

**[SOP Reference Number: SOP Title]**

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 Reference Number]** describes the process for *[Standard Operating Procedure Title]*. Attachment templates include:

A: *[Attachment A Title]*

B: *[Attachment B Title]*

C: *[Attachment C Title]*

D: *[Attachment D Title]*

1. **Responsibility**

The College of Medicine Clinical Trials Management Organization (COM-CTMO) is responsible for developing, implementing, and maintaining SOPs in collaboration with department administrators and clinical research teams. 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 |

1. **Definitions**

Please refer to the SOP Glossary document for detailed definitions of commonly used clinical research terminology.

1. **Procedures**

 **A. Procedure for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** *(List out details of tasks to be completed and who is responsible for completing the task, for example)*

# Applicable Regulations, Guidances and Policies *(for example)*

|  |  |
| --- | --- |
|  **Regulation/ Guidance/Policy**  | **Title**  |
| **21 CFR 50**  | [Protection of Human Subjects](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50)  |
| **21 CFR 312**  | [Investigational New Drug Application](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312)  |
| **21 CFR 812**  | [Investigational Device Exemptions](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812)  |
| **45 CFR 46**  | [Protection of Human Subjects](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)  |
| **OSU Office of Responsible Research Practices HRPP**  | [Additional Requirements for Clinical Research: ICH GCP](http://orrp.osu.edu/irb/osuirbpolicies/hrpppolicies/)  |
| **OSU Office of Responsible Research Practices HRPP**  | [Responsibilities of Principal Investigators, CoInvestigators and Key Personnel](http://orrp.osu.edu/irb/osuirbpolicies/hrpppolicies/)  |
| **ICH E6** (R2) | [Good Clinical Practice: Consolidated Guidance](https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf) |
| **FDA Guidance for Industry**  | [Investigator Responsibilities: Protecting the Rights, Safety, and Welfare of Study Subjects. October 2009](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf)  |

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