



MINUTES (*draft version 1*)
HUMAN SUBJECTS POLICY BOARD
9:00 – 10:30 AM
November 21, 2008
Gerberding 142

Members Present

Cheek, Jeff, **Chair**
Barker, Theresa
Brown, Zane
Buck, Steven
Burns, Stephen
Chronister, Lynne
Crutchfield, Robert
Karpen, Richard
Mason, Robert
McCutchen, Deborah
Mitchell, Pamela
Moe, Karen
Rein, Rebekah
Rimmele, Carl
Saxon, Andrew
Slattery, John
Spigner, Clarence
Takeuchi, David
Thomas, Karen
Thummel, Ken
Turns, Jennifer
White, Emily
Wilensky, Alan

Members Absent

Brunzell, John Steven
Burke, Wylie
Hamblin, Mark
Neff, Margaret
Sherrard, Donald
Spieker, Susan

Welcome:

Jeff called the meeting to order at 9:00 a.m. He welcomed members Stephen Burns and Rebekah Rein, who serve as IRB Chairs at the Veteran's Administration (VA).

Role of HSPB in IRB policy creation and implementation (Bob Mason)

The Board members revisited the discussion as to whether HSPB should be considered an "advisory" or "governing" board. Jeff reminded Board members that if the HSPB served as an governing board, this would require the Board to comply with the Open Meetings Act (e.g., all meetings and records be public). Conversely, if the HSPB were to serve as an advisory committee, the question to be addressed is who "owns" policies and processes. Jeff suggested that the Vice Provost for Research and HSD must ultimately own institutional human subjects policy, since those offices have to comply with federal regulations and reporting requirements. He suggested that the Board's critical role would involve examining current and future policies

and processes to address problems that are reported to the Board by campus stakeholders, and advising HSD on applicable changes. The Board could also provide a valuable service by recommending how current and revised policies are communicated to the researcher community.

Approval of minutes from meetings of 9/19/08 (Jeff Cheek)

The Board accepted the minutes of the 9/19/08 meeting as submitted.

Update on UW Human Subjects Compensation Plan (Karen Moe)

Karen provided background information on the current UW Human Subjects Compensation Plan, which will be renamed to the UW Human Subjects Assistance Program. In general, the current plan provides medical treatment (or compensation for medical treatment) research subjects experiencing physical Adverse Events (AEs) while participating in UW human subjects research. The Plan is funded by UW Risk Management and by UW Medicine; it is not an insurance plan. Several factors have made it necessary to revise the current Plan: the increasing complexity of UW research, which often involves multiple institutions and other countries; increased costs and expectations about treatment; lack of clarity and understanding about some specific details and management of the Plan; and interactions with the Medicare Secondary Payer rule. An *ad hoc* working group has been reviewing and working on these issues and the PIN for the past year.

The Board members were provided with a handout describing the draft revisions to the plan. Currently, the draft revisions are being routed to major stakeholders for input.

The revised Plan has two components:

- 1) A medical assistance program which provides free care at UWMC facilities for qualifying AEs, with a cap of one million dollars. Out of pocket expenses related to medical treatment will continue to be reimbursed by the Office of Risk Management, up to \$10,000.
- 2) Development of a discretionary program. This program would allow the UW to provide some discretionary treatment or reimbursement to subjects whose AEs don't meet the qualifying criteria. The researcher or the subject would nominate the subject for the program and the Plan management group would review the application.

Karen stated that the compensation program will not apply to any industry-sponsored-and-initiated studies. The revised program will cover some psychological and psychiatric AEs, in addition to physical AEs. There is strong sentiment by UW investigators to continue coverage of international research. The revision process includes preparation of template language describing the Plan, which researchers can use in subject consent forms.

Vice Provost for Research Mary Lidstrom and SOM Dean Paul Ramsey have agreed to serve as Executive Sponsors of the revised Plan. There will be a cross-office group that manages the Plan; it will include Karen Moe, Dean Ramsey's representative, representatives from the Office of Risk Management and UW Medicine, several researchers, the Attorney General's Division, and other key individuals.

