Report of the Task Force on Human Subjects Protections and Procedures

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Task Force on Human Subjects Protections and Procedures

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.
Report of the Task Force on Human Subjects Protections and Procedures

Chapter 1

Why was the Task Force formed?

The Task Force on Human Subjects Protections and Procedures was formed in August, 2000. Its formation reflects our commitment to maintain the highest standards for the protection of human subjects involved in research at the University of Washington.

In this introductory chapter, we provide a brief overview of both the national and local context for the Task Force's activities. We summarize the charge given to the Task Force by the Vice Provost and then note the regulatory foundations of human subjects protections and provide a brief overview of the operations and programs of the Human Subjects Division at the University of Washington.

Research gives the University of Washington much of its identity, stature, and funding. It contributes to our educational mission at every level. The research mission is thus at the heart of the University and the Human Subjects Division supports that mission. However, the importance placed on protections for subjects extends well beyond the research mission to color the moral stance of the institution as a whole. Concern for such protections must therefore be a part of our institutional culture at all levels. The Human Subjects Division and the Institutional Review Boards it supports play central roles in assisting faculty, staff, and students to fulfill their ethical responsibilities to the human beings who participate in their research. Their primary
mission is to protect subjects by guiding researchers to ethically acceptable practices in
timely and effective ways.

It is axiomatic that research involving human beings creates significant societal
benefits and requires on-going oversight not only to avoid abuses, but also to ensure
public confidence in the process. The scientific enterprise ultimately depends on public
participation and trust. Although subjects generally express high levels of trust in
researchers (e.g., Sugarman, et. al., *IRB: A Review of Human Subjects Research*, 1998),
there is also a vigorous national debate about the quality of protection afforded to human
subjects in research. Concerns have been expressed in a series of recent reports from the
AAU Task Force on Research Accountability, the National Bioethics Advisory
Commission, the Office of the Inspector General, Public Responsibility in Medicine and
Research (PRIM&R), and several others. These concerns will become even more
important as the pace of clinical research accelerates in the wake of recent scientific
advances in genomics and proteomics.

Public concern has been heightened by federal shutdowns of research programs at
a number of institutions including Duke University, University of Illinois/Chicago, the
Virginia Commonwealth University, the University of Colorado Health Sciences, the
University of Alabama/Birmingham, the University of Pennsylvania, and the University
of Oklahoma. Federal regulatory actions against local institutional review boards (IRBs)
increased by 300% in 1998-1999 (Burman, et. al., *Annals of Internal Medicine*, January
16, 2001). Concerns were further galvanized by death of 19-year-old Jesse Gelsinger in a
gene therapy trial at the University of Pennsylvania in 1999. In addition to uncovering
evidence of conflicts of financial interest, the FDA investigation into this tragedy
indicated that the researchers had repeatedly and deliberately violated the regulations governing clinical trials. According to the FDA, they had inappropriately enrolled patients, failed to provide adequate informed consent, failed to monitor patients adequately, and failed to halt the study when serious adverse events occurred (Science, December 15, 2000).

Finally, because so much research at the University of Washington is clinical, it is important to emphasize that significant changes have occurred in the clinical research process itself. Many studies are now multi-center in nature, requiring timely coordination of protocols, consent forms, budgets, and enrollment with other institutions. Centers unable to provide such services will not be competitive in their attempts to participate in such trials. The competition is further intensified by the proliferation of commercial, for-profit, research organizations outside of universities. University-based researchers whose institutions cannot provide rapid, comprehensive review and approval of complex protocols involving coordination researchers across multiple sites will ultimately experience frustration and failure.

Thus far, the University of Washington has been spared many problems that have befallen other universities. We can be proud of our conscientious faculty, staff, and students as well as the tireless and professional efforts of those serving on our Institutional Review Boards and in the Human Subjects Division. They have set and achieved high standards for the conduct of research. We cannot, however, become complacent. There is real cause for concern as the volume, complexity and diversity of research activity increases. Even without the impetus of the national debate, a thorough analysis and re-engineering of human subjects protections and procedures would
obviously be in order. An additional impetus for the formation of this Task Force stems from increasing faculty concerns over delays in processing of human subjects applications and the increasing complexity of meeting HSD requirements and expectations.

**Task Force Charge and Goals**

In his August 14, 2000 charge letter to the Task Force, Vice Provost Alvin Kwiram called for an examination of the “service provided to users and on the operational aspects of providing excellence in the management and protection of human subjects.” The letter called for attention to the five aspects of human subjects protections.

The charge letter went on to observe: “Your review should be focused on the UW context, but you are encouraged to note practices at other major research institutions when they point to useful benchmarks or 'best practices.' In addition, although the primary charge of the Task Force is with operational issues, you are free to note larger administrative or structural issues that can not be dissociated from daily operations.”

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**Charge to the Task Force**

To assess five broad categories of topics:

- The number and structure of IRB’s (e.g., number, size, diversity, expertise).
- The support provided for IRB’s (e.g., compensation for chairs, staff support, space, equipment).
- Training and professional development for IRB members and Human Subjects Division staff.
- Procedures followed by the IRB’s, including:
  - adequacy of information obtained from researchers
  - management of conflicts of interest
  - adequacy of review and monitoring
  - adequacy of documentation and systems.
- Education, training, and communication
The regulatory context

Over the past 50 years a series of ethical codes, policy guidelines, and regulations have evolved to protect research participants' rights and welfare. The Nuremberg Code, formulated in 1947, is widely viewed as the seminal and most enduring statement of ethical principles for the conduct of human research. Foremost were those relating to consent: that consent must be voluntary, informed and given by those with the mental and physical capacity to give it; that subjects must comprehend the risks and benefits involved; that there be no coercion, and that subjects retain the right to withdraw. The Nuremberg Code also articulated several other standards for research practice that are echoed in current regulations. International bodies have regularly reaffirmed these principles in subsequent years.

In 1966 the U.S. Public Health Service (PHS) announced a new policy that required institutions receiving federal research funds to establish local peer review boards to address issues of research ethics. The policy reflected an historic compromise between the perceived need for clear, enforceable national standards governing the ethical conduct of human research, and a desire to leave the control of research in the hands of the local research community. This policy became law in 1974 when Congress passed the National Research Act. This legislation endorsed the principles of both the Nuremberg Code and the Declaration of Helsinki and called for the establishment of institutional review boards (IRBs) which were to be responsible for implementing rules protecting human subjects at the local institutional level.
The National Research Act also established the National Commission for the Protection of Human Subjects in Research. By far the most influential of the Commission’s reports was *The Belmont Report* published in 1978. It set forth three basic ethical principles for the conduct of all research involving human subjects:

- **Respect for persons** involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.

- **Beneficence** entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.

- **Justice** requires that the benefits and burdens of research be distributed fairly.

The application of these ethical principles has expanded steadily since 1978. In 1981 both the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) embraced the Commission’s recommendations and codified their respective regulations, hewing to the IRB structure. In 1991 sixteen federal agencies (including DHHS) that conduct or support human research activities promulgated a revision to the rules by adopting the Federal Policy for the Protection of Human Subjects (or the “Common Rule”), as it is often called. FDA followed suit by incorporating many of its provisions. These rules can be found at 45 CFR Part 46 (DHHS) and 21 CFR Parts 50 and 56 (the basic FDA requirements). A convenient on-line source for additional information about these and related policies is:

http://ohrp.osophs.dhhs.gov/polasur.htm

The ethical principles that govern research continue to co-evolve with research itself. Since 1995, for example, the National Bioethics Advisory Commission (NBAC) has issued recommendations regarding international research, human fetal stem cell research, cloning, human biological materials, and research on persons with mental
disorders. In December 2000 the NBAC issued a comprehensive report containing recommendations for major revisions of the oversight and IRB system governing human research activities. Moreover, there is currently an active and unresolved national debate regarding what types of financial involvement clinical investigators should be allowed to have with companies sponsoring their research.

This is the historical and legal context within which the University of Washington has developed its system for protecting human subjects. The University formally committed itself to complying with federal regulations when it signed the Multiple Project Assurance (MPA) it holds with the Department of Health and Human Services (DHHS). In the MPA the University formally gave assurances that it will adhere to all applicable federal regulations for the protection of human subjects, explicitly stating that it will be guided in doing so by the ethical principles set forth in *The Belmont Report*. This includes all research involving human subjects at the University, regardless of whether it is funded or the source of funding.

