		<b>Standard Operating Procedure</b>	
<b>SOP 101, Version 3</b>	<b>Issued by:</b> SOM CRSO	<b>Issue Date:</b> May 26, 2021	<b>Effective Date:</b> September 13, 2021

### 101.3: CRSO SOP on SOPs

#### PURPOSE

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

#### SCOPE

These procedures apply to SOM Clinical Research Support Office (CRSO) staff who develop and manage CRSO SOPs.

#### PROCEDURE

##### 1. **Development**

- a. New SOPs may be proposed by the following parties:
  - i. Any member of the UNC SOM research community
  - ii. CRSO staff members
  - iii. The CRSO Advisory Committee
- b. The CRSO will make a collaborative decision as to which SOPs will be developed and the order of priority.
- c. A CRSO staff member will present a general description of the proposed SOP to the CRSO Advisory Committee for review and feedback.
- d. When it is determined that a new SOP will be developed, a member of the CRSO (who has appropriate knowledge and understanding of the process) is assigned as SOP author.
- e. The SOP author drafts the SOP in collaboration with SOM clinical research professionals and institutional research administrators, as applicable, to promote accuracy, completeness, and quality.
- f. The SOP author prepares the SOP using the CRSO SOP template (Appendix A). The template contains the following sections:
  - i. SOP Numbering: The SOP number is a chronological number starting at 101 followed by a period and a number indicating the version number.
  - ii. Document Header: SOP number, version number, issue date, effective date, SOP title (Format: SOP #.Version #: SOP Title). The issue date and effective date is designated as "DRAFT".
  - iii. Purpose: A brief statement indicating the reason for and/or intent of the SOP
  - iv. Scope: A brief statement specifying to what and/or whom the SOP applies.
  - v. Background: A brief summary of any applicable background information relevant to this procedure. This section is optional; include only if needed based on SOP content. This section may be in paragraph form or in a bulleted list.
  - vi. Procedure: Step-by-step instructions that enables personnel to complete work processes with uniformity, consistent quality, and in accordance with applicable regulations and best practices.

1. Procedures clearly describe what is to be done, who is responsible for doing it, and when it is to be performed.
2. Procedures are written with sufficient detail so that different people can carry out the procedures consistently, and so that the document can be used to train new personnel. However, procedures should be broad enough that various departments can execute them easily.
3. Use of names of individuals, room/building numbers, phone numbers, and specific pieces of equipment should be avoided as it may require revision of the SOP each time these details change.
4. Where possible, illustrate procedures by using a graphic, such as a table, chart, or process map.
5. If applicable, provide circumstances under which the SOP may be deviated from or alternative steps may be used.
6. Study teams may supplement SOPs with work instructions when additional detail is required.
- vii. Definitions: A list of alphabetized terms, abbreviations, or acronyms that are useful in understanding the SOP.
- viii. Associated policies, regulations, guidelines: A list of applicable federal, state, or institutional policies related to this procedure referenced within the SOP by number in superscript.
- ix. Review history: Table for documenting the changes 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.
- x. Footer: SOP title and page number.
- xi. Watermark indicating “DRAFT” (which will be removed after the SOP is finalized).
- xii. Appendices: Any supplementary materials are added as individual appendices at the end of the SOP. Appendices are arranged sequentially by the order they were first referenced in the text.
- g. CRSO staff and others knowledgeable about the procedures of the SOP, as applicable, review and test the SOP to ensure that the procedures are clear and appropriately reflect clinical research workflows.

## 2. Review and validation

- a. Institutional review
  - i. Following review and testing by CRSO staff (and others as applicable), the SOP is reviewed by relevant institutional research administrators and officials who are knowledgeable about the procedures of the SOP and applicable local, state, and federal regulations and guidelines.
  - ii. Any necessary revisions will be made based on the institutional review.
- b. SOM community review
  - i. Following institutional review, the SOP is made available for public review and feedback by the SOM research community for a 3-week period.
  - ii. An invitation to review the survey is distributed via the CRSO listserv that includes a link to the SOP and the survey.
  - iii. All feedback is reviewed, categorized, and discussed by CRSO staff, and institutional officials as applicable.

