

	Human Subjects Research
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Responsible Office	IRB Office
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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:

- x Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship);
- x 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;
- x Collection and analysis of information, biopecimens, 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;
- x 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.

Determining Engagement in

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.

4.1.1.1.