



<b>Procedure Name:</b> Training	<b>Number:</b> SOP 15 v5.0
<b>Subject:</b> Clinical Research	<b>Effective Date:</b> June 02, 2017
<b>Linked Policy:</b> Clinical Research Operations & Compliance Policy	<b>Revised Date:</b> November 14, 2025

**PURPOSE:**

To establish the Office of Clinical Research (OCR) Human Subjects Protection and Education & Training Program requirements.

**SCOPE:**

Research team members responsible for the conduct of clinical trials with human subjects.

**RESPONSIBILITY:**

The training requirements are applicable to any research team member who will be actively involved in human subject research. Each research team member must complete and file all trainings and must keep trainings up to date while participating in clinical research. All research team members must provide proof of training 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:**

Research staff will be onboarded by the OCR. Required training will be documented by the Sr. Manager of Regulatory and Compliance. If you are a third party affiliate, please review SOP 21-Onboarding and Training of Third Party Affiliates on the [SOP & Guidance Documents](#) page.

**Human Subject Protection and Education Required Training**

Collaborative Institutional Training Initiative (CITI)

The following courses are required through [CITI Program](#).

- Health Information Privacy and Security (HIPS): Required prior to participating in research
- Good Clinical Practice (GCP): Required by GWU prior to conducting any clinical research activities. Must be renewed every 3 years.
- Biomedical Investigator Training: Required prior to conducting any clinical research activities and renewed every 2 years (CITI IRB Members training can substitute biomedical requirement.)



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- Financial Conflict of Interest: For NIH funded projects, must be renewed every 3 years.

All trainings should be completed before any involvement in research. **Do NOT let CITI trainings expire; it is crucial to the integrity and regulatory compliance of research that training remains valid.**

Training completed under prior institutions can be transferred to GWU.

Office of Clinical Research Standard Operating Procedures

Review [OCR Standard Operating Procedures](#) within the first two weeks of hire. Documentation of attestation and supervisor verification of training is required on the new hire checklist.

**Recommended Training**

Association of Clinical Research Professionals (ACRP) should be completed within 2 weeks of hire date for any person involved in research. ACRP is offered through Children’s National Hospital. To register for an account, go to the [ACRP website](#), enter assigned GW email, and select Children’s National Hospital as the organization. Recommended courses vary by role on study as coordinators, managers, & PIs.

Clinical Trial Management System (CTMS)

OnCore is the source of truth for clinical trials management and is the required CTMS for the GWU academic medical enterprise. OnCore training should be completed within 2 weeks of hire date. GWID is required prior to enrolling in this training. Refer to the [CTMS- OnCore Policy](#)

Sponsor Protocol Specific Trainings

All protocol specific trainings will be completed as outlined by each sponsor and protocol. All protocol specific trainings should be documented on a training log in the regulatory file.



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### 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 (NTF) to document the location of where the records/certificates are housed. Protocol specific trainings must be filed in the corresponding protocol's regulatory binder.

### **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.
ICH GCP E6 R3 2.0	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human use Guideline for Good Clinical Practice Investigator Responsibilities.



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**REVISIONS:**

Revision #	Date Revised	Changes Made
4	11/11/2025	Added "CITI IRB Members training can substitute biomedical requirement". ACRP training is required vs recommended. Removed Epic training. Added OnCore training. Removed IATA training and institutional trainings. Removed attachments. Removed outdated references.