



Procedure Name: Research Team Responsibilities	Number: SOP 2 v.4.0
Subject: Clinical Research	Effective Date: June 02, 2017
Linked Policy: Clinical Research Operations & Compliance Policy	Revised Date: December 16, 2025

PURPOSE:

To outline the responsibilities of the research team members, as delegated by the Principal Investigator (“PI”), of record.

SCOPE:

This procedure applies to all research team members responsible for conducting clinical research at Medical Faculty Associates (MFA) and GW University Hospital (GWUH).

RESPONSIBILITY:

This Standard Operating Procedure (SOP) defines the roles, responsibilities, and accountability of research team members engaged in the conduct of clinical research at the George Washington University (GWU), the Medical Faculty Associates (MFA), and the George Washington University Hospital (GWUH), in accordance with ICH Good Clinical Practice (GCP) E6(R3) and applicable regulatory and institutional requirements.

Consistent with ICH GCP E6(R3), the Principal Investigator (PI) retains ultimate responsibility and accountability for the ethical, scientific, and regulatory conduct of the clinical research, including the protection of research participants and the integrity and reliability of study data. While the PI may delegate specific study-related tasks to qualified research team members, such delegation does not transfer overall responsibility for study conduct.

All delegated duties must be prospectively documented on a study-specific Delegation of Authority Log prior to the performance of the delegated activities. The PI is responsible for ensuring and documenting that each individual assigned delegated responsibilities is appropriately qualified by education, training, experience, and licensure (as applicable), and is authorized to perform the assigned tasks within their institutional role and scope of practice.

In accordance with ICH GCP E6(R3), the PI shall maintain appropriate oversight of all delegated activities, commensurate with the complexity, risk, and criticality of the study, and shall ensure that delegated tasks are performed in compliance with the approved protocol, applicable regulations, and institutional policies. Documentation of delegation, qualifications, and oversight shall be maintained in the study regulatory file and made available for institutional review, monitoring, inspection, or audit. Refer to the Delegation of Responsibilities Sample Form for additional guidance.



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PROCEDURES:

1. Administrative Responsibilities

1. The research team may include, but is not limited to, the Principal Investigator (PI), research manager, research nurse, research coordinator/assistant, nursing staff, and administrative support.
2. All research team members shall be provided with clearly defined authority and responsibility guidelines through formal job descriptions or role-specific documentation. Assignment of responsibilities shall be based on institutional, departmental, and human research compliance standards.
3. Research team (depending on the role within the team) responsibilities may include, as appropriate:
 - o Interacting with subjects, study sponsors, collaborators, contract laboratories, the MFA Investigational Drug Service (IDS), federal agencies, and institutional review boards (IRBs);
 - o Preparing, maintaining, and submitting study documentation, including informed consent forms, IRB applications, recruitment materials, and correspondence;
 - o Coordinating and participating in monitoring visits, audits, and inspections;
 - o Hiring, training, and supervising research team members;
 - o Assigning qualified research staff to manage study activities; and
 - o Managing study budgets and other administrative aspects of research.

2. General Responsibilities

All research team members, including the PI, sub-investigators, research managers, research nurses, coordinators, pharmacists, and support staff, shall:

- Conduct clinical research in accordance with applicable federal and state regulations, FDA regulations and guidance, ICH GCP E6(R3), OCR SOPs, and institutional policies;
- Ensure timely communication of study-related activities to the PI; and
- Protect the safety, welfare, and rights of study participants by maintaining familiarity with study protocols, investigational products, and updated study information.



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3. Individual Responsibilities

Principal Investigator (PI)

1. Maintain overall responsibility and accountability for the conduct of the study, including adherence to ethical, regulatory, and institutional requirements.
2. Complete, sign, and date Form FDA 1572 (if applicable), listing all sub-investigators and study sites, including clinical laboratories and research laboratories as specified in the protocol. Update the 1572 form whenever there is a change in PI, sub-investigator(s), study site address, clinical laboratory, or IRB. Retain copies of all versions.
3. Ensure delegated responsibilities are documented on a study-specific Delegation of Authority Log, and that all delegated tasks are assigned only to qualified individuals whose credentials, training, and licensure (if required) are appropriate to perform the assigned duties.
4. Supervise research team members and provide oversight proportionate to the complexity and risk of the study, consistent with ICH GCP E6(R3) principles.
5. Protect participant safety and welfare by maintaining knowledge of ongoing protocols and investigational products.
6. Personally administer, or appropriately delegate the administration of, study drugs, biologics, or devices.
7. Maintain accurate records of investigational product disposition, including returns or destruction of unused materials.
8. Participate in hiring, training, and assignment of study staff as appropriate.
9. Meet sponsor requirements and engage with sponsor representatives regarding study progress.
10. Facilitate and participate in internal and external audits, monitoring visits, and regulatory inspections.
11. Ensure timely implementation of corrective and preventive actions in response to audit findings.
12. Complete all mandatory research training as required by GWU OHR or applicable IRB guidance.



