Center for Clinical and Translational Research Standard Operating Procedure

Section: **Clinical Research Center**
Title: **Insufficient Accrual**
SOP Number: **SM52**
Date Created: **August 28, 2023**
Version Date: **August 28, 2023**

PURPOSE: The purpose of this standard operating procedure (SOP) is to outline the process for the review and assessment of ongoing support of CRC coordinated studies for insufficient accrual.

SCOPE: The tools the Clinical Research Center (CRC) offers for investigators to assess protocol feasibility can be applied to any clinical research study being considered at University of Nebraska Medical Center (UNMC)/Nebraska Medicine (NM).

PERSONNEL RESPONSIBLE: Principal Investigators (PI), Sub-Investigators, and CRC leadership are responsible for opening and supporting research studies that utilize resources appropriately.

DEFINITIONS:

- **Insufficient Accrual –** Less than 30% of the accrual goal for the projected cumulative accrual goal to date at the time of review

PROCEDURES:

1. Identification of a study that the Clinical Research Center (CRC) supports that has insufficient accrual after being Open to Accrual for at least 12 months via periodic study reviews and CTMS Low Accrual Report.
2. CRC leadership team will meet to discuss study and review options.
3. CRC leadership team or team member will meet with PI and, if applicable, the lead study coordinator to assess enrollment on the study.
4. Based on the meeting findings, a study specific action plan will be developed in conjunction with the study PI to increase enrollment.
5. CRC leadership will reassess study enrollment after the study has been Open to Accrual for at least 18 months.
6. If enrollment is still deemed insufficient, CRC leadership may recommend no longer supporting coordination of the study.
    a. The PI will be notified via letter of the services no longer supported.

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Department Approval

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