

HUMAN SUBJECTS POLICY BOARD

MINUTES

10:00-12:00 p.m., May 12, 2005

142 Gerberding Hall

Members Present

Hogan, Craig (Chair)
Bruce, Harry
Brunzell, John
Crutchfield, Robert
McCutcheon, Deborah
McGough, Helen
Mitchell, Pamela
Moe, Karen
Parks, Malcolm
Rein, Rebekah
Robinson, Nancy
Streidl, Gigi
Thummel, Kenneth
Tolnay, Stewart
Wilensky, Alan J.
Zuiches, Carol

MEMBERS Absent

Brown, Zane A
Burke, Wylie
Cauce, Ana Mari
Eaton, David
Handsfield, H. Hunter
Kharasch, Evan
Kuszler, Patricia
Sherrard, Donald

Review and Approval of Minutes of 2/11/2005 (Craig Hogan)

Minutes of the 2/11/2005 meeting were available for review. The minutes were accepted as submitted.

OHRP Site Visit Report (Craig Hogan and Helen McGough)

(Members received copies of the 4/1/05 OHRP site visit letter and the UW 4/27/05 response letter)

Craig said the site visit report emphasizes the importance of human subjects review and oversight. We have been in the public spotlight. We need to make compliance a priority and do exceptionally well at being compliant. Some intensive work will be done over the summer.

Helen provided the following background. OHRP has conducted thirteen “not for cause” site visits at various institutions since 1999. Sites are selected based on institutional size, geographical spread, level of reporting, and FDA audits. In early February OHRP called to notify the Human Subjects Division (HSD) that they would be conducting a not-for-cause site visit. HSD had three weeks to prepare for the audit and was required to send preliminary materials to OHRP. The audit was conducted from February 23-25 by a team of four: two OHRP compliance staff and 2 non-OHRP employees (a committee chair from the University of Kansas IRB and an IRB administrator from UCLA).

The site-visit report, addressed to President Mark A. Emmert, contains seven “findings” and seven “concerns.” OHRP posted the report on their website seven days after the date of the report, redacting all items that were not “findings.” On 4/17/05 the University made the decision to publish the entire letter on the HSD website. President Emmert issued a statement to the press, making the process transparent. There were seven or eight articles in local papers. The response, signed by David Thorud on behalf of President Emmert, was sent to OHRP on 4/27/2005. At this point we’re waiting for OHRP’s response. Helen has been summoned to meet with Senator Patty Murray and Congressman Norm Dicks. Representatives from OHRP were invited to be present at this meeting but they declined.

HSD has already taken action to correct some procedures that were faulted in the findings (anniversary dates are being revised to reflect the date of committee meetings, new procedures are in place for determining which applications/modifications need to go back to the full committee for review and approval). Researchers have been

responsive. It will take longer to correct some of the findings. Some research projects have been placed on hold until status reports can be reviewed at a committee meeting. Studies involving prisoners have been placed on hold until they have received OHRP secretarial review and approval in compliance with OHRP regulations. Karen Moe is in the process of submitting the appropriate materials for each prisoner study. The review process is now slower because most responses and many modifications need to go to the full committee for review and approval.

Craig thanked Helen and Karen and the staff for the quick response and action they have taken in response to the OHRP report. Helen said OHRP told her this is the first time an institution didn't ask for an extension.

Accreditation Update/Organization and Review of Policies and Procedures (Karen Moe)

(Members each received a copy of an outline of HSD Policy and Procedures)

The current plan is to apply for accreditation in late summer or early fall. As policies and procedures are drafted over the summer drafts will be sent to board members for review and comment. Fred Hutchinson Cancer Research Center (FHCRC) is applying for accreditation at the same time; Karen is working closely with a colleague at FHCRC to develop policies and procedures. Also, she is drawing liberally from policies and procedures from other institutions. New procedures will make a more efficient, compliant, and consistent review process.

The first section of policies and procedures to be drafted is Compliance.

