



Office of the
Vice Provost
for Research
and Advanced
Studies

Office of
Biotechnology

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Compliance: Human Subjects Research

ISU follows federal and ISU guidelines 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 approve all research involving human subjects not exempted by the Policy on Course-Related Student Projects Involving Human Subjects (see web site below). IRB approval is also required prior to additional research use of data that was collected under earlier approval or for a purpose other than research.

Consent

- Consent forms and other information given to the subjects should —
 - Be written for a lay audience. Explain the research clearly with 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) and/or supervising faculty member, if a student project, in case a subject may have additional questions about the research.
 - 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.
- If there is potential physical risk(s) to the subject(s), the *Tort Claims statement* must be added to the consent form (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 explain who will be handing out the survey, how the survey will be collected, and how the survey will be transmitted to the PI, if the PI is not physically present in the room at time of collection.

If modified consent is proposed, the basic elements of consent must be communicated to the prospective subjects. Include, in the proposal, a description of how this information will be communicated. In some instances, the elements of consent can be explained just prior to a survey or read to the subjects before asking their consent.

Electronic Data Collection

Confidentiality is an important consideration when collecting data using email or an on-line form (web site). Please consult with your departmental systems support personnel to ensure the confidentiality of data collected electronically.

Reminder: The required forms, instructions, training modules, and policies and procedures are on the Human Subjects Research Office web site: <http://grants-svr.admin.iastate.edu/VPR/humansubjects.html>. For questions regarding human subjects, please contact: Janell Meldrem, IRB Administrator, meldrem@iastate.edu or 294-4566.

If you have any questions about this tip sheet or working with industry, please contact: Lisa Lorenzen, Biotechnology Industrial Liaison, 1210 Molecular Biology Building, Phone: (515) 294-0926, Email: llorenze@iastate.edu

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Copies of these and other industry tip sheets can be found at:

http://www.biotech.iastate.edu/Industrial_resources/tip_sheets/tip_sheet_index.html