Clinical Research Enterprise (CRE)

Standard Operating Procedures

Protocol Training

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Approval:

Approved By	Date
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Revision History:	**Version**	**Effective Date**	**Description**

Purpose

The purpose of this SOP is to ensure individuals conducting clinical research within the CRE are appropriately trained in regards to the specifications of the sponsor protocol, and to ensure appropriate documentation of this training.

References

- FDA (Food and Drug Administration) requirements

Scope

This SOP applies to all members of the CRE staff.

Allowable Exceptions

This SOP is to be followed without deviation.

I. Details

Training in clinical research is critical to assuring all aspects of good clinical practices are adhered to, as well as the specifics of the protocol .

A. Training Requirements

1. The investigator will be aware of, and will comply with, GCP of the applicable regulatory requirements, and make sure all staff members are trained on the protocols.
2. The following personnel are required to complete protocol training:
    - PI
    - Sub-I
    - Coordinators
    - Research Pharmacist
    - Ancillary areas (Radiology, CRU, etc.)

3. Protocol training will be completed by the Principal Investigator and maintained throughout the duration of the site staff's involvement with the trial.

B. Training Documentation

1. Documentation of Protocol training for all CRE personnel will be saved electronically on the CRE server

II. QA

Annually, each personnel record will be reviewed for completeness.