



**Center for Clinical and
Translational Research
Standard Operating Procedure**



Section: **Clinical Research Center**

Date Created: **November 1st, 2010**

Title: **Site Qualification/Evaluation Visit**

Version Date: **January 1, 2023**

SOP Number: **SM02**

PURPOSE: The purpose of this standard operating procedure (SOP) is to outline the services the Clinical Research Center (CRC) can provide to University of Nebraska Medical Center (UNMC)/Nebraska Medicine (NM) investigators in order to facilitate the investigational site selection process. The Site Qualification/Evaluation/Selection Visit includes a sponsor representative or Clinical Research Organization (CRO) completing either an onsite visit or phone call to assess if the site has the ability and resources to conduct the research. The site must adequately prove that it has the staff, training, education, experience, and adequate resources.

SCOPE: This SOP applies to all sponsored clinical trials in which the CRC will be contracted to provide study coordination at UNMC/NM.

PERSONNEL RESPONSIBLE: Principal Investigator-- and when delegated by the Principal Investigator--Sub-investigators, Study Coordinator, Regulatory Coordinator and/or other pertinent staff.

DEFINITIONS:

- **Contract Research Organization (CRO)** - A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.
- **Laboratory reference ranges** -A set of values used by a health professional to interpret a set of medical laboratory tests results from blood, urine, or other body fluids samples.
- **Site Evaluation Visit (SEV)/Site Qualification Visit (SQV)/Site Selection Visit (SSV)** – all are names for the visit conduct prior to the start of a study when a study monitor/sponsor representative makes a visit to the study site to determine whether the Principal Investigator and research staff are qualified and if the site has adequate resources to conduct the study.
- **Sponsor** - An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of the research.

PROCEDURES:

- The principal investigator or his/her designee will schedule the visit as requested by the sponsor representative. An agenda will be provided by the sponsor representative and communicated to the site before the visit.
- If requested, a tour of the CRC facilities will be scheduled so the sponsor can assess whether the site has the necessary equipment, adequate and secure space to conduct the research.



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- If requested by the sponsor, CRC personnel can assist in providing the following information to the sponsor/CRO representative:
 - NM lab credentialing certificates (CLIA and CAP)
 - Current Reference lab normal values
 - PI's CV and license
 - Any site addresses that may be needed
 - IRB submission deadlines and approval process information
 - Equipment listing with service dates
 - IATA certifications for CRC personnel
 - Copies of any CRC SOPs
 - Appropriate start-ups contact information
 - Current copies of research personnel's CVs

CRC personnel may also be asked to provide any follow-up information following the site evaluation visit/phone call to the sponsor representative.

RESOURCES:

- 21 CFR 312.53 Selection Investigators and Monitors

Department Approval

Signed Serena Gaines
Research Nurse Manager

Signed: 2/21/2023

Signed [Signature]
Assistant Vice Chancellor for Clinical Research

Signed: 4/3/2023