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NRP

Biomedical Behavioral Translational Social

Network for Research Professionals

NRP November 2025 Education Session

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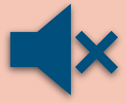

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Writing Unit-Level and Study-Level Clinical Research Standard Operating Procedures (SOPs)

NRP Education Session, November 17, 2025

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UNC | OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
Research Compliance Services

Purpose of Standard Operating Procedures (SOPs)

- Define consistent, compliant procedures for study conduct
- Support GCP, FDA, and university policy compliance
- Reduce variability in how work is carried out across roles, teams, and sites
- Protect study participants and minimize risks
- Serve as training and audit documentation

Examples of Common SOP Topics

These are typical areas SOPs cover across research units, teams, and individual studies. The exact scope depends on the process and the level of detail needed.

Informed consent documentation and storage procedures

Clear steps for preparing, documenting, and maintaining consent records.

Participant screening and enrollment workflows

Standards for capturing screening information and confirming eligibility.

Source documentation expectations

Guidance on creating, maintaining, and correcting source records.

Data entry and data quality checks

Procedures that support accurate entry, verification, and ongoing quality review.

Safety event reporting and follow-up

Requirements for documenting, assessing, and reporting safety information.

Delegation of duties and training file management

How responsibilities are assigned and how staff training is tracked.

Sample management procedures

Instructions for collecting, labeling, storing, and shipping study samples.

Archiving and closeout activities

Steps for completing documentation and securing required records at study end.

SOP Levels and Responsibilities

Dimension	University-Level SOPs or Procedures	Unit-Level SOPs	Study-Level SOPs
Scope	Apply across all studies at UNC-Chapel Hill	Apply across multiple studies within a unit, such as a department, division, program, or research team	Apply to a single research protocol
Purpose	Define institution-wide regulatory expectations for compliant research operations	Standardize recurring operational procedures within a unit that aren't fully detailed in university-level SOPs	Tailor institutional or unit procedures to meet the needs of one study
Owners	Research administrative and compliance offices (e.g., OHRE, CRCO, OSP)	A unit, such as a department, division, program, or research team	Principal Investigator (PI) and study team
Location	UNC's Electronic Policy Repository and on policy owners' websites	Systems or shared drives controlled by the unit	Study's regulatory binder or eReg system

Unit-Level SOPs

Unit-level SOPs define recurring operational activities for a **unit**, such as a department, division, program, or research team. They apply across multiple studies within that unit and create consistent practices for functions shared across several projects.

When to Use

- When a process applies to multiple studies within a unit
- When the procedure isn’t addressed in a university-level SOP
- When units want a standardized approach to onboarding and training staff

Examples

- Unit SOP for onboarding and training new study staff
- Department SOP for escalating safety events before they reach institutional channels
- Program SOP for maintaining shared screening logs or participant tracking workflows
- Team SOP for maintaining shared regulatory documents, such as CVs and license logs

Study-Level SOPs

Study-level SOPs describe processes or responsibilities specific to one research protocol. They ensure all study tasks are carried out consistently and in compliance with regulatory and sponsor requirements.

When to Use

- When study requirements differ from existing University or unit SOPs
- When the study involves complex or high-risk procedures
- When UNC or the PI acts as the sponsor for an investigator-initiated trial
- When sponsor-delegated tasks require study-specific documentation

Examples

- SOP outlining the study-specific process for evaluating reporting Serious Adverse Events (SAEs) to the sponsor and IRB
- SOP outlining the process for screening participants and documenting eligibility based on protocol-specific criteria.
- SOP detailing study-specific procedures for receiving, storing, dispensing, and documenting investigational product (IP).

Structure of an SOP

01

Title & Identifier

Include the SOP title, version number (for example, **v1.0** or **2024-03-15**), and the applicable owner (unit, department, team, or study)

02

Purpose

Explain why this SOP exists

03

Scope

Define who and what the SOP covers

04

Responsibilities

Specify roles and their duties involved in the procedure

05

Procedures

Describe the overall process flow, the sequence of actions, decisions, and handoffs. Focus on what happens and who is responsible, not every system click or step

06

Documentation & Records

Identify all logs, forms, systems, or files used to document the activity (for example, delegation log, AE form, eReg, REDCap)

07

References

List governing documents that support or inform the procedure (e.g., GCP, FDA regulations, UNC or sponsor policies).

08

Version Control

Record authors, reviewers, approval dates, and revision history to show when and how the SOP has changed.

Tip: Keep it concise and focused. Use **work instructions** for detailed, task-level steps or system-specific guidance.