**Overview of UW Human Subject Division Operations and Programs.**

Federal, state, and university regulations require that the use of human subjects in research be reviewed and approved by an Institutional Review Board (IRB). The issues related to Human Subjects Division (HSD) cross the entire university, affecting faculty, staff, and students. Research is broadly defined in the UW Human Subjects Manual as:

…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.
A human subject is defined as:

…a living individual about whom an investigator (whether professional or student) conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information.

The sponsoring department assures reviews of all applications made to the HSD. In many cases, of course, peer review processes at NIH, CDC, NSF, or other institutions are utilized for this purpose. In cases where external peer reviews are not utilized, the responsibility for reviews of scientific merit and investigator qualifications rests with the department. Faculty sponsors review and approve student research.

The HSD also reviews proposals and provides certifications of review to funding agencies, reviews modifications to existing approvals, receives reports of adverse effects resulting from research with human subjects, monitors complaints from human subjects, advises researchers and departments on human subjects review.

The University currently has four institutional review boards that provide full committee reviews:

- Committee A – Biomedical research
- Committee B – Biomedical research
- Committee C – Social and Behavioral research
- Committee D – Biomedical/behavioral

A full-time lead administrator and one half-time coordinator support each IRB. Additional work includes application screening, answering investigator and staff questions, managing adverse event reports, and evaluating requests for exemption and minimal risk review.
Also, administrative reviews of studies seeking Minimal Risk ("expedited") status and studies that might be handled by certificates of exemption are provided by a human subjects administrator who acts as “Committee E.” When questions arise in these categories related to subject protections and/or confidentiality issues, the application is routed to one of the other committees for full review.

Applications going to full committee review are processed in the manner depicted in Figure 1 on the next page.

**Education.** The Human Subjects Division provides a variety of education and training experiences and materials to the University community. The division offers a tutorial entitled, “The Ethical Conduct of Research with Humans” on a quarterly basis and supports a web-based tutorial on research ethics issues hosted by the University of Miami. (http://www.miami.edu/UMH/CDA/UMH_Main/1,1770,4706-3,00.html.) Between June, 2000 and January, 2001, just over 2,000 people at the University of Washington completed these tutorials to satisfy recently promulgated NIH requirements.

**Data management.** The HSD has an electronic database for tracking the application and investigator, but the system is outdated and outmoded. All actions taken by either the coordinator and/or the committee are logged into this system. The burden on this system has grown dramatically in the face of growing regulatory and reporting requirements.

**Personnel.** Ten permanent employees, three temporary employees, and one part-time student worker staff the Human Subjects Division. Advertisements are placed in the University bulletin (weekly job opening listings) and job placement web page when openings occur in the HSD. No additional announcement efforts are made such as paid
advertisements in newspapers or professional journals. The director is beginning to place notices on the HSD web page and on list servers such as MDRN, Clinical Trials Group.

Figure 1. New application flow chart.
and the "McWirb" discussion list. There is no line item in the budget for advertisement and recruitment costs.

Employee orientation involves informal “on the job” training. The director personally orients new people, spending about an hour with them daily. She also utilizes an informal mentoring system, by teaming up more senior staff with new staff. All new staff members attend a six-hour Human Subjects class in Training and Development taught by the Human Subjects Director. In addition, administrators are encouraged to attend off-campus meetings on IRB issues once every two years. Additional training and continuing education activities include a monthly in-house newsletter, retreats every six months, and staff meetings twice a month.

The IRBs themselves range in size from 8 to 15 members. Three of the four review committees have a community member and efforts are being made to recruit a replacement for the one whose community member left. The remaining members are UW faculty recruited by the HSD Director. Although each IRB had at least one relatively new member, the average IRB member had served in excess of seven years. There appear to be no formal mechanisms or procedures for recruiting IRB members, although some effort is made to obtain representation from departments with frequent applications. Terms of appointment are one-year and are renewable. Most recruiting appears to happen by word of mouth with current members. New members are provided with a four-hour group orientation and on-going personal orientation by the Director and the IRB administrator. Currently, neither the chair nor members of UW IRBs are compensated or given release time for their significant efforts.
Chapter 2

How was information gathered?

The Task Force met nearly every week from early September 2000 through the end of January 2001. During this time, members responded to their charge by drawing information from a wide variety of sources. While it is not possible to list every source consulted, the primary sources are summarized in this chapter. Six major types of sources were utilized: interviews with HSD staff, interviews with IRB members, analyses of caseloads and workflow, user surveys and interviews, document reviews, and comparisons with practices and materials at other institutions.

Interviews with Human Subjects Division Staff

A focus group was organized so that the Task Force could meet with the staff of the Human Subjects Division as a group. The discussion focused primarily on the staff perceptions of the major problems and challenges facing the HSD and its IRBs. Specific areas addressed during the discussion included the overall functioning of the system, areas for improvement, priorities for faculty/staff training, and the adequacy of the staff’s own training and expertise. Considerable attention was also given to understanding the space and office resource problems being experienced in HSD.

Helen McGough, the Director of the Human Subjects Division, met with the Task Force on three occasions and informally with individual members of the Task Force several other times. Individual interviews were also conducted on an on-going basis with
HSD staff. These interviews addressed a broad range of issues including the structure of HSD, staffing and compensation, recruitment issues, the structure and composition of IRBs, space issues, equipment needs, procedures for record keeping and documentation, the handling of information requests from researchers, reasons why some cases took an unusually long time to approve (outliers), and procedures for handling complaints and reports of adverse events.

**Interviews with IRB members**

Two members of the Task Force conducted group interviews with members of all of the UW Institutional Review Boards (A-E). In most cases the interviews were done following the regular meeting of the IRB. We were not able to speak with all members, but did speak to a majority on each committee and solicited comments from the rest using e-mail.

Interviews were conducted in a semi-structured format, but IRB members were provided with a list of possible questions in advance of the meeting. These included items dealing with meeting preparation, interactions with HSD staff, interactions with researchers, group dynamics during the meeting, common problems with applications and procedures for alleviating them, suggestions for improving application forms and procedures, IRB member background and training, and mechanisms for recruiting and recognizing IRB service. Most of these topics were discussed during the interviews as well as a number of additional issues that were raised by IRB members themselves. The most common of these were concerns about the adequacy of HSD staffing and facilities.
Analyses of caseloads and workflow

Orlando Trias in the Human Subjects Division made a valuable contribution by helping us compile workload data for the FY1996-FY2000 period. Data were broken down by year, by IRB, and by the type of action. We categorized committee actions into four categories: new applications, renewals, modifications, and emergency actions.

The Task Force also gathered data on how quickly applications moved through the review process. The overall review process was divided into four phases: submission and initial review, from review to sending a letter to the PI, the time it takes PIs to respond to IRB letters, and the time it takes for the IRB to make a decision following a response from the investigator. We then tracked the amount of time it took 272 recent cases to move through each of the four steps in this sequence. Turn-around times for each committee (A-E) were examined and a separate set of calculations was made for industry-sponsored clinical trials in committees A and B.

Workload and turn-around data were augmented by interviews with HSD staff in order to understand better the nature and quantity of the workload as well as the factors that were most likely to produce delays.

User surveys and interviews

The opinions and concerns of users of the Human Subjects Division, primarily faculty and staff, were assessed in three ways. First, faculty and staff comments that had been gathered in the survey conducted in 1999 by the Grant and Contract Process Enhancement Team (GC-PET) were reviewed. Although the GC-PET focus was
considerably broader, their data did include a number of comments about human subject processes.

Second, the concerns and suggestions of the UW research community were assessed using a web-based survey. The survey was described in an article in *University Week*, a broadcast e-mail was sent to all UW faculty, and an additional e-mail notification was sent to subscribers of the UW clinical trials list server. Approximately 100 responses were received in total. Most were from faculty and staff, although a few were from students as well. A total of 44 departments and units from 13 different colleges and schools were represented. The survey solicited open-ended responses to two questions:

- What are your suggestions for improving the human subjects review process at the UW? (Please suggest specific improvements in any aspect you wish—availability of education and training, submission, processing of cases, notification, monitoring, Human Subjects Division staffing and, facilities, procedures, etc.

- Do you have any specific concerns about the way research involving human subjects at the UW is handled?

The responses were summarized and grouped into a series of representative themes. An effort was made to capture the variation in perspectives as well as the perspectives that appeared to be most commonly expressed.

