



Procedure Name: Onboarding and Training 3rd Party Individuals	Number: SOP 21 v2.0
Subject: Clinical Research	Effective Date: May 24, 2023
Linked Policy: 3 <sup>rd</sup> Party Onboarding Policy	Revised Date: February 20, 2025

**PURPOSE:**

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

**SCOPE:**

This SOP applies to all persons engaged in clinical research projects (trials or studies) as a non-workforce member of the Medical Faculty Associates (MFA).

**RESPONSIBILITY:**

This SOP sets forth the onboarding and training requirements for any 3<sup>rd</sup> 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 and throughout the duration of their participation.

**PROCEDURE:**

Onboarding

- The onboarding process can take 3-4 weeks to complete. Individuals are not permitted to participate in research activities or engage in human subjects research until they are fully onboarded, complete all required trainings, and receive their credentials. Please plan accordingly when submitting your request.
- All 3<sup>rd</sup> party applicants are required to complete the 3<sup>rd</sup> Party Onboarding Form. The form must be signed by the PI. Completed forms should be sent to [clinicalresearch@mfa.gwu.edu](mailto: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.



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- The Executive Associate sends onboarding information to MFA Human Resources (MFA HR) for processing.
- MFA HR completes onboarding weekly and sends MFA IDs back to the EA.
- EA sends MFA ID numbers and a welcome email to the applicant which will include the 3rd Party Training Checklist and remaining onboarding instructions.
- The Training Checklist includes all required compliance trainings and must be completed in its entirety and initialed by the PI to confirm completion.
  - HIPAA training is included as part of the required training. HIPAA training sessions are one hour long and held every other Monday. All 3<sup>rd</sup> party applicants are required to attend the earliest sessions to avoid onboarding delays. HIPAA training is still required even if the applicant is only requesting GWUH specific access.
- 3rd party applicant returns the signed and completed checklist, along with IRB approval and their CITI training certificates to [clinicalresearch@mfa.gwu.edu](mailto: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 EA
- IT notifies the Epic team that credentials have been created.
- The EA sends the new credentials and login instructions to the 3<sup>rd</sup> 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*



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**ATTACHMENTS:**

- 3<sup>rd</sup> 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)			
<a href="#">Review Institutional SOPs</a> (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.**



# Office of Clinical Research

## 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.

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Signature

Date