THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-16: Data Management

1. Objective

To ensure 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, guidances, 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 The Ohio State University Wexner Medical Center (OSUWMC), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

SOP-16 describes the process for data management including quality control, Case Report Form completion, data query resolution, and record retention for clinical research.

2. Responsibility

The College of Medicine Center for Clinical Research Management (COM-CCRM) develops, implements, and maintains 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 or Co-I (Sub-I or Co-I)	Clinical Research Assistant (CRA)
Clinical Research Manager (CRM)	Other Research Staff as appropriate
Clinical Research Specialist (CRS)	Administrative and Support Staff

3. Definitions

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

4. Procedures

The PI or delegated research team members will create and maintain study-specific subject files for each consented clinical research study subject. This file will contain required original essential documents such as source documents used for Case Report Form (CRF) data elements, original signed informed consents, assents, HIPAA authorization forms, protocol deviations, Adverse Event and SAE reports, and Notes to File.

The OSU Office of Responsible Research Practices (ORRP) policy states that all research-related records need to be maintained for at least 3 years after the research has ended, unless longer is required by other entities (sponsor, contractual requirement, patent requirements, publication, FDA, etc.). However, the primary research data, as outlined in the ORRP research data policy, must be retained at Ohio State for a minimum of 5 years after final project closeout.

For an FDA regulated study:
Drugs/Biologics: An investigator shall retain records for a period of 2 years following the date a marketing application is approved for the drug indication being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

Device: An investigator or sponsor shall maintain the records for a period of 2 years after the latter of the following two dates:

1. The date on which the investigation is terminated or completed, or
2. The date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

A. Source Documentation

Source data is information from the original records, or certified copies of original records, with clinical findings, observations, or other activities in a clinical research study necessary for the reconstruction and evaluation of the clinical research study.

Source data are contained in source documents (original records or certified copies). Source documents are the original documents containing data for a clinical research study. These documents may be paper or electronic.

All source documents and data containing protected health information (PHI) will be kept confidential and secured per institutional policies.

Examples of acceptable source documentation may include, but are not limited to, the following:

- Electronic Medical Records
- Paper medical records
- Pharmacy records
- Subject diaries or questionnaires
- Lab reports
- Physician progress notes
- Radiology images and reports
- Nurse notes
- Research notes
- Notes to File
- Emails
- Clinical research study flow sheets and worksheets
- Original signed Informed Consent Forms

All pertinent source documentation should be recorded, handled, and stored in a manner that allows accurate reporting, interpretation, and verification. The investigator should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial subjects. Source data should meet ALCOAC-CEA criteria:

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
- Complete
- Consistent
- Enduring
- Available

All source documentation should clearly identify the research subject and contain the signature and date of the person who created the source document.

Any change or correction to a source document will be dated, initialed, and explained (if necessary) and will not obscure the original entry. There will be a single line through the error in a paper source document with the initials of the person correcting the error and the date corrected. Any changes to electronic record will reflect the user, date and time, but the original entry will be maintained. An audit trail will be visible for all source documents.

Case histories include CRFs and supporting source documentation including signed and dated consent forms and medical records such as progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.

Only Medical Information Management (MIM) can certify the medical record at OSUWMC.

B. Data Entry

CRFs may be provided by a sponsor and can either be electronic or paper. If CRFs are required for investigator-initiated studies, they will be developed by the investigational site based on the protocol and in collaboration with the PI and biostatistician (as needed). Generally, CRFs will not be used as source documents. If data is entered directly into the CRFs, this must be clarified in the study regulatory files.

CRFs collect relevant data in a specific format to allow for easy statistical analysis in accordance with the protocol and in compliance with regulatory requirements. Final CRFs for investigator-initiated clinical research studies will be submitted to the IRB at the time of initial protocol review. CRFs will be updated and approved as needed.

Data recorded on the CRFs, which are derived from source documents, should be consistent with the source documents or the discrepancies should be explained. The investigator will ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.

Any change or correction to a CRF will be dated, initialed, and explained (if necessary) and will not obscure the original entry. An audit trail will be visible. This applies to both written and electronic changes and corrections.