A third survey was done in order to get a more detailed picture of faculty perceptions and opinions. A random sample of 50 investigators whose applications had been reviewed by the HSD in the previous 6 months was selected. Equal numbers (n = 10) of investigators were randomly chosen from Committees A, B, and E; while 20 were randomly chosen from Committee C. Committee D was not sampled because it is new. Investigators were emailed a questionnaire and asked to return it within one week. Those
not returning the questionnaire within that time frame were contacted again, by e-mail
and/or telephone, and asked to respond. Of the 35 who responded, 32% were Professors,
21% Associate Professors, 24% Assistant Professors, 9% staff, 6% doctoral students and
3 were “other.” The majority (66%) had six or more years of experience conducting
research at the UW that involved human subjects; only 6% had one year or less
experience.

Some survey items dealt with how researchers learned about the review process
and the adequacy of information and assistance available to researchers. Other items
focused on the problems and suggestions associated with application forms, the factors
that were most time-consuming for researchers, and the problems that researchers
experienced with the review process itself. Suggestions for improving the overall process
were also solicited.

**Document reviews**

An effort was made to evaluate all of the major documents associated with the
human subjects protections process. This included the materials posted on the HSD
website, the forms and help documents associated with applications, advertisements and
other recruiting materials for HSD staff positions, training materials for researchers, and
information available to the public on UW human subjects research. There was no
standardized format for evaluating documents and the reviews were typically done
informally in connection with the other information gathering activities of the Task
Force.
Comparisons to Practices and Materials at Other Institutions

In spite of our focus on operational and procedural issues at the University of Washington, we found it useful to examine how other institutions were handling many of the same issues we were examining here. This was done in several ways.

One source of information on activities at other universities was the "McWirb" mailing list—an electronic forum for human subjects professionals across the United States. A message asking for information about how other universities were approaching the topic of post-approval monitoring and compliance was posted to the group.

Another sort of reference point was provided by one member’s visit to the Western Institutional Review Board in Olympia, a private for-profit service specializing in human subjects reviews. This was done to explore the costs, benefits, and risks of outsourcing human subject reviews as an option. Materials were also gleaned from the company’s website (http://www.wirb.com).

Our primary information on practices elsewhere, however, came from six research universities selected as comparison institutions. These were Columbia, Harvard, Johns Hopkins, Michigan, Minnesota, and the University of California at San Diego. Two approaches were used to gather information. The first involved a review of materials available on their websites. The second involved telephone interviews with one or more of those responsible for the administration of human subjects programs at each of the universities. Our primary interest was in understanding the numbers, size, composition, and jurisdiction of their IRBs, their staffing and workload, and the manner in which staff and IRB members were compensated. We also explored how each institution addressed a
number of matters associated with compliance (e.g., handling of adverse events and complaints, management of conflicts of interest, post-approval monitoring).

Finally, an effort was made to scan the external environment for materials and policies that might define “best practices” and thus act as targets for our own quality improvement activities. A large set of application forms, policy descriptions, procedural outlines, and webpages were collected in this regard.
Chapter 3

What were the major findings of the Task Force?

This chapter summarizes the major findings that, in our opinion, require immediate and significant institutional attention if we are to continue to provide high quality protection for human subjects and create high quality service for the research community. Additional, more detailed observations will be presented along with the recommendations in a later chapter.

1. **Inadequate space and poor working conditions adversely affect nearly every aspect of HSD operations.** The 13 staff members who occupy the Human Subjects Division office on a daily basis are packed, along with all their equipment and files, into space totaling about 1000 square feet. In addition to the eight to 10 IRB members who cycle through the space regularly, still more occupants are added by the steady flow of visitors asking for information or dropping off materials.

   We were told that one of the IRB chairs does his last minute meeting preparation in the men’s toilet because it is the only place to sit down. Last summer, a first time visitor described her response to the HSD office in a letter to the Provost:

   *A shocking condition I witnessed in one of the University's facilities prompts my letter to you. ... My work for my honors thesis in the Jackson School requires that I go through the Human Subjects Review Committee. Upon my arrival at the Human Subjects Review facilities, I saw the aggravating, sub-minimal working conditions..., a basement of about 1,000 sq ft, crammed with papers and stacks of documents that extend from wall to wall. This circumstance is not the result of disorganization but lack of space. The staff works in a crammed environment, with no air conditioning, little sunlight, and little walking or breathing room.*
A short list of the adverse working conditions attributable to inadequate space that we observed or that were reported to us includes:

- Constant disruptions and resulting loss of staff productivity
- Files that cannot be accessed during IRB meetings (because they are stored in the conference room).
- Inadequate space for filing leads to confusion, delays, and lost files.
- Conversations about confidential matters are easily overheard.
- The space is so inhospitable for visitors that they often either avoid coming to the office or leave before completing their business.
- Crowding increases stress on staff, resulting in lower productivity and poorer service to researchers.
- Colds and other illnesses spread easily through the staff, resulting in lost productivity.
- Poor working conditions make it more difficult to recruit and retain quality staff.

2. **The size and complexity of HSD’s workload has increased significantly in the last five years.** Over the last five years (FY1996-FY2000) the workload for all types of actions in the Human Subjects Division has increased by 77%. There have been substantial increases in the number of new applications requiring review (33.7%) and in the number of applications subject to on-going review/renewal (48.4%). Furthermore, the complexity and detail of each application has increased. However, the largest change has been in the number of modifications. Modifications to previously approved protocols have increased by 303% since 1996. This has been caused by both actual and perceived changes in the regulatory climate. Both HSD and investigators are strongly motivated to avoid perceived risk by subjecting every change in research protocols, no matter how inconsequential, for HS review. In addition, the increase in multi-center clinical trials necessitates frequent modifications to protocols.
and consent forms to make them uniform among participating sites. Workload data are
presented in the tables on the following page.

### Human Subjects Workload Data: FY1996-2000

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The fact that there has been more change in some years than others reflects the timing of both actual changes in federal regulations and anticipatory responses to changes in the federal regulatory environment.

3. Increases in HSD staff and resources have not kept pace with workload increases. During the five-year period from FY1996 through FY2000, as we noted, the total number of cases and actions coming to the Human Subjects Division increased by nearly 77%. During that same period, staff positions in the Human Subjects Division increased from 7 to 10 FTE—an increase of approximately 43%. However, only one of the three new positions was funded directly by the University. Two of the three were funded by a new charge to industry sponsors for IRB reviews of clinical trial protocols.
($1,250 per review). Thus, while caseload increased 77%, total staffing increased by only 43% and UW-supported staffing increased by only 14.3%.

Staffing in the Human Subjects Division has clearly not matched the sharp increase in its caseload over the last five years. Not only are there far more cases, but, as we noted elsewhere, the cases themselves are often more complex because of the advance of research into new arenas and because of greater regulation and scrutiny. HSD budgets, like its staff, have failed to keep pace. Between FY1996 and FY2000, the Human Subject Division’s funding grew by 37%. Almost all of this increase is attributable to salary increases and the modest increase in the number of HSD staff. Funding for technology (including basic office equipment), supplies, and travel has remained largely unchanged for the last five years.

Finally, the number of review committees (IRBs) increased from three to four (33%) between FY1996 and FY2000. Again, this increase was not enough to keep pace with the 77% increase in total workload. It is worth noting once more that the most of the additional IRB capacity was funded by a surcharge to industry sponsors of clinical trials.

4. **There are significant delays in the review process.** Our analysis of turn-around times for 272 applications revealed significant delays in start-to-finish processing time. The median number of days it took for reviews by full committees ranged from 56 to 89 days across the IRBs. Even reviews of proposals involving minimal risk (once called “expedited reviews”) took an average of 37 days. The full results of our analysis are summarized in the table on the next page.
Although the largest single source of delay across all committees is the time it takes researchers to respond to letters from the IRB’s, the fact that researchers take so long may reflect inadequacies in the review process itself. Certainly some researchers are delayed because of other responsibilities, but some of those who responded to our surveys felt that the letters made demands that were unnecessary and picky. Many researchers complained that they were not given sufficient guidance as to how to respond to the IRB’s concerns. Setting aside researcher-related delays, however, it is clear that
each step of the process takes time far out of proportion to the actual work involved. For example, it takes an average of three weeks before an application receives its first review. These problems cannot be explained by pointing to a set of "outliers" that eat up a disproportionate amount of review time. Instead, the problems appear to be more uniformly distributed across applications and investigators.

