NIH SBE GCP

Best Practices in Social and Behavioral Research

In September 2016, the NIH issued a Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials. Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials. The principles of GCP help assure the safety, integrity, and quality of clinical trials. Investigators and clinical trial staff who are competent in GCP principles will be better able to assure that the rights, safety and well-being of human subjects are protected; that clinical trials are conducted in accordance with approved plans and with rigor and integrity, and that data derived from clinical trials are reliable.

The National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), through the Clinical and Translational Science Awards (CTSA) Program initiated a project in 2014 to streamline and standardize GCP training for clinical study personnel, including researchers conducting clinical trials. Ample GCP training exists for investigators conducting drug-, device-, or biologic-related studies, but it does not address *clinical trials using behavioral interventions and social science research*.

The CTSA Program project team recognized a critical need for training in applying GCP principles to social and behavioral research and thus developed the *Best Practices in Social and Behavioral Research* e-Learning Course for GCP to fill the gap. In 2016, the Best Practices in Social and Behavioral Research Course e-Learning Course for GCP was released to *provide researchers with training that applies GCP principles to social and behavioral research*.

The e-Learning course is comprised of nine video course modules and can be accessed in **UCLC**:

- **Module 1: Introduction**
    - Define the role and context of ICH in providing guidelines for regulations
    - Show how ICH guidelines are applied to social and behavioral research
    - Define GCP
    - List the goals of GCP
    - Explain how GCP relates to the regulation of clinical trials in social and behavioral research
    - Compare the roles and responsibilities of the sponsor, institutional review board (IRB), research investigator, research coordinator, and other team members

- **Module 2: Research Protocol**
    - Describe the elements of clinical and IRB protocols
    - Explain the importance of standard operating procedures (SOPs)
    - Explain and evaluate treatment fidelity
    - Recognize protocol deviations, identify strategies to minimize them and prevent re-occurrence, and list reporting requirements

- **Module 3: Recruitment and Retention**
    - Identify potential recruitment strategies and best practices for recruitment

- Assure methods are appropriate for achieving adequate participation of populations under-represented in research
- Identify potential strategies for participant retention

- **Module 4: Informed Consent Communication**
  - Outline the Informed Consent process
  - List the required elements of informed consent process per GCP guidelines
  - Identify key aspects of communication strategies for the consent process to ensure participants' (including vulnerable participants') rights, safety, and well-being are prioritized
  - Critique informed consent communication between a study team member and participant to determine areas for improvement

- **Module 5: Confidentiality and Privacy**
  - Differentiate concepts of confidentiality and privacy
  - Select strategies to ensure data are collected and managed in ways that assure participant confidentiality and privacy
  - Identify instances when confidentiality or privacy are compromised
  - Identify when and to whom reporting is necessary

- **Module 6: Participant Safety and AE Reporting**
  - Develop communication strategies for detecting adverse events that can be used by the entire study team
  - Develop common strategies for reporting adverse events
  - Define the role and responsibilities of a data safety and monitoring board in a behavioral clinical trial

- **Module 7: Quality Control and Assurance**
  - Explain the importance of quality control/assurance in a clinical trial
  - Select strategies that can help systematically monitor participant progress through a study, including identifying incomplete/missing and out-of-range data
  - Identify sources of bias that can affect data quality
  - Assess how different biases can affect data quality using a case-based example

- **Module 8: Research Misconduct**
  - Define research misconduct
  - Identify behavior that constitutes misconduct
  - Describe the process for reporting an instance of misconduct
  - Explain the consequences of research misconduct

- **Module 9: Conclusion/wrap-up**
  - This module revisits key ideas learned throughout the modules, as well as resources and job aids that learners can utilize while conducting social and behavioral research.