UNC SCHOOL OF MEDICINE	Standard Operating Procedure		
SOP 101, Version 4	**Issued by:** SOM CRSO	**Issue Date:** 10.25.2023	**Effective Date:** 10.25.2023

101.4: CRSO SOP on SOPs

PURPOSE

This Standard Operating Procedure (SOP) describes processes for the development, review, revision, approval, and management of SOPs to facilitate consistency, compliance, and efficiency in clinical research conducted in the UNC School of Medicine (SOM).

SCOPE

These procedures apply to SOM Clinical Research Support Office (CRSO) personnel and other individuals and groups that support or govern the process for developing, managing, and maintaining SOM SOPs as defined below:

- SOP Group: Team members designated to support the SOP development process.
- SOP Lead: Team member designated to guide, direct, and lead the SOP development process.
- SOP Author: A member of the SOP Group who outlines and drafts the SOP.
- SOM SOP Committee: A group of UNC-Chapel Hill, UNC Health, and SOM clinical research SOP stakeholders who guide the selection and prioritization of SOM SOPs, reviews SOPs during each phase of development, and provides final approval of SOPs. SOM SOP Committee membership is guided by the Research Leadership Committee (RLC), a committee that provides general oversight for clinical research in the SOM.

PROCEDURE

1. **Develop SOP**
    a. SOP Group: Identify and prioritize SOM SOPs with SOM SOP Committee and UNC-Chapel Hill clinical research SOP stakeholders.
        i. New SOPs may be proposed by any member of the UNC-Chapel Hill clinical research community.
    b. SOP Lead and SOP Group: Identify a qualified SOP author who is knowledgeable about the procedures of the SOP selected for development and confirm the choice of SOP author with CRSO leadership.
    c. SOP Author: Prepare the SOP as follows:
        i. Request, review and consider content of existing unit SOPs on the topic of the SOP.
        ii. Use the CRSO SOP template. (Appendix A)
        iii. Apply the Principles of SOM SOP Development. (Appendix B)
    d. SOP Group: Review and revise SOP outline, as applicable.
    e. SOM SOP Committee: Evaluate the organization and content of the SOP outline.
    f. SOP Author: Develop SOP draft with the SOP Group.
    g. SOM SOP Committee: Evaluate the SOP draft to ensure that the procedures are clearly written and appropriately reflect clinical research workflows, and aligns with Institutional policies, standards, procedures, and state and federal regulations.

h. CRSO SOP Group: Integrate the feedback from the SOM SOP Committee on the outline and draft, respectively.

2. **Complete stakeholder review**
Internal SOPs intended only to support operations of the CRSO will not undergo institutional or SOM community review.
   a. Initiate institutional review.
      i. SOP Group: Identity relevant stakeholders (institutional research administrators and officials) who are knowledgeable about the topic and procedures of the SOP and applicable local, state, and federal regulations and guidelines.
      ii. SOP Lead: Share SOP with selected reviewers and obtain their feedback.
      iii. SOP Author and Lead: Integrate feedback from reviewers, and document changes and decisions.
   b. Initiate SOM community review.
      i. SOP Lead: Upload draft SOP to the CRSO SOP webpage, update the SOM Community Review announcement, and prepare the REDCap community review survey.
      ii. SOP Lead: Release the SOM community review announcement to the CRSO Listserv and launch the survey to stay open for 21-calendar days.
      iii. SOP Author and Lead: Catalog, organize, and integrate feedback from reviewers, and document changes and decisions.
   c. SOP Group: Review and discuss the changes.
   d. SOM SOP Committee: Review the updated SOP and change summary.
   e. SOP Group: Review and integrate the SOM SOP Committee's feedback for final approval.
3. **Obtain Approval of SOP**
   a. SOP Lead: Initiate and route an approval request to the SOM SOP Committee.
   b. SOP Group and SOP Lead: Work to resolve any stipulations from the SOM SOP Committee and reroute for approval, as applicable.
   c. SOP Lead: Once the SOM SOP Committee approves the SOP, communicate the approval decision to the SOP Group, and save a copy of the approved SOP with other SOPs to be issued at the next planned SOP release.
4. **Disseminate SOP**
   a. SOP Lead: Upload to the CRSO website, announce on the CRSO Listserv, and issue the SOP in the SOM Clinical Research Personnel Profile and Training System (PaTS).
   b. SOP Lead and SOP Group: During issuance period, offer SOP review session to introduce and answer questions about the SOP, as applicable.
   c. SOP Lead: Upon the effective date, at least 30-calendar days post the issue date, upload the effective SOP to the CRSO SOP webpage and announce the effective SOP on the CRSO Listserv.
5. **Review SOPs routinely**
Effective SOPs are reviewed at least annually to ensure relevance, consistency, completeness, and continued adherence to institutional policies and standards, best clinical research practice, and regulations. If a need is identified, an SOP may be reviewed earlier.
   a. SOP Lead and SOP Group: Determine if revisions are needed and assign a new or the original SOP author, as applicable.