When HSD staff members were asked to identify and rank the substantive topics that most often required follow-up with investigators and took the most time to resolve, they identified:

1. **Consent forms and procedures.**

2. **Indemnification.** Industry sponsors of clinical trials often seek to insert language in consent forms that improperly seeks to alter UW policy regarding liability for payment of medical expenses in event of harm or injury. Revisions requested to conform to UW policy often result in hassles with sponsors and sponsors' lawyers.

3. **Confidentiality issues.** Tissue banks and genetic research (these two especially, but not alone) are inherently thorny areas and often involve time-consuming consideration of confidentiality and privacy issues.

4. **Advertising.** Advertising is part of recruitment and of the consent process. Ad copy, both visual and textual, needs to be evaluated and at times revised.

These are the "hot spots" in the process. Delays could be reduced if they were targeted for specific attention.

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5. **Slow turn-around time, onerous paperwork, and a lack of help are creating significant frustration among researchers.** The investigators we surveyed were nearly unanimous in expressing concerns about onerous paperwork and reporting
requirements, slow turnaround time and a need to streamline the entire process. The following quotes are representative of the feedback we received:

*The process is extremely long. Having spoken with my colleagues across the country, we have one of the slowest review processes in the country (months compared to weeks). This has actually caused me problems in some of my multi-center trials (i.e., unable to get approval for months while my colleagues have theirs within weeks).*

*Turnaround time on applications is too long, especially when investigators answer committee questions. The staff does not respond to inquiries - phone or e-mail. Investigators should be told when to expect a decision or further questions.*

*The turn around time is also unacceptable. Waiting 3 months is ridiculous when you are an untenured assistant professor who has a full teaching and administrative load and the only window for research is summer.*

*The process is taking much too long! Reviews are now taking 2 months or more. In addition to my own research, I am responsible for up to 30 masters student theses per year, and all of these reviews are taking 2 months or more.*

In our more in-depth survey, we asked investigators to indicate what the single most time-consuming aspect of preparing their most recent human subjects application had been. They were asked to select from a list of six factors or to provide a short description of the problem. Responses indicated that preparing consent form (36%) and responding to the open-ended questions on the application form (32%) were the most time-consuming aspects of preparing an application. Some indicated that for them responding to the post-review letter (14%), preparing supporting documents to accompany the application (7%), preparing of recruitment and enrollment materials (4%), and communicating with HSD staff (4%) took the most time. One respondent felt that filling out the seven-page application was the single most time-consuming aspect of the process. Consistent with this last response, 77% of the respondents reported that, relative to other aspects of the review process (i.e., responding to committee concerns, preparing
modifications to a previously approved application and preparing annual renewals),
preparing the initial application required the most time.

When asked what topic generated the most discussion or negotiation with the
HSD staff, 71% reported that it was the consent form. Data management (12%), and
consent procedures (9%) were also mentioned, though much less often.

Respondents were also asked to indicate what factors contributed most to the time
it took to process their most recent application. The two most commonly endorsed
factors were lack of adequate staff in the HSD (45%) and too few IRBs (45%). Less
frequently endorsed were problems getting on the agenda (17%), IRB not understanding
the project (17%), requests from the HSD for more information prior to the review
(14%), responding to contingencies (14%), deferred action because more information was
needed (7%), and requirements that were unclear (7%).

6. Slow turn-around time and the lack of help are impeding research and
wasting resources. The nature of the problem is perhaps best conveyed in the words of
the researchers themselves:

Realize that UW is losing millions annually. Sponsors will not implement studies here
because IRB turnaround is so notoriously slow. Sponsors and CROs keep track of each
site's IRB turnaround and we’re not on the “good” list. … In this competitive climate
(both for NIH$ and pharma$), a 6 month IRB turnaround is incompatible with survival of
the institution and retention of productive faculty.

We have had problems with turnaround time in the past 6 months. In the 3 renewals or
modifications in that time, we have not received our renewals or modifications back in
writing in a timely fashion. The best one was submitted August 3, approved Sept 13, and
received Oct 4. Another submitted August 3 has still not been received on Nov 21. Our
prior approval expired in mid-Sept and I received verbal feedback that it had been
approved prior to expiration and that we could continue enrolling and following subjects.
The modification was submitted Sept 26. On Oct 17 we replied to the committee's
questions. We have heard no more despite several phone calls to them. These delays
[make me] think the coordinators are trying their best, but have more work than they can
handle.
My last annual renewal of Human Subjects approval was turned in before the deadline I was given. The current approval was set to expire six weeks after that. ... I still had not heard back from the Human Subjects Division by the expiration date. My study involves subjects who are scheduled literally 6 months in advance, for a pre- and post-treatment protocol that involves two 72-hour stays at the Clinical Research Center (CRC). The CRC rightly is very careful about monitoring the continued status of Human Subjects approval for CRC-based studies. I had two 72-hour inpatient studies scheduled for that week when my approval was scheduled to expire. The CRC contacted me to say I could not do them without renewal. I made several frantic phone calls over the next couple of days. My approval actually expired before I was able to get oral confirmation of renewal over the phone, (despite the fact that I turned in my renewal paperwork before the requested deadline, and with only a minor modification), and it was almost 4 weeks after the expiration date before I received the officially stamped renewal form (which the CRC requires us to file with them). This situation creates a tremendous hardship for groups like ours with on-going subjects on long term treatments with outcome assessments that require difficult and complex scheduling negotiations among subjects, study staff, CRC, night technicians, and facilities. Can we really be expected to shut down our studies, take subjects off treatments (which cannot later be resumed), etc., in this situation?

My research often involves many steps in which the next is dependent on the current step. Many modifications must be submitted. Current staffing is such at the Human Subjects office that modifications can often sit on a desk untouched for literally weeks. During this time, my staff, being paid by grant money, sit and wait to be able to do anything.

The deleterious effects of such delays on research defy easy quantification. We believe, however, that cases such as these are unacceptably common. Put simply, there is significant evidence that the length of time it takes to obtain approvals is reducing our institutional competitiveness, making it more difficult to obtain and retain both subjects and facilities, and costing real dollars in the form of payments for wasted staff and facility time.

One further implication of delays must be considered. Slow turn-around time and the lack of help may encourage some researchers to work “outside the system.” In expressing frustration about the lack of accessibility and delays, one of our respondents commented, “As it is, a ‘don’t ask, don’t tell’ strategy often seems to be best for marginal projects!” We have no idea how many researchers have on occasion simply decided to opt out of the system. We have no reason to believe that the number is large, but we do
believe that the potential for this sort of behavior poses significant risks for the institution and, most importantly, for subjects.

The decision to work outside the system can take several forms. The most serious, of course, is the decision to avoid the review process altogether. But several more specific choices also create institutional and individual risks—starting data collection before approval is received, modifying protocols without approval, failing to make changes required by the IRB, failing to report adverse events, and so on. Again, we have no way of determining if, or how frequently, these behaviors occur. But we do know that they are far more likely to occur when researchers are frustrated with the system and believe that compliance is an uncertain, onerous, time-consuming process.

7. Slow turn-around time and the lack of help are beginning to disrupt graduate instruction. Delays and the lack of adequate information resources adversely affect efforts to involve students in “hands-on” learning experiences as part of their methods classes. It is now nearly impossible to do even a simple project involving human subjects from start to finish within an academic term. Graduate students are most affected, but undergraduates are becoming more affected as faculty strive to implement our institutional commitment to involve undergraduates in the research experience. In addition, the length of time it takes for IRB review is beginning to influence the nature of projects that graduate students can take on for their theses and dissertations. There is simply not enough time in the typical Masters program to tackle a project that will require review by a full IRB. And depending on the program, the same may be true for many dissertations. The six weeks it takes for minimal risk reviews may be too long for
many Masters students who only have one or two quarters to complete their theses. As a result, the substantive research questions that graduate students are able to address are becoming shaped, not by intellectual interests and priorities, but rather by the length of delay they are able to tolerate.

