AGENDA

HUMAN SUBJECTS POLICY BOARD
http://www.washington.edu/research/main.php?page=orAdvisory&group=hspb

9:00 – 10:30 AM
January 21, 2011
Gerberding 142

1. Approval of minutes from meeting of September 17, 2010     Jeff Cheek

2. Regulatory Updates     Karen Moe

   • New FDA draft guidances (when an IND is required; electronic source documentation)
   • New FDA rule requiring a statement in consent forms
   • New OHRP guidance about IRB approval of research with conditions
   • New OHRP guidance about IRB continuing review of research (i.e., annual status reports)

3. Process Improvement Updates     Karen Moe

   • Application intake process
   • Clarification about what UW research is reviewed by the Hutch’s Cancer Consortium IRB
   • Improved WIRB turn-around time due to two UW changes
   • Exemption form revision (and circling back from last meeting about duration of exempt status)

4. Other brief reports     Karen Moe / Shannon Sowards

   • MD members of the IRBs (Shannon)
   • Accepting 2-sided applications and materials
   • Three I’s: IRB coordination with Institutional Biosafety Committee (IBC) and IACUC (animal equivalent of IRB)

5. Discussion – Post-approval monitoring     Zane Brown

6. Discussion - UW non-salaried clinical faculty and UW IRB review     Karen Moe

7. Discussion – Elimination of IRB appeal process     Karen Moe

8. New business / future agenda items     Board Members

Next meeting:      March 18, 2011, 142 Gerberding