

MEMORANDUM

DATE: June 20, 2023

TO: Island Health Research Community

FROM: Research Compliance

RE: Access and Use of Standard Operating Procedure (SOP) Templates for

Clinical Research and Investigator Initiated Studies through Network of Networks

What is Network of Networks (N2)?

N2 is a not-for-profit incorporated organization and an alliance of Canadian research networks and organizations working to enhance national clinical research capability and capacity. N2 provides a common platform for sharing best practices, resources and research-related content to ensure efficient and high-quality research, integrity of clinical practices and accountability. Island Health has been a contributing member since 2013.

What are the N2 SOPs?

N2 SOPs are developed and maintained by the N2 SOP Committee, a group of volunteers made up of N2 members from health authorities, research institutes, academia and industry. The SOPs go through a review/revision process every two (2) years and are reviewed by an external Compliance Specialist before they are published. The SOPs were initially developed for clinical trials and Investigator Initiated trials (regulated by Health Canada), but, provide benefit for the conduct of clinical research as well.

What are face sheets?

From the Island Health Policy Framework and Development Guide "Face sheets look similar to existing policy document templates, but simply direct staff to where the guidance is located online, rather than provide any specific direction or guidance."

Where are the N2 SOP face sheets located?

The N2 SOP face sheets are located on the Intranet under Policies & Procedures in the Category of Research/Network of Networks (N2).

How to use the Network of Networks (N2) SOP face sheets?

There is one face sheet for each N2 SOP. Each face sheet identifies the title of the SOP, its purpose, scope, outcome and how to obtain a copy of the entire SOP.

Who can use the N2 SOPs?

Although, the N2 SOPs have been developed specifically for clinical trials and Investigator Initiated trials (studies that are regulated through Health Canada), clinical researchers in general will benefit from N2 SOPs such as informed consent, Research Ethics Board communication and clinical data management.

How to use the N2 SOPs (no previous SOPs)

If your study team does not have a set of SOPs currently in use for your research, review the N2 SOP face sheets to determine which SOP(s) would most effectively support your team and then reach out to ResearchCompliance@islandhealth.ca for a copy of the SOP(s). The team will need to store the SOPs and provide documentation that team members have been trained on the N2 SOPs.

How to use the N2 SOPs (previous SOPs)

If your study team currently uses a set of SOPs and would like to transition to the N2 SOPs, reach out to ResearchCompliance@islandhealth.ca for copies of the SOPs required. Once training has been completed on the N2 SOPs and documented, complete a memo outlining the current SOPs that will be retired from use by your team and the new N2 SOPs that will be adopted. If there are remaining SOPs that N2 does not cover, identify them and note that your team will continue to follow them.

Responsibility of Investigator and/or study team

The N2 SOPs will be reviewed/revised every two (2) years and published. It is the responsibility of the Investigator and/or study team to look out for the notification for the new version of the N2 SOPs through Research Compliance's web page under 'Resources' and other forms of communication (i.e. The Weekly, List Servs). The study team is responsible for obtaining the new version of the N2 SOPs, storage, training, documentation and updating any corresponding guidance for the SOPs.

To learn more about the N2 SOPs or other resources available through N2, please contact:

ResearchCompliance@islandhealth.ca

Sincerely,

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