

N2 Standard Operating Procedures Update

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CALGARY

Learning Objectives

- Overview of the latest release of the Network of Network Standard Operating Procedures (N2 SOPS)
- Understand how to properly adopt these SOPs and document training

Purpose of the Updates

- Modernization and regular update cycle
- International Council of Harmonization (ICH) E6(R3) updates, adopted by Health Canada on April 1, 2026.

Highlight of the changes

- Alignment with ICH E6(R3)
 - Risk-based approach
 - Emphasis on quality management and oversight
 - Focus on electronic systems
- Separation of Responsibilities
 - Clear differentiation between site and sponsor level roles
- Improved Usability
 - Improves navigation and reduces duplication
- Terminology Updates
 - Data Acquisition Tool (DAT) replaces CRF/eCRF
 - Clinical Investigation Plan (CIP) for Medical Devices
 - Electronic system terminology (SOC2, SSL)

Site – Initiated SOPs



SOP Table of Contents

SOP# version	Title	Effective Date (dd-Mon-yyyy)
Site-Initiated SOPs (001 – 005, 007 – 014, 016 – 017, 019, 025)		
001_11	Standard Operating Procedure (SOP) Administrative Management by Network of Networks	17-Feb-2026
002_11	Research Team Roles and Responsibilities	17-Feb-2026
003_11	Research Team Training	17-Feb-2026
004_11	Clinical Research Protocol Feasibility and Site Selection	17-Feb-2026
005_11	Site Preparation for Study Initiation	17-Feb-2026
007_11	Research Ethics Board: Submissions and Ongoing Communication	17-Feb-2026
008_11	Informed Consent Process	17-Feb-2026
009_11	Participant Recruitment and Screening	17-Feb-2026
010_11	Management of Investigational Products	17-Feb-2026
011_11	Management of Biological Specimens	17-Feb-2026
012_11	Adverse Event/Drug Reaction Documentation, Assessment and Reporting	17-Feb-2026
013_11	Study Monitoring and Communication	17-Feb-2026
014_11	Essential Records and Source Records Management	17-Feb-2026
016_11	Study Close-Out and Archiving	17-Feb-2026
017_11	Audits and Inspections	17-Feb-2026
019_11	Confidentiality and Privacy	17-Feb-2026
025_07	Equipment and Device Fitness for Purpose	17-Feb-2026

- SOP006_10 Informed Consent Form and Assent Form Management was retired and content merged into SOP112_01 (Sponsor-Initiated)
- SOP015_10 Investigator Site File Management was retired, and content was merged into SOP014_11
- SOP018, 023, and 024 (CTA, ITA, NHP) were retired and merged into SOP114_01 (Sponsor-Initiated)

Sponsor –Initiated SOPs



SOP Table of Contents

SOP# version	Title	Effective Date (dd-Mon-yyyy)
Sponsor-Initiated SOPs (110 - 124)		
110_01	Sponsor Roles and Responsibilities	17-Feb-2026
111_01	Study Design	17-Feb-2026
112_01	Informed Consent / Assent Development	TBD
113_01	Quality Risk Management	17-Feb-2026
114_01	Regulatory Applications	17-Feb-2026
115_01	Study Contracts and Budgets	17-Feb-2026
116_01	Investigational Product	17-Feb-2026
117_01	Sponsor Electronic Systems	17-Feb-2026
118_01	Study Database	17-Feb-2026
119_01	Essential Records	TBD
120_01	Sponsor Oversight, Monitoring, and Audits	TBD
121_01	Safety Assessment and Reporting	TBD
122_01	Study Analysis and Reporting	17-Feb-2026
123_01	Study Close-Out and Archiving	17-Feb-2026
124_01	Investigational Medical Devices	TBD

SOP# version	Title	Effective Date (dd-Mon-yyyy)
Other Documents (update as required)		
N/A	Glossary of Terms	17-Feb-2026

- Brand new set of Sponsor-Initiated SOPs.
- The previous set from version 10 SOP100-109 have been retired and content merged into the relevant new or existing SOPs.
- 5 SOPs pending release in the coming months

Accessing the SOPs

Standard Operating Procedures

Quality Assurance for Clinical Trials

Regulatory authorities require that clinical research sites utilize standard operating procedures (SOPs) to ensure that their research is conducted in manner that protects the rights and safety of study subjects and the integrity of the research data collected. The University of Calgary is strongly recommending that all clinical research groups adopt the use of the SOPs created by the Network of Networks' (N2). These SOPs are externally reviewed by an independent expert to ensure compliance with the regulations governing clinical research.