Faculty expressed these concerns in the following ways:

*Sometimes the delay is a problem. In my grad student classes we are often trying to conduct a survey within a 10-week period. We don’t have the time to wait …for approval. The research we do is always low risk and not federally funded. I need a better way to handle this or I’m just going to quit trying to even teach a course in survey research methods.*

*I have had graduate classes carry out studies in a single quarter. It's fast-paced but rewarding. Students design the skeleton of the study by the fourth week, get Human Subjects permission, then do the study at the end of the quarter. (Data analysis is done after the quarter, as independent studies and/or uncredited work that results in publication.) With a six-week expedited review period, this becomes impossible. Barring the switch to the semester system, I am forced to abandon a very fruitful approach to teaching graduate classes.*

*…consider the situation for a graduate student, like one of our own current students. This student completed his prospectus at the end of Fall 2000, and he hopes to begin his doctoral research this quarter. With a rapid review process, he would be able to turn in his application this quarter and immediately begin collecting data. With a six-week delay, it is difficult to prepare for an experimental study and collect the data before the quarter ends.*

*The turn around time for applications, particularly if they are for student researchers, can be too long. This seems to be a joint problem of having the committees review the applications and then having staff to process the outcomes. A student of mine recently had the experience of having his proposal reviewed this summer but not hearing about the outcome until early November. He literally sat in the HS office and waited until the staff person typed up the results of a meeting that had occurred at least two months earlier. Something needs to be done about speeding up the paperwork - and it seems that the Division is sorely understaffed to get the job done.*

8. Researchers frequently submit incomplete, inaccurate applications.

**Most Frequent Errors in New Applications:**

1. Failure to include grant application
2. Failure to include research protocol or proposal
3. Lack of information on drugs used in the research
4. Missing documentation on how subjects were to be approached (advertisements, phone scripts, etc.)
5. Inadequate description of procedures or overly
Human Subjects Division staff estimate that 90% of new applications going to full committee require more information before they can be processed further. About 20% of the applications going to full committee for renewal and continuation also require additional information. The problem is even greater for minimal risk applications. Only about 10% of the minimal risk status reports being submitted are complete. And, according to the staff person who oversees minimal risk applications, less than 1% of new applications can be approved as submitted and that less than 5% are truly close to being ready to go.

The problem of incomplete materials is often not solved prior to the time materials go to the IRB for review. The lone screener for new applications simply does not have time to catch everything. Thus, the IRB members we interviewed pointed to inadequate and incomplete applications as a major source of delay. Pre-meeting screening is inadequate and extra iterations are needed just to complete the application.

9. Information and guidance regarding the application process are inadequate. IRB members recognize a major problem with investigators submitting incomplete applications and not following directions. As we noted above, investigators often complain about the lack of useful information and guidance available as they prepare applications. According to our more in-depth survey, the overwhelming majority of respondents (91%) reported learning about the UW review process through trial and error (i.e., via their own prior applications). Other sources of information included the HSD staff (60%), colleagues (49%), and mentors (49%). The official HSD training
(37%), manual (26%), and website (23%) were sources of information for only a minority of investigators.

To be sure, more information is available than is utilized. Indeed, the most common errors (e.g., failing to include the proposal or protocol) are obvious ones and easily avoided. While the responsibility for incomplete applications ultimately falls on researchers, we believe that more could be done to assist and educate researchers. We found numerous examples of forms and websites at other institutions that were more informative and user friendly than our own.

Perhaps the most disturbing aspect of this problem is that it sometimes fosters a self-defeating cycle. Some researchers believe that HSD staff or the IRB will find fault with their application no matter how much time they invest trying to make it complete and compliant. As a result, they submit materials in preliminary form and wait for HSD staff or the IRB to tell them what else they have to do. Although there is certainly merit in a dialogue between researchers and those doing reviews, this particular cycle only results in greater delays and escalating frustration. Worse yet, it sows the seeds of an adversarial relationship between researchers and those charged with the protection of human subjects.

10. **Lack of attention to group process factors within the IRBs results in delays, unnecessary restrictions, and inconsistencies.** Our interviews suggested that the IRBs take a more or less "ad hoc" approach to many of their meetings, often with little or no pre-meeting planning and no structured way of proceeding. Committees generally lack procedures for prioritizing discussions and making decisions. While each
member certainly deserves to be heard, decision-making often defaults to a consensus model in which each individual has veto power. This slows the process and contributes to the backlog.

Furthermore, the IRBs operate as relatively sealed social groups with little ongoing education and training and few external checks on the biases that creep in as a natural result of the group process. IRBs operate as isolated groups and there is little cross-fertilization between them. Helen McGough mentioned that she used to have periodic meetings in which IRB chairs and/or members got together to discuss common problems, but that these became less frequent as the workload increased. Without external feedback, however, appropriate caution can easily cycle into overly broad interpretations, unexamined prohibitions, and inappropriate rulemaking. We found instances of this. Moreover, as this group dynamic plays out across several different IRBs, researchers are likely to encounter inconsistent interpretations from one IRB to the next. Indeed several of our survey respondents did complain about different treatment from different IRBs.

11. **Recruiting IRB members with appropriate expertise and diversity is an on-going difficulty.** During each of our interviews with IRB members, comments were made regarding unfilled committee positions and the difficulty of recruiting replacement members. These problems are, of course, not unique to the University of Washington. Nearly all of the research institutions we contacted were struggling with similar problems. Nonetheless, we have had particular challenges recruiting people who were willing to serve as chairs. Members also expressed concern over gaps in the technical
expertise of the review committee. And there was concern whether the committees were adequately diverse. It has also been especially difficult to recruit true community members who are not associated with the university in some way.

IRB members and HSD staff noted that there is little recognition and no compensation for those who serve on the Institutional Review Boards. This is undoubtedly part of the cause. Beyond this, there appears to be no regular or coherent effort to recruit IRB members. There is no mechanism for assuring that units submitting high numbers of applications are represented on the IRBs. Finding community members is particularly haphazard, but the lack of recruitment planning extends to all types of members.

12. **Most of our peer institutions provide compensation for IRB chairs and members.** Information on compensation practices was gathered through telephone interviews with officials at Columbia, Harvard, Johns Hopkins, Michigan, Minnesota, and University of California at San Diego. All of them, except UCSD, provided some sort of compensation. What we learned about the nature of the compensation is summarized in the table below.
13. **Colleges and departments within the University generally play only a minor role in human subjects protections and procedures.** With few exceptions, little departmental or college attention is devoted to supporting human subjects protections and procedures. Beyond the assistance provided specifically for clinical trials in the School of Medicine, the schools of Nursing and Social Work are almost alone in providing staff support to assist faculty and students with the application process. We found little evidence of seminars or training sessions on human subjects issues within the colleges and departments themselves. Though they have eagerly participated in the most recent round of training offered by the Human Subjects Division, few resources and less time have been devoted to creating training and mentoring experiences at the local level.

Internal review committees appear to exist in only three college-level units-- the School of Social Work, the School of Nursing, and the College of Education. Moreover,
there appears to be substantial variation in departmental participation on IRBs. There is no mechanism for encouraging departments submitting large numbers of applications to also contribute members to the committees.

In many cases, it is not clear what level of attention and review the department chair has given when she or he signs off on an application. Presumably this signature implies an endorsement of the applicant's technical competence and of the scientific merit of the project. Based on our surveys and interviews, as well as the observations of Task Force members in their home units, however, we have little confidence that chairs are adequately informed of their responsibilities and even less confidence that they exercise them with diligence.

14. **The Human Subjects Division is buried in paper.** Record keeping is entirely paper-based, resulting in storage problems and cumbersome flow of information. The phrase “buried in paper” has a ring of literal truth to anyone who has visited HSD offices. There are stacks of paper everywhere. Work being done by one person is disrupted by others sorting through piles and files. Although software is available, programming that would improve information flow and quality assurance/improvement is not. For example, committee minutes are not comprehensive, making it hard to do a process study of how committees work and arrive at their decisions. Paper communication between IRB and investigator takes extensive time that could be streamlined with use of e-mail communication. In short, the current paper-based system of submission and review of all HSD documents is costly, inefficient, and likely to become inadequate. Furthermore, space for filing of materials that are in the midst of the
review process is inadequate. This leads to inefficiencies that contribute to excessive review time.

15. The Human Subjects Division lacks the information systems and service standards necessary for performance management. Whether paper or electronic, every unit requires a system that allows decision-makers and resource managers to track performance against the unit’s objectives. The Human Subjects Division has pieces and elements of such a system, but critical components are missing. There are no resources to develop necessary information systems and databases. The current process does not provide for an efficient and comprehensive approach to establishing performance metrics, to setting measurable goals, or to the on-going assessment of how well performance goals are being met.

Thus most of the performance measures we utilized in preparing this report were created especially for the Task Force. There was no detailed compilation of workload data. Turn-around time was not routinely tracked. Data on the number of adverse event reports and complaints had not been compiled. Although HSD staff do a good job of following the flow chart for new applications (presented in the previous chapter), there is currently no event-time recording that enables managers to track how long it takes for applications to move from one point to another. These deficiencies make it impossible to track performance and to set meaningful standards for service.

