Center for Clinical and Translational Research Standard Operating Procedure

Section: **Clinical Research Center**

Title: **Study Intake Process**

SOP Number: **SM03**

Date Created: **August 28, 2018**

Version Date: **January 1, 2023**

PURPOSE: The purpose of this standard operating procedure (SOP) is to explain the study intake process for requesting services from the Clinical Research Center (CRC), Clinical Trials Management System (CTMS) team and/or contracting offices (UNeHealth and Sponsored Programs Administration).

SCOPE: This SOP applies to clinical research that meets the requirements in the CTMS decision tree.

PERSONNEL RESPONSIBLE: CRC Leadership, Study Coordinators and/or other staff are knowledgeable of and can facilitate investigators accessing available resources to assist with protocol feasibility.

PROCEDURES: The purpose of this form is to gather information regarding the study that is being requested for CRC, CTMS and/or contracting services. Whether using the CRC or needing your study built in the CTMS there is a centralized intake process to aid in initiating start-up activities and tracking activation timelines.

1. Complete the Study Intake Form on the CRC website at https://www.unmc.edu/cctr/resources/crc/intakeform.html.
2. Regular status updates are provided to the contact who completed the study intake form. Questions should be addressed by email to StudyIntake@unmc.edu.
3. Submission of the study intake form starts the stopwatch for institutional tracking on activation timelines.

RESOURCES:

UNMC: Center for Clinical & Translational Research

Decision Tree for Research Studies Built in CTMS https://www.unmc.edu/cctr/clinical-trials/ctms-training/wp-content/uploads/2022/09/Decision-Tree-09-2022.pdf

Department Approval

Signed Katie Penas
Clinical Research Manager

Signed: 5/3/2023

Signed
Assistant Vice Chancellor for Clinical Research

Signed: 5/3/2023