

L. Policy Concerning Investigations Involving Human Subjects

Knox College Institutional Review Board (IRB)

A. Mission, Goals, And Guidelines

A.1 - Mission

The U.S. government requires that any research project involving human subjects conducted at institutions that receive federal funding must be reviewed by an Institutional Review Board (IRB) at that institution before data collection commences; this is true even if the project is not receiving federal funding. The IRB at Knox College is responsible for overseeing all research at Knox College that involves the use of human subjects. The ultimate goal of the IRB is to safeguard the well-being of individuals who participate in research conducted by Knox College and/or its faculty, staff, and students and to ensure that research occurring at Knox College meets accepted ethical standards. The Knox IRB also reviews projects conducted by outside researchers who wish to collect data from members of the Knox College community.

The Knox College IRB is not intended to be an impediment to research; it seeks to work with researchers to develop research protocols that will receive IRB approval.

A.1.a - Definition of Research with Human Subjects

Knox College follows established federal guidelines by defining "research" as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." A research project will usually be defined as using "human subjects" if it involves acquiring information/data from at least one living person and if **any** of the following four conditions are met:

Condition 1 - the researcher(s) will be interacting with the person or intervening in or interrupting the normal daily activities of that individual;

Condition 2 - the researcher(s) will gather information from the person that would ordinarily be private, such as the person's beliefs or attitudes;

Condition 3 - the researcher(s) will be acquiring, either directly from the person or in some other manner, identifiable private information about the individual, such as medical conditions, sexual identity, and so forth; or

Condition 4 - the researcher(s) will observe behavior in a situation in which the person might reasonably expect privacy and freedom from observation.

A.1.b - Basic Standards for Research with Human Subjects

The Knox College IRB ensures that researchers adhere to the following minimum standards for research with human subjects, as specified by U.S. Federal Law.

Standard 1 - Human subjects should not be placed at undue risk. Subjects are considered to be at "minimal risk" if "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." If the risk of the study is somewhat higher than minimal, it is absolutely necessary to inform subjects of this possibility during the consent procedures (see below). No research procedures may be used that are likely to cause serious or long-lasting physical or psychological harm to a research subject.

Standard 2 - Subjects must give informed consent before participating in research. The purpose of informed consent is to provide potential subjects with sufficient information in order to make a decision as to whether they would like to participate, to ensure subjects comprehend the nature of their involvement in the research project, and to ensure that subjects have actually chosen to participate. Researchers shall inform subjects about all aspects of the procedure that may influence the subjects' willingness to participate. The IRB will provide researchers with detailed information as to what sorts of information it expects to be included in informed consent procedures.

Standard 3 - Some potential subjects have limited capacity to consent; examples include children under age 18 years of age, individuals with severe developmental delays or psychotic symptoms, prisoners, etc. If individuals deemed to have limited capacity to give informed consent will participate in the research project, both the consent of a parent (or other responsible adult) and the assent of the child (or other individual who has limited capacity to give consent) are required. Said differently, children and people with limited capacity to consent cannot consent to participate on their own, but they must at least assent to participate.

Standard 4 - Researchers must respect an individual's right to decline participation in the study or to withdraw from research participation without pressure to continue. Any penalties the subjects incur for withdrawing from a study (e.g., loss of extra credit or monetary payment) must be clearly specified during consent procedures.

Standard 5 - All information acquired about individual subjects in research should usually be kept confidential. There are two main exceptions to this rule. First, sometimes researchers are required by law to release information, for example, when they uncover suicidal or homicidal intent, abuse of a child or an elder, etc. Second, researchers may request that a subject allow the researcher to use the subject's name and/or other identifying information in research reports and presentations; confidentiality may be waived if the subject gives explicit permission to do so.

Standard 6 - After subjects have participated in a research project, they have the right to learn more about their role in the project, the nature of the study, and any deception that may have been involved. That is, the subjects must have the opportunity to be debriefed. Ideally, debriefing occurs immediately after the subject is done with the project; it must be done immediately if the procedures were highly stressful or if the subjects received information (accurate or bogus) that could affect them negatively after they leave the research situation. In other cases, the opportunity for debriefing may be delayed until all data have been collected for the project. If subjects have been deceived, during the debriefing the researcher must: a) explain why the deception was necessary; b) provide information about who the subject should contact if s/he feels that the deception was harmful; and c) provide the subject with the option of withdrawing his/her data from the study without penalty.