   i. If revisions are not deemed necessary, send SOP to SOM SOP Committee for review (skip to step 5.d.).
b. SOP Author: Revise SOP and summarize revisions in the revision history table within the SOP.
c. SOP Group: Review SOP and evaluate revisions.
d. SOM SOP Committee: Review SOP and evaluate revisions, as applicable.
e. SOP Group: Integrate the feedback from the SOM SOP Committee, as applicable.
f. SOP Lead: Initiate applicable stakeholder review, approval, and dissemination procedures.
   i. If substantial revisions, initiate step 2 (stakeholder review), 3 (SOP Committee approval), and 4 (issue SOP in PaTS).
   ii. If minor revision, determine appropriate review and approval procedures with the SOP Group and issue SOP in PaTS in accordance with step 4.
   iii. If no revisions, document the review and decision not to revise.

6. **Manage SOP**
   a. SOP Lead:
      i. Archive terminated and previous versions of SOPs to be available for historical data review.
      ii. Maintain master list of all SOM SOPs that denotes the SOP number, version number, effective date, title, author, status, and change history.

DEFINITIONS, ABBREVIATIONS, ACRONYMS

Click the link or scan the QR code to access the SOM Clinical Research Glossary for definitions, abbreviations, and acronyms pertaining to the SOP.

Revision History		
Version	**Effective Date**	**Change Summary**
101.1	05.26.2021	First approved version
101.2	08.12.2021	• New standard header added • Procedure 1.f.viii. updated to indicate that in-text references are numbered in superscript
101.3	09.13.2021	Correction to multilevel list format
101.4	10.25.2023	SCOPE Added roles of individuals and groups involved in SOP under scope previously listed under definitions. PROCEDURES Added the role and responsibilities of the SOM SOP Committee. Reorganized SOP procedural steps for better flow. Removed reference to CRAU and Personnel Manager accountability for individual level SOP review.

		Moved SOP template instructions under Procedures to Appendix A: SOM SOP Template. Added Appendix B: The Principles of SOM SOP Development. DEFINITIONS Replaced definition list with links to definitions embedded in text Added QR Code to SOM Clinical Research Glossary.

APPENDIX A: SOM SOP Template

SOP Header: SOM SOP number, version number, title
SOP Footer: Page number

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SOP #, Version #	**Issued by:** SOM CRSO	**Issue Date:** DRAFT	**Effective Date:** DRAFT

The SOP # is a chronological number starting at 101 followed by a period and a number indicating the version number. The issue date and effective date is designated as "DRAFT".

SOP #.Version #: SOP Title

PURPOSE
Brief statement indicating the reason for and/or intent of the SOP.

SCOPE
Brief statement specifying to what and/or whom the SOP applies.

BACKGROUND
(this section is optional; include only if needed based on SOP content)
Brief summary of any applicable background information relevant to this procedure.

PROCEDURE
Step-by-step instructions that are sufficiently detailed to enable personnel to complete the tasks with uniformity, consistent quality, and in accordance with applicable regulations and best practices. In-text glossary links to definitions that will aid in the understanding the SOP.

DEFINITIONS
Link and QR code to the UNC-Chapel Hill SOM Clinical Research Glossary:

UNC-Chapel Hill SOM Clinical Research Glossary

ASSOCIATED POLICIES, REGULATIONS, GUIDELINES
(this section is optional; include only if needed based on SOP content)
List of applicable federal, state, or institutional policies related to this procedure.
Proposed Subheaders:
Federal Regulations and Guidelines:
UNC-Chapel Hill Policies, Standards, and Guidelines:
Other Sources:

APPENDICIES
(this section is optional; include only if needed based on SOP content)

Templates, figures, or other content that support or enhance the SOP. Appendices are arranged sequentially by the order they were first referenced in the SOP.

Revision History		
Version	**Effective Date**	**Change Summary**
#.#	Date SOP is in effect	Brief summary of changes

Table documenting the SOP change history. This table includes SOP #.Version #, effective date and a brief summary of changes. If the SOP is the original SOP, “first approved version” is indicated in place of a summary of changes.

APPENDIX B: The Principles of SOM SOP Development

1. Identify an SOP author who has experience or knowledge in conducting the process.
2. Write SOPs to inform study teams on how to conduct clinical research procedures.
3. Write SOPs for the intended audience.
4. Clearly define the start and endpoint for the process to be described.
5. Balance depth and usability – ensure that the SOP has enough detail to be usable but not so much detail that it is overwhelming for the user.
6. Do not include any details that are simply for educational purposes.
7. Do not include any details that are “debatable” best practices.
8. Write in the active voice and begin each step with a simple action verb.
9. Develop SOPs such that an individual with no experience could easily follow the procedure in complete alignment with the SOP.
10. Be concise – fewer words are better than more words.
11. Focus on process, not tools.
12. Use common language.