SOPs vs. Work Instructions

Characteristic	SOPs	Work Instructions
Purpose	Define what needs to happen and who is responsible for the process	Describe how to complete a specific task step-by-step. UNC SOM Work Instructions Template
Focus	Operational workflows	Detailed task execution (e.g., system clicks, forms, documentation).
Level of Detail	Moderate – define workflow, decision points, and responsibilities	High – provides exact steps, screens, fields, or screenshots
Audience	Anyone who must follow the process	Anyone performing the specific task.
Control	Approved, version-controlled document.	May be referenced or appended; not always controlled at the same level.

Example

SOP (Study-level): Outlines the study-specific process for evaluating and reporting Serious Adverse Events (SAEs) to the sponsor and IRB.

Work Instruction: Step-by-step guide for entering an SAE into Advarra EDC, including required fields, navigation, and system actions.

Best Practices for SOP Writing

- Use active voice
- Keep instructions concise and direct
- Use consistent terminology aligned with federal regulations, GCP and UNC-Chapel Hill policy language
- Define acronyms the first time they appear
- Maintain headers and version control and headers on every page (title, version, date, page number).
- Write for the newest person on the team.

Style reference: Follow the UNC Policy Style Guidebook to keep language clear, consistent, and professional across all research and compliance documents.

Managing SOPs (The 'SOP on SOPs')

Purpose: To define how SOPs are created, approved, implemented, and maintained across a research unit or study team.

Key Components

Development: Describe how new SOPs are drafted, reviewed, and formatted

Approval: Identify who must approve SOPs before implementation (e.g., PI, QA, or unit lead)

Version Control: Outline how updates, effective dates, and retired versions are tracked

Access and Storage: Specify where SOPs are stored (e.g., eReg, shared drive) and who can edit them

Training and Implementation: Define how staff are trained on new or revised SOPs

Review Cycle: Establish how often SOPs are reviewed (e.g., annually or as regulations change)

Why It Matters: An "SOP on SOPs" ensures consistency, accountability, and audit readiness for all procedural documents

Common Pitfalls

Copying Without Tailoring

Using university-level SOPs without adapting them to your team's or study's specific needs

Overcomplicating Instructions

Including unnecessary detail that makes SOPs difficult to follow

Missing Version Control

Failing to include version numbers, approval dates, or effective dates to show which version is current

Inconsistent Terminology

Using different terms between SOP and protocol documents

Skipping Re-training

Not retraining staff after SOP updates or failing to document that training

Fix: Write SOPs for the person who will perform the task— clear, practical, and easy to follow

Institutional Resources

Unit Procedure (SOP) Template

Official UNC template for developing unit- or study-level SOPs and procedures:

View Template

SOP and Forms Library

The UNC Clinical Research Compliance Office (CRCO) provides SOP templates tailored for clinical research:

View Templates Library

New and updated templates coming soon!

Clinical Research Playbooks

The Clinical Research Support and Operations (CRSO) office offers step-by-step guidance for study start-up, conduct, and closeout:

View Clinical Research Playbooks

Using AI Responsibly in SOP Development

AI Can Help With

- Drafting structure and standard language for SOPs
- Suggesting workflows and process outlines
- Checking clarity and readability
- Maintaining consistent terminology

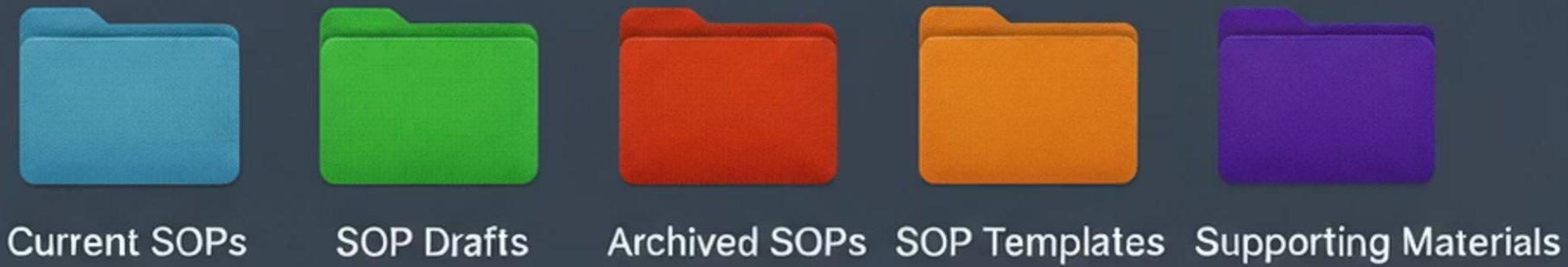
Responsible Use at UNC

- Treat AI outputs as *drafts only* — always validate against UNC SOPs
- Don't upload confidential or study-identifiable information
- PI and compliance team retain full authorship and responsibility
- Note AI use transparently if it contributed to drafting

Example: Use Copilot or ChatGPT to outline a "Data Management SOP," then cross-check against UNC guidance and finalize internally.

