IASIS HEALTHCARE	**POLICY TITLE**: Following the Research Plan
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 1.2.4 ☐ 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 following the IRB-approved research plan, to ensure that the rights and welfare of research participants are protected by conducting all study procedures according to the IRB-approved investigational plan and amendments and to ensure proper documentation of deviations if they do occur.

SCOPE:

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

DEFINITIONS:

IRB-approved investigational plan: This includes all IRB-approved documents that describe how the research will be conducted at the site, including the IRB "application" for review (or equivalent), protocol, consent form, additional protections for vulnerable populations, etc.

Deviations/Violations:
This Guideline does not distinguish between deviations and violations; these terms may be used interchangeably. This Guideline delineates three types of deviations:

- Investigator-initiated deviations: These are errors committed by the study team with regard to following the IRB-approved investigational plan, such as failure to perform a study procedure, performing a study procedure outside of the protocol-specified timeframe, and failure to perform a study procedure according to some other protocol specification (e.g., randomization procedures, titration procedures, etc.)
- Subject-initiated deviations: These are deviations from the IRB-approved investigational plan that are initiated by the study participant and outside of the direct control of the study team, such as not showing up for a visit and not complying with medication instructions.

- Sponsor-initiated deviations: These are deviations from the IRB-approved investigational plan that are due to errors committed by the sponsor, such as failure of equipment supplied by the sponsor or failures in the randomization system used by the sponsor.

PROCEDURE:

Compliance with the Research Plan:

Given that any change in the conduct of an IRB-approved study can change the risk/benefit ratio for the research participants as well as the validity of the data being collected for the purpose of evaluating an investigational product, all studies are conducted according to the IRB-approved investigational plan. More specifically,

- No exceptions/waivers of the IRB-approved enrollment criteria are permitted, unless they have been approved in writing by the sponsor and the IRB prior to enrolling or dosing the subject. (NOTE: When inclusion/exclusion criteria are somewhat vague and subject to interpretation, some sponsors use the word "waiver" or "exception" or similar language even when they are simply approving a subject for enrollment based on their interpretation of the inclusion/exclusion criteria. ICARE/IASIS does NOT consider this to be a deviation from the IRB-approved investigational plan and, therefore, enrollment of such subjects is allowed without advance IRB approval. Advance written IRB and sponsor approvals ARE required for enrollment of any subject that does not meet the explicit enrollment criteria. Once these approvals have been obtained, it is no longer considered to be a deviation to enroll such subjects, regardless of the terminology used by the sponsor to document their approval).
- Study team members are not permitted to make changes to or deviate from the IRB-approved investigational plan, unless the changes have been approved in writing by the sponsor and the IRB prior to implementation. The only exceptions in which deviations are permitted without IRB approval are situations in which the exception/deviation is necessary to eliminate apparent immediate hazards to human subjects. If a study team member deviates from the investigational plan by mistake, the deviation is documented as described below (also see definition of "investigator-initiated" deviation above).
- If a subject wants to make changes to or deviate from the IRB-approved study procedures and these changes/deviations are outside of the control of the study team, the study team encourages the subject to comply with the investigational plan (unless the subject wants to withdraw consent). The deviation is documented as described below (also see definition of "subject-initiated" deviation above).
- If a deviation occurs due to sponsor error, the sponsor is notified and the deviation is documented as described below (also see definition of "sponsor-initiated" deviation above).

Documentation of Deviations:

Deviations are documented in one of the following ways:

1) if the sponsor has a preferred method for documenting deviations, this method is followed
2) if the sponsor does not have a preferred method, the attached form is used and filed in the subject's source documents.

Reporting Deviations:
Deviations are reported as follows:
IRB: Any deviations that were implemented to eliminate immediate hazards to the subject, that increase the risk to the subject, and/or that significantly affect the conduct of the trial are reported to the IRB (per Guideline 1.2.7).
Sponsor: Deviations are reported to the sponsor per sponsor specifications.
Institution: If the IASIS institution where the research is being conducted has an incident-reporting system, deviations that meet the institution's definition of "incident" are reported per the institution's specifications.

Responsibility:
The study coordinator and the PI are responsible for:

- Conducting the study in accordance with the relevant, current investigational plan
- Not making any changes in the research without written approval from the IRB and sponsor
- Making changes in the investigational plan only when necessary to protect the safety, rights, or welfare of subjects
- Notifying the IRB of any deviations that were implemented to eliminate immediate hazards to the subject, that increase the risk to the subject, and/or that significantly affect the conduct of the trial (per Guideline 1.2.7)

FORM REFERENCES:

Not Applicable

REFERENCES:

Food and Drug Administration

DEVIATION FORM

DEVIATION

Protocol #: _____

Subject #: _____

Study Coordinator: _____

Deviation Type:
☐ Investigator-initiated
☐ Subject-initiated
☐ Sponsor-initiated

Description of Deviation: _____

_____

_____

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ACTIONS (if any)

Dates:	Actions Taken:
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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