Clinical Operations Manual

Policy Name: Principal Investigator Responsibilities

Approved by: Tedd S. Adair II

Title: Vice President, Clinical Operations

Date: January 1, 2011

In any clinical trial, The PI is responsible for personally conducting or supervising the trial. The following sections describe these responsibilities according to federal regulations and ICARE standard operating procedures.

The PI is directly responsible for…

- Being knowledgeable about the clinical trial prior to the enrollment of research participants and throughout the duration of the study.
- Reading the protocol and investigator brochure, including potential risks and side effects of the drug, and any revisions of these documents.
- Conducting the study in accordance with the relevant, current protocol.
- Not making any changes in the research without written approval from the IRB and sponsor, unless those changes are necessary to protect the safety, rights, or welfare of subjects.
- Documenting all trial-related medical care and decisions, including:
    - Decision to randomize/enroll a subject
    - Review of serious and/or unanticipated adverse events
    - Review of all study-related procedures/test results (e.g., labs, EKG's, etc.)
    - Decision to discontinue study medication for medical reasons
- Ensuring adequate care is provided for any adverse event related to the trial and for informing a subject if care is needed for intercurrent illness.
- Ensuring adequate back-up medical care coverage is available any time the PI is unavailable.
- During an inspection:
    - Answering questions from the inspector honestly
    - Allowing the inspector access to all relevant documents EXCEPT:
        - Internal QA audit sheets/results
        - Documents indicating financial arrangements between Pikeville Medical Center, Inc., the investigator, and the sponsor
        - Subject names, unless the records of particular individuals require a more detailed study of the cases or unless there is reason to believe that the records do not represent actual case studies or do not represent actual results obtained.
    - Giving the inspector access only to those specific documents requested by the inspector

The PI is responsible, with support from ICARE staff, for ensuring that…

- All associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations with regard to following the IRB-approved protocol, the informed consent process, and reporting adverse events.

- Access to the investigational product is controlled
- The investigational product is administered properly and only to those authorized to receive it.
- All subjects are informed that the drugs/agents are being used for investigational purposes and that they are informed of all relevant information about the study.
- An appropriately trained member of the study team conducts informed consent discussions and completes the consent process and documentation.
- The IRB is notified of any protocol deviations that were implemented to eliminate immediate hazards to the subject, that increase the risk to the subject, and/or that significantly affects the conduct of the trial
- Adverse events are solicited from the patient/subject
- Adverse events are documented and reported to the sponsor
- All serious and/or unanticipated adverse events are promptly reported to the sponsor and the IRB.

SOP Agreement

As a physician who is or intends to be a PI for studies conducted at any ICARE site, my signature below confirms that I have read and understand the PI Responsibilities. I agree to fulfill these responsibilities in all professional activities conducted as an ICARE Principal Investigator or a Principal Investigator conducting research at an ICARE site.

PI Name (print): _____

PI Signature: _____

Date of Signature: _____/_____/_____