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



Who is Required to Attest in PaTS?

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"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?



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30 Days from Issue Date December 14, 2023



SOP Attestation Demo



SOP 201.1 Format



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Purpose Scope Background **Procedural** Steps Definitions References





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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

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<u><u><u></u></u>UNC</u>

SOPs

Outline <u>what</u> needs to be done by <u>whom</u> to fulfill a standard or policy

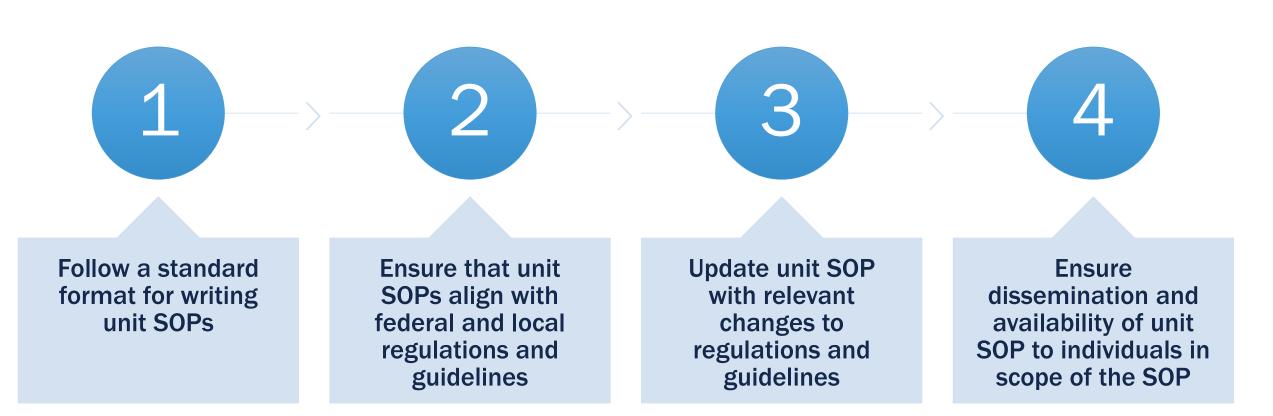
Work Instructions

are narrower in scope; focus on <u>how</u> specific tasks are performed

Procedural Steps



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Questions