IASIS HEALTHCARE	**POLICY TITLE**: Guidelines - Introduction and Index
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 1.0.0 ☐ 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:

The purpose of the IASIS Investigator Guidelines is:

1) to provide consistently high quality services to our customers
2) to improve efficiency by standardizing our operations
3) to facilitate the training of new employees
4) to ensure compliance with federal regulations regarding the conduct of clinical trials

SCOPE:

All IASIS/I-CARE employees, investigators, researchers and associates are responsible for understanding the Guideline's and for following those that apply to them. The I-CARE Research Supervisor is responsible for ensuring compliance with the Guidelines by all those involved in research at an IASIS facility and for informing them when any changes are made to the Guidelines.

DEFINITIONS:

Not Applicable

PROCEDURE:

REVIEW OF GUIDELINES

Monitors and other authorized agents may review the content of the Guidelines; however they are not given copies of the Guidelines (unless authorized by law or regulation). Upon request, they may be given a copy of the index/introduction only.

CHANGES TO THE GUIDELINES

To add, delete, or revise a Guideline, the following process is followed:

1) Suggestions are forwarded to the I-CARE Research Supervisor.
2) The I-CARE Research Supervisor solicits feedback from appropriate resources (e.g., relevant staff members, industry experts, etc.).
3) If the suggestion is consistent with regulatory and institutional requirements, the I-CARE Research Supervisor initiates the formal Guideline review and approval process.
4) Once approved by appropriate institutional officials and signed by the IASIS Healthcare, Inc. signatory, the I-CARE Research Supervisor ensures that the changes are made and disseminated to the staff.

COMPLIANCE

These Guidelines are organized in accordance with the Code of Federal Regulations governed by the FDA, OHRP and ICH-GCP guidelines.

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

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PART 1
Guidelines for Conducting Clinical Trials