Data should be collected, entered, and submitted promptly and within the timeframe required by the sponsor or specified in the protocol, if applicable. Data should be completed using a ball-point pen when using paper CRFs.

If queries or data clarification forms are issued by the sponsor, they should be resolved promptly and within the timeframe provided by the sponsor. Errors will be corrected and submitted according to the method provided by the sponsor. Copies of queries or data clarification forms will be kept on file.

Upon request of the monitor, auditor, IRB, or regulatory authority, the PI and delegated research team members will make available direct access to all requested clinical research study related records including original source documents and CRFs for review during a monitoring visit or an audit.

Sponsor monitors and auditors may be granted limited view-only access to subject medical records to verify source documentation. The appropriate research access process will be followed as required by the OSU Wexner Medical Center Privacy Office.

C. Data Security

Please refer to university data policies and other regulations to determine how to securely save research data.

Please utilize the Institutional Data Policy (IDP) calculator provided by The Ohio State University Cybersecurity Department to determine the Institutional Data Element Classification Assignment and appropriate storage method for study records.

5. Applicable Regulations, Guidances and Policies

Regulation/ Guidance/Policy	Title
21 CFR 11	Electronic Records; Electronic Signatures
21 CFR 50	Protection of Human Subjects
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions
45 CFR 46	Protection of Human Subjects
45 CFR 160	HIPAA Privacy Rule
45 CFR 164 Subparts A and E	HIPAA Privacy Rule
OSU Office of Responsible Research Practices HRPP	Additional Requirements for Clinical Research: ICH GCP

OSU Office of Responsible Research Practices HRPP	Data and Safety Monitoring
OSU Office of Responsible Research Practices HRPP	Documentation of the Informed Consent Process
OSU Office of Responsible Research Practices HRPP	Event Reporting
OSU Office of Responsible Research Practices HRPP	Privacy and Confidentiality
OSU Office of Responsible Research Practices HRPP	Research Involving Human Subjects
OSU Office of Responsible Research Practices HRPP	Research Involving Investigational Drugs
OSU Office of Responsible Research Practices HRPP	Research Involving Medical Device
OSU Office of Responsible Research Practices HRPP	Research Performance Sites and Collaborative Off-Site Research
OSU Office of Responsible Research Practices HRPP	Responsibilities of Principal Investigators, Co-Investigators, and Key Personnel
OSU Office of Research	Research Data Policy
OSU Office of Research Compliance	Human Gene Transfer
OSU Office of the Chief Information Officer	Institutional Data Policy
OSUWMC	Use of Patient Information by Hospitals and Medical Staff
OSUWMC	Patient Information & HIPAA Requirements
OSUWMC	Photography of Patients
OSUWMC	Information Security Policy
OSUWMC Investigational Drug Services	IDS Policies and Procedures
COM Office of Human Resources	Training & Assessment Requirements
ICH GCP E6(R2)	Guideline for Good Clinical Practice: E6 Integrated Addendum
FDA Guidance for Industry	Investigator Responsibilities- Protecting the Rights, Safety, and Welfare of Study Subjects, October 2009

FDA Guidance for Industry	FDA Inspections of Clinical Investigators Information Sheet, June 2010
FDA Guidance for Industry	Computerized Systems used in Clinical Investigations, May 2007
FDA Guidance for Industry	Part 11, Electronic Records, Electronic Signatures- Scope and Application, August 2003
FDA Guidance for Industry	Adverse Event Reporting to IRBs- Improving Human Subject Protection, January 2009
FDA Compliance Program Guidance Manual	Program 7348.11 Bioresearch Monitoring: Clinical Investigators and Sponsor-Investigators
FDA Guidance for Industry	Oversight of Clinical Investigations- A Risk-Based Approach to Monitoring, August 2013
FDA Guidance for Industry	Sponsor- Investigator- IRB Interrelationship- Information Sheet
FDA Guidance for Industry	Frequently Asked Questions- Statement of Investigator (Form FDA 1572), May 2010
FDA Guidance for Industry	Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials, October 2008
FDA Guidance for Industry	Electronic Source Data in Clinical Investigations

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