Hannibal-LaGrange University
Institutional Review Board Policy

The Hannibal-LaGrange University Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Hannibal-LaGrange College. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations (Code of Federal Regulations, Title 45, Part 46) and local institutional policy. The IRB makes its independent determination whether to approve or disapprove the research protocol based upon whether or not human subjects are adequately protected.

Federal regulations apply "to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency" that has adopted the human subjects regulations [Federal Policy §46.101(a)]. **Research** is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" [Federal Policy §46.102(d)]. **Human subjects** are defined as "living individual(s) about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" [Federal Policy §46.102(f)].

Some research that involves human subjects may be exempt from the regulations requiring IRB review [Federal Policy §46.101(b)]. Examples include educational testing and survey procedures where no identifying information will be recorded that can link subjects to the data, and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, or reputation; and research that involves the use of existing data, documents, or specimens, where no identifying information will be recorded that can link subjects to the data.

Membership, Functions, and Operations

The Hannibal-LaGrange University Institutional Review Board (IRB) is a committee composed of 5 or more members with varying backgrounds and education. According to federal regulations (§46.107), the IRB includes both male and female members, one member from a scientific area, one member from a nonscientific area, and one member not affiliated with the institution.

The IRB is given the responsibility to review research projects involving human subjects. The purpose and role of the IRB is to assure the protection, safety, rights, and welfare of research participants (human subjects). This is accomplished by reviewing proposed research at convened meetings at which the majority of members are present. Approval of research proposals requires a majority vote of members present (§46.108).

The IRB shall review and have authority to approve, require modifications in, or disapprove research proposals. The institution and the researcher must be notified of the board’s decision. If a research proposal is disapproved, specific reasons must be given with an opportunity to respond in writing or in person (§46.109). Approval is given to research when the IRB is satisfied that the risks to subjects are minimal and reasonable related to the anticipated benefits; the selection of subjects is equitable; informed consent is obtained

and documented; and provisions are made for protecting privacy and confidentiality and safety of data (§46.111). Research may be reviewed and approved or disapproved by officials of the institution. Officials may not, however, approve research that was disapproved by the IRB (§46.112)

In the case of an "Expedited Review," the review may be carried out by the IRB chairperson (or one or more experienced IRB members designated by the chair) with the authority of the IRB except that the research may not be disapproved. All members of the IRB are to be advised of approved proposals (§46.110).

Records of IRB meetings must be kept by the IRB Chairperson for at least three years after completion of the research. Documentation should include: copies of research review proposals, approved sample consent documents, progress reports, and reports of subjects' injuries; minutes of meetings including attendance, actions taken, votes on actions (for, against, abstain), basis for requesting changes or disapproving, and a written summary of the discussion; records of continuing review activities; copies of all correspondence; listing of IRB members with their qualifications, educational background, and experience; written procedures for IRB; and statements of significant new findings provided to subjects (§46.115).

All research is subject to periodic review at the IRB's request.

Types of Review

The IRB uses the following 3 types of review when evaluating research proposals:

Full Review

If the research project involves any of the following, the project will receive a full review by the IRB Board:

- Support from non-university sources (e.g., government agencies) that requires full IRB approval before they will release funds.
- The likelihood of risk or substantial stress or discomfort to the subject.
- Personality tests, inventories or questionnaires of a personal and sensitive nature where subjects' identities will not be anonymous to the researcher.
- Sensitive aspects of a subject's behavior that could reasonably place a subject at risk of criminal/civil liability or be damaging to a subject's financial standing or employability.
- Sensitive aspects of a subject's behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
- Diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice.
- Deception or procedures that are not known to the subject (e.g., the subject will not be fully informed about study objectives.)
- Special populations (e.g., children, prisoners, pregnant women, or individuals who are mentally or psychologically ill, or incompetent.)
- Greater than minimal risk to subjects.

Expedited Review

If none of the above descriptors apply to the research proposal, the project may require a less rigorous, expedited review. The following criteria determine whether a project will receive expedited review:

Does the proposed research:

- Involve minimal risk? (If more than minimal, it needs full review.)
- Involve recording data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice?
- Involve analysis of voice recordings made for research purposes?
- Involve moderate exercise by healthy volunteers?
- Involve research on individual or group behavior, or characteristics of individuals, without manipulation of a subject's behavior and in a manner that does not cause stress to subjects?

Exempt Review

If none of the preceding descriptors for full or expedited review apply to the project, the research proposal falls under the category of exempt review. Such proposals still require IRB review. Exempt review means that the proposal only requires a review by one single IRB member to confirm that the proposal does not warrant a more in-depth review by the IRB. Some types of research proposals that may qualify for exempt review:

- Investigations of commonly accepted educational practices in established or commonly accepted settings (e.g., a faculty member or teacher is examining a new method of teaching instruction to determine educational effectiveness).
- Analysis of information from educational tests that will be recorded in such a manner that subjects cannot be identified.
- Surveys or interviews in which responses will be recorded in such a manner that a subject cannot be identified directly or through identifiers linked to a subject. To qualify for exempt status, the surveys would not involve vulnerable populations (e.g., juveniles) or ask questions about sensitive aspects of a subject's behavior (e.g., criminal behavior).
- Observations of public behavior (participant observation).
- Collection or study of publicly available existing data, documents, records or specimens.
- Collection or study of existing data, documents, records or specimens in which information will be recorded or reported in such a manner that a subject cannot be identified directly or through identifiers linked to a subject.

