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 2.19 describes the process for use of third-party healthcare providers (i.e., home health nurses) to conduct research activities.

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

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

4. PROCEDURES

A. Healthcare Providers Contracted by the Sponsor

If a sponsor decides to contract research activities out to a third-party provider to assist the LSU Health research team, the Sponsor is responsible for establishing a contract and paying the provider for services rendered.

B. Healthcare Providers Contracted by LSU Health

If an investigator decides to contract research activities out to a third-party provider, the following documents must be in place:

- Contract between LSUHSC and the third-party provider; and
- Business Associates Agreement (BAA).

The investigator and research staff are responsible for ensuring all third-party personnel are appropriately trained on the protocol and appropriate regulatory approvals are in place.

5. APPLICABLE REGULATIONS AND GUIDANCE

LSU Health Guidance/Policy	Title
LSUHSC Institutional Review Board	HIPAA & Research
LSUHSC Office of Compliance Programs	Privacy Requirements
LSUHSC Office of Compliance Programs	Use and Disclosure of Protected Health Information to Business Associates
LSUHSC Office of Compliance Programs	Checklist for HIPAA Business Associates Contracts

Federal/International Regulation/Guidance/Policy	Title

6. MATERIALS

6.1. None

Approved by:

Jawed Alam
Jawed Alam (Feb 15, 2023 11:26 CST)

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

SOP 2.19 Use of Third-Party Healthcare Providers for Research

Final Audit Report 2023-02-15

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