N2 NETWORK OF NETWORKS
RÉSEAU DES RÉSEAUX

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N2 Network of Networks
C/O First Stage Enterprises
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Dear N2 Members:

Regulatory authorities require that clinical research sites utilize standard operating procedures (SOPs) to ensure that their research is conducted in a manner that protects the rights and safety of study participants and the integrity of the research data collected. SOPs are generally designed to reflect 'how' a procedure is to be done. An understanding of 'why' concepts tend to fall under learning and development or within the scope of clinical research personnel training.

The Network of Networks' ("N2") Clinical Research SOPs were developed to be a comprehensive, robust set of national standard operating procedures that are applicable to any therapeutic area or research environment. The goal has been to facilitate distribution, adoption and maintenance of a single national standard set. A dedicated committee of N2 members with a range of clinical research and regulatory affairs experience and expertise are responsible for the oversight, conduct, and support of N2 processes for regular review of all SOPs which occurs every two years, or sooner if dictated by changes in the current regulations or guidance documents. The review process also involves independent expert review to ensure ongoing compliance with current regulations and guidelines.

These official Clinical Research SOPs are compliant with Health Canada and the US Food and Drug Administration regulations, current ICH-GCP Guidelines and the revised Canadian Tri-Council Policy Statement on Research Involving Human Subjects. As a result, changes to the official set of SOPs at the site/institutional level are NOT recommended and may result in the SOPs no longer being compliant. It is for this reason that the SOPs appear as print only PDF documents. Supportive documents may be created/adapted as needed to assist sites to 'bridge' between the SOPs and site-specific/local procedures (e.g., tools, checklists, sample forms, local guidance documents) but these are not considered part of any N2 official SOP.

N2 encourages comments, feedback and requests for additional SOPs or tools to be directed to N2 via the member organization's representative.

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ACCESS TO AND USE OF THE N2 STANDARD OPERATING PROCEDURES

The Network of Networks ("N2") grants permission to each member organization and their constituents to use the N2 Clinical Research SOPs for sites, including SOP attachments in accordance with the terms and conditions outlined below.

a. It is recommended that end users download the SOPs directly from the member section of the N2 website (www.n2canada.ca).
b. Passwords will be available to the end user via the member organization's representative. This password is for the exclusive use of member organizations and their constituents only and must not be circulated outside the organization.
c. Member organizations may copy, distribute and use the SOPs within their own clinical research sites. It is strictly prohibited for N2 SOPs to be sold, distributed, exported, leased, loaned, or rented to any third/external party.
d. When required, study sponsors, regulatory inspectors or auditors may be granted access to view the SOPs at the clinical research sites. If a sponsor does not conduct on-site audits, a request can be made to the N2 SOP committee, via the N2 member representative of an organization to provide the sponsor with copies.

2. COPYRIGHT

The member organization acknowledges and agrees that N2 is the sole and exclusive owner of all title and intellectual property rights for these SOPs. This includes all SOPs provided by N2 to its members, any SOP updates, attachments, and related supplements that N2 may provide or make available to its members.

3. TERMINATION OF AGREEMENT

N2 reserves the right to terminate this SOP Agreement if the member organization is in breach of this Agreement or terminates its membership in N2. In such an event, the member network shall promptly cease to access the N2 website including the SOPs.