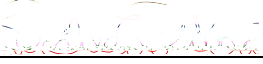



SOP Title	External Inspection or Audit
Number.Version	N901.002
Effective Date	05/11/2018

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics		2019-02-26
Dr. Randal Graham Chair, Non-Medical Research Ethics Board		2019-03-06

1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedures to be followed before, during, and following an external inspection or audit.

2. GENERAL POLICY STATEMENT

The US Office for Human Research Protection (OHRP) has the authority to audit Canadian Research Ethics Boards (REBs) that oversee studies that are federally (US) funded.

Sponsors, funding entities, or others authorized by regulations or agreements with the institution have the authority to audit or inspect study-related documents and procedures.

These audits or inspections may involve the Non-Medical Research Ethics Board (NMREB); therefore, the NMREB must have policies in place for dealing with external audits and inspections.

3. RESPONSIBILITY

This SOP applies to all Office of Human Research Ethics (OHRE) staff, Health Sciences Research

- 5.1.4 The Director, Research Ethics or designee will arrange for access to the online system for the inspector/auditor;
- 5.1.5 The Director, Research Ethics or designee will confirm that the individuals/groups listed in 5.1.2 are available for interviews or to assist the inspector/auditor;
- 5.1.6 The Director, Research Ethics or designee will arrange a suitable work area (e.g., and with sufficient space, with access to a computer and in close proximity to a photocopier and telephone) for the inspector/auditor.

5.2 Participating in an Inspection or Audit

- 5.2.1 The HSREB Chair, vice chair(s) and/or the NMREB Chair and the Director, Research Ethics will meet with the inspector/auditor as scheduled. Prior to being granted access to ~~the~~ ^{specific} OHRE documentation, the inspector/auditor must exhibit proof of authority or authorization to conduct the inspection/audit;
- 5.2.2 The Director, Research Ethics or designee will record the name, contact information and title of the inspector/auditor and retain any written notices of inspection/audit for ~~OHRE files~~ ^{OHRE files};
- 5.2.3 The Director, Research Ethics or designee will provide a brief orientation to ~~the~~ ^{the} inspector/auditor of OHRE procedures;
- 5.2.4 The Director, Research Ethics or designee will provide access to ~~the~~ ^{specific} documents requested by the inspector/auditor and maintain a list of the documents reviewed;
- 5.2.5 The Director, Research Ethics or ~~designee~~ ^{designee} will accompany the inspector/auditor at all times while in confidential areas of the ~~OHRE~~ ^{OHRE};

