Research Road Map

May 2018 **SOPs for Clinical Research Issue**

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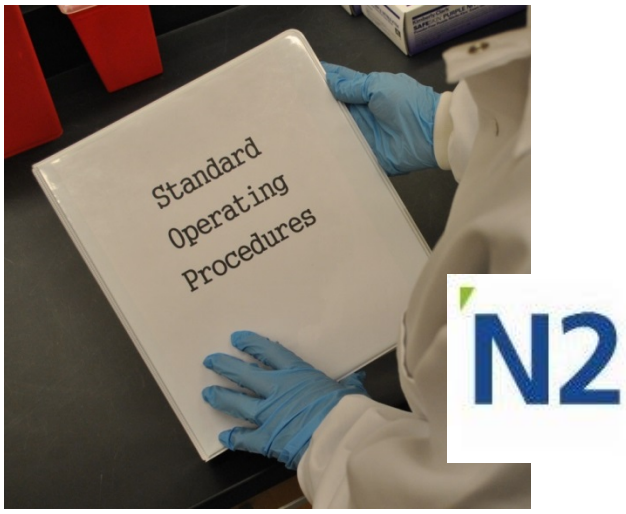

Standard Operating Procedures for Clinical Research:

Standard Operating Procedures (SOPs) are official, detailed, written instructions for the management of clinical research (including clinical trials) at research sites and are required to ensure that clinical research is conducted in a manner that protects the rights and safety of humans participating in research ("research participants"), guards the integrity of the research data being collected, and adheres to all federal and provincial policies, laws, and regulations. Kingston Health Sciences Centre (KGH and HDH Sites) have adopted the Network of Network's (N2) SOPs for Clinical Research as our institutional SOPs. Researchers, research staff, students and trainees must adhere to these SOPs when conducting clinical research within KHSC. For further details, please consult KHSC's Administrative Policy 11-152: Standard Operating Procedures for Clinical Research.

KHSC is a member of N2. Our membership in N2 provides researchers, research staff, students and trainees with access to networking opportunities with colleagues across the country, sharing of best practices tools, free online training (i.e. GCP, TDG/IATA, Health Canada Division 5, Privacy), access to clinical research SOPs (available in English and French), and the ability to attend N2's annual meeting. In order to obtain access to the N2's website to download copies of the SOPs, obtain access to the free online training and/or to obtain a copy of KHSC's Administrative Policy 11-152, please contact Lisa McAvoy at Lisa.McAvoy@kingstonhsc.ca or KHSC-KGH ext.3344.

http://www.kgh.on.ca/research

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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. Bringing together trialists and clinical research professionals from across the country, 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. The organization is truly representative of clinical research in Canada and acts as a national voice and advocate on behalf of a broad range of stakeholders that have an impact on the efficiency and quality of clinical trials conducted in Canada.

N2 has created a unique environment for clinical researchers to benefit from the sharing of "best in class" tools and the experience and expertise of others. N2 is a membership organization. Today, over 100 organizations representing over 3000 clinical research professionals, from over 200 sites and across numerous therapeutic disciplines have joined N2's initiative. Members include organizations as varied as research networks, universities, hospitals, government entities and industry. The breadth of N2's member organizations and the depth of their collective experience have enabled N2 to become an important voice in the national clinical research debate. To learn more about N2, please go to: http://n2canada.ca/

LIST OF N2 SOPS

A list of N2's SOPs for clinical research is outlined below:

- Standard Operating Procedure (SOP) Administrative Management by N2
- Research Team Roles and Responsibilities
- Research Team Training
- Clinical Research Protocol Feasibility and Site Selection
- Study Initiation/Activation
- Informed Consent Forms
- Research Ethics Board: Submissions and Ongoing Communication
- Informed Consent Process
- Subject Recruitment and Screening
- Management of Investigational Drug Products
- Management of Biological Specimens
- Serious Adverse Reaction Reporting in Clinical Trials
- Study Monitoring and Communication
- Clinical Data Management
- Investigator Study Files and Essential Documents
- Study Close-Out
- Audits and Inspections
- Clinical Trial Application
- Confidentiality and Privacy
- Clinical Trial Application (Natural Health Products)
- Investigational Testing Authorization (ITA) for Medical Devices (non-IVDD) and Manufacturer/Sponsor Obligations
- Equipment Calibration and Maintenance

- Case Report Form Design
- Study Analysis and Reporting
- Protocol Development
- Data Management Plan
- Database Set-up
- Database Maintenance and Management
- File Transfer
- Database Lock and Archiving
- System Setup, Maintenance, and Security
- System Backup and Recovery Planning
- Acronyms and Glossary of Terms

Copies of these SOPs are available to all researchers, research staff, students and trainees who are affiliated with KHSC. Please contact Lisa McAvoy at Lisa.McAvoy@kingstonhsc.ca or KHSC-KGH Site ext. 3344.