What is Good Clinical Practice and Why is it Important?

Definition and Purpose:

- GCP is defined as a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials or studies

- It provides assurance that the data and the reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected

GCP is established in:

- FDA Regulations (21CFR)
- FDA Guidance Documents
- International Standards (ICH)
- StrokeNet and Local SOPs
- Local Law (Institutional and IRB Policies)
- State Law

Who is responsible for GCP compliance in research?

- Sponsors
- Clinical investigators
- Institutional Review Boards (IRBs)
- Contract Research Organizations (CROs)
- Research nurses
- Clinical Research Coordinators (CRCs)
- Clinical Research Associates (CRAs)
- Medical monitors
- Data entry personnel
- Data Managers
- Others

Who is responsible for GCP compliance in research?

- Sponsors –Prime PI of the Study (and NINDS)
- Clinical investigators – YOU, the PI, the subinvestigators
- Institutional Review Boards (IRBs) – Univ of Cin /Advarra
- Contract Research Organizations (CROs) – NCC @ Univ of Cin
- Research nurses - YOU
- Clinical Research Coordinators (CRCs) - YOU
- Clinical Research Associates (CRAs) – DMC @ MUSC
- Medical monitors – Identified by the Prime PI
- Data entry personnel – YOU
- Data Managers - DMC @ MUSC
- Others - eg. Local Compliance Office, Local IRB

What constitutes GCP in research?

The Basics:

- Current Standard Operating Procedures
- **Sponsor / Monitor / Investigator responsibilities**
- **Informed Consent process**
- Institutional Review Board approval
- **Compliance with study protocol and related procedures**
- *Controls of investigational supplies*
- Adequate safety surveillance
- *Quality Assurance*
- *Financial Disclosure*