Members Present: Zane Brown, Jeff Cheek, Chair, Steve Majeski, Ann Melvin, Karen Moe, Mark Oberle, Jeff Purcell, Kenneth Thummel, Jennifer Turns, JoAnne Whitney, Karen Thomas, Karina Walters
Members Absent: Elizabeth Berggren, Steve Buck, Wylie Burke, Robert Crutchfield, Jane Hitti, William Jones, Kathryn Korslund, Deborah McCutchen, Carl Rimmle, Susan Spieker

Guests: Emily Guthrie, Maria Savage, Shannon Sowards

1. **Review of minutes from meeting of 3/15/2013 (Jeff Cheek)**
   The Board accepted the minutes of the 3/15/2013 meetings as submitted.

   **Action Item:** Post the 3/15/2013 meeting minutes and the final 5/17/2013 meeting agenda on the HSPB website.

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

   **Regulatory Updates:** OHRP recently published a determination letter regarding a multi-site study that uses high oxygen levels to support neonates. OHRP’s main finding was that “standard of care” risks were not adequately described in the consent forms. The P.I.s and colleagues are arguing against the allegations and stated that they followed standard care procedures for the use of oxygen in neonatal care. Note that the UW was not one of the study sites. Karen will provide more information at the next HSPB meeting.

   **Process Improvement efforts:**
   With respect to e-submission, HSD is making progress in identifying potential commercial electronic systems as well as completing the “build vs. buy” due diligence. They have begun interviewing peer institutions about the systems they use.

   HSD continues to hear from P.I.s about the complex clinical trial start-up process for industry-sponsored clinical trials. Recently HSD learned that many P.I.s continue to submit applications and
materials sequentially to respective oversight offices, rather than concurrently. Concurrent or parallel submission is strongly encouraged as an important way to reduce start-up time.

HSD will continue to use the FHCRC IRB to review oncology studies. FHCRC has asked the UW to pay a fee for each review, since the workload associated with UW investigators has increased significantly over the last few years.

All staff positions in HSD are now filled which includes the hiring of a new regulatory compliance manager.

3. **Information: Standard Operating Procedures (SOP) Renovation Project in HSD (Karen Moe)**

HSD is developing SOPs that will help both IRB staff and investigators find and follow its policies. Staff will receive intensive training on the new or revised SOPs, which will involve multiple days (including a couple of full day retreats where the HSD will be closed for business). This training will allow staff to provide any input into the SOPs. IRB members will also be trained on all relevant SOPs. HSD will publish all new or revised SOPs on their website by the end of September, which will also include an improved organization for search capability.

Along with SOPs, there will be “tools” that will help inform the staff and IRB on HSD’s processes. These include worksheets will be publicly posted that can be used by staff and researchers. The worksheets will help both staff and PIs identify whether or not a specific project meets the definition of human subjects research, in addition to many other considerations such as institutional engagement. Worksheets will be posted at the end of each month through October, with the earliest one being posted in June.

**Action Item:** Karen will circulate draft worksheets to the HSPB for their input, questions and concerns.

4. **Discussion: Proposed changes to Executive Order 24 (UW policy governing human subjects research) (Karen Moe)**

Changes to EO 24 are being prompted by a 2012 audit finding by UW Internal Audit. The finding identified that EO 24 is out of date, contains inaccurate information, and does not delegate authority for oversight of human subjects research to the VP of Research. HSD has worked with the President’s office to produce a draft revised EO to replace the old EO.

Karen worked with Rebecca Deardorff on formatting, and received chief-of-staff Jack Johnson’s approval. In a couple weeks, Karen will present the draft EO to the Faculty Council on Research and the Research Advisory Board. One HSPB member recommended that Karen take out her contact information and instead include a generic HSD contact. The final step is to obtain Faculty Senate review.

**Action Item:** Revise EO 24 draft to include general HSD contact information.

5. **Continuing discussion: harmonization across UW IRBs (Karen Moe)**

HSD understands that there are occasional inconsistencies in how the individual UW IRBs handle some challenging issues, such as what are considered best practices for contacting potential and active human subjects via social media. Some investigators experience inconsistent reviews and requirements because of gaps in SOPs (now being corrected). HSD recognizes that inconsistencies among the IRBs aggravate P.I.s. However, since IRBs function much like peer review panels, there will always be a dynamic of different reviewers having her/his own opinions as to what constitutes a
best practice. Nonetheless, there are several efforts underway that should encourage greater consistency between the different IRBs.

The new/revised SOPs will help provide guidance and resources both to IRBs and researchers. One Board member suggested that the IRB Chairs routinely meet to discuss development of some standard practices. HSD staff is trying to assign the same reviewers, when possible, who reviewed the initial application to also review the renewals.

One Board member offered to help identify inconsistencies between IRBs. Karen suggested that this topic be discussed at the 2nd HSPB meeting next year, after implementation of six pending major changes that will occur prior over the summer and which should help improve the consistency of IRB review.

**Action Item:** Solicit IRB Chairs on what inconsistencies they perceive between IRBs.

6. **Discussion: Upcoming changes to review process for Confidentiality Agreements (as required by RCW 42.48) (Jeff Cheek)**

State law RCW 42.48 describes that state agencies or their affiliates that have records with identifiable information must protect the privacy of the records. Additionally, the state law indicates two responsibilities: 1) The IRB must determine when waiver of consent is appropriate for researchers to use any personally identifiable information from the state agencies, without the individual’s consent, and 2) the state institution must sign a legally binding Confidentiality Agreement with the researcher. It is not clear which office would be responsible for the 2nd step, which presents not only a workload issue but an institutional risk. HSD has been taking on this responsibility of facilitating Confidentiality Agreements, a practice that UW Internal Audit identified as inappropriate. A task force is assessing whether the authority for entering into Confidentiality Agreements should be delegated to the UW Data Custodian for each area of content. This would require significant education and outreach for Data Custodians.

7. **New Business/Future agenda items (Board Members)**

Next year’s meetings are to be scheduled. Board members agreed that meeting from 9 – 1030 AM on the 3rd Friday in September, November, January, March and May will continue to work best for the majority of the Board.

Meeting ended at 10:30 a.m.