IASIS HEALTHCARE	**POLICY TITLE**: Final Report
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 1.3.1 ☐ 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 submitting final trial reports, to ensure that the sponsor and the IRB/IEC receive adequate information on the conduct of the trial after it is completed.

SCOPE:

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

DEFINITIONS:

Not Applicable

PROCEDURE:

Reports:

Upon completion of the investigator's participation in a trial, final reports are submitted as follows:

- A summary of the trial's outcome is submitted to the IRB/IEC in the format requested by the IRB/IEC.
- Any final reports requested by the sponsor are complete and submitted to the sponsor according to their specifications.

Once a study is complete and the final report has been submitted to the IRB, the investigator must continue to honor any commitments regarding the confidentiality of identifiable patient health information/study data or any other commitments that are consistent with the IRB-approved investigational plan (e.g. notification of study results to participants).

Responsibility:

- The Principal Investigator/assigned party, with assistance from applicable site operations staff, is responsible for ensuring the submission of the final report to the IRB/IEC.
- The study coordinator is responsible for ensuring that all required reports are submitted to the sponsor.
- The Principal Investigator and other members of the research team are responsible for continuing to honor any commitments regarding the confidentiality of identifiable patient health information/study data or any other commitments

FORM REFERENCES:

Not Applicable

REFERENCES:

Food and Drug Administration CFR Title 21 Part 56

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