



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



Section: **Clinical Research Center**

Date Created: **November 1, 2010**

Title: **Development and Review of Policies and SOPs**

Version Date: **January 1, 2023**

SOP Number: **AD21**

PURPOSE: The purpose of this procedure is to describe the standard methods for developing and maintaining standard operating procedures (SOP) for the Clinical Research Center (CRC).

SCOPE: This procedure applies to all CRC SOPs which describe department specific activities, clarify expectations for staff performances, provide supporting documentations for auditors, and facilitate the critical evaluation of department practices.

PERSONNEL RESPONSIBLE: The Medical Director/Assistant Vice Chancellor for Clinical Research and Clinical Research Center Leadership are responsible for reviewing, updating, and approving SOP's or delegating these responsibilities to designated staff as needed. Research staff are responsible for complying with departmental policies and SOP's. The Medical Director/Assistant Vice Chancellor for Clinical Research and Clinical Research Center Leadership give final approval and sign all Policies and SOPs.

DEFINITIONS:

- **Date Created:** Indicates the initial creation date for the Policies/SOP.
- **Version Date:** Indicates the date that it was last modified.
- **Standard Operating Procedures (SOPs):** Detailed, written instructions which describe department specific activities, clarify expectations for staff performances, provide supporting documentation for auditors and facilitate critical evaluation of department practices.

PROCEDURES:

Development and Approval

- SOPs are identified by members of the management team and staff, department liaisons, and other institutional departments.
 - To provide consistency, standard templates will be used when drafting a new SOP.
- SOPs are written by the appropriate staff and routed through the Medical Director/Assistant Vice Chancellor for Clinical Research of Clinical Research Center's office.
- Content input will be sought from the subject matter experts on the UNMC/NM campus, online resources, and outside agencies.
- Supporting documents are drafted and included in Policy/SOP, as referenced in the associated forms section of the template.
- Resources should be cited in the Resources section.
- Approval Process



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- The SOP draft is evaluated by the Clinical Research Center Leadership, staff and department liaisons as appropriate.
- The SOP draft is submitted to the Medical Director/Assistant Vice Chancellor for Clinical Research and Leadership of the CRC for review, revisions, and final approval.
- It is then routed to the Medical Director/Assistant Vice Chancellor for Clinical Research and the Leadership for sign off.

Staff Responsibilities

- All CRC SOPs are available to CRC staff on the Clinical Research Center Teams site which employees gain access to upon employment with the CRC department.
- SOPs made available for campus-wide use will be posted on the UNMC website.
- CRC employees will review all SOPs for CRC at least annually and when new/updated/changes have been implemented.
- All new/updated/changed SOPs will be communicated with all CRC staff within a timely manner.
- The signed original copies of the CRC SOPs will be maintained within the CRC department Teams site.

Maintenance and Review of SOPs

- SOPs will be reviewed regularly for any necessary changes. This review will be noted by updating the review date on each specific SOP in lieu of signing each SOP separately.
- Discontinuing a SOP, if during a review, it is discovered that a SOP is no longer needed or the procedures duplicated in another SOP, the SOP may need to be discontinued. Final decision to discontinue a SOP is determined by the Clinical Research Center Leadership.
- The numbering system of SOPs will not change when an SOP is retired. Retired SOPs are kept in an archived file.



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Department Approval

Signed Charles E Miller Date: 5/3/2023
Clinical Research Center Administrator

Signed Katie Penas Date: 5/3/2023
Clinical Research Manager

Signed Serena Gaines Date: 5/3/2023
Research Nurse Manager

Signed [Signature] Date: 5/3/2023
Assistant Vice Chancellor for Clinical Research