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| SOP Title | External Inspection or Audit |
| Number.Version | N901.002 |
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Approvals

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

## 1. PURPOSE

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

## 2. GENERAL POLICY STATEMENT

The US Office for Human Research Protection (OHRP) has the authority to audit Canadian Rese 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); ther 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 Resear

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., private 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 study or 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;

5.2.3 The Director, Research Ethics or designee will provide a brief orientation to 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 will accompany the inspector/auditor at all times while in confidential areas of the OHRE;