

Section Clinical Research Center

Date Created: November 1<sup>st</sup>, 2010

Title: Site Initiation Visit

Date Reviewed/Modified: April 1, 2019

SOP Number: SOP- 29

Version Number: 4

**PURPOSE:** The purpose of this standard operating procedure (SOP) is to outline the activities to be completed by study personnel in order to facilitate the clinical trial site initiation process.

**SCOPE:** This SOP applies to all sponsored clinical trials in which the Clinical Research Center (CRC) has been contracted to provide study coordination at University of Nebraska Medical Center (UNMC)/Nebraska Medicine (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.
- **Sponsor** - An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of the research.
- **Site Initiation Visit (SIV)** - is conducted by a sponsor to assure that the clinical trial site and facility are prepared to initiate and have everything required to initiate the study.

#### **PROCEDURES:**

- The Principal Investigator or his/her designee will schedule and arrange the site initiation visit as requested by the sponsor representative or CRO.
- The study coordinator or other designated research personnel will make sure all pertinent study staff are notified about the SIV and provide them with study information needed prior to the SIV (if available).
- Typically an agenda will be provided by the sponsor representative before the visit. This should be used to facilitate scheduling with ancillary departments, as needed (e.g., MRI, CT, Investigational pharmacy).
- Prior to the visit, the Principal Investigator or his/her designee should ensure the sponsor representative is registered with REPTrax per UNMC and NM Policies.
- At the site initiation the sponsor representative will review trial procedures in detail and document that site personnel are prepared to implement the trial. The details of the discussion and review are typically documented on a training log which SIV attendees must sign and date. The Regulatory Coordinator or the Nurse Coordinator will scan and then email the training log to the sponsor/CRO. The training log must then be filed in the site's regulatory binder.



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



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- The sponsor will also require that the site Delegation/Signature Log be completed at the SIV. The Principal Investigator and/or his/her designee will ensure this log is completed and placed in the site’s regulatory binder with a copy scanned and emailed to the sponsor/CRO.

**RESOURCES:**

UNMC: [#8015 Health Care Vendor Interactions](#)

Nebraska Medicine: [MS 40 Vendor Interactions](#)

**Staff Accountability:**

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

Reviewed By: Regulatory Coordinator, Clinical Research Center

**Department Approval**

<p>Signed <u></u> Director of Clinical Research Operations</p>	<p>Signed <u></u> Medical Director of Clinical Research Center</p>
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