# Clinical Research Enterprise (CRE)

Standard Operating Procedure for Onboarding and Research Training of Prospective New Investigators and research staff working with the CRE

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## Purpose

The purpose of this SOP is to explain the new investigator research onboarding process including the roles and responsibilities of the Clinical Research Enterprise team and prospective new investigators. New Investigators for the purposes of this SOP will be defined as such if they have not conducted clinical research in the past or have never collaborated with the CRE on a previous study regardless of years of research experience.

## Scope

This SOP applies to all new investigators who wish to collaborating with the CRE on clinical research projects. The utilization and enforcement of this SOP process applies to all CRE regulatory staff, CRE administration, and the CRE education team.

## I. Roles, responsibilities, and expectations are outlined below for applicable CRE staff and new onboarding investigators.

## II. CRE Regulatory Staff & CRE Administrative Staff

A. Upon receiving notification that a new investigator would like to be added to or initiate a new study, the regulatory coordinator or administrative staff member will send an introductory email to the new investigator, cc'ing CRE Education team at the CRE Education email address, CRE-Education@uabmc.edu.

B. Upon receiving confirmation from the CRE Education team that new investigator has completed all UAB and CRE specified training the CRE Regulatory staff member will work on completing any IRB actions or sponsor specified trainings and documents to complete their addition to the study.

**III. CRE Education Team**

A. Upon receiving communication from CRE administrative or regulatory staff the CRE Education team member will reach out to the investigator in question with a welcome email and new investigator packet within 3 business days.

B. CRE Education team will include referring CRE regulatory staff and CRE director and CRE nurse manager on this welcome email

C. If no response is received within 2 weeks of initial email the CRE-Education team will reach back out to investigator with a follow-up email.

D. If no response is received or training completed within 1 month of initial email CRE director will reach out to discuss compliance and assistance needed with training completion

E. If no response is received and/or training remains uncompleted within 2 months of initial email, escalation will occur with Vice chair of Department of Medicine (DOM) reaching out to further assist with compliance and resolution.

**IV. CRE Administration (CRE Director, CRE Nurse Manager, Vice Chair DOM)**

A. The CRE Administrative staff will support and assist in compliance of SOP and assist CRE Education team should investigator be unresponsive or other situations arise necessitating their involvement to ensure that training is completed.

**V. New Investigator**

A. New Investigators for the purposes of this SOP will be defined as such if they have not conducted clinical research in the past at our institution or if they have never collaborated with the CRE on a previous study regardless of years of research experience.

B. Upon reaching out to begin research with the CRE, the prospective investigator will receive a welcome email and New Research Personnel Orientation Packet. Within this packet will be the Research Onboarding checklist. All items of the checklist must be completed with documentation sent to appropriate parties as outlined in the checklist before any additions to studies can be initiated.

C. All issues with completing necessary trainings should be communicated to the CRE Education team at CRE-education@uabmc.edu

D. It is the expectation that all onboarding tasks are completed within one month of request or that an alternative timeline is communicated to the CRE Education team.

E. This new SOP has been put in place to ensure that we are providing the appropriate resources and support to enable our new investigators to be successful and remain in compliance with IRB, FDA, and GCP guidelines.

# New Investigator SOP

Final Audit Report 2023-10-03

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