OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Study Management
	SUBJECT	Subject Recruitment and Screening
	SOP #	2.9
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	January 3, 2018

Provide the common steps in the recruitment and screening of subjects for clinical research trials. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin County Medical Center campus.

APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46	Protection of Human Subjects
21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions
DHHS	http://www.hhs.gov/ocr/hipaa/
FDA Information Sheet	Screening Tests Prior to Study Enrollment, Recruiting Study Subjects
FDA Information Sheet	Payment to Research Subjects

REFERENCES TO RELATED SOPs

SOP 2.1
SOP 2.8
SOP 2.10
SOP 2.11

ATTACHMENTS

Sample Screening Log
Sample Master Subject List

1) Identify the target population(s) for study subjects based upon study inclusion/exclusion criteria.

2) Identify sources of potential subjects.

3) Devise recruitment methods, i.e. advertising, databases, or referrals.
   a) Ensure that methods comply with HIPAA, HSRC requirements, and pertinent federal, state, and local regulations.
      i) If potentially planning to enroll subjects outside of usual care, get permission of the attending or primary care physician(s).
      ii) A representative of the outside care area must approach the subject initially about the study.
   b) The study must be approved by the HSRC before looking at PHI for recruitment purposes.

4) Develop a screening log based on inclusion/exclusion criteria. Use sponsor provided screening log if available.

5) Develop a master subject log. Use sponsor provided master subject log if available.

6) Initiate recruitment strategies.

7) Prescreen potential subjects utilizing basic, non-invasive inclusion/exclusion criteria.

8) Enter each potential candidate on the screen log.

9) Schedule a time to review the study and informed consent with the potential study subject.

10) Note on the screening log if a subject is enrolled in the study. If enrollment was not accomplished, document the reason.

11) List all enrolled subjects onto the study master subject list.

12) Assess the recruitment rate on a regular basis to ensure adequate recruitment. Institute alternative strategies if recruitment is inadequate.

SAMPLE SCREENING LOG

SCREENING DATE	SUBJECT INITIALS	ENROLLED? YES/NO	REASON FOR NON -ENROLLMENT

SAMPLE MASTER SUBJECT LIST

NAME	MEDICAL RECORD NUMBER	ADDRESS/PHONE NUMBER	ALTERNATE CONTACT INFORMATION	DATE ENROLLED	SUBJECT IDENTIFICATION NUMBER