



MINUTES
HUMAN SUBJECTS POLICY BOARD (HSPB)
9:00 – 10:30 AM
May 16, 2008
142 Gerberding

Members Present

Cheek, Jeff, **Chair**
Barker, Theresa
Booth-LaForce, Cathryn
Burke, Wiley
Crutchfield, Robert
Mason, Robert
McCutchen, Deborah
Mitchell, Pamela
Moe, Karen
Saxon, Andrew
Slattery, John
Thomas, Karen
Thummell, Kenneth
White, Emily
Wilensky, Alan

Members Absent

Brown, Zane
Brunzell, John
Buck, Steven
Kuszler, Patricia
Sherrard, Donald J.
Rimmele, Carl
Spigner, Clarence
Streidl, Gigi
Takeuchi, David

Visitors present:

Shannon Seward, HSD Assistant Director for Operations

Announcements

Jeff called the meeting to order at 9:00 a.m. He welcomed new member Emily White who is the Associate Dean of Research for the School of Public Health. She is replacing outgoing HSPB member Dave Eaton.

Approval of minutes from meetings of 3/21/08 (Jeff Cheek)

The Board accepted the 3/21/08 as submitted.

Update VA AAHRPP visit (Karen Moe)

Karen updated the Board that the Seattle Puget Sound VA recently underwent an accreditation visit from AAHRPP. She reported that the site visit went very well. AAHRPP had a few minor concerns related to how conflict of interest is managed and scientific merit is assessed which should be easy to address. Karen reminded the Committee that the UW Human Subject's Division (HSD) submitted the draft AAHRPP application in March of this year, and the final draft will be sent to AAHRPP later this year. She explained that the site visit team for the UW accreditation will likely include more AAHRPP visitors and will likely be longer by a few days than for the Seattle VA site visit. She indicated that one or two members of the HSPB may be interviewed but HSD will know who will be asked within 10 weeks of the visit to allow for enough time to accommodate schedules.

Update on changes related to processes at HSD (Karen Moe)

Improvements:

a. Minimal Risk application turnaround times:

Karen informed the Board that typically HSD receives a surge of minimal risk application submissions during the spring quarter of every year, mostly based on graduate students wanting to complete their thesis or dissertation work. In the past, IRB approval of these applications has taken up to 12 weeks from the time they were submitted to HSD. She reported that thanks to Shannon Sowards, Assistant Director of Operations in HSD, and the Minimal Risk team, bottlenecks have been identified and strategies implemented to improve turnaround time of these applications to approximately 4-6 weeks. Shannon reported that most of the bottlenecks were discovered through HSD staff self-reports or through internal HSD audits of IRB files. She also reported that HSD staff has adopted the mindset of asking if certain research constitutes human subjects research and that the resulting determinations of some projects not meeting this criterion (and thus not requiring review) have assisted in decreasing the overall workload. Those applications that don't meet the definition of human subjects are sent back to PIs with an appropriate explanation. The Board members were invited to provide feedback on whether they have noticed this shorter turnaround time or if they continue to experience problems. Most Board members reported that UW investigators have commented on noticeable improvements.

b. Submission of VA applications:

Karen described that another system improvement is that VA PIs can now submit their applications directly to the IRB's office at the VA. This will decrease turnaround time, because it eliminates a multi-day step from the review and handling process for VA application. This change was made possible because the VA now has access to the UW HSD's new database and can therefore do the initial data entry instead of the main UW office. The Board agreed that this is a major improvement and will be widely accepted by the VA research community.

Areas to make changes:

Strengthening relationship with FHCRC:

Karen reported recently becoming an *ex officio* member of the FHCRC IRB Liaison Committee, which involve representatives from the FHCRC and UW research community as well as the FHCRC IRB Chairs. In the last couple months, the Committee has focused on improving coordination between the Seattle Cancer Care Alliance (SCCA) and the UW IRBs and Radiation Safety Committees (RSCs). There currently are no cooperative agreements between SCCA and UW RSCs. Therefore, if a UW oncologist performs most of their radiation research procedures using SCCA radiation equipment, but may on occasion need to use UW radiation equipment if the SCCA radiation equipment is not operating, this activity would require UW RSC approval as well. Karen described that both institutions would like to streamline this dual review process and develop a system to coordinate reviews. One Board member asked what the IRBs roles are with respect to radiation involved in research. Karen described that the IRB requires that language related to the risks of radiation procedures be included in the consent and that the language is at a readable level.

Work in progress:

IRS requirements regarding collection of Social Security Numbers (SSN) from research subjects who are compensated for their participation:

Karen reported that she met with Financial Management to discuss payments to subjects, social security numbers, and confidentiality related to this. She referred to guidance documents sent to Board members describing IRS regulations describing methods to minimizing the number of

people who have access to this information. She is working with Financial Management to see if there are any additional changes that can be made with regard to this requirement. She reminded the Board that this is a financial control issue for UW and the State of Washington to make sure funds are not being misused, in addition to being an IRS requirement.

