

Protocol Review & Monitoring System

Standard Operating Procedures

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

Date Created: January 15, 2021

Date Reviewed: August 8, 2024

SOP Number: **SOP-1**

SOP Type: **Administrative**

Version Number: 1

PURPOSE: The purpose of this procedure is to describe the standard methods for developing and maintaining policies and standard operating procedures (SOP) for the Protocol Review & Monitoring System (PRMS).

SCOPE: This SOP applies to all PRMS Policies/SOPs, which describe department specific activities, clarify expectations for staff performance, provide supporting documentation for external departments, and facilitate the evaluation of department practices.

PERSONNEL RESPONSIBLE: The Associate Director of Clinical Research for the Fred & Pamela Buffett Cancer Center (BCC) and the Manager of PRMS and OnCore Oncology are responsible for reviewing, updating, and approving SOPs, or delegating these responsibilities to designated staff as needed. Research staff are responsible for complying with departmental policies and applicable SOPs. The Associate Director of Clinical Research of the BCC and the Manager of PRMS and OnCore Oncology give final approval and sign all SOPs. The applicable committee responsible for that policy will approve PRMS Committee specific policies.

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

- 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 policy or SOP.
- SOPs are written by the appropriate staff and routed through the Manager of PRMS and OnCore Oncology.
- 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.

Approval Process

- The Policy/SOP draft is evaluated by the Manager of PRMS and OnCore Oncology, staff and department liaisons as appropriate.
- The Policy/SOP draft is submitted to the Manager of PRMS and OnCore Oncology and Associate Director of Clinical Research of the BCC for review, revisions, and final approval signatures.

Staff Responsibilities

- The Policy/SOP will be posted on the PRMS 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.
- PRMS employees will review all SOPs at least annually and when new/updated/changes have been implemented.
- All new/updated/changed SOPs will be communicated with all PRMS staff within a timely manner.
- All PRMS SOPs are available to PRMS staff on the department share drive which employees gain access to upon employment with the PRMS department.
- All PRMS SOPs will be signed by the Manager of PRMS and OnCore Oncology and the Associate Director of Clinical Research of the BCC.
- The signed original copies of the PRMS SOPs will be maintained within the PRMS 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 are duplicated in another Policy/SOP, the Policy/SOP may need to be discontinued. Final decision to discontinue a Policy/SOP is determined by the Manager of PRMS and OnCore Oncology.