Procedure Name: Onboarding and Training 3rd Party Individuals	Number: SOP 21 v1.0
Subject: Clinical Research	Effective Date: June 25, 2024
Linked Policy: Clinical Research Operations and Compliance Policy	Revised Date:

PURPOSE:

This Standard Operating Procedure (SOP) outlines the onboarding and training requirements for 3rd party applicants.

SCOPE:

This SOP applies to all persons engaged in clinical research projects (trials or studies) as a visitor.

RESPONSIBILITY:

This SOP sets forth the onboarding and training requirements for any 3rd party research team member who will be actively engaged in human subject research. Each research team member must keep a record of all completed trainings and must keep the trainings up to date while participating in clinical research. All research team members must provide the training record to the Office of Clinical Research, Regulatory and Compliance division, prior to engaging in any research related activities. It is the responsibility of the Principal Investigator (PI) to ensure that all research team members have completed all required trainings and have been added to the IRB application prior to participating in a research study.

PROCEDURE:

Onboarding

- All 3rd party applicants are required to complete the 3rd Party Onboarding Form. The form must be signed by the PI. Completed forms should be sent to clinicalresearch@mfa.gwu.edu.
- The form is reviewed by the Executive Associate (EA) and sent to the Executive Director of Research Operations for approval and signature.
- The Executive Associate sends onboarding information to Human Resources for processing.
- HR completes onboarding weekly on Thursdays and sends MFA IDs back to the EA.
- EA sends MFA ID numbers and a welcome email to the applicant

Procedure Name: Onboarding and Training 3rd Party Individuals	Number: SOP 21 v1.0
Subject: Clinical Research	Effective Date: June 25, 2024
Linked Policy: Clinical Research Operations and Compliance Policy	Revised Date:

which will include the 3rd Party Training Checklist and remaining onboarding instructions.

- 3rd party applicant returns the signed and completed checklist, along with IRB approval and their CITI training certificate to clinicalresearch@mfa.gwu.edu within two weeks of receiving the welcome email.
- After it is confirmed that all onboarding checklist items are completed, the EA then submits a System Access Request Form to IT to request credentials.
- IT sends credentials to Executive Director
- IT notifies the Epic team that credentials have been created.
- The EA sends the new credentials and login instructions to the 3rd party individual.
- The Epic team sends the View Only Epic access training packet to the new MFA email address.
- *If full coordinator template is necessary, this will require approval from OCR leadership*

ATTACHMENTS:

- 3rd Party Training Checklist

Office of Clinical Research

Third Party Clinical Research Training Checklist

Applicant Name: _____ Start Date_____/_____/_____

Required Trainings:

Courses/Programs	Employee initials	Completion date	Supervisor initials
CITI: GCP-expires every 3 years, HIPs, Biomedical investigator Training (within 2 weeks of hire)			
Review Institutional SOPs (as needed); sign attached attestation			
MFA HIPAA & Compliance Training (within 2 weeks of hire)			

****Please submit the completed checklist and SOP attestation to the Office of Clinical Research and file a copy in your records.**

Institutional SOP Training Attestation

I hereby confirm that I have thoroughly reviewed all institutional SOPs, completed all required training, and will abide by all institutional practices outlined in the SOPs.

Signature Date