Central IRB review of national cooperative VA studies

Karen invited the Board to provide feedback on whether a central VA IRB should be used to review large multi-site, national cooperative-sponsored VA trials. The use of a central IRB would mean that PIs would no longer need to obtain individual IRB approvals from each performance site. To implement this change, the UW IRB would need to develop and sign a memorandum of understanding with the central VA IRB. Karen clarified that the central IRB would periodically report to the UW IRB, including any adverse effects and noncompliance, but the ongoing monitoring and IRB review of the research would reside at the central IRB. Additional and separate oversight would be provided by the VA R&D Committee on an ongoing basis and would not be substituted by the central IRB. One Committee member pointed out that, in general, using a central IRB for these types of studies would lead to increased efficiency, but there may be extenuating circumstances for some multi-site studies that may not be appropriate for central IRB review. For example, there are Washington State laws restricting certain uses of DNA and identifiable material that may require local review. Karen reported that she would follow-up on how to best handle provisions impacted by state laws.

Update and discussion – UW Clinical Trials Policy

Karen reported that in the last month a new Clinical Trials Policy in UW Medicine requires that certain information must be recorded in patient medical records for subjects who have had any clinical procedures for a research study at a UW medical facility. The Clinical Research Budget and Billing (CRBB) office has been responsible for training and educating investigators impacted by this policy. This new policy involves an increase in risk to some subjects, since information related to their participation in research studies, the name of the study, and certain medical information may be entered into their medical records. Since many entities have access to an individual's medical records (e.g., employers and insurers), this could have a negative impact on some subjects' employability and/or life or health insurability. HSD has worked with CRBB to implement a special modification form for PIs who would be involved in billing participants for research studies for clinical research procedures; these modification forms are to be completed and submitted to HSD by 6/30/08. This special modification instructs PIs to change their consent forms to include any additional risks that may occur to subjects based on their participation in the research. Additionally, template consent language is provided along with instructions on how to modify the consent.

Ongoing metrics of HSD performance (Karen Moe)

Karen reported that the HSD has implemented its new database. Therefore, new reports and metrics can now be generated. One new report in preparation is one that will track the movement of applications through IRB review and what steps present bottlenecks. HSD is also working with the Office of Research Information Services (ORIS) to develop a turnaround time query. This query will identify how much time an application spends in HSD and how much time it spends in other offices (e.g., on the investigator's desk). The report should be ready in the summer and the average turnaround times will be reported online beginning in the fall.

IRB member recruitment (Jeff Cheek as proxy for Clarence Spigner)

Jeff reported that Clarence, who could not attend the meeting, asked that the discussion of encouraging faculty to serve as IRB members be revisited. Jeff presented copies of the September 2007 HSPB meeting minutes where this topic had been previously discussed. Jeff conveyed for Clarence that one complaint with IRBs in general is that there is not enough specific expertise on the panels for some types of research, which leads to inconsistent reviews and longer turnaround times. Therefore, there needs to be a more diverse membership with respect to disciplines on UW IRBs. Jeff reminded the Board that this argument has been presented to various department chairs and Associate Deans about this issue, but there has been resistance from the faculty. One Board member stated that an argument has to be made to faculty which is based on distribution of effort in regards to service and time commitment. If faculty and their departments can be convinced that serving on the IRB is a valuable experience, then they may be more open to serving on the IRB. In addition, providing additional staff support to the IRBs and developing easy-to-complete forms may decrease the amount of work placed upon individual IRB members, which would make it more attractive to potential members. The Committee discussed whether junior faculty and graduate students should be recruited, as this may give them valuable experience in understanding the research process as a whole. Karen clarified that each IRB has a graduate student serving as IRB member. One Committee member suggested that the type and number of faculty represented on the IRB Committees should represent the percentage of proposals submitted to the IRB from that faculty's school. If there are more proposals submitted by that faculty but not representative faculty on the IRB Committees, then the proposals from that unit should be put to the bottom of the pile. Not all Committee members agreed with this proposal, especially since in some departments graduate students submit more IRB applications than faculty. One member inquired if the possibility of compensating members or their academic units for participating was under consideration. Another member noted that the School of Medicine is opposed to the idea of compensating IRB members, since this activity should be considered part of a faculty member's service obligation, and the funds for compensation should be invested in staff support for the IRBs. Jeff replied that the idea of compensation was under consideration, but that a "one size fits all" approach would be problematic. The Committee agreed that this topic needs to be revisited and discussed further.

Jeff thanked Board members for their service and continued commitment. He reminded Board members that this is the last HSPB meeting for the academic year and that the next meeting will be held in September. He invited Committee members to provide feedback on what day and time would be best to hold the bimonthly HSPB meetings. Most Committee members agreed that Fridays in general still work. Jeff announced that HSPB member Cathryn Booth-LaForce would be stepping down as the representative from the Faculty Council on Research, and invited Board members to offer names of other individuals who could potentially serve on the Board to represent other stakeholder groups.

