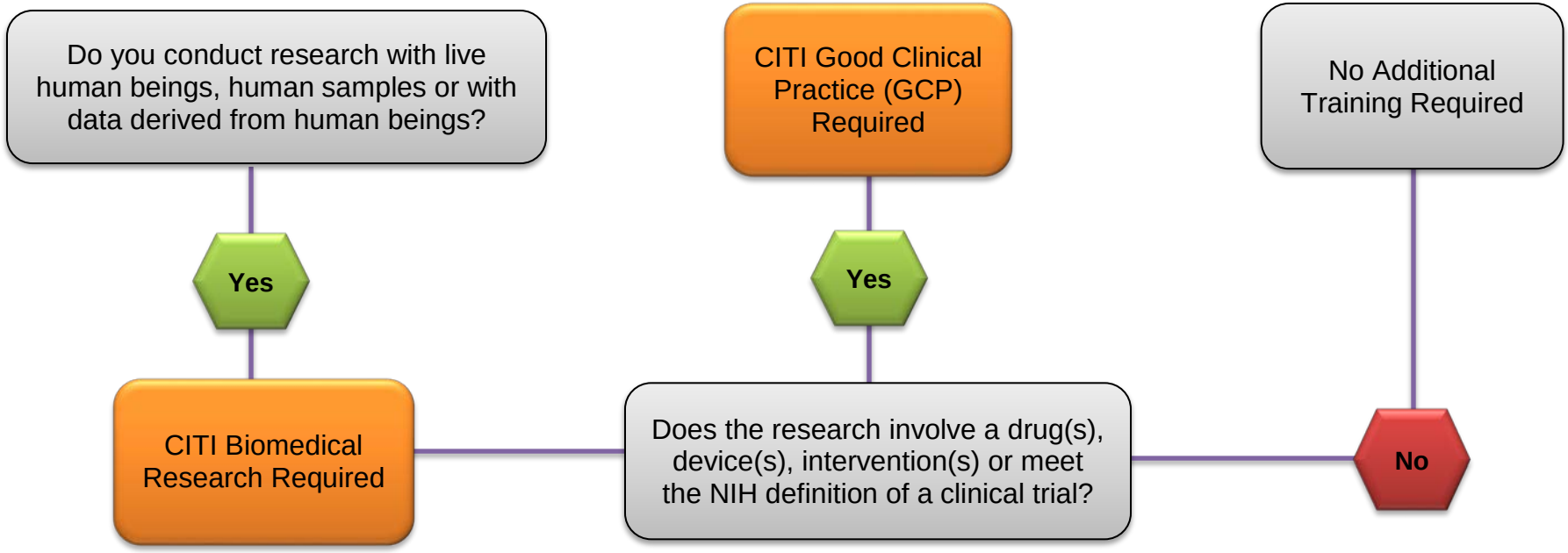
CITI Training for Pennington Biomedical Employees Involved in Human Subjects Research



For those who select the Biomedical Research Investigators curriculum, you may also be required by NIH policy to take the **Good Clinical Practice (GCP)** course **if your research involves a drug(s), device(s), intervention(s) or you are an Investigator or clinical trial staff responsible for the conduct, management and oversight of clinical trials.**

Clinical Trial: A clinical trial is defined by NIH as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Intervention*:* A manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. (Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. (e.g., Principal Investigator).

Clinical trial staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection, and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.