MINUTES
HUMAN SUBJECTS POLICY BOARD
http://www.washington.edu/research/main.php?page=orAdvisory&group=hspb
9:00 – 10:30 AM
May 11, 2012
Gerberding 142

Members Present
Buck, Steven
Cheek, Jeff, Chair
Chronister, Lynne
Jones, William
Majeski, Steve
Moe, Karen
Purcell, Jeff
Slattery, John
Takeuchi, David
Thummel, Ken
Whitney, Joie
Wilensky, Alan

Members Absent
Berggren, Elizabeth
Brown, Zane
Burke, Wylie
Crutchfield, Robert
Korslund, Kathryn
McCutchen, Deborah
Melvin, Ann
Rimmele, Carl
Speiker, Susan

Guests:
Wendy Brown
Ella Mae Kurashige
Shannon Seward
Stefan Shipman

1. **Approval of minutes from meetings of 3/9/2012 (Jeff Cheek)**
The Board accepted the minutes of the 3/9/2012 meeting as submitted.

   **Action Item:** Post approved 3/9/2012 meeting minutes and final 5/11/2012 meeting agenda on HSPB website.

2. **Standing Items: HSD/IRB Update (Karen Moe)**
   **Regulatory Updates:**
   In June, the FDA will propose an increase in enforcement and penalties to investigators who don’t register their clinical trials within a certain time frame. Karen will keep the Board updated on the progress.

   **Process Improvement Updates:**
   In the past year, HSD has focused on an effective change management approach.
   1. HSD’s overall approach involves a combination of analysis and implementation. The analysis involved recognizing the unique challenges presented by people and (e.g., staff turnover, experience, flexibility), processes (e.g., benchmarking with peer institutions) and culture (e.g., attitudes of staff and campus). Campus has provided several positive comments on process improvements.
   2. Future efforts will include more change management efforts and working via the Research Roadmap initiative to automate more processes.
3. **Compliance report 2011 (Stefan Shipman)**

Stefan Shipman, new HSD Compliance Administrator, will take over as the institutional point person for compliance in HSD. HSD will communicate this to campus in the next couple weeks. Stefan provided an overview of investigation findings that occurred in 2011:

- Generally investigations take 30 minutes. 1 out of 3 require a more substantive time.
- In general, the quality of reporting is high. Industry sponsored protocols are locked in so noncompliance tends to be low.
- Tend to see significant numbers of minor noncompliance findings.
- Investigations are prompted by investigators self-reporting.

HSD has created operational definitions of “minor” versus “serious” or “continuing” noncompliance, as federal regulations and guidance do not provide these definitions. Noncompliance reporting patterns help HSD understand what’s going on related to workload and staffing and where targeted education is needed most.

4. **Post-approval Monitoring program: introduction (Wendy Brown)**

HSD has support to create a post approval monitoring program, headed up by Wendy Brown:

Early conceptual basis of the program:
- Will be a Post Approval Verification and Education (PAVE) program
- Addresses trends towards increased non-compliance reports over past three years
- Risk to institution for not having this type of program in place
- Will use collegial and targeted/individual educational approach to confirm that human subjects research done is in compliance with all external and internal regulations/policy.
- Scope will include all UW IRB-approved studies reviewed by full Committee or minimal risk and any UW study that was approved by another IRB on behalf of the UW IRB.

Wendy provided examples of content she would review during a visit (e.g., consent, HIPAA, recruiting, screening, eligibility, etc.).

She will share findings with researchers to not only ensure accuracy of her findings but to also promote a collegial approach with campus. Monitoring reports will not be finalized without input from the researcher. The visits will emphasize strengths of research programs as well as areas for improvements.

Board members were invited to provide feedback on a more final plan. HSD will gather feedback on plan from campus.

**Actions Item:** Wendy will email Jeff her presentation to circulate to rest of the Board.

5. **HSD Workload report and metrics (Karen Moe)**

HSD compared current data to date with respect to data in previous years back to 2008. The main findings include:

- Steady increase in workload
- Increase in workload per FTE in the office
- Increase in workload from unfunded mandates
- Addition of post-approval monitoring
• Increase in workload due to required certification of genetic data submitted to NIH’s dbGaP database
• Increase in workload for management of adverse events and registration of clinicaltrials.gov
• Institution-wide repositories
• Unknown impact of revised NIH expectations about the timing of IRB approval with respect to a new grant award.

6. **Discussion (continued) UW Executive Order 24 “Use of Human Subjects” (Karen Moe)**
Karen will come back in Fall 2012 with a specific proposal to revise this EO (which is not fully compliant with federal regulations).

7. **Update: New PHS regulations on Financial Conflicts of Interest and upcoming (Jeff Cheek)**
**revision of UW significant financial disclosure policy (GIM-10)**
Next week the Office of Research will roll out a general “heads-up” announcement, first using the DDC list. Subsequent emails will go to MRAM and PHS-funded investigators. All faculty will be emailed when there are more definitive communications. The email will let audiences know about the regulations, UW’s forthcoming implementation plan and website. The mandatory training will be ready in June so investigators can complete before the August deadline. Remaining processes are still being developed but will be finalized by late August. Jeff will provide multiple informational sessions throughout the summer to walk people through the training requirements.

**Action Items:** Jeff will forward email to HSPB.

7. **HSD meeting schedule for 2012-2013 (Jeff Cheek)**
The Board agreed to change meetings to the third Friday of September 2012-May 2013.

**Action items:** Schedule 2012-2013 HSPB meetings to third Fridays.

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

Meeting ended at 10:30 a.m.