Holland Bloorview
Kids Rehabilitation Hospital

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| | **REB QUALITY IMPROVEMENT** | | |
| **POLICY: REB-901** | **AUDITS AND INSPECTIONS OF REB OPERATIONS** | | |
| **This policy pertains to:** | The activities of the Research Ethics Board (REB) operating under the authority of Holland Bloorview Kids Rehabilitation Hospital | | |
| **Responsibility for executing this policy:** | Chair, Holland Bloorview REB (or designate) | | |
| **Effective date:** | September 30, 2014 | **Supersedes documents dated:** | V1: August 2013 |
| **Approved:** | Chair of the REB<br><br>Research, Teaching & Learning Advisory Committee (RTLAC) | | |

## 1. PURPOSE

The purpose of this SOP is to describe the processes to be followed prior to, during, and following regulatory and other audits and inspections of REB operations.

## 2. POLICY STATEMENT

Certain regulatory, accreditation and qualification agencies have the authority to audit or inspect the operations of the REB to assess compliance with research ethics regulatory standards and policy requirements.

The following regulatory and/or accrediting bodies may audit and/or inspect the REB's operations:

- Health Canada
- US Food and Drug Administration (FDA)
- US Office of Human Research Protections (OHRP)
- Federal granting agencies: CIHR, NSERC, SSHRC
- Sponsors or other funding entities of research
- Other authorized regulatory, accreditation, and qualification bodies, or representatives of Holland Bloorview Kids Rehabilitation Hospital

## 3. SPECIFIC POLICIES

### 3.1 Preparation for an Audit/Inspection

When the REB is informed of an upcoming external audit or inspection involving Health Canada, the federal granting agencies, the FDA or OHRP, the REB Office must immediately notify the Vice-President of Research at Holland Bloorview.

## REFERENCES

ICH GCP 4.8.10 (n)

TCPS2 Article 6.17

3.1.1 General Procedures

Upon being informed of an upcoming audit or inspection, the REB Office will confirm the