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Introduction**TABLE OF CONTENTS, ABBREVIATIONS, & GLOSSARY OF TERMS****Table of Contents****List of Abbreviations****Glossary of Terms****1.0 GENERAL ADMINISTRATION****SOP 1.01 Development and Maintenance of SOPs**

Describes the process for writing, training, and maintaining standard operating procedures for clinical research.

SOP 1.02 New Employee Orientation

Describes the process and documentation required for the initial and ongoing education and orientation of research team members involved in clinical research.

SOP 1.03 Contract and Budget Negotiations

Describes the key steps in creating and finalizing a Clinical Trial Agreement (CTA) and budget. When creating a budget for a clinical trial, all pertinent LSU Health policies and Medicare rules must be followed. Standard budget guidelines such as Research Floor Rates for clinical procedures/tests, standard invoiceables, and other non-patient costs shall be strictly adhered to for sponsored studies unless otherwise approved.

SOP 1.03A HSC-Specific Processes for Contracts and Budgets**2.0 STUDY TEAM ADMINISTRATION****SOP 2.01 Delegation of Responsibilities**

Describes the responsibilities of the PI and the procedures for identifying and delegating specific responsibilities to research team members for conducting clinical research.

SOP 2.02 Protocol Feasibility

Describes the process for reviewing feasibility for clinical research.

SOP 2.03 Site Qualification Visit

Describes the process for conducting a site qualification visit, also known as a pre-study site visit.

SOP 2.04 Site Initiation Visit

Describes the process for conducting Site Initiation Visits for clinical research.

SOP 2.05 Essential Document Management and Retention

Describes the process for creating and maintaining study regulatory files, subject records, and record retention which are periodically reviewed by the sponsor and may be requested by the FDA or other regulatory authorities.

SOP 2.06 Developing and Obtaining Informed Consent

Describes the process for fulfilling the regulatory and ethical requirements for developing and writing the Informed Consent Form (ICF) for clinical research; and the process for obtaining informed consent of subjects for clinical research.

SOP 2.07 Protocol Implementation

Describes the process for protocol implementation of clinical research.

SOP 2.08 Subject Screening and Recruitment

Describes the process for subject screening and recruitment for clinical research.

SOP 2.09 Protocol Compliance

Describes the process for ensuring protocol compliance and documenting and reporting protocol deviations for clinical research

SOP 2.10 Adverse Event Reporting

Describes the process for adverse event reporting for clinical research.

SOP 2.11 Research Specimen Management

Describes the process for the proper collection, handling, and management of biospecimens for clinical research.

SOP 2.12 Investigational Product Management

Describes the process for the receipt, storage, dispensing, reconciliation and return or authorized destruction of an investigational product (IP; e.g., drug or device).

SOP 2.13 Data Management

Describes the process for data management including *development of source documentation*, quality control, Case Report Form completion, data query resolution, and record retention for clinical research.

SOP 2.14 Monitoring Visits

Describes the process for preparing and participating in sponsor-conducted monitoring visits for clinical research.

SOP 2.15 Clinical Research Audits

Describes the process for preparing and participating in an audit (including internal, sponsor, IRB or FDA) for clinical research.

SOP 2.16 Payment to Human Subjects

Describes the process for payments to human subjects for clinical research.

SOP 2.17 ClinicalTrials.gov Study Registration and Record Management

Describes the process for the registration and results reporting of clinical trials to ClinicalTrials.gov.

ARCHIVED SOPs

Link to CTO Sharepoint

Approved by:



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