



**Research, Grants
and Contracts**



What is a Human Subject?



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Agenda:

- Definition of research
 - Systematic
 - Generalizable knowledge
- Definition of human subjects
 - Intervention
 - Interaction
 - Private information
 - Identifiable private information
 - Readily ascertained
 - Identifiable biospecimen
- Other important information

Institutional Review Board (IRB)

Our Purpose



Research (Definition)

A systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge.

Systemic investigation

Generalizable
knowledge

Systemic Investigation

Systemic investigation

Generalizable
knowledge

The dictionary defines systematic as:

- Having a method or plan, possibly concerned with classification.
- Detailed or careful examination, exploration, or to learn the facts about something complex or hidden.
- Attempting to answer a question or prove/disprove a hypothesis are clear indications that an activity is a systematic investigation.

Generalizable Knowledge

Systemic investigation

Generalizable knowledge

- Hardest of the definitions to interpret
- Intend on sharing the information you produce with others (i.e. publications, presentations, etc.)
 - Not a catch-all.
 - Can publish a program evaluation study and it may not meet the federal definition of human subjects research
 - It is all about INTENTION!

Human Subject Definition (IRB)

- Living individual
- Intervention
- Interaction
- Identifiable private information
- Identifiable biospecimens

What is a HUMAN SUBJECT?

A living individual about whom an investigator EITHER:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens

AND/OR

- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

Intervention



Intervention includes both physical procedures by which data are gathered and manipulation of a subject or the subject's environment that are performed for research purposes

Examples:

- Blood draw
- Testing a hearing device
- Studies involving deceit can be intervention

Interaction



Interaction includes communication or interpersonal contact between investigator and subject.


Examples:

- Interview (in-person or via internet)
- Survey



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 (e.g., medical record information).



Identifiable Private Information

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.



Readily Ascertained

The identity of the subject may be readily identifiable whenever:

- Director identifiers (e.g., names, phone numbers) are stored with the study data
- The study data is de-identified and the investigator has access to the key that links the subjects IDs with direct identifiers
- The investigator could probably re-identify individuals through deductive reasoning by using unique characters and combinations of data points within a dataset, even when the direct identifiers are removed.



Identifiable Biospecimen

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associate with the biospecimen.



Important Information

- When in doubt call or email us!
- You cannot conduct human subjects research without prior approval
- Retrospective approval cannot be given

- When in doubt...call us!

If you have any questions or need additional information about anything shared within this presentation, please contact the RGC office.

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The logo features the letters 'NKU' in a white, serif font. A stylized yellow and orange flame is positioned above the letter 'U'.

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