Final Thoughts

> "Write your SOPs as if someone new joined tomorrow and had to run a study perfectly on their first day."



Building Effective SOPs: Supporting Quality, Compliance, and Audit Readiness

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CTQA Audits Include SOPs

Standard Operating Procedures is a critical component of CTQA audits. The CTQA review University SOPs regularly and reassess these upon revision. The following SOPs are requested during the CTQA audit:

Department SOPs

Departmental procedures governing operational standards

Study Team SOPs

Team-specific protocols tailored to research group workflows

Study Level SOPs

Protocol-specific procedures unique to individual clinical trials

The specific SOPs requested during your audit will be determined by the study team structure and trial complexity.

Common Findings Related to SOPs

Auditors consistently identify recurring deficiencies in SOP management that compromise study integrity and regulatory compliance.

Document Control Failures

Inadequate version control systems and poor tracking of SOP revisions

Practice-Procedure Misalignment

SOPs that fail to reflect actual current operational practices and workflows

Training Deficiencies

Insufficient or undocumented training on both new and revised procedures

CAPA Effectiveness Review Gaps

Absence of systematic evaluation to confirm implemented SOPs resolve identified issues

Post-CAPA Non-Compliance

Failure to adhere to revised SOPs developed in response to corrective actions

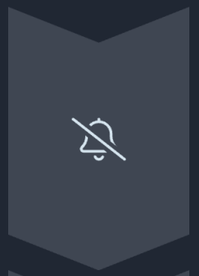
Missing SOPs

Complete absence of documented procedures for critical trial activities

High-Risk Areas Requiring SOPs

Establishing formal SOPs for high-risk clinical trial activities is essential to protect participant safety, ensure data integrity, and maintain regulatory compliance.

Critical Areas Where SOP Absence Creates Significant Risk:



Adverse Event Review

Systematic evaluation, documentation, and reporting of safety events requires standardized procedures to ensure timely and accurate response

Informed Consent Process

Comprehensive protocols for obtaining, documenting, and maintaining informed consent protect participants and study validity

Eligibility Review

Structured procedures for evaluating and documenting participant eligibility prevent enrollment errors and protocol deviations

Implementing an Effective SOP Review Schedule

A robust SOP management system prevents audit findings and ensures continuous quality improvement through systematic tracking and review.

Establish a Tracking System

Implement centralized digital tracking to monitor all SOPs, versions, and review dates

Document Revision Details

Capture summaries including rationale, responsible parties, and implementation dates for every change

Create Review Schedules

Establish routine review cycles ensuring SOPs remain current and aligned with evolving practices

Align CAPAs with SOPs

Verify that corrective actions integrate seamlessly with relevant SOPs to prevent recurring issues

Maintain Training Records

Track and document all staff training on SOPs, including initial training and updates following revisions

Approaches to SOP Management at the Clinical Trials Office

Presented by *Anly M Thomas*

Compliance Manager

SOP Committee Chair

Key Features of SOP Management

DEVELOPMENT

APPROVAL

VERSION CONTROL

ACCESS AND STORAGE

TRAINING AND IMPLEMENTATION

REVIEW CYCLE

SOP Development

Trigger: new process, compliance requirement, recurring errors, or onboarding needs.

Action: Define the purpose of the SOP.

SOP Authors: Compliance team and Subject Matter Experts (SMEs)

Creation Process: Notify the SOP Chair to issue new SOP numbers and record expected revisions

