Introduction and Index

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## PURPOSE

The purpose of the IASIS Investigator Standard Operating Procedures 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

## RESPONSIBILITIES

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

## REVIEW OF SOP'S

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

## CHANGES TO THE SOP'S

To add, delete, or revise an SOP, 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 SOP 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 SOPs are organized in accordance with the Code of Federal Regulations governed by the FDA, OHRP and ICH-GCP guidelines.***

# INDEX

## PART 1

**Standard Operating Procedures for Conducting Clinical Trials**



## PART 2

**General Study-Related Standard Operating Procedures**