UNIVERSITY POLICY 15
HUMAN SUBJECTS POLICY

Approved: September 5, 2013
Policy Topic: Research and Sponsored Activities
Administering Office: Office of Sponsored Research

I. POLICY STATEMENT

Kettering University encourages and supports the scholarly endeavors of its students, faculty, and staff. Pursuit of scholarly work and research will often involve the use of Human Subjects for data collection and analysis. Kettering’s Institutional Review Board (IRB) reviews human subjects research proposals to ensure that the rights and welfare of human subjects used in research studies by University personnel are protected; that risks have been considered and minimized; that the potential for benefit has been identified and maximized; that all human subjects only volunteer to participate in research after being provided with legally effective informed consent; that any research is conducted in an ethical manner and in compliance with established standards. Those individuals seeking to conduct such research may not solicit subject participation or begin data collection until they have obtained clearance by the Kettering University Institutional Review Board.

Some research projects involving human subjects are exempt from full IRB approval requirements. The types of research generally exempt from IRB approval requirements include normal educational practices such as work undertaken as a part of a course; educational tests when the subjects are not identified; and surveys or interviews in which the subjects volunteer and are not personally identified. Exemption must be approved by the IRB Chair.

The Institutional Review Board (IRB) for Human Subjects Research at Kettering University has responsibility to oversee procedures for carrying out the University’s commitment to protect human subjects in research. The role of the IRB is to review proposed research projects that involve the use of human subjects; ensure that the individuals involved in the project are treated ethically; ensure that all subjects are provided with substantial information about the study and consent to be a subject in the study; and that all private information will be handled with confidentiality. The IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the University using human subjects.

The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project’s compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants.
II. DEFINITIONS

Research: Defined in 45 CFR 46.102(d) (see Related Policies and Resources) as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human Subject: Defined in 45 CFR 46.102(f) as a living individual about whom an investigator (whether professional or student) conducting research obtains

1. data through intervention or interaction with the individual, or
2. identifiable private information.

Intervention: Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes 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.

III. DETAILS/PROCEDURES

Kettering University has established one Institutional Review Board, registered with the Office for Human Research Protections (OHRP), as IRB FWA00010695. According to the terms of the Federal Wide Assurance (FWA), Kettering University adopts the following reporting procedure:

All Principal Investigator(s) and all Kettering University employees are required to report to the Chair of the IRB Committee any of the following upon knowledge of:

1. Unanticipated problems involving risks to subjects or others; and
2. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

Upon receipt of such information, or if a research project is suspended or terminated by the IRB, the IRB Chair will make a written report to the Kettering University IRB committee, the Provost of Kettering University, the head of any department or agency conducting or supporting the research, any applicable regulatory body, and to OHRP.
As part of this assurance, Kettering agrees to consider all research involving the use of humans as research participants as being subject to federal regulations regardless of the source of funding, if one or more of the following apply:

1. The research is sponsored by this institution (unless the research is conducted at another institution with which Kettering has an “IRB Authorization Agreement” as specified in Kettering’s FWA), or
2. The research is conducted by or under the direction of any employee or agent of this institution (unless the research is conducted at another institution with which Kettering has an “IRB Authorization Agreement” as specified in Kettering’s FWA), 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 involves the use of this institution’s non-public information to identify or contact human research subjects or prospective subjects.

The following principles apply to all research, including student projects, involving human subjects at Kettering University to ensure that adequate safeguards are provided:

1. Subjects’ legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.
2. Risks to subjects must be minimized and reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.
4. Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified.
5. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.
6. Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.
7. All research programs that involve human subjects must be reviewed by and must receive approval of a formally constituted review prior to their initiation or prior to initiating any changes to the protocol. Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

Additional information about the constitution and procedures of the Kettering University IRB are incorporated by reference, and can be found in the document “Kettering University Human Subjects Policy and Institutional Review Board Charter and Standard Operating Procedures” available from the IRB website maintained by the Office of Sponsored Research.
IV. POLICY REVIEW

This policy shall be reviewed and revised as necessary every four (4) years or more frequently as laws or regulations change.

V. RELATED POLICIES AND RESOURCES


University Policy 11, University Code of Ethics, specifically mentions the protection of the welfare of human research subjects in section I.II, paragraph 4. General statements in Policy 11 also undergird the ethical dimension of the current proposed policy.

The Code of Federal Regulations, Title 45, Part 46 (45 CFR 46, informally known as the “Common Rule”) regulates the protection of human research subjects, and is available from the website of the Office for Human Research Protections (OHRP), part of the Department of Health and Human Services. The Kettering IRB policies and procedures conform to these requirements.