POLICY TITLE: Human Subjects Research

POLICY PURPOSE: To protect the rights, wellbeing, and personal privacy of individuals; to assure a favorable climate for the conduct of scientific inquiry; to protect the interests of Fort Hays State University; and to ensure compliance with the Public Health Service Act (Pub. L. 93-348), as amended; Department of Health and Human Services, 45 CFR 46.101-.409; and the federal-wide Common Rule, "Federal Policy for the Protection of Human Subjects," (56 Fed. Reg. 28004).

BACKGROUND:

APPLIES TO: Researchers whose project is sponsored in any way by Fort Hays State University or conducted by anyone connected with Fort Hays State University (this includes all students, faculty, administrators, and other employees) whose research involves any form of information gathering about humans, either as individuals or members of groups. This policy also applies to researchers not affiliated with Fort Hays State University who desire to conduct human subjects research involving anyone connected to the university.

DEFINITIONS: IRB: Institutional Review Board

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human research subject: a living individual about whom a research investigator (whether a professional or a student) obtains data through 1) intervention or interaction with the individual, or 2) identifiable private information.

Intervention: physical procedures by which data is gathered and the manipulation of the subject and/or their environment 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.

Identifiable information: specific information that can be used to identify an

individual.

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The purpose of the Fort Hays State University Institutional Review Board (FHSU IRB) is to protect the rights, wellbeing, and personal privacy of individuals; to assure a favorable climate for the conduct of scientific inquiry; and to protect the interests of Fort Hays State University.

All of the Institution's human subjects research activities, regardless of whether the research is subject to federal regulations, will be guided by the ethical principles in:

1. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or

2. Other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule.

The FHSU IRB will ensure that all requirements of Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46) will be met for all human subject research, regardless of sponsorship. 45 CFR 46 is the set of regulations under which the FHSU IRB operates.

The involvement of human subjects in research will not be permitted until the FHSU IRB has reviewed and approved the research protocol and informed consent has either been obtained from the subject or the subject's legal representative or waived in accordance with 46.111, 46.116 and 46.117.

Before human subjects are involved in research the FHSU IRB will consider:

• The risks to the subjects,

• The anticipated benefits to the subjects and others,

• The importance of the knowledge that may reasonably be expected to result, and

• The informed consent process to be employed.

General Issues of Subject Protection

By law, the IRB can only grant approval to projects that satisfy certain requirements. The requirements for approval include the following:

• Risks to subjects are minimized.

• Risks to subjects are reasonable in relation to anticipated benefits.

• Informed consent will be sought from each subject (or the subject's legal representative) and documented.

• Adequate provisions for monitoring data to insure the safety of subjects.

• Adequate provisions to protect the privacy of subjects and maintain confidentiality.

• Appropriate additional safeguards for subjects who are especially vulnerable.

Ethical Principles

This institution is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research [the "Belmont Report"]), regardless of whether the research is subject to federal regulation or with whom conducted or source of support (i.e., sponsorship).

- FHSU and the individual members of its faculty, staff, and student body recognize their responsibility for protection of the rights and welfare of human subjects.

- Appropriate professional attention and facilities shall be provided to insure the safety and wellbeing of human subjects. No subject in a research activity shall be exposed to unreasonable risk to health or wellbeing.

- Research or other data collection activities including program evaluations involving minors and/or others for whom the ability to provide informed consent may be limited must receive full board review and may be approved if there is no risk or suffering for the individual subject. Research involving children, or others who may be unable to give informed consent and which involves greater than minimal risk may be approved by the FHSU IRB and must receive full board review and be evaluated on a case-by-case basis. Research involving children, or others who may be unable to give informed consent requires written parent/guardian permission and must receive full board review.

- The confidentiality of information received from subjects in experiments or respondents to questionnaires shall be fully protected, both during and after the conduct of a research activity, within the limits of the law. The application and the consent form must describe what measures will be taken by researchers to protect the confidentiality of research participants, including who will have access to the data, how participants' names are shielded from unauthorized third parties, how data will be stored, and what happens to the data upon completion of the research project. Research that incorporates audio or video recording must describe who will have access to the files, how the files will be kept secure, and what are the researcher's plans for the files upon completion of the project. Files may be erased or destroyed, returned to participants, or archived. However, research participants must be informed about the planned disposition of the audio or video recordings and must agree to those plans.