- There are several levels of noncompliance. Depending on the seriousness of the noncompliance, the noncompliance may be acted upon by staff alone, by staff and committee chair, or by the full committee. Actions taken on noncompliance can range from no action to suspension. Noncompliance occurs with both faculty and students and throughout campus. Most cases of noncompliance involve primary data collection.
- The focus should be on serious and continuing noncompliance.
- Most noncompliance by students involves research conducted without review. In these instances the committee may recommend that subjects be re-contacted and re-consented; or, the committee can require destruction of data. The department and graduate school will make the final determination about whether or not the student can use the research for fulfillment of a degree requirement.
- Helen and Karen have met with campus groups to discuss ways to educate students, departments, and advisors. Currently, department chairs and faculty advisors receive copies of letters from the committee.
- The Graduate School views its role as educational. They are working to get word out to students about the need for Human Subjects approval.
- It is difficult to know what to do when faculty openly/flagrantly advise students not to go through the review process.
- Oversight is needed at the department/program level.

Committees have asked for guidance on using a lottery system for subject compensation. Karen consulted with other institutions and determined that compensation in the form of a lottery is okay in some circumstances.

Carol Zuiches hired a consultant to do team building with OSP and HSD. Vision and mission statements will be developed.

Report on Budget Request and Staffing/Temporary Staff (Craig Hogan)

A budget request has been submitted to provost for three additional program coordinators and one post-approval monitor. Also, a request was submitted to make all temporary staff permanent. The OSP and HSD budgets will be separated. Depending on OHRP's response, there may be additional budget requests--possibly add another IRB, add a position for expedited review and for continuing compliance. Craig anticipates the budget request will be granted. The Board asked if there is a possibility of funding to compensate departments that provide committee members. The committee chairs' departments have been compensated for the past four years with \$10,000 per year but there isn't compensation for members. The Board recommends pushing for member compensation in order to get the best expertise, to open membership to a broader representation, and to increase turnover.

UWISE Update (Mac Parks)

Formal deployment of UWise began on March 31. Twenty-four departments are in one stage or another. UWise started first with high-load units with review spread among all committees. Departments that have gone through training will, after a certain time, be expected to submit all applications electronically. Phase I is now 120 days; eventually, this will work down to 60 days. Faculty users have been uniformly positive about UWise. Staff and Committee members, the most intensive users of the system, have requested changes in the system to make it work better for them. The deployment team is working hard with staff and committee members to optimize the system to make it most effective and efficient. Sharon sets the training schedule on campus. The UWise vendor is Click Commerce (formerly Webridge). There is a user consortium of about 20 members that meets twice annually. The base system incorporates suggestions from other institutions. Our own system is customized.

HSD Website (Karen Moe)

The HSD website, newly designed by Sharon Elsayed and Jill Yetman, is two or three weeks away from being available to users. A test site is available for feedback. The new site will have specific sections for users (researchers, staff, sponsors, subjects, committee members) and will have educational features, guidance, policies and procedures. All except the staff and committee sections will be available to the public. The current website will be retained for a couple of months. The website will be able to be updated easily.

External Relations: WIRB and Cancer Consortium (Helen)

Effective June 1, 2005, applications for industry-sponsored clinical trials will be reviewed by Western IRB (WIRB). Investigators will still need to go through the Office of Sponsored Programs as well as appropriate UW compliance offices (Radiation Safety, Biosafety Committee, etc.). WIRB will require researchers to use the University of Washington consent form templates. WIRB has been accredited by AAHRPP.

A Cancer Consortium IRB, housed at Fred Hutchinson Cancer Research Center (FHCRC), will start reviewing applications in September 2005. Applications that are submitted by members of the cancer consortium will be eligible for review by this committee. Helen expects there will be about 40 new applications submitted through this committee each year. Renewal applications will be transferred to the Consortium IRB as they come up for renewal beginning in January 2006. These research protocols are already going through scientific review at the FHCRC. Our committees haven't had the expertise to review the protocols. Approximately 130 researchers are members of the consortium.

Future Agendas, New Business

Some Board members request clarification of the type of review required for use of coded data. Guidance is needed. Helen attended a conference of the American Psychological Association, attended primarily by behavioral scientists. The group failed to agree on definition of minimal risk. They did come up with an algorithm that has some promise. Assessments of risks include evaluating the following:

- sources of risks
- types of risk
- vulnerability of population
- strategies to reduce risk.

Meeting adjourned at 12:00 p.m.

Recorder: Nancy E. Grout

Electronic Attachments:

OHRP site visit letter: http://www.washington.edu/research/hsd/forms/ohrp_letter.pdf

UW response letter: <http://depts.washington.edu/hsd/ohrp.pdf>