Kansas Wesleyan University
Institutional Review Board (IRB) Policies
Committee for the Ethical Treatment of Human Subjects

Who must apply for IRB approval and why?
The Institutional Review Board must review proposals for university-affiliated research involving human subjects. Projects are considered "research" if they involve a systematic investigation designed to develop or contribute to generalizable knowledge. Projects for which the end result is publication or public presentation are generally considered research. Human subjects are considered to be involved when interactions or interventions with living individuals are the primary source of data, or when data are collected from a private/confidential source.
Projects are considered "university-affiliated" if they, entirely or in part,
a) are any way sponsored by the University (e.g. affiliated with the University in name),
b) are conducted by, or under the direction of, any KWU faculty, staff, or student
c) use KWU facilities or property for the collection or analysis of data, or
d) involve the use of the institution's non-public information to contact or identify participants or prospective participants.

IRBs are formed in universities nationwide in compliance with the National Research Act of 1974/1983 in order for the institution to be eligible for behavioral or biomedical research grants from federal sources. In addition, university IRBs review projects without federal funding as a protection for the participants, the researcher and the university. The IRB is responsible for protecting the rights of participants participating in university-affiliated research, taking into account the risks to the participant and the expected benefits of the research. The purpose of the IRB is to review all proposals for human research **before** the research is conducted to determine whether the research plan has adequately included the ethical dimensions of the project, reviews projects which take longer than an academic year, and documents all changes to or adverse effects of a proposal. At Kansas Wesleyan University, as at other universities, the IRB review procedure is guided by the Code of Federal Regulations (Title 45, Part 46), which sets the minimum standards for protection of human subjects, as well as "The Belmont Report," which set forth a system of ethical principles regarding all research involving humans as subjects.

Decisions
Researchers complete an IRB Proposal Submission form and return it and any supporting documentation to the office of the Dean. The proposal is forwarded to the Chair (or designated individual in the Chair's absence), who reviews it and sends it to reviewers as necessary. Review decisions are sent to the principal investigator in writing, along with any comments or suggestions for improvement. Proposals may be accepted, accepted with revision, or rejected. In most cases, proposals that are accepted with revision are approved following submission of corrections to the IRB Chair. It is not the purpose of the IRB to reject proposals, rather to guarantee that the proper ethical protections are in place, so the "rejection" decision is reserved for rare instances. In cases where the project is rejected, researchers are welcomed to revise and resubmit their proposal.

Types of Review

Proposals fall into one of three categories: Exempt, Expedited, and Regular. Researchers may make recommendations as to the category of their proposals, but the IRB is ultimately responsible for determining the category of the submission. If a submission cannot be reasonably considered at one category, it is upgraded to the next higher category.

Exempt: Research that poses no risk to the subject and does not deal with sensitive or personal aspects of the subject's behavior may be exempt. *Exempt proposals still require submission of a proposal document and notice of approval*, but the process is much faster. Exempt proposals are reviewed by one member of the committee (usually the Chair), and cannot be rejected.

Categories of Exempt Review

1. Research conducted in established or commonly accepted educational settings, involving normal education practices, such as research on regular and special education strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, *unless*: (a) information obtained is recorded in such a manner that individuals can be identified, directly or through identifiers linked to the individual; and (b) any disclosure of the individual's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation. The only exceptions are if: (a) participants are elected or appointed public officials or candidates for public office; or (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that the participants cannot be identified, directly or through identifiers linked to the participant.
4. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs, (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of services under those programs.
5. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Research in Schools: In order for a project involving educational research (conducted in classrooms) to be reviewed under the exempt category, the investigator must supply a letter from the appropriate school district official that certifies that the project meets the following conditions. The research activities will: (a) not differ in

any significant ways from the normal range of activities of the classroom, school or district; (b) involve only customary and con-controversial instructional goals; (c) not deny any students educational benefits they would otherwise receive; (d) promise direct benefits (at least in the form of evaluative information) to the classroom, school or district; (e) incorporate adequate safeguards to protect the privacy (anonymity or confidentiality) of all individuals who might be subjects of the research or (f) involve only existing data on students that is, or is to be rendered, non identity specific.

