

HUMAN SUBJECTS POLICY BOARD

MINUTES

11:00 a.m.-1:45 p.m., November 12, 2004
Regents Room

MEMBERS

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

**Denotes member's absence*

Welcome and Introduction of New Members (Craig Hogan)

Craig welcomed new board members, Karen E. Moe, Assistant Director, Human Subjects Division; Stewart Tolnay, Professor of Sociology; and Harry Bruce, Associate Dean, the Information School. Donald Sherrard, Chair of Human Subjects Review Committee V, was unable to attend.

Review of Minutes: The minutes of 6/14/2004 were not available for review. [NOTE: Policy Board minutes can be viewed at the following website: <http://www.washington.edu/research/hspb.html>.]

Plans to deal with approval delays, minimal risk, modifications (Karen E. Moe)

Karen Moe presented a seven-step plan for dealing with delays in approval of minimal risk applications and modifications:

1. The volume of applications handled by the Human Subjects Division (HSD) is high. There are approximately 5,000 active applications. Several steps are being taken to deal with this volume:
 - A new committee, Committee V, has been formed to review all applications involving the Veterans Administration. Committee V has already had training and has conducted three meetings. This committee will do both minimal risk and full-committee review.
 - Negotiations with Western IRB are underway to outsource review of industry-sponsored research. Using Western IRB will be voluntary. It is anticipated there may be 100-200 protocols eligible for this review each year.

- HSD has been given funds to support one additional program coordinator to work with the minimal risk team to develop a more efficient triage system.
2. Improvement of Internal work flow.
 - Pinch points have been identified. There has been just one person with signatory authority to sign off on minimal risk review. Minimal Risk will have two teams with two persons on each team, one to review applications from biomedical departments and one to review those from behavioral departments.
 - HSD staff has been housed in four separate locations. On December 3rd the staff, with the exception of Committee V staff, will move to one location. This will allow greater efficiency.
 - Consideration is being given to staff specialization in certain areas and creation of guidance in those areas: for example, medical chart review, oral history, ethnographic research, etc. Specific applications may be developed for each type of research.
 - The minimal risk team has been isolated from working with the full-committee teams. The new space will allow location of the minimal risk teams close to the appropriate full-committee teams.
 - Better metrics are being developed to measure performance and to identify areas to improve process. This will also help determine where to target resources.
 3. Policies and Procedures.
 - HSD is applying for accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). This will involve writing operating policies and procedures. Policies and procedures haven't been updated in recent years, leading to inconsistencies.
 4. Hiring strategies. HSD is looking for and attracting candidates with more scientific experience.
 5. Improving application quality. HSD is investigating and implementing a variety of ways to help researchers prepare high-quality applications. This includes: the development of a new website with more explicit content and guidance that is easier to navigate; the availability of more examples; revision of forms and application questions (through the UWISE system); and the development of education and help sessions for specific types of research and researchers. .
 6. HSD is working to have better communication with researchers. The new electronic application system, UWISE, will allow researchers to see where their applications are in the review process. Meeting schedules will be posted.
 7. Long-term strategic thinking will include working with other institutions for ideas of improving process. The Policy Board is encouraged to share ideas.

Board members shared the following comments/recommendations: the seven-point plan should be shared with the research community (Craig and Karen will work together to communicate with Deans, Directors, and chairs); departments should have a point person to improve the quality of applications (department resources are a problem); it may be helpful to have reviewers contact the principal investigator (PI) prior to meetings and/or to invite PIs to attend meetings; student mentors need to provide more support/guidance to students; HSD procedures should include examples of good/bad practices; user groups can share and distribute information.

Report from Post-Approval Monitoring Subcommittee (Ken Thummel)

The subcommittee is close to making final recommendations. The subcommittee has met with Risk Management. There is nothing to keep this process from covering all research; i.e., biomedical and non-biomedical research. The central theme for post-approval monitoring is compliance and education-- to protect subjects and to educate researchers. The subcommittee is developing standard operating procedures to describe how the monitoring process will work and to give a heads up so researchers know what to expect. Input is sought from a variety of stakeholders. The subcommittee will recommend that the post-approval monitoring is separate from HSD. An unresolved issue is how the monitoring process will be funded. The subcommittee plans to have a recommendation ready to present at the next policy board meeting.