Changes to the formal set of SOPs at the site/institutional level are NOT recommended and may result in the SOPs no longer being compliant.

Due to our agreement with N2, the SOPs are not available to be brought to the site by external parties. The Sponsor may review the SOPs while on site, but is unable to bring a copy with them. If a site is unable to access the SOPs as part of your site activation, you may send them a copy of the Table of Contents.

Researchers and their teams are responsible for providing training on SOPs.

Access the full set of SOPs

- [N2 SOPs](#) (University of Calgary authentication required)
- [Table of Contents](#)
- [SOP Training Record Template](#)
- [Study Team SOP Adoption Letter Template](#)
- [Letter of Assurance](#)
- [N2 FAQs](#)

Tools to aid with training & adoption

Adopting the SOPs



Standard Operating Procedures (SOPs) ADOPTION RECORD

The [PROTOCOL] research team has adopted the use of the N2 SOPs. The N2 SOP set, [version] was reviewed on by [PI/SOP REVIEW TEAM], on [DATE]. [Outline any revisions or exemptions for example "Revisions are not required, but Exceptions and considerations are explained below for each of the adopted SOPs."]

PI/QI
Signature: _____ Title: _____

Print Name: _____ Date: _____
(DDMMYY)

Site Initiated SOPs (001 – 005, 007-014, 016-017, 019, 025)	
SOP001_11 Standard Operating Procedure (SOP) Administrative Management by Network of Networks	[EXAMPLE: Site team is adopting this SOP without any edits or exceptions.]
SOP002_11 Research Team Roles and Responsibilities	[EXAMPLE: Site team is adopting this SOP with the following exceptions - - -]

- SOPs should be adopted for each study or each study team (as applicable)
- Only adopt the SOPs that directly apply to your projects
- SOPs should not be modified but this record can document any site or sponsor-specific deviations from the SOP set
- Recommend referencing additional process documents or job aids that provide more details of your processes

Documenting SOP Training



INDIVIDUAL TRAINING RECORD N2 SOPs VERSION 11

Principal Investigators (PIs) must review all N2 SOPs. All other research staff must review N2 SOPs which are relevant to their role in research studies. If you are not a PI, and if individual N2 SOPs do not pertain to your role in research studies, you may write 'NA' or 'Not Applicable' under the column 'Initials and Date Reviewed'.

SOP#* V11	SOP Title	Initials and Date Reviewed
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025_07	Equipment and Device Fitness for Purpose	

- All delegated study staff need documented SOP training
- The number of SOPs for review can be role-based

Sharing the SOPs



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N/A	Glossary of Terms	17-Feb-2026

- Due to our agreement with N2, the SOPs *may not* be shared with parties external to our institution.
- If a Sponsor requests to see your SOPs as part of your site activation, you may send them a copy of the Table of Contents, Adoption Record and Training Documents

Other SOP tools

- Letter of assurance

Standard Operating Procedures

Quality Assurance for Clinical Trials

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Researchers and their teams are required to provide

- [N2 SOPs](#) (University of Calgary authentication)
- [Table of Contents](#)
- [SOP Training Record Template](#)
- [Study Team SOP Adoption Letter Template](#)
- [Letter of Assurance](#)
- [N2 FAQs](#)

