THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-04: Protocol Feasibility

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

- **A: Protocol Feasibility Tool**
- **B: Protocol Feasibility Score Card**

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. Protocol Feasibility

The delegated clinical research team members will ensure the site has received critical study documents such as the protocol, consent template, the Investigator's Brochure (if applicable), lab, pharmacy and/or other manuals (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 Tool and Attachment B: Protocol Feasibility Score Card)*. The following will be assessed:

- Must be able to demonstrate (e.g., based on retrospective data) the 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 members, will identify key research personnel who will be involved in the conduct of the clinical research study.

5. 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	Responsibilities of Principal Investigators, Co-Investigators, and Key Personnel
OSU Office of Responsible Research Practices HRPP	Additional Requirements for Clinical Research: ICH GCP
OSU Office of Research Compliance	Conflict of Interest
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	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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