

HUMAN SUBJECTS POLICY BOARD MINUTES

1:00 - 3:00 p.m., June 14, 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 (arrive 1:15)
Kharasch, Evan**
Kuszler, Patricia*
McCutchen, Deborah
McGough, Helen
Mitchell, Pamela*
Parks, Malcolm
Rein, Rebekah*
Robinson, Nancy*
Streidl, Gigi*
Thummel, Kenneth
Tolnay, Stewart*
Wilensky, Alan J.
Zuiches, Carol*

**Denotes member's absence*

***Present by teleconference for Post-Approval Monitoring Subcommittee report*

WELCOME AND INTRODUCTION OF NEW MEMBER (Craig Hogan)

Craig Hogan announced that Stewart Tolnay, Chair, Sociology, is a new member of the Board.

REVIEW AND DISCUSSION OF MINUTES OF APRIL 9, 2004 MEETING (Craig Hogan)

There were no corrections or additions to the minutes.

REPORT FROM MINIMAL RISK SUBCOMMITTEE (Ana Marie Cauce)

The minimal risk subcommittee will meet for the first time on 6/24/04. Ana Marie asked for clarification of the goals of the subcommittee. The subcommittee should consider alternative models for review of minimal risk, identify pinch points, and brainstorm ways to improve turnaround time.

The 2001 Task Force recommended a target turnaround time of 21 days for new minimal risk applications and 5 days for minor modifications. The current average time for approval of new minimal risk applications is 42 days (this includes the time it takes for the researcher to respond to requests for more information). Exemptions have a one-week turnaround time. The high volume of minimal risk applications and incomplete applications play a role in the turnaround time. UWISE will have an improved application form that should improve the quality of the applications. UWISE will also generate more accurate data.

Hunter Handsfield will join the subcommittee. The subcommittee was asked to consider ways to improve turnaround time for modifications to applications that are more than minimal risk but for which the change is of minimal risk.

REPORT FROM POST-APPROVAL MONITORING SUBCOMMITTEE (Evan Kharasch)

The subcommittee met for the first time the week of June 14th. The subcommittee defined the following objectives: to create an operational model, to create an administrative model, and to determine financial needs. The subcommittee has reviewed current policy, national regulatory guidelines, and policies at peer institutions. The group determined that a post-approval monitoring board (PAMB) would need a risk scale to determine which protocols should be monitored and the frequency with which they should be monitored. The risk level would be assigned by the IRB, based on the level of risk to research subjects. Research in a low risk category would not be monitored. Monitoring would be of two types: for cause (triggered by signs of violations) and random. The PAMB could be an integral function of the IRB or it could be under the QA umbrella. There may be a legal benefit in keeping the PAMB separate from the IRB. Evan Kharasch will meet with Marcia Rhodes (Health Sciences Risk Management) and Elizabeth Cherry (UW Risk Management) to learn how QA operates within UW Medicine and the whole university. At U Penn the PAMB is under QA in the School of Medicine but they cover all departments. The subcommittee will define criteria for "for-cause" monitoring and will describe categories of protocols in order to define need for and frequency of monitoring. The criteria should be mapped out clearly in order that monitoring is not perceived as being punitive. The subcommittee will review AAHRPP's policy on post-approval monitoring and will determine whether the UW currently meets their requirements. The subcommittee will meet again and will develop proposals, options, and rankings to present to the larger group.

REPORT FROM TASK FORCE SUBCOMMITTEE (Mac Parks)

In 2000 a Task Force was formed to understand the challenges facing the Human Subjects Division (HSD). The published report of the Task Force included a number of recommendations (Mac provided a handout listing the recommendations, actions and status). Most of the recommendations have been completed, a few were undone, and a few haven't been addressed. The top issue was space. HSD moved into new space in November 2001 but has now outgrown the space. The second recommendation was need for an electronic application system. This is now well underway. A third issue, IRB capacity, has been addressed: a fifth IRB has been added and a new VA committee has a targeted start date of October 2004. There has also been discussion with Western IRB regarding review of industry-sponsored clinical trials. Another issue, adequate training for researchers, needs to be reconsidered.