Report on Outsourcing contract to WIRB (Helen McGough)

Mac Parks and Helen McGough approached Western Institutional Review Board (WIRB) with a proposal to outsource review of industry-supported research. The Office of Risk Management and the Attorney General's office have reviewed a preliminary contract. After the final contract is signed the infrastructure will be developed. The UW will retain liability and will have an obligation to monitor approvals and will maintain a complete copy of all applications reviewed by WIRB. The contract can be cancelled at any time. The advantage to researchers for using WIRB will be turnaround time (usually two weeks from the time of the meeting to final approval). Gigi Streidl said the School of Medicine currently has 116 industry-sponsored trials, down from the 120-150 in the past. Existing applications will not be eligible for review by WIRB. Outsourcing will be revenue neutral to the UW since the sponsor will need to pay the fees for WIRB review. The UW will continue to charge the IRB fee. WIRB requires researchers to be credentialed and board certified. Also, they require researchers to complete human subjects training. The HSD website will post a list of pros and cons of using WIRB as the reviewing institution. The integration of WIRB review and UWISE is being developed.

Updates: Space, Personnel, Training (Helen McGough)

1. The Human Subjects Division will move to 3935 University Way NE on Friday, December 3rd. Open House is scheduled for Friday, December 17.
2. Personnel: Dorothy Poulsen, administrator for behavioral Committee G, is leaving. A minimal risk human subjects review coordinator (HSRC) has been promoted to administrator (HSRA). HSD is interviewing for a new HSRC, a HSRA, and a program coordinator.
3. Last Friday Helen and Sharon Elsayed attended a meeting in collaboration with the Northwest Association for Biomedical Research (NWABR) with the purpose of setting up a speakers' bureau made up of researchers and research volunteers who would be willing to go out in the community to talk about research and to get the community's perception of research. Two dozen attendees were expected—forty attended.
4. HSD staff, chairs, and committee members attended a full-day IRB conference, sponsored by NWABR, in Bellevue. Keynote speakers were Wylie Burke and Ernie Prentice. There were 20 breakout sessions.

Update: UWISE (Sharon Smith Elsayed and Chris Naslund)

Training of staff and the research community was underway in July 2004. Seven units are participating in pilot testing and two applications are in the departmental approval phase. Sharon and Chris said feedback from researchers and research staff has been very positive. UWISE is accessible from everywhere. Anyone can look at the UWISE training website to see when departments are scheduled for training. On-line tutorials will be available. All human subjects review committees have been trained and will be receiving electronic applications to review in the next few weeks. Sharon and Chris presented a demonstration of the UWISE application process. UWISE has a flexible framework that is being used by other institutions. The long-range intention is to expand the system to other areas of research compliance; e.g., Radiation Safety, Biosafety Committee, Technology Transfer, etc.

Updates: Accreditation, Draft policies (Karen Moe)

In 2001 members of Public Responsibility in Medicine and Research (PRIM&R) got together to develop standards for protection of human subjects in research. The AAHRPP accreditation process was established two years ago. The University is committed to accreditation through AAHRPP. The benefit of accreditation is that we'll have assurance that the UW is in compliance. The process will involve a self-assessment and development of new written policies and procedures. Self assessment includes five components: the large organization; IRB review; investigators; sponsors; and participants. Five or six visitors will conduct the site visit over a one-week period. Karen attended an AAHRPP workshop in August and also attended relevant workshops at the ARENA conference in October. She has identified the most vulnerable areas and is working on writing procedures, devising a system to review policies, meeting with other organizational units, reviewing policies and procedures from other institutions, and conducting internal audits. The time-line for accreditation is 12/04 through 6/05. Helen and Karen will draft policies and submit them to subgroups of policy board members (and others) for review.

Report on Meeting of Associate Dean for Research and Research Administrators in the social and behavioral sciences to discuss issues and concerns related to UW human subjects' compliance, policies, and procedures. (Harry Bruce)

Alpha DeLap, Research Services Administrator, and Harry Bruce from the Information School, met with Peggy West from the School of Social Work to share issues and concerns about the human subjects review process. Shared concerns include the following: communication seems adversarial; advice is incomplete; there is a lack of understanding, especially about ethnographic research; determining level of risk is ambiguous; review time is long; the level of review (exempt/minimal/full committee) isn't clear; training is needed for department coordinators.

Some recommendations include: encourage positive interaction; provide additional resources; revise forms; data that is publicly available and data sets that will be provided to researchers without identifiers should be exempt; training should have subcategories to deal with social science; clearer guidelines should be available for educational research; research conducted by master's students should be reviewed quickly; better communication should be promoted.

The meeting adjourned at 1:45 p.m.

Recorder: Nancy E. Grout