Report of the Task Force on Human Subjects Protections and Procedures

Submitted to Alvin Kwiram, Vice Provost for Research
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Executive Summary

The Human Subjects Task Force was formed in August 2000 in response to the vigorous national debate about the quality and protection afforded to research subjects, and dramatic increases in the volume, complexity and diversity of research activity at the University. It was charged by Vice Provost Alvin Kwiram to examine the service provided to Human Subjects Division (HSD) users and the operational aspects of its management and protection of human subjects.

The Task Force met weekly between September 2000 and January 2001 to collect information from a wide range of sources: these included interviewing HSD staff and director, and Institutional Review Board (IRB) members and chairs; gathering data on HSD/IRB workloads and application turnaround time; eliciting opinions and concerns of researchers; and examining HSD operations and practices at other universities for purposes of benchmarking.

Major findings

- Inadequate space and the poor working conditions associated with it adversely affect nearly every aspect of HSD operations.
- The size and complexity of HSD’s workload has increased significantly in the last five years.
- Increases in HSD staff and resources have not kept pace with workload increases.
- There are significant delays in the review of applications of nearly every kind.
- Slow turn-around time, onerous paperwork, and a lack of help are creating significant frustration among researchers.
- Slow turn-around time and the lack of help are impeding research and wasting resources.
- Slow turn-around time and the lack of help are beginning to disrupt graduate instruction.
- Researchers frequently submit incomplete, inaccurate applications.
- Information and guidance regarding the application process are inadequate.
- Lack of attention to group process factors within the IRBs results in delays, unnecessary restrictions, and inconsistencies.
- Recruiting IRB members with appropriate expertise and diversity is an on-going difficulty.
- Many of our peer institutions provide compensation for IRB chairs and members.
- Colleges and departments within the University generally play only a minor role in human subjects protections and procedures.
- The Human Subjects Division is buried in paper.
- The Human Subjects Division lacks the information systems and service standards necessary for performance management.
A “siege mentality” has crept into many aspects of HSD and IRB operations.

**Performance expectations**

The primary responsibility of the HSD and its IRBs is to protect human subjects by carrying out its legal charge of reviewing and approving research. HSD must also support and actively assist researchers in meeting their responsibilities. As part of a management strategy that will ensure timely review of applications and ultimately improve human subjects protection, we suggest the following service targets for the completion of reviews: 40 working days for new full reviews; 21 working days for expedited reviews and major modifications; and 5 working days for minor modifications. Submission deadlines for researchers, along with clear and specific communication to them about an application’s inadequacies, will also facilitate the timeliness of IRB reviews. We also suggest establishing performance criteria for departments, HSD and IRBs, in which success is defined as an application moving through in two or fewer reviews. Developing metrics to gauge other aspects of the process besides application review (e.g. the ratio of adverse events or subject complaints to the number of active protocols) would promote a culture of service improvement.

**Recommendations**

The following principles should guide service improvements: strengthening the effectiveness and independence of the IRBs; recognition of shared responsibilities; efficiency; consistency; preference for simple solutions; and promoting partnership with researchers. Achieving these goals would clearly require additional resources, which can be broadly outlined but not specified in great detail. The major recommendations are:

1. Address the space crisis immediately and provide a long range plan for adequate space.
2. Convert HSD operations to electronic research administration by the end of FY2002 and begin the conversion process immediately.
3. Provide additional IRB review capacity immediately.
4. Improve communication between researchers and IRB members and HSD staff.
5. Compensate IRB chairs and consider compensation and/or additional recognition for all IRB members.
6. Enhance IRB and HSD staff recruiting, training, and professional development.
7. Create a Human Subjects Policy Board.
8. Prioritize efforts to streamline HSD and IRB operations.
9. Plan and implement a program of post-approval auditing and monitoring.

The highest priorities are to address the current space crisis in HSD by finding additional space for meetings and staff and to increase IRB capacity sharply by making HSD’s temporary staff positions into permanent ones and by increasing the number or size of IRBs or by outsourcing. The revision of HSD’s materials and website as well as the conversion to an electronic system for processing human subjects applications also require immediate attention.