Procedure Name: Subject Screening and Enrollment	**Number:** SOP 19 v3.0
Subject: Clinical Research	**Effective Date:** July 01, 2017
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** February 15, 2023

PURPOSE:

To establish the GW Medical Faculty Associates (MFA) procedure outlines the responsibilities of the research team members when using ClinicalTrials.gov

SCOPE:

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

RESPONSIBILITY:

This SOP sets forth responsibilities for research team members involved in screening potential subjects to determine eligibility to participate in a clinical research study. The principal investigator retains this responsibility always but may delegate this duty to a research team member. This is documented on a study specific Delegation of Authority Log.

PROCEDURES:

Screening and Enrollment

- List all subjects considered for the clinical research, i.e., all subjects screened for the study, on a study specific subject screening/ enrollment log
- Identify/ list subjects using a study/screening number; do not use name or other personal identifiers.
- Discuss the eligibility criteria with the subject to see if they meet the requirements for the clinical research.
- Note the reason why a subject was not enrolled, when applicable.
- Unless otherwise IRB approved (a Partial HIPAA Waiver was submitted and approved), subjects should not be screened until they have signed an informed consent form.
- If a Partial HIPAA Waiver has been approved, study coordinators can pre-screen subjects through EPIC or other platforms like CERNER
- Templates can be found on the OCR website under “Templates”

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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 Screening Log
Sample Enrollment Log

REFERENCES:

21 CFR 312.57	Recordkeeping and record retention.
21 CFR 312.60	General responsibilities of investigators.
21 CFR 312.62	Investigator recordkeeping and record retention.
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 E6 (R2)	Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)

Office of
Clinical Research

Sample Enrollment Log

Name	Subject ID	Enrollment Date	ICF Signed? (Yes, No)	Comments

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Sample Screening Log

Name	DOB	Pre Screen Date	Eligible? (Yes/No)	Subject ID, if Eligible	Screen Failure? (Yes/No)	Comments