- iv. CRSO personnel document the review process and maintain a record of all feedback.
  - v. CRSO staff will document what revisions were made to the SOP based on feedback, and if revisions were not made, why.
  - vi. All agreed-upon revisions will be made.
  - c. Any SOPs that are internal and intended only to support operations of the CRSO will not undergo institutional or SOM Community review and validation.
3. **Approval**
- a. Upon completion of the review process, the SOP is presented to the SOM Research Leadership Committee for final approval.
  - b. The approved SOP is updated with the issuance and effective dates.
  - c. A read-only copy of the finalized SOP is uploaded to the [CRSO SOP webpage](#).
4. **SOM community dissemination and application of SOPs**
- a. The finalized SOP and any supplemental resources to support the review of the SOP are uploaded to the SOM Clinical Research Personnel Profile and Training System.
  - b. SOM clinical research investigators and personnel receive an automatic notification from the SOM Clinical Research Personnel Profile and Training System when a new or revised SOP requires review. The notification is sent no later than one month in advance of the effective date of the SOP.
  - c. SOM clinical research investigators and personnel are responsible for reviewing the SOP and providing attestation of reading and comprehension in the SOM Clinical Research Personnel Training System prior to the effective date of the SOP (or within 1 month of receiving notification that review/attestation is required).
  - d. Individual personnel supervisors and/or CRAU leadership are responsible for ensuring that investigators and clinical research personnel complete the review and attestation of SOPs as relevant to their research responsibilities and may choose to provide supplemental education sessions.
  - e. SOM clinical research supervisors are responsible for ensuring that the SOP is applied correctly in practice.
    - i. This may require additional training and the development of detailed work instructions specific to the unit and/or research project. The CRSO SOP review is not intended to replace general job training.
5. **Revisions**
- a. CRSO 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.
  - b. An SOP revision can be triggered earlier if a need is identified.
  - c. If no revisions are deemed necessary, no additional actions are required.
  - d. If the CRSO determines that revisions are necessary, an SOP author is assigned to begin the process of revising the SOP.
    - i. The SOP author makes a copy of the SOP that requires revision and add the watermark "DRAFT".
    - ii. Substantive SOP revisions follow the procedures outlined in step 2 (review and validation) and 3 (approval).
    - iii. Minor SOP revisions follow review and approval procedures as determined by the CRSO.
    - iv. All revisions require training and attestation as outlined in step 4.
    - v. The revision history table within the SOP is updated with each revision.

**6. Finalization/Management**


- a. Upon the effective date, the watermark indicating “DRAFT” is deleted from the new or revised SOP.
- b. A read-only format of the final version is posted on the CRSO website.
- c. Outdated versions will be archived on the CRSO server to be available for historical data review.
- d. SOPs will remain in effect until terminated or revised.
- e. A master list of all CRSO SOPs will be maintained that denotes the SOP number, version number, effective date, title, author, status, and change history.

**DEFINITIONS**

- Effective date: The date upon which SOP is in effect for the SOM.
- Issue date: The date upon which the SOP is issued for training. SOPs are issued no later than one month prior to the effective date.
- SOM Clinical Research Support Office (CRSO): Central administrative office supporting all human subjects research across the SOM
- Standard Operating Procedure (SOP): Written step-wise instructions with sufficient detail to achieve uniformity of the performance of a specific function (ICH GCP 1.55)

<b>Revision History</b>		
<b>Version</b>	<b>Effective Date</b>	<b>Change Summary</b>
101.1	May 26, 2021	First approved version
101.2	August 12, 2021	<ul style="list-style-type: none"> <li>• New standard header added</li> <li>• Procedure 1.f.viii. updated to indicate that in-text references are numbered in superscript</li> </ul>
101.3	September 13, 2021	Correction to multilevel list format

APPENDIX A: CRSO SOP Template

 <b>Standard Operating Procedure</b>			
<b>SOP #, Version #</b>	<b>Issued by: SOM CRSO</b>	<b>Issue Date: DRAFT</b>	<b>Effective Date: DRAFT</b>

**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.

DEFINITIONS

List of alphabetized terms, abbreviations, or acronyms that are useful in understanding the SOP.

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.

APPENDICIES

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

Templates or documents that support or enhance the content of the SOP.

<b>Revision History</b>		
<b>Version</b>	<b>Effective Date</b>	<b>Change Summary</b>
#.#	Date SOP is in effect	Brief summary of changes (if initial version, state “first approved version”)