THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-05: Site Qualification Visit

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-05 describes the process for conducting a site qualification visit, also known as a pre-study site visit. Attachment templates include:

A: Site Qualification Visit Agenda
B: Checklist for a Site Qualification Visit
C: Site Qualification Visit Summary

2. 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

3. Definitions

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

4. Procedures

A. Site Qualification Questionnaires

The PI, in collaboration with the other research team members, will complete a site questionnaire that provides basic information for the study sponsor to perform a cursory evaluation of the site. Site qualification questionnaires are used to assess staff experience, facilities, and other operational needs necessary to perform a clinical research study. Often, the questionnaires request basic information related to the Investigator, Sub-Investigator(s), Study Coordinator, and/or Pharmacy, as well as details about the IRB. Questions specific to the disease/therapeutic area being studied and expected enrollment numbers are also often requested.

B. Preparing for a Site Qualification Visit

If the PI wishes to pursue the clinical research study and the sponsor requests a site qualification visit, the delegated research team members will work with the PI and sponsor to find a mutually agreed upon date. The PI will identify key research personnel who will be involved in the conduct of the clinical research study. In preparation of the visit, a Site Qualification Visit Agenda should be completed, if not provided by the sponsor or sponsor representative, and the Checklist for a Site Qualification Visit reviewed *(See Attachment A and B)*.

C. Site Qualification Visit

The PI, Sub-Investigator and delegated research team members will meet in person or participate in an online meeting or conference call with the sponsor or representative. The research site should be prepared to review:

- Protocol
- Recruitment, Retention and Enrollment Goals
- Investigator's Brochure (if applicable)
- Case Report Forms
- Source Documents (if being provided)
- A monitoring and communication plan for the sponsor/CRO and investigational site

The PI or research team members will:

- Provide the sponsor representative with copies of the current CVs from key site personnel, as requested.
- Ensure the sponsor representative has a chance to tour the research facility, as requested, including: exam rooms, lab areas, special testing areas, pharmacy, hospital unit, work areas for research team members, storage area for investigational product, space used for processing and shipping research samples, and data entry area.
- Document the details of the site qualification visit and address any follow-up questions the sponsor representative may have.
- Ensure all persons assisting with the research 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.

The PI and delegated research team members will be qualified by education, training, and experience to assume responsibility for the proper conduct of the study, will 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 and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.

Following the Site Qualification Visit, a visit summary should be completed *(See Attachment C: Site Qualification Visit Summary)*.

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	Additional Requirements for Clinical Research: ICH GCP
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	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 GCP 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 to 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, September 2013

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