AGENDA

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

9:00 – 10:30 AM
May 20, 2011
Gerberding 142

1. Approval of minutes from meeting of March 18, 2011
   Jeff Cheek

2. Standing item: Regulatory Updates
   Karen Moe
   • New FDA Guidance: Emergency Medicine and Waiver of Consent
   • HIPAA enforcement news (recent fines imposed by federal agency)
   • Several minor changes in consent form template due to regulatory or compliance issues
   • Internal Audit compliance audit of HSD

3. Standing item: Process Improvement Updates
   Karen Moe
   • Two-sided copying policy starts June 1
   • Definition of human subject
   • HSD work group on social media
   • Metrics on modifications
   • HIPAA policy and procedures
   • Approval in Principle
   • Pilot projects
     o Workflow flexibility re who does minimal risk reviews
     o Initial application: what materials do the IRB members receive?

4. Other brief announcements
   Karen Moe / Jeff Cheek
   • “Ethical Considerations in Research Collaborations” Sept. 22/23, 2011

5. Discussion – new HSPB meeting date/time for FY 2012?
   Jeff Cheek

6. Discussion – IRB as “final compliance checkpoint?”
   Karen Moe

Should the IRB withhold final full approval until after other relevant compliance requirements have been fulfilled, so that there is institutional oversight to ensure that compliance requirements are met? Current status: ambiguity. It is handled different across the IRB committees and, within an IRB, across studies. Significant discomfort about this lack of clarity: are we doing our job properly?

The other compliance requirements are:
• Radiation Safety approval
• Institutional Biosafety Committee (IBC) approval
• Radioactive Drug Research Committee (RDRC) approval
• Material Transfer Agreements (MTAs)
• Significant Financial Interest review (SFI)
• Completion of a funding contract
• IRB Authorization Agreements with other institutions
• Devices: cleared for billing to Medicare
• Data Use Agreements

_Metrics._ **The turnaround time for solely the IRB's approval can easily be separated from the overall turnaround time for obtaining all of the above approvals.**

7. Follow up items – Creation of Task Forces
   • Post-approval monitoring
   • Non-salaried clinical faculty and UW IRB review

8. New business / future agenda items

Karen Moe / Jeff Cheek

Board Members