Clinical Research Enterprise (CRE)

Standard Operating Procedure for Completing Initial and Refresher CITI IRB and GCP training.

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

Purpose

The purpose of this SOP is to explain the roles, responsibilities, procedures, and expectations for completing Initial and Refresher CITI IRB and CGP training for studies being managed by the CRE regulatory department.

Scope

This SOP applies principal investigators (PI), all listed study staff, CRE regulatory staff, CRE Education and Compliance team members.

Allowable Exceptions

This SOP is meant to be followed without deviation. If there is a reason that this SOP cannot be adhered to it is the responsibility of that PI or listed study staff member to reach out to the head of compliance Dr. Cynthia Joiner, cirwin@uabmc.edu with a justification for this exception along with an action plan no longer 7 days after receiving notified by UAB regulatory team that training is required.

I. UAB IRB Guidance for IRB and GCP Training

A. UAB requires key personnel engaged in human subjects research complete training in human subjects protections. Training must be completed once every 3 years.
B. Initial IRB Training- All key personnel must complete an initial training course.
C. Continuing IRB Training- Initial IRB training is valid for 3 years from the date of completion. After 3 years, continuing/refresher IRB training will need to be completed. Continuing/refresher IRB training will need to be repeated every 3 years for active key personnel.
D. GCP Training- All UAB investigators and staff involved in clinical trials, regardless of funding source, are required to meet the NIH policy regarding GCP training for basic GCP training and refresher GCP training every three years.
E. Notice Number: NOT-OD-16-148: Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html

II. Roles, Responsibilities, Procedures, and Expectations are outlined below for Completing Initial and Refresher CITI IRB and GCP Training for the PI, all listed study staff, CRE Regulatory Staff, and CRE Education and Compliance team members.

CRE Regulatory Staff

A. Upon becoming aware of PI or listed study staff member needing initial or renewal CITI IRB or GCP training the CRE Regulatory staff member will reach out to person who requires training with instructions for completing training and sending completion certificate and cc the study PI (if applicable) on this communication.

B. If no response is received within 14 days (2 weeks) a second reminder email/prompt will be sent to the study staff member and PI.

C. If no response is received within 14 days of this second attempt. a 3rd reminder email will be sent to the listed study staff member and PI notifying them of 1 week deadline to remain in compliance of they will be removed from the study (if not the PI) and referred to the CRE compliance team for resolution, the CRE Education and Compliance team at cre-education@uabmc.edu will be cc'd on this communication.

D. If no response is received by the stated one-week deadline the regulatory staff will notify the CRE Education and Compliance cre-education@uabmc.edu and remove study staff member from the study. If the respondent is the PI and cannot be removed from the study, they will be place all research activities under that PI on hold.

E. Once this matter has been resolved and required information is provided to the CRE Regulatory staff, they will submit the documents as needed to the IRB. Once approved, research activities can be resumed.

CRE Education and Compliance Team

F. The CRE Education and Compliance team will assist the regulatory staff in ensuring timely completion of initial or renewal CITI IRB or GCP training.

G. Upon receiving notice of non-response to final 3rd email reminder the CRE Education and Compliance team member will reach out to the PI or study staff member in question and instruct them to cease all study activities until this matter has been resolved.

H. The PI or study staff member will be instructed to set a meeting time with the CRE Education and Compliance team to discuss the reason for non-compliance. Training completion certificates will be provided and a corrective action plan created to prevent further non-compliance.

I. If no response is received to this correspondence within 5 business days, escalation will occur with Vice Chair of Department of Medicine (DOM) reaching out to further assist with compliance and resolution.

PI and/or Delegate of the PI

J. It is the PI and/or study staff members responsibility to maintain up to date CITI IRB and GCP training and to provide the CRE regulatory team with the needed completion certificates as required by the IRB to remain in compliance with FDA mandated regulation. Completion of training is not a task that can be delegated. It is the responsibility of the study staff member or PI to complete their own training and submit requested certificates and documents to the regulatory coordinator as requested.

K. Failure to remain up-to-date with this training and provide CRE regulatory staff with this information in a timely manner represents a compliance issue that can incur further actions by the IRB, FDA, and other regulatory bodies.

L. 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.