



Office of the Vice
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Office of
Biotechnology

**Industry Tip
Sheet -
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Compliance: Human Subjects Research

ISU follows federal guidelines for human subject protection and has established university policies for all human subjects research conducted on campus, regardless of the funding source. In addition to traditional biomedical and clinical studies, human subjects research includes social and behavioral research such as surveys, exercise and nutrition studies, learning experiments, etc. The following information provides a brief overview of procedures for performing research involving human subjects.

Approval

The Institutional Review Board (IRB) is a committee that, prior to data collection, must review and approve all research involving human subjects, even if the research falls within the Exempt or Expedited categories of the federal regulations. New IRB approval is also required for additional use of data that was collected under a prior approval or for a purpose other than research.

Informed Consent

Informed Consent documents and other information given to the subjects should —

- Be written in simple terms that the subjects can understand. This is not the place to rely on abbreviations and scientific jargon for getting your message across.
- Include contact information for the Principal Investigator (PI), major professor and/or supervising faculty member for a student project, in case a subject may have additional questions about the research. The IRB contact information is required in the event a subject(s) has questions about his/her rights of research or a research-related injury.
- Be given to both parents and minors if applicable. Parental consent is required for research involving minors. The assent of the minor is obtained to demonstrate respect for the minor's right to know what he/she is volunteering for.

A template for the Informed Consent Document is available at the Office of Research Compliance web site (see web site below).

Proposals

In the proposal to the IRB committee, provide a clear description of the research procedures. For example, in a proposal that involves a survey handed out in classes, clearly indicate the type of questions in the survey, how long the survey will take, whether or not students will receive credit for participation, who will be handing out and collecting the survey, whether or not the survey will be anonymous and how the survey will be transmitted to the PI, if the PI is not physically present in the room at time of collection.

Electronic Data Collection

Confidentiality is an important consideration when collecting data using e-mail or an on-line form (web site). Please consult with your departmental systems support personnel to ensure the confidentiality of data collected electronically. You must also address how you will ensure confidentiality in the application for approval.

Reminder: The required forms, *complete* instructions, training modules, and policies and procedures are available at <http://www.compliance.iastate.edu>, the Office of Research Compliance web site. For questions regarding human subjects, please contact: Ginny Austin-Eason, IRB Administrator, austingr@iastate.edu or 294-4566.

If you have any questions about this tip sheet or working with industry, please contact: Lisa Lorenzen, Director of Industry Relations and Biotechnology Liaison, 2810 Beardshear, Phone: (515) 294-0926, Email: llorenze@iastate.edu