

This note is to inform interested members of the UW research community about some ongoing changes in the way we handle reviews of research involving human subjects.

All research that involves human subjects at the University requires an independent evaluation of the potential benefits of the research and possible risks to the subjects. The staff of the Human Subjects Division (HSD) coordinates the work of six Human Subjects Review Committees, sometimes called Institutional Review Boards or IRBs, and two subcommittees. The committees themselves are comprised of volunteer representatives from the UW research community, as well as members of the community at large not associated with the University. They review about 5000 new and continuing protocols every year, from student projects using archival sociological survey data to new experimental devices and procedures in the operating room, and are also responsible for reviewing modification requests, adverse events, and complaints from research subjects.

These reviews are critically important both to protect the research subjects and to advance the research. It is demanding work, and becoming more so due to the growing volume of activity, increasing regulation and oversight, increasing legal exposure, and increasing public awareness and sensitivity.

For several years now the UW research community has suffered delays in getting their protocols approved. I am writing this note not to announce that the problems are solved, but to let you know that the problems are getting attention and that significant changes are being implemented to address the problems:

1. We are increasing review capacity. A new IRB has been started for reviews associated with research based at the Seattle, American Lake, and Boise VA hospitals; we are nearing completion of a contract to allow outsourcing of industry-sponsored clinical trials; and we have increased staffing levels for review of minimal risk applications.
2. We are implementing a web-based system for creating, routing, reviewing, and managing applications from researchers to the UW Human Subjects Review Committees. This system, called UWise, will save research time and reduce delays by using a “smart forms” system that asks only for information relevant to a particular application, by facilitating collaboration among those assembling an application, by providing a just-in-time training platform, and by enhancing tracking and communication between researchers and the Human Subjects Division. UWise is currently undergoing final testing. Deployment of UWise is expected to begin in January with phased involvement of Schools, Departments, and Divisions. More information about UWise can be found here: <http://www.washington.edu/research/hsd/uwise/public.html>
3. We are streamlining internal work processes. Signature bottlenecks have been identified and removed; the operations of the Division, previously divided at five different locations, are being consolidated in one office; a better triage system is being put in place to correctly classify minimal risk and exempt protocols; staff training has been improved; a new Assistant Director has been hired to coordinate operational

improvements. Hiring policy in the future will emphasize experience in reviewing human subjects research.

4. We are rewriting policies and documenting procedures, some of which have never been written down at all. This exercise and a thorough self-assessment are coordinated with preparation for our first institutional accreditation, set to start in 2005. Procedures for modifications are being streamlined. The HSD website is being re-organized and revised, and the UWise system is being written to incorporate this documentation in a way that will deliver it to the user at the time it is needed. The new website will be available in January.

5. We are working to reduce the problem of incomplete or inadequate applications. An education coordinator will help train staff and students; a new room is available for training sessions; forms in UWise are being redesigned to eliminate unnecessary and confusing questions; the new website is being designed with more useful educational content; groups are being identified who could benefit from more training.

6. We are improving communication with researchers. In addition to the new initiatives already described, we have established a new Human Subjects Policy Board, including broad representation from the human subjects research community, to advise on policies and procedures, identify problem areas, and bring up new ideas. This group has already contributed significantly to shaping new directions and will be important as we move towards accreditation and new issues, such as post-approval monitoring. The UWise system will also improve communication between HSD and researchers, and it will provide researchers with “real time” information about the status of applications and reviews.

7. Finally, the Division is committed to improving its service to the community of researchers and research subjects. We are open to new ways of doing things, in particular to practices that have proved successful at other institutions.

The HSD staff clearly have their hands full implementing all these changes at the same time they continue to handle the considerable load of applications, but with their extremely high level of professionalism, and their deep personal commitment to their work and to our University, I am confident that we will be seeing tangible improvements by the end of the academic year.

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