

Section **Clinical Research Center**

Date Created: **November 1, 2010**

Title: **Development and Review of Policies and SOPs** Date Reviewed/Modified: **July 21, 2021**

SOP Number: **SOP - 7**

Version Number: **6**

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

**SCOPE:** This procedure applies to all CRC Policies/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 of Clinical Research Center and Director of Clinical Research Operations are responsible for reviewing, updating, and approving Policies/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 of Clinical Research Center and Director of Clinical Research Operations give final approval and sign all Policies and SOPs.

**DEFINITIONS:**

- **Date Created:** Indicates the initial creation date for the Policies/SOP.
- **Date Last Reviewed/Modified:** Indicates when the review process was last completed.
- **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**

- SOP's 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 policy or SOP.
- SOPs are written by the appropriate staff and routed through the Medical Director of Clinical Research Center office.
- Content input will be sought from the subject matter experts on the UNMC/NM campus, online resources and outside agencies may be contacted
- 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

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- Approval Process
  - The Policy/SOP draft is evaluated by the Director of Clinical Research Operations, staff and department liaisons as appropriate.
  - The Policy/SOP draft is submitted to the Medical Director and Director of Clinical Research Operations of the CRC for review, revisions and final approval.
  - It is then routed to the Medical Director & the Director of CRO for sign off.

### **Staff Responsibilities**

The Policy/SOP will be posted on the CRC intranet for all associated research staff to review and familiarize themselves. New versions will be shared with all responsible personnel. Employees will receive information on all new Policies/SOPs.

- 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.
- All CRC SOPs are available to CRC staff on the department share drive which employees gain access to upon employment with the CRC department.
- The signed original copies of the CRC SOPs will be maintained within the CRC department share drive.

### **Maintenance and Review of Policies and SOPs**

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

### **RESOURCES:**

**CRC SOP # 63 Staff Competencies**



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



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**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  
Medical Director for Clinical Research Center, Clinical Research Leadership

**Department Approval**

Signed *LuAnn Larson* Date: Jul 21, 2021  
Director of Clinical Research Operations

Signed *Matt Lunning* Date: Aug 2, 2021  
Medical Director of Clinical Research Center









# SOP-7 Development and Review of Policies and SOPs- Final Edits

Final Audit Report

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