Overview of Good Clinical Practices (GCP)
Investigator and Study Team Responsibilities

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Good Clinical Practice is the compilation of accepted ethical and scientific standards governing clinical research that ensure the integrity of data obtained and the protection of human research subjects.
Good Clinical Practices Components

- Food and Drug Administration (FDA) regulations and guidance documents
- International Conference on Harmonization (ICH) guidelines
- State and local laws
- Medical Standard of Care
- Medical Ethics
Shared Responsibilities

• Responsibility for following GCPs is shared among the following:
  • Institutional Review Board (IRB)
  • Investigator (study team)
  • Sponsor
  • Monitor
Investigator Responsibilities
In a Nutshell

- **Follow** Approved Protocol
  - Responsible for research team’s adherence as well
- **Protect** Human Subjects
  - Ensure informed consent
- **Control** Investigational Product
- **Document** Study Progress
  - Submit appropriate reports
  - Retain records
Investigator Responsibilities (FDA)

Clinical Investigator/Site (21 CFR 312 and 812):

- Conduct the study according to the signed agreement, the investigational plan and applicable FDA regulations
- Protect the rights, safety, and welfare of subjects under the investigator’s care
Investigator Responsibilities (FDA)

Clinical Investigator/Site (21 CFR 312 and 812):

- Control investigational product
- Dispose of/return investigational product
- Ensure that an IRB that complies with its requirements (21 CFR 56) will be responsible for initial and continuing review and approval
Investigator Responsibilities (FDA)

Clinical Investigator/Site (21 CFR 312 and 812):

• Obtain Informed Consent per 21 CFR 50 prior to study participation

• Submit Reports (progress, safety, final, financial disclosure)
Investigator Responsibilities (FDA)

Clinical Investigator/Site (21 CFR 312 and 812):

• Maintain accurate, complete, and current records relating to the investigator’s participation in an investigation
• Retain records and make them available for review
Investigator Responsibilities (FDA/PHS)

Clinical Investigator/Site (21 CFR 54, PHS Regulations & UC Davis P&Ps):

- Disclosure of Conflicts of Interest that affect the design, conduct, reporting, and analysis of the research (Disclose to Sponsor and UC Davis)
  - Compensation or equity interest of $5,000 or more (publicly traded)
  - Compensation of $5,000 or more, or equity interest of any amount (non-publicly traded)
  - Intellectual property interests of $5,000 or more
  - Travel expenses paid for in any amount
Investigator Responsibilities (FDA)

The Form FDA 1572

It is important to remember that the Form FDA 1572 is a contract between the PI and the FDA.
Investigator Responsibilities (FDA)

Clinical Investigator/Site:
Statement of Investigator Form FDA 1572

By signing the form (contract), the Investigator:

• Agrees to personally conduct or supervise the study in accordance with the approved, relevant, current protocol
Investigator Responsibilities (FDA)

1572

- Inform subjects (including controls) that drugs are investigational
- Meet the requirements of obtaining Informed Consent (21 CFR 50)
- Report Adverse Events to the IRB and Sponsor
Investigator Responsibilities (FDA)

(1572)

• Maintain adequate and accurate records (available for inspection)
• Read and understand the information (including potential risks and side effects) in the investigator’s brochure
Investigator Responsibilities (FDA)

(1572)

• Ensure all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above requirements

• Ensure that an IRB that complies with FDA requirements (21 CFR 56) will be responsible for initial and continuing review and approval
Investigator Responsibilities (FDA)

(1572)

• Promptly report to the IRB all changes in research activity and all unanticipated problems related to the study
• Comply with all other requirements regarding obligations of clinical investigators and all other pertinent requirements in 21 CFR 312
Investigator Responsibilities (FDA)

(1572)

- Not change the research without IRB approval except where necessary to eliminate immediate hazards to subjects
- PI affixes his/her signature at the bottom of the form attesting to all of the above. Below the PI signature line the form states:
  
  "(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001)"
Investigator Responsibilities (ICH)

Site Personnel Qualifications:
• Qualified by education, training and experience in the field being researched
• Familiar with the investigational product and its proper use
• Document that responsibilities are delegated only to qualified personnel
Investigator Responsibilities (ICH)

Resources:

- Sufficient access to the patient population being studied
- Sufficient time to properly conduct and complete the study
- Adequate number of qualified personnel
- Adequate facilities and equipment
- Personnel trained on protocol, investigational product, and assigned duties and functions
Investigator Responsibilities (ICH)

Medical Care of Subjects:

- Medical decisions should be made by a qualified physician who is an investigator or sub-investigator for the study.
- Adverse events and other medical issues should be managed adequately.
- Subject’s Primary Care Physician should be notified of participation, with subject’s approval.
- Withdrawn subjects should be assessed.
Investigator Responsibilities (ICH)

Document Study Progress:

- The PI must ensure proper documentation of the study including, but not limited to:
  - Consent of subjects (both via the IRB approved form, and research notes in the subject record.)
  - Research records (including subject charts, medical records, databases where study data is captured, etc.)
  - Correspondence between the PI and the IRB
  - Proper storage and retention of records
Investigator Responsibilities (ICH)

Interaction with IRB:

- Written and dated approval should be obtained for the protocol, informed consent form, advertisements, subject literature and amendments prior to being implemented.

- All documents to be reviewed should be provided in a timely manner and updated as necessary throughout the trial.
Investigator Responsibilities (ICH)

Protocol Compliance:

- The investigator should formally agree to comply with the approved protocol and confirm this by signing the protocol.
- The investigator should not deviate from the protocol without prior knowledge and agreement from the sponsor and the IRB.
- The investigator should not implement protocol amendments prior to review and approval by the IRB.
Investigator Responsibilities (ICH)

Control Investigational Product:

• The investigator must oversee and ensure the appropriate:
  • Receipt of the investigational product
  • Storage of the investigational product
  • Documentation of the accountability of the investigational product
  • Dispensing of the investigational product
  • Return or disposal of the investigational product
Remember

Your Responsibilities are another person’s Rights!
For More Information

- Consult FDA regulations
- Consult ICH GCP Guidelines
- Complete the Good Clinical Practices Module within the CITI Training Program
Questions?