THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-01: Writing, Training, and Maintenance of SOPs

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-01 describes the process for writing, training, and maintaining standard operating procedures for clinical research. Attachment templates include:

A: SOP Template
B: RPA Template
C: SOP Training & Compliance Form
D: SOP Revision History Log

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. Department Procedure for Writing SOPs or RPAs

The writing of the department research SOP or RPA may be delegated to an appropriate member of the clinical research team.

The SOP or RPA content will contain enough details to guide clinical research team members through a particular procedure and establish uniformity in the daily operations of the department. Processes should be established that can be followed without deviation and that can be easily implemented.

The SOP format, at a minimum, will contain the following elements: Title, , Effective Date, Department Name, Signature and Approval Date lines, Objective, Responsibility, Definitions, Procedures, Applicable Regulations, Guidelines and References to other SOPs, and Attachments *(See Attachment A: SOP Template)*.

The RPA format, at a minimum, will contain the following elements: Addendum Title, Reference of COM SOP Title and, Addendum Effective Date, Objective, and Procedures *(See Attachment B: RPA Template)*.

The appropriate department administrator, director, or PI will review, sign and date the final SOP or RPA for approval. Addendums developed by the department or research team will be maintained with the referenced COM SOP. Final documents with original signature and date will be kept on file.

B. Procedure for Distribution and Training on SOPs

Supervisors will ensure that each new research team member reviews all applicable SOPs prior to undertaking any responsibilities at this investigational site and will document the date of review and training of each SOP.

Supervisors will also ensure that each current research team member has continuous, documented training on the new or revised SOP *(See Attachment C: SOP Training & Compliance Form)*.

Documentation of training for SOPs will be kept on file for all research team members and available for review upon request.

C. Procedures for Maintaining SOPs and RPAs

All department research SOPs and RPAs should be reviewed by the appropriate team members to assess applicability and revise and/or edit the document a minimum of every 3 years.

If revisions or additions are required at any time, the procedures will be followed as outlined above.

If no changes are required, the SOP Revision History Log will be updated to reflect the date of last review *(See Attachment D: SOP Revision History Log)*.

5. Applicable Regulations, Guidances and Policies

Regulation/ Guidance/Policy	Title
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
OSU Office of Responsible Research Practices HRPP	Additional Requirements for Clinical Research: ICH GCP
OSU Office of Responsible Research Practices HRPP	Responsibilities of Principal Investigators, Co-Investigators, and Key Personnel
ICH 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

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