MINUTES
HUMAN SUBJECTS POLICY BOARD
http://www.washington.edu/research/main.php?page=orAdvisory&group=hspb
9:00 – 10:30 AM
January 21, 2011
142 Gerberding Hall

Members Present
Brown, Zane
Buck, Steven
Burke, Wylie
Cheek, Jeff, Chair
Chronister, Lynne
Crutchfield, Robert
Whitney, Joie
Jones, William
Majeski, Steve
McCutchlen, Deborah
Moe, Karen
Oberle, Mark
Rimmele, Carl
Slattery, John
Takeuchi, David
Thomas, Karen
Thummel, Ken
Turns, Jennifer
Wilensky, Alan

Members Absent
Berggren, Elizabeth
Korslund, Kathryn
Melvin, Ann
Purcell, Jeff
Speiker, Susan

Guests
Shannon Sowards

Approval of minutes from meetings of 9/17/2010 (Jeff Cheek)
The Board accepted the minutes of the 9/17/2010 meeting as submitted.

Action Item: Post approved 9/17/2010 meeting minutes and final 1/21/2011 meeting agenda on HSPB website.

Regulatory updates (Karen Moe):
New FDA draft guidances (when an IND is needed; electronic source documentation)
Guidance describes when an IND application is required for a research study.
Electronic guidance has more to do with electronic case report forms for research studies, rather than hospital medical center records.

New FDA rule requiring a statement in consent forms
Will be implemented a year from March 2011.
New OHRP guidance about IRB approval of research with conditional approval
Guidance for when this type of approval is and isn’t appropriate.

New OHRP guidance about IRB continuing review of research (i.e., annual status reports)
Guidance is primarily for internal HSD processing.

Also, new guidance was recently issued from FDA to describe what sponsors need to report to the FDA.

Process Improvement Update (Karen Moe)
Application intake process at HSD has been revised extensively, resulting in a smoother process and slightly improved turnaround time.

Clarification about what UW research is reviewed by the Hutch’s Cancer Consortium IRB
For UW researchers who are members of the Cancer Consortium: the research is reviewed by the Cancer Consortium IRB. The following exceptions are reviewed by the UW IRB and/or the UW Human Subjects Division: repositories physically maintained at a UW facility; requests for exempt status; requests for a determination that the research does not meet the federal definition of human subjects research.

Improved WIRB turn-around time due to two UW changes
(1) HSD has eliminated the three-day “hold” applied to WIRB-approved documents, because consent forms are now reviewed for UW-specific issues prior to the researcher submitting the IRB application to WIRB. (2) WIRB and the UW agreed to change the reading level requirement for consent forms 8th grade to 8th-10th grade level. This substantially reduces WIRB’s processes and turnaround time for reviewing and revising UW consent forms.

Exemption form revision (and circling back from last meeting about duration of exempt status)
Board members discussed previously about whether or not to allow duration of exempt status to be shorter or longer than current 5-year approval period. Based on staff and Board input, HSD decided to keep the current 5-year approval period.

The new exempt application form is currently being beta-tested. HSD also created more robust guidance documentation to assist researchers in determining if their research is exempt or not.

Other short reports (Karen Moe)

MD members of the IRBs (Shannon)
The School of Medicine recruited a large number of faculty to serve on the UW IRBs. HSD has been able to place more than half of these on an IRB and is working on finding the most suitable schedule for others. Drs. Deborah Schwinn, Wylie Burke, and John Slattery were particularly instrumental in recruiting MDs to serve on the IRBs. John Slattery described how SOM manages commitment level of MD members on other oversight committees. He will send a copy of this guidance to Karen.

Action Item: John Slattery will send guidance on member commitments to Karen.
**Three I’s: IRB coordination with Institutional Biosafety Committee (IBC) and IACUC (animal equivalent of IRB)**

HSD, the IBC, and IACUC have recently started regular meetings, to improve compliance coordination and to reduce any redundancy.

