Thunder Bay Regional Health Sciences Centre

Policies, Procedures, Standard Operating Practices

No. RA - 04

Title: Adherence, Development & Management of Policies, Procedures and Standard Operating Practices for the Conduct of Research	☒ **Policy** ☒ **Procedure** ☐ **SOP**
Category: General **Dept/Prog/Service:** Research	**Distribution:** Organization Wide
Approved: Vice President, Research **Signature:**	**Approval Date:** Apr. 5, 2016 **Next Review Date:** **Reviewed/Revised Date:** Apr. 5, 2019

Cross references: ADMIN-01 "Policy, Procedure, Standard Operating Practices, Medical Directive and Pre-Printed Direct Order Development & Management" (draft); The Research Institute Glossary of Terms

PREAMBLE

Thunder Bay Regional Health Research Institute (The Research Institute) and Thunder Bay Regional Health Sciences Centre (The Hospital) have adopted joint Policies, Procedures and Standard Operating Practices (SOPs) to govern the conduct of research by our personnel and at our facilities.

The Network of Networks (N2) is an alliance of Canadian research networks and organizations working to enhance national 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. As a member organization, The Hospital agrees to distribute N2 Standard Operating Procedures (SOPs) to all personnel engaged in research activities and adhere to these procedures for the conduct of all research involving humans.

1. PURPOSE

The following policy outlines the responsibility of all staff engaged in research to adhere to all pertinent policies, procedures and SOPs for the conduct of research. Also described is The Hospital/The Research Institute's adoption of the N2 SOPs to guide research on topics for which The Research Institute Institutional documents do not exist. The procedures below describe additional consultation and review requirements that apply to joint Research Institute/Hospital documents.

2. SCOPE

This policy and procedure applies to all employees and anyone involved in conducting work at The Research Institute/The Hospital or using The Research Institute/The Hospital resources.

As the research arm of The Hospital, all Research Institute policies, procedures and SOPs apply to The Hospital employees while engaged in research activities.

3. DEFINITIONS

For additional definitions, refer to N2 SOP Glossary of Terms and The Research Institute Glossary of Terms.

Clinical Research Services Department (CRSD) - The group that oversees the operational and administrative aspects of research involving humans and clinical trials at The Research Institute and The Hospital.

External Document- Any Policy, Procedure, Standard Operating Practice, Guideline etc. that is generated outside of The Research Institute/The Hospital but is referred to and considered applicable to research conducted at Thunder Bay Regional Research Institute or Thunder Bay Regional Health Sciences Centre.

Institutional Document- A currently approved Policy, Procedure or Standard Operating Practice held either individually or jointly by Thunder Bay Regional Health Research Institute and/or Thunder Bay Regional Health Sciences Centre.

Investigator - A general term used to represent both the Qualified Investigator for Regulated clinical trials or the Principal/Lead Investigator for all other research.

Principal or Lead Investigator - For non-Regulated studies, the term Principal Investigator or Lead Investigator may be used to indicate the investigator most responsible for the conduct of a study.

Qualified Investigator - *(terminology as applied to studies covered by Division 5 of the Canadian Food and Drug Regulations)* The person responsible to the sponsor of the clinical trial for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where that clinical trial site is located, and who is:

- in the case of a clinical trial respecting a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association;
- in any other case, a physician and a member in good standing of a professional medical association.

There can only be one QI per study per Canadian study site.

Researcher- means anyone who participates in research related work, study or development activities at one or both organizations using, in any way, facilities or resources owned, operated, rented or administered by one or both organizations and/or funds of, or funds administered by, one or both organizations and includes employees, Professional Staff, individuals with scientific appointments in part or in whole at one or both organizations, research associates, research assistants, clinicians, technologists, trainees/students, and any person with temporary privileges (e.g. visiting researchers, affiliated scientists, etc.) who participate in work, study, research or development activities at one or both organizations. "**The Research Institute or The Hospital Researcher**" is a subset of Researchers who have a formal affiliation with one or both organizations through employment, contract, or an affiliation agreement.

