Procedure Name: Subject Recruitment	**Number:** SOP 12 v3.0
Subject: Clinical Research	**Effective Date:** July 01, 2004
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** June 09, 2023

PURPOSE:

This Standard Operating Procedure (SOP) outlines the procedure to follow when recruiting potential subjects to participate in clinical research studies to be conducted at GWU MFA.

SCOPE:

This SOP applies to research team members responsible for recruiting potential subjects into clinical research studies conducted at GWU MFA.

RESPONSIBILITY:

This SOP sets forth responsibilities for research team members involved in recruiting potential subjects into clinical research studies conducted at GWU MFA. The principal investigator retains this responsibility unless the investigator has expressly delegated this duty to a research team member and the delegation is documented on a study specific Delegation of Authority Log.

PROCEDURES:

Develop Recruitment Plan

Recruitment plan may consist of one or more of the following activities:

1. Records Review: Review records from patient population to determine the suitability and availability of candidates meeting the inclusion and exclusion criteria of the study protocol.
2. Community Contacts: Solicit volunteers through personal contacts in the community. Draft letters to be sent to referring physicians in the community advising them of the study and the qualifications necessary for patient participation.
3. Advertising: Possible avenues for advertising include poster, flyers, form invitational letters, public service announcements on local radio or TV stations (including community bulletin boards), newspaper ads, Web site, and various electronic media.

Requirements of Recruitment Material/Advertising

- Name and address of the investigator and/or research facility;
- Condition under study and/or the purpose of the research;
- Essential Inclusion/exclusion criteria;
- A list of participation benefits, if any (e.g., a no-cost health examination);

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- Time or other commitment(s) required of the subjects; and
- Location of the research and the person or office to contact for further information.

IRB Submission

Use of any recruitment materials that have not been IRB approved is prohibited.

Explain proposed recruitment plan in the IRB submission:

- If proposing to use radio/TV advertisements, submit a tape of the actual recording that is to be aired.
- Complete a Partial HIPAA Waiver to access PHI for Recruitment Purposes, if applicable.

Obtain IRB approval of recruitment plan and partial waiver, if applicable, before proceeding.

- An IRB approved HIPAA Partial Waiver must also be approved and signed off by the Privacy Officer of the covered entity (ie. MFA, GWUH) prior to accessing PHI for recruitment purposes.
- Implement IRB approved recruitment plan.
- Ensure that all printed recruitment materials disseminated to potential subjects are the IRB approved versions. In the regulatory binder maintain the original printed recruitment material that is IRB approved. Use of printed recruitment material that have not been IRB approved is prohibited.

Revisions to IRB Approved Recruitment Plan

- If an approved recruitment plan requires revision, submit revised plan to IRB as a protocol modification.
- If the revision requires new or revised recruitment materials, submit new/revised recruitment materials (redlined and clean versions) along with the protocol modification.
- Implement revised recruitment plan after receiving IRB approval of the modification.
- Ensure that all revised recruitment materials disseminated to potential subjects are the IRB approved versions and remove/destroy old versions that are posted.
- In the regulatory binder maintain the original printed recruitment material that is IRB approved.

Review and Revision

This SOP shall be reviewed every 2 years. This SOP may be reviewed more frequently if it does not reflect current operations.

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REFERENCES:

21 CFR 50.20	General requirements for informed consent.
21 CFR 56.109	IRB review of research.
ICH E6 (R2)	Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)
21 CFR 312.60	General responsibilities of investigators.
21 CFR 812.40	General responsibilities of sponsor.
21 CFR 814.42	FDA and IRB approval.
21 CFR 812.43	Selecting investigators and monitors.
21 CFR 812.100	General responsibilities of investigators.
21 CFR 812.110	Specific responsibilities of investigators.
GWU, OHR Investigator Guidance Documents and IRB policies/SOPs	Investigator Guidance Documents and IRB policies/SOPs
GWU MFA Clinical Research SOPs	SOP 02- Research Team Responsibilities SOP 04- Research Team Communication/Interactions with IRB