



## N2 SOPs Version 9

The Network of Networks (N2) has released version 9 of the Standard Operating Procedures (SOPs) for Clinical Research, which will be effective as of May 15, 2021.

The SOPs are reviewed every two years by N2. Version 9 reflects changes made to address questions raised by its members that were received by the N2 SOP Committee as part of the feedback process throughout the past two years. For all SOPs, changes are documented in the revision section at the back of the SOP. The complete set of current SOPs (Version 9) are also translated into French and are available to you. The next version of the SOPs can be anticipated to be rolled out in 2023, unless urgent changes are required due to regulatory changes.

All revisions made to the N2 SOPs were reviewed by an external independent expert to ensure compliance with Health Canada, US Food and Drug regulations, ICH-GCP Guidelines and the Canadian Tri-Council Policy Statement on Research Involving Human Subjects. A compliance letter is available for your records.

***\*\*\*The SOPs may be used by your research team but are not to be shared with anyone outside the institution or your research group.\*\*\****

Due to the size of the document files, if you would like a copy of any of the following documents, please email KGHRI and Lisa McAvoy [Lisa.McAvoy@kingstonhsc.ca](mailto:Lisa.McAvoy@kingstonhsc.ca) will be happy to forward the documents to you directly. You can access the files directly by contacting Lisa for the N2 log in details. The documents available are the following:

- Glossary of Terms for the SOPs.
- English Version 9 of the N2 SOPs (May 15, 2021).
- Revision Summary in English for each SOP detailing where the changes have occurred between Version 8 (May 15, 2020) and Version 9 (May 15, 2021), if changes are significant.

- Scanned signature pages (Page 1 only) for each SOP (English) in case your site requires a copy for monitoring purposes. ***This is available from KGHRI only.***
- French Version 9 of the N2 SOPs (May 15, 2021).
- Scanned signature pages (Page 1 only) for each SOP (French) in case your site requires a copy for monitoring purposes. ***This is available from KGHRI only.***
- SOP Training Log for your site to document training of the new SOPs.
- SOP Quiz to help you train your members within your research group; an answer sheet is available for those who oversee other research personnel.
- N2 SOP Request Change Form: to be completed if you would like KGHRI to forward any of your concerns regarding existing SOPs to the N2 SOP Committee for review and consideration for future iterations.
- Compliance Letter from N2.

Changes to the formal set of N2 SOPs are not allowed as they may result in the SOPs no longer being compliant. It is for this reason that the SOPs appear as *print only* PDF documents. Documents that assist the clinical research sites/groups/teams to ‘bridge’ between the SOPs and site-specific/local procedures (tools, checklists, sample forms, local guidance documents) are not part of the official SOP and can be created or adapted as needed, to meet the needs of the end user. N2 has provided some WORD template tools to assist you. These can be downloaded from the [N2 site](#).

**Please note:** The KGHRI office maintains the original SOPs for KHSC and will archive them according to Health Canada Regulations for 25 years. For monitoring purposes if your sponsor is satisfied with the archived originals being maintained within our office and does not require you to retain additional paper copies within your research site for 25 years once your research project is completed, please make a *note to file* indicating that:

***“The KGHRI office maintains the original SOPs and will archive them according to Health Canada Regulations for 25 years. The SOPs are available for auditing purposes by any government and/or regulatory authority, sponsor and/or funding agency or the Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board upon request.”***