

SOM SOP 201.1

Developing and Maintaining Clinical Research Standard Operating Procedures
for Individual Units



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Clinical Research Profile and Training System (PaTS) SOP Attestation Demo

Overview of SOP 201.1

Questions

Who is Required to Attest in PaTS?



**“Developing unit
standard operating
procedures and/or work
instructions”**

Instructions for creating a PaTS profile and attesting to documents in PaTS are available at
www.med.unc.edu/crso/training/pats/

When Is the Attestation Due?

30 Days from Issue Date

December 14, 2023



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SOP Attestation Demo

PaTS

UNC SOM PROFILE
& TRAINING SYSTEM



SOP 201.1 Format



Purpose

Scope

Background

Procedural
Steps

Definitions

References

Background

Federal and state regulations and guidelines

UNC & UNC Health standards, policies, procedures, guidelines

UNC & UNC Health SOPs

SOM SOPs

Unit SOPs

Work Instructions Versus SOPs

SOPs

Outline what needs to be done by whom to fulfill a standard or policy

Work Instructions

are narrower in scope; focus on how specific tasks are performed

Procedural Steps

1

Follow a standard
format for writing
unit SOPs

2

Ensure that unit
SOPs align with
federal and local
regulations and
guidelines

3

Update unit SOP
with relevant
changes to
regulations and
guidelines

4

Ensure
dissemination and
availability of unit
SOP to individuals in
scope of the SOP



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Questions