MINUTES
HUMAN SUBJECTS POLICY BOARD
http://www.washington.edu/research/main.php?page=orAdvisory&group=hspb
9:00 – 10:30 AM
October 23, 2009
Gerberding 142

Members Present
Brown, Zane
Buck, Steven
Cheek, Jeff, Chair
Crutchfield, Robert
Jones, William
McCutchten, Deborah
Moe, Karen
Rimmele, Carl
Spieker, Susan
Spigner, Clarence
Thomas, Karen
Thummel, Ken
Turns, Jennifer
White, Emily
Whitney, Joie
Wilensky, Alan

Members Absent
Burke, Wylie
Chronister, Lynne
Slattery, John
Takeuchi, David

Welcome:
Jeff called the meeting to order at 9:03 a.m. Because there are so many new Board members present, all members introduced themselves and announced their academic affiliations.

Jeff described HSPB as an Advisory Board to the Vice Provost of Research. HSPB meetings are a venue for the Board to have high-level discussions about issues that impact researchers. When the Board needs to address an issue in more detail, a task group is pulled together to address the issue and develop recommendations. Board members are also expected to bring forth issues applicable to their academic units.

Approval of minutes from meetings of 5/15/09 (Jeff Cheek)
The Board accepted the minutes of the 5/15/09 meeting as submitted. All minutes from all meetings are publicly posted on the Office of Research website (noted above). Board members are asked for their input and edits to draft minutes prior to posting.

HSD policy change: expedited research (minimal risk) (Karen Moe)
Human subjects regulations define nine categories of research that qualifies for minimal risk review. The Office for Human Research Protections (OHRP) posted a request for comments about these categories and how they should be changed. In that posting, OHRP provided explicit guidance about its intent concerning Category 5. This category is for research involving specimens and data collected initially for other purposes. The original definition of this category was interpreted by all IRBs as excluding research based on specimens or data that had been collected previously for non-clinical purposes. The recent posting by OHRP makes it clear that OHRP’s intent has always been that this category should include...
research based on specimens and data that already exist and that were collected initially for some other research purpose. For example, if someone had IRB approval for banking identifiable blood specimens, the use of those identifiable specimens for another research purpose would have in the past required full board IRB review. Now, however, the UW IRB has revised its definition of category 5 to include the new information from OHRP such that this example is now eligible for minimal risk review.

One member commented that some researchers would prefer that applications go through full IRB review rather than minimal risk review because full review is a faster process. However, Karen pointed out this may be based on experiences of many years ago, because published HSD metrics show that minimal risk review is now on average almost three times faster than full IRB review. Karen recommended that Board members refer any researchers concerned with delay in review processes to metrics reports posted on the HSD website, which show turnaround time. Some Board members recommended that the HSD office distribute an email to the campus community to let them know about recent process improvements.

In response to Board inquiries regarding the minimal risk review process in HSD, Karen replied that the Division has up to five minimal risk reviewers who are all HSD staff. If the reviewers have any questions, they consult with IRB Chairs. Board members who serve as IRB Chairs commended the judgment and experience of the minimal risk reviewers. One Board member requested that there be consistency when referring to research that may qualify for expedited review since using the terms “expedited” review or “minimal risk” interchangeably may confuse some researchers. Another Board member recommended that the current UW draft definition of category 5 be revised to clearly state that if data or specimens are de-identifiable, this research may be exempt.

**Action Items:**
- Revise UW definition of category 5 to include the information that data and/or specimens that are completely de-identified may be exempt from IRB oversight.

**FDA and OHRP guidance about data retention (Karen Moe)**
The FDA and OHRP recently released guidance about data retention when subjects withdraw (or are withdrawn) from a study. The two agencies “harmonized” their respective guidances to be consistent with one another in almost all respects. The FDA guidance states that not only are researchers allowed to retain the data of research subjects who withdraw from studies but that researchers are required to retain such data. The purpose of this requirement is to ensure that safety and efficacy data are not biased. However, researchers cannot continue to collect specimens or data after subject drops out. Also, researchers may keep specimens, but the specimens can no longer be used to generate new data if the specimens have not be used by the time the subject withdraws.

This guidance creates a conflict between two of the major ethical principles from the Belmont Report: 1) respect for persons (autonomy) and 2) beneficence. Karen invited discussion from Board members on this information from the FDA.

**Board member comments:**
- Specimens and/or data from research subjects who decide to no longer participate in a study should no longer be used. Doing so would put the interest of research before human subjects when the whole purpose is to protect human subjects.
- Conversely, specimens and/or data from who drops out may almost as important as specimens and/or data from who stays in for some research studies.
- There are two consent form issues: 1) when subjects end participation early, a separate consent could inform subjects that research may continue on specimens already collected or 2) original consent language should say once you drop out, we will still use your data and/or specimens. FDA requires that data and specimens be retained.
  - The consent should have already informed subjects that their data may be retained. Retroactively consenting subjects could be problematic.
Having a secondary consent describing potential for continuing research on already collected specimens may be beneficial and will be clearer to researchers.