Expedited: Expedited proposals are reviewed by two members of the IRB in addition to the Chair, and approved unless one or both of those reviewers recommends rejection, in which case the proposal is sent for Regular review. Research activities may be expedited if they present no more than minimal risk to participants and involve procedures in one or more of the following categories:

1. Collection of data from voice, video, digital, or image recordings made for research purposes;
2. Research on individual or group characteristics or behaviors (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies, not otherwise considered exempt;
3. Research involving materials (data, documents, records, or specimens) that have been collected for non-research purposes (such as medical research or diagnosis);
4. Clinical studies of drugs or medical devices that do not require federal approval for their use;
5. Limited collection of blood samples (the lesser of 50ml or 3ml per kg in an 8-week period, collection no more than two times per week);
6. Collection of biological or physiological data and/or biological samples through non-invasive means.
7. Renewals of projects previously approved by the IRB.

Regular: Research activities that do not fit either the exempt or expedited classifications are submitted under regular review. Regular review is generally reserved for projects involving more than minimal risk to the participant or that involves vulnerable participants. Regular review involves discussion and vote before the full committee at its regular meeting. The researcher is invited to be present at the meeting to answer any questions from the committee members. The proposal is accepted if it is approved (completely or with revisions) by a majority of the committee, and a formal record is kept as to the number of votes for, against, and abstaining. Projects **must** go before regular review if they fall into one of the following categories:

1. Any research involving the use of *vulnerable participants* (participants who may not be able to make fully informed consent). Populations routinely considered to be vulnerable include: children under the age of 18, prisoners, pregnant women, persons not proficient in English, the mentally disabled, persons engaged in illegal activities, persons under treatment for an illness relevant to the project, and individuals who may risk retribution by a person with authority over them as a consequence of participation or non-participation in the study (e.g. employees, students in classes…).

2. Any research involving *more than minimal risk*. Risk can be mental, physical, psychological, or social. Minimal risk is defined as harm that is not greater than an individual would normally encounter in his/her everyday life. Examples of proposals of this type would include surveys or questionnaires that solicit information regarding personal or sensitive aspects of the participant's behavior, including sexual practices, instances of child or sexual abuse suffered by the participant, criminal activities, drug and alcohol use, or studies regarding eating disorders. More than minimal physical risk includes stress testing, drug and alcohol use by participants for research purposes, and studies involving more than moderate physical exercise that could result in injury.

Criteria for evaluation

The IRB considers the following when making its recommendations:

1. the risks to the participants,
2. the anticipated benefits to the participants and others,
3. the importance of the knowledge that may reasonably be expected to result,
4. the informed consent process to be employed,
5. the provisions to protect the privacy of participants, and
6. the additional safeguards for vulnerable populations

Responsibilities of the Principal Investigator

The person conducting the research is responsible for protecting the rights and welfare of the participants of that study. Therefore, the principal investigator has the responsibility to *submit a research proposal* to IRB to be approved prior to data collection, as well as propose any *changes in research projects* previously approved by IRB. In addition, the principal investigator shall report promptly to the IRB any *unanticipated problems* involving risks to participants and others. The principal investigator is required to certify that he/she has received training in the ethical treatment of human research subjects. In the cases where the study is to have federal funding, the principal investigator, the IRB, and the KWU administration are required to submit a *Statement of Assurance* to the federal OPRR office, stating institutional compliance with federal regulations on the protection of human subjects in biomedical and behavioral research.

Authority of the IRB

The IRB is responsible for ethical behavior in the research projects it approves, including compliance with federal, state, and local laws as they may relate to such research. Therefore, the IRB has the authority to approve, require modification in, or disapprove research activities involving human subjects before data are collected, in accordance with the principles of respect for persons, beneficence, and justice as described in The Belmont Report. The IRB shall determine that protections for human participants are adequate, train IRB reviewers and researchers in the ethical considerations involved in conducting research with human subjects, review ongoing projects annually, and suspend or terminate research in cases of non-compliance or unexpected serious harm to participants. The IRB shall comply with federal regulation 45 CFR 46 regarding committee composition, quorum, and record-keeping.