THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-02: Delegation of Responsibilities

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-02 describes the responsibilities of the PI and the procedures for identifying and delegating specific responsibilities to research team members for conducting clinical research. Attachment templates include:

- **A: Delegation of Authority Log**
- **B: Study Team Training Log**

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. Investigator Responsibilities

The PI will conduct and/or supervise the clinical research study to ensure that it is conducted according to the signed investigator statement/Form FDA 1572 (if applicable), IRB approved protocol, institutional policies, GCP, and applicable regulations.

During and following a subject's participation in a study, the PI will ensure that adequate medical care related to study participation is provided to the subject.

The PI is ultimately responsible for the conduct of the research study but may delegate tasks to qualified research personnel when appropriate. The PI and delegated research team members will, at minimum:

Delegation of Authority, Training, and Regulatory Compliance

- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the study.
- 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, job description, and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.
- Disclose financial interests or relationships with sponsors as required by federal regulations and institutional policies.
- Maintain a list of appropriately qualified persons to whom the investigator has delegated significant research study-related duties *(See Attachment A: Delegation of Authority Log)*.
- Ensure that individuals are approved by the IRB as key personnel or Sub-Investigators for the research tasks they will be performing prior to engaging in such tasks.
    - If external collaborators are engaged in research, these individuals will also need to be approved by the IRB as key personnel or Sub-Investigators (Please see ORRP Engagement Determination Tool).
- Conduct study activities only after IRB approval and in accordance with the approved protocol, and ensure all regulatory requirements are fulfilled.
- Ensure all persons assisting with the research study are adequately trained on the protocol, the investigational product(s), and their study-related duties and functions *(See Attachment B: Study Team Training Log).*
- Ensure an adequate number of qualified staff and adequate facilities are available for the foreseen duration of the study to conduct the research properly and safely.
- Implement modifications in approved research only after review and approval of the modification by the IRB, *except* when necessary to eliminate immediate hazards to subjects.

Human Protection and Protocol Compliance

- Be aware of and comply with GCP, applicable regulatory requirements, and institutional policies and procedures.
- Protect the rights, safety, and welfare of subjects under the investigator's care.

- Maintain attributable, legible, contemporaneous, original, accurate, and complete records.
- Ensure timely reporting of data and pertinent information to the subjects, sponsors, and regulatory authorities.
- Ensure adequate control and accountability of investigational product.
- Ensure adequate control and security of protected health information (PHI) and study data.
- Ensure only a qualified member of the research team, who is an investigator or a sub-investigator, will be responsible for all related medical care.
- Ensure data reported on the Case Report Forms (CRFs) are consistent with the source documents and discrepancies will be explained in detailed documentation.
- Report to the IRB/Sponsor/FDA unforeseen events that may present risks or affect the safety and welfare of subjects or others, or that may affect the integrity of the research.
- Ensure biospecimens are collected, processed, and stored in accordance with the protocol, institutional policies, OSHA standards, and Good Laboratory Practice (GLP).
- Retain all pertinent study-related records as required by the sponsor, federal agency, and/or institution.
- Ensure protocol compliance (e.g., subject eligibility, consent, and randomization).
- Ensure appropriate business and financial oversight to meet grant, contract, and billing requirements.
- Register and report results of the research study to ClinicalTrials.gov, if required.

B. Procedure for Delegation of Research Responsibilities

The PI is the individual who assumes the authority and responsibility for the conduct of a clinical research study. However, the PI has the authority to delegate responsibilities to individual members of the research team, if appropriate.

The PI may select Sub-Investigators with appropriate education and training to ensure the investigation is conducted according to the signed investigator statement, the investigational plan, GCP, institutional policies, and applicable regulations.

The PI may determine the appropriate delegation of authority to specific research team members for each clinical research study conducted at this investigational site.

Delegation of specific responsibilities will be documented appropriately and kept on file with the regulatory documents for each clinical research study *(See Attachment A: Delegation of Authority Log)*. Study team members that have significant trial-related duties as determined by the PI will be listed on the DOA log. Duties that are considered significant may vary by study, but are generally duties that could impact subject safety, protocol compliance, and data quality/integrity. Examples of significant duties include, but are not limited to obtaining informed consent, performing study-specific procedures (not related to standard of care or normal job duties), collecting data, regulatory compliance, assessment of the primary endpoints, attribution of adverse events, and dispensation of investigational product.

Personnel that perform administrative tasks (e.g., some regulatory activities) or perform routine procedures and are operating within their scope of practice (e.g., commercial services or standard of care assessments) are not considered key personnel and will not be listed on the DOA log.

All members of the research team who are delegated specific responsibilities should have regular communication with the PI to ensure he/she is informed in a timely manner of all study-related activities.

Individual research team members may have regular evaluations of performance to ensure they are performing delegated tasks appropriately and meeting department expectations.

C. Information Required on Delegation of Authority Log

It is acceptable for study teams to use the sponsor DOA log, or a site developed DOA log. At a minimum it is recommended that the Delegation of Authority Log should contain the individual's full name, signature, initials, duties assigned, date duties assigned, dates duties completed (if applicable) and signature of PI indicating that he/she has reviewed the duties delegated to an individual. The log must be updated with any staff changes that would result in a change or termination of duties as it pertains to that particular protocol.

D. Signing the Delegation of Authority Log

Each study team member will acknowledge the duties delegated to him/her by the PI by signing, dating, and initialing the DOA log, as applicable. If electronic signatures are used, the system must be 21 CFR part 11 compliant for trials that are FDA regulated or federally funded.

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

42 CFR 50 Subpart F	Responsibility of Promoting Objectivity in Research (Research COI)
45 CFR 94	Responsible Prospective Contractors
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	Noncompliance
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
OSUWMC Investigational Drug Services	IDS Policy and Procedures
COM Office of Human Resources	Training & Assessment Requirements
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	FDA Inspections of Clinical Investigators- Information Sheet, June 2010
FDA Guidance for Industry	Frequently Asked Questions- Statement of Investigators (Form FDA 1572), May 2010
World Health Organization	Good Laboratory Practice
United States Department of Labor	Occupational Safety and Health Administration (OSHA)