IASIS HEALTHCARE	**POLICY TITLE**: Internal Audits – Clinical Research
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 2.0.4 ☐ 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 conducting routine internal audits, to ensure that clinical trials are conducted in a way that meets or exceeds regulatory requirements and customer expectations by performing internal quality audits on an as needed basis as determined by the ICARE Office of Research.

SCOPE:

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

DEFINITIONS:

Active Study: A study in which one or more subjects are enrolled and that subject(s) has not yet completed all study events and is not a "discontinued subject."
Discontinued Subject: An enrolled subject who has not completed and will not be completing all study events for some reason; in order to be considered "discontinued," there must be documentation of this status in the subject's source documents.
High Volume Study: A study in which more than 10 subjects have been enrolled.

PROCEDURE:

Audit Procedures:
The following procedures are performed by the ICARE Office of Research:

1) The regulatory binders/documents of all active studies are audited. Audit findings, if any, are given to designated operations staff to address.
2) The consent forms of all consented subjects are audited. Audit findings, if any, are given to designated operations staff to address.

3) The source documents for all enrolled subject are audited to assess protocol compliance; (this includes audits of any re-consents); and the timeliness of serious and/or unanticipated events reporting.
   For high volume studies, the sampling procedures described below may be implemented for the auditing of enrolled subjects. Audit findings, if any, are given to designated operations staff to address.
4) General office documents are audited using the ICARE office audit tool to ensure compliance with IASIS Research SOP's. Audit findings, if any, are given to designated operations staff to address.
5) At the end of each audit, the Auditor completes a Significant Error Alert form and delivers, faxes, or e-mails it to the Research Supervisor for the ICARE Office of Research, as well as to designated operations staff, if any significant errors were found that day. The ICARE Quality Management department assists operations staff as needed to ensure significant errors are addressed properly. Quality Auditors continue to re-check the status of these errors until resolved or otherwise addressed.

If relevant documents are unavailable for auditing for any reason, the Quality Auditor makes arrangements with operations staff to ensure these documents are made available and audited in a timely manner.

Sampling Procedures:
For high volume studies, the audits of the enrolled subject data are performed using the following methods:

1) For the first 10 enrolled subjects, 100% of the subjects are audited.
2) For additional subjects beyond the first 10, 10% of the subjects are audited using a random number table to randomly select the subjects to review.

Monitor Visit Letters/Reports:
All monitor letters/reports received by the site are sent to the Research Supervisor for the ICARE Office of Research for review within one week of receipt. Any Significant Errors found in these letters/reports are reported using the Significant Error Alert audit tool and distributed as described above.

Responsibility:

- The ICARE Research Supervisor and Quality Auditors or designees are responsible for performing the above audit procedures and for notifying their supervisor if they are unable to complete any of the above procedures for any reason.
- The operations staff responsible for maintaining study documents is responsible for making these documents available and addressing all audit findings in a timely manner.
- The lead clinical research coordinator assigned to each study is responsible for sending copies of all monitor letters/reports to the ICARE Research Supervisor within one week of receipt.
- The ICARE Research Supervisor is responsible for reporting any Significant Errors found in the monitor letters/reports as described above.
- All IASIS employees/Principal Investigators/researchers/associates are responsible for protecting the confidentiality of all audit documents.

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