

HUMAN SUBJECTS POLICY BOARD MINUTES

3:00-5:00 p.m., April 9, 2004
142 Gerberding Hall

MEMBERS

Hogan, Craig (Chair)
Brown, Zane A.
Brunzell, John
Burke, Wylie
Cauce, Ana Mari
Crutchfield, Robert*
Eaton, David
Handsfield, H. Hunter*
Kharasch, Evan
Kuszler, Patricia*
McCutchen, Deborah
McGough, Helen
Mitchell, Pamela
Parks, Malcolm
Rein, Rebekah*
Robinson, Nancy
Streidl, Gigi
Thummel, Kenneth
Wilensky, Alan J.
Zuiches, Carol

**Denotes member's absence*

WELCOME AND INTRODUCTIONS (Craig Hogan)

Craig Hogan welcomed everyone to the first meeting of this Policy Board and asked members to introduce themselves. Membership includes representatives of the University research community, administration, and Human Subjects Review Committees. More members may be appointed in the future.

REVIEW OF CHARGE AND INFRASTRUCTURE REVIEW (Craig Hogan)

In the year 2000 the Human Subjects Task Force recommended the creation of a Human Subjects Policy Board. The charge of the Board is to focus attention on issues of human subject protections in research and to provide a mouthpiece for the research community.

HSD UPDATES/UWISE/ACCREDITATION (Helen McGough)

UWISE. The Human Subjects Task Force, conducted in 2000, recommended that the operation of the Human Subjects Division should be converted to an electronic system. In 2001 Mac Parks submitted a proposal to OHRP for an enhancement grant. The UW received a grant for \$250,000. The University contracted with a Portland-based company, Webridge, to create a "cradle to grave" web-based electronic system for the submission, review, and processing of human subject applications. The electronic submission will give researchers more control of their applications and they will be able to complete and submit applications on line; also, they will receive instant notification of actions on line.

Committee members will receive and review agenda materials on line (no more formidable blue bags) and will be provided with laptop computers at committee meetings. The system will have search and note-taking capabilities. The face-to-face committee review process will not change.

UWISE deployment will begin with a few departments in May. Departments will be selected on the basis of high volume, requiring different levels of review (i.e., exempt, minimal risk, full committee), and including both biomedical and behavioral research. Campus-wide implementation is expected to occur in September 2004. Training will be easiest for faculty and staff. The changes will impact the HSD staff and committees more profoundly.

The review process may slow down at the beginning but should show improvement in the future. For about 18 months HSD will be operating on a dual system. It will take at least five years to be paper free. It is anticipated that new and improved forms with required fields will result in better applications. Researchers will be required to submit new applications electronically. No hard copies will be necessary (however, everything will be printable for those who wish to keep a printed copy). The system will have a dedicated backup server. In the long range, the UWISE system will be linked to a research compliance system.

The UW was the first institution to work with Webridge. Other institutions (including John Hopkins, Duke, Pittsburgh) are now buying into the system. A user group has been formed which will help leverage the investment.

Accreditation. There are two non-profit associations that do accreditation: Association for the Accreditation of Human Research Protection Program (AAHRPP) and National Council for Accreditation and Quality Assurance (NCQA). The University of Washington has elected to do accreditation through AAHRPP. Helen announced that she is a board member of AAHRPP. The program will evaluate compliance in all areas, including human subjects review, monitoring, radiation, risk management, etc. The process involves four months of self-assessment, a site visit, and a report within two to three weeks. The institution has two months to respond. A final report is then issued with full approval, pending approval, or denial. A date for accreditation will be set after an assistant director for HSD has been hired. An estimated date is early 2005. About ten institutions have gone through the AAHRPP process. Institutions have said the process was educational and helpful and it has improved their programs. CDC will evaluate the outcomes of accreditation.

