MINUTES
HUMAN SUBJECTS POLICY BOARD

http://www.washington.edu/research/main.php?page=orAdvisory&group=hspb
9:00 – 10:30 AM
January 18, 2013
Gerberding 142

Members Present
Elizabeth Berggren
Zane Brown
Jeff Cheek, Chair
Robert Crutchfield
Kathryn Korslund
Karen Moe
Mark Oberle
Jeff Purcell
Carol Rhodes
John Slattery
Karen Thomas
Kenneth Thummel
JoAnne Whitney
Alan Wilensky

Members Absent
Steve Buck
Wylie Burke
William Jones
Steve Majeski
Ann Melvin
Deborah McCutchen
Carl Rimele
Susan Spieker
Jennifer Turns
Karina Walters

Guests:
Emily Guthrie
Shannon Sowards

1. Approval of minutes from meetings of 11/16/2012 (Jeff Cheek)
   Jeff will send the 11/16/2012 meeting minutes off-line for Board member review and approval.

   Action Item: Post the 11/16/2012 meeting minutes after the Board approves as well as the final
   1/18/2013 meeting agenda on the HSPB website.

2. IRB Chair acknowledgement (Karen Moe)
   IRB Committee B Chair Alan Wilensky is stepping down from that position. Jeff asked that the
   Board recognize Alan’s longstanding commitment to HSD and his service to the UW. He has been
   an IRB Chair since 1989 and will continue to serve as a Neurology consultant for the IRBs.

3. Standing Items: HSD/IRB Update (Karen Moe)
   Regulatory Updates:
   The Department of Health and Human Services (HHS) published a statement that it plans to publish
   draft human subjects’ regulations in April 2013. Karen will keep members informed.

   The Commerce Department revised the Children’s Online Privacy Protection Act (COPPA),
   published January 2013, which will be implemented March 2013. The Act was broadened to now
   apply to research studies and requires new protections to include obtaining consent from parents of
   children. Karen will work the Attorney General’s Office to determine how this new rule should be
   implemented at the University.
4. **Official launch of the Post-Approval Monitoring Program (Karen Moe)**

   HSD has developed its post-approval monitoring program called Post Approval Verification and Education Program (PAVE). The charter and procedures have been developed. Four post-approval monitoring visits have been performed as a “beta test”. Now the official program is being launched. Karen Moe presented a 5-7 minute Powerpoint presentation, which was followed by Q-and-A with the Board members. Discussion points include:
   - Approach is educational and collegial by observation.
   - The objective of PAVE is to give IRBs an inside look about how studies are conducted relative to what the IRB has approved.
   - Regulations grant authority to IRBs to observe; most of our peer institutions already have a post-approval monitoring program.
   - Will start with investigator-initiated studies using IND or IDE applications, and some studies at the request of the UW IRB.
   - Review will include recruitment, screening, eligibility, whether or not appropriate consent/HIPAA was obtained, study procedures conducted appropriately, tracking of IRB approval dates/requirements, oversight by lead researcher and other aspects as appropriate.
   - Final findings will be reported and will include deviations from protocols, noncompliance as well as strengths. They will be reported to the lead researcher, IRB Committee and responsible offices and will include suggested remedies.
   - Approximately thirty visits will occur every year.

5. **OHRP Final Audit Report (Karen Moe)**

   Findings and concerns: OHRP provided its final audit report to HSD a couple days before Christmas, for the on-site audit that occurred in September 2012.

   HSD has developed a coordinated plan for addressing the findings of the three not-for-cause audits that occurred in 2012. There were twenty-two findings across the three audits with very few issues overlapping across the audits. The corrective actions for several of the findings have already been completed or are in progress.

   A few findings will require significant changes, some of which will affect UW researchers. The significant changes include:
   - Substantial revision and expansion of IRB procedures (“SOPs”);
   - Better identification and management of studies with lapsed IRB approval;
   - Broader application of FDA regulations, to more studies;
   - Improved IRB expertise in reviewing certain types of studies;

6. **Procedure changes (Karen Moe)**

   HSD is planning to change the method used for assigning applications to specific IRBs. The new method will be based largely on the investigator’s department. In other words, applications from a specific department will always be assigned to the same IRB. Karen requested feedback and discussion from the Board members about this plan.

   HSD is also considering implementing a “Restricted” list to help manage and respond to the significant number of studies with lapsed IRB approval. Karen proposed that HSD will not accept new IRB applications from an investigator who has a lapsed approval until that approval has been restored.
7. **Updates from ORI conference in Washington D.C. Jan 14/15, 2013 (Jeff Cheek)**
This was a joint meeting held by the Office of Research Integrity that included IRB officials and Research Integrity Officers that addressed the inherent regulatory conflict between research misconduct investigations and the IRB’s role in protecting human subjects. ORI seeks to publish guidance that helps institutions address the challenges with the need for maintaining confidentiality in misconduct investigations vs. the IRB’s need to know if risks are posed to human subjects.

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

Meeting ends 10:30 a.m.