MINUTES
HUMAN SUBJECTS POLICY BOARD
http://www.washington.edu/research/main.php?page=orAdvisory&group=hspb
9:00 – 10:30 AM
January 15, 2010
Gerberding 142

Members Present
Brown, Zane
Buck, Steven
Cheek, Jeff, Chair
Chronister, Lynne
Crutchfield, Robert
Jones, William
Majeski, Steve
McCutchen, 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
Slattery, John
Takeuchi, David

Guests
Shannon Sowards

Welcome:
Jeff called the meeting to order at 9:03 a.m.

One member requested that a Board member roster listing each member’s contact information and affiliations be circulated at the next HSPB meeting.

Action Item: Develop and provide a handout listing Board member contact information and affiliations to circulate at the next HSPB meeting.

Approval of minutes from meetings of 11/20/09 (Jeff Cheek)
The Board accepted the minutes of the 11/20/09 meeting as submitted.

Genetics research: follow-up from last meeting and additional developments (Karen Moe)

Karen updated Board members that a working group will be established to begin discussions on issues the IRB and HSD struggle with when reviewing genetics research. Three major issues will need to be addressed by the working group:
   1) The IRB application and genetics research,
   2) Template language in consent forms regarding data sharing, and
3) Draft guidance for both the IRBs and researchers for describing risks related to genetics research.

Karen reported that HSD has developed a genetics supplement to the main IRB application form, which was reviewed by Wylie Burke and other faculty/staff in the Department of Bioethics & Humanities. HSD has also completed the development of draft procedures and forms for researchers to submit genetic results to NIH’s dbGaP database of genotypic and phenotypic information.

Karen requested additional volunteers to the working group which will meet in the spring. One Board Member suggested recruiting IRB administrators to the working group as well.

**Action Items:**
- Recruit additional volunteers to the working group, including an IRB administrator.
- Circulate drafts of genetics supplement, consent language, and guidance documents for input.

**Office for Human Research Protections (OHRP) – Northwest Association for Biomedical Research (NWABR) Community Forum and follow-up biorepository meeting (Karen Moe)**

OHRP is working together with NWABR to put together a community forum conference which will be held in a day-long format in February. HSD will be sending several staff. The new OHRP Director, Jerry Menikoff, and the Director of Human Research Affairs at Partners HealthCare Systems, Pearl O’Rourke, will be plenary speakers. Dr. Menikoff has made substantial changes at OHRP in the less than one year of being in office, including efforts to harmonize OHRP and FDA regulations. Dr. O’Rourke is an expert on biorepositories.

The day after the public / community forum, Karen will be attending a large “invitation only” meeting which will focus on biorepositories and was organized by Wylie Burke and NWABR.

**Main IRB application: revision project (Karen Moe)**

Karen reviewed a major new HSD process improvement initiative, which is designed to address the long-standing problem of extensive “back and forth” correspondence and iterations between the IRBs and researchers during the review of a new IRB application. The latest HSD Performance Metrics report shows that over the last three calendar quarters, very few IRB applications are approved at the time of the first IRB review. Most applications submitted for the first time for IRB review by Committee are not approved out right but instead are deferred. Analysis shows that much of this occurs because the existing IRB application does not provide the IRBs with the information they need to do their reviews. The existing application form was created in 1994 and has had no significant revisions since that time.

**Why do a major revision now?**
- Numerous regulatory changes since 1994.
- New and evolving research areas & methods is challenging,
- IRBs: “We don’t get the information we need”
- Researchers: “The form doesn’t fit my research”
- Researchers: “I don’t understand the questions”,
- Improve efficiency of the IRB review process.

One Board member suggested that draft questions related to international research be circulated to the Global Support Office for input.

The overall project plan is:
- Step 1: Revise content - implementation in late spring 2010.
- Step 2: Revise format (from Word to “smart” PDF forms) – implementation in fall/winter 2010.

Content changes include:
- New questions addressing regulatory issues,
- New questions for specific research areas and methods (e.g., qualitative research questions),
- New explanatory material, definitions, and examples,
- Questions that are not applicable to many researchers will be separated out into application Supplements There is a real challenge to using a “one size fits all” approach, which is the driver behind creating Supplements.

Expected impact of the changes:
- The application will be much longer, but the length will be consistent with IRB application forms at our peer institutions.
- Faster, more efficient IRB review, because there should be:
  o Fewer deferrals, more approvals with first IRB review,
  o Shorter review letters (which may therefore be written more quickly)
  o Less “back and forth” iterative correspondence between IRBs and researcher.
- Increased capacity of IRB committees, because fewer applications will need to go on an IRB meeting agenda for a second time
- Important transitional step toward electronic submission, when the PDF format is implemented in Step 2. Researchers will see and complete only those sections that are applicable to their research.

