THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-10: Subject Screening and Recruitment

1. Objective

To ensure that the Principal Investigator (PI) and all research team members assisting in the conduct of clinical research are informed about their obligations and responsibilities as they pertain to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidances, and institutional policies. This Standard Operating Procedure (SOP) applies to the written procedures followed by all members of a clinical research team involved in the conduct of human subjects' research at The Ohio State University Wexner Medical Center (OSUWMC), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

SOP-10 describes the process for subject screening and recruitment for clinical research. Attachment templates include:

- **A: Screening Log**
- **B: Subject Eligibility Criteria Checklist**
- **C: Enrollment Log**

2. Responsibility

The College of Medicine Clinical Trials Management Organization (COM-CTMO) develops, implements, and maintains SOPs. The need to write a new or revise an existing SOP is based upon changes to federal regulations, guidelines, institutional policies, or procedures. These documents will be provided to departments and research teams conducting human subjects' research. Departments or research teams may develop additional research SOPs or a Research Procedure Addendum (RPA) to expand on an existing SOP, however this need should be limited.

The PI is ultimately accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow the SOPs. The clinical research team may include but is not limited to the following members:

Research Team Members

Principal Investigator (PI)	Clinical Research Coordinator (CRC)
Sub-Investigator (Sub-I)	Clinical Research Assistant (CRA)
Clinical Research Manager (CRM)	Other Research Staff as appropriate
Clinical Research Specialist (CRS)	Administrative and Support Staff

3. Definitions

Please refer to the SOP Glossary document for detailed definitions of commonly used clinical research terminology.

4. Procedures

A. Development of Screening and Recruitment Plan

Prior to opening a research study for recruitment, the delegated clinical research team member assigned to the protocol, in collaboration with the PI, will identify the target population for potential research study subjects.

An appropriate screening and recruitment plan will be developed prior to the IRB submission for each protocol which may include, but is not limited to, physician referral and marketing materials such as broadcasts or print advertisements.

Covered entities may use and disclose PHI to researchers to aid in study screening and recruitment. This may allow a researcher to identify potential study participants if an appropriate Partial or Full Waiver of HIPAA Authorization has been approved for the research study, there is an IRB approved recruitment protocol, or the potential research subject has provided written HIPAA Authorization.

All screening and recruitment plans will be outlined in detail in the IRB submission materials for review and approval prior to implementation. If at any time additional or alternative strategies need to be implemented, the PI in collaboration with the delegated research team members will develop these and submit to the IRB for review and approval prior to implementation.

B. Screening Procedures

Based on the inclusion/exclusion criteria for a study, identify the target population for finding potential study subjects. Identify subjects who meet all criteria that are able to be assessed prior to informed consent (e.g., lab values needed to determined eligibility that are not drawn as standard of care).

Patient information from approved hospital sources may be used for screening for IRB-approved research protocols by OSU investigators and OSU research team members if one of the following is met:

- An appropriate Partial or Full Waiver of HIPAA Authorization has been approved for the research study
- There is an IRB approved recruitment protocol
- The potential research subject has provided written HIPAA Authorization

Approved hospital sources include clinical records that are controlled by Medical Information Management (MIM) and the Information Warehouse (IW).

If a screening log is not provided by the sponsor, the delegated research team member may develop a screening log based upon the study inclusion/exclusion criteria to collect screening information on all potential subjects. *(See Attachment A: Screening Log).* If a potential subject declines to enroll in a study, *no* identifiable information may be retained on that individual except in the following specific instances:

- If the study or study sponsor requires a record of individuals who were screened but not consented or enrolled, the record should *not* include any identifiable information. If identifiable information is needed, a waiver of HIPAA Authorization from the IRB or Privacy Board is required and all identifiers must be destroyed at study termination.

If an investigator wants to include information about the individual in a study-specific do-not-call or do not-contact registry, the investigator can seek a waiver of Consent and Authorization to record name, medical record number, phone number and clinic visit date. The individual must provide verbal consent to be placed on a study-specific do-not-call list with the understanding that identifiable information will be maintained by the study team.

C. Recruitment Procedures

The delegated research team members will work with the PI, Sub-Investigators, referring physicians and other clinical team members to implement an appropriate recruitment process as outlined in the examples below and ensure that appropriate institutional approvals are in place.

The delegated research team members, in collaboration with the clinical team, will be responsible for discussing the details of participation in the clinical research study. Informed consent and HIPAA authorization will be obtained from the subject prior to performing study specific procedures.

Recruitment: Without an Existing Patient Care Relationship
If an investigator or research team member does not have an existing patient care relationship (college employee) with a potential subject, the investigator or research team member may be permitted to access patient information of potential subjects for recruitment purposes by either of the following processes:

- Obtaining a partial waiver of individual HIPAA authorization for recruitment purposes from the IRB before accessing clinical patient information to identify or recruit potential research subjects to that specific IRB approved study.
- Through an IRB-approved recruitment protocol that describes how research team members will access the patient information of potential subjects for screening and recruitment purposes.

Recruitment: Existing Patient Care Relationship
If the investigator is a credentialed clinical care staff member and has an existing patient care relationship with a potential subject, then the investigator and members of the clinical treatment team (clinical care employees) who are under the direct supervision of the investigator may access patient information for identifying and contacting potential subjects for the protocol that has been approved by the IRB.

