MINUTES
HUMAN SUBJECTS POLICY BOARD
http://www.washington.edu/research/main.php?page=orAdvisory&group=hspb
9:00 – 10:30 AM
September 17, 2010
142 Gerberding Hall

Members Present
Berggren, Elizabeth
Brown, Zane
Buck, Steven
Cheek, Jeff, Chair
Chronister, Lynne
Whitney, Joie
Jones, William
Korslund, Kathyrn
McCutch’en, Deborah
Melvin, Anne
Moe, Karen
Oberle, Mark
Rimmele, Carl
Spieker, Susan
Takeuchi, David
Thomas, Karen
Thummel, Ken
Wilensky, Alan

Members Absent
Burke, Wylie
Crutchfield, Robert
Majeski, Steve
Purcell, Jeff
Slattery, John
Turns, Jennifer

Welcome and introductions (Board members)
Jeff called the meeting to order at 9 a.m. New and returning HSPB members were welcomed.

Approval of minutes from meetings of 5/21/2010 (Jeff Cheek)
The Board accepted the minutes of the 5/21/2010 meeting as submitted.

Discussion item:  Change the duration of a Certificate of Exemption (Karen Moe)

One of HSD’s goals is to revise all their policy and procedures to make them more efficient and clear, while at the same time ensuring compliant with external regulations. HSD is currently focusing on the forms, policies and procedures related to exemption. Karen raised for discussion the question of whether the current 5-year approval window for exempt studies should be changed to a longer approval window or to an indefinite approval period, unless the researcher changes the research or the work is transferred to a new PI. Some of the challenges to keeping a 5-year approval window include: there is nothing in the federal regulations that describe an ideal exempt approval window, many investigators don’t reapply for exempt status at the end of the 5 years, and HSD does not have a mechanism in place to confirm that investigators are reapplying for exempt status.
In general, the Board agreed that the 5-year window could either be extended or removed as long as there is an increased education effort to investigators on when they should formally modify their existing exempt applications or apply for a new exempt application. However, this was not a unanimous decision. The Board agreed that the larger problem (and one that is not relevant to exempt research) that should be discussed at a future HSPB meeting is how to reduce risk where the IRB doesn’t have ongoing post-approval monitoring (i.e., how to ensure that investigators adhere to their approved protocols).

**Action Items:**
- Discuss how to reduce risk after the IRB has approved a protocol.

**Discussion item: Disclosure of Significant Financial Interest (SFI) in consent forms**
(Karen Moe)

The Office of Research (OR) administers institutional oversight of significant financial interest, also known as financial conflict of interest. When SFI is disclosed by investigators and subsequently addressed by a management plan from OR, the IRB receives a copy of the management plan, and the IRB determines how best to utilize that plan with respect to human subjects research. Although there is no federal requirement to inform subjects about the existence of a significant financial interest, most institutions and regulatory agencies consider it to be a best practice. Board members were asked for their opinion and discussion about adding a section called Financial Interest to the consent form template for all studies with greater than minimal risk, to disclose any significant financial interest of any member of the researcher team or the University. A handout was provided with draft language for the new section.

Board members supported the proposed policy, however, they suggested the following changes:

- Apply this policy to all studies, not just those that are greater than minimal risk. Subjects should be fully informed of any significant financial interest regardless of the risk level.
- Make optional the wording that states that no significant financial interest exists if none is present. This wording may actually dissuade subjects from joining the study and serve as a disincentive, especially for social/behavioral studies.

**Action Items:**
- Apply proposed policy to all studies.
- Do not require the section if Make optional disclosure no one has a significant financial interest.

**New FDA draft guidance on suicidality (information)**
(Karen Moe)

A printed copy of 12-page draft guidance from the Food and Drug Administration (FDA) on suicidality was provided. The FDA is collecting comments on the guidance in the next 60 days.

