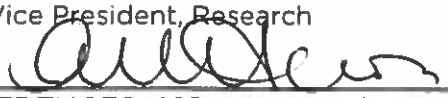
Thunder Bay Regional Health Sciences Centre **Policies, Procedures, Standard Operating Practices**	No. CR-02
Title: Monitoring of Investigator Initiated Studies	☐ **Policy** ☐ **Procedure** ☒ **SOP**
Category: General **Dept/Prog/Service:** Clinical Research Services	**Distribution:** Organization Wide
Approved: Vice President, Research **Signature:** 	**Approval Date:** Jun. 7, 2016 **Reviewed/Revised Date:** **Next Review Date:** Jun. 7, 2019

CROSS REFERENCES: (CR-01) Investigator Responsibilities in the Conduct of Research, (CR-02) Monitoring of Investigator Initiated Studies

1. PURPOSE

This policy describes the roles and responsibilities in monitoring research involving humans conducted at Thunder Bay Regional Research Institute (The Research Institute)/ Thunder Bay Regional Health Sciences Centre (The Hospital).

2. POLICY STATEMENT

When The Research Institute is acting as the Sponsor of a clinical research study or supporting an Investigator-sponsored research project, The Research Institute and The Hospital have the authority and responsibility to approve and oversee study monitoring to allow for continuing evaluation and oversight, assuring human research participant protection.

3. SCOPE

This policy applies to all Investigator-Initiated regulated studies conducted at The Hospital/ The Research Institute as well as non-regulated studies deemed to be high risk.

4. DEFINITIONS

Monitor – The person responsible for ensuring the appropriate conduct and documentation of a study. Study monitors do not need to be independent of the study team; team members not directly involved in collecting data or recruiting participants may perform study monitoring as long as they are not monitoring their own work. Study coordinators from other trials may also monitor each other's studies.

Observation - A deviation or deficiency noted during a monitoring visit or audit.

Sponsor Representative – The person designated by the Sponsor to be the first point of contact between the Sponsor and the study monitor or research team.

Study Monitoring - The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

5. RESPONSIBILITY

This document applies to the Sponsor, Investigator, Sponsor Representative and Monitor.

5.1 When a study is Investigator-Initiated, the Investigator is responsible for developing and implementing a study and data monitoring plan. See CR-01 "Investigator Responsibilities in the Conduct of Research" and N2 SOP013_6 "Study Monitoring" (in draft). The Research Institute and The Hospital retain the right and responsibility to approve monitoring plans, request reports and conduct audits at any time.

5.2 Duties of the Monitor are detailed in N2 SOP013_6 "Study Monitoring" (in draft) and Health Canada *Guidance for Industry – Good Clinical Practice ICH Topic E6 (1997)*.

5.3 Study monitoring is the responsibility of the Sponsor. As per CR-01 "Investigator Responsibilities in the Conduct of Research" in the case of Investigator-Initiated Regulated studies, this responsibility is delegated to the Qualified Investigator (QI). As such, the Monitor is appointed by and reports to the QI. All study monitoring reports and correspondence are to be addressed to the Sponsor Representative and copied to the QI.

6. PROCEDURES

6.1 Investigators must use the The Research Institute monitoring plan template (available through the CRSD or online on the The Hospital iNtranet and TBRRI Member's Area) when developing study monitoring plans for regulated clinical trials. Investigators developing monitoring plans for non-regulated studies may elect to use this template. Investigators should also consult N2 SOP013_06 "Study Monitoring and Communication" and the US FDA document Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring guidelines for the development and administration of a study monitoring plan.

6.2 The monitoring plan must provide adequate oversight based on the assessed risk of the study and must be reviewed and approved by The Research Institute.

6.3 The Monitor selected must be appropriately trained and qualified as described in GCP E6 Section 5.18.2 (b) and credentials must be recorded in the files of the sponsor.

6.4 A pre-trial monitoring visit should occur prior to participant enrolment and should include an additional review of administrative and regulatory requirements to ensure that the site is suitable for the trial. This may be combined with the Site Initiation Visit (see 6.1.5)

6.5 The study monitor is to attend the Site Initiation Visit (SIV) and provide a site initiation monitoring report. The SIV monitoring report is to be filed in the Site Master File.

6.6 The schedule for monitoring visits should be proportional to the risk level of the study and must be approved by TBRRI in the Study monitoring Plan.

6.7 The Monitor will recommend or require corrective actions and preventative actions based on observations.

6.8 Corrective actions and preventative actions may include a recommendation for the provision of additional resources, training, or education; the development of or revisions to SOPs; or changes to forms, checklists or templates.

6.9 The Monitor will review the QI's response to confirm all observations have been appropriately addressed within the timeframe required in the monitoring plan.

6.10 The Monitor may conduct a follow-up visit to observe corrective actions at their discretion.

6.11 The Monitor may be required to participate in audits and other follow-up as necessary.

7. REFERENCES

N2 SOP013_06 Study Monitoring and Communication

US Department of Health and Human Services, Food and Drug Administration . Guidance for Industry. Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring. August 2013.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

Sunnybrook Research Institute, Monitoring Plan (Template): Investigator-Initiated Studies.

Health Canada *Guidance for Industry – Good Clinical Practice ICH Topic E6 (1997).*http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php#a5.18