Procedure Name: Onboarding and Training	**Number:** SOP 15 v4.0
Subject: Clinical Research	**Effective Date:** June 02, 2017
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** November 21, 2023

PURPOSE:

This Standard Operating Procedure (SOP) outlines the training requirements prior to conducting a clinical trial.

SCOPE:

This SOP applies to all persons involved with conducting clinical trials.

RESPONSIBILITY:

This SOP sets forth the training requirements for any research team member who will be actively involved in human subject research. Each research team member must keep a record of all completed trainings and mist keep the trainings up to date while participating in clinical research. All research team members must provide the trainings to the Principal Investigator (PI) or delegated regulatory official prior to conducting any research procedure. It is the responsibility of the PI to ensure that all research team members have completed all required trainings prior to participating in a research study.

PROCEDURES:

Please document all trainings on the Research Training Checklist attached to the SOP. All new research staff will be onboarded by meeting with the Executive Director of Clinical Research and the Sr. Manager of Regulatory and Compliance to go over expectations of the researcher and to review required trainings. If you are a third party employee, please review SOP 21- Onboarding and Training of Third Party Employees.

REQUIRED TRAININGS:

CITI Training
The following trainings should be completed through CITI Program. Training certificates can be accessed on the CITI webpage. Training completed under other institutions can be transferred to GWU. All trainings should be completed BEOFRE any involvement in research. **Do NOT let any of the CITI trainings expire, it is crucial to the integrity and regulatory compliance of**

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research that this training remains valid.

The following courses are required by GWU, unless specified otherwise:

- Biomedical Investigator Training: Required by GWU prior to conducting any clinical research activities and renewed every 2 years
- Health Information Privacy and Security (HIPS): Required by GWU prior to participating in research
- Good Clinical Practice (GCP)- Expires Every 3 years: Required by GWU prior to conducting any clinical research activities. Must be renewed every 3 years.
- Financial Conflict of Interest: For NIH funded projects, must be renewed every 3 years.

SOP Training
Review all institutional SOPs located on the Office of Clinical Research website under 'SOPs & Guidance Documents' within the first two weeks of hire. SOPs will be routed to all staff involved with research through Florence e-Binders. Staff will electronically sign each SOP verifying that they have reviewed all of the material.

ACRP Training
Association of Clinical Research Professionals (ACRP) is required to be completed within 2 weeks of hire date for any person involved in research. ACRP is offered through Children's National.

- To register for an account, go to the ACRP website, enter assigned GW email, and select Children's National Hospital as the organization.
- It takes about 15 hours to complete the mandatory modules.

EPIC Training
EPIC training is an online, full day course. Training should be completed within 2 weeks of hire date, depending on the availably of trainers. The training is scheduled with Informatics Training Coordinator in the IS&T Department.

OnCore Training
OnCore training should be completed within 2 weeks of hire date, depending on the availably of trainers. Training can be scheduled with Kate Weber, Sr Applications Administer for Clinical Research.

- GWID is required prior to enrolling in this training

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Institutional Trainings
HIPAA training is required annually by the institution

IATA Training: for shipping of biomedical specimens- required every 2 years unless the guidelines change requiring new training. This training is often required by industry sponsored trials. Training can be scheduled by emailing labsafety@gwu.edu.

RedCap Training
If using RedCap, training can be found here:
- Complete the RedCap Account Agreement Form.
- Online Training for RedCap is located here.

Sponsor Protocol Specific Trainings
All protocol specific trainings will be completed as outlines by each sponsor and protocol. All protocol specific trainings should be documented on a training log and filed in the regulatory binder. Please see attachments for a sample training log.

Training Records
If it is not required by the study sponsor to file the general training records with protocol specific training records, the general training records/completion certificates may be retained in a single location. Create a Note to File explaining the location of where the records/certificates are housed and file the NTF in the regulatory binder.
- Protocol specific trainings must be filed in the corresponding protocol's regulatory binder.

Review and Revision
The SOP Review Committee shall review this SOP every 2 years. This SOP may be reviewed more frequently if it does not reflect current operations.

Attachments
Sample Training Log
Clinical Research Training Checklist
IATA Training Request Form

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REFERENCES:

21 CFR 312.60	General responsibilities of investigators.
21 CFR 312.62	Investigator recordkeeping and record retention.
21 CFR 312.68	Inspection of investigator's records and reports.
21 CFR 812.40	General responsibilities of sponsors.
21 CFR 812.43	Selecting investigators and monitors.
21 CFR 812.100	General responsibilities of investigators.
21 CFR 812.110	Specific responsibilities of investigators.
21 CFR 812.140	Records.
21 CFR 812.150	Reports.
Aug2013	FDA Guidance for Industry: Oversight of Clinical Investigations- A Risk-Based Approach to Monitoring
June 2010	Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators
ICH E6 (R2)	Integrated Addendum to International Council for Harmonization (ICH) E6 (R1): Guideline for Good Clinical Practice E6 (R2)

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Oct 2015	MFA Investigational Drug Service Policies and Procedures
June 2017	GWU MFA Clinical Research SOPs
	SOP 02: Research Team Responsibilities
	SOP 03: Regulatory Binder and Study File Maintenance
	SOP 06: Source Documentation

Office of Clinical Research

Clinical Research Training Checklist

Name: _____ Hire Date_____/_____/_____

Required Trainings:

Courses/Programs	Employee initials	Completion date	Supervisor initials	Comments
CITI: GCP-expires every 3 years, HIPs, Biomedical investigator Training (within 2 weeks of hire)				
OnCore training (within 2 weeks of hire) Haneefa Johnson-Willis hwillis@mfa.gwu.edu				
Epic Training (within 2 weeks of hire) Charles Bright cbright@mfa.gwu.edu and Stephanie Dodson sdodson@mfa.gwu.edu				
IATA - Shipping Infectious Substances Category B (every 2 years) complete the form below and email it to labsafety@guw.edu				
IATA - Shipping with Dry Ice (every 2 years) complete the form below and email it to labsafety@guw.edu				
Review Institutional SOPs (as needed); sign attached attestation				
iRis (GW IRB) ohrirb@email.gwu.edu				
WIRB or Advarra (account)				
Cerner Powertrials shahrzad@gwu-hospital.com				
ACRP modules clinicalresearch.gwu.edu/training-education				

Office of Clinical Research

Clinical Research Training Checklist

Name: _____ Hire Date_____/_____/_____

As Applicable Trainings:

Courses/Programs	Employee initials	Completion date	Supervisor initials	Comments
Concur training				
Phlebotomy skill refresher				
C-SSRS				
PI Dashboard				
ClinicalTrials.gov (account setup, if needed)				
Florence e-Consent				
Redcap Training				

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

Institutional SOP Training Attestation

I hereby certify that I have thoroughly reviewed all institutional SOPs and will abide to all institutional practices outlined in the SOPs.

Signature Date

Office of Clinical Research

Office of Laboratory Safety

IATA Training Request Form

Date of Request: ___/____/____

Name of Requestor: _____

Net ID: _____ Phone Number:_____

Department: _____

PI Name: _____

PI Title: _____

Lab Number (Building, Room #s): _____

Signature: _____ Date: ___/____/____

For more information please contact our office: *Ross Hall Room B05, Extension: 4-8258, Email: labsafety@gwu.edu*

TRAINING LOG

Protocol ID: _____ IRB #: _____ PI: _____ Sponsor: _____

Trainee Name/Title (Please Print)	Trainee Signature	Training Description	Method of Training	Trainer Name/Title (Please Print if applicable)	Trainer Signature (if applicable)	Date of Training