

## Brief Summary of Investigator Responsibilities Related to Protection of Human Subjects

---

All University of Wisconsin-Madison faculty, staff, students, and agents of the institution are required to submit for Institutional Review Board (IRB) review any research project involving human subjects. Human subjects research includes a wide range of activities, including clinical trials, the collection or use of specimens obtained from human subjects, survey and interview research, research involving medical records, and the creation of databases for research purposes. By campus policy human subjects research that may qualify for exemption from IRB review must nonetheless be submitted to an IRB for a determination regarding the appropriateness of an exemption.

The University of Wisconsin - Madison has three Institutional Review Boards (IRBs) which review human subjects research to ensure that Federal, State, and institutional requirements are met for protecting human subjects involved in research. The Health Sciences IRBs review research involving medical interventions, procedures where medical expertise is required for evaluation, or require knowledge of the health care setting. The Education and Social/Behavioral IRB reviews education, social, behavioral, and non-medical health research. Protocols include human subjects research about the education process, effectiveness of education programs and child development as well as studies that focus on the decision processes and individual functioning in social environment. Compliance with regulations and policies governing human subjects research ensures the integrity of the University of Wisconsin - Madison as a research institution.

The IRBs and their office staff encourage investigators to seek assistance in meeting these standards. Please contact us:

- Health Sciences IRBs: 608-263-2362, Suite 105, 800 University Bay Drive, <http://kb.wisc.edu/hsirbs>
- Education and Social/Behavioral Science IRBs: 608-263-2320, 310-322 Lathrop Hall, 1050 University Avenue, <http://www.irb.wisc.edu>

Some of the responsibilities that researchers assume when conducting research involving human subjects include, but are not limited to, the following:

- **Compliance with the principles of the Belmont Report and adherence to the regulations outlined in the Common Rule (45 CFR 46) and the Food and Drug Administration (when applicable).** The University of Wisconsin's Federalwide Assurance with the U.S. Department of Health and Human Services, Office for Human Research Protections states that all human subjects research activities will be guided by the ethical principles outlined in the Belmont Report and the Common Rule. Investigators should become familiar with these principles and regulations to ensure that their research complies with such principles and regulations. Failure to comply with these principles can place both subjects and the institution at risk.
- **Completion of required human subjects protection training.** The University of Wisconsin requires all key personnel on a human subjects protocol to complete the online Human Subjects Protection Training Module (<https://my.gradsch.wisc.edu/citi/index.php>) and any relevant HIPAA Privacy Rule training. It is the responsibility of the principal investigator to ensure that all key personnel on a protocol have completed required training related to research involving human subjects.
- **Providing adequate training to and oversight of study personnel and, in the case of clinical research, ensuring protocol procedures comply with Good Clinical Practice requirements.** Although principal investigators may delegate research responsibilities to others, they retain ultimate responsibility for the conduct of those to whom they delegate research responsibilities. Investigators are responsible for certifying that key personnel have received adequate training to ensure they are aware of the regulations governing human subjects research and understand and adhere to the IRB-approved research protocol. Good Clinical Practice is an international ethical and scientific quality standard for designing, conducting, monitoring, auditing, recording, analyzing and reporting trials that involve the participation of human subjects. Compliance with these standards helps to provide assurance that the rights, safety, and well-being of human subjects are protected.
- **Obtaining legally effective informed consent.** Unless the IRB determines that a waiver of informed consent or waiver of documentation of informed consent is appropriate for a protocol or has determined a protocol to be exempt, an investigator is responsible for (a) obtaining and documenting consent using only current IRB-approved consent forms and (b) ensuring informed consent is obtained prior to the conduct of research procedures. Consent documents that have the IRB approval and expiration date-stamp should be used for making

copies for subjects. All subjects should be given a copy of the consent form and the original signed consent form must be kept in the investigator's research files for at least seven years after the completion of the research. When appropriate, the investigator also should place a copy of the consent form in the subject's medical record. If the research is conducted at the William S. Middleton Memorial Veteran's Hospital, additional consent requirements apply (see the VA Research Policies and Forms link on the HS-IRBs website). Obtaining informed consent is a process and not solely obtaining a signature on a form. The IRB expects investigators to conduct a consent process that is appropriate to the research.

- **Obtaining permission for the use and disclosure of protected health information in compliance with the HIPAA Privacy Rule.** As of April 14, 2003, all researchers who are part of the University of Wisconsin Health Care Component (HCC) or collaborating with someone within the HCC and who are using or disclosing protected health information (PHI) must obtain written permission (i.e., an authorization) from patients for the use of the PHI or obtain a waiver of authorization from an IRB.
- **Submitting a continuing review progress report.** Federal regulations require IRBs to review and approve all research protocols at intervals appropriate to the degree of risk but not less than once per year. As a courtesy, the IRB sends email reminder notices to principal investigators approximately one month prior to the expiration of approval date. However, investigators are responsible for monitoring their approval periods and submitting a Continuing Review Protocol Progress Report form for IRB review in a timely manner (i.e., one that allows sufficient time for resolution of any potential modification requests that the IRB may make). If IRB approval of a protocol expires, research activities must cease until reapproval of the protocol is obtained unless the PI demonstrates that procedures are necessary to ensure subject safety.
- **Comparing contracts with consent documents.** Ensuring that contracts or funding agreements are compared to IRB-approved consent documents to confirm that any language addressing provisions for medical care or other services for research-related injuries is consistent and reconciling any differences between the documents.
- **Obtaining IRB approval prior to the implementation of changes of protocol and prompt reporting of changes of protocol.** All alterations to the protocol, study procedures, or consent or other documents provided to subjects must be approved by the IRB prior to their implementation unless the change must be made to prevent an apparent immediate hazard to the subject. To change any aspect of a research study, including revisions to your approved protocol, consent documents, HIPAA authorization forms, instruments, and recruitment methods and materials, a Change of Protocol form must be submitted to the IRB for review and approval. Proposed changes of protocol are required to be submitted to the IRB promptly.
- **Reporting unanticipated problems to the IRB.** Federal regulations and institutional policies require that investigators report to the IRB any unanticipated problems that pose risks to subjects or others. These should be reported to the IRB in accordance with the campus unanticipated problems policy available via the Health Sciences IRBs website.
- **Reporting adverse events to the IRB.** Investigators are expected to report any adverse events that constitute potential unanticipated problems. In the case of research that falls under the purview of the Madison VA, all serious adverse events must be reported to the IRB regardless of their potential relationship to the study and must be reported within 5 business days of the local research team becoming aware of the events. For more details, see the campus unanticipated problems policy available via the Health Sciences IRBs website.
- **Reporting noncompliance to the IRB.** Federal regulations and institutional policies require that investigators report to the IRB any noncompliance with an IRB-approved protocol or research regulations that is potentially serious or continuing. Please see the Noncompliance Reporting and Protocol Exceptions and Deviations policies for guidance regarding what needs to be reported as well as the timing and content of the report. In the case of research that falls under the purview of the Madison VA, all potential noncompliance must be reported to the IRB within 5 business days of the local research team becoming aware of the noncompliance. For more details, see the noncompliance policy available via the Health Sciences IRBs website.
- **Submitting a final report to the IRB.** When the research protocol is completed, investigators are expected to provide the IRB with a Protocol Closure form.
- **Complying with the campus Conflict of Interest Policy.** Investigators are required to file an Outside Activities Disclosure prior to the submission of a protocol to an IRB for review and keeping these disclosures current. Additionally, investigators must comply with the campus Conflict of Interest policies related to human subjects research.