Can be provided to
Sponsors as evidence
of compliance

Other SOP tools

- N2 SOP FAQ

Standard Operating Procedures

Quality Assurance for Clinical Trials

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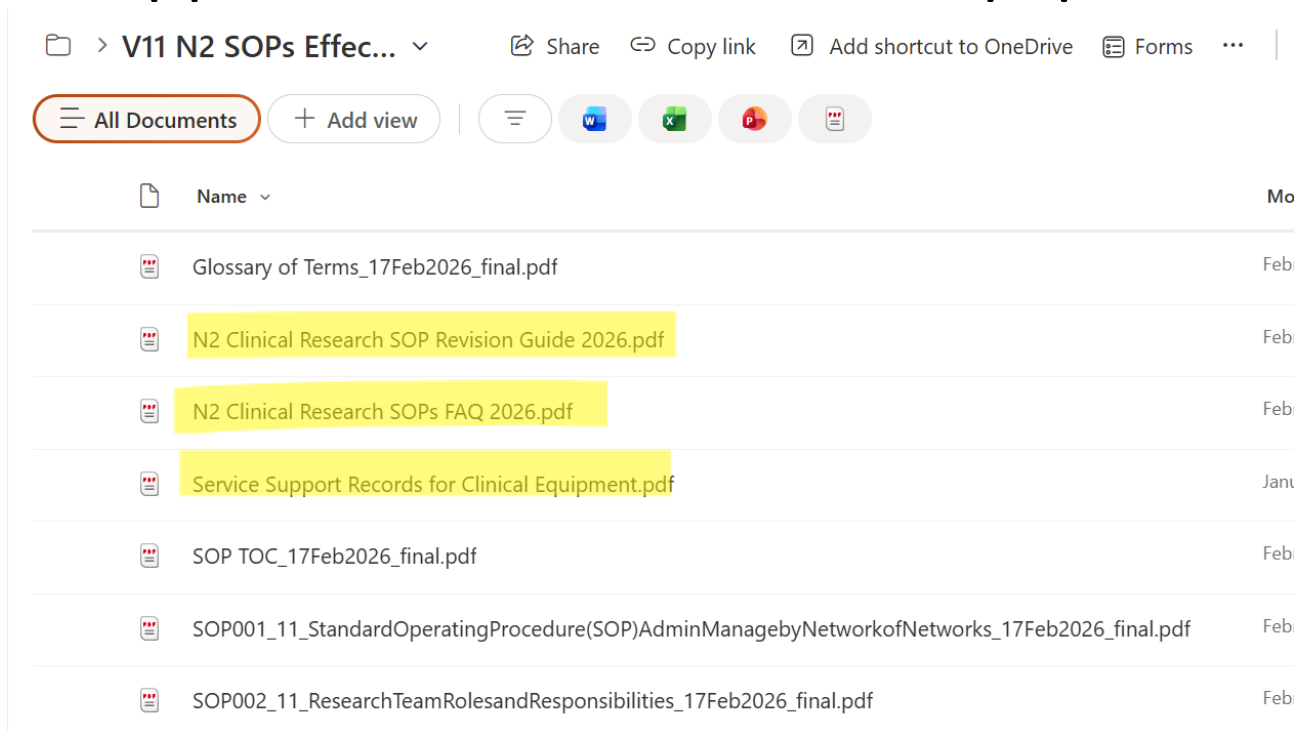
Researchers and their teams are required to provide documented proof of training on SOPs.

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- [Letter of Assurance](#)
- [N2 FAQs](#)

Additional
information on the
SOPs

Other SOP tools

- N2 SOP Revision Guide
- Service Support Records for Clinical Equipment



The screenshot shows a OneDrive file list for the folder 'V11 N2 SOPs Effec...'. The interface includes a search bar with 'All Documents' selected, an 'Add view' button, and icons for Word, Excel, PowerPoint, and Forms. The file list contains the following items:

Name	Mo
Glossary of Terms_17Feb2026_final.pdf	Feb
N2 Clinical Research SOP Revision Guide 2026.pdf	Feb
N2 Clinical Research SOPs FAQ 2026.pdf	Feb
Service Support Records for Clinical Equipment.pdf	Jan
SOP TOC_17Feb2026_final.pdf	Feb
SOP001_11_StandardOperatingProcedure(SOP)AdminManagebyNetworkofNetworks_17Feb2026_final.pdf	Feb
SOP002_11_ResearchTeamRolesandResponsibilities_17Feb2026_final.pdf	Feb

Thank you!

For more information go to

ucalgary.ca/research/cccr/clinical-trials-office/quality-assurance-clinical-trials/standard-operating-procedures

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