**Discussion: post-approval monitoring**

A comprehensive compliance program (as referenced by the “Federal Sentencing Guidelines”) has eight “elements”. One element is a “post-approval monitoring” process to ensure that researchers comply with all requirements imposed by the IRB and/or institution in the conduct of their research activities. UW does not have a post-approval monitoring process, due to resource limitations.

Researchers do receive training from different sources (e.g., CITI and ITHS). Nevertheless, UW IRBs and HSD compliance staff still observe significant noncompliance issues that may result in risk to subjects as well as to the institution.

In the absence of resources to hire staff dedicated to post-approval monitoring, the UW should consider strategies to address both the individual and institutional risks incurred. For example, requiring that new investigators work with staff well-practiced in conducting research studies, such as the Clinical Research Center, may reduce noncompliance and risks. Another strategy would be for the HSD to identify high risk research and triage which risk issues need to be monitored first.

HSD does have some mechanisms in place to protect the confidentiality of “whistleblowers”. Also, HSD does coordinate with other UW offices, such as Internal Audit and UW Medicine Compliance, in doing a small number of investigations or monitoring.

Points to consider raised by HSPB members:
- The level of risk varies greatly for each research study and thus the post-approval monitoring should be flexible enough to address the relative level of risk.
- Senior faculty as well as junior faculty should be subject to post-approval monitoring.
- It would be a good idea to “benchmark” post-approval monitoring processes at other institutions.
- Post-approval monitoring findings should be published and shared with the broader research community to educate them on the types of issues that are uncovered.
- The status reports submitted by researchers should document all protocol deviations.

Lynne shared that she used to work at an institution that did have post-approval monitoring which included survey assessments; these worked well.

Jeff invited HSPB members to nominate individuals to serve on a task force to determine what UW can do to address post-approval monitoring needs in our resource-strapped environment, with the intent to bring recommendations back to the Board.

**Action Item:** Jeff will work with Karen convene a task force to review potential strategies and establish priorities for identifying research that should be monitored.
**Discussion: UW non-salaried clinical faculty and UW IRB review**

Non-salaried UW clinical faculty whose primary appointment is as salaried employees at other institutions sometimes request that the UW IRB review their research, even when the research funding is going through the non-UW institution. Karen raised the issue of whether the use of the UW IRB is an appropriate privilege to grant in this situation.

The issue HSD is most concerned about is that the UW has no authority over these individuals who are not UW personnel, which increases institutional risks and possible risks to subjects. The workload for HSD is significant enough that this issue has become one of workload as well as institutional liability. Also, is the UW truly engaged in human subjects research as defined by the federal government when the investigators are conducting said research at another institution (and the funding does not flow through the UW)?

The Board suggested that a task force be convened to discuss these issues and possible solutions. Board members suggested the following individuals as some possible members:

- Mark Green from SOM Finance and Administration
- Dr. Larry Robinson (SOM Vice Dean, Clinical Affairs and Graduate Medical Education)
- Faculty representative from Psychology
- Representative from Academic HR

**Action Item:** Jeff and Karen will convene a task force to identify issues and potential solutions.

**Discussion: Elimination or revision of IRB appeal process**

HSD’s appeal process allows researchers to formally disagree with an IRB’s decisions under certain circumstances. There have been three appeals in the last six months. Each appeal takes a lengthy time. Researchers appear to mis-understand what is meant by “appeal”, and to request this lengthy process simply out of disagreement with the IRB rather than because there is a mis-understanding or inaccurate information. Therefore, HSD proposed eliminating or revising the appeals process.

The Board recommended that the appeals process be revised, not eliminated, so that there is still a clearly communicated process in place to allow investigators to have a dialogue with the IRB. The revision should continue the current practice of inviting the researcher to attend the IRB meeting.

**Action Items:**
- Revise the appeals process to include existing IRB practice.
- Bring back revised process to March HSPB meeting.

**New business / future agenda items (Board Members)**

The next HSPB meeting occurs in March 18, 2011. No members had any suggested issues.

The meeting ended at 10:30 a.m.