SPACE, HSD ASSISTANT DIRECTOR, STAFFING (Carol Zuiches)

Space. Grant and Contract Services and the Human Subjects Division currently occupy about 7100 square feet. The infrastructure review received 200 requests for funding. Space for GCS and HSD was selected as the number one priority. A request for 14,000 square feet has been made. Carol Z. and Helen M. have looked at the fourth floor of a building on the NE corner of 45th and 11th that is available for lease. CASPO is moving ahead and evaluating the cost. It would probably take at least six months before the move could take place since only the core of the building is complete.

HSD Assistant Director. Many candidates have applied for the position. Cuts will be made in the next few weeks and a short list will be created after telephone interviews. Interviews will be open to all who wish to meet the candidates.

Staffing. The infrastructure report gave priority to additional staffing for HSD and GCS. This includes temporary funding for two program coordinators for HSD and a couple of administrators for GCS. Some positions have not been filled because of lack of space.

VA Only IRB. A new Human Subjects Review Committee is being formed that will review all applications that involve VA patients or VA sites. The Central Office of the VA has implemented enhanced regulatory requirements that place extra burden on the committees. This committee will review both minimal risk and full committee applications and will include biomedical and behavioral research. The reciprocity agreement will work like the one with CHRMC--it's a one way agreement. The VAPSHCS will provide salary for one administrator but the University will continue to provide other support. Eventually the VA committee will be supported entirely by the VA. Dr. Donald Sherrard, an experienced IRB member, will chair the

committee. Some VA representatives who are members of our existing committees may transfer to the new committee. It is expected that the caseload will be about twenty per cent of existing applications.

REVIEW & DISCUSSION OF POLICY BOARD TASKS (Helen McGough and Craig Hogan)

Additional membership. Federal regulations mandate that the board membership includes at least one member who is a scientist, one who is a nonscientist (does not conduct research and does not have training as a scientist), and one who is unaffiliated (neither affiliated nor part of the immediate family of a person who is affiliated). Existing members are encouraged to refer persons who may be interested in serving as a community member of the board. Helen McGough will send an email reminder soliciting referrals.

Financial disclosures in consent forms (decision). The media and regulatory agencies have focused attention on conflict of interest in research. The UW has a zero threshold for conflict of interest. If the conflict is not manageable then the research will not be conducted. Members received a handout, "Financial Disclosures in Consent Documents," describing the issue, regulations, principles, guidance, and policy followed by other institutions. There was discussion of Helen's recommendation to the policy board that "UW consent forms must include a statement that discloses the financial support of the study in simple language such as: "The University of Washington is receiving funds from [INSERT NAME OF SPONSOR] to conduct this study." Discussion:

- If conflict is off the table, why include a statement at all?
- Leave it up to the IRB to determine whether there should be a statement of financial interest.
- There may be a conflict of interest even if there are no funds (support could be provided in other forms).
- If the process of review identifies and removes conflict of interest, then the statement could be removed. The pressure should be with UW procedures and institutional transparency.
- Having a sponsor identified on a consent form could be misleading.
- Discussion of conflict of interest is already part of the HSRC review process.

DECISION: The recommended policy will be changed to "UW consent forms should generally include a statement that discloses the financial support of the study." The sponsor's name can be general (e.g., instead of "funds from National Cancer Society" it could say "funds from the government"). The committee can make an argument to exclude a statement altogether.

Post-approval monitoring. Evan Kharasch, Ken Thummel, and Alan Wilensky volunteered to serve on the subcommittee. Mac Parks has a report from a working group with possible methods for monitoring that he can share. Helen will provide AAHRPP standards for monitoring.

Review of task force recommendations. David Eaton and Mac Parks volunteered to serve on the subcommittee.

Reorganizing the review of minimal risk ("expedited") proposals. Ana Mari Cauce (Chair), John Brunzell, Pamela Mitchell, Deborah McCutchen, and Wylie Burke volunteered to serve on the subcommittee.

Other. There has been inappropriate use of email within some research teams, risking disclosure of identifiable information. Education should be provided via the Human Subjects Division newsletter. Research teams could be required to use encrypted email systems.

Next Meeting. The next meeting will be scheduled for June.

Recorder: Nancy E. Grout