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Research Manager

1. Support the PI in oversight and regulatory compliance.
2. Oversee study documentation, regulatory submissions, and maintenance of study files.
3. Hire, train, and supervise research team members.
4. Prepare and manage departmental study budgets.
5. Ensure the team meets mandatory research training requirements communicated by GWU OHR.
6. Perform additional responsibilities as defined in departmental job descriptions aligned with institutional and human resource standards.

Research Nurse / Coordinator / Data Manager

1. Develop organizational tools and checklists to support recruitment, enrollment, and accurate data collection.
2. Assist with subject recruitment, screening, informed consent discussions, and enrollment.
3. Coordinate subject participation according to ethical, regulatory, and protocol-specific requirements.
4. Participate in quality assurance activities, including monitoring visits and audits.
5. Support the preparation and maintenance of IRB documentation.
6. Complete all mandatory research training as communicated by GWU OHR.

4. Review and Revision

This SOP shall be reviewed by the SOP Review Committee at least every two years or more frequently if operational or regulatory changes warrant updates.

5. Attachments

- Sample Delegation of Authority Log

REFERENCES:

- 21 CFR 312.53 Selecting investigators and monitors.
- 21 CFR 312.60 General responsibilities of investigators.



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21 CFR 312.61 Control of the investigational drug
 21 CFR 312.62 Investigator recordkeeping and record retention.
 21 CFR 312.64 Investigator reports.
 21 CFR 312.66 Assurance of IRB review.
 21 CFR 312.68 Inspection of investigator’s records and reports.
 21 CFR 312.69 Handling of controlled substances.
 21 CFR 812.7 Prohibition of promotion and other practices.
 21 CFR 812.40 General responsibilities of sponsors.
 21 CFR 812.42 FDA and IRB approval.
 21 CFR 812.43 Selecting investigators and monitors.
 21 CFR 812.46 Monitoring investigations.
 21 CFR 812.100 General responsibilities of investigators.
 21 CFR 812.110 Specific responsibilities of investigators.
 21 CFR 812.140 Records.
 21 CFR 812.145 Inspections.
 21 CFR 812.150 Reports.
 ICH E6 (R3) Good clinical Practice E6(R3)
 ICH E6 (R2) Integrated Addendum to International Council for Harmonization
 (ICH) E6 (R1): Guideline for Good Clinical Practice E6 (R2)
[GWU, OHR Investigator Guidance Documents and IRB policies/SOPs](#)
 Oct 2015 MFA Investigational Drug Service Policies and Procedures
 WIRB Investigator Handbook [A Guide for Researchers](#)
 June 2017 GWU Clinical Research SOPs
 SOP 03: Regulatory Binder and Study File Maintenance
 SOP 08: Source Documentation
 SOP 15: Subject Recruitment

REVISIONS:

Revision#	Date Revised	Changes Made
3	12/16/2025	Added language to “Responsibility” section to cover federal guidelines and DOA. Restructured and reworded language regarding responsibilities and procedures



DELEGATION OF AUTHORITY LOG

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

Name (Please print)	Signature	Initials	Project Role ^a	Delegation Duties ^b (Please circle all that apply)	Start Date	PI Signature /Date	End Date	PI Signature /Date
				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20				
				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20				
				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20				
				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20				
				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20				
				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20				
				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20				
				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20				

a. PI = Principal Investigator; CoPI = Co-Investigator; SI = Sub-Investigator; CRC = Clinical Research Coordinator; P = Pharmacist; O = Other, specify

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|--------------------------|----------------------------|-----------------------------------|-----------------------------------|--------------------------|
| b. 1=Confirm Eligibility | 2=Obtain Informed Consent | 3=Study Related Medical Decisions | 4=Evaluation of Study Lab Results | 5=Assess Adverse Events |
| 6=Unblinding | 7=Perform Study Procedures | 8=CRF Signatures | 9=Perform Physical Exams | 10=Eligibility Screening |
| 11=CRF Completion | 12=Query Resolution | 13=Randomization/Resupply | 14=Study Drug Accountability | 15=Study Drug Dispensing |
| 16=Certify Copies | 17=Other _____ | 18=Other _____ | 19=Other _____ | 20=Other _____ |

PI Signature at Close Out: _____ Date: _____