



MINUTES (draft version 1)
HUMAN SUBJECTS POLICY BOARD
9:00 – 10:30 AM
September 19, 2008
EE 403

Members Present

Cheek, Jeff, **Chair**
Barker, Theresa
Brunzell, John
Buck, Steven
Chronister, Lynne
Crutchfield, Robert
Karpen, Richard
Mason, Robert
McCutchen, Deborah
Mitchell, Pamela
Moe, Karen
Rimmele, Carl
Saxon, Andrew
Spigner, Clarence
Takeuchi, David
Turns, Jennifer
Wilensky, Alan

Members Absent

Brown, Zane
Burke, Wylie
Hamblin, Mark
Neff, Margaret
Sherrard, Donald
Spieker, Susan
Slattery, John
Thummel, Ken
Thomas, Karen
White, Emily

Visitors present:

Shannon Seward, HSD Assistant Director for Operations
Wendy Brown, HSD Assistant Director for Quality & Compliance

Welcoming of new and returning members:

Jeff called the meeting to order at 9:00 a.m. and welcomed all returning and new members. He distributed appointment letters, which thanks members for their service and describes that each member will serve a yearly appointment on HSPB. HSPB members introduced themselves and described their affiliation to the University of Washington (UW) and their representational role on the Board.

Approval of minutes from meetings of 5/16/08 (Jeff Cheek)

The Board accepted the minutes of the 5/16/08 meeting as submitted.

Update on HSD personnel and ClinicalTrials.gov (Karen Moe)

Karen and Jeff reported that due to a recent shift of staff at the UW School of Medicine and a new staff position added to the UW Human Subject's Division (HSD), HSD is now serving as the central UW office coordinating the required registration of all UW clinical trials with ClinicalTrials.gov.

Karen briefly described that ClinicalTrials.gov is a website maintained by NIH with the all overall purpose of registering information related to ongoing clinical trials and making it available to the public. All clinical trials are required by federal regulations to register here or at a similar approved trial registry, and significant individual penalties may occur if researchers don't comply with the registration requirements (e.g., journals may not publish the results if clinical trials are not registered). This requirement applies to federally funded and privately funded research, including research funded by industry.

To accommodate this new responsibility and to assist in centralizing this process, HSD has recently created a new staff position known as the Clinical Trials Administrator. The Clinical Trials Administrator will work to educate research faculty on what is considered a clinical trial and when registration requirements to clinicaltrials.gov may apply. In addition, the administrator will assist faculty with the registration process. One HSPB member asked if these services extend to Veteran Administration (VA) researchers as well. Karen offered to discuss this further with VA research administrators. Another HSPB member asked if there might be a different registration process required for international research; Karen offered to investigate this question.

She explained that the deadline for registering trials to clinicaltrials.gov includes a transition for existing trials. If clinical trials have existed for less than four months, they need to register right away. However, for trials that are further along, these trials may not need to register. For long-standing clinical trials, some journals may not publish the findings without a clinicaltrials.gov registration number. Therefore, the recommendation is that investigators register all clinical trials.

Federal Certificates of Confidentiality (Karen Moe)

Karen described that NIH may grant Certificates of Confidentiality to researchers for specific research proposals, which is a federal mechanism to allow research institutions and their researchers to resist subpoenas for sensitive research data (e.g., studies on HIV or substance abuse). Researchers interested in obtaining a Certificate of Confidentiality are required to apply individually.

Two specific issues have been brought to HSD's attention:

- 1) Some of the NIH's Institutes that issue Certificates of Confidentiality are concerned about Washington state reporting laws requiring that all child, elderly, and substance abuse cases must be reported to the state. They have told UW researchers that they won't issue Certificates of Confidentiality to our researchers if the state is mandating that abuse cases be reported. This issue can be resolved in the short-term by researchers stating in the consent forms that they are "voluntarily choosing to report abuse cases described in state regulations."
- 2) Another issue affecting the ability of UW investigators to obtain a Certificate of Confidentiality is the UW Medicine policy that researchers are required to put information about research studies in the subjects' medical records. The purpose of this policy is to assist medical providers and to ensure accurate billing for study-related expenses. Some NIH Institutes have refused to grant Certificates of Confidentiality when research information is placed in subjects' medical records.

Karen is starting with work with these Institutes to resolve these issues. She invited investigators to inform her of any problems they may encounter with regard to Certificates. HSD will help

investigators navigate the process for obtaining Certificates of Confidentiality. However, this is also a broader national issue that requires multiple universities working with NIH to be resolved.