16. A “siege mentality” has crept into many aspects of HSD and IRB operations. The combination of crowded working conditions, sharp increases in case
loads, perceptions of low pay and low status, as well as being caught between escalating faculty frustration and rising regulatory expectations has left the staff of the Human Subjects Division and many members of the IRBs in a state of disarray. We repeatedly came across what can only be described as a “siege mentality” in the course of our interviews with staff and IRB members.

Although this response is understandable given the circumstances, it has congealed into an adversarial stance with faculty on occasion and, worse, prevents those involved from detaching from the current situation long enough to consider how it might be re-engineered. It is not that HSD staff lack good ideas and intentions; it is that they do not feel they have the time needed to think about them and implement them. In spite of an outstandingly able and dedicated staff and in spite of the competent and tireless efforts of IRB members, the UW system is simply overwhelmed. In our opinion, the present siege mentality is as serious an impediment to improved performance as the lack of resources.
Summary of Major Findings

1. Inadequate space and poor working conditions adversely affect nearly every aspect of HSD operations.

2. The size and complexity of HSD’s workload has increased significantly in the last five years.

3. Increases in HSD staff and budgets have not kept pace with workload increases.

4. There are significant delays in the review process.

5. Slow turn-around time, onerous paperwork, and a lack of help are creating significant frustration among researchers.

6. Slow turn-around time and the lack of help are impeding research and wasting resources.

7. Slow turn-around time and the lack of help are beginning to disrupt graduate instruction.

8. Researchers frequently submit incomplete, inaccurate applications.

9. Information and guidance regarding the application process are inadequate.

10. Lack of attention to group process factors within the IRBs results in delays, unnecessary restrictions, and inconsistencies.

11. Recruiting IRB members with appropriate expertise and diversity is an on-going difficulty.

12. Most of our peer institutions provide compensation for IRB chairs and members.

13. Colleges and departments within the University generally play only a minor role in human subjects protections and procedures.

14. The Human Subjects Division is buried in paper.

15. The Human Subjects Division lacks the information systems and service standards necessary for performance management.

16. A “siege mentality” has crept into many aspects of HSD and IRB operations.
Chapter 4

What are the performance criteria by which human subjects procedures should be judged?

Two things are necessary before we outline the specific recommendations of the Task Force and discuss the resources required to implement them. The first is a broader strategic framework for thinking about human subjects protections in the modern research university. The second is a set of performance criteria that will serve as a basis for making recommendations and, in the long term, for managing the on-going activities of the Human Subjects Divisions and the Institutional Review Boards. The goal of this chapter is to provide both these things.

Perspectives on Human Subjects Protections

The primary responsibility of the Human Subjects Division, and of the IRBs through which it carries out its reviewing responsibilities, is most certainly to protect human subjects in research. The IRBs are formally and legally charged with a "review and approval" function. The University, through its Multiple Project Assurance, has committed itself to abide by federal regulations. Federal statutory foundations call for IRBs to engage broadly in activities that "protect the rights of human subjects" and these clearly seem to extend beyond a limited set of quasi-judicial functions. The "Common Rule" (45 CFR 46), for example, requires IRBs to provide feedback to investigators regarding their decisions. While care must be taken not to compromise the independence of IRBs, it is clear that their charge includes providing additional information and service
to the research community. Recognizing these service responsibilities is critical because, of course, researchers are subject to their own set of formal and legal responsibilities. It is, after all, their actions that are the object of nearly every federal regulation and declaration of research ethics from the Nuremberg Code onward. The ultimate responsibility for the protection of human subjects rests with the researchers and their staff engaged in the front line activities of research.

Because it exists in the nexus of multiple obligations and responsibilities, the Human Subject Division must be responsive to a multi-faceted mission. It must support the IRBs in their mission to pass judgment on the adequacy of proposed protections. It must facilitate broader service activities of the IRBs as appropriate. But it must also support faculty, students, and staff in meeting their individual responsibilities. If the mission of the Human Subjects Division is reduced to merely supporting the quasi-judicial functions of the IRBs, then its broader mission to assist faculty in finding and adopting ethically acceptable research practices is lost. In short, the mission of the IRBs cannot be reduced to a limited set of quasi-judicial functions and the multi-faceted mission of the Human Subjects Division cannot be reduced to the more focused mission of the IRBs.

The broader mission of the Human Subjects Division must value and actively pursue service and assistance to the faculty. It must educate the research community, provide efficient service to the research community, and actively collaborate with members of the research community to address concerns, solve problems, and devise new ways of meeting requirements for the ethical conduct of research.
Performance Management

The University should commit to a management strategy that will provide professional and timely review of human subjects applications and that will assist researchers in meeting their ethical and legal obligations to protect human subjects.

High quality service is closely related to high quality protection. Subjects are most likely to be protected when researchers and those involved with oversight work in a collaborative fashion. We must guard against the sort of frustrations and adversarial stances that discourage participation in the system by researchers and result in undue stress and turnover among HSD staff members.

Based on our own expectations and our survey of turn-around times at other institutions, we suggest the following service targets for the completion of reviews:

- New full reviews – 40 days
- Expedited reviews – 21 days
- Renewals & major modifications – 21 days
- Minor modifications - 5 days

In pursuing these goals, we believe it is also desirable to establish submission deadlines, especially in relationship to known grant submission dates, and with regard to specific IRB meetings. The deadlines should be accompanied by similar response deadlines indicating when researchers can expect a response from the IRB. While HSD should be accountable for the timeliness of their responses, they should not be held accountable for delays that occur on the researcher's side. However, IRB members and HSD staff should recognize that effective, clear, and specific communication of an application's inadequacies to investigators is an essential component in meeting these performance objectives.
We also suggest that HSD establish performance goals for Departments, HSD staff, and for the IRBs in which "success" is defined as an application that is approved in two or fewer review cycles. HSD should track the proportion of applications (new and renewal) requiring two or fewer passes as well as higher rates of multiple passes and delays greater than, say, 60 days. The reasons for delays should also be tracked. We emphasize, however, that the responsibility for success falls on individual researchers and their departments as well as on the IRBs and HSD staff.

There should be continuous (e.g., monthly, quarterly and annual) tracking systems and reports to the Directors of HSD and GCS and to the Office of Research to allow them to manage to these standards. If a department has a high rate of delays, if a staff member or committee stands out because of higher than normal rates of re-reviews, this can be used to direct educational efforts, system improvement efforts to promote continuous improvement in HSD, and to establish a culture of service improvement.

Thus far we have emphasized the elements of service that relate most closely to the review process (responses times, re-review rates, etc.). We believe that attention should be also devoted to developing metrics by which we might gauge the quality of protection. Some possibilities might include:

- Ratio of adverse event reports to the number of active protocols.
- Ratio of complaints reported to HSD to the number of active protocols.
- Subject satisfaction surveys
- Post-approval monitoring measures

The committee realizes it cannot prescribe the actual measures and goals in detail. But we emphasize that the HSD needs to focus on these elements of improved service. Simply adding resources, holding conferences, and adding responsibilities to departments may actually prolong the process of human subject review without achieving more
efficient, higher quality protection. Clearly stated goals, outcomes, and standards must accompany or even precede a major addition in resources.
Chapter 5

What must be done to improve performance and what resources are required to do so?

In this chapter we present a series of recommendations for the improvement of human subjects procedures and protections. It is not our purpose to micro-manage those involved. Indeed, the Human Subjects Division and others already face many demands from many stakeholders. They cannot respond to every recommendation or suggestion and should not try. Accordingly, we have endeavored to distinguish between higher priority recommendation and lower priority "additional suggestions to consider" in the discussion that follows. Given our confidence in the management of the Human Subjects Division, it may be more important to articulate a set of principles that will guide their decision-making and planning than to dictate lists of required actions. For us, the principles guiding service improvements should be:

- Strengthening the effectiveness of the IRBs
- Recognition of shared responsibilities
- Efficiency
- Consistency
- Preference for simple solutions
- Communication with researchers

Achieving our goals will necessarily involve additional resources. These should be viewed as overdue investments in the UW research enterprise. Detailed specification of the resource requirements is, of course, beyond the scope of our charge. Nevertheless, addressing the problems we have identified is likely to entail immediate, one time
expenditures in the six-figure range as well as a commitment to significant increases in continuing support. Our recommendations are summarized in the table below and described in greater detail on the pages that follow.

