval monitor program, concerns with missing written policy and procedures, need for additional training of IRB
staff, members and researchers, and problems with inaccurate language contained in Presidential Executive Order 24 (i.e., UW policy that is not in compliance with current federal regulations) (see below).

**Process Improvement Updates**

HSD Staffing: All review-type positions are filled, which is an improvement from six months ago. HSD is currently looking for a second Assistant Director of Operations to help with reducing the burdensome workload of the existing sole Assistant Director of Operations. The job vacancy is posted and has received a fair amount of national interest. The Training Director position is now vacant, leaving HSD with no trainers. The management team is working on filling this position very quickly, which is a good opportunity to revise the program.

Handout: National Benchmarking of IRB Turn-around Time. The handout reflects findings of two major organizations that collect IRB metrics: AAHRPP and IRBNet. The findings reflect overall exempt, minimal risk, and full review turnaround times in days. The UW is very competitive compared to published results, with equivalent or lower median averages (e.g. exempt review turnaround times). One limitation of such benchmarking compilations is that each institution starts the clock for calculating turnaround times differently, which is not reflected in the overall findings.

Handout: Research Roadmap and HSD. HSD has been working with ORIS to identify goals with regard to development of an e-submission system for IRB applications. HSD has hired someone to help draft detailed process maps. HSD has two deliverables: create detailed HSD process maps to reflect how they do work to identify gaps, inefficiencies and redundancies and the other is to identify ideal goals for a web-based submission system and identify pros/cons of buying such a system. An electronic system will be several years in development, but HSD has initiated this project. Karen will provide periodic updates to HSPB.

3. **Report: Subject number issues (Karen Moe)**

HSD revised some forms to consistently define subjects and capture subject numbers, since they found that the applicants’ answers to some of the questions were inconsistent. Campus had some complaints about the revised questions. HSD staff has taken another look at how questions are asked and taken another attempt to revise the questions accordingly. HSD has looked at existing regulations and have interpreted them to mean that only subjects who have completed all procedures in a study should be counted, versus the number of subjects who are screened at the beginning of the study. The initial application will ask investigators to reflect how many subjects are needed to complete the study, and routine status reports will capture those individuals who have dropped out due to serious side effects. HSD will obtain feedback from campus, IRB Committees and HSPB to evaluate and provide feedback on revisions.

This item will be placed on May 2012 HSPB agenda to further discuss.

**Action Items:** Place item on May 2012 HSPB agenda.

4. **Discussion: UW Presidential Executive Order 24 “Use of Human Subjects” (Karen Moe)**

One finding from the internal audit resulted in HSD being out of compliance with Presidential EO24, version 1972, describing the use of human subjects in research. Karen worked closely with Internal Audit to identify exactly where EO24 is out of compliance with external regulations. HSD found that the order is inconsistent with current federal regulations and other current statutes that govern HSD policy and procedures. HSD will recommend to Faculty Senate that EO 24 be revised to remove
inaccurate content and so that it presents more of a high-level concept to ensure the protection of human subjects at UW.

There is also a gap where there is a lot of research that requires interactions with humans who, by federal definition, are not “human subjects” and thus not subject to IRB policy. HSD will recommend that a code of conduct be established to describe expectations of faculty involved with such activities.

5. Discussion: New PHS regulations on Financial Conflicts of Interest and upcoming revision of UW significant financial disclosure policy (GIM-10) (Jeff Cheek)

Jeff walked through his presentation from a recent Monthly Research Administrator Meeting (MRAM) describing the purpose of tracking financial conflicts, what constitutes a significant financial interest (SFI), and how the UW needs to revise its policy to ensure compliance with new federal regulations. UW policy GIM-10 reflects federal regulations established in 1995, as well as related issues regarding the State Ethics Act (e.g., restrictions on use of state resources for private gain); GIM-10 applies to all research, externally sponsored or not. GIM-10 will be revised to reflect the revised PHS regulations; the discussion what will impact all researchers versus only those funded by PHS. UW is still figuring out how to implement the more problematic PHS regulations, which will go into effect on August 24, 2012.

Main changes in PHS regulations: (1) lower minimum threshold from $10,000 to $5,000 for disclosure of compensation for services or equity interest in a publicly traded company, with a $0 threshold for disclosure of equity in a non-publicly traded company; (2) requires investigators to disclose all SFI related to their institutional responsibilities (rather than only those related to the PHS-funded research); (3) increases the institution’s responsibilities reporting SFIs related to PHS-funded awards; managing financial conflict of interests; and ensuring sub-recipient compliance; (4) requires public transparency by use of either a publicly accessible website or a written response to any requestor within five business days of a public records request; (5) requires all PHS-funded investigators to complete mandatory training prior to engaging in research related to any PHS-funded grant or contract, with re-training required every 4 years; (6) PHS-funded investigators must disclose the occurrence of travel paid directly to them by an external entity; some exceptions are allowed. The institution must subsequently determine if any travel reimbursement is a financial conflict of interest with respect to the investigator’s PHS-funded research.

The revised UW GIM-10 will need to be vetted by the Attorney General’s Office to ensure compliance. Jeff walked through what will change for everybody versus just PHS-funded investigators. Everyone will be subject to new thresholds and disclosure requirements. ORIS will develop an electronic disclosure process. PHS-funded investigators will have to take training and disclose travel reimbursements. There are still processes that need to be identified and developed. Updates and the communication process will be forthcoming.

6. New business/future agenda items (Board Members)

None at this time.

Meeting ended at 10:30 a.m.