Revising the plan will take significant time. There are multiple offices involved, and several stakeholder groups need to be consulted. In addition, the existing plan is based on a Standing Order from the Board of Regents. Current efforts involved getting broad feedback on the revisions. She also explained that the working group will be spending time on developing operational definitions for key terms. She invited Board member input. When the revision has

been completed and ready for implementation, there will be a large outreach and education program to explain it.

One Board member asked how this program might apply to research studies where AEs might not appear until well after the end of the study. Karen stated that this is one of the issues the working group is discussing. One possibility is that there would be a time limit imposed on claims, similar to medical malpractice. For example, subjects would need to ask for treatment, or compensation for treatment, within 3 years after completing a study.

There was a discussion by Karen and Board members about the interaction of the revised Plan with the Medicare Secondary Payer rule.

The Board discussed who will make the decision of whether a specific AE is covered by the program. Karen responded:

- 1) The IRB will determine whether the Plan applies to a study during the initial review of the study's IRB application.
- 2) The PI will report the AE to a subcommittee of the Plan management group, together with his/her assessment of whether the AE is directly related to the research.
- 3) The subcommittee will primarily consist of people who routinely review AEs for clinical care.

Audit of Seattle VA (Karen Moe)

Karen described a recent major not-for-cause audit of the Seattle VA Human Research Protection Program (primarily the IRB and the VA's Research & Development office). The audit was part of a national VA program to audit all VA research centers. The audit was performed by the VA's Western Regional Office of Research Oversight (ORO). The audit findings identified significant problems that have been similarly found at other VA locations, although there were no findings of noncompliance with federal regulations. Instead, the main findings identified noncompliance with the VA Handbook and VA policy, and failure to follow some best practices identified by the audit team.

The Director of the Seattle VA has imposed several restrictions and requirements on the VA's research program because of the audit findings. These include: (1) all existing studies must be re-reviewed before they can continue to enroll new subjects (though already enrolled subjects can continue to participate); and (2) no new studies can be reviewed by the IRB or the R&D Committee until the re-review has been completed. Because of the growing number of VA-specific regulations and expectations, it was also strongly suggested that the Seattle VA develop its own independent IRB instead of relying upon the UW IRB.

The Human Subjects Division is assisting the VA in every way possible to meet these requirements. The audit affects many UW researchers as well as VA researchers, because of the close connections and collaborations between the two institutions. One current challenge is to identify which UW research programs are affected. As much as possible, both the VA and UW will work to minimize any additional burdens placed upon researchers and the IRB Committees.

Human subjects research in non-social science research units (Bob Crutchfield)

Board members discussed the issue of departments whose graduate students are unfamiliar with human subjects research regulations and which activities might be considered human subjects research. The Board generally agreed that it is the primary responsibility of faculty to educate their graduate students about what activities might be considered human subjects research and therefore may require additional permissions and IRB oversight. The Board agreed that activities that meet the definitions of human subjects and research as described in the Code of Federal Regulations would be the only activities requiring IRB oversight. The Board also agreed that broad-based efforts to educate faculty and graduate students on what might constitute human subjects research need to be considered, as it is not always clear

The Board requested that this topic should be placed for continued discussion at the next HSPB meeting.

Update on compensation plan for service on social/behavioral IRBs (Jeff Cheek)

Jeff reminded Board members that the pilot project to compensate UW Departments that provide faculty members to serve on IRBs will begin in 2009. The problem we're trying to address is the dearth of faculty participation on the IRBs (particularly from upper campus) and the need to have a greater diversity of disciplinary expertise on our social/behavioral IRBs at the UW. Specifically, the faculty members themselves will not be directly paid for their service; rather, the funds will be made available to the academic unit instead. It will be up to the Dean and/or Dept. Chairs to determine how the unit wants to use the funding as an incentive to encourage faculty to serve on IRBs (e.g. course buyout, individual allocation for IRB member travel or research, etc.) He invited Board members to contact him if they have Departments that might be interested in participating in this pilot incentive project.

Submitted by Kim Blakemore