Members Present
Elizabeth Berggren
Zane Brown
Steve Buck
Jeff Cheek, Chair
Robert Crutchfield
Kathryn Korslund
Steve Majeski
Ann Melvin
Karen Moe, Acting Chair
Mark Oberle
Jeff Purcell
Carol Rhodes
Karen Thomas
JoAnne Whitney
Alan Wilensky

Members Absent
Wylie Burke
William Jones
Deborah McCutchen
Carl Rimmele
John Slattery
Susan Spieler
Kenneth Thummel
Jennifer Turns
Karina Walters

Guests:
Shannon Sewards

1. Approval of minutes from meetings of 5/11/2012 (Jeff Cheek)
Since the 5/11/2012 the minutes were released a day prior to the 9/21/2012 HSPB meeting, Board members were given additional time to review. Jeff asked members to provide edits by Tuesday of next week. One correction to the minutes is that Board member Steve Majeski was present at the last meeting but is documented as absent.

Action Item: Post corrected and approved 5/11/2012 meeting minutes and final 9/21/2012 meeting agenda on HSPB website after Tuesday 9/25/2012.

2. Standing Items: HSD/IRB Update (Karen Moe)
Regulatory Updates: None have occurred since last HSPB meeting.

Process Improvement Updates:
- NEW Assistant Director for Social/Behavioral Operations Emily Guthrie was hired. This new position was added to management team. This new position will allow HSD to split operations between biomedical and social behavioral and to allow for more specific staff focus on the two areas.
- NEW form to replace and expand use of Medical Records Review form: Use of Identifiable Specimens or Data. This smart PDF form is now available on HSD website.
- Status of the post-approval monitoring program: Two pilot post-approval monitoring visits have occurred to date and a third and fourth pilot will occur soon. After a few more pilots, the program will be final and rolled out to campus to provide input.
• The IRB File Standardization project will help IRB members and Chairs by facilitating their ability to review documents. This project began its one-year implementation period in late July.

3. **HSD’s audit trifecta of 2012 (Karen Moe)**

HSD underwent three not-for-cause audits by three different agencies. It had been at least seven years since the last audit by each agency. Audit #1 was conducted by UW Internal Audit over a one-year period, and was completed in March 2012. Audit #2 was conducted by the Drug Division of the Food and Drug Administration (FDA) during three weeks in late July and early August. Audit #3 was conducted by the federal Office of Human Research Protections (OHRP) in mid-September.

Each audit found non-compliance in some areas. Examples include:

- Failure to report a suspension of IRB approval to the FDA
- Failure to report an adverse event to the FDA
- Missing written procedures in some areas
- Problems with IRB meeting minutes

No restrictions were placed on the UW’s ability to review or conduct human subjects research.

HSD has already provided UW Internal Audit and the FDA with a corrective action plan. A similar plan will be developed for OHRP when the UW receives its final audit report. The use of HSD resources and time will be significantly affected this coming year by the need to address the audit findings. There may also be some significant changes affecting researchers. Specific details will be provided to the Board and to campus as they become available.


Does the academic community feel that this will have ramifications? The approach they are advocating is to let researchers decide if their research will involve no more than minimal risk and to not involve the IRB. This is at odds with well-established tradition so it’s doubtful that this approach will have any impact.

5. **Update: Implementation of the new federal regulations about financial conflict of interest (Jeff Cheek)**

UW now has a revised GIM-10 policy and new electronic disclosure system in place. Jeff has conducted outreach on the new policy and system to numerous academic units. In general, investigators are complying with the new policy and correctly utilizing the new disclosure system. However, investigators are over-reporting significant financial interest (SFI) (i.e., falsely identifying SFI as related to all their research projects) and the Office of Research (OR) has received many more disclosures that anticipated, resulting in an exponential increase in workload. OR will provide more specific education to investigators to reduce the false positive reporting, and adjustments to the Financial Interest Disclosure System (FIDS) should further reduce this problem. Jeff invited members to ask questions or request presentations on the new FCOI regulations.

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

- Which studies are subject to FDA regulations: the coming changes and their significant impact.
- Metrics: Turnaround time for review of new IRB applications: time on the researcher’s desk versus time at HSD

Meeting ended at 10:30 a.m.