A.2 - Types Of Projects And Their Relation To The IRB

Researchers might conduct a variety of types of projects. In terms of their relationship to the IRB, these can be classified into four groups, each of which has a distinct relationship to the IRB.

A.2.a - Projects that do not Fit the Federal Definition of Research

As noted above, the federal government defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Some projects might include the collection of data from human subjects but not fit this definition of research.

For example, "oral history, journalism, biography, and historical scholarship activities that focus directly on the specific individuals about whom the information is collected" are usually not aimed at developing or contributing to generalizable knowledge. As such, they are typically not considered to be research and usually do not have to be reviewed by the IRB. That said, if an oral history, journalism, biography, or historical project uses methods of systematic investigation (like surveys or experiments) that are typically used in the testing of hypotheses or theories, or if such projects are attempting to develop or contribute to generalizable knowledge, then a proposal should be submitted to the IRB.

Similarly, projects conducted by a professor, or by students in his/her class, that are only for pedagogical/educational purposes would not fit the definition of research. For example, a professor who runs a mock experiment (or conducts a survey) using the students in the class as subjects during a teaching demonstration or a class project does not need IRB approval to do so. IRB approval is also not required if students conduct a project with people outside of the class, so long as the project does not meet the definition of research specified above. On the other hand, professors must seek IRB approval before collecting

data if they or their students are conducting a project that does fit the definition of research specified above.

A.2.b - Projects that are Exempt from IRB Review

According to federal guidelines "Research conducted in established or commonly accepted educational settings, involving normal educational practices" is typically exempt from IRB review. This typically includes "(i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods."

Federal guidelines also specify that "Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior," is exempt "unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation." As such, most research conducted by the Knox College Office of Institutional Research and Assessment that tracks longitudinal and/or comparative data from Knox students and/or students at other colleges and universities would be exempt. Further, most data gathered from Knox students by faculty or administrators with the goal of informing policy decisions, and other information-gathering activities consistent with the advancement of the mission of the college, would also be exempt.

The analysis of data collected in an earlier study is also usually exempt from further IRB review. If existing data of this type have been stripped of any identifying information about the human respondents, the project does not count as "research with human subjects" and no IRB approval is required. For example, suppose that a professor in the Political Science department gains access to survey data about voter attitudes toward controversial political topics that were collected by a consulting firm one week before the 2004 presidential election. The people in the survey were a random sample of 500 voters from Knox County, Illinois. The professor wants to take a new look at the data to answer questions that were not addressed in the original analysis. As long as no individual voter can be identified via the survey data, this project would not need approval by the IRB.

A.2.c - Projects that are Eligible for Expedited IRB Review

If a project meets the definition of research with human subjects and is judged by the IRB chair(s) as having a low probability of creating risk for subjects, and the magnitude of the possible risk is minimal, then the project will undergo an expedited review (see B.2.a below).

A.2.d - Projects that Require Review by the Full IRB

If a project meets the definition of research with human subjects and is judged by the IRB chair(s) as either having a moderate or high probability of creating risks for subjects OR having moderate to high magnitude of risk, then the project will undergo review by the full IRB (see B.2.b below).

A.3 - Commencing Research

If a project meets the definition of research with human subjects and is not exempt, data collection may not begin until the IRB has approved the project.

A.4 - Organization And Composition Of The Knox College IRB

A.4.a - The IRB's Standing in the College

The IRB is a standing committee of the faculty, and it is also subject to the regulations of the U.S. Department of Health and Human Services (DHHS). The Executive Committee appoints Knox faculty members to the IRB for renewable terms of three years. An outside member of the committee is appointed by the chair(s) of the IRB (see below).

A.4.b - Composition of the IRB

The Knox IRB consists of five individuals. Four of these individuals are Knox College faculty members, at least one of whom represents a non-science field. The fifth member of the committee is recruited from outside of the Knox College community, per federal guidelines. The IRB will never consist solely of members of one gender or from one academic discipline.

B. IRB Procedures

B.1 - The IRB Application Process

B.1.a - The Application Mechanism

The Knox College IRB will provide a mechanism for researchers to submit applications for review by the IRB.

B.1.b - Minimum materials Required with an IRB Application

In their applications, researchers will be asked to answer a series of questions about their research projects. The purpose of these questions is to provide the IRB with enough information to determine whether the research project meets all necessary ethical standards and whether they might harm subjects.