- The consent could note that if a subject withdraws from study, all data and specimens will be used and analyzed.
- Another possibility: Consent forms could say that all identifiers associated with data and/or specimens will be destroyed.
- HSD will develop some consent language and incorporate it into the posted consent templates.

- One member had a question about data collected through behavioral research. What if a subject withdraws participation after collection of data on video tapes, where the data isn’t analyzed until later in the study? Does this mean that researcher can’t use data on withdrawn subjects? Karen will look into this issue.
- One board member expressed distress about the new FDA guidance because subjects are sometimes dropped from studies for being non-compliant with the study protocol. Other board members responded that this issue can be addressed through appropriate data analyses. Karen indicated that HSD information about this issue would make it clear that the requirement (as opposed to permission) to retain drop-out data applies only to FDA-regulated research.
- One board member requested information or guidance on how best to handle situations in which subjects who are withdrawing want to have their data withdrawn as well. Karen will consult with the Attorney General’s Office about this.

**Action Items:**
- HSD will develop template consent language addressing these issues.
- Karen will follow-up about subjects who request that their data be withdrawn from studies that are not FDA-regulated.

**Familiarizing new UW researchers with the IRB review process (Zane Brown)**

There sometimes appears to be an adversarial relationship between researchers and the IRBs. Some of this may be due to lack of researcher knowledge about the IRB process. Zane proposed that researchers who have submitted an IRB application for the first time be required to attend an IRB meeting as an observer. The goal of this requirement would be to increase understanding and acceptance of IRB procedures. Also, it may also assist in recruiting new members for the IRBs.

Some members felt that it would be more productive and less onerous to invite, rather than require, new researchers to attend an IRB meeting. Also, there may be other effective approaches, such as encouraging new researchers to work closely with the IRB staff. There was some consensus that the Board needed to know how many researchers submit applications for the first time each year before issuing any guidance for researcher attendance at IRB meetings.

The Board discussed whether student researchers should be invited or required to attend IRB meetings when submitting IRB applications. Confidentiality is a concern. Also, students leave the UW relatively soon. Focusing on faculty researchers would allow positive long-term relationships between the IRBs and researchers to develop. One Board member was concerned about how to handle questions from researchers who attend IRB meetings. Another member suggested that IRB staff could serve an important role in this regard before and after IRB meetings.

It was also recommended that HSD provide researchers with model applications, consent templates, and examples, to assist researchers in getting through the IRB review process.

One member suggested that there be an intermediate process that occurs at the unit and departmental level to help demystify the IRB process. This may a more feasible level of intervention.

Karen informed the Board that HSD sent invitations in early October to all new faculty members to attend one of two sessions to talk about the IRB process. She suggested that her office could do this again.
Conclusions about the proposal:
- IRBs need new faculty members, which is a constant struggle. This could serve to facilitate the IRB’s ability to review applications as well as familiarize more faculty with the IRB review process.
- Important to continue relationship building with faculty and IRBs.
- Logistically impossible to mandate researchers to attend IRB meetings. It should be a voluntary process and new researchers should be invited rather than required to attend an IRB meeting.
- Consider other ways to proactively educate new researchers.
- Board would like to review data about how many new researchers submit applications each year. The data should distinguish new faculty researchers from new student researchers.
- IRB Chairs should encourage IRB staff to work more with researchers submitting to IRB for first time to submit better applications, and should invite researchers to attend IRB meeting.

Upcoming topics for Board discussion and scheduling (Karen Moe) and New business / future agenda items (Board Members)

The Board discussed the following items for future agendas:
- Focus on genetic issues at next meeting (impacts on biomedical and behavioral research).
  - A Genetic Supplement to the initial IRB application.
  - Issues about Genome Wide Association Studies (GWAS), and NIH’s requirement to submit genetic data to NIH databases for sharing with other researchers.
  - State law RCW 70.02 about personal health information, which affects some genetics research because DNA is included in the law’s definition of “personal health information”.
- Creation of task force to look at data confidentiality and security issues. Board talked about data encryption last year but a policy was not developed because UW is doing a high level assessment of policies about data management and incident reporting, which will need to be incorporated into IRB policy.
  - The Board is in consensus that a task force should address the issue of laptops with research data and whether those data should be encrypted.
- FDA regulated studies and relevant issues and how to make research easier for researchers.
- Changes to the injury compensation plan.