Clinical Research Enterprise (CRE)
Standard Operating Procedures
GCP 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 good clinical practices, to identify appropriate training mechanisms, and to ensure appropriate documentation of 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, from protecting human subjects to collecting rigorous data.

A. Training Requirements

1. The investigator will be aware of, and will comply with, GCP and the applicable regulatory requirements.
2. The following personnel are required to complete GCP training:
    - PI
    - Sub-I
    - Coordinators
    - Research Pharmacist
3. GCP training will be completed via Miami CITI training website

4. GCP re-fresher courses are required every three years and are also offered via the Miami CITI training website.

B. Training Documentation

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

II. QA

Annually, each personnel record will be reviewed for completeness.