THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-08: Site Initiation 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-08 describes the process for conducting Site Initiation Visits 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 Site Initiation Visit (SIV) prepares the research site to conduct the research study. This meeting generally takes place after the investigational site has received IRB approval and a Clinical Trial Agreement (CTA) has been fully executed. In addition, the SIV should occur prior to the first subject enrollment. The PI or member of the research team will schedule and arrange the SIV which can be conducted in person, on-line, or via conference call at the discretion of the sponsor. The SIV is led by the sponsor representative and provides protocol training for the PI, Sub-I(s), and delegated research team members.

Delegated research team members involved in supervising, managing, or conducting study-related activities should have all required study documents available for review prior to and during the SIV.

The PI will personally conduct or supervise the clinical research study to ensure the investigation is conducted according to the signed investigator statement, the investigational plan, GCP, and applicable regulations.

The PI and delegated research team members will be qualified by education, training, and experience to assume responsibility for the proper conduct of the research study, will meet all the qualifications specified by the applicable regulatory and sponsor requirements, and will provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB and/or other regulatory authorities.

The PI and delegated research team members will ensure all persons assisting with the research study are adequately informed about the protocol, the investigational products, and their research study-related duties and functions. These individuals will be informed about their obligations, will have adequate education and training to conduct the tasks delegated, and delegation will be documented appropriately.

Aspects of conducting the clinical research study will be reviewed at the SIV including, but not limited to the following:

- Study objectives
- Regulatory requirements
- Regulatory documents and file management
- Appropriate patient screening procedures
- Inclusion and exclusion criteria
- Schedule of events
- Study procedures and study specific forms
- Investigational product accountability and management
- Adverse events and protocol deviation reporting
- Source documentation
- Case report form completion
- Data management

The Sponsor representative will obtain the investigator's agreement to conduct the research study in compliance with GCP, applicable regulatory requirements, and the protocol which has been agreed to by the sponsor and approved by the IRB.

The Sponsor representative will ensure the investigator and delegated research team members agree to comply with procedures, expected turn-around time for data reporting, and permit study monitoring, auditing,

and inspection. The sponsor and the investigator/institution should sign the protocol, or an alternative document/contract, to confirm these agreements.

The Sponsor representative should present the information for the SIV. After the SIV is complete, the PI or delegated research team will follow up on any outstanding items. Once all outstanding items have been addressed the site should be officially activated by the sponsor to begin subject enrollment.

5. Applicable Regulations, Guidances and Policies

Regulation/ Guidance/Policy	Title
21 CFR 50	Protection of Human Subjects
21 CFR 54	Financial Disclosure by Clinical Investigators
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
49 CFR 107	Transportation: Hazardous Materials Program Procedures
49 CFR 171	Transportation: General Information, Regulations, and Definitions
ICH GCP E6(R2)	Guideline for Good Clinical Practice E6 Integrated Addendum
OSU Environmental Health & Safety	Research/Biosafety Programs and Services

OSU Office of Responsible Research Practices HRPP	Additional Requirements for Clinical Research: ICH GCP
OSU Office of Responsible Research Practices HRPP	Event Reporting
OSU Office of Responsible Research Practices HRPP	Noncompliance
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	Recruiting Methods, Recruitment Materials, and Participant Compensation
OSU Office of Responsible Research Practices HRPP	Responsibilities of Principal Investigators, Co-Investigators, and Key Personnel
OSU Office of Business & Finance	Petty Cash and Change Funds
OSU Office of Research	Institutional Biosafety Policy
OSU Office of Research	Research Data Policy
OSU Office of Research Compliance	Human Gene Transfer
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 Service	IDS Policies and Procedures
FDA Form 1572	Statement of the Investigator
FDA Guidance for Industry	Investigator Responsibilities- Protecting the Rights, Safety, and, Welfare of Study Subjects, October 2009

FDA Guidance for Industry	Frequently Asked Questions- Statement of Investigators (Form FDA 1572), May 2010

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