Thunder Bay Regional Health Sciences Centre

Policies, Procedures, Standard Operating Practices	No. CR-04
Title: Clinical Research Support Services for Researchers	☒ Policy ☐ Procedure ☐ SOP
Category: Unit Specific **Dept/Prog/Service:** Clinical Research Services	**Distribution:** Organization wide
Approved: Vice President, Research **Signature:**	**Approval Date:** Jun. 7, 2016 **Reviewed/Revised Date:** **Next Review Date:** Jun. 7, 2019

CROSS REFERENCES: (CR-07) "Project Registration and Authorization" (in draft); Policy (ADMIN-13) "Research Oversight"; TBRHSC REB Guidelines.

1. PURPOSE

The objective of providing research services is to enable research through the support of project development, funding applications, project execution and operations oversight, while ensuring a high standard of regulatory compliance for research involving humans. The Clinical Research Services Department (CRSD) offers a variety of research services to Investigators wishing to conduct research at Thunder Bay Regional Health Sciences Centre (The Hospital) or Thunder Bay Regional Research Institute (The Research Institute). This policy describes the services available to assist Investigators develop and execute the study at The Hospital/ The Research Institute.

2. POLICY STATEMENT

Project Development and Operations services are available to all Researchers on a fee-for-service basis.

It is mandatory that Project Operations be conducted through the CRSD for all Clinical Trials. Services will be provided on a fee-for-service basis.

3. SCOPE

This policy applies to all Researchers.

4. DEFINITIONS

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

Clinical Trial - Any Regulated investigation in research involving humans intended to discover or verify the clinical, pharmacological and/ or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
Note: A clinical trial may also involve a device, observation, questionnaires, interviews or diagnostic tests.

Fully developed – Fully developed research has in place a research question, study design, protocol, budget and all study documents required to submit for Research Ethics approval and Project Authorization.

Investigator - A general term used to represent both the Qualified Investigator for clinical trials or the 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.

Needs Assessment - A meeting conducted with Investigators proposing projects that are not fully developed during which the Investigator's needs are assessed as well as the level of support they would like CRSD to provide.

Regulated – A project that is regulated by Health Canada, the US Food and Drug Administration (FDA), or another regulatory body depending on the type of research.

Research Ethics Board (REB) - A body whose principal mandate is to approve the initiation of, and conduct periodic reviews of research involving humans in order to ensure the protection of their rights, safety and well-being.

Research Ethics Office (REO) – The group that accepts and processes applications to the Research Ethics Board.

Researcher: Anyone who participates in research related work, study or development activities at The Research Institute or The Hospital or uses, in any way, facilities or resources owned, operated, rented or administered by The Research Institute or The Hospital, and/or funds or, or administered by The Research Institute or The Hospital regardless of employment status or affiliation.

5. PROCEDURE

5.1 Research Support Services

The CRSD offers services to support Investigators and Researchers throughout the research process. Projects that are not fully developed and/or require the expertise of the CRSD will be offered access to the Research Services outlined below. The use of Research Services for Project Development is optional for all projects and, after an initial consultation, will be provided on a fee-for-service basis.

Regulated clinical trials are mandated to operate through CRSD and as such, are obligated to contract CRSD Clinical Trials staff for Project Operations. Non-regulated projects have the option of contracting CRSD staff to execute and manage their study.
Services available at each stage of the research process are listed below. Not all services will be required by every Investigator. Service options will be assessed on a project-by-project basis through a Needs Assessment conducted during Project Registration (see Policy CR-07 "Project Registration and Authorization" (in draft)).

5.1.1 Project Development

For Investigator-Initiated research, it is assumed that the Investigator or the research team will take the lead in developing the project. CRSD Research Services are available to work in collaboration with the Investigator and research team to complete development activities.

Research Services available during the Project Development phase include:

- Protocol development (in collaboration with the Sponsor and/or Investigator)
  - Study design and methodology
  - Study team identification
  - Protocol writing
  - Literature review
  - Initial study document preparation
  - Scientific review
- Contracts and Budget
  - Clinical Trials Agreement
  - Budget development
  - Ongoing contract management
- Compliance
  - Assistance with initial REB application
  - Assistance with initial regulatory applications
  - Assistance with ongoing regulatory submissions (notifications, CTSI, SUSARs)
- Assistance with Authorization submission package
- Grant submission assistance
  - Grant writing assistance
  - Budget development
  - Opportunity review of granting agency policies and procedures

5.1.2 Project Operations

Research Services available during the Project Operations phase include:

- Human Resources
  - Hiring contract research assistants
  - Oversight of contract research assistants (ensure hired assistants adhere to The Research Institute / The Hospital policies and procedures and communicate with PI/QI to manage performance expectations)
- Preparation and maintenance of trial master file
- Research project administration
  - Regulatory services
    - HC submission – if required
    - safety management/reporting (SAEs)
    - safety reporting
    - study closure
    - facilitate responses to inspection findings

        - support in preparation of initial REB submissions, annual renewals, ongoing amendments and receivables
- Research project operations
    - Study management
        - investigator meetings
        - clinical trial coordination services
        - trial registration
        - site management
        - site start-up processes
        - communications
        - meetings
    - Study implementation
        - Medical records reviews
        - Visit scheduling
        - Study visits
        - Data entry
        - Site liaison
    - Data Management
        - Source document preparation
        - Data storage and retention*
- Grant and financial management*
    - Report writing
    - Invoice tracking

*In the case of Regulated, Investigator Initiated studies, these responsibilities are retained by The Research Institute; see Policy CR-01 "Investigator Responsibilities in the Conduct of Research Involving Humans".

6. RELATED PRACTICES AND/OR LEGISLATION

N2 SOP 02_06 Research Team Roles and Responsibilities,
N2 SOP 102_04 Protocol Development,
N2 SOP 006_06 Informed Consent Forms, Health Canada,
BRHSC/LU/St. Joseph's Care Group REB Guidelines

7. REFERENCES

International Conference on Harmonisation. Guideline for Good Clinical Practice, E6(RI). June 10, 1996.
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

Tri-council Policy Statement. Ethical Conduct for Research Involving Humans. 2014
http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf

Network of Networks. Standard Operating Procedures. Available online on the in the TBRRI Member's Area and on the TBRHSC iNtranet at:
http://intranet.tbrhsc.net/Site_Published/i5/iic_doclist.aspx?nid=cltr&hid=cltr_2&DocList.QueryId.Categories=4323&DocList.XslFilePath=/resources/xsl/doclist_2.xsl
N2 SOP Glossary of Terms