Introduction

TABLE OF CONTENTS, ABBREVIATIONS, & GLOSSARY OF TERMS

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:

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