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, guidance, 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 LSU Health New Orleans, including the Health Sciences Center (HSC), the Stanley S. Scott Cancer Center (SSSCC) and the Healthcare Network (HN), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

SOP 2.08 describes the process for subject screening and recruitment for clinical research.

2. RESPONSIBILITY

The HSC, SSSCC, and HN Clinical Trials Offices develop, implement, and maintain 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)	Other Research Staff
Clinical Research Nurse Coordinator (CRNC)	Administrative and Support Staff

3. DEFINITIONS

Electronic Medical Record (EMR): An electronic (digital) collection of medical information about a person that is stored on a computer including information about a patient's health history, such as diagnoses, medicines, tests, allergies, immunizations, and treatment plans.

Eligibility: The determination that a potential subject satisfies or meets the enrollment criteria for inclusion into a clinical study. Subjects not meeting the criteria are ineligible to participate in the study.

Enrollment: The point at which a potential subject, who has met the enrollment criteria and any other study screening processes, has completed the informed consent process and is ready to actively participate in a study.

Enrollment Criteria: A set of specific criteria (demographic, physical, laboratory) that determine whether or not a potential subject can be enrolled into a clinical study. They may also be referred to as inclusion and exclusion criteria.

HIPAA Authorization: A detailed document that gives covered entities permission to use protected health information for specified purposes, which are generally other than treatment, payment or healthcare operations, or to disclose protected health information to a third party specified by the individual.

Informed Consent: The process by which a subject voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the subject's decision to participate.

Informed Consent Form (ICF): The form on which the process of conducting and achieving informed consent from potential study subjects is documented.

Screening: A planned examination and/or interview process of a potential subject to assess his or her eligibility for enrollment in a clinical study.

Screen Failure: When a potential subject does not meet one or more criteria for inclusion in a clinical study.

Please refer to the SOP Glossary document for other 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
- The potential research subject has provided written HIPAA Authorization

If a screening log is not provided by the sponsor, the research team can use the LSU Health 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 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.

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.

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, HIPAA authorization, and Acknowledgement of Notice of Privacy Practices (for treatment studies) 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.
- 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.

D. Determining Eligibility

The delegated research team member should use the LSU Health 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. There must be source documentation to support all requirements for determining eligibility. Eligibility must be verified and signed by the Principal Investigator or Sub-Investigator (either wet ink or electronic). 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. While waivers of eligibility are not good practice, in certain instances the sponsor may allow a subject to be enrolled who does not meet the inclusion/exclusion criteria. If this occurs, it should be documented as a protocol deviation.

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.

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.

5. APPLICABLE REGULATIONS AND GUIDANCE

LSU Health Guidance/Policy	Title
LSUHSC HRP Policies & Procedures	6.01 Informed Consent
LSUHSC HRP Policies & Procedures	6.02 Child Assent
LSUHSC HRP Policies & Procedures	7.02 Subject Entry Site Approval
LSUHSC HRP Policies & Procedures	7.04 Recruitment & Advertisement for Subjects
LSUHSC HRP Policies & Procedures	7.05 Educational Material for Subjects
LSUHSC Institutional Review Board	HIPAA & Research
LSUHSC Office of Compliance Programs	Privacy Requirements
LSUHSC Office of Compliance Programs	Information Security Requirements
LSUHSC Office of Compliance Programs	Penalties for Violating HIPAA Regulations
LSU System	LSU PM #36 Information Security Plan
LSUHSC Clinical & Translational Research Center (CTRC)	PM 208 SOP for Screening, Eligibility, and Enrollment on a Study

Federal/International Regulation/Guidance/Policy	Title
21 CFR 50.20	General Requirements for Informed Consent
21 CFR 50.25	Elements of Informed Consent
21 CFR 56.109	IRB Review of Research
21 CFR 56.111	Criteria for IRB Approval of Research
21 CFR 312.60	Investigational New Drug Application: General Responsibilities of Investigators
21 CFR 312.62	Investigational New Drug Application: Investigator Recordkeeping and Record Retention
21 CFR 812.20	Investigational Device Exemptions: Application
45 CFR 46	Protection of Human Subjects
ICH E6(R2)	Guideline for Good Clinical Practices E6 Integrated Addendum
FDA Guidance for Industry	Investigator Responsibilities- Protecting the Rights, Safety, and Welfare of Study Subjects
FDA Guidance for Industry	A Guide to Informed Consent- Information Sheet
FDA Guidance for Industry	Payment and Reimbursement 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

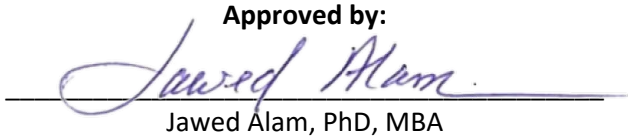
6. MATERIALS

6.1. Screening Log

6.2. Inclusion/Exclusion Criteria Checklist

6.3. Enrollment Log

Approved by:



Jawed Alam, PhD, MBA
Executive Director, Office of Research Services