MINUTES
HUMAN SUBJECTS POLICY BOARD
http://www.washington.edu/research/main.php?page=orAdvisory&group=hspb
9:00 – 10:30 AM
May 21, 2010
420 Mary Gates Hall

Members Present
Brown, Zane
Buck, Steven
Cheek, Jeff, Chair
Chronister, Lynne
Cooper, Claudette Lee
Crutchfield, Robert
Jones, William
Majeski, Steve
McCutchen, Deborah
Moe, Karen
Rimmele, Carl
Spigner, Clarence
Thomas, Karen
Thummel, Ken
White, Emily
Whitney, Joie
Wilensky, Alan

Members Absent
Burke, Wylie
Slattery, John
Speiker, Susan
Takeuchi, David
Turns, Jennifer

Welcome:
Jeff called the meeting to order at 9:05 a.m. Jeff reminded Board members that the May 21, 2010 HSPB meeting is the last of this academic year.

Karen invited the Board to forward her any issues they’d like placed on future agendas and for discussion in the Fall.

Approval of minutes from meetings of 3/19/2010 (Jeff Cheek)
The Board accepted the minutes of the 3/19/2010 meeting as submitted.

Action Item: Post approved 3/19/2010 meeting minutes and final 5/21/2010 meeting agenda on HSPB website.
**Proposed change in requirement for PI and department chair signatures on IRB application and forms (Karen Moe)**

Current HSD policy requires original inked PI signatures on almost all applications and forms. In addition, there are complex rules about when the PI’s signature authority can be delegated to others. This also applies to the requirement for the Department Chair’s signature on new applications. Keeping track of the delegated authority for these signatures and checking each item when it arrives at HSD requires significant time and effort from HSD staff. In addition, PIs and department chairs do not always inform HSD when there are changes in delegated signature authority. This issue does not impact the Institutional Review Boards (IRB). However, collectively these issues can slow down an application’s progress through the review process by up to several days. Karen sought input from the Board on whether there is value in continuing to collect these signatures – and if yes, on which forms and under what circumstances. Karen proposed the following changes as a starting point for discussion:

- Requiring the original inked PI signature only on initial IRB applications and on Confidentiality Agreements. The PI would not be able to delegate this function. This change would reduce HSD workload, reduce confusion and complicated rules, and would also emphasize the importance of the PI’s responsibilities.
- Requiring the Department Chair’s signature only on the initial IRB application but allowing the Chair to delegate signature authority to someone appropriate and allowing a stamped signature.

**PI signature.** Karen and the Board discussed the possible rationale(s) for the PI signature requirement. It is not required by federal or state regulations. The PI signatures document that PIs are aware that their staffs have prepared IRB materials on their behalf. It also confirms that the PI accepts responsibility for the oversight and conduct of the research. After discussion, the Board reached a consensus that the PI signature should be required (and not delegated) on an initial IRB application and on Confidentiality Agreements but not on any other forms or documents.

**Department chair signature.** Per UW policy, the department is responsible for fulfilling the regulatory requirement for scientific review. The Chair’s signature documents that the review has occurred. The Chair’s signature also attests that PI is qualified to do the study and that department resources to conduct the research are available.

The Committee’s feedback included the following:

- Departments vary considerably about scientific review – from having a formal process for internal review to seemingly not performing any review at all. Some Board members wondered why the Chair signature is required at all, in light of the inconsistency. Providing a signature may not be meaningful under these circumstances.
- There was some discussion about whether the Chair signature requirement slows down the overall application process.
• Some Board members stated that a Chair signature requirement was appropriate because it reflects the Chairs accountability for all department research activities.

• Some Board members felt that local unit review strengthens the entire review process. Additionally, there is value to the local unit’s expertise in the research that is being done that might not be present at the IRB level.

• The Board discussed that it should be made explicit that the signature line for the Chair means that the Chair is attesting that the PI is qualified, the department has adequate resources for the research, and concurrence that the research is worthwhile. Adding this statement could potentially allow administrators sign instead of the Chair, presuming that the Chair is informed and agrees. Karen updated the Committee that the revised IRB application (currently under beta testing) makes explicit what the Department Chair signature means.

