Ochsner Research

SOP-10: Subject Screening and Recruitment

1. Objective

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 Ochsner Health, hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research. The objective of this SOP is 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 related to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidance, and institutional policies.

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

A: Screening Log

B: Screening Checklist

C: Subject Eligibility Criteria Checklist

D: Enrollment Log

2. Responsibility

Ochsner Research 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 Centers of Excellence (COEs) and research teams conducting human subjects research. COEs 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 Principal Investigator (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 conductingstudy-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	Clinical Research Coordinator
Sub-Investigator	Associate Clinical Research Coordinator
Clinical Research Manager	Data Coordinator and Regulatory Specialist
Clinical Research Supervisor	Other Research and Administrative 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.

Patient information from approved hospital sources may be used for screening for IRB-approved research protocols by investigators and 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, or
- the potential research subject has provided written HIPAA Authorization.

Approved hospital sources include EPIC.

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 pre-screening information on all potential subjects *(See Attachment A · Screening Log)* If a potential subject is not consented, or declines to enroll in a study, *no* identifiable information may be retained on that individual except when

- 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, or
- a waiver of HIPAA Authorization from the IRB or Privacy Board is obtained, and all identifiers will 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 appropriate institutional approvals are in place *(See Attachment B Screening Checklist)*

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 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, or
- 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 who 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 OHRPP policies.

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 C 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. If a subject meets any exclusion criteria, the subject is not eligible for enrollment 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 All consented subjects will be tracked on an enrollment log. If an enrollment log is not provided by the sponsor, the delegated research team member may develop a screening log to collect relevant information on all consented subjects (See

Attachment D. 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, 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.

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Revised

Approved by W Mark Roberts, MD, Dean of Research

Signature

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