UPDATES: SPACE, ASSISTANT DIRECTOR, PERSONNEL (Helen McGough)

The current plan is that GCS will move into leased space at a building on 45th and 11th and HSD will move to the GCS Building at 3935 University Way after GCS moves out. The Office of Research is providing temporary space for the new training coordinator and one other HSD staff. Temporary space is needed for four staff, files, and a conference room while renovations are made to the basement of GCS due to the flooding that occurred on May 27.

Sharon Elsayed Smith has been hired as education and training coordinator and Amy Meadows has been hired as administrator for the new VA committee.

There are two very qualified finalists for the assistant director position. Hiring should occur soon.

UPDATE: UWISE (Mac Parks)

Mac provided a power-point presentation of UWISE covering the history of the development of UWISE, the players, the benefits to user groups, and the deployment timeline. UWISE is a cradle-to-grave web-based system for human subjects review applications. The system can be customized and revised internally and it meets security requirements. Funded by the provost's office, the system has been developed by the Office of Research, the Human Subjects Division, and Webridge. About a half dozen major institutions in

the US are using Webridge and have formed a consortium. Prototype tests have been done with faculty and staff and surveys have been completed with IRB members. The system will track interactions of the researchers, approvers, and reviewers. It will be able to plug in with other systems such as the Radiation Safety Committee (RSC) and Conflict of Interest (SFI). Some benefits to HSD include less data entry, filing and labeling; better forms with built in training; and improved information about application status. Benefits to committee members include no more blue bags to carry, reading on-line, and availability of wireless computers at committee meetings. The process for this system started in December 2002. Full deployment is expected by December 2004. The UWISE team meets weekly and is doing *beta* and pilot testing. The following departments have been identified for pilot testing (a few applications at a time): Social Work, Nursing, Allergy & Infectious Diseases, Medicine, and Psychology. One-on-one training with researchers will begin early in July. At the same time, staff and IRB members will receive training. The first electronic applications should be reviewed by the end of July. Within five years all existing applications will need to be resubmitted as electronic files. The total cost of UWISE from start to full deployment is \$524,128; of that amount, \$361,200 was funded by a NIH grant. The UWISE model can be used as a model for other compliance offices on campus.

NEW BUSINESS (OUTSOURCING REVIEW OF CLINICAL TRIALS) Mac Parks

The Task Force recommended looking into outsourcing of industry-sponsored clinical trials to a commercial IRB. There are other models of universities outsourcing to commercial IRBs (e.g., Johns Hopkins has an agreement with Western IRB). Initial discussions among Mac Parks, Helen McGough, and Carol Zuiches with Western IRB (an AAHRPP-accredited IRB) indicate there could be an agreement. An investigator would have a choice of using the UW or Western's IRB. The fee for each application would be about \$3000 (\$1500 initial fee, \$500 for each modification and/or adverse event). The UW would still require the GCS fee of \$1200; otherwise, using Western IRB would be revenue neutral for the UW. The Human Subjects Division currently reviews between 130-150 industry-sponsored trials. The perceived benefits of outsourcing for researchers include less delay in getting started and facilitation of multi-site trials. The advantage to HSD would be the reduction of the number of labor-intensive applications. HSD would still need minimal information for tracking and oversight.

Over the summer further work will be done to evaluate outsourcing. Some things to consider include: how to plug in RSC and SFI; how to handle post-approval monitoring; should some trials stay at the UW; concerns about endorsing research for which the UW doesn't have control. Other institutions that outsource to commercial IRBs should be asked about how their contracts work and their satisfaction with the way things work.

There are other commercial IRBs that can be considered besides Western. Board members are encouraged to send messages about concerns or issues to be explored to Mac Parks, Helen McGough, or Craig Hogan.

Recorder: Nancy E. Grout