

**SOP-04: Protocol Feasibility**

# 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-04** describes the process for reviewing feasibility for clinical research. Attachment templates include:

# A: Protocol Feasibility Form

**B: Protocol Feasibility Score Card**

1. **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

# Definitions

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

# Procedures

* 1. **Protocol Feasibility**

The delegated clinical research team members will ensure that the site has received critical study documents such as the protocol, consent template, the Investigator’s Brochure (if applicable), lab and/or pharmacy manual (if applicable), Case Report Forms (if available), sample budget worksheet, and a draft contract after the Confidential Disclosure Agreement (CDA) has been executed by the Technology Commercialization Office.

The PI, in collaboration with the other research team members, will review the protocol and applicable study- related materials to assess the feasibility of conducting the study at this site *(See Attachment A: Protocol Feasibility Form and Attachment B: Protocol Feasibility Score Card)*. The following will be met:

* + - Must be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.
    - Must have sufficient time to properly conduct and complete the research study within the agreed study period.
    - Must have an adequate number of qualified staff available and adequate facilities for the foreseen duration of the study to conduct the study properly and safely.

If the PI wishes to pursue the clinical research study and the sponsor requests a site qualification visit, the research team members will work with the PI and sponsor to find a mutually agreed upon date. The PI, in collaboration with the research team member, will identify key research personnel who will be involved in the conduct of the clinical research study.

# Applicable Regulations and Guidances

**Regulation/ Guidance/Policy Title**

**21 CFR 11** Electronic Records; Electronic Signatures

**21 CFR 50** Protection of Human Subjects

**21 CFR 54** Financial Disclosure by Clinical Investigators

**21 CFR 56** Institutional Review Boards

**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 Office of Responsible Research Practices HRPP

**OSU Office of Responsible Research Practices HRPP**

Additional Requirements for Clinical Research: ICH GCP

Responsibilities of Principal Investigators, Co- Investigators and Key Personnel

**OSU Office of Research Compliance** Conflict of Interest

**OSUWMC** Patient Information & HIPAA Requirements

**OSUWMC** Information Security Policy

**OSUWMC Investigational Drug Services** IDS Policies 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** Recruiting Study Subjects- Information Sheet

**FDA Guidance for Industry**

Oversight of Clinical Investigations- A Risk-Based Approach for Monitoring, August 2013

**FDA Guidance for Industry** Sponsor-Investigator-IRB Interrelationship- Information Sheet

**FDA Guidance for Industry**

Frequently Asked Questions- Statement of Investigator Form FDA 1572, May 2010

**FDA Guidance for Industry** Electronic Source Data in Clinical Investigations

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