SOP#: ADGC-1   **SOP Review and Approval Process – Developing and Maintaining SOPs**

Version #: 2.1   **Next Review Date: 08/2024**

Approved Date: 08/2022   **Review Interval Period: Biennial**

**NCI Clinical Director Signature/
Effective Date:**

POLICY:

All Standard Operating Procedures (SOPs) for the Center for Cancer Research (CCR) will be developed, maintained, and updated in compliance with this SOP. CCR staff will have input into the development of SOPs as applicable. Staff will receive notification of new and revised SOPs as appropriate.

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.

PROCEDURE: NEW SOP

STEP 1: **Develop and Submit New SOP**

- SOPs will be developed by the staff of the Office of the Clinical Director (OCD), Office of Education and Compliance (OEC).
    - o SOPs will include:
        - Category and number
        - Approval date
        - Next review date
        - NCI Clinical Director Signature/Effective Date
        - Policy Statement
        - Purpose
        - Resources if applicable
        - Process / Procedures / Step-by-step instructions, as applicable
- The Director of OEC or designee, will review the SOP for content, format, and completeness, including appropriate references and regulations. Other OCD Leadership, CCR staff and designated PIs will be consulted as needed.
    - o Changes will be discussed and made with the author as needed

    Note: The OEC will solicit assistance from technical experts to review, when applicable.

STEP 2: Request for Public Comment, as applicable

- For those SOPs that pertain to study team processes, the OEC will email the draft SOP to the Office of Research Nursing (ORN) listserv and the CCR Clinical PI listserv, with a two-week comment period. Other staff (mid-level providers, Patient Care Coordinators) will be contacted for comment as applicable.

- The OEC staff will collate the comments, review with OCD leadership and the SOP author as needed and final SOP will be confirmed.

- The OEC staff will ensure accurate formatting, verify references, and web links.

PROCEDURE: SOP MAINTENANCE

STEP 3: **Review Existing SOP**

- OEC staff will review SOPs for updates to processes and to ensure website links are active.

- Review will take place at the interval defined on the SOPs, usually every other year. If processes change prior to the review period, the SOP will be reviewed and revised at an earlier timepoint.

- OEC will solicit assistance from technical experts to review, when applicable.

- Minor revisions will not require additional review outside of the OEC.

- For those SOPs that pertain to study team processes:

  o OEC will email the draft SOP to the Office of Research Nursing (ORN) listserv and the CCR Clinical PI listserv, with a two-week comment period.

  o The OEC staff will collate the comments, review with OCD leadership and the SOP author as needed and final SOP will be confirmed.

- The OEC staff will ensure accurate formatting, verify references, and web links.

PROCEDURE: APPROVAL, POSTING AND NOTIFICATION OF SOPS

STEP 4: **SOP Approval and Posting**

- CD will review and sign the final PDF version, and this will be saved in OCD SOP folder.

- Final SOP will be uploaded by OEC onto the CCR SOP wiki-page.

- OEC will update the SOP tracking log in the OCD SOP folder.

STEP 5: **Notification of Posting of Approved SOP**

- Once a new or revised SOP is posted, the OEC will email the following groups as appropriate: ORN listserv, CCR Clinical PI listserv, NP/PA listserv, PCC listserv, Protocol Support Office listserv.

  o A track changes document comparing previous version to the revised SOP will be included with the email as appropriate.

  o The web link to the CCR SOP website and any pertinent information will be provided.

  o Team-based training will be provided as requested for new SOPs.

- If an SOP is reviewed and updates are limited to typos and updated web links, an email notification is not required to be sent.