IASIS HEALTHCARE	**POLICY TITLE**: Medical Care
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 1.2.6 ☐ Addendum to Corporate Policy ☐ Form Available In I-REPP System
SECTION (as applicable): Clinical Research	**POLICY OWNER**: Tedd Adair, Vice President Clinical Operations and Chief Clinical Officer
ORIGINATION DATE: 01/01/2011	**FINAL APPROVAL DATE**: April 30, 2016

POLICY:

When providing medical care to research participants, to protect patient safety and welfare by ensuring proper medical care is provided throughout the subject's participation in the trial.

SCOPE:

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

DEFINITIONS:

Not Applicable

PROCEDURE:

Investigational Drug:

- The investigational drug/device is administered only to subjects under the investigator's personal supervision or under the supervision of a duly licensed sub-investigator who is responsible to the investigator.
- The investigational drug is never given to any person not authorized to receive it.

Medical Care:

- All trial-related medical decisions are made by qualified physicians who are either investigators or sub-investigators for the trial.
- During and following a subject's participation in a trial, adequate medical care is provided to a subject for any adverse events related to the trial.
- If the investigator becomes aware that medical care is needed for an intercurrent illness, the subject will be informed of this need.

Documentation of Medical Care:

- The investigator documents his/her supervision of all trial-related medical decisions by signing or co-signing all relevant patient assessments, physical examinations, progress notes, drug prescriptions, and any other medical assessments and/or decisions. In particular, the investigator signs or co-signs documentation to verify the following study-related medical decisions:
    - Decision to randomize/enroll a subject
    - Review of serious and/or unanticipated adverse events
    - Review of all study-related procedures/test results (e.g., labs, EKG's, etc.)
    - Decision to discontinue study medication for medical reasons

Lost to Follow Up:

In the event that a patient does not show for an appointment or other protocol-required activity, the study coordinator ensures that the procedures listed below are followed and documented:

- An attempt is made to reach the patient by phone. If the patient is unavailable, a message is left (if possible) asking the patient to return the call.
- If the patient does not call within a week of the phone call, a second call is placed and a message is left if possible.
- If the patient does not call within a week of the second call, a third call is placed along with a message if possible.
- If the patient does not call within a week of the third call, the patient is sent a letter via registered mail with return receipt (or any other comparable delivery method that documents receipt). The letter requests that the patient contact the study staff to make arrangements to complete any relevant protocol-specified activities and to follow up regarding any adverse events or other safety issues.
- If the patient does not contact the site within a week of receipt of the letter (or if the letter is unable to be delivered), the patient is considered "lost to follow up."
- The attempted contacts and "lost to follow up" status are documented in the source documents
- The IRB and the Sponsor is notified that the patient is lost to follow up.

Responsibility:

- The PI is responsible for personally conducting or supervising the clinical trial.
- The PI and all members of the study team are responsible for documenting the patient care they provide to the subject.
- The PI is responsible for ensuring adequate care is provided for any adverse event related to the trial and for informing a subject if care is needed for intercurrent illness.
- The PI is responsible for ensuring that the investigational drug is administered properly and only to those authorized to receive it.
- The PI is responsible for ensuring adequate back-up coverage for medical care decisions is available any time he/she is unavailable.
- The study coordinator is responsible for understanding and using the PI's system for back-up coverage for medical care decisions when needed.

The study coordinator, with support as needed from Principal Investigator/assigned party, is responsible for notifying the IRB and Sponsor of any subjects who are lost to follow up.

Documentation of Enrollment

Patient Name: _____

Study Sponsor: _____

Protocol Number: _____

Date of Decision to Enroll: _____

All pre-enrollment activities were completed according to the protocol. All study-related information was reviewed by an investigator who is a physician authorized to make medical decisions for this study. This investigator confirmed that the patient meets all inclusion and exclusion criteria and is appropriate for this study. On the date specified above, the investigator instructed the study coordinator to enroll this patient per the protocol.

Additional notes/comments: _____

_____

Study Coordinator Signature: _____

Investigator Signature: _____

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 Clinical Operations & CCO	Scheduled review; converted to ISO Policy Template