

	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.