Jeff introduced and welcomed guest Mei-Chih Huang, Professor at the Department of Nursing at the National Cheng Kun University and President of the Taiwan Association of Nursing Education. She is a Fulbright scholar and a former student of HSPB member Karen Thomas. New HSPB members Dick Meisinger and Jeff Purcell introduced themselves.

Karen Moe unexpectedly was unable to attend the meeting and thus will write and circulate a summary of regulatory updates.

1. Approval of minutes from meetings of 3/18/2011 (Jeff Cheek)
Some HSPB members alerted Jeff of some minor corrections to the minutes prior to the meeting. Corrections will be applied prior to posting the minutes on the HSPB webpage. The Board accepted the minutes of the 3/18/2011 meeting after corrections are applied.

Action Item: Apply corrections and post approved 3/18/2011 meeting minutes and final 5/20/2011 meeting
2. Standing item: Regulatory and compliance updates

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

Action Item: Karen will provide a written summary and circulate through email. Update: these will be modified and updated after the Sept. 10, 2011 meeting.

3. Standing item: Process Improvement Update

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:
The term will be replaced with another term to clarify that only certain activities can occur since researchers were misunderstanding the original term.

Pilot projects
  - Workflow flexibility regarding who does minimal risk reviews
  - Initial application: what materials do the IRB members receive?

Action Item: Karen will provide a written summary and circulate through email. Update: these will be modified and updated after the Sept. 10, 2011 meeting.

4. Other brief announcements (Jeff Cheek)
The Office of Research Integrity has partially funded an upcoming conference “Ethical Considerations in Research Collaborations” which will occur September 22/23, 2011 and will occur at Meany Hall, University of Washington. Nationally distinguished speakers including Jeremy Sugarman and speakers from NIH and NSF will present. Funding from sponsors CHRMC, FHCRC, and ITHS will support graduate students. Information about the conference will be sent to HSPB members. Focus will be on research collaborations, peer-to-peer relationships, mentoring, conflict-of-interest, and cross-cultural collaborations. There will be opportunity for graduate students to volunteer in exchange for paying for conference, such as assisting in Working Groups. We want to first identify how much scholarship will be available before we invite students to volunteer. Abstracts will also be invited and those deemed
sufficiently relevant will be incorporated into conference program. Updates will be sent on when scholarships will be available and when abstracts will be invited.

**Action Item:** Jeff will send conference announcement and flyer to HSPB.

### 5. Discussion: New meeting day/time starting in the fall? (Board members)

Traditionally the HSPB meets five times a year on the third Friday every month and then takes a break during the summer months. However, due to a scheduling conflict for new member Jeff Purcell, IRB Chair of Committee D (which meets on the 1st and 3rd Fridays each month), Jeff Cheek proposed to move the meeting to the second Friday of the month starting in September. The Board agreed to this scheduling change.

**Action Item:** Reschedule HSPB meetings to second Friday of the months of September, November, January, March and May each year.

### 6. Discussion - IRB as “final compliance checkpoint?” (Jeff Cheek)

The Committee was asked to discuss whether or not the IRB should withhold final full approval until after other relevant compliance requirements have been fulfilled so that there is designated institutional oversight to ensure that all compliance requirements are met. The current process is ambiguous and is handled different across the IRB committees and, within an IRB across studies. The alternative is that investigators are provided with IRB approval but that they cannot start their work until all other oversight approvals are granted.

The other compliance requirements include:
- Radiation Safety approval
- Institutional Biosafety Committee (IBC) approval
- Radioactive Drug Research Committee (RDRC) approval
- Material Transfer Agreements (MTAs)
- Significant Financial Interest review (SFI)
- Clinical Research Budget and Billing (CRBB)
- 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. Jeff will follow-up with Karen to determine the risk each compliance review poses.

**Members comments included:**
- Avoid unduly burdening an already burdened office and thus needlessly holding things up.
- One office should ensure all compliance requirements are fulfilled.
- This decision process mainly impacts Clinical Trials or biomedical issues rather than Social Behavioral thus it might be better to create a Clinical Trials HSPB task force.
Some issues are within IRB purview and some are not, such as medical billing issues that CRBB oversees as long as consent contains blanket language that covers that participant won’t be responsible for payment.

A separate Committee called the Research Compliance and Integrity Committee (RC&IC) meets and is overseen by Executive Sponsors. One of the charges of RC&IC is to identify what a comprehensive research compliance program may look like and identifying roles and responsibilities. The part that is missing from the program is ensuring roles and responsibilities. Right now, current work of the RC&IC is focused on developing a webpage that shows investigators all the trainings they are required to take and which office provides the training. The process of identifying which UW office is responsible and what they offer and communicating this to researchers has been a complex process. If investigators are ultimately responsible for ensuring compliance requirements are met, the University has to implement post-approval monitoring to hold the investigators accountable. The RC&IC will discuss post-approval monitoring and possibly come up with a plan in September.

**Action Item:**
- RC&IC discussion of post-approval monitoring will be shared with HSPB next time HSPB convenes.
- Jeff will consult with Karen on the relative risk of each compliance review.
- Create task force to focus on impact of each compliance review.

### 7. Status of Task Forces

**Post-approval Monitoring**

*Non-salaried clinical faculty and UW IRB review*

**Action Item:** Karen will provide a written summary and circulate through email.

### 8. New business/final agenda times (Board Members)

None

Meeting ended at 10:15 a.m.