



## 201.1: Developing and Maintaining Clinical Research Standard Operating Procedures for Individual Units

### PURPOSE

This [Standard Operating Procedure \(SOP\)](#) describes procedures for developing and maintaining clinical research SOPs for teams, centers, divisions, and departments (hereinafter and individually referred to as unit SOPs) within the UNC School of Medicine (SOM).

### SCOPE

This SOP applies to all SOM administrators, investigators, and study personnel responsible for developing and maintaining unit SOPs to operationalize clinical research.

### BACKGROUND

The intent of clinical research SOPs is to provide consistent written instruction outlining the steps that are required to complete a task while ensuring that compliance, quality, efficiency, data integrity, and participant safety are realized. The SOM provides high-level SOPs that map federal and state regulations, UNC-Chapel Hill and UNC Health policies and standards, and Good Clinical Practice guidelines with step-by-step actions. SOM units may also create and maintain specific and individual unit SOPs (and/or [Work Instructions](#)<sup>1</sup>) as long as these do not conflict with SOM SOPs.

### PROCEDURE

1. Follow a standard format for writing unit SOPs.
  - a. Unit SOPs should include the following key elements, at minimum: purpose, scope, procedural steps, effective date, and revision date (as applicable).
2. Ensure unit SOPs align with relevant UNC-Chapel Hill, UNC Health and SOM policies and SOPs<sup>2</sup>, as well as applicable state and federal regulations and guidelines.
  - a. Assign a point of contact or responsible party to review each unit SOP as needed to ensure relevance, consistency, completeness, and continued alignment with state and federal regulations and guidelines, as well as UNC-Chapel Hill, UNC Health (as applicable), and SOM policies and SOPs.
3. Update unit SOPs as needed to maintain alignment with relevant changes to UNC-Chapel Hill, UNC Health, and/or SOM policies and procedures.
4. Ensure dissemination and availability of unit SOPs for all individuals within scope of each unit SOP.
  - a. Assign a point of contact or responsible party to ensure review of each unit SOP by individual(s) within scope of the SOPs to facilitate continued understanding and adherence.

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.

ASSOCIATED POLICIES, REGULATIONS, GUIDELINES, RESOURCES

1. [SOM Work Instructions Template](#)
2. [Clinical Research Support Office \(CRSO\) Website: UNC-Chapel Hill and UNC Health Policies and Procedures](#)

<b>Revision History</b>		
<b>Version</b>	<b>Effective Date</b>	<b>Change Summary</b>
201.1	12.14.2023	New