Purpose: To describe the process for the development, maintenance, and education of Standard Operating Procedures (SOPs) in the Center for Cancer Research (CCR). SOPs set forth standards for practice of clinical research at this institute.

STEP 1: Develop and Submit New SOP
- SOPs will be developed by the staff of the Office of the Clinical Director (OCD).
  - SOPs will include:
    - Category and number
    - Next review date
    - Approval date
    - Purpose
    - Step-by-step instructions
- The OCD leadership will review the SOP for content, format, and completeness, including appropriate references and regulations.
  - Changes will be discussed and made with the author as needed
  - Note: The OCD will solicit assistance from technical experts to review, when applicable.

STEP 2: Draft will be Reviewed by the Clinical Director (CD) and Deputy Clinical Director (DCD)
- The OCD leadership will send the new or updated SOP in electronic format to the CD and DCD for review.
- The CD and CDC will review and edit or approve the SOP.
- The OCD leadership will collect and document all proposed edits to the SOP.
- The OCD will perform a final review before posting for Public Comment or final approval.

STEP 3: Posting for Public Comment
- The CCR Educator will post for public comments. The posting time period will be 2 weeks.
- The Educator will collate the comments, review with OCD leadership, DCD, and CD, and final SOP will be confirmed.
- The OCD leadership will ensure accurate formatting, verify references, and update SOP tracking log.
STEP 4: Submission of SOP for Final Posting
- CD will sign the final pdf version using an electronic signature and this will be saved in OCD SOP electronic folder.
- Final SOP will be sent to the Protocol Support Office for posting.
- OCD leadership will conduct review of SOP on Website.

STEP 5: Notification of Approved SOP
- The OCD will email CCR clinical staff including the Office of Research Nursing and Patient Care Coordinators, the NCI Institutional Review Board staff, the Data Management contract staff, and the Protocol Support Office staff to announce the posting to the approved SOP(s).
  - The URL to the SOP, any pertinent instructions, and any in-service information will be included.
  - In-services will be conducted for any complex SOP or as appropriate.

STEP 6: Review of Approved SOP
The OCD will review each approved SOP as indicated in the “next review date” noted in each SOP. The review occurs biennially, unless otherwise noted in the SOP.