

## HUMAN SUBJECTS POLICY BOARD

### MINUTES

11:00-12:00 p.m., March 15, 2006

142 Gerberding Hall

#### **Members Present**

Lidstrom, Mary (Chair)  
Barker, Theresa  
Brown, Zane A.  
Buck, Steven  
Burke, Wylie  
Chaney, Edmund F.  
Crutchfield, Robert  
Eaton, David  
Handsfield, H. Hunter  
Kuszler, Patricia  
Mason, Robert M.  
McCutcheon, Deborah  
McGough, Helen  
Moe, Karen  
Morrison, Diane M.  
Neff, Margaret  
Rein, Rebekah  
Rimmele, Carl  
Sherrard, Donald J.  
Slattery, John T.  
Streidl, Gigi  
Thummel, Kenneth  
Wilensky, Alan J.  
Zuiches, Carol

#### **Members Absent**

Booth-LaForce, Cathryn  
Brunzell, John  
Mitchell, Pamela

#### **INTRODUCTIONS (Mary Lidstrom)**

Mary welcomed everyone to the first Human Subjects Policy Board under her leadership. Mary said she will set up regular meetings of the Board and will use the Board as a team representing members from across the campus. Her goal is continuous improvement in the area of Human Subject Protections and a program that becomes a shining example of protection, service to researchers, and compliance with regulations. She feels we should focus on the first two with a balance between protection and service.

#### **UPDATE ON SEARCH FOR NEW ASSOCIATE VICE PROVOST (Mary Lidstrom)**

The Provost and President view compliance as a top priority for the University of Washington. The Provost has requested a full-time Associate Vice Provost who will help coordinate research compliance across campus. Human Subjects protection is just one aspect of compliance; other areas of compliance include animal research, isotopes, scientific misconduct, and OSP. Currently, compliance is decentralized. Ken Thummel is the chair of the search committee for a new Associate Vice Provost for Research Compliance; other members include David Eaton and Patricia Kuszler. Board members should let Ken know if they want to be involved in the interview process. The position, which was advertised widely, has drawn about eighty-five percent of the candidates from out of the area.

#### **UPDATE ON HSD (Helen McGough and Karen Moe)**

**Space and Staff.** HSD has received funding for new positions and will have maxed out on space by the end of the fiscal year. New positions that have been filled include the following: (1) a compliance manager to handle

complaints, ongoing non-compliance, and post-approval monitoring; (2) a third human subjects review administrator to review minimal risk applications and certifications of exemption; (3) a half-time education and training coordinator; (4) a program coordinator and human subjects review coordinator to support Committee V at the VA; and (5) a compliance analyst to support the accreditation team. Positions yet to be hired include (1) an assistant director of operations; (2) an additional administrator to support accreditation; (3) an administrator and coordinator for a new behavioral committee; and (4) additional staff to support an eighth new committee.

**Noncompliance.** There are currently two ongoing non-compliance cases.

**Western IRB (WIRB).** WIRB started reviewing industry-sponsored clinical trial applications for UW last summer. They have reviewed about 100 applications to date. Clinical trials have high maintenance so this has taken a load off the biomedical committees. There has been ongoing quality assurance with WIRB.

**Seattle Cancer Care Alliance.** A committee (CCIRB) at FHCRC is reviewing applications that involve cancer protocols from investigators who are members of the Seattle Cancer Care Consortium.

**Turnaround time.** The number of applications for the biomedical committees is decreasing with the transfer of review of some applications to WIRB and CCIRB; however, Committee V at the VA is overloaded. After getting new staff hired and trained, HSD has plans for assessment activities and targeted turnaround times. There will be a focus on pre-review so that regulatory issues are resolved before applications go to the committee.

**Dave Eaton announced that Bernard A. Schwetz, head of Office for Human Research Protections, has been invited** to come to the UW on 4/5/2006. The first session will be in the morning in the Henry Art Gallery. All Board members are invited to attend.

**OHRP Site Visit Update.** The OHRP not-for-cause site visit occurred about one year ago. All the correspondence has been published on the HSD website. In October 2005 we received notification that OHRP was satisfied with UW's responses. Almost all findings have been addressed internally with positive effects on the office.

**Accreditation.** The site visit slowed the accreditation process. The AAHRPP fee was submitted in December 2005. HSD is examining all policies, procedures, guidance, and forms. The accreditation process will have major positive effects on quality and effectiveness of our Human Subject Protections program. Mandy Vick (compliance manager) and Sharon Elsayed (training specialist) will be key persons in the accreditation process. All policies will come to the Policy Board for review and comment. Karen expects to start posting drafts on the website in about one month. Benefits of AAHRPP include: having a framework for the program, being more efficient, and not doing what we don't need to do. We will be less likely to have audits; we will have best practices and efficiencies. It is a goal to make review requirements transparent, making it easier for researchers and IRBs.

**Metrics:** HSD will be getting a new database in a few months, one that has been developed and used by FHCRC. The new database is friendly and intuitive and will allow a lot more tracking capabilities than the current ACCESS database. This database is offered free as a "carrot" for participating in the development of an electronic application system. UWise has been on hold since March 15 and will be so for at least one year. This new database will allow other compliance offices to have read-only views but it won't be able to interface with other compliance programs.

## **DISCUSSION: SET AGENDA FOR FUTURE MEETINGS (All)**

Only those policies that are controversial will be discussed at board meetings. The board will need to discuss which policies have issues that should come to the whole group. One current issue is training requirements for the research community—who should be required to have training, how frequently, and what kind of training. Another issue that could be discussed is the definition of research. Mary recommends that meetings be quarterly for the whole group but that small groups meet more frequently.

Meeting adjourned at 12:05 p.m. Recorder: Nancy E. Grout