IASIS HEALTHCARE	**POLICY TITLE**: Interim Reports to the IRB-IEC
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 1.2.7 ☐ 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 providing reports to the IRB/IEC during the course of the clinical trial, to protect patient rights, safety and welfare by informing the IRB/IEC of the progress of the study and any additional information that relates to the risk/benefit ratio.

SCOPE:

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

DEFINITIONS:

Not Applicable

PROCEDURE:

Continuing Review:

The clinical trial is submitted to the IRB/IEC for continuing review annually, or more often if required by the IRB/IEC, so long as the research is ongoing and until research-related interactions and interventions with human subjects or the obtaining/analysis of identifiable private information described in the IRB-approved research plan have been completed. The completion of the study must be communicated to the IRB in writing and the study must be properly closed or terminated by the investigative site in accordance with relevant sponsor and IRB procedures before continuing review is no longer necessary.

Documentation required for continuing review is submitted according to relevant IRB policies and procedures and must be submitted in sufficient time to allow for board review prior to the IRB approval expiration. If IRB approval should ever expire before continuing review and approval occur, the investigator must stop all research activity involving human subjects related

to that study, unless in the investigator's judgment, the ongoing participants' safety and well-being will be jeopardized by halting research participation. The IRB must be notified immediately of the study expiration and relevant IRB procedures followed with regard to the clinical investigation for which the approval has expired.

Other Reports:

In addition to reporting serious and/or unanticipated adverse events to the IRB/IEC, the following are reported promptly to the IRB/IEC:

- Deviations from the IRB-approved investigational plan that were implemented to eliminate immediate hazards to the subjects.
- Any change that increases the risk to subjects and/or affects significantly the conduct of the trial.
- New information that may affect adversely the safety of the subjects or the conduct of the trial
- Other information or reports required by the Institutional Review Board

IRB Follow-up:

- When an IRB requests information or gives instructions to the research site, the site provides the information and/or complies with the instructions promptly and within any timeframes specified by the IRB.
- Any commitments made by the site to the IRB are fulfilled accordingly.

Responsibility:

- The Principal Investigator/assigned party is responsible for ensuring that continuing reviews are submitted on time.
- The Principal Investigator/assigned party is responsible for ensuring proper, timely follow-up on IRB requests and commitments.
- The Study Coordinator is responsible for providing the necessary information to the Department of Regulatory Affairs to ensure timely submission of continuing reviews.
- The Principal Investigator and the study coordinator are responsible for ensuring that the other items above are reported to the IRB.

All research team members are responsible for complying with any special reporting requirements of the Institutional Review Board, and delegation of report completion/submission responsibilities should be made prior to study initiation to ensure timely submission of such documentation.

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:
April 30, 2016	Tedd Adair VP of Clinical Operations & CCO	Scheduled review; converted to ISO Policy Template