Karen suggested that HSD move forward with the proposed change in signature requirements and that over the summer, HSD discuss the importance of the department chair signature serving as local review. She will then bring this issue back in the fall for further discussion. The Board agreed. Jeff reminded the Board that the IRB has the primary responsibility for assessing the relative risks and benefits of research. He explained that HSD has no control over how a department handles scientific review; therefore the best that can be done to address OHRP’s requirement for scientific review is to increase the diversity of scientific expertise on the IRBs themselves.

Action Items:
• HSD will move forward in changes to signatory authority.
• Karen will revisit issue of how most appropriately to capture scientific review at the department level in Fall 2010.

Human subjects issues related to Northwest Hospital (Karen Moe)
- Who does the IRB review?
- Who is responsible for research-related HIPAA activities?

Karen informed the Board that Northwest Hospital is now part of UW Medicine, effective 1/1/2010. HSD is still working with UW Medicine about two specific issues.

(1) Who is responsible for IRB review of research occurring at Northwest that does not involve UW faculty members? It is likely that physicians at Northwest that have no UW faculty affiliation will obtain IRB review from a non-UW source (e.g., WIRB). Karen emphasized that UW faculty conducting human subjects research at Northwest are covered by the UW IRB. Karen asked the IRB Chairs to have the IRB staff contact her if the IRBs encountered applications from Northwest physicians who are not UW faculty. It will take several months to work out details for how and when UW IRBs provide oversight (if any). Until then, the UW IRB always has the option to do IRB authorization agreements on a case-by-case basis. Currently, Northwest does little human subjects research, but this is likely to change significantly.
(2) Who will handle HIPAA issues for research use of medical records from Northwest?
Richard Meeks, Privacy Officer at UW Medicine is discussing these issues with the Northwest Privacy Officer. For example, HIPAA law requires that the covered entity (UW Medicine) and PIs account for all medical records that are accessed without HIPAA authorization. At the UW, the PI does this by uploading an Excel spreadsheet to a secure UW Medicine website. Northwest is not currently a part of this process. Another issue is that UW Medicine uses electronic medical records, but Northwest does not. PIs at UW will have to deal with paper records making it even more important to get Northwest to recognize and accept UW’s HIPAA forms.

Submission of genetics data to NIH's dbGaP (Karen Moe)
Subheader: when it is human data but not the result of human subjects research?

Most new NIH and NSF grants now have data sharing requirements. This often includes a requirement to share human genetic information with the federal dbGaP database of genotype and phenotype information. The data in dbGaP are de-identified and made available to other researchers. NIH requires the IRB to certify the submission of this data, before a researcher sends it, even if the data being submitted are coming from activities that are not defined by federal regulations as “human subjects research”. For example, genetic analyses from completely anonymous samples are usually not considered human subjects research, but the IRB must still certify the submission of the results to dbGaP. Shannon Sowards (Assistant Director of Operations) has created and beta-tested a process, documents, and forms required for PIs, the IRBs, and HSD for dbGaP. They will be publicly released this summer. Note that this NIH requirement for IRB certification is another unfunded mandate and added workload for IRBs – i.e., a required activity that is not part of the human subjects regulations.

Standing item: HSD/IRB process improvement report (Karen Moe)
- Progress of beta testing the revised IRB new application form.
  - About 22 applications have been submitted using the beta-test form. This first round of beta testing should be completed by the end of the summer.
  - It is already clear from researchers and staff feedback that there is a strong preference to convert the application form to PDF format at the same time as the implementation of the content changes. PIs, study coordinators, and staff want all changes to occur at once and not deal with sequential changes. Also, everyone is interested in having a shorter form than the beta test form, which a PDF format will allow.
  - Karen will bring back issue at the next several meetings and inform the Board on how HSD is progressing, what they are doing, and metrics.
- Progress of file revision project and implications for HSD, IRB, and researchers. HSD will be changing its IRB file system. The first step will be implemented in the fall. Another step in the winter will reduce the number of copies that researchers are required to provide. This will also reduce the stamping work required at HSD.
• IDRI arrangement (IDRI = Infectious Diseases Research Institute). HSD now has an arrangement with IDRI that allows UW students to do research at IDRI without UW IRB review. Instead, IDRI’s IRB does the review. This has reduced duplicate IRB review.

