THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-03: New Employee Orientation

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-03 describes the process and documentation required for the initial and ongoing education and orientation of research team members involved in clinical research. Attachment templates include:

A: New Employee On-Boarding 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

A. New Employee Orientation

All new employees of the research team are required to complete all applicable training as determined by institutional policies and their supervisor.

The PI and delegated research team members will ensure that all persons assisting with the study are adequately informed about the protocol, the investigational product(s), and their study-related duties and functions. These individuals will be informed about their obligations and will have adequate and appropriate education and training to conduct the tasks delegated.

Research team members engaged in clinical research activities will have IRB approval as key personnel or as a Sub-Investigator prior to performing study-specific tasks.

All new research staff are expected to complete the following prior to independently conducting delegated tasks of a clinical research study:

- Complete appropriate eLearning Modules through BuckeyeLearn within the first 30 days of employment.
- Complete Collaborative Institutional Training Initiative (CITI) Biomedical Human Subject Protection modules, Good Clinical Practice modules (FDA focus), and Responsible Conduct of Research modules within the first 30 days of employment.
- Review and receive training on COM-CCRM SOPs within the first 60 days of employment.
- Complete research conflict of interest disclosure certification (eCOI).
- Complete appropriate electronic medical record (EMR) training sessions and computer-based learning (e-Learning) sessions prior to gaining access to any electronic medical records.
- Complete appropriate biosafety, occupational health and Environmental Health Services (EHS) training for all employees who will be in direct contact with patients, biohazardous materials, or who work in the clinical setting.
- Complete sponsor-required training to ensure adherence to protocol requirements, as applicable.

The new research staff will be instructed, according to their role, in various aspects of conducting a clinical research study including but not limited to:

- Study implementation and design
- Regulatory requirements
- Fiscal and contractual requirements
- Orientation to appropriate clinics and labs
- Patient screening and recruitment procedures
- Consent process
- Source documentation and Case Report Form completion

All new clinical research staff members will complete an On-Boarding checklist. *(See Attachment A: New Employee On-Boarding Checklist)*. The new employee's supervisor will ensure the new staff has successfully completed all required training as outlined on the On-Boarding Checklist. Once completed, the original On-Boarding checklist will be maintained in the employee file.

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
45 CFR 160	HIPAA Privacy Rule
45 CFR 164 Subparts A and E	HIPAA Privacy Rule
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	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 Research Compliance	Conflict of Interest
OSUWMC	Use of Patient Information by Hospital and Medical Staff
OSUWMC	Patient Information & HIPAA Requirements
OSUWMC	Information Security Policy
OSUWMC Investigational Drug Service	IDS Policy and Procedures
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

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

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