IASIS HEALTHCARE	**POLICY TITLE**: Principal Investigator Responsibilities
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 1.0.3 ☐ Addendum to Corporate Policy ☐ Form Available In I-REPP System
SECTION (as applicable): Clinical Research	**POLICY OWNER:** Tedd Adair, Vice President of Clinical Operations and Chief Clinical Officer
ORIGINATION DATE: 01/01/2011	**FINAL APPROVAL DATE**: April 30, 2016

POLICY:

In any clinical trial, The Principal Investigator (PI) is responsible for personally conducting or supervising the trial. The following sections describe these responsibilities according to federal regulations and ICARE Guidelines.

SCOPE:

This procedure applies to all clinical trials conducted at any IASIS facility.

DEFINITIONS:

Not Applicable

PROCEDURE:

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 IASIS Healthcare, 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.

FORM REFERENCES:

Not Applicable

REFERENCES:

US Department of Health and Human Services; Food and Drug Administration.

Guidelines 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: _____/_____/_____

Review/Revised Date:	Title:	Description of Change or Location of Change in Document:
04/30/2016	Tedd Adair VP Clinical Operations & CCO	Scheduled review; converted to ISO Policy Template