When possible, a member of the clinical care team that has an existing patient care relationship with the potential subject should introduce research team members that may not be members of the clinical team or clinical care employees to the patient and bridge the gap to discuss possible research study participation. This can be accomplished by in-person introduction or by sending an IRB approved joint letter regarding potential participation in the study to the individual. This can also be accomplished by an IRB approved phone script.

Investigators are responsible for the security of patient information used for research and must comply with the privacy and security requirements outlined by the following institutional policies:

- Use of Patient Information by Hospitals and Medical Staff Policy
- OSU Institutional Data Policy
- OSUWMC Information Security Policy
- OSU Research Data Policy
- OSU Information Security Standards
- Patient Information and HIPAA Policy

D. Determining Eligibility
The delegated research team member should develop an inclusion/exclusion checklist for each clinical research study with detailed guidelines for evaluation of patient eligibility if such a form has not been provided by the sponsor *(See Attachment B: Subject Eligibility Criteria Checklist)*. There must be source documentation to support all requirements for determining eligibility. The subject's medical history and all relevant research screening tests and procedures must meet inclusion criteria and not meet exclusion criteria. Eligibility should be based on the current IRB approved protocol; waivers of eligibility are not good practice.

After the Informed Consent Form is signed by the subject and all screening procedures are complete, the delegated research team member will review all relevant medical records (internal and external) and relevant source documents to assess the subject's full medical history. Track all consented subjects on an enrollment log *(See Attachment C: Enrollment Log).*

All tests, assessments, and procedures must be done within the protocol specified timeline. If there is no timeline specified, the sponsor should provide guidelines as to what is acceptable in writing prior to enrolling any subjects.

If the subject is deemed ineligible or wishes to not proceed with enrollment, then the delegated research team member will document the reason the subject was not enrolled in the research study and will update the Screening and/or Enrollment Log appropriately.

5. Applicable Regulations, Guidances and Policies

Regulation/ Guidance/Policy	Title
21 CFR 50	Protection of Human Subjects
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions
45 CFR 46	Protection of Human Subjects
45 CFR 160	HIPAA Privacy Rule
45 CFR 164 Subparts A and E	HIPAA Privacy Rule
42 CFR 50 Subpart F	Responsibility of Promoting Objectivity in Research (Research COI)
45 CFR 94	Responsible Prospective Contractors
OSU Office of Responsible Research Practices HRPP	Additional Requirements for Clinical Research: ICH GCP
OSU Office of Responsible Research Practices HRPP	Assent and Parental Permission
OSU Office of Responsible Research Practices HRPP	Documentation of the Informed Consent Process
OSU Office of Responsible Research Practices HRPP	Emergency Use of Investigational Drugs, Biologics or Devices
OSU Office of Responsible Research Practices HRPP	Informed Consent Process and the Elements of Informed Consent
OSU Office of Responsible Research Practices HRPP	Organizational Financial Conflicts of Interest
OSU Office of Responsible Research Practices HRPP	Planned Emergency Research
OSU Office of Responsible Research Practices HRPP	Privacy and Confidentiality

OSU Office of Responsible Research Practices HRPP	Recruiting Methods, Recruitment Materials, and Participant Compensation
OSU Office of Responsible Research Practices HRPP	Research Involving Children
OSU Office of Responsible Research Practices HRPP	Research Involving Data and or Biological Specimens
OSU Office of Responsible Research Practices HRPP	Research Involving Human Subjects
OSU Office of Responsible Research Practices HRPP	Research Involving Investigational Drugs
OSU Office of Responsible Research Practices HRPP	Research Involving Medical Devices
OSU Office of Responsible Research Practices HRPP	Research Involving Pregnant Women, Fetuses or Neonates
OSU Office of Responsible Research Practices HRPP	Research Involving Prisoners
OSU Office of Responsible Research Practices HRPP	Research Involving Radiation
OSU Office of Responsible Research Practices HRPP	Responsibilities of Principal Investigators, Co-Investigators, and Key Personnel
OSU Office of Responsible Research Practices HRPP	Review of Research by Convened IRB
OSU Office of Responsible Research Practices HRPP	Short Form Informed Consent
OSU Office of Responsible Research Practices HRPP	Vulnerable Populations: Students, Employees, and Adults Unable to Provide Consent
OSU Office of Business & Finance	Petty Cash and Change Funds
OSU Office of Research Compliance	Human Gene Transfer
OSUWMC	Use of Patient Information by Hospitals and Medical Staff
OSUWMC	Patient Information & HIPAA Requirements
OSUWMC	Information Security Policy
ICH GCP E6(R2)	Guideline for Good Clinical Practice E6 Integrated Addendum

FDA Guidance for Industry	Investigator Responsibilities- Protecting the Rights, Safety, and Welfare of Study Subjects, October 2009
FDA Guidance for Industry	A Guide to Informed Consent- Information Sheet
FDA Guidance for Industry	Payment to Research Subjects- Information Sheet
FDA Guidance for Industry	Recruiting Study Subjects- Information Sheet
FDA Guidance for Industry	Screening Tests Prior to Study Enrollment- Information Sheet

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