Update on UW Human Subjects Compensation Plan (Karen Moe)

Karen described the UW Human Subjects Compensation Plan, which provides treatment at a UW medical facility or reimbursement of treatment costs for any physical injury resulting from an individual's participation in UW human subjects research. The UW is unusual in that few academic health centers offer any sort of human subjects compensation plan. However, the current plan has not been revised since the 1970s. Some of the challenges with the current plan include that the nature and complexity of UW research has changed dramatically; a significant amount of UW research is now occurring in international locations; and the regulatory environment has changed (for example, the rules about Medicare reimbursement of research-related costs, including the Medicare Secondary Payer rule). In addition, there has been a lack of sufficient documentation detailing the Plan and its benefits.

A task force of stakeholders from HSD, UW Medicine, and Risk Management is holding weekly meetings to review the compensation plan and policy and will be soliciting stakeholder feedback on the draft revision in December and January. This will include feedback from a sampling of researchers. Jeff noted that the compensation plan is also one of the seven Standing Orders of the UW Board of Regents, who will ultimately need to approve any changes to the current plan.

IRB member recruitment strategies

Jeff reminded the Committee that today's Board's discussion regarding recruiting IRB members began last spring. Some of the challenges related to the UW's difficulty in recruiting faculty to serve on IRBs are as follows: 1) The culture of some departments do not value participation on the IRBs as providing academic service towards the department's research enterprise; 2) serving as an IRB member is very labor intensive and may not be appropriate for junior faculty who need to devote their time towards obtaining tenure; 3) some departments can't devote release time of their faculty from teaching commitments.

Based on discussions with the Board and other stakeholders, Jeff described a proposal that has been presented to the Provost which would provide compensation to academic units for their faculty's participation on IRBs. Initially, this will be implemented as a pilot project targeted for the three UW social / behavioral IRBs. The social behavioral IRB committees are targeted for this pilot project since the work load for the social / behavioral IRBs is greater than that of the biomedical IRBs, and the range of subject matter reviewed by the social / behavioral IRBs requires a wide-ranging diversity of expertise. Specifically, the pilot project proposes to provide each academic unit with \$2500 per year for each member who serves on the IRB. The funds would be given to the School, College or department, and the academic unit will determine how the funds will be used, including options for course buy outs or providing these funds back to faculty member to support their travel or research.

Jeff clarified that this will likely not begin until January 2009, but that members can start informing their faculty accordingly.

HSPB procedures and online archiving of minutes and agenda

Jeff invited the HSPB members to provide input on how long the HSPB meeting agendas and minutes should be archived on the HSPB website. Right now, all HSPB meeting proceedings are Human Subjects Policy Board Meeting Minutes for 9/19/08 - draft ver. 1

included dating back to the Board's inception in 2005. The current practice is that the full agenda and approved meeting minutes are posted on the HSPB website. The Committee discussed several scenarios. They agreed that meeting minutes of the last academic year and previous academic year should be immediately accessible with all remaining minutes put on a separate page of the HSPB minutes as archived minutes. They agreed that the older meeting minutes should be made readily accessible to assist users in gaining a historical account of meeting discussions. One member requested that the URL to the HSPB website be included in future emails announcing upcoming agendas.

Jeff also asked the members to provide feedback on whether forming smaller task forces to work through the details of specific issues, such as when a task force was formed to work on audiotaping in exempt research, is still acceptable. He also suggested that in the event that a more pressing issue arises before the HSPB meets again, an email could be sent to members describing the issue in the interim. The members agreed to both approaches. Jeff described that the HSPB serves as an advisory board to the HSD and also a conduit for HSD staff, other oversight offices, and the researcher community.

The members discussed that since the HSPB is considered advisory to the Vice Provost for Research, but does not implement University IRB policy, the name of the board may need to be changed to clarify its role. The members suggested the name of the "Human Subjects Policy Advisory Board". The members also suggested that the appointment letter be revised to clarify the charge of the Board is advisory; Jeff agreed that the appointment letters should be revised to reflect this. He offered to bring the revised appointment letters to the next HSPB meeting.

One member asked about the status of electronic submissions to the IRB. Karen reported that ongoing efforts are occurring between collaborating institutions, such as FHCRC, to explore this process. Currently, there are financial restrictions that have put these efforts on hold. The timeline to produce an electronic submission system is most likely two years away. In the interim, other alternatives for electronic submission are being considered, such as allowing researchers to submit IRB forms through email.

One member asked if there is a way to assess the workload of different departments. Karen reported that one project underway is to develop metrics to report this type of information to the HSPB and to the public. This will likely be available in February 2009.

One member asked about the possibility of producing "best practices" IRB guidelines for undergraduates performing research in the classroom. Karen described two different approaches:

- 1) The Education Team of HSD will focus on student based research, developing information and tools just for students and
- 2) Completion of policies currently undergoing development may help – for example, guidance on what is or isn't research.

Submitted by Kim Blakemore