Student researchers are required to supply the name and email address of a Knox College faculty or staff member who is sponsoring the research project.

Researchers will provide a description of the procedure(s) to be used in the study. There is no need to inform the IRB of the hypotheses or the rationale for the hypotheses. The description of the research procedures should explain who the subjects will be and how they will be recruited. For most experimental, survey, and interview studies, the researcher should provide the IRB with copies of any materials that will be used in the project, such as questionnaires, interview scripts, stimuli the subjects will see or hear, and so forth. If the researcher is using ethnographic methodologies, such as semi-structured interviews or participant observation, the researcher should provide as much information as possible about the nature of the interviews (including sample questions and the overall goal of the interviews) and about the settings in which participant observations will occur.

Researchers must also provide detailed information about the means by which informed consent (and/or assent) will be attained, given the particular research methodologies they are employing. If consent procedures entail written consent forms, a copy of such forms should be provided. In addition to the names and contact information of the researchers, the form should also provide the name and contact information of the IRB chair(s). If the researcher will use multiple semi-structured interviews or participant observation methodologies, or will have numerous contacts with participants, the researcher should specify the means by which subjects will be reminded of their rights as subjects, including means of assessing ongoing consent to participate in the project.

B.2. - The IRB Review Process

Applications from faculty/staff members will be automatically forwarded to the chair(s) of the IRB. If the researcher is a student, the researcher must also have a mentor approve the IRB application before the IRB chair(s) will begin the review process.

B.2.a - Expedited Reviews

Research projects that have a low probability of risk and that pose a minimal magnitude of risk to the subjects will receive an expedited review from one of the IRB chair(s) or another member of the IRB with expertise in the methodologies used by the project; the IRB will strive to provide a decision within one week's time. The IRB chair(s) will provide the full IRB with regular updates regarding, and access to information concerning, projects approved via the expedited review process.

B.2.b - Full IRB Reviews

When one of the IRB chair(s) decides that a proposal does not meet the criteria for an expedited review, then s/he will send the application to the full IRB for review and discussion. The IRB will meet in person, and in closed session, to discuss the proposal. Approval of the application in this case requires a majority of members of the full IRB to vote in favor of approving the project. Given this more involved process, decisions

regarding these types of projects are likely to take a bit longer. The full IRB will strive to provide a decision for this type of proposal within two weeks.

B.2.c - Review of Research Previously Approved by an IRB at another Institution

Researchers collecting data from individuals at Knox College need to apply for approval from the Knox College IRB. If the study has been previously approved by an IRB at another institution, this information should be included with the Knox College IRB application.

B.2.d - Applications that have been Rejected

If the IRB finds that it cannot approve a proposal, the IRB chair (or the member of the IRB with primary responsibility for reviewing the proposal) will inform the researcher of the additional information that must be submitted or the changes that must be made to the procedures of the research project; the researcher may then submit a new, revised proposal to the IRB. If a proposal is rejected, explicit feedback concerning the reason for denial and instructions for improving the application will be provided. Appeals concerning the need to revise the proposal should be taken up with the IRB chairs.

B.2.e - Amendments to Approved Research Projects

If, during the course of the research project, the researcher wants to change any procedures from what the IRB already approved, or finds that the direction of questioning in semi-structured interviews has changed substantially from what was proposed, the researcher must contact the IRB and request an amendment to the project before continuing with the revised procedure. Amendment requests should include a clear statement of exactly what has changed and exactly what the proposed new procedure will entail.

B.2.f - Conflicts of Interest

If a researcher is a member of the IRB or a student whose project is being supervised by a member of the IRB, the member of the IRB with the conflict of interest will not review the application.

B.3 - IRB Record Keeping

As stipulated by federal law, records of proposals submitted to the IRB, correspondence between the IRB and researchers, and other IRB activities and decisions will be retained for a minimum of three years after the completion of the relevant research project.

B.4 - IRB Reporting Mechanisms

The full IRB will meet in person at least once per academic year. This meeting will be announced in advance to the Knox College community and is open to any of its members. Minutes of all meetings of the full Knox IRB will be recorded and kept by the IRB chairs. As

is the case with other standing committees of the faculty, a report of the activities of the IRB will be made to the faculty at the end of each academic year.