THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-17: Monitoring Visits

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-17 describes the process for preparing and participating in sponsor-conducted monitoring visits for clinical research.

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. Scheduling a Monitoring Visit

The PI and delegated research team members will permit monitoring and auditing by the sponsor and inspection by the appropriate regulatory authorities. The research team will maintain a list of appropriately qualified persons to whom the PI has delegated significant clinical research study-related duties. The delegated research team member assigned to the clinical research study that will be monitored will be the main point of contact for scheduling and organizing the monitoring visit.

The PI, research team member, and monitor will arrange a mutually agreed upon date and time to conduct the monitoring visit, that allows for the appropriate scheduling of site resources (e.g., IHIS access, monitoring space, coordinator availability, etc.). The research team member will schedule an appropriate room for the monitor to conduct the monitoring visit and schedule any meetings with key personnel, which may be requested by the monitor. Upon request of the monitor, the investigational site must make available direct access to all requested clinical research study-related records.

If the site is using an ancillary service (e.g., Investigational Drug Service) please refer to their operating procedure for scheduling monitoring visits.

B. Preparing for a Monitoring Visit

An agreement should be secured from all involved parties to ensure direct access to all clinical research study-related sites, source documentation, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by regulatory authorities.

The PI and research team member, in collaboration with other delegated research team members, should prepare for the scheduled monitoring visit by ensuring that all clinical research study-related documents are current, organized, complete, and accurate prior to the monitoring visit. They will also ensure that all requested source documents and clinical research study-related documents are available to the monitor during the monitoring visit.

When appropriate, the PI or delegated research team member will request monitor access to the electronic medical record to review source documents directly in the system. *Please note that this request takes two weeks to process.* If direct access is not requested, copies of the electronic source documents will be made available to the monitor on the day of the visit.

The PI and delegated research team member will be prepared for the monitor to review and verify all of the following:

General Site Review

- The PI has adequate qualifications and resources and these remain adequate throughout the clinical research study period, and that the staff and facilities, including laboratories and equipment, are adequate to safely and properly conduct the clinical research study and these remain adequate throughout the clinical research study period.
- The PI and delegated research team members are adequately informed about the clinical research study.
- The PI and the delegated research team members are performing the specified clinical research study functions in accordance with the protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.
- The investigator and delegated research team members follow the approved protocol and all approved amendments, if any.

Informed Consent

- Each subject has consented, in writing, to direct access to his/her original medical records for clinical research study-related monitoring, audit, IRB review, and regulatory inspection.
- Written informed consent was obtained before each subject's participation in the clinical research study.
- The PI is enrolling only eligible subjects.

Clinical Research Data/Documents

- Source documentation, case histories, CRF entries and other clinical research study records are accurate, complete, current, and maintained.
- The PI provides all required reports, notifications, applications, and submissions, and these documents are accurate, complete, timely, legible, dated, and identify the clinical research study.
- Adverse events (AEs) are appropriately reported within the time periods required by the protocol, IRB, and applicable regulatory requirements.
- The PI and delegated research team members are maintaining the essential documents as outlined in the Essential Documents SOP.

Investigational Product

- The investigational product storage conditions are acceptable and that supplies are sufficient throughout the clinical research study.
- The investigational products are supplied only to eligible subjects and at the protocol specified doses.
- Subjects are provided with necessary instruction on properly using, handling, storing, and returning the investigational products.
- The receipt, use, and return of the investigational products at the clinical research study site are controlled and documented adequately.
- The disposition of unused investigational products complies with applicable regulatory requirement and is in accordance with the sponsor's authorized procedures.

C. Monitoring Visit

When the monitor arrives, the research team member will ensure that the monitor signs the monitoring visit log and orient them to the investigational site facilities. They will also provide the monitor with all clinical research study documents requested for review and will check in with the monitor throughout the day to address any questions.

The PI and delegated research team member should expect to discuss deviations from the protocol, as well as SOPs, GCP, and the applicable regulatory requirements pertinent to ensuring that the investigational site takes appropriate measures designed to prevent recurrence of the identified deviations.

They should also be prepared to discuss CRF entry error, omission, or illegibility with the PI and delegated research team members and ensure that appropriate corrections, additions, or deletions are made, dated, explained (if necessary), and initialed by the PI or by a member of the research team who is authorized to initial CRF changes for the PI.

The monitor is expected to provide the investigational site, within a reasonable amount of time, a monitoring report that includes a summary of what the monitor reviewed and the monitor's statements concerning the significant findings/facts, deviations and deficiencies, conclusions, actions taken or to be taken, and/or actions recommended to secure compliance.

The PI and research team member will address all findings, deviations and deficiencies presented by the monitor within a specified timeline that is acceptable to the sponsor and the investigational site. Any corrective actions will be documented and filed appropriately.

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
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	Informed Consent Process and the Elements of Informed Consent
OSU Office of Responsible Research Practices HRPP	Noncompliance
OSU Office of Responsible Research Practices HRPP	Privacy and Confidentiality
OSU Office of Responsible Research Practices HRPP	Recruiting Methods, Recruitment Materials, and Participant Compensation
OSU Office of Responsible Research Practices HRPP	Research Involving Data and or Biological Specimens
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	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 Responsible Research Practices HRPP	Review of Research by Convened IRB

OSU Office of Responsible Research Practices HRPP	Suspension and Termination of IRB Approved Research
OSU Office of Responsible Research Practices HRPP	Vulnerable Populations: Students, Employees, and Adults Unable to Provide Consent
OSU Office of Research	Research Data Policy
OSU Office of Research Compliance	Human Gene Transfer
OSU Office of Research Compliance	Research Misconduct
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	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	IRB Continuing Review after Clinical Investigation Approval, February 2012
FDA Guidance for Industry	Screening Tests Prior to Study Enrollment- Information Sheet
FDA Guidance for Industry	FDA Inspections of Clinical Investigators- Information Sheet, June 2010
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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