CCTST | Center for Clinical & Translational Science & Training

CIRTIfication

IN-PERSON TRAINING

CURRICULUM OVERVIEW

University of CINCINNATI | Cincinnati Children's changing the outcome together

PART I: HUMAN RESEARCH RULES & REGULATIONS

TRAINING GOALS:

- Demonstrate knowledge of the history of research abuse
- Demonstrate familiarity with federal regulations
- Define the three ethical principles that underline research (The Belmont principles):
    - Respect of persons
    - Beneficence (Do no harm to anyone)
    - Justice
- Explain the purpose of an Institutional Review Board

DISCUSSION POINTS:

Definitions on research terms such as:

- **Human Research -**A study that collects information from or about living people.
- **Research Participant(Human Subject, Research Subject, Subject, Participant) -** A living person about whom information is collected in research
- **Clinical Trials, Clinical Studies, Clinical Research Study -** A research study using human subjects to evaluate biomedical or health-related outcomes.

History of Human Research Abuse and Regulations

- **The Belmont Report:** Ethical Principles for Research - Federal research regulations are based on these 3 rules: Respect of Person; Beneficence (Do good, not harm); and Justice (Fairness)
    - Abuse Studies: 1) Tuskegee Syphilis Study; 2) The Nazi Experience; 3) Willowbrook School for Mentally Retarded Children; and 4) Twin/Triplet Study: Three Identical Strangers
- **Institutional Review Board (IRB) Protections:** Committee that reviews research to ensure that participants will not be harmed; enforce these rules at the local level.

Community-Engaged Research (CEnR)

- Building community strengths & resources through collaboration in all phases of research with a commitment to local health issues. Creating a collaborative environment for academic researchers and the community to learn together.

PART II: ASKING PEOPLE TO PARTICIPATE IN A RESEARCH STUDY

TRAINING GOALS:

- Explain the informed consent process including the requirements of information, understanding, and voluntariness and ensuring they are fulfilled during the informed consent process;
- List the kinds of information that should be provided to potential research participants;
- Recognize the kinds of statements that should and should not be made to potential research subjects during recruitment; and
- Identify certain groups that may have special requirements for research participation

DISCUSSION POINTS:

The Inform Consent Process

Provides explanation as to the nature of the research project, why they are candidates for the research, what risks, benefits, and alternatives are associated with the research, and what rights they have as research subjects.

Emphasizes that the most critical piece of Informed Consent is to protect the participant, highlighting the additional protections for special populations such as children, prisoners, and people with limited abilities.

The training on Informed Consent will include the following:

- That it is a written document summarizing a research study;
- that it is a tool that will help recruit participants in a way that is ethical and fair;
- That it explain the participant's rights,
- That it should be written in understandable language for participants
- That IRB oversite of studies and the informed consent process

PART III: BEING CAREFUL WITH RESEARCH INFORMATION

TRAINING GOALS:

- Understand good practices for collecting and storing research data
- Know what to do if they observe a co-worker not following appropriate procedures
- Discuss how to maintain participants' privacy and the confidentiality of their information; and
- Identify some of harms that may occur to participants if privacy and confidentiality are not protected

DISCUSSION POINTS:

Protection of Data

Starts with a discussion on why each piece of information collected

- must be necessary for the research,
- provide an answer to a particular question sought for the research, and
- must reflect what actually occurs and is true.

Discussion will also address why all information provided by the participant should be kept safe, and all procedures for conducting research must be carefully followed. This includes special rules when research involves medical records..

The correct and incorrect handling of research data is presented along with discussion scenarios focused on protections and study procedures.