The FDA is proposing that certain types drugs used in clinical trials are associated to suicidality. The guidance describes a specific approach to assess suicidality of subjects.
Karen invited comments from Board members. Board member Kathryn Korslund already provided comments on suicide assessment in general. She shared that in general the guidance is straightforward, with there being no particular harm associated to the guidance. The only concern is by prospectively assessing suicidality; researchers will have to manage it. She recommends that there be guidance issued on how researchers and Data Safety Monitoring Boards (DSMBs) will manage suicidality while also conducting the research. The UW IRB will have to deal with how this guidance will be implemented within UW research studies. The IRB will not likely adopt this guidance for drugs that are not investigational as blanket guidance since the IRB would have to make this determination.

ITHS is willing to work with the IRBs to develop models on how to best approach this issue and provide resource information (e.g., King County crisis line).

**Action Items:**
- ITHS and HSD will work collaboratively to develop models on approach and resources.

**Announcements (Karen Moe)**

Last year, Karen regularly updated the Board on ongoing or upcoming process improvements. Below are some that occurred during the summer:

- **Effective 9/1/10: Increased IRB fee**
  
  The IRB fee for industry sponsored, industry initiated research studies was increased from $1000 to $1500, which applies to research studies that go to WIRB. This fee supports the stipend program for IRB members and Chairs.

- **8/15/10: Change to WIRB submission process: campus reaction, how it is going**

- **Status of new HSD process implemented 8/15: comparing consent forms, contracts, and budgets**

  OSP, HSD, and FHCRC have been comparing consent template language, industry contract language, and budgets to ensure the content is in harmony regarding what subjects are paying, who’s paying for treatment of adverse events, and that there is inappropriate language with respect to what Medicare will be charged. HSD has been managing the central coordination, including review of studies reviewed by UW, FHCRC, and WIRB. They are requiring that the contract be finalized first before sending to WIRB since investigators were sending proposals to WIRB before the contract and budget worked out. There has been some push back from people that this process would slow down the start up of clinical trial. HSD is closely tracking this information with Ella Mae Kurashige and study coordinators at the SCCA. Although this change in process may be adding time at the beginning of a study, it will reduce time later in the overall trial start-up process since investigators won’t have to fix consents later and pay modification fees.

  Puget Sound Blood Center (PSCB): discussions with PSBC about what UW IRBs review for its investigators
UW IRB does IRB reviews for PSBC since most of their researchers have some kind of faculty appointment here, even when the money for the research goes to PSBC. HSD has clarified that when the contract goes to PSBC, they will not review those IRB protocols.

- Recognition of our role & expertise in emergency medicine research (HHS fellow)

HHS has a program allowing physicians to go to various places to do one year fellowships. UW IRB is recognized as experts by HHS in review of emergency medicine. Some time in November, there may be a conference having to do with review of emergency medicine. Additionally, approximately a week ago, UW IRB was recognized for their review of dbGap and is now considered a national model (efficient and clear to researchers).

- Status of the new IRB members with MDs

Deborah Schwinn, Chair of Anesthesiology, worked with SOM Department Chairs in each clinical medicine division to recruit MD members on IRB Committees. As a result, 28 new MD members will be serving on one of the IRB Committees in the next few months.

- New HSD website [http://www.washington.edu/research/hsd](http://www.washington.edu/research/hsd)

The HSD website has been in development for quite some time and was finally rolled out Monday. Board members were encouraged to contact Sharon Elsayed if they encounter any difficulties.

- HSD’s growing reputation in certain areas:

HSD is receiving a lot of attention from people from other countries inquiring about training people on how to review studies. The deputy director from OHRP asked HSD to accept a class of 34 people from China for 6 months to help them learn how to set up and run an IRB. HSD can’t accommodate this request at this time, although they are pleased by their growing reputation.

- PDF forms: HSD has initiated rollout

Last year, HSD proposed the idea of using smart PDF forms. Use of smart forms, starting with forms HSD uses internally in their office, was implemented about a month ago. They want to work out bugs with internal smart forms before moving to external forms.

**New business / future agenda items (Board Members)**

The next HSPB meeting occurs in November. No members had any suggested issues.

Meeting ended at 10:24 a.m.