4. POLICY

4.1 Adherence to Policies, Procedures and SOPs

4.1.1 The Research Institute has created a number of Institutional Documents to guide the conduct of research at The Research Institute and The Hospital. In instances where an Institutional Document does not exist, The Research Institute has adopted the following Network of Networks Standard Operating Procedures (N2 SOPs) to guide research:

- Glossary of Terms
- SOP 001 to 019
- SOP 023 to 025
- SOP 100 to 109

The N2 SOPs adopted are available online on The Hospital intranet under Departments>Clinical Trials>Policies and Procedures or in The Research Institute Member's Area>Clinical Research>Policies and Procedures.

4.1.2 In adopting the N2 SOPs, The Research Institute has also adopted the N2 SOP glossary of terms to govern the use of language in all documents. To define terms not included in the N2 SOP glossary of terms and to accommodate different uses of terms, a Research Institute glossary of terms has been created.

4.1.3 In the event of a conflict or inconsistency between the content of any Institutional Document and an external document, the Institutional Document shall prevail.

5. PROCEDURE

The following procedure describes review and approval requirements for The Research Institute joint documents which should be followed in addition to the procedures described in Policy ADMIN-01.

The Research Institute Executive Management Council (EMC) is responsible for all documents within The Research Institute. Their role is to confirm that the proper consultation is in place, endorse documents for The Hospital Senior Leadership Council approval and to provide final approval for distribution and implementation of new/revised Research Institute policies, procedures and SOPs.

Any of the following activities may be delegated to appropriately qualified staff.

5.1 Developing a Policy, Procedure or SOP

5.1.1 When developing a new document, identify the staff member most responsible for the document (referred to hereafter as the "Lead") and obtain his/her support for developing the document. The Lead may be a manager, coordinator or executive depending on the scope of the document.

5.1.2 The Lead will follow process as described in ADMIN-01 for developing a policy, procedure or SOP. In addition:

- Review and endorse the draft document (if the Lead is not the document author);
- Submit joint documents to EMC for consultation. EMC may recommend a legal review.

5.1.3 Once a document is approved, it will be distributed to The Hospital employees as per Policy ADMIN-01 and to The Research Institute employees as described in Section 5.4 below.

5.2 Reviewing and Revising Existing Policies, Procedures and SOPs

5.2.1 The Lead is responsible for tracking and identifying joint documents requiring review. The Lead will review the document and determine if revisions are needed.

5.2.2 If revisions are needed, the Lead will follow process as described in ADMIN-01 for revising a policy, procedure or SOP. In addition::

- Highlight the parts of the document that have been changed and submit the revised document to EMC for consultation.

5.2.3 If there are no revisions needed, the Lead will:

- Submit the document to EMC for endorsement indicating that the document has been reviewed and there are no changes;
- Adhere to The Hospital Policy and Procedure Committee process as described in ADMIN-01.

5.2.4 Documents that have no or minor changes will not require the Lead to attend the EMC meeting.

5.2.5 Once a revised document is approved, it will be distributed to The Hospital employees as per Policy ADMIN-01 and to The Research Institute employees as described in Section 5.4 below.

5.3 Endorsement

5.3.1 For joint documents, the Lead is responsible for:

- Submitting document to The Research Institute EMC for endorsement.
- Submitting document to The Hospital P&P Committee for endorsement, as described in ADMIN-01.

5.4 Communication and Education

5.4.1 Once all requisite signatures are obtained, the Lead will submit the document to the The Research Institute Operations Coordinator who is responsible for distributing the document to The Research Institute staff and submitting the document to be posted online in the The Research Institute Member's Area within three (3) business days. If a document is reviewed but no changes are made, the document is to be updated online with new dates but distribution is not required.

5.4.2 It is the responsibility of the Clinical Research Services Assistant and the Clinical Research Associates to distribute documents to all impacted Researchers.

6. REFERENCES

N2 Network of Networks, About N2, Brief Description of Network of Networks, http://n2canada.ca/about/.