THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-09: Protocol Implementation

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-09 describes the process for protocol implementation of clinical research. Attachment templates include:
A: Protocol Implementation Checklist

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

After IRB approval and the sponsor Site Initiation Visit (if applicable), the delegated research team members should complete the Protocol Implementation Checklist *(See Attachment A: Protocol Implementation Checklist)* or other similar form. This should be completed prior to enrolling subjects to the clinical research study.

The PI and delegated research team members will ensure that:

- The budget is finalized, and the contract is executed with appropriate OSP account created.
    - *Note*: A device purchase agreement may be required and is independent of the study contract. Please contact hospital purchasing, as applicable.
- The Research Billing Office has been notified of the study and the study has been added to the hospital Research Master File to allow for appropriate billing of services and flagging of subjects within the Electronic Health Record.
- All essential regulatory documents are completed, organized, and filed appropriately.
- All Sub-Investigators and key personnel will have IRB acknowledgment for their role in the study.
- Written IRB approval for the study and supportive study documents have been received and final documents are available to the study team.
- Study activities are conducted only after IRB approval and in accordance with the approved protocol.
- All study products, laboratory supplies, and Case Report Forms (CRFs) have been created or received and have been documented and accounted for.
- All protocol specific documentation, worksheets, and checklist tools are finalized and available to the research team.
- Study-specific source documents, as well as screening and enrollment materials, are prepared.
- Any applicable in-service and training sessions with the research team members and ancillary support staff have been completed.
- The site is in receipt of an adequate investigational product (IP) supply and records are maintained for delivery and inventory. Appropriate IP security and storage are available.
- A delegated primary research team member has been identified and assigned to the research study.
- If applicable, the PI and all delegated research team members are thoroughly familiar with the appropriate use of the IP as described in the protocol, the current Investigator's Brochure, and in other information provided by the sponsor.
- The Delegation of Authority Log will be updated and outline specific roles and responsibilities delegated by the PI to the research team members.

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. The delegated team members will meet all the qualifications specified by the applicable regulatory and sponsor requirements. Evidence of such qualifications will be provided through a current curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.

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
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 Services	IDS Policies and Procedures
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	Frequently Asked Questions - Statement of the Investigator (Form 1572), May 2010

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