



THE OHIO STATE UNIVERSITY

WEXNER MEDICAL CENTER

SOP-06: Essential Document Management and Retention

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, 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-06 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. Attachment templates include:

- A: Essential Document Checklist**
- B: Regulatory Documents Checklist**
- C: IRB Submission Checklist**
- D: Study Termination Checklist**

2. Responsibility

The College of Medicine Clinical Trials Management Organization (COM-CTMO) 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 (Sub-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

A. Prior to Clinical Research Implementation

The PI or delegated research team members will create and maintain study regulatory files for each clinical research study that will contain required, original, and revised essential documents (*See Attachment A: Essential Document Checklist and Attachment B: Regulatory Documents Checklist*).

All study-related essential regulatory and subject case history documents will be kept confidential and stored in a secure and limited access location, meeting institutional privacy and security policy expectations. Upon request of the monitor, auditor, IRB, sponsor or regulatory authority, the PI and delegated research team members will make all essential documents available for review.

The PI or delegated research team members will provide the IRB with a complete IRB application, a current copy of the protocol, investigator brochure, investigator manual, consent/assent forms, HIPAA authorization form, IND or IDE FDA information, data collection forms, recruitment materials and any additional required documentation for review (*See Attachment C: IRB Submission Checklist*).

A research study will be registered to ClinicalTrials.gov if deemed an Applicable Clinical Trial by study design or funding source (e.g., NIH). Studies may also register for publication purposes.

The investigational site will receive written and dated approval from the IRB and other regulatory bodies, if required, for the protocol, Informed Consent Form, HIPAA authorization, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects prior to implementing any study activities.

B. During the Conduct of the Research Study

The PI or delegated research team members will create and maintain study specific subject files for each consented clinical research subject. These files will contain required original essential documents such as source documents used for case report form data elements, original signed Informed Consent Forms (ICF) and HIPAA authorization forms, protocol deviations, adverse events (AE), Case Report Forms (CRF) and Serious Adverse Event (SAE) reports (*See Attachment A: Essential Document Checklist*).

During the conduct of the study the PI and delegated research team members will provide to the IRB all documents subject to review, such as:

- Amendments to the protocol, Informed Consent Form, Investigator's Brochure, or other approved materials
- Addition/removal of Sub-Investigators and key personnel
- Continuing Review documents
- Subject safety information
- IND safety reports, protocol deviations, Data Safety Monitoring Committee (DSMC) reports (if required)
- Adverse Events and Serious Adverse Events

The PI or delegated research team member will submit written summaries of the study's status to the reviewing IRB, as part of the annual renewal process, which will occur at least annually. Under specific conditions IRB-approved research may undergo annual continuing review via expedited or administrative review. In some cases, a brief annual status report can be submitted for administrative review. The PI or delegated research study team member will also promptly provide written reports to the sponsor and IRB, where required by the applicable regulatory requirements, on any changes significantly affecting the conduct of the study and/or increasing the risk to subjects. This may include any changes to:

- Protocol
- Informed Consent Form
- Safety of the investigational product (including IND safety reports)

The PI or delegated research team members will ensure that the study regulatory files are organized, complete and accurate. Any additional documentation created or received over the course of the study will be filed appropriately. All original documents will be maintained and revised documents will be added to the study regulatory file (*See Attachment B: Regulatory Documents Checklist*).

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 criteria:

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
- Complete

Changes to source documentation should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., via an audit trail). When corrections are necessary, the original entry should be struck through by a single line and indicate the date, reason for correction, and the initials as found on the Delegation of Authority Log of the individual making the correction.

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

C. Termination (Closure) of the Study

To prepare for a study termination/close-out visit with the sponsor, the PI or delegated research team member will:

- Review all study regulatory files for accuracy and completeness.
- Resolve all outstanding sponsor queries.
- Reconcile all investigational study product accountability and shipment records.
- Evaluate requirements for data storage and prepare for a potential sponsor quality assurance review or FDA inspection (*See Attachment D: Study Termination Checklist*).
- Update ClinicalTrials.gov status and report results (if applicable).

The PI or delegated research team member will notify the IRB of record, the Office of Responsible Research Practices (ORRP), the Research Billing Office (RBO) and the Office of Sponsored Programs (OSP) when the study has been closed. The notification to the IRB, at a minimum, will include the number of subjects enrolled, notice that all Serious Adverse Events have been reported (if required), subject withdrawals from study, and deaths on study, if any, have occurred. The sponsor will also receive a copy of this report from the site. The investigational site will ensure the return or destruction of all study-related materials.

If the study is terminated prematurely or suspended for any reason, the PI or delegated research team member will promptly inform the study subjects, ensure appropriate therapy and follow-up for the subjects receiving intervention/treatment, and, inform the regulatory authorities including the IRB of record and the FDA (if applicable).

If the PI terminates or suspends a study without prior agreement from the sponsor, the investigator will inform the sponsor and the IRB and provide a detailed written explanation of the termination or suspension.

If the sponsor terminates or suspends a study, the PI will promptly inform the IRB and provide the IRB a detailed written explanation of the termination or suspension.

If the IRB terminates or suspends its approval of a study, the PI will promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

Upon closure of the study the PI will provide the sponsor with all required reports, the IRB with a summary of the study outcome, and any regulatory authority that may require a report.

D. Essential Document Retention

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

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.

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 54	Financial Disclosure by Clinical Investigators
21 CFR 56	Institutional Review Boards
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

42 CFR 50 Subpart F	Responsibility of Promoting Objectivity in Research (Research COI)
45 CFR 94	Responsible Prospective Contractors
ICH GCP E6(R2)	Guideline for Good Clinical Practice E6 Integrated Addendum
OSU Office of Responsible Research Practices HRPP	Additional Requirements for Clinical Research: ICH GCP
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	Informed Consent Process and the Elements of Informed Consent
OSU Office of Responsible Research Practices HRPP	IRB Actions and Communications
OSU Office of Responsible Research Practices HRPP	IRB Submission and Pre-Review
OSU Office of Responsible Research Practices HRPP	Organizational Financial Conflicts of Interest
OSU Office of Responsible Research Practices HRPP	Privacy and Confidentiality
OSU Office of Responsible Research Practices HRPP	Recruitment Methods, Recruitment Materials and Participant Compensation
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 Devices
OSU Office of Responsible Research Practices HRPP	Responsibilities of Principal Investigators, Co-Investigators, and Key Personnel
OSU Office of Responsible Research Practices HRPP	Review of Research by Convened IRB
OSU Office of Responsible Research Practices HRPP	Short Form Informed Consent
OSU Office of Responsible Research Practices HRPP	Suspension and Termination of IRB Approved Research
OSU Office of Research	Institutional Biosafety Policy
OSU Office of Research	Research Data Policy

OSU Office of Research Compliance	Conflict of Interest
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
FDA Guidance for Industry	Investigator Responsibilities- Protecting the Rights, Safety, and Welfare of Study Subjects, October 2009
FDA Guidance for Industry	IRB Continuing Review after Clinical Investigation Approval, February 2012
FDA Guidance for Industry	A Guide to Informed Consent- Information Sheet
FDA Guidance for Industry	Adverse Event Reporting to IRBs- Improving Human Subject Protection
FDA Guidance for Industry	Oversight Clinical Investigations Risk-Based Approach Monitoring
FDA Guidance for Industry	Frequently Asked Questions- Statement of Investigator (Form FDA 1572), May 2010
FDA Guidance for Industry	Electronic Source Data in Clinical Investigations

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