

**Office of Internal Audit**



**Program Review**

**POLICIES AND PROCEDURES FOR THE  
PROTECTION OF  
HUMAN RESEARCH SUBJECTS**

**August 2000**

---

## SCOPE

---

The Office of Internal Audit reviewed University of Wisconsin (UW) System institutions' policies and procedures for the protection of human research subjects. Review procedures included visits to nine Institutional Review Boards (IRBs) at six UW System institutions, including UW-La Crosse, UW-Madison, UW-Milwaukee, UW-Oshkosh, UW-Stout, and UW-Whitewater; and analyses of policies and meeting minutes of the IRBs at UW System institutions not visited.

During the visits, we interviewed IRB chairs and IRB administrators and reviewed IRB documentation, including minutes and record files. We reviewed a total of 49 sets of minutes and 111 research proposals. The visits to the IRBs were conducted between January and March 2000. The visits to the IRBs at UW-Madison were done in collaboration with UW-Madison's internal audit staff and as a part of UW-Madison's self-initiated review of its policies and procedures. We also received and reviewed 19 sets of meeting minutes from eight IRBs we did not visit.

---

## BACKGROUND

---

**The Nuremberg Code and the Declaration of Helsinki provided the foundational principles for the protection of human research subjects.**

The basic principles of the current system for the protection of human research subjects, including the system in the United States, were derived from the Nuremberg Code and the Declaration of Helsinki. The Nuremberg Code was developed in 1949 for the Nuremberg Military Tribunal as standards by which to judge the human experimentation conducted by the Nazis. The first provision of the Code addresses voluntary consent, which has become the cornerstone of ethical experimentation involving human subjects. The Declaration of Helsinki was adopted by the World Medical Assembly in 1964. The Declaration of Helsinki extended the basic principles in the Nuremberg Code.

### **Human Subject Protection Regulations**

Regulations for the protection of human research subjects are almost exclusively federal. Currently, there are no comprehensive regulations in Wisconsin for the protection of human research subjects. The few requirements that exist are applicable to certain specific populations or facilities, such as:

- §51.61(1)(j), Wis. Stats., grants individuals who are receiving services for mental illness, developmental disabilities, alcoholism or drug dependency the right not to be subject to experimental research without their express and informed consent and the consent of their guardians. A treatment facility's research and human rights committee must also approve all proposed research.
- §51.61(4)(a), Wis. Stats., requires treatment facilities for alcoholic, drug dependent, mentally ill or developmentally disabled persons to establish a research and human rights committee consisting of not less than five persons.

In addition, there are numerous statutory references to record confidentiality, which could apply to human subject research. Confidentiality remains an area of legislative interest. During the 1999-2000 legislative session, for example, the Wisconsin Assembly passed a bill prohibiting any school board official, employee or agent from conducting surveys or questionnaires of students that may reveal certain information about the students or their families without written consent of the students' parents or guardians.

Federal regulations protecting human research subjects were first issued in 1962. The Drug Amendments of 1962 (Public Law 87-781) were enacted in response to findings that many of the patients participating in clinical trials of a drug that was found to have caused severe birth defects had not been properly informed, nor had many given their consent. Public Law 87-781 required consent of research subjects.

**The Belmont Report sets forth the basic principles for acceptable conduct for research that involves human subjects.**

Motivated by the syphilis study in Tuskegee, Alabama, in which treatment was withheld from participants with syphilis, Congress enacted the National Research Act (Public Law 93-348) in 1974. The National Research Act established the Institutional Review Board (IRB) as one mechanism through which human subjects would be protected. The National Research Act also established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission issued its report, the Belmont Report, in 1978. The Report sets forth three basic ethical principles underlying the acceptable conduct of research involving human subjects and describes how the principles apply to the conduct of research. The three principles in the Report are:

- (1) Respect for Persons -- The principle requires that individuals be treated as autonomous agents and that individuals with diminished autonomy be protected.

(2) Beneficence -- The principle requires that persons be protected from harm by maximizing possible benefits and minimizing possible risk of harm.

