

# Knowing Investigator Responsibilities Leads to a Strong Research Team



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# What Do We Mean by a Strong Research Team?

- *Research Team*: A group of people working together in a systematic and scientific manner to establish facts
- *Strong Research Team*: Committed to applying the principles of Good Clinical Practice (GCP) in clinical research that may have an impact on the safety and well-being of human subjects

# Good Clinical Practice (GCP)

GCP is an international and scientific *quality standard* for designing, conducting, recording and reporting trials that involve the participation of human subjects

Compliance with GCP provides *public assurance* that the rights, safety and well-being of trial subjects and are consistent with the Declaration of Helsinki and that the clinical trial *data and reported results are accurate and credible*

# Why Do We Need GCP?



# Evolution Towards Standards of GCP

- International concern for the protection of human subjects has increased
  - Historical influences
  - Need for research to advance medical knowledge
- Unified to facilitate mutual acceptance of clinical data by regulatory authorities (1996)

# Motivation for Conducting Clinical Research

- Individual patients and potential patients may benefit
- Public health may be improved (economic benefits)
- Investigators may benefit
  - Financial inducements
  - Enhancement of career

# How Can the Principal Investigator Apply GCP?

- By being familiar with GCP
- By knowing his or her role and responsibilities in the conduct of clinical research

# Who are the Other Members of the Research Team at the Site

- Co-Investigators or Associate Investigators
- Clinical Research Coordinator -?
- Data Manager
- Clinical Pharmacist
- Statistician - ?
- Patient(s)
- Institutional Review Board (IRB)
- Regulatory Bodies

# Qualifications of the PI

- An appropriately qualified person in the relevant field of health care(MD, PhD, Pharm D, nurse)
- Trained and experienced in clinical research
- Familiar with the background of the study and requirements of the study
- Has high ethical standards and professional integrity

# Principal Investigator- Definition

- The individual who actually conducts the clinical trial or research study (usually given the acronym title of “PI”)
- The leader of the research team at the site

# Responsibilities of the PI

- Familiar with the background of the study (e.g., disease, management of the disease, management of side effects of treatment)
- Familiar with the study itself, particularly the protocol document & procedures
- Remember – **READING IS FUNDAMENTAL AND NECESSARY *IF you want to be an effective PI***



*Acknowledgement*  
*RIF*

# Questions or Food for Thought

- How many errors or deviations could be avoided if one takes the time to read the entire protocol document?
- If you only read the treatment schema, will you be prepared to “conduct the protocol” and be effective as the “leader” of the research team? (Don’t set a bad example!)
- What if you or your institution is unable to carry out some protocol-related procedures, tests or treatments? (Should you agree to participate?)

# Responsibilities of the PI

- Obtain institutional review board(s) (IRB) approval of the protocol document/informed consent document *prior* to the initiation of (i.e., patient enrollment) of the study
- Be familiar with any national laws that may impact your participation in or design of a study
  - Drug approval
  - Importation of drugs (where, how, costs)
  - Transport of human tissues outside of your institution and/or country
  - Funding policies and rules

# Responsibilities of the PI

- Obtain informed consent from patients or parents/guardians of patients who are children *prior* to starting protocol treatment (and particularly in the case of randomized studies before “randomizing” the patient to a particular treatment arm)

# Informed Consent

- Informed consent is a “process” – it does not end with the signature of the patient or parent on a piece of paper
- On-going and interactive process between the research team and the patient to ensure that the patient/family understands the study and what it means to participate in the study

# PI Responsibilities in the Informed Consent Process

- Providing the necessary information to the patient and or parent about the study and obtaining the informed consent
- May designate Associate Investigators who are familiar with the protocol to obtain consent as long as they are familiar with the responsibilities of obtaining consent

# What Should be Conveyed in the Informed Consent Process

- Participation is voluntary
- Background information about disease and rationale for specific therapy
- Description of the “research” objectives & inform what is “standard of care”
- Patient’s “required involvement” – duration of participation, hospitalizations, OPD visits
- Alternative approaches to treatment (and state none if that is truly the case!)

# What Should be Conveyed in the Informed Consent Process

- Risks or discomforts (side effects of treatment or procedures)
- State how patient's confidentiality will be maintained
- Provisions for research-related injuries and compensation for disability or death
- Costs to the patients as a result of participation
- Contact information for problems or questions
  - PI
  - Patient advocate

# Responsibilities of the PI

- Enroll only eligible patients
- Observe, evaluate, manage (treat) and document all effects of treatment
  - Response or other study end points
  - Adverse events (AEs)
  - Deaths
- Report adverse events and deaths as specified within the protocol
  - IRB
  - Sponsor

# Responsibilities of the PI

- Notify IRB/Sponsor of any issues that pose a threat to the safety and well-being of the patients in the study
- Submit protocol changes (amendments) to the IRB for approval
- Provide information about protocol progress to the IRB on an annual basis

# Responsibilities of the PI

- Record all data pertinent to the study
- Maintain study documentation and make this available for data verification (per the study set up)
- Comply with all procedures specified in the protocol in accordance with GCP

# Things to Remember

- As the PI, one may “delegate” certain responsibilities to others, but *if* the PI delegates responsibilities, there are things to remember
  - Do not make any assumptions
  - Supervision of the work performed is essential
    - Quality of the care delivered by the staff responsible for the patients on a day-to-day basis
    - Quality of the information recorded on the study data collection forms

# Conclusions - 1

- The PI has many responsibilities in the conduct of clinical research
- Although the PI may delegate certain responsibilities to others, he or she is ultimately responsible and accountable for the conduct of the study

# Conclusions - 2

- The PI should strive to meet the high standards of GCP, but why?
- To provide *public assurance* that the:
  - Rights, safety and well-being of patients are **PROTECTED**
  - Data is **ACCURATE**
  - Reported results are **CREDIBLE**

# Thank You

