Procedure Name: Research Team Responsibilities	**Number:** SOP 2 v.3.0
Subject: Clinical Research	**Effective Date:** June 02, 2017
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** February 23, 2023

PURPOSE:

To establish the GW Medical Faculty Associates ("MFA") procedure outlines the responsibilities of the research team members as delegated by the Principal Investigator ("PI") of record, e.g., if an IND study - the individual listed as PI on the signed Form FDA 1572.

SCOPE:

This procedure applies to all research team members responsible for conducting clinical research at MFA and GWUH.

RESPONSIBILITY:

This SOP sets forth responsibilities for research team members conducting clinical research at GWU/ MFA/GWUH. The PI retains all clinical research responsibility unless the investigator has expressly delegated specific duties to research team members and the delegation(s) is documented on a study specific Delegation of Authority Log. The PI must confirm that the individual is qualified to serve in the capacity that he/she is. delegated See Delegation of Responsibilities Sample Form.

PROCEDURES:

<u>Administrative Responsibilities</u>

1. Research staff may consist of one or more of the following research team members: the PI, research manager, research nurse, research assistant/coordinator, nursing staff and administrative assistant.
2. Individuals designated as research staff will be provided with clear authority/responsibility guidelines via appropriate supporting job descriptions. Such authority/responsibilities are determined within each department/division/practice based on established human research standards.
3. Research staff responsibilities may include one or more of the following, as appropriate:
   • Interacting/communicating with various individuals/entities involved in research including subjects, study sponsors, study collaborators, contract laboratories, the MFA Investigational Drug Service ("IDS"), federal agencies, the GWU IRB, etc.;

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- Drafting/completing/maintaining/submitting study documentation, e.g., drafting informed consent documents, IRB application and submission, recruitment letters, etc.;
- Coordinating and participating in audits and monitoring visits;
- Hiring/training members of the research team;
- Assigning trained research staff to manage clinical research; and/or
- Managing business aspects of studies, e.g., study budget.

General Responsibilities

The following general responsibilities are applicable to team members including the PI, sub-investigator, research manager, research nurses, research assistant/coordinator, study pharmacist and research support staff:

- Conduct clinical research according to applicable government regulations/guidelines, specifically, FDA regulations and guidelines governing clinical research (ICH/GCPs), these MFA Clinical Research SOPs and applicable GWU OHR research-related policies and procedures;
- Ensure that the PI is informed in a timely manner of all study-related activities through the best approach identified by the team; and
- Ensure the safety and welfare of subjects by being knowledgeable about ongoing study protocols and updated investigational information.

Individual Responsibilities of the Research Team Members

Principal Investigator

1. If applicable, complete, sign and date the Form FDA 1572 agreeing to conduct the study in accordance with the commitments listed on page 2 of the 1572. The Form FDA 1572 must include the names of all sub-investigators for the study and location of all sites where the study will be conducted (all sites where subjects will be examined). For Section 4, only clinical laboratory facilities need be included. **Research laboratories must be identified in the Protocol, and on the Form FDA 1572.**
2. A new form 1572 must be completed when the following occurs:
   - Change in PI;
   - Change in sub-investigator(s);
   - Change in address of study site;
   - Change in clinical laboratory; and/or

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- Change in IRB.

3. Keep all versions, with the most recent in front. A copy of the current 1572 can be found on the FDA website: https://www.fda.gov/media/71816/download
4. Retain knowledge of and overall authority for the conduct of clinical research, supervise members of the research team that are qualified by their education and training, as well as assume/accept the responsibilities for delegated study activities not directly performed by the PI as required by GWU OHR, MFA policy and state and federal laws
5. All delegation of responsibilities must be documented. See Sample Delegation of Authority Log. Delegation may only occur if the research team member is qualified to perform the task and the task is within the person's professional licensure if the task requires a license. Thus, such delegation determinations must be based on FDA regulations as well as local laws/regulations;
6. Protect the safety and welfare of subjects by being knowledgeable about ongoing study protocols and investigational articles;
7. Personally administer or supervise the administration of study drug/biologic/device or delegate the administration of the study drug/biologic/device to a sub-investigator or a qualified research team member;
8. Maintain adequate/accurate records of drug/biologic/device disposition including return of unused product or destruction thereof;
9. As appropriate, participate in the hiring and training of research staff and assignment of study protocols;
10. Meet specific Sponsor requirements;
11. Meet with Sponsor representatives to discuss ongoing and/or planned studies;
12. Meet with auditors (internal, IRB, Sponsor, FDA) during and at the conclusion of studies to review findings;
13. Meet with the research team, IRB, and Sponsor to review audit findings and develop corrective actions as indicated; and
14. Meet mandatory research training requirements as communicated through the GWU Office of Human Research ("OHR") or WIRB.

Research Manager

1. Work closely with the PI on the above issues. Specifics of this role within a department/division/practice should be carefully documented in a job description that satisfies applicable Human Resources standards;

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2. Oversee all regulatory and compliance issues;
3. Prepare, submit and maintain the required study documents, (e.g., IRB reports, correspondence,) regulatory and study files for each research study;
4. Hire, train and supervise research team members;
5. Prepare departmental budgets; and,
6. Meet mandatory research training requirements as communicated through the GWU OHR.

Research nurse/coordinator/data manager

1. Develop organizational aids and checklists to aid in subject recruitment/enrollment and collection of complete and accurate study data;
2. Assist in the recruitment, screening, and enrollment process, e.g., discuss eligibility, the informed consent form and research subject authorization form with potential subjects;
3. Enroll eligible subjects in studies and coordinate their participation according to ethical, regulatory and protocol-specific requirements;
4. Participate in quality assurance activities (e.g., monitoring visits, internal audits, Sponsor audits, FDA audits);
5. Assist in the preparation of IRB documents and maintenance of IRB records; and 6. Meet mandatory research training requirements as communicated through the GWU OHR.

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 Delegation of Authority Log

REFERENCES:

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

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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 (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

Office of Clinical Research

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

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: _________________________________