KENNESAW STATE UNIVERSITY
OFFICE OF RESEARCH
Research Compliance

Policy Title	Determining Engagement in Human Subjects Research
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Responsible Office	IRB Office
Contact Information	IRB Office Email: irb@kennesaw.edu

1. **Policy Purpose Statement**

The purpose of this policy is to define activities requiring IRB review by the Kennesaw State University (KSU) IRB.

2. **Definitions**

Research (DHHS): A systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(l))

Per DHHS, the following activities are deemed not to be research:

- Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship);
- Public health surveillance activities conducted, supported, requested, ordered or authorized by a public health authority limited to those activities necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance;
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes;
- Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.

Systematic Investigation: A predetermined and organized method of data collection, intervention and interaction, and/or analysis to study a specific topic, answer a specific question, test a hypothesis, or develop a theory. It is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective. (Examples of systematic investigations include: surveys and questionnaires, interviews and focus groups, analyses of existing data or biological specimens, epidemiological studies, cognitive and perceptual experiments, medical chart review studies)

Generalizable knowledge: Information that will expand the knowledge base of a scientific discipline or other scholarly field of study and can be expressed in theories, principles, and statements of relationships; Results that can be generalized to a larger population beyond the site of data collection or participants studied; or Results that may be replicated or transferrable to other settings. (Examples of activities that are typically not generalizable: biographies, service or course evaluations, services or courses where it is not the intention to share the results beyond the KSU community, classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices, quality assurance activities)

Human Subject (DHHS): a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR 46.102(e).)

"About whom": the information/biospecimens received from the living individual is about the person. If the purpose is to obtain data about a topic other than the individual, it may not be considered human subjects research. Examples: asking an employee to describe the different functions performed by different positions at an organization, asking a teacher to describe common teaching methods or techniques used in the classroom. Example that is considered human subjects research: asking a teacher to describe his/her/their personal experience using different teaching methods

Intervention: includes both physical procedures by which data are gathered (e.g., 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.

Human Subject (FDA): An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient [21 CFR 56.102(e)]. In addition, a human subject includes an individual on whose tissue specimen an investigational device or control is used, even if the specimen is anonymous [21 CFR812.3(p)].

Test Article: any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act.

Clinical Investigation (FDA): The FDA has defined clinical investigation to be synonymous with research, clinical research, clinical study, and study. Any experiment that involves a test article (i.e., drug, medical device, food substance, biological product, or electronic product for human use), one or more human subjects, meets requirements for prior submission to FDA, or results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit [21 CFR 56.102].

Clinical trial: a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes (45 CFR 46.102(b).

Secondary research: research use of information or biospecimens originally collected for non-research purposes or for research studies other than the currently proposed one.

3. **Policy**

3.1. Investigators are responsible for seeking IRB review and obtaining approval or determination of exemption PRIOR to initiating any research activities involving human subjects including advertising, recruitment and/or screening of potential subjects.
3.2. For an activity to require KSU IRB review, it must be determined that it is human subjects research, as defined in the DHHS and the FDA regulations, and that KSU is engaged in the research.
3.3. An activity is determined to be human subjects research when its purpose and design meet the definition of both "human subject" and "research" (or "clinical investigation") as defined by DHHS (or FDA).
    3.3.1. Research testing the safety and effectiveness of an In Vitro Diagnostic (IVD) device using human tissue specimens (identifiable or unidentifiable) requires IRB review per 21 CFR Parts 50 and 56, even though under DHHS regulations research involving unidentified tissue specimens would not be considered human subjects research.
    3.3.2. Some classroom activities are designed to teach research techniques and have no intent to develop or contribute to generalizable knowledge. Simulations of human experimentation and course-assigned data collection do not constitute human subjects research if the activities are designed for educational purposes only and
        3.3.2.1. The data will not be generalized outside the classroom;
        3.3.2.2. The data will not result in a master's thesis, doctoral dissertation, poster session, abstract, or other publication or presentation; and
        3.3.2.3. The student volunteers or other participants are clearly informed that the activities are an instructional exercise, and not actual research.
        3.3.2.4. Exceptions: Any activity that is a clinical investigation or involves medical intervention or procedures, even when they are part of a course curriculum, constitutes human subjects research and requires prior IRB review and approval.
        3.3.2.5. See guidance on Class Projects for more information.
3.4. KSU becomes engaged in human research when its faculty, staff, or students (a) Intervene or interact with living individuals for research purposes; or (b) Obtain individually identifiable information for research purposes; or (c) Obtain consent from subjects.
    3.4.1. KSU is not engaged if activities of its faculty, staff, or students are limited to
        3.4.1.1. Informing prospective subjects about the availability of research;
        3.4.1.2. Providing prospective subjects with written information about research, which may include a copy of the relevant informed consent document, and other IRB-approved materials but do not obtain subjects' consent or act as authoritative representatives of the investigators;
        3.4.1.3. Providing prospective subjects with information about contacting investigators for information or enrollment;
        3.4.1.4. Obtaining and appropriately documenting prospective subjects' permission for investigators to contact them;
        3.4.1.5. Providing space for the US researcher to conduct their own research.
    3.4.2. When KSU is a direct recipient of federal funding for a human subjects research project, even if it conducts no work with human subjects itself, it is engaged.

4. Procedures

4.1. Prior to beginning research activities involving human subjects, Investigators must complete Initial IRB Review Request Form in Cayuse and submit for review.
    4.1.1. Upon completion of IRB review, IRB Office will send an email to Investigators via Cayuse to communicate decision of the IRB.

4.1.1.1. Emails with decision “Return to PI” communicate review comments and requests for additional information or changes needed before approval can be granted.

4.1.1.2. Investigators should respond to review comments and requests for additional information or changes in a timely manner and must not begin research activities until receipt of email with decision “Approved”, determination “Exempt”, or decision “Not Human Subjects Research”.

4.1.1.3. Emails with decision “Approved” indicate approval for investigators to begin research activities as proposed.

4.2. Investigators seeking official determination from the IRB Office that their project does not require IRB review should complete Request for Determination of Human Subjects Research in Cayuse and submit for review.

4.2.1. Upon completion of review by the IRB Office Staff, an email will be sent to indicate determination via Cayuse.

4.2.1.1. Determinations of “Not Human Subjects Research” indicate is no requirement for IRB oversight for the project as proposed.

4.2.1.2. Determinations of “Exempt” indicate the project was determined to be Human Subjects Research and was determined to be Exempt from additional requirements of the IRB.

4.2.1.3. Other determinations are communicated in a “Return to PI” communication and will provide further instructions for the investigators.