Bloomington Campus Committee for
The Protection of Human Subjects (HSC)
Approval Process*

An overview of the Bloomington Campus approval process for research involving human subjects:

**Human Subjects Committee (HSC) - What is it?**

The HSC is an “institutional review board”, created pursuant to the federal regulations on human subjects research (45 CFR Part 46). It is responsible for reviewing all research involving human subjects, ensuring the protection of human subjects in research conducted by researchers on the Bloomington Campus (including non-IU researchers using subjects on the Bloomington Campus), and overseeing the University’s compliance with the federal regulations and guidelines.

**Why do you need HSC approval?**

Under Federal regulations and University policy, all researchers who conduct research that involves human subjects or materials of human origin must submit an application to the HSC. Approval of the research protocol must be in place BEFORE the researcher (referred to as the principal investigator in federal law parlance) begins data collection. “Data collection” refers to any gathering of information from or about living human beings.

Research includes not only faculty research, but also, research conducted for master theses and doctoral dissertations, and may include undergraduate, staff, postdoctoral and research scientist research as well.

**What constitutes Research Involving Human Subjects?**

Research is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”. Such studies may involve various invasive or non-invasive procedures such as removal of body tissues or fluids, administration of drugs, alteration of diet or environment, interviews, surveys, simple observation, administration of questionnaires, or review of records.

A good rule of thumb for determining whether or not a particular project qualifies, as research is to consider whether or not the results will be published in some form or forum outside of the institution. For example, is the project being undertaken with the notion that a paper or journal article may be published or that a paper may be presented at a conference? If so, the project most likely will be considered as research, and thus, is subject to review by the HSC.
Examples that you may be familiar with include:

- Interviews, telephone, or mail surveys;
- Behavioral or educational testing;
- Observation of individual or group behavior;
- Collection of blood (or other biologic) samples;
- Clinical studies of drugs and medical devices; and
- Study of existing data, documents, and archives on databases.

Thus, a survey of students on their attitudes about drinking, observation of teachers in a classroom, interviews with chief executive officers of corporations on decision making processes, if conducted to “develop or contribute to generalizable knowledge,” would all constitute research involving human subjects.

The important point is that the umbrella of covered research is much broader than simply clinical research. If you have a question as to whether your research would be considered “research involving human subjects”, call the HSC at (812) 855-3067.

**How do you get HSC approval?**

There are three possible occasions prior to and during collection and analysis of your data in which you will need to involve the HSC. These are initial approval of your protocol, renewal/termination of your approval, and revisions to your project.

1. **Initial Approval**

   Application materials are available on the website at <http://www.indiana.edu/~resrisk/hmpg.html>. You should apply for HSC approval for your project AT LEAST one month prior to the time you plan to begin data collection. Certain “exempt” and “expedited” studies are reviewed weekly, but you’ll want to leave room for any comments or questions by reviewers, since you cannot collect data before you receive approval.

   If you are a student, you will need a faculty sponsor for your application. Therefore, you will need to work with your sponsor to complete the application, and HSC must have his or her signature prior to reviewing the application. If you are a faculty sponsor, you are responsible for making sure the student’s research complies with the regulations throughout the research.

   Along with your application (which must be on a current form), you will need to submit any survey or testing instruments, interview questions, intervention scripts, brochures or recruiting materials, and consent forms that will be used with your study. Review of your protocol cannot proceed without these materials!

2. **Renewal/termination of Approval**

   Approval for non-exempt studies is only effective for up to one calendar year (occasionally for shorter periods, if the research is considered of risk to subjects and HSC believes it necessary to monitor the project more closely). Therefore, if your data collection and analysis extend beyond one year, you will need to RENEW your approval.
If you let your approval lapse while you are collecting data, you may not use the data collected during that time. You must file a termination report when your study is completed.

3. Revision of Your Project

If you change your subject recruiting strategy, your survey instrument, your interview questions, your consent form language, or ANY other part of your project in any way, you’ll need to submit that revision to HSC and receive approval PRIOR to implementing the change.

Instruction for each of these actions is on the HSC website, or you may call (812) 855-3067 or stop by the office at Bryan Hall, Room 110, to consult with staff about your project.

**Informed Consent: What is this all about?**

One of the most important elements of an application for HSC approval is the provision by the investigators for the informed consent of research subjects. While informed consent is usually written, occasionally oral consent may be obtained in situations in which written consent is deemed culturally disrespectful or inappropriate. In all cases - for written or oral consent - the HSC must review in advance the language that will be used in the informed consent process.

Due to the diverse nature of research involving human subjects it is nearly impossible to provide a “template” for informed consent. There are, however, specific requirements regarding the types of information that must be offered to participants, and recommendations for the type of language that should be used in informed consent documents. Samples of consent documents are included in the HSC application packet.

Information must be present to enable persons to decide voluntarily whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons who may be willing to offer their bodies and experiences to assist investigators in research without promise of benefit. The procedures used in obtaining informed consent should be designed to educate the subjects in terms that they can understand. Therefore, informed consent language and its documentation must be written in “lay language” (i.e. understandable to the people being asked to participate). Think of the document primarily as a teaching tool, not as a legal instrument. Use of scientific jargon is not appropriate.

Simple declarative sentences are most appropriate for explaining the study’s purpose, duration, experimental procedures, alternative treatments (if applicable), risks, and benefits.

**Basic Elements of Informed Consent**

Federal regulations require that the following information must be given to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental.

2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others that may reasonably be expected from the research.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

5. A statement describing the extent to which confidentiality of records identifying the subject will be maintained. Since there are situations in which a researcher may be compelled to break the confidentiality of subjects (e.g. in response to a subpoena), absolute guarantees of confidentiality are not possible.

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.

7. An explanation of whom to contact for answers to pertinent questions about the research and research subject’s rights, and whom to contact in the event of a research-related injury to the subject. **IN ADDITION**, the form should contain contact information for the HSC separate from that of the Principal Investigator for participants with questions about their role as a subject of research.

8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of any benefits to which the subject is otherwise entitled.

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**Special Note for Graduate Students**

The Graduate School requires that any dissertation that involves human subjects have HSC approval. Therefore, if you do not receive HSC approval for your project prior to beginning data collection, and keep your approval current during the entire time that you collect and analyze data, your project may not receive approval by the Graduate School. Similarly, many academic journals will not publish research conducted without IRB approval.

**More Information**

HSC maintains a website with forms, guidelines, deadlines and additional information at: [http://www.indiana.edu/~resrisk/hmpg.html](http://www.indiana.edu/~resrisk/hmpg.html).

Indiana University has its web based education on the basics of conducting research with human subjects at: [http://www.iupui.edu/~resgrad/Human%20Subjects/HumanSubjectsCourse.html](http://www.iupui.edu/~resgrad/Human%20Subjects/HumanSubjectsCourse.html).


*This overview is based in part on an article by Andrea L. Beach, “University Committee on Research Involving Human Subjects (UCRIHS): What it is; Who needs it, and Where to get it.” outlining procedures at Michigan State, and printed in Michigan State University, Research Integrity, Vol. 4, No. 1 Spring 2000 at 18 and on Northwestern University’s Research Regulations and the Institutional Review Board.*

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