Institutional Review Board Policy Declaration

It is the policy of St. Ambrose University that research conducted under the jurisdiction of the University should not expose participants or respondents to unreasonable risks to their health, general well-being, or privacy. Further, it is the policy of the University that research conducted under its jurisdiction should not be contrary to the mission of the institution.

Specifically, the University is concerned that in **all research development, and related activities** involving the use of human participants:

- The rights and welfare of the individuals involved are adequately protected.
- Participation is based on freely given informed consent; and the individual is free to withdraw consent and discontinue participation at any time without loss of benefits or other negative consequences.
- The risks to the participant are reasonable in relation to anticipated benefits to the participant and the importance of the knowledge to be gained as to warrant a decision to allow the participant to accept these risks.

Therefore all research development, and related activities involving the use of human subjects are submitted for prior review by the University Institutional Review Board to (1) ensure that the above conditions are met, and (2) encourage and promote a high level of campus awareness and communication regarding University research projects.

Human Subjects Research

Research

Research is defined by federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" 45 CFR §46.102 (d). The St. Ambrose University IRB requires submission of all activities involving human subjects, whether the activity is regarded as **research** by the federal definition or if the activity involves the collection of any ***sensitive information***, including but not limited to

implications for criminal or civil liability, employability, damage to the subject's financial standing or reputation, or gender identity or sexual preference.

Human subjects

Human subjects are defined by federal regulations as living individuals about whom an investigator (whether faculty, staff, or student) conducting research obtains either 1) data through intervention or interaction with the individual, or 2) identifiable private information 45 CFR §46.102 (f).

Definitions

Intervention: both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction: communication or interpersonal contact between investigator and subject.

Private information: information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Investigation: A searching inquiry for facts, or detailed or careful examination.

Systematic: Having or involving a prospectively identified approach to the investigation, based on a system, methods, or plans.

Designed: The activity has a predetermined purpose and intent.

Develop: To form the basis for a future contribution.

Contribute: To result in.

Knowledge: Truths, facts, information.

Generalizable: The data and/or conclusions are intended to apply more broadly beyond the individuals studied or beyond a specific time and/or location, such as to other settings, circumstances, or categories.

Research FAQ

But is it actually research?

Examples of research:

- A survey of college students' television watching preferences.
- Teaching a different variation of phonics for learning reading, and gathering data to assess the success of the technique.

- Testing whether relaxation training reduces pain for individuals with chronic back pain.

Examples of projects which are probably not "research" as defined above:

- Reviewing and compiling information from published sources, as in a term paper.
- A subjective comparison of two PowerPoint presentations.
- Classroom demonstrations of use of a memory technique.
- Shadowing a professional through a day.

What Is Considered Research Involving Human Subjects?

If your project is:

- Research,
- Your source of data is Human Beings, and
- Collecting information about the person

Then your project falls under the requirement of submission to the Institutional Review Board for Protection of Human Subjects at St. Ambrose University.

Examples:

- Surveys
- Interviews
- Answers to tests, entries in journals
- Observation of human behavior or physiology (progression of a disease, for instance)
- Information from clients' files at an agency, school, or medical setting.

Examples of research which probably is not defined as "human subject"

- Questions on a survey that are not about the person or their opinions.
- Recording and analyzing the content of television shows, magazine articles, published books, or published music.
- Use of publicly available, compiled, anonymous data sources, such as U.S. census data or stock market prices.
- Use of data sources involving elected officials.
- Quality assurance or program improvement information

Review Categories

Research subject to IRB review can be reviewed at two levels.

Level 1

Level 1 includes research development, or related activities that involve no more than minimal risk to participants, or that involves minimal changes to previously approved research during the period of one year or less from the approval date. Minimal risk is understood to mean "that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" 45 CFR §46.102 (i).

Level 1 Categories

Level 1 categories do not apply to research involving prisoners, children*, fetuses, or pregnant women, but to other research with human subjects. For example:

1. Education Research
2. Surveys, Interviews, Educational Tests, Public Observations (that do not involve children*) and are of minimal risk.
3. Analysis of Previously-Collected, Anonymous Data
4. Public Benefit or Service Program
5. Consumer Acceptance, Taste, and Food Quality Studies

** The only research activities involving children that may fall under this level are those involving educational tests or observation of public behavior where the investigators do not participate in the activity being observed. Please see an IRB member for clarification.*

Level 1 FAQ

What Research Does **Not Qualify** for Level 1 Review?

In general, Level 2 review is required when your research:

- is greater than "minimal risk" (Federal regulations define "minimal risk" as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).
- involves children or adolescents as subjects (less than 18 years old).
- involves administration or use of drugs or devices.
- involves prisoners as subjects.

Level 2

The Level 1 review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing.

Level 2 includes research development, or related activities that involve more than minimal risk to participants, including work that uses deception of participants.

