MINUTES
HUMAN SUBJECTS POLICY BOARD
http://www.washington.edu/research/main.php?page=orAdvisory&group=hspb
9:00 – 10:30 AM
March 18, 2011
142 Gerberding Hall

Members Present
Berggren, Elizabeth
Brown, Zane
Buck, Steven
Spieker, Susan
Burke, Wylie
Cheek, Jeff, Chair
Chronister, Lynne
Crutchfield, Robert
Jones, William
Korslund, Kathryn
Majeski, Steve
Melvin, Anne
Moe, Karen
Oberle, Mark
Rimmele, Carl
Slattery, John
Thomas, Karen
Thummel, Ken
Turns, Jennifer
Whitney, Joie
Wilensky, Alan

Members Absent
McCutchen, Deborah
Purcell, Jeff
Takeuchi, David

Guests
Shannon Sowards

Approval of minutes from meetings of 1/21/2011 (Jeff Cheek)
The Board accepted the minutes of the 1/21/2011 meeting as submitted.

Action Item: Post approved 1/21/2011 meeting minutes and final 3/18/2011 meeting agenda on HSPB website.

Standing item: Regulatory updates (Karen Moe):
Although there are no regulatory updates for this agenda, regulatory updates will continue to be a standing item on future agendas.
Standing item: Process Improvement Update (Karen Moe)

*Revised Exemption application form*
Major revisions to this form and creation of new guidance have been received favorably. Campus will be informed of an interactive PDF of the form (implementation to be by April 1).

*Case Reports form and guidance*
HSD has created questions and flow chart to help researchers self-determine if they need IRB review for their case report.

*Most recent metrics report: improved full committee turn-around time*
Overall range for turnaround times of initial IRB applications has gotten better. Reasons for why turnaround times may vary are based on variety of reasons which the report does not reflect. HSD will better be able to track reasons for delays once PIs can submit forms online.

*NSF proposals and JIT (Just In Time) IRB reviews*
From the UW IRB perspective, researchers do not have to complete an IRB application at the same time they submit an NSF proposal. Instead, PIs who check yes on their eGC1 to needing an IRB application will receive a reminder from HSD five months later requesting an IRB application if NSF funding is received.

*Other brief announcements (Karen Moe/Jeff Cheek)*
UW, as part of WWAMI region, to cosponsor a conference along with Children’s Hospital Regional Medical Center (CHRMC) and Fred Hutchinson Cancer Research Center (FHCRC). The conference is sponsored by The Office of Research Integrity (ORI) and will be held September 22nd and 23rd on the UW campus in Meany Hall. An agenda and conference website is forthcoming. The tenor of the meeting will be focused on collaborations between international and domestic researchers and biobanks.

Board member John Slattery provided names of staff from his school who could assist in conducting break out sessions covering both conflict-of-interest and significant financial conflict-of-interest as well as the adjudication of research misconduct.

**Action Item:**
- John Slattery, Karen Ellidge, or Dan Schwartz would be interested in participating in financial conflict-of-interest break-out sessions.
- Jeff will circulate a conference planning update.

**Discussion: Revised Appeals Policy and Procedure (Karen Moe)**
HSD revised the appeals policy and procedures in January to make the process clearer to researchers. Revisions include clarifying that researchers can appeal to the same IRB to change its decision if the decision was due to inaccurate information, a misunderstanding or IRB noncompliance.
Discussion: Researcher Non-Compliance (Karen Moe)

Policy and procedure (especially definitions, roles & responsibilities, IRB options, consequences to researcher)

HSD has developed new policy and procedures to describe noncompliance, a compliance team, a more systematic way of tracking noncompliance which the IRB will review and approve. Once the policy and procedures are approved, they will be distributed widely throughout campus.

Over-enrollment
Postpone to the next HSPB meeting.

2010 Non-compliance Report
Karen provided a summary of all determinations of noncompliance as tracked by the HSD compliance team which included 83 reports of noncompliance documented in 2010: 53 were minor noncompliance, 5 were serious or continuing, 16 were found not to be noncompliant, 6 were found to be IRB versus researcher noncompliance.

The compliance team also tracks the type of researcher noncompliance. The biggest category of researcher noncompliance is *not following procedures as approved by IRB*. HSD is tracking these trends because it will help them in determining what guidance to provide and which forms to revise to clarify instructions. One member noted that some of the numbers don’t add up in the first table. Karen will check with compliance team and revise the table appropriately.

HSD will continue to track and identify trends in noncompliance. Any trends will be reported to the HSPB.

Action Items:
- Karen will check with compliance team regarding errors in the first table.
- The topic of *overenrollment* will be posted on the next HSPB agenda.

Follow-up items: Creation of Task Forces

Post-approval Monitoring: Jeff will follow-up with specific HSPB members regarding serving on a task force.

Non-salaried clinical faculty and UW IRB review: Jeff will follow-up with specific HSPB members regarding serving on a task force.

New business / future agenda items (Board Members)
The next HSPB meeting occurs May 20, 2011. No members had any suggested issues.
Meeting ends 10:40 a.m.