

# IRB New Member Training

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THE UNIVERSITY OF  
**TENNESSEE**  
KNOXVILLE

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RESEARCH INTEGRITY &  
ASSURANCE

# What is Research?

- A *systematic investigation*, including research development, testing and evaluation, designed to *develop or contribute to generalizable knowledge*.
- Systematic investigation: involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.
  - Surveys and questionnaires
  - Interviews and focus groups
  - Analyses of existing data or biological specimens
  - Cognitive and perceptual experiments
  - Medical chart review studies

# What is Research?

- Designed to *develop or contribute to generalizable knowledge*:
  - Results are applicable to a larger population beyond the site of data collection or the specific subjects studied
  - Results are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
- NOTE: Publishing or presenting does not necessarily make something research, and, conversely, something can be considered research if it is never published or presented.

# Who is a Human Subject?

- A human subject is a living individual about whom an investigator (whether professional or student) conducting research:
  - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.



# Who is a Human Subject?

- 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.
  - includes online only interactions

# Who is a Human 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.

# Levels of IRB Review

- Exempt and Expedited studies:
  - Reviewed by one reviewer in HRPP Office
  - Involve no more than minimal risk
  - Minimal risk - the probability and magnitude of physical or psychological harm is no more than is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
- Full Board studies:
  - Reviewed by two full board members and discussed at a convened meeting of the full board
  - Involve greater than minimal risk and/or a vulnerable population



# Criteria for Approval of Research

- 45 CFR 46/21 CFR 56 §111(a)
- “In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied”



# The 111 Criteria

- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is appropriately sought from each subject
- Informed consent is appropriately documented
- Privacy and confidentiality of subjects is protected

## When applicable:

- data collection is monitored to ensure subject safety
- additional safeguards are included for vulnerable populations

