IASIS HEALTHCARE	**POLICY TITLE**: Study Team Preparation
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 1.1.1 ☐ 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:

When preparing the Principal Investigator and other study team members for a clinical trial, to ensure that the Principal Investigator and all study team members are knowledgeable about the clinical trial and their roles and responsibilities prior to the enrollment of research participants and throughout the duration of the study.

SCOPE:

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

DEFINITIONS:

Investigator: An individual who actually conducts a clinical investigation.

Principal Investigator: The responsible leader under whose direction a team of individuals conducts an investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. For all clinical investigations conducted at any IASIS facility, the Principal Investigator is a licensed physician or dentist.

Sub-Investigator: Any individual qualified member of the clinical trial team designated and supervised by the Principal Investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows, research nurses, research pharmacists).

PROCEDURE:

The following procedures are completed prior to consenting or enrolling any research participants in a clinical trial.

Principal Investigator Credentials:

- All studies involving investigational drugs and/or devices conducted at IASIS facilities are required to have a licensed physician or dentist as Principal Investigator.
- The following documents pertaining to the physician Principal Investigator are filed in the regulatory binder:
    - current curriculum vitae
    - current medical license
    - current controlled substance license, if the study involves a controlled substance or if the sponsor requires a copy
      Class I license, if required by the study
- The Principal Investigator's credentials are verified
- Physicians serving as the principal investigator for studies being conducted at IASIS facilities and any Principal Investigator conducting federally-supported trials with ICARE or conducting studies at an IASIS facility are required to provide:
    - Signed assurance that he/she has read and will comply with PI responsibilities described in ICARE Guideline's
    - Signed agreement to read and comply with ICARE's Code of Conduct
    - Signed and completed Investigator Disclosure Forms
    - Documentation that he/she meets one or more of the following:
        - Completed "investigator certification" by DIA, ACRP, or the American Academy of Pharmaceutical Physicians
        - Completed the CITI training course
        - Completed some other training program on investigator responsibilities in clinical research that has been approved by the ICARE Research Supervisor

Additional Study Team Member Requirements:

- The Principal Investigator or designee must complete and submit to the ICARE Office of Clinical Research a Research Evaluation Form, Clinical Trials Research Feasibility Review, along with the final protocol, copy of the completed IRB application, Informed Consent Form, and GCP training, annual investigator's financial disclosure form as described in the IASIS Research Policy prior to IRB submission.
- IASIS employees involved in the conduct of clinical research at an IASIS facility must complete an IASIS Confidentiality Agreement and submit a signed and dated agreement to the ICARE Office of Clinical Research.
- The Principal Investigator or designee must verify and document the study being conducted has first been approved by one or more of the following agencies prior to being conducted at an ICARE site:
    - U.S. Food and Drug Administration
    - U.S. Department of Health and Human Services
    - Other government Agencies pre-approved by IASIS Legal Department
- All study team members comply with the policies and procedures of the institutions in which they conduct study activities, including credentialing requirements and requirements for proper documentation in medical records.

- All study team members comply with the policies and procedures of the institution, the Institutional Review Board (IRB), and the clinical trial sponsor(s), if consistent with applicable federal regulations/guidelines and state/local laws; if a policy exists that is similar to any policy outlined in the ICARE Guidelines (GUIDELINEs), then the more stringent of the two policies is followed.
- All study team members comply with the policies and procedures of any IASIS Healthcare facility in which they are conducting study activities, including all ICARE Guidelines, and the ICARE Code of Conduct.
- Any staff involved in the preparation of hazardous materials for shipment (e.g., lab specimens, any item that must be packed with dry ice, etc.) completes hazardous material training and keeps this training current.

Review of Study Purpose and Procedures:

- The roles and responsibilities of each study team member are defined based on relevant credentials, training, experience, and expertise.
- Members of the study team receive study-specific training, as needed, consistent with their roles in the conduct of the clinical trial.
- Both the Principal Investigator and the study coordinator review the following documents:
    - Investigator brochure (for applicable studies)
    - Device Instructions for Use (for applicable studies)
    - Most current protocol version
    - Most current approved Informed Consent
- The study team identifies where data will be originally recorded (i.e., source documentation). When designated, and with approval from the sponsor, the Case Report Form may be used as the source document.

ONGOING PROCEDURES

The following procedures are completed throughout the duration of the study.

Documentation of Study Preparation:

- The roles and responsibilities of each team member are documented according to sponsor's instructions (employees undergoing training, whether observing study activities or performing them under observation, are included in this documentation).
- All study team members use the attached *Study Personnel Training/Meeting Log* (or an equivalent documentation method) to document the following:
    - Study-related training received by members of the study team
    - Study-related training conducted by ICARE employee/representative
    - Meetings in which significant study-related issues are discussed
- The Principal Investigator documents that he/she has read the relevant version of the protocol by signing the protocol signature page and any amendments approved by the IRB.
- The Principal Investigator documents that he/she has read the investigator brochure (for applicable studies) by signing and dating the copy received from the sponsor.
- The Principal Investigator documents that he/she has read and agrees with the Statement of Investigator Commitments on page 2 of the FDA form 1572 by signing and dating the original (for applicable studies).

- Copies of the above documentation are maintained in the regulatory binder.

Responsibility:

- The Study Coordinator staff/assigned party is responsible for ensuring that the PI is a physician and that copies of the physician PI's CV and licenses are obtained and filed in the regulatory binder.
- The Study Coordinator staff/assigned party is responsible for ensuring that PI credentials are verified.
- The Study Coordinator staff/assigned party is responsible for ensuring that relevant PIs provide documentation of their agreement to comply with ICARE GUIDELINE's and ICARE's Code of Conduct, documentation of their disclosures, and documentation of the required training and/or certification.
- The study coordinator/assigned party is responsible for ensuring and obtaining documentation of all study-related training and meetings and review of study-related documents.
- The PI is responsible for reading the current protocol, investigator brochure (for applicable studies), most current approved informed consent, and device instructions for use (for applicable studies), including potential risks and side effects of the drug.

The PI is responsible 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.

FORM REFERENCES:

Not Applicable

REFERENCES:

New or Experimental Procedures Policy; National Institute of Health

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

STUDY PERSONNEL TRAINING/MEETING LOG

Sponsor: _____ Topics (list or attach agenda/handout):

Protocol #: _____ _____ _____

Date of Training/Meeting: _____ _____ _____

Trainer (if meeting, put "n/a"): _____ _____ _____

Print Name	Signature	Role