Procedure Name: SOP Preparation, Maintenance, Revision and Training	**Number:** SOP 1 v3.0
Subject: Clinical Research	**Effective Date:** June 21, 2017
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** June 08, 2023

PURPOSE:

To establish the GW Medical Faculty Associates, Inc. ("MFA") procedure for developing, maintaining and revising GW Medical Faculty Associates ("MFA") Clinical Research procedures ("SOP")s that are in compliance with current Food and Drug Administration ("FDA") regulations and guidelines, ICH/GCPs, and GWU IRB Research Policies and Procedures. This SOP includes required training on the SOPs and documentation of that training.

SCOPE:

This SOP applies to all persons involved with the development, maintenance and revision of MFA Clinical Research SOPs.

RESPONSIBILITY:

This SOP sets forth the responsibilities for individuals involved in the development, maintenance and revision of Clinical Research SOPs.

PROCEDURES:

<u>General Practice Procedures:</u>

1. Clinical Research SOPs must reflect current federal regulations/guidelines, ICH/GCPs, the current GWU IRB SOPs, and current MFA policies and procedures.
2. Clinical Research SOPs will be revised when there are changes to federal regulations/guidelines, ICH/GCPs, the GWU IRB SOPs or MFA research-related policies and procedures and those changes affect current SOPs.
3. The MFA Clinical Research SOP Review Committee will review MFA Clinical Research SOPs at a minimum of every 2 years. SOPs may be reviewed more frequently if SOPs do not reflect current operations. In the event that an SOP needs to be revised prior to the biannual review, the current SOP will remain in effect until the new SOP has been revised, reviewed and approved by the MFA Clinical Research SOP Review Committee

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Drafting Clinical Research SOPs:

1. Include a Table of Contents and a Glossary for all collective SOPs.
2. Include the following for each individual SOP:
   - Number
   - Title (e.g., Standard Operating Procedure for Assessing Protocol Feasibility);
   - Version Number & Date and Superseded Version Number & Date, if applicable;
   - Effective Date;
3. Utilize the following format for each SOP:
   - Applicable regulations, guidelines and polices, when applicable;
   - Purpose;
   - Scope;
   - Responsibility;
   - Procedures;
   - Review and Revision; and
   - Attachments.
4. Review draft SOP to ensure accuracy and completeness.
5. Approval of Draft Clinical Research SOPs
   a. Forward draft SOP to appropriate GWU, GWU Hospital and/or MFA research manager/director for review.
   b. Revise draft SOP, if requested.
   c. Obtain approval of SOP. SOP must be signed and dated by appropriate GWU, GWU Hospital and/or MFA research manager/director.
   d. Forward approved SOP to GWU Clinical Research SOP Review Committee for approval/concurrence and obtain approval.

Disseminating Approved Clinical Research SOP:

1. Disseminate approved SOPs to all MFA research staff.
   a. Explain the reason for the SOP (new or revised) as well as the SOP effective date. The SOP effective date should be the version date, unless otherwise indicated.
   b. Maintain a SOP Distribution List.
   c. If the SOP revises a previous SOP, collect the previous SOP.

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2. Maintain a historical archive of all previous versions of SOPs to be available in the event of an audit.
3. Revising SOPs: If revisions/additions to an SOP are needed, follow the procedure described above for drafting, approval and disseminating SOPs.

Training on Approved SOPs
1. Provide training to all research team members within one month of new or revised SOPs.
2. Provide training to newly hired research team members within one month of hire.
3. Document the scope/date of the training for each research team member.
4. Maintain a record of SOP training and review for all research team members.

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.

Contingencies
At a minimum, MFA developed Clinical Research SOPs are to be followed. MFA developed SOPs may be supplemented with any Sponsor/CRO provided SOPs