Some Board members asked why separate application forms were not developed to fit different types of research as opposed to having all researchers complete the same form. The Board discussed the issue of how researchers would know which application form to use, especially if they are doing interdisciplinary research.

The Step 1 process of the project:
- Complete the draft revision of the application form content,
- Seek feedback from stakeholders, starting with IRB members and HSD staff, and then broadening to include the Human Subjects Policy Board and other compliance office partners.
  o IRB members and HSD staff,
    ▪ The application will be posted on a discussion board website for all staff and IRB members to comment.
    ▪ Brown bag sessions will be held with HSD staff to obtain feedback.
    ▪ Karen will meet with as many IRB members as possible to get their input.
    ▪ In February, the application will be revised again to incorporate feedback.
  o HSPB. Karen will circulate draft application to HSPB to get input. The IRB Chairs have already done this.
  o Other compliance partners (Global Support, OSP, ITHS, etc)
- Beta test, in which 20-25 researchers will be invited to test the application to submit as real IRB applications. Every Minimal Risk team and IRB Committee will review two “submitted” beta applications. The implementation date for the new form is highly dependent upon the beta testing.
- Final review by HSD staff and IRB members after incorporation of all other feedback.
- Campus-wide communication and training about the new form, its changes, and how to use it. This will be extensive. It will start at least 6 weeks before implementation of the new form and will continue for a few months after implementation.

Karen reported on a concurrent process improvement project related to the major revisions to the new application: HSD’s filing system. Changes to the filing system are likely to reduce the number of copies HSD requires to submit for all materials. This will assist researchers (less time, paper, money to prepare applications) and will reduce HSD workload related to filing, stamping, etc., so that staff can spend more time on screening and review activities.

In conclusion, HSD is hoping revisions to the new application form will lead to a faster and more efficient IRB review. After the necessary inconvenience posed by the initial steps towards the application form revision, the new form should result in fewer application deferrals, shorter review letters, and faster overall turnaround time.
**Action Item:**
- Obtain Global Support input draft questions related to international research.

**Ex officio membership: consideration for HSPB members (Karen Moe / Board Members)**

At end of year, the HSPB typically revisits the composition of the Board to determine whether there is appropriate representation of all key stakeholders. We have already identified a need for a representative from information technology (systems development). Are there any *ex officio* members whose participation would benefit HSPB and/or researchers? Karen recommended adding Noella Rawlings, who is the Assistant Attorney General that represents UW research (and HSD), representative from the Attorney General’s office. The Board agreed to this addition.

**Action Item:** Invite Noella Rawlings as an *ex officio* HSPB member.

**University of Michigan Demonstration Project: UW participation? (Karen Moe)**

University of Michigan is an institution similar in size to UW. Their IRB office has recently reported the results of two pilot projects designed to take advantage of regulatory flexibility. Karen provided a summary of both pilot projects entitled: *Reducing Regulatory Burden: Michigan Demonstration Project.*

One project focused on the lengthening the duration of the IRB approval period. IRB approval periods have always been one year or less; each year, the researcher provides a Status Report in order to renew the IRB’s approval. Michigan found that increasing the approval period to two years for certain types of studies reduced the IRB workload by about 15% (and, of course, reduced researcher workload as well).

The second project focused on the creation of a new category for exempt status. Certain research studies that were previously reviewed through Michigan’s equivalent of the UW minimal risk process were now considered to be exempt. This means that there was no need for annual Status Reports and re-review by the IRB. Again, the project demonstrated a significant and positive impact on the workload of the IRB and researchers.

Michigan is recruiting other institutions to participate together in a broader test of these concepts. Karen invited Board members to provide input on whether UW should participate.

Comments from Board members included:
- This could reduce workload related to IRB reviews but also related to application submission.
- These changes would have a significant positive effect on researchers working with datasets.
- New faculty and students who do not have federal funding are likely to benefit the most from these changes (because of the criteria used to identify the studies that qualify for these changes).
- The downside of not rigorously reviewing work by students is that their research may not be as heavily monitored.
- These changes may conflict with the requirement of some research funding agencies and organizations.

Consensus: The Board supports these changes with no reservations.

**Action Items:**
- Follow-up discussion of this idea will be brought back to HSPB in March since Karen will find out more about the proposed pilot projects in a week or so.
- Shannon Sowards will work with Minimal Risk team to find out capacity of taking on a new project along with file and new application revision project. We will assess and find out more information.

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

Discussion will continue on:
- Data encryption
- Facilitation of interactions and immersing researchers into IRB system.