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), 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 2.14 describes the process for preparing and participating in sponsor-conducted monitoring visits 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

Certified Copy: A copy of original information that has been verified, as indicated by dated signature, as an exact copy having all of the same attributes and information as the original.

Direct Access: Permission to examine, analyze, verify and reproduce any records and reports that are important to evaluation of a clinical study.

Documentation: All records, in any forms (including, but not limited to, written, electronic, magnetic and optical records; and scans, x-rays and electrocardiograms) that describe or record the methods, conduct and/or results of a study, the factors affecting a study and the actions taken.

Essential Documents: All the documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

Monitor: The person who periodically oversees the progress of a clinical study and ensures that it is conducted, recorded and reported in accordance with the protocol, SOPs, GCP and applicable

regulatory requirement(s).

Monitoring: The act of overseeing the progress of a clinical study and of ensuring that it is conducted, recorded and reported in accordance with the protocol, SOPs, GCP and applicable regulatory requirement(s).

Monitoring Report: A written report from the monitor to the Sponsor after each monitoring visit and/or other study-related communication according to the Sponsor's SOPs.

4. PROCEDURES

A. Scheduling a Monitoring Visit

The PI and delegated research team members will permit monitoring and auditing by the sponsor and inspection by the appropriate regulatory authorities. The research team will maintain a list of appropriately qualified persons to whom the PI has delegated significant clinical research study-related duties. The delegated research team member assigned to the clinical research study that will be monitored will be the main point of contact for scheduling and organizing the monitoring visit.

The PI, research team member, and monitor will arrange a mutually agreed upon date and time to conduct the monitoring visit, that allows for the appropriate scheduling of site resources (e.g., monitoring space, coordinator availability, etc.). The research team member will schedule an appropriate room for the monitor to conduct the monitoring visit and schedule any meetings with key personnel, which may be requested by the monitor. Upon request of the monitor, the investigational site must make available direct access to all requested clinical research study-related records.

If the site is using an ancillary service (e.g., Investigational Drug Service) please refer to their operating procedure for scheduling monitoring visits.

B. Preparing for a Monitoring Visit

The PI and research team member, in collaboration with other delegated research team members, should prepare for the scheduled monitoring visit by ensuring that all clinical research study-related documents are current, organized, complete, and accurate prior to the monitoring visit. They will also ensure that all requested source documents and clinical research study-related documents are available to the monitor during the monitoring visit.

If a monitor requests to review source documents directly in the electronic medical record, the PI or delegated research team member should contact the appropriate office at the study site to identify the appropriate way for the monitor to view the source documents. Acceptable, suggested methods for allowing monitors direct access include allowing the monitor over the shoulder access to the electronic medical record with a research team member; or a research team member sharing their screen showing the electronic medical record. If direct viewing is not requested, copies of the electronic source documents may be made available to the monitor. These requests will be reviewed and approved at the discretion of the study team.

The PI and delegated research team member will be prepared for the monitor to review and verify all of the following, if applicable:

General Site Review

- The PI has adequate qualifications and resources and these remain adequate throughout the clinical research study period.
- The staff and facilities, including laboratories and equipment, are adequate to safely and properly conduct the clinical research study and these remain adequate throughout the clinical research study period.
- The PI and delegated research team members are adequately informed about the clinical research study.
- The PI and the delegated research team members are performing the specified clinical research study functions in accordance with the protocol and any other written agreement between the sponsor and the investigator/institution, and the PI has not delegated these functions to unauthorized individuals.
- The investigator and delegated research team members follow the approved protocol and all approved amendments, if any.

Informed Consent

- Each subject has consented, in writing, to direct access to his/her original medical records for clinical research study-related monitoring, audit, IRB review, and regulatory inspection.
- Written informed consent was obtained and documented before each subject's participation in the clinical research study.
- The PI is enrolling only eligible subjects.

Clinical Research Data/Documents

- Source documentation, case histories, CRF entries and other clinical research study records are accurate, complete, current, and maintained.
- The PI provides all required reports, notifications, applications, and submissions, and these documents are accurate, complete, timely, legible, dated, and identify the clinical research study.
- Adverse events (AEs) are appropriately reported within the time periods required by the protocol, IRB, and applicable regulatory requirements.
- The PI and delegated research team members are maintaining the essential documents as outlined in the Essential Documents SOP.

Investigational Product

- The investigational product storage conditions are acceptable and that supplies are sufficient throughout the clinical research study.
- The investigational products are supplied only to eligible subjects and at the protocol specified doses.
- Subjects are provided with necessary instruction on properly using, handling, storing, and returning the investigational products.
- The receipt, use, and return of the investigational products at the clinical research study site are controlled and documented adequately.
- The disposition of unused investigational products complies with applicable regulatory requirement and is in accordance with the sponsor's authorized procedures.

C. Monitoring Visit

When the monitor arrives, the research team member will ensure that the monitor signs the

monitoring visit log and orient them to the investigational site facilities. They will also provide the monitor with all clinical research study documents requested for review and will check in with the monitor throughout the day to address any questions.

The PI and delegated research team member should expect to discuss deviations from the protocol, as well as SOPs, GCP, and the applicable regulatory requirements pertinent to ensuring that the investigational site takes appropriate measures designed to prevent recurrence of the identified deviations.

The monitor is expected to provide the investigational site, within a reasonable amount of time, a monitoring report that includes a summary of what the monitor reviewed and the monitor's statements concerning the significant findings/facts, deviations and deficiencies, conclusions, actions taken or to be taken, and/or actions recommended to secure compliance.

The PI and research team member will address all findings, deviations and deficiencies presented by the monitor within a specified timeline that is acceptable to the sponsor and the investigational site. Any corrective actions will be documented and filed appropriately.

5. APPLICABLE REGULATIONS AND GUIDANCE

LSU Health Guidance/Policy	Title
LSUHSC Institutional Review Board	LSUHSC HRP Policies & Procedures
LSUHSC HRP Policies & Procedures	5.02 Record Keeping by Investigators
LSUHSC Office of Compliance Programs	Electronic Data Interchange Requirements
LSUHSC Office of Compliance Programs	Privacy Requirements
LSUHSC Office of Compliance Programs	Information Security Requirements
LSUHSC Office of Compliance Programs	Compliance Training Policy
LSU System	LSU PM #36 Information Security Plan
LSUHSC Policy	Records Retention and Disposition Policy
Louisiana Secretary of State	Records Retention Schedule

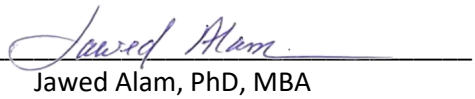
Federal/International Regulation/Guidance/Policy	Title
21 CFR 312.50	Investigational New Drug Application: General Responsibilities of Sponsors
21 CFR 312.56	Investigational New Drug Application: Review of Ongoing Investigations
21 CFR 312.59	Investigational New Drug Application: Review of Ongoing Investigations

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 312.64	Investigational New Drug Application: Investigator Reports
21 CFR 312.68	Investigational New Drug Application: Inspection of Investigator's Records and Reports
21 CFR 812.45	Investigational Device Exemptions: Informing Investigators
ICH E6(R2)	Guideline for Good Clinical Practices E6 Integrated Addendum
FDA Compliance Program Guidance Manual	Program 7348.810 Sponsors, Contract Research Organizations and Monitors
FDA Compliance Program Guidance Manual	Program 7348.811 Bioresearch Monitoring: Clinical Investigators and Sponsor-Investigators
FDA Guidance for Industry	Oversight of Clinical Investigations – A Risk-Based Approach for Monitoring

6. MATERIALS

6.1. None

Approved by:



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