

List of frequently asked questions - SOP

Question	Response
1. Can I print the SOP onto site specific letter head?	This is not a regulatory requirement. If the institution allows you to use the N2 SOPs as your “set”, you can indicate this through a note to file.
2. Can we make changes / add additional information to the SOP?	It is STRONGLY recommended you do not “modify” the SOPs as you risk making them non compliant. N2 has ensured compliance through an expert reviewer, but cannot ensure compliance if edited outside of N2.
3. What does the effective date mean?	The effective date on the N2 SOPs is for N2 only. Site effective date is the “date of implementation” by the site. The effective date for your area may be different depending on when your training is completed. Complete a note to file with the appropriate effective date and keep on file.
4. Can the sponsor of my study review and take the N2 SOPs?	Every sponsor is encouraged to review the SOPs. This needs to occur onsite as the SOPs cannot be distributed outside the organization. A “Not for Distribution” watermarked set of SOPs can be requested from N2@N2canada.ca for this purpose.
5. Can I make copies of my SOPs?	You can make copies of the SOPs provided you do not distribute them outside your organization. Please ensure you are aware of the date when copying the SOPs to ensure you are working with the version that you need.
6. What happens to the old version on an SOP?	Old versions of the SOPs are retired in an archive folder on the N2 website and will remain there in case you require access to them.
7. Can I share the SOPs with others in my institution, outside my therapeutic areas?	If your institution is a member of N2, the SOPs can be made available to all hospital staff, as long as they are not shared outside the organization. HOWEVER , if you are a member of N2 through a network and your institution is not an N2 member, the SOPs cannot be shared with other groups in your institution outside your therapeutic area.

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8. How do we know when an SOP is no longer active?	N2 reviews and amends as necessary all SOPs every two years , at which time, the revised set will be rolled out with the current effective date. The old set will be archived and will be stored on the N2 web site for you to access in case of an audit.
9. What is the difference between Revision history “Summary of Changes” (in the back of each SOP) and “Revision Summary?”	In the back of each SOP there is a brief history called “Revision History” to document what was changed. The “Revision Summary” is a separate document that goes with the SOP and expands on the “Revision History” to explain where exactly the changes are, what it states and why the change was made. This was done to make it easier for you to be educated on the SOP and the changes.
10. Where can I go to find answers to my questions?	There is a Frequently Asked Question Document available to you. In addition you are encouraged to speak with your N2 representative and/or Research administration or education staff. They can ensure that the N2 SOP committee is informed. If new SOPs or changes are deemed necessary by the N2 SOP committee they will be incorporated in a timely fashion. (immediately if a regulatory change; with the annual review if not urgent).
11. What do I do if the N2 set of SOPs does not have the SOP I need?	You are encouraged to speak with your N2 representative and/or Research administration or education staff. They can ensure that the N2 SOP committee is informed. If new SOPs are deemed necessary by the N2 SOP committee they will be developed in a timely fashion. (immediately if a regulatory change; with the annual review if not urgent)
12. Can I obtain a copy of the N2 SOP approval process for an audit inspection?	Yes, you can speak with your N2 representative and/or Research administration or education staff. They can ensure that you receive the documents you require from the appropriate contact in N2.
13. Who do I contact for any questions or comments about the N2 SOPs?	Questions or concerns should be shared with your N2 representative or sent by email to: n2@n2canada.ca . The systems administrator will ensure information is conveyed to the N2 SOP committee.

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14. Can one team within an organization adopt the N2 SOPs, or does it have to be the entire organization, meaning the entire hospital?	N2 Member organizations may elect to apply the N2 series as they deem necessary. It is recommended to ensure other departments that may have responsibilities under any procedures (e.g. pharmacy) also agree to follow any SOPs used.
15. If we adopt the N2 SOPs and a sponsor has a specific SOP required that is not part of the N2 SOPs, what should we do?	You may elect to use a Note to the applicable Trial File(s) to indicate what sponsor-specific procedures were followed, superseding the standard N2 SOPs.
16. If we choose not to adopt some SOPs, when asked to document, does it mean a note to file?	Yes, per SOP001_10 §5.7.2.
17. Who is the site representative as mentioned SOP001_10 section 5.7.1?	This would be the individual(s) each site designates who can oversee the administrative functions required for SOPs' implementation and management to ensure site compliance outlined in this section. E.g., creating applicable Notes to File, oversight of SOP training activities, etc.