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**Recommendation 1: Address the space crisis**

The lack of adequate space adversely affects nearly every aspect of HSD operations and must be addressed in both immediate and long-term ways. The immediate need is to find additional space for existing and new staff without compromising meeting
space. To accomplish this, immediate support and advocacy is required from the central administration.

It is time to develop a plan for the longer term as well. There is every reason to believe that current growth trends in UW research involving human subjects will continue. Federal research continues to expand and industry-sponsored research continues to grow. The number of clinical trial protocols submitted to IRBs nationally has, for example, grown by 42\% in the last five years (Annals of Internal Medicine, January 16, 2001). Even if the growth in the number of modifications were to flatten out (an unlikely prospect), we might reasonably expect continued growth in the number of new applications and renewals. If the growth of the last five years continues, we may modestly expect increases in the order of 35-45\% over the next five years. The temporary measures we take today, vital as they are, will not be adequate to accommodate continued growth in the activities of the Human Subjects Division.

The Human Subjects Division occupies a space not much larger than a good-sized garage in the suburbs. The former director of Grant and Contract Services, Don Allen, estimated that approximately 40\% of the grant and contract dollars coming to the UW are associated with human subjects research. That would mean that approximately $260M of the $652M awarded to the UW last year depends on human subjects reviews. Images of businesses started in garages may have considerable romantic appeal these days, but no one seriously contemplates trying to run a $260M business out of a garage. The time has come to get the Human Subjects Division out of the garage.
**Recommendation 2: Commit to converting Human Subjects Division operations to electronic research administration by the end of FY2002.**

Members of the Grant and Contract Initiative, working closely with the Director of the Human Subjects Division, are close to identifying a software package that can handle a wide range of record keeping and meeting-related activities pertaining to human subjects. One option is to build on a more general package currently under consideration. Another is to integrate a software product designed for human subjects processes with more general University systems. One example is the BRAIN software developed at Baylor. It has been evaluated here and appears to address our needs (or can be modified to do so).

Our goal should be to create a system that allows electronic submission of IRB applications, electronic routing of prior approvals, and electronic distribution of protocols to IRB members for review. In addition, it should support the electronic exchange of comments prior to meetings as well as post-review functions such as the production of meeting minutes, letters to researchers, and electronic submission of researchers' responses to the IRB.

Conversion to an electronic system not only will reduce dramatically the clutter and confusion of HSD operations, but will also ensure that forms arrive in more complete form. A field can be set so that the person filling it out cannot move forward in the form until that particular field has been completed. Moreover, the use of an electronic system opens the door to much faster and more frequent communication with researchers, to potential for on-line meetings and consultation among members of the review committee. In addition, web-based tracking will allow researchers to know exactly where their
proposal is in the process and will allow HSD managers to evaluate performance more easily.

Again, a package that meets our needs is close to being selected. We strongly recommend that efforts to implement this package be given the highest administrative priority and support. Requirements must be specified in greater detail, of course, but it is likely that the equivalent of at least one full-time programmer will be needed to implement the package. Should BRAIN be the choice, implementation time will be reduced if travel support is provided so that our people can work with the Baylor team directly. These activities go beyond what is presently supported in the Grant and Contract Initiative. While they might become part of that initiative, additional budgetary support will be required to achieve the goals described here. Additional staffing also may be required to develop web-based tools for tracking and reporting. Moreover, if we are to utilize the capabilities of the BRAIN package for the management of IRB meetings, laptops and access to printers may be required for IRB members.

**Recommendation 3: Provide additional IRB review capacity immediately.**

The IRBs face huge and growing caseloads. Significant backlogs and delays have resulted from the collision of stricter interpretations of the rules, high caseloads, and low staffing. Immediate steps must be taken to increase the rate at which cases can be processed and to decrease the existing backlogs. The Human Subjects Division currently has three temporary staff. The first step in addressing the problems we have outlined must be to commit to permanent funding for these positions.

Several additional options should be considered, although the choice among them is obviously a matter best left in the hands of those with direct management
responsibility. Some of the options include increasing the number of IRBs, increasing the size of IRBs with the use of alternates and then shifting to a more frequent meeting schedule, and outsourcing some cases to a commercial review service. Whatever the options, the overriding goal must be to reduce backlogs and to increase review capacity to the point where the performance standards we articulated can be met.

**Recommendation 4: Improve communication between researchers and IRB members and Human Subjects Division Staff.**

Our findings point to inadequate information and guidance for researchers, a communicative climate that ranges from hurried to hostile, and a counterproductive lack of involvement and commitment by departments and colleges. Some do better than others, but the overall information climate is woefully lacking in detail and assistance. We need to greatly expand our education and outreach efforts, to not only meet our current needs, but also to anticipate new federal standards by the FDA and OHRP.

Our broad recommendation encompasses the entire application and review process. Toward this end, we offer the following more specific recommendations for revising the HSD website, training materials, and communication practices as well as for enhancing involvement and responsibility at the unit level:

- Revise and expand the discussion of common errors and problems on the HSD website ([http://depts.washington.edu/hsd/info.htm](http://depts.washington.edu/hsd/info.htm)). Provide suggested solutions to common problems. Prioritize consent form problems. Consider creating advisory groups of users to assist with revisions.

- Prepare on-line templates for consent forms, element by element, that possess enough quality and detail that researchers can be reasonably confident of IRB acceptance. Develop a “consent form wizard” that creates interactive drafts.
Overhaul the HSD website to allow easier navigation using pulldown menus and multiple pathways to reflect differences in user experience levels. Consider the University of Minnesota website as one model.

Post standardized language regarding indemnification on website.

Alert researchers of rule changes with updates in OR newsletter, website, list server.

Completely revise education and training to modularize education into components addressing specific needs (e.g. consent in special situations, special/vulnerable populations, unique settings, different disciplines, etc.). Publish case studies or case examples.

Working with the Office of Research, each department/unit should develop a plan to train all graduate students, postdoctoral fellows, and new faculty members in research ethics and scholarly integrity. Training should focus on understanding regulations as well as the practical process of preparing human subjects applications. Provide model curricular materials to participating departments and charge them with implementation in graduate methods courses.

Charge Graduate Faculty Representatives with checking for human subjects approvals on dissertation research.

Make assistance available immediately by phone during business hours.

Make assistance available by e-mail with same-day service.

Emphasize departmental responsibility for scientific review and completeness of forms. Placing screening responsibilities in the schools/departments will give the schools/departments firsthand information about how to target their faculty education efforts.

Implementing these recommendations will require additional staff. Temporary staff must be hired if printed and web-based materials are to be revised in a timely way. It is not realistic to expect existing HSD staff to take on tasks of this magnitude in addition to their regular duties. They have neither the time nor the expertise required. But permanent staffing for the Human Subjects Division must increase as well. Revisions in
procedure must go hand in hand with enhanced staffing, to be sure, but without additional 
staff resources it will not be possible to provide adequate service for researchers.

Several other ways that communication might be improved were suggested in the 
course of our investigation. We pass them along as suggestions to be considered:

✓ Establish a rotation so that each UW unit conducting human subjects research 
is visited by a committee coordinator at least once every three years.

✓ The Human Subjects Division should collaborate with colleges and 
departments to identify and train a cadre of faculty members to serve as 
mentors on human subjects issues. The issue of compensation for these 
mentors should be considered, appropriate to the level of time and training 
required. The effectiveness of the mentoring program should be evaluated 
by the quality of the applications received at HSD.

✓ Helen McGough should be encouraged and enabled to spend less of her time 
on routine tasks at the HSD and more time devising training programs and 
explaining the review and approval process to the University community. 
She is a talented educator.

✓ Target units with high levels of complaint or with inappropriately low levels 
of participation for special visits and assistance.

✓ Make names of IRB members publicly available and assist them in meeting 
their informal educational responsibilities.

✓ Review the current algorithm for assessing review requirements with the goal 
of greater clarity and a re-examination of the range of projects that may 
legally fall into the “no review,” “exempt,” and “minimal risk” categories. 
Provide researchers with examples of cases that will help them better 
understand the distinctions.

✓ Create an automated on-line version of the current algorithm for determining 
if review is needed, and, if it is, the type of review that is required. Provide 
support for research decision making with appropriate e-mail and telephone 
service.