Minimal Risk

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life (§46.102).

When making a decision about minimal risk of research:

1. *Consider both magnitude and likelihood of risk*
   A more serious event may be permissible if its probability is extremely low; Example: Airplane flight carries a risk of death, but it occurs only once in some millions of passenger miles.
2. *Risks of ordinary, non-invasive diagnostic tests are permitted*
   Examples: pen-and-paper tests
3. *Minimal risk may be age- or context-dependent*
   Example: Certain procedures may be minimal risk for someone old enough to give consent, but not for a small child.
4. *Remember that risks need not be "physical" in order to be "more than minimal"*
   Examples: A serious privacy risk, confidentiality risk, informational risk or risk of embarrassment may be enough to push a study into the "greater than minimal risk" category and thus to full committee review.

Some minimal risk research is exempt from full IRB review. Exemption waives only the need for full IRB review and does not negate the need for the consent of subjects where applicable.

The authority to determine and confirm exempt status rests with the IRB and not with the investigator nor student advisor. Thus, an Application Form is required for your exemption to be confirmed and granted by the IRB.

Classroom Curriculum Research Projects

Student research for which the overriding and primary purpose is learning the method and procedures of research is typically not subject to IRB review. A good example of this is research that is carried out by students as part of a research methods class. Such research is further characterized by minimal risk (or null risk) to human subjects and clearly falls within ethical guidelines of the greater institution.

The key factors to consider are the potential risks to subjects posed by the research activity itself, in terms of:

1. Potential harm from subject participation in the study;
2. Possibility of dissemination of confidential information;
3. Whether the subjects are either unable to give consent or are subject to significant coercion or pressure to participate.

Classroom curriculum projects in which students conduct research involving human subjects need not be reviewed by the IRB if all three of the following conditions are satisfied:

- The project(s) involve minimal risk to subjects; and
- They do not involve vulnerable populations; and
- Results will never be distributed outside the classroom and/or institutional setting. If there is even a remote chance that the data or the report/manuscript will be used in the future for a conference presentation, or a related research project, the research should go through IRB review. If the project is not subjected to a pre-data-collection IRB review, the data will most likely not be permissible for inclusion in future presentation or research.

If the results of the student project will be published or otherwise distributed off campus, in any form of media, the project must be reviewed by the IRB.

Even though some classroom-initiated research does not require review by the IRB, it is nevertheless important that instructors discuss the guidelines and ethics for the protection of research subjects with their students and incorporate these into their methodology. Particular emphasis should be placed on:

- Developing an awareness of the types of risk subjects may be exposed to in various types of research projects, i.e., psychological, social, physical, economic, and legal.
- Obtaining voluntary informed consent to participate in a way that honestly informs subjects of the purpose and potential risks and benefits of the research.
- Management of potential risks to subjects.
- A risk/benefit analysis for all populations, with special consideration of vulnerable populations.
- Protection of privacy and confidentiality of the subjects.
- Identification of benefit to be derived from participation in the research.

Informed Consent

Informed consent is a process in which a research participant learns the key facts about the research before he or she decides to participate in the study. In addition to talking about the facts of the study with the researcher, all information will be included in a written consent form. The participant will be able to take the consent form home to read and discuss with family members. Participants may continue to ask questions before, during and after the consent form is signed. The participant's agreement to be in a study after being fully informed about what participation will involve, length of the study, benefits and risks, confidentiality, purpose of the study, and withdrawal/discontinuation procedures is informed consent. Participants will receive a copy of the signed consent form (§46.117) .

Every consent form must include these essential elements of informed consent as described in federal regulations:

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 which 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 which 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, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and/or 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 subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or decrease in benefits to which the subject is otherwise entitled, and that

the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Regulations further provide that the following additional information be provided to subjects, where appropriate:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to an embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

Procedures for IRB Review

The plan for the research activity is submitted to the IRB for review before research begins. The IRB Review Form includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s) and the proposed methods of analysis that will be performed on the collected data. A cover letter to subjects and informed consent agreement for subjects must also be attached.

All student research involving human subjects must be supervised by a faculty member. In consultation with your faculty advisor, you must complete the IRB Review Form. Your advisor must be the one to initiate your IRB review by forwarding it to the chairperson of the IRB. By forwarding the form, your advisor indicates that he or she approves of the project as outlined in your research proposal and the IRB submission form.

For most research proposals (e.g., projects that do not involve vulnerable populations and that represent minimal risk to subjects), the IRB makes every attempt to return proposals within 10 to 14 days of submission. Normally the IRB does not review proposals during the summer or other school holidays.

If a project raises particular issues that the IRB feels are not adequately addressed in the proposal, the researcher may be asked to submit additional material, clarify a point, or rewrite a section of the proposal. To reduce delay, these changes are usually solicited electronically. However, on rare occasions, the researcher (and faculty supervisor, if appropriate) may be asked to appear before the IRB to resolve matters of procedure, etc.

When the IRB approves the research proposal, written notice will be provided to the student's faculty advisor. You may not begin to collect data from human subjects before you have received approval of the project from the IRB.

All research is subject to periodic review at the IRB’s request.

(Approved by Graduate Advisory Committee on February 20, 2008; Academic Affairs on February 26,

2008; Faculty on March 10, 2008)