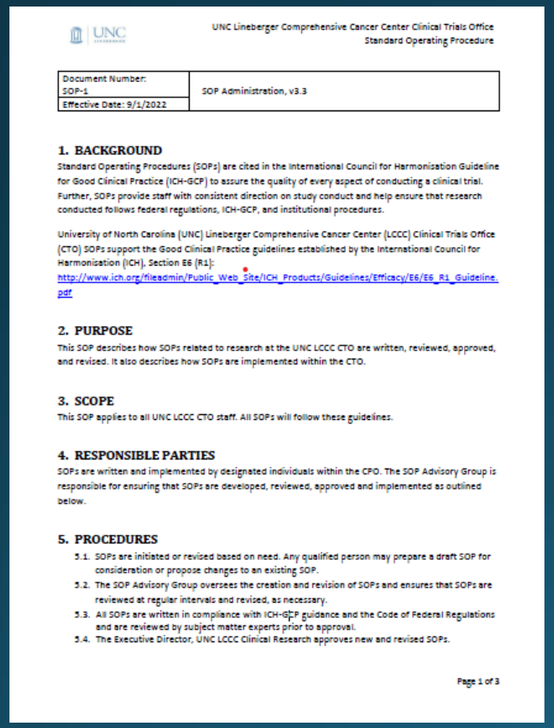
Drafting Tools: Standard Word document template

Stakeholder Collaboration: Reviews conducted by SMEs and Functional Group leadership

Drafting the SOP

- Create draft using current signed version.
- Apply changes and track revisions.
- Assign reviewers and collect feedback.
- Finalize and prepare clean version for approval.
- Convert to PDF and collect signatures.
- Post signed SOP in LMS and set effective date.
- **Work Instructions** can be created in tandem or separately.

Drafting the SOP
SOP Sections



UNC Lineberger Comprehensive Cancer Center Clinical Trials Office
Standard Operating Procedure

Document Number: SOP-1	SOP Administration, v3.3
Effective Date: 9/1/2022	

1. BACKGROUND

Standard Operating Procedures (SOPs) are cited in the International Council for Harmonization Guideline for Good Clinical Practice (ICH-GCP) to assure the quality of every aspect of conducting a clinical trial. Further, SOPs provide staff with consistent direction on study conduct and help ensure that research conducted follows federal regulations, ICH-GCP, and institutional procedures.

University of North Carolina (UNC) Lineberger Comprehensive Cancer Center (LCCC) Clinical Trials Office (CTO) SOPs support the Good Clinical Practice guidelines established by the International Council for Harmonization (ICH), Section E6 (R1): http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

2. PURPOSE

This SOP describes how SOPs related to research at the UNC LCCC CTO are written, reviewed, approved, and revised. It also describes how SOPs are implemented within the CTO.

3. SCOPE

This SOP applies to all UNC LCCC CTO staff. All SOPs will follow these guidelines.

4. RESPONSIBLE PARTIES

SOPs are written and implemented by designated individuals within the CPO. The SOP Advisory Group is responsible for ensuring that SOPs are developed, reviewed, approved and implemented as outlined below.

5. PROCEDURES

5.1. SOPs are initiated or revised based on need. Any qualified person may prepare a draft SOP for consideration or propose changes to an existing SOP.
5.2. The SOP Advisory Group oversees the creation and revision of SOPs and ensures that SOPs are reviewed at regular intervals and revised, as necessary.
5.3. All SOPs are written in compliance with ICH-GCP guidance and the Code of Federal Regulations and are reviewed by subject matter experts prior to approval.
5.4. The Executive Director, UNC LCCC Clinical Research approves new and revised SOPs.

Page 1 of 3

- Title
- Background
- Purpose
- Scope
- Responsible Parties
- Procedures
- Related Documents
- References
- Revisions History

Approval

Subject Matter Expert

Functional Group Managers

SOP Committee

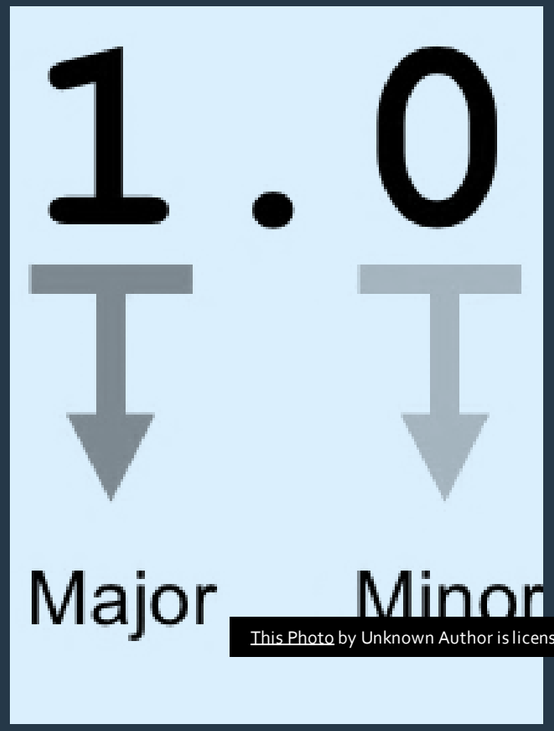
Leadership Review and Signoff

Timeline: ~6 months from draft to publication

Role of the SOP Committee or SOP Advisory Group

- Cross-functional review and input
- Ensures quality, consistency, and compliance
- Resolves conflicts and evaluates impact
- Reviews work instructions
- Recommends and advances SOPs

Version Control



Administrative changes (Minor updates, formatting, or clarifications) use **decimal increments**:
Example: 1 → 1.1 → 1.2 → 1.3.

