IASIS HEALTHCARE	**POLICY TITLE**: External Inspections
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 2.0.3 ☐ 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:

When participating in an inspection by an external organization, to ensure that all relevant documents are accessible for inspection by an authorized external organization and that the inspectors and IASIS facility and ICARE staff are treated with respect during an inspection.

SCOPE:

This procedure applies to inspections conducted at any IASIS facility by the FDA, OSHA, DOT, FAA, DOL, OHRP, or any other duly authorized federal, state or local government agency or by any sponsor or IRB responsible for overseeing the conduct of a clinical trial at any IASIS facility.

DEFINITIONS:

Inspection: Any inspection or audit conducted by any external organization for the purpose of determining compliance with relevant regulations, guidelines, or practices. This does not include routine monitoring visits.
Inspector: This refers to any inspector, auditor, or agent responsible for conducting the inspection.

PROCEDURE:

Prior to the Inspection:
For inspections that are announced in advance, the Research Supervisor at the ICARE Office of Research and the facility Risk Manager are notified in writing of the upcoming inspection within 24 hours of the site becoming aware of the inspection. For unannounced inspections, the Research Supervisor at the ICARE Office of Research and the facility Risk Manager are notified immediately. If the inspection is associated with a specific trial that is being conducted at the

site, the Principal Investigator, the Study Coordinator,and the sponsor of the study should be also notified.

When the inspector arrives at the IASIS/ICARE site, the staff on site performs the following procedures prior to the inspector's review of any documents:

- verify the inspector's credentials
- record the inspector's badge number (if applicable)
- obtain a copy of the 482 (inspector's assignment; applicable for FDA inspections only)

During the Inspection:

The following procedures are performed throughout the inspection at any IASIS facility:

- The ICARE Research Supervisor, or his/her designee and a Legal Department Representative, is on site throughout the duration of the inspection and serves as the primary contact through whom the inspector coordinates his/her inspection.
- Staff answers all questions honestly. Staff never conceals or deceives.
- If the site has been issued a written citation of violation (e.g., 483) as a result of a previous inspection with which the site disagrees and the current inspector is the same one issuing the previous violation OR if the inspector becomes disrespectful or seems to be going beyond the scope of their assignment, the Corporate Compliance Designee is are notified so that special arrangements (e.g. legal representation on site during inspection, videotaping of the inspection, etc.) can be made if deemed necessary.
- The inspector is given access to all relevant study-related documents EXCEPT:
    - Internal QA audit sheets/results (the only exception regarding disclosure of internal audit findings is when an institutional official from a client organization requests these findings. In such situations, disclosure of this information is coordinated through the Quality Management department)
    - Documents indicating financial arrangements between the site management organization, 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.
- The inspector is not allowed to take original documents from the site.
- Every document that is copied and given to the inspector is copied and kept in a file on site as a record of what was given to the inspector (Note: This item does not apply to inspections conducted by sponsors).

After the Inspection:

After the inspection, all correspondence to and from the organization performing the inspection and/or any other party (e.g., sponsor, IRB, etc.) regarding the inspection is coordinated through the Research Supervisor and the ICARE Office of Research with routing through the IASIS Healthcare Legal Department.

Responsibility:

- The recipient of the inspection announcement is responsible for ensuring that the Research Supervisor with the ICARE Office of Research, Risk Manager for the IASIS facility receive notification of announced inspections according to the above procedure.

- The study coordinator and/or the Regulatory Affairs staff are responsible for ensuring that all relevant study documents are maintained and accessible for inspection at any time.
- The PI is responsible for permitting access to and copying and verifying any relevant study records during an inspection.
- The ICARE Office of Research Supervisor is responsible for getting to the site being inspected as quickly as possible and for serving as the inspector's primary contact to coordinate the inspection (or assigning a designee to serve in this role).
- The ICARE Ethics and Compliance designee is responsible for coordinating all correspondence to and from any external party regarding the inspection.
- All IASIS facility/ICARE and Principal Investigator staff and research staff are responsible for:
    - answering questions from the inspector honestly
    - allowing the inspector access only to those documents specified in this procedure
    - giving the inspector access only to those specific documents requested by the inspector
    - making copies of all documents that were copied and given to an inspector according to the above procedure

FORM REFERENCES:

Not Applicable

REFERENCES:

Not Applicable

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