University of Nebraska Medical Center

Center for Clinical and Translational Research Standard Operating Procedure

Nebraska Medicine

Section **Clinical Research Center**

Title: **Site Qualification/Evaluation Visit**

SOP Number: **SOP- 30**

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

Date Reviewed/Modified: **April 1, 2019**

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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 (PI) and when delegated by the principal investigator, designated CRC study 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.
- 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-up 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

Staff Accountability:

Developed By: Director of Clinical Research Operations, Clinical Research Center
Associate Vice Chancellor for Clinical Research, Clinical Research Center
Reviewed By: Director of Clinical Research Operations, Clinical Research Center

Department Approval

Signed _____
Director of Clinical Research Operations

Signed _____
Medical Director of Clinical Research Center