Significant changes (Changes to processes or roles requiring full committee review) use **whole number increments**:
Example: 1 → 2 → 3.

The **effective date** is two weeks from the approval signature.

Each SOP includes a **revision history** that includes the version numbers, date of revision, authors, changes to the documents.

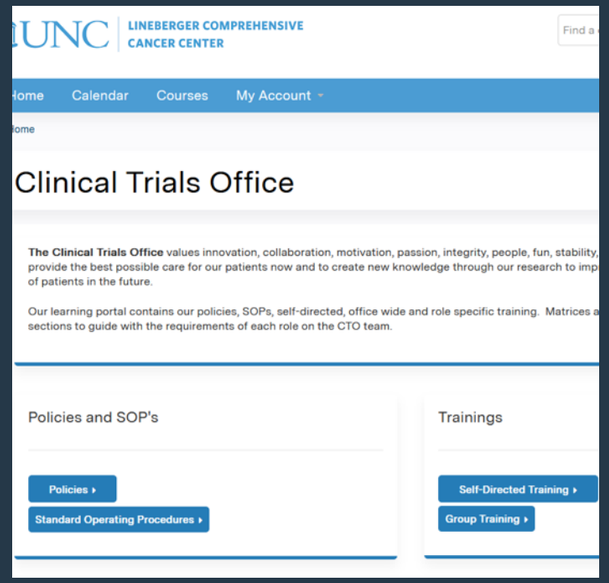
Access and Storage

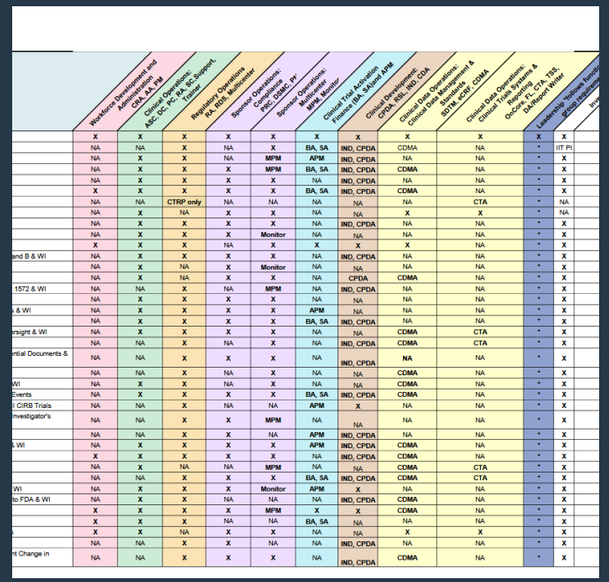
LMS Repository: Centralized, authenticated system housing all SOPs, WIs, and job aids

SOP Matrix: Defines which role needs to review each document

New Hire Requirements: Required to review key SOPs within set timelines based on guidance from managers/mentors.

Draft Storage: Word documents and drafts maintained on a shared drive.





Training and Implementation

- Once the SOP is uploaded into the LMS, the office is informed about the publication via email.
- The email indicates who are impacted by the SOP/ revisions and individuals are asked to review.
- Trainings are conducted at the functional group level to ensure that the team is aware of the revisions impacting their workflows.
- The staff are to attest within LMS that they have read the SOP and a report can be retrieved if necessary.

Review Cycle

Frequency: Every 3 years

Triggers for revision:

- New systems or tools
- Regulatory changes
- Recurring deviations or errors
- Feedback from users or audits
- Periodic Review

Actions:

- Confirm the SOP is still relevant and accurate.
- Update content if necessary.
- Increase version number and document changes in a change log.
- If unchanged, document the review and extend validity.
- SOP Committee reviews and approve revisions following the same workflow.

Questions?

We welcome your questions and insights.

Thank you for your engagement and attention.

Evaluation

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Post-session evaluation:

Link https://go.unc.edu/NRPSOPeval

or scan the QR code.

Attendance Certificate: An option to **download** certificate, BEFORE submitting the eval, is located within the post session eval survey.

Email: NRP@unc.edu if further questions or suggestions for future education.