✓ Co-sponsor training sessions on a quarterly basis with requesting colleges 
and schools.
**Recommendation 5: Compensate IRB chairs and consider compensation and/or additional recognition for all IRB members.**

IRB service is difficult and time-consuming. The burden falls most heavily on the chair, but all members experience demands that are far in excess of the normal commitments of university service. Faculty members serving on IRBs currently receive little recognition and have no way of adjusting their regular duties to compensate for the increased demands of review work. This makes it far harder to recruit and retain members. It may even create a selection bias in which the most knowledgeable and active researchers are discouraged from considering a tour of duty on an IRB. Lack of recognition also poses challenges for the recruitment and retention of community members. Recognition of these facts has led many other major research universities to offer some sort of compensation for IRB chairs and members. In this light, we recommend:

- ✓ Provide release time for IRB chairs (20-50%) and members (10-15%).
- ✓ Recruit at least one more community member for each IRB. Compensate them.
- ✓ IRB members perform an essential and difficult service. They deserve recognition from the President. Chairs and Deans should also be encouraged to provide greater recognition and flexibility for faculty who serve on IRBs.

**Recommendation 6: Enhance IRB and HSD staff recruiting, training, professional development.**

Two factors prompt our recommendation for enhanced recruiting, training, and professional development for those involved in human subjects work. First, we simply cannot expect these people to stay abreast of the rapid changes in the regulatory
environment without providing better support for training and continuing education.
Research is posing difficult new ethical challenges. New technologies and methodologies require new ways of thinking about ethical standards. Enhanced public concern pushes institutional review in new directions and to new levels of detail. We cannot respond to these changes without more attention to training and education for IRB members and HSD staff. Second, enhanced support for these activities is essential if we are to attract and retain competent personnel. It is also essential if we are to overcome the malaise that appears to have settled over many of those involved in human subjects work. Our **specific recommendations** include:

- Extend advertising for HSD hiring to Seattle newspapers, Chronicle, and SRA publications.
- Develop and support professional development and training tracks for HSD staff.
- Send chairs and the primary committee staff person to the annual national PRIM&R meeting. Information from this meeting gives a national and international perspective unavailable elsewhere and can be integrated into human subjects education programs for the other committee members and for the university community.
- Expand and regularize training for new IRB members.
- Limit terms and use shorter terms (e.g., 2-3 years) to encourage more faculty participation on the IRBs.
- Enlarge committee size by naming alternate members.

We also believe that some consideration should be given to participation in staff certification and IRB accreditation programs. The extent to which these programs are necessary or add value should be explored.
**Recommendation 7: Create a Human Subjects Policy Board**

We recommend the creation of a Human Subjects Policy Board composed of committee chairs, the HSD Director, and other users of the system. The board would function to monitor national policy and research developments with local implications. It might be charged with creating an appeals process for handling significant disagreements between researchers and the IRBs.

Other activities to consider for the Policy Board in conjunction with the Office of Research might include the creation of a standing faculty committee that can serve as ombudsmen for complaints or other problems arising from human subjects research. This committee might also work with the Office of Research to create an external review mechanism involving human subjects professionals and managers from peer universities and government bodies.

**Recommendation 8: Prioritize efforts to streamline HSD and IRB operations.**

Increased staff and resource support are essential if we are to achieve acceptable levels of service and protection. So, too, however, are a number of changes the procedures and operations of the IRBs and the Human Subjects Division. Researchers and Task Force members suggested many, but many also came from IRB members and HSD staff members themselves. The result was a long list of suggestions of varying levels of detail and importance. They obviously require scrutiny by those charged with the management of HSD operations, but the most important ones in our view are:

- Use process mapping and related tools to re-engineer handling of modifications.
✓ Create “sunshine” mechanisms that provide IRBs with feedback about
decision-making patterns from faculty and external advisory groups.

✓ Devise a system for determining different levels of risk in applications going
to full review. Use this information for planning committee agendas so that
applications with higher levels of risk are likely to receive greater scrutiny.

✓ Periodically re-evaluate the use of risk categories such as “psychological
distress” or “discomfort” with an eye toward eliminating uses where no
direct evidence of problems exists.

✓ Return seriously incomplete forms with screener’s worksheet, but without
review.

✓ Identify and resolve inconsistencies between IRBs with regard to acceptable
language for contact scripts, consent forms, and advertising.

✓ Post model advertisements.

✓ Work with colleges and departments to create one or more panels of experts
who are “on-call” to address technical questions.

✓ Develop specialized review sensitivities and capabilities for areas such as
gene therapy, international research, semi-structured interviews and
ethnographies, working with pre-existing databases, tissue banks.

✓ Inform IRB members of changes in NIH procedures that delay their review
until a proposal receives a fundable score through the peer review process.
This means NIH proposals have already received detailed review and
approval on grounds of scientific merit by the time they reach the IRBs.

✓ Formalize current procedures and understanding for managing potential
conflicts of interest on the part of IRB members.

✓ Determine if the IRBs are getting adequate information regarding disclosures
and management of researcher’s financial interests. Clarify IRB
responsibilities and needs.

Other suggestions for streamlining operations include:

✓ Develop consensus among staff on procedures for locating each other’s open
case files.

✓ Hire additional screener for HSD. (Pending conversion to electronic
submissions)
✓ Publish screener’s worksheet.

✓ Encourage IRBs to move away from decision-making models that require complete consensus for action.

✓ Provide additional staff support during meetings to ensure better quality meeting minutes.

✓ Provide laptop computers to staff so that drafting of letters may begin during the meeting.

✓ Encourage coordinators/administrators to seek information about their counterparts’ operations by attending each other’s committee meetings.

✓ Bring in an outside operations manager or consultant to review IRB meetings and recommend process improvements.

**Recommendation 9: Plan and implement a program of post-approval auditing and monitoring.**

The current system for protecting human subjects emphasizes *prior review* by local Institutional Review Boards. Subjects are protected because research is not allowed to begin unless and until it is approved by an IRB. Once approval is obtained, the investigator is entrusted with completing the research activity in accordance with federal rules, ethical standards, and any conditions the IRB might have imposed. A number of exceptions to this practice have emerged over the years (e.g., annual reviews/renewals, investigations following adverse events, FDA inspections and audits), but the overall process still depends heavily on prior reviews. This system, however, is now undergoing dramatic change. All signs point toward a system in which, after IRB approval, individual investigators will be held much more strictly accountable than ever before for the research activities they conduct. This trend is unlikely to be reversed.
The Office of Research at the University of Washington has already begun planning for a new set of “post-approval monitoring and auditing” procedures that will complement the existing system of prior review. The Task Force endorses that effort. The goal of these efforts should be to establish a system for monitoring and auditing the actual conduct of human research activities that both provides strong protection and works within the culture of the academy. With the exception of the literature monitoring program, all of the new procedures described below are enforcement measures, taken after a project has been approved by an IRB. Such a system will require resources, staff support within the Human Subjects Division and outside it, and logistical support (e.g. electronic files and a relevant data base). It may also require new language in standard consent forms as well as additional requirements for what investigators must retain in their files. This system might include, though not be limited to, the following types of measures and features:

- Risk-based or random selection of a subset of cases for continuing review by IRBs at intervals that are more frequent than annual.

- On-site audits or inspections of certain research activities based on risk, random selection, complaints, or the occurrence of adverse events associated with the research activity, significant or not. These audits or inspections could, but need not, be incidental to regulatory efforts of other agencies (e.g. the FDA).

- The monitoring of published literature to identify studies conducted by University investigators that have never been reviewed or approved by an IRB, but should have been. One successful model is the program currently in effect at University of California at San Diego.
The creation of such a program brings with it the need to consider its link to our existing mechanisms for handling cases of scholarly misconduct. Particular attention must be paid to:

- Protection of whistleblowers from academic or employment related retaliation who in good faith make reasonably based reports of non-compliance or violations.
- Appropriate sanctions for non-compliance and violations, accompanied by procedures for protecting the rights of those involved.

We understand that such a comprehensive system of post-approval monitoring and auditing must be thoughtfully assessed, and the costs and benefits must be understood, before being fully implemented. On the other hand, certain measures can be instituted sooner rather than later (e.g. more frequent risk-based continuing IRB review, literature monitoring), and they should be. We recommend that the process begin immediately.

**Summarizing the Priorities**

Several factors merit immediate attention. It is our conclusion that the highest, most immediate priorities are to address the current space crisis in HSD by finding additional meeting and staff space, 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. It is also essential to begin immediately on the revision of HSD’s materials and website as well as the conversion to an electronic system for processing human subjects applications.