- Before a subject participates in research involving risk or substantial stress or discomfort, this shall be carefully explained; the investigator shall be satisfied that the subject understands the explanation; and the consent of the subject shall be obtained. Minimum standards for informed consent are established by the federal government and may be augmented by the University according to 45 CFR 46. The research participant or the research participant's legal guardian must be legally empowered, by virtue of age and also be cognitively competent to understand and agree to the terms of the consent document. The board may require a researcher to alter the language of a consent form to ensure that it is written at a language level that the participant or the participant's guardian can understand. The IRB also requires that, even if a parent or legal guardian gives permission for their child/ward to participate, the researcher must obtain "assent" from the research participant.

- A request by any subject for withdrawal from a research activity shall be honored promptly without penalty or without loss of benefits to which the subject is otherwise entitled. Consent forms, information statements, and assent procedures must include a statement that participants may withdraw their participation at any time with no adverse consequences.

Classroom activities may include instructing students in research methodologies and techniques. If the sole purpose of the activity is to teach research techniques or methodology to students and not to develop or contribute to generalizable knowledge, it is not considered to be research. However, if students will practice research methodologies on human beings, they should be instructed in the ethical conduct of such activities and should be advised to obtain informed consent from their practice subjects.

Quality improvement and quality assurance activities conducted solely for the intent of maintaining or improving quality of services provided by an institution, likewise, are not considered research activities. However, if the data collected involve vulnerable populations or are generalizable and are to be shared outside of the institution through discussion, presentation, or publication, the activity qualifies as research. Sometimes, data from a quality improvement or quality assurance activity become of interest to the external community after they have been analyzed. In these cases, the research use of the data collected for another purpose must be reviewed.

The same distinction may apply to routine observation activities. For example, what begins as an observation of classroom activity may evolve into a research project that goes beyond the classroom. Researchers are obligated to submit the research activity for review as soon as the research activity changes. For example, a research activity involving analysis of teaching methods or classroom management for review may prompt the researcher to look for academic achievement or discipline problems outside the classroom. So, what was initially a research project that was exempt from full board review because the research was conducted within a regular or special education setting becomes a research activity that must receive

review and approval by the full board.

POLICY STATEMENT:

All research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship must be approved by the Fort Hays State University Institutional Review Board (FHSU IRB) if one or more of the following apply:

1. The research is sponsored by this institution, or
2. The research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or
3. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
4. The research is conducted by an individual not affiliated with the University upon subjects affiliated with the university, or
5. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

The term "research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.

See http://www.fhsu.edu/research/compliance/irb/ for the elaboration of policies and procedures relevant to research involving humans.

The IRB reviews all research with human participants. There are three broad categories of studies requiring review: those that require full board review, those that qualify for expedited or limited review, and those that meet the criteria for exemption from IRB review. Research projects that meet the criteria for Exemption from IRB review are not exempt from any review at all, but must be reviewed by a qualified departmental human subjects research committee or the IRB Administrator. The IRB Administrator reviews and approves all exempt proposals, which are made available for review by the IRB.

The FHSU IRB will review, and have the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research. For approved research, the IRB will determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval.

The FHSU IRB has the authority to suspend or terminate approval of

research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

Review by Institution

Research covered by this policy that has been approved by the FHSU IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the FHSU IRB.

EXCLUSIONS OR SPECIAL CIRCUMSTANCES:

RELATED DOCUMENTS:

Policies:

Forms:

Other: Ethical Principles and Guidelines for the Protection of Human Subjects of Research ("The Belmont Report"), National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Department of Health, Education, and Welfare, April 18, 1979.

Office for Human Research Protections http://www.hhs.gov/ohrp/

FHSU IRB website: http://www.fhsu.edu/research/compliance/irb/

KEYWORDS:

RESPONSIBLE OFFICE: Office of Scholarship and Sponsored Projects (OSSP)

RESPONSIBLE UNIVERSITY OFFICIAL: Dean of the Graduate School

ORIGINATION DATE: 9/03/2014

REVIEW CYCLE: Every three years

POLICY ADDRESS:	
LAST APPROVED ON:	Approved by Cabinet on 12/01/21 Approved by President on 12/01/21
REVIEW/CHANGE HISTORY:	Adopted by Cabinet on 10/01/14
NEXT REVIEW DATE:	12/2021