• The UW has an institutional responsibility to ensure that the contract, consent form, and budget are consistent for clinical trials. HSD has been working on this issue with the Office of Sponsored Programs (OSP) and the Clinical Research Budget and Billing Office (CRBB) for the past year, to clarify which office is responsible for which pieces, and how to coordinate the comparison across the offices. The new process is being implemented on August 15th. The three offices will work together on this process. Among other things, this means that the IRBs will no longer need be responsible for comparing contracts with consent forms; the comparison will be done by office staff during the IRB review process, and the results will be shared with the IRBs.

Budget issues – impacts on HSD operations (Karen Moe)
All units in the Office of Research have had to accommodate reductions in FTEs and other resources. HSD recently cut one position and consolidated some administrative and reception functions with the Office of Sponsored Programs, so as to minimize the impact of budget cuts on service to campus.

HSD will continue to look for ways to make the IRB review process more efficient, and to minimize the effects of any future additional budget cuts.

Followup from previous meetings (Karen Moe)
Genetics and GWAS forum

HSD will be holding a forum to inform researchers on how to navigate the NIH data sharing requirements about genetic data. This has been delayed from the planned spring date because NIH has been continuing to develop its guidance about this process and HSD wants to incorporate these changes. HSD will communicate this information and get feedback in two community forums this fall/winter.

New business / future agenda items (Board Members)

Jeff invited members to provide input on any new business items for future agenda items or suggestions on recruitment to the Board.

• Over a year ago, under the pressure of the DHHS OIG, NIH issued an Advance Notice of Proposed Rule making (ANPRM), listing proposed changes to current regulations about financial conflicts of interest and seeking comment. NIH’s response to the requested commentary was issued yesterday in the form of a Notice of Proposed Rule Making (NPRM). New proposed requirements include:
  ○ NIH will require institutions (as opposed to investigators) to determine when financial interest affect research projects, and to inform NIH when conflicts exist and how they are managed.
o NIH is proposing to change the minimum level at which PIs would have to report financial interests from $10,000 to $5000 in compensation, or any equity interest whatsoever.

o A significant new unfunded mandate will require institutions to report all financial conflict of interest disclosures into a database that would be available to the public.

o The most substantive requirement will be that all investigators on any NIH funded project will be required to complete training for financial COI before expending NIH funds.

NIH is allowing 60 days for comment. Jeff will lead an effort to gather comment and this will be brought back to the Board for discussion this fall.

• One Committee member had a request to visit an old item under new business. The recommendation was that HSD send a letter to Department Chairs encouraging their new faculty to at least visit IRBs to see how IRBs do business and to observe the review process. HSPB had a previous discussion about this but the UW has not implemented any action to date.
  o Karen responded that HSD will to ask the IRB Chairs if they are willing to participate in this; if so, HSD will send the letters to the department chairs.
  o One Board member suggested making a requirement that if a researcher want to do research at UW, they have to spend one year serving on the IRB.
    ▪ Jeff reminded the Board that several measures have been undertaken to increase recruitment IRB members. For example, we now provide a modest financial incentive to departments that provide IRB members.
    ▪ Karen has been working with John Slattery and Debra Schwinn (Chair of Anesthesiology) to get one MD member from every department in the School of Medicine and from every division in the Department of Medicine. This will triple the number of MD IRB members.
    ▪ Several communication forums have been used to communicate the need for more IRB members (e.g., DDC email list).
    ▪ Karen reminded the Board that it is also HSD’s policy to have at least one student member on each IRB.

• Jeff reminded Board members that they serve on the Board because they represent UW stakeholders and/or our IRBs. He will ask someone from ITHS to serve on the Board next year. He invited members to provide more recommendations.
  o The Board members agreed that more graduate students should be recruited to serve on the Board. Jeff will approach GPSS again about this issue.

**Action Items:**

• Karen and Lynne will inform new faculty who attend the OSP training in September of service they can contribute to the IRB as members.
• Jeff will approach GPSS again to solicit recruitment options to the HSPB.

Meeting ended at 10:28 am.