
Clinical Research Enterprise (CRE)

Standard Operating Procedure for Training of New Employees

SOP #: 1.05

Version: 1.0

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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 explain the process of training for new employees for the CRE.

Scope

This SOP applies to all members of the CRE staff.

I. Work site tour and explain the relevance of each site.

- A. UAB Hospital Units
- B. Kirklin Clinic
- C. Administrative Offices of Applicable Division
- D. Research Offices
- E. Monitor Rooms
- F. Physical Security Office
 - Burleson Building
909 18th Street South, Suite 230
Birmingham, AL 35294
 - Badge
 - Office keys
 - Pager
- G. Restroom Locations and Passcodes

II. Online Training Courses

- A. Investigation Review Board Training
 - B. Collaborative Institutional Training Initiative Good Clinical Practices
 - C. Financial Conflict of Interests in Research
 - D. UAB HIPAA Training
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- E. UAB Code of Conduct Training
- F. IRB Informed Consent
- G. IRB Investigator 101
- H. Other UAB/CRE training as necessary

III. Necessary Classes

- A. Impact/Horizon Training Class
- B. IDX training
- C. UAB Orientation
- D. OnCore
- E. Research Coordinator Training Program
- F. For those entering into arrhythmia, device training in Kirklin Clinic
- G. Other UAB/CRE training as necessary

IV. Shadowing (for Study Coordinators)

- A. Follow Lead Coordinator assigned to each study within the section during a procedure
- B. Follow Lead Coordinator assigned to each study within the section during a study visit in clinic
- C. For those entering into the Arrhythmia or Interventional section, observe various procedures in the procedural lab for a minimum of 3 days.
- D. Follow associated physician to hear the explanation of the disease and its treatment options.
- E. Observe discharge teaching if applicable
- F. Observe scheduling process if applicable
- G. Observe coordinator entering study information into electronic data capture.
- H. Observe coordinator utilizing IMPACT and OnCore
 - o Screening process
 - o Necessary information for source documentation

V. Discuss uniform compliance

VI. Kirklin Clinic Traveler Packet

VII. Specific clinical trial training with the applicable sponsors

Training