Level 2 Categories

1. All research development or related activities that include more than minimal risk (see Level 2 FAQ for specific examples)
2. All research development or related activities that involve children, adolescents, or prisoners.
3. Clinical studies of drugs and medical devices only when certain conditions are met
4. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in certain populations and within certain amounts
5. Prospective collection of biological specimens for research purposes by noninvasive means (e.g. hair or nail clippings, teeth, secretions, etc.)
6. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves (e.g. physical sensors, EEG, ECG, weight measurements, etc.).
7. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes
8. Collection of data from voice, video, digital, or image recordings made for research purposes
9. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Level 2 FAQ

Examples of research requiring Level 2 include:

- Surveying participants about
  - Their sexual preferences
  - Whether they have sexually transmitted diseases
  - Whether they use or have used performance enhancing drugs
- Conducting interviews with immigrants or refugees
- Collecting height and weight measurements
- Asking participants to complete any physical testing
- Deceiving participants

Review Process

Primary responsibility for assuring that the rights and welfare of the individuals involved are protected continues to rest with the principal investigators conducting research involving the use of human participants. This responsibility is shared by others engaged in the conduct of the research. Faculty or staff members who assign or supervise research conducted by students have an obligation

to consider carefully whether those students are qualified to safeguard adequately the rights and welfare of participants.

Review Procedures

All members of the St. Ambrose University (faculty, staff, students) who wish to conduct research involving human participants are to complete each of the items listed and submit it for review to the Institutional Review Board.

1. Each investigator listed must complete NIH training and provide a certificate as proof of completion.
2. Compile instruments, consent forms, and all applicable documents (including scanned signature page).
2. Complete the Research Proposal Form.

The Board will then determine whether or not the research meets University policy guidelines.

- It is the researcher's responsibility to submit this information to the committee prior to conducting research, including pilot studies. You must adhere to these due dates and deadlines.
- Faculty members who intend to conduct research in their classrooms with their students should submit these forms prior to beginning that research.
- Projects are approved for a one (1) year period.
- Researchers are required to submit a status report either upon completion of a project, or within one year of approval, whichever comes first.
- Ongoing projects require annual submission of a status report.

Level 1 Review Procedure

If an investigator feels their proposal is eligible for a Level 1 review, select "Level 1" on the Research Proposal Form*. Within 3 business days of submission, the proposal will be assigned to the IRB chair, or one or more committee members for review, and the Principal Investigator will be notified of the assignment. Within one week of submission, the members assigned to review the proposal will do one of the following:

a) Approve the proposal
b) Approve the proposal with changes (change requests will be communicated and discussed with the Principal Investigator), or
c) Change the level of review to Level 2, send the proposal to the full committee for the next scheduled committee meeting, and notify the Principal Investigator of the level change (proposal change requests will be communicated and discussed with the Principal Investigator).

*Please note that if you classify your proposal as Level 1 and it is deemed Level 2, it could extend the review process. If you have any questions regarding your study's level, we encourage you to contact a member of the IRB.

Level 2 Review Procedure

If an investigator feels their proposal requires a Level 2 review, select "Level 2" on the Research Proposal Form. Proposals requiring a Level 2 review should be submitted at least one week prior to the next scheduled meeting. Level 2 proposals will be reviewed by all members of the committee at the next scheduled full IRB meeting. Within one week of that meeting**, you will receive notification from the Chair that the committee has decided to do one of the following:

a) Approve the proposal
b) Approve the proposal with changes (change requests will be communicated and discussed with you), or
c) Request that the proposal be resubmitted.

**The amount of time required to supply feedback after a full IRB meeting is dependent on the number of changes that will be requested. If you would like to make the review as quick and seamless as possible, we encourage you to contact a member of the IRB prior to submitting your proposal to ensure you have all of the necessary information and documentation.

Violations and Sanctions

The principal investigator(s) and faculty sponsor(s) both are responsible for Institutional Review Board policies. Failure to apply for and receive permission for human participants research from the Institutional Review Board or altering the research process in a substantive manner after securing Institutional Review Board approval violates the St. Ambrose University Institutional Review Board policy and may result in any of the following sanctions:

1. The data may be rendered as unusable;
2. The Institutional Review Board may request the surrender of documents;
3. A citation of violation of academic integrity may be entered in the individual's professional file;
4. The collected data may be destroyed;
5. The principal investigator(s) and/or faculty sponsor(s) may be required to provide a letter of apology to research participants and representatives of external organizations including a plan of correction to address deficiencies in human participants protections;
6. The principal investigator(s) and/or faculty sponsor(s) may be required to provide a memorandum addressed to the Institutional Review Board explaining the actions of the investigator(s), acknowledging a violation of Institutional Review Board policies and procedures, and providing assurances that future violations will not occur;

7. The principal investigator(s) may be required to submit an acknowledgment in published work or work submitted for publication that the research did not conform to Institutional Review Board policies and procedures;
8. The Institutional Review Board may direct a formal memorandum of censure to the principal investigator(s) and, where appropriate, the principal investigator's faculty sponsor, department head, or dean (or any other recipient of the data); and/or
9. Other actions warranted by the specific circumstances surrounding the violation.

Members of the Institutional Review Board will address alleged violations of the St. Ambrose University Institutional Review Board policy. The Institutional Review Board will make a determination regarding the need for additional information or further investigation. The Dean and/or Department Head may be copied on all correspondence between the committee and the involved parties.

Upon determination that a violation of this policy has occurred, the Institutional Review Board may require that the activity in question be discontinued permanently or until such time corrective action is taken. Any suspension or termination of approval will include a statement of the reasons for the Institutional Review Board's suspension or termination action and the sanctions imposed. These will be sent promptly to the principal investigator and/or faculty sponsor and any other necessary university representative. Any appropriate agencies may also be notified of terminations and/or suspensions of the research.

The principal investigator(s) or faculty sponsor(s) who believe that there have been "errors in fact" in relation to decisions made by the Institutional Review Board may appeal those decisions to the St. Ambrose University Vice President for Academic and Student Affairs.