(3) Justice -- The principle requires that benefits and burdens of research be distributed fairly.

**DHHS regulations were used as the basis for all federal departments' regulations on human research subjects.**

Subsequent to the passage of the National Research Act and release of the Belmont Report, the various federal agencies promulgated regulations to implement provisions in the legislation and report. These regulations shared little uniformity, however. In 1981, following the recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, the various regulations were revised to ensure uniformity across all federal departments and agencies that conduct or support research involving human subjects. In 1991, a set of regulations based on the core of the Department of Health and Human Services (DHHS) National Institute of Health's (NIH) regulations was published. The DHHS regulations became the basis for the regulations adopted by all federal departments and agencies (referred to as the Common Rule). DHHS Food and Drug Administration (FDA) developed its own regulations, which are distinct but very similar to NIH's.

DHHS/NIH's regulations for the protection of human research subjects are codified in Title 45 of the Code of Federal Regulations (45 CFR 46). Some key provisions of 45 CFR 46 include:

**Federal regulations establish minimum requirements and review criteria for the Institutional Review Boards.**

- establishing a minimum number of committee members for the IRB and delineating the functions and responsibilities of the IRB;
- delineating review procedures and establishing criteria for the IRBs to follow when reviewing and approving research proposals;
- specifying what documentation must be maintained; and
- establishing requirements for informed consent.

The regulations apply to all research involving human subjects when the federal government supports the research. Many institutions, however, by their assurances to DHHS, adopt the federal regulations for all human subject research, regardless of how they are funded.

## **Federal Oversight**

Within the DHHS, the new Office of Human Research Protection (OHRP) and FDA have responsibilities for human subject research oversight and guidance. OHRP has oversight responsibilities for all DHHS funded research while FDA has oversight responsibility for FDA approved products. To carry out their oversight responsibilities, OHRP and FDA conduct investigations and inspections of Institutional Review Boards (IRBs) and institutional performance.

**The General Accounting Office and Office of Inspector General found that the human subject research protection system has been threatened.**

In 1994, the U.S. General Accounting Office (GAO) conducted an audit of the Office Protection from Research Risk (OPRR) (former oversight office) and FDA enforcement of IRB compliance with DHHS human subject protection regulations. GAO released its report of the findings in 1996. GAO found that various factors have reduced or threatened to reduce the human research subject protection system's effectiveness and that there is a need for continued vigilance over human subject research by agencies charged with oversight. A separate evaluation by the DHHS Office of Inspector General (OIG) also confirmed the GAO finding that even though there does not seem to be widespread abuse of human research subjects, the effectiveness of the human research protection system is in jeopardy.

Since the release of these two reports, OHRP and FDA stepped up their oversight activities. For instance, between April 1997 and May 1998, when OIG conducted its first evaluation, OHRP had conducted an on-site investigation at only one institution. Between June 1998 and March 2000, OHRP conducted on-site investigations at ten institutions. FDA's number of on-site investigations of IRBs increased from 213 in FY 1997 to 253 in FY 1998, and 336 in FY 1999.

**Investigations conducted by the Office of Human Research Protection led to the suspension of research at eight institutions around the country.**

As of July 2000, OHRP's investigations led to temporary suspension of some or all federally-funded research at eight institutions, including Duke University, the University of Illinois at Chicago, The Charles R. Drew University of Medicine, the University of Alabama at Birmingham, University of Oklahoma Health Sciences Center, and Virginia Commonwealth University. In addition, a number of institutions, including Mount Sinai School of Medicine and Queens College, were allowed to continue with their research but under severe restrictions and federal oversight.

At the time of our visits in February 2000, OHRP had notified UW-Madison of a planned on-site investigation of its policies and procedures. OHRP later postponed the visit. OHRP visited UW-

Madison in August 2000 and issued an investigative report complimenting the university for its commitment to human subject protection, its actions to enhance the university's system for protecting human subjects, and requiring a few changes in its review process.

**DHHS has proposed a number of new initiatives to strengthen research oversight.**

More recently, DHHS has proposed a number of new initiatives to strengthen oversight of research involving human subjects, such as:

- requiring universities, as a condition of the grants they receive from DHHS for research, to educate researchers and administrators about federal regulations governing research with human subjects;
- urging universities to audit researchers' records regularly; and
- seeking congressional authority to impose fines of up to \$1 million for institutions and \$250,000 for each researcher for rule violations.

Even though there is no indication of whether federal enforcement agencies will eventually visit other UW System institutions, it is clear that recent federal actions point toward increased enforcement of the regulations. Regardless of changes at the federal level, however, UW System institutions need to be vigilant in their efforts to ensure the health and safety of participants involved in university research.

---

**DISCUSSION AND  
RECOMMENDATIONS**

---

This review will describe: (1) the level of research activities involving human subjects at UW System institutions, and (2) UW System institutions' compliance with federal regulations, as evidenced by their policies and procedures, Institutional Review Boards (IRBs), and various other documentation.

All UW System institutions conducting research that involves human subjects are committed in their assurances or policies to comply with federal regulations, regardless of whether or not the research is supported by the federal government. Due to the nature and funding sources of research conducted by UW System institutions, regulations that are most applicable to UW System institutions are Title 45 of the Code of Federal Regulations and FDA. In addition, UW System institutions, which are required to

have assurances on file with DHHS, must comply with the terms and conditions of their assurances.

**UW System institutions show solid commitments to protecting human subjects involved in university research.**

Overall, we found solid commitments among UW System institutions to ensuring the health and safety of individuals participating in university research. All UW System institutions have developed policies and procedures, have established IRBs, and have maintained documentation as required by federal regulations. The policies and procedures are generally consistent with federal regulations. The few deviations we found were unlikely to result in harm to the subjects but should be remedied over time. These deviations can largely be remedied by revising policies, enforcing policies, and providing more training to IRB members.

## **RESEARCH ACTIVITIES INVOLVING HUMAN SUBJECTS AT UW SYSTEM INSTITUTIONS**

**All UW System institutions, except UW Extension, conduct research involving human subjects.**

To determine the level of research activities involving human subjects, we reviewed the number of research proposals UW System institutions received from their faculty, staff, and students. Even though research is not a primary emphasis for all UW System institutions, we found that all UW System institutions except UW Extension have research activities involving human subjects. As expected, the bulk of research activities involving human subjects occurs at UW-Madison. (See Appendix.)

UW System institution officials with whom we talked reported having seen an increase in the number of proposals submitted for IRB approval. The increase was due in part to a recent push for more undergraduate research and a greater awareness of federal requirements among faculty, staff, and students conducting research.

## **WRITTEN PROCEDURES**

Federal regulations require that institutions conducting human subject research supported by federal agencies provide assurances that they will comply with federal requirements. One of the assurances is written procedures, which the IRB will follow. We found various written documents detailing policies and procedures at UW System institutions.

### **Assurances**

Both UW-Madison and UW-Milwaukee have written Multiple Project Assurances (MPA) approved by and on file with DHHS.

**UW-Madison and UW-Milwaukee have assurances approved by and on file with DHHS.**

UW-Madison's assurances were approved for the period of November 1, 1998 through October 31, 2003. The UW-Madison assurances cover all investigators employed at UW-Madison. UW-Milwaukee's assurances were approved for the period of May 7, 1999 through May 6, 2004. The assurances lay out the institution's system for protecting human subjects, including the IRB structure, general ethical principles, and policies for the IRB and research investigators.

### **Guidelines for Researchers**

All UW System institutions, including UW-Madison and UW-Milwaukee, have developed guidelines for researchers. The guidelines were intended to provide instructions for the researchers to complete their proposals and to submit their proposals for approval. Generally, the guidelines are consistent with federal regulations. One deviation is the absence of some of the elements of informed consent from some UW System institutions' guidelines.

**All UW System institutions conducting human subject research have developed guidelines for researchers.**

Federal regulations require that an informed consent document include at least these eight basic elements:

- an explanation of the purposes of the research;
- a description of foreseeable risks;
- a description of the benefits of the research;
- a disclosure of appropriate alternative procedures;
- a records confidentiality statement;
- an explanation of any compensation and available medical treatments if injury occurs;
- the name of the contact person for the research; and
- a voluntary participation statement.

The guidelines at two IRBs we visited allow the informed consent to exclude certain elements when written consent is not required. These institutions' understanding is that all elements of informed consent are not required in instances in which written consent is not used. However, the IRB must approve a motion to waive consent showing regulatory standards for waiver are met. We also found that the sample informed consent documents in the guidelines of some UW System institutions we did not visit do not contain all the elements. *To be consistent with federal regulations, we recommend that UW System institutions ensure that all required elements of informed consent be included in the guidelines whether or not written consent is required.*

## **Procedures for the Institutional Review Boards**

**Some UW System institutions have developed written procedures for their Institutional Review Boards.**

Federal regulations require that institutions engaging in research that involves human subjects and is supported by a federal agency develop written procedures for the Institutional Review Boards (IRBs). Only UW-Madison and UW-Milwaukee reported having research involving human subjects supported by federal funds. At the time of our visits, UW-Milwaukee's IRB and UW-Madison's Health Science IRB had written procedures. The other UW-Madison IRBs were in the process of developing their procedures.

Even though written procedures for the IRB are not required for institutions whose research is not supported by federal funds, one UW System comprehensive institution has adopted written procedures for the IRB in addition to guidelines for researchers. With periodic turnover in IRB membership and the need to provide formalized structure and guidance for IRB operations, written procedures for the IRB may be essential. *We recommend that all UW System institutions consider developing written policies and procedures for their IRBs, even if their research does not involve federal funds.*

## **INSTITUTIONAL REVIEW BOARDS**

Federal regulations require that research involving human subjects be reviewed and approved by an Institutional Review Board (IRB). We reviewed composition of the IRBs and how they operate.

### **Membership**

Federal regulations require each IRB to have at least five members with varying backgrounds and diversity in gender, race, and cultural background, and to include representation from the community and nonscientific areas. We found that all UW System institutions have established IRBs as required and that their IRBs appear to meet the composition requirements.

**All Institutional Review Boards have the minimum number of members and the membership includes representation from the community and non-scientific areas.**

In order to ensure that the IRB membership always includes a community representative, a number of institutions have appointed multiple community representatives or have appointed alternates to the IRBs. Some UW System institutions we visited have had some success in finding qualified racial/ethnic minority representation on their IRBs. Should an IRB's membership lack expertise when the IRB reviews research proposals involving special populations, including children, prisoners, and people with disabilities, the

institutions typically invite outside consultants with the appropriate expertise to help with the review.

While the composition of the IRBs and qualifications of the IRB members appear to meet federal requirements, we found that at two UW System institutions the grant administrators also serve as voting members of the IRB, which may raise concerns about the potential of conflict of interest. In one IRB, the grant administrator serves as the chairperson of the IRB. In the other IRB, the grant administrator serves as the nonscientific representative on the IRB. OHRP has determined in other instances that having individuals involved in grant administration serve as voting members will constitute a conflict of interest.

### **Review Procedures**

#### **Procedures used to review and approve research proposals vary among UW System institutions.**

Review procedures vary among UW System institutions' IRBs. Some IRBs meet at least once a month. Others meet only as needed, but at least once a year. All IRBs use a primary reviewers system, which involves having only a few IRB members review the research proposal materials rather than the full IRB. Some IRBs use the system during the initial and continuing review process while others use the system only to review modifications to previously approved proposals. While the proposals or modifications to previously approved proposals are made available to all the IRB members, the system enables a few IRB members to conduct an in-depth review.

All IRBs also use expedited review procedures. Federal regulations allow expedited review procedures to be used for certain kinds of research involving no more than minimal risk, and for minor changes in previously approved research. Research proposals reviewed using expedited review procedures can be approved without a convened meeting of the full IRB. Some IRBs use the procedures to review and approve initial research proposals that meet federal criteria. Others use the procedures to review and approve only minor modifications to previously approved proposals. At most UW System institutions, the expedited review procedures are carried out by the IRB chairpersons and the IRB administrators.

All but one IRB grant exemptions to proposals that meet exempt criteria. UW-Madison's Health Sciences IRB does not grant exemptions because the research proposals the IRB typically receives pose more than minimal risk to the participants and are not likely to meet the exempt criteria. UW-Stout grants some exemptions, but prefers using expedited review procedures for proposals that would typically meet the exempt criteria. UW Stout's practices are consistent with federal regulations.

A number of IRBs have also developed databases to log and track research proposals. Some of the databases enable the IRBs to quickly identify research proposals that are close to their approval expiration date and to notify the researchers to submit applications for renewal.

While all IRBs we visited have procedures, not all procedures are comprehensive or appear to be consistently enforced. However, the deviations do not appear to be widespread among all the IRBs. Even some of the more common deviations are confined to just a few IRBs. Aspects of the procedures that will require more attention include ensuring that all informed consent documents contain the required elements, approving continuing review proposals in a timely fashion, reviewing the grant application for proposed research as part of the approval process, ensuring that a quorum is achieved when research proposals are discussed and approved, and limiting the use of contingent approval.

**Some informed consent documents do not include all elements of informed consent.**

**Informed Consent Document** – All non-exempt research proposals we reviewed at the IRBs we visited were approved with an informed consent document. However, we found at most of the IRBs, at least one research proposal was missing one or more elements of informed consent from the informed consent document. This may reflect the absence of some elements of informed consent from researchers’ guidelines discussed earlier. However, some elements were also omitted at UW System institutions with comprehensive guidelines.

**Some ongoing research proposals were approved after their initial approval periods had expired.**

**Continuing Review** – All but two of the nine IRBs we visited have established procedures for continuing review of research projects that pose more than minimal risk to the subjects or that go beyond the initial approval period. The procedures at five of the IRBs appear to be adequate, but enforcement could be improved. We found at least one research proposal at four of these five IRBs that was approved after its approval period had expired. Such after-the-fact approval is not appropriate. At the other IRB, the IRB relies exclusively on the researchers to submit applications for renewal. None of the proposals we selected for review had lapsed, however. In general, institutions that have the procedures automated seem to do a better job of ensuring that all continuing proposals are approved in a timely fashion.

**The grant applications for proposed research are not reviewed as part of the review process.**

**Grant Application for Proposed Research** – Reviewing the grant application for proposed research is a requirement for institutions with an approved assurance on file with DHHS. UW System institutions’ IRBs have not typically reviewed the grant

application for proposed research. OHRP is enforcing this requirement.

**Some research proposals were approved without a quorum.**

**Quorum** – Our review of IRB meeting minutes reveals at least one full IRB meeting at five different IRBs during which research proposals were discussed and approved without a quorum. Some of the other meeting minutes did not record attendance.

**Contingent approval may not be appropriately used in some instances.**

**Contingent Approval** – Approving a research proposal contingent upon certain conditions is a common practice of all IRBs at UW System institutions. The IRBs use contingent approval with research proposals that come before the full IRB as well as proposals reviewed through expedited review procedures. When a research proposal is approved contingent upon certain modifications, the researcher is asked to provide satisfactory modifications before the research proposal receives final approval. Federal regulations permit the use of contingent approval, but only for minor, non-substantive modifications. However, we found a number of instances where the IRBs appear to have overextended the use of contingent approval. In one instance, the proposal was incomplete. In two other instances, the proposals required more than ten modifications, including substantive changes to the proposals and to the informed consent documents. In these instances, the IRBs should have deferred approving the proposals rather than approving them contingent upon the modifications, as the modifications are not typically reviewed by the full IRB again.

Having comprehensive procedures and enforcing these procedures are important to ensure that all research proposals are reviewed and approved in accordance with federal regulations. *We recommend that UW System institutions review their IRB procedures to ensure compliance with regulations and the assurances, and ensure that the procedures are consistently enforced.*

### **Training**

Training is critical to ensure that IRB members have a comprehensive understanding of the regulations. At the time of our visits, training for IRB members consisted of providing them with copies of the federal regulations, guidelines, and other written documentation, and of relying largely on on-the-job learning. A few institutions with more resources were able to send their IRB chairpersons to national or regional conferences.

**IRB administrators and chairpersons interviewed agree that more training should be provided to IRB members.**

All IRB administrators and chairpersons we interviewed agreed that more training should be provided to the IRB members. At UW-Madison, the All-Campus Committee has identified training as a

need and has required mandatory training consisting of the NIH-based interactive computer program and the University of Rochester's book, *Protecting Study Volunteers in Research*, for all IRB members. Other UW System institutions do not currently have concrete plans for developing training programs for their IRB members. Some UW System institutions also expressed concerns about the amount of training, if any, they will be able to provide to their IRB members due to financial constraints.

UW System Administration (UWSA) can play a potentially significant role in the training of IRB members. UWSA could facilitate the planning for and development of training programs. UWSA's involvement may also help to ensure that training is available systemwide and is provided consistently across UW System institutions. Certain UW System officials had indicated it might even be more cost effective to develop systemwide training programs for the IRB members. *We recommend that UW System institutions offer more training to their IRB members and that UW System Administration help facilitate the development of training programs for IRB members.*

### **Administrative Support**

Adequate administrative support is essential if the IRB functions are to be carried out smoothly. We reviewed the staffing level of the IRBs we visited. The level of staffing ranges from nine full-time equivalent (FTE) positions at UW-Madison's Health Sciences IRB to less than one FTE position at each of the other IRBs we visited.

**UW-Madison and UW-Milwaukee's self-initiated analyses indicate that some of their IRBs are understaffed.**

There are no national standards for IRB staffing. Our approach in this review was to assess the staffing level in the context of the number of research proposals the IRBs receive, the procedures they use, and the degree of risk exposure for noncompliance. UW-Madison and UW-Milwaukee initiated analyses of the ratio of FTE positions to the number of research proposals received. The analyses showed that three of the four IRBs at UW-Madison and UW-Milwaukee's IRB are understaffed in comparison to peer institution averages. At other IRBs, while certain deviations we note in this report are due to differences in interpreting the federal regulations, it was apparent that some were caused by the lack of adequate staff resources. *To ensure that IRB functions are carried out properly and adequately, we suggest that UW System institutions evaluate the staffing resources assigned to IRB functions to determine whether adjustments are needed.*

## DOCUMENTATION

Federal regulations require that the following documents be maintained in IRB records: (a) copies of research proposals reviewed, (b) minutes of IRB meetings, (c) records of continuing review activities, (d) copies of all correspondence between the IRB and the researchers, (e) a list of IRB members, written procedures for the IRB members, and (f) statements of significant new findings to the subjects.

**UW System institutions have maintained records as required.**

How records are organized varies among IRBs. Nonetheless, we did find the required documents in the files we reviewed. We concluded that, in general, the IRBs have maintained records as required. However, the IRBs need to ensure that certain required information is consistently and adequately recorded in the IRB meeting minutes.

Federal regulations require that minutes be kept in sufficient detail to show: (a) attendance, (b) actions taken by the IRB, (c) the vote on these actions, (d) the reasons for approving, requiring changes or disapproving the protocols, and (e) a written summary of the discussion. We found that some IRB meeting minutes lack the detail required. Missing more frequently from the minutes are the voting results and summaries of the discussion. In some instances, the minutes simply indicate that the IRB approves the research proposals, with no other details offered.

To ensure that records are maintained as required and minutes are kept in required detail, UW-Madison has developed a checklist for its IRBs to follow. The checklist contains certain specific items that must be included in all minutes. UW-Madison will also institute a process to select samples of their IRB minutes for periodic review.

UW-Madison and UW-Milwaukee, which have approved assurances on file with DHHS, are required to conduct annual procedural and record keeping audits. Other UW System institutions are not subject to the same requirement. However, adequate and complete documentation is essential, as documentation helps to provide support for the IRBs' decisions. *We suggest that all UW System institutions consider conducting periodic review of the completeness of their IRB records.*

## FUTURE POLICY CONSIDERATIONS REGARDING THE PROTECTION OF HUMAN RESEARCH SUBJECTS

It is apparent that DHHS has stepped up its effort to enforce federal regulations governing research involving human subjects. While

many of the issues we address in this report are procedural and are not likely to lead to harm to the subjects, some are clearly inconsistent with federal requirements.

**A UW System policy may help to heighten the need for staying in compliance with federal regulations.**

Currently, there is no UW System policy for the protection of human subjects involved in university research. A policy may help to heighten the need for UW System institutions to stay in compliance with federal requirements. A system policy may not need to be as comprehensive as some of the UW System institutions' current policies, which specify forms that researchers must use when submitting their research proposals for IRB review and provide sample informed consent documents for researchers to follow. Rather, a system policy should only set the minimum expectations for UW System institutions.

We conducted a search of other peer university systems' policies and found that a number of university systems have developed system or Board of Regents policies. These university systems include the University of California System, University of Texas A&M System, University of Minnesota System, University of Maine System, and the University of Maryland System. With the exception of the University of Texas A&M System's policy, all other policies are brief in comparison to their system institutions' policies. *We recommend that UWSA develop a UW System policy statement for the protection of human research subjects.*

---

## **CONCLUSION**

---

Our review found solid commitments from UW System institutions to protect the health and safety of individuals participating in university research. All UW System institutions have developed some necessary policies and procedures, have established IRBs, and have maintained records. While we found some deviations from federal regulations, they appear to be procedural and are not likely to lead to harm to the subjects. Nonetheless, they are issues that UW System institutions need to address. Thus, we have made the following recommendations or suggestions for UW System institutions' consideration:

- ensure that the informed consent documents in the researchers' guidelines include all required elements;
- review procedures to ensure that they are consistent with federal regulations and ensure that the procedures are followed;

- develop written procedures for the IRBs that do not have them;
- provide more training to the IRB members;
- evaluate staffing resources assigned to IRB functions to assess their adequacy; and
- conduct a periodic review of the completeness of IRB records.

We have also recommended that UWSA develop a UW System policy statement for the protection of human subjects involved in university research. Finally, we have suggested that UWSA consider helping to facilitate the planning and development of training programs for IRB members.

APPENDIX

NUMBER OF HUMAN SUBJECT RESEARCH PROPOSALS RECEIVED

Institution	Number of Initial Protocols			Number of Continuing Review Applications		
	1997	1998	1999	1997	1998	1999
Madison						
Health Sciences *	518	517	559	612	359	764
Education **	98	154	123	102	74	132
Letters & Sciences ***	50	90	175	11	46	115
Agricultural & Life Sciences ****	52	58	67	4	4	5
Milwaukee *****	140	119	167	35	33	27
Eau Claire *****	43	39	51	0	1	1
Green Bay *	---	11	1	---	1	0
La Crosse *	---	103	116	---	0	0
Oshkosh *****	---	75	81	---	0	0
Parkside *	22	12	19	28	31	24
Platteville *****	45	38	31	0	0	0
River Falls ***	---	34	55	---	0	0
Stevens Point ***	31	30	29	0	0	0
Stout *	71	145	112	0	0	0
Superior *****	0	0	0	0	0	0
Whitewater *	---	106	65	---	24	22
UW Colleges *	9	20	8	0	0	0
UW Extension	0	0	0	0	0	0

\* Calendar Year (1/1 to 12/31)

\*\* Grant Year (9/1 to 8/31)

\*\*\* Academic Year (8/1 to 7/31)

\*\*\*\* Fiscal Year (7/1 to 6/30)

\*\*\*\*\* UW-Superior received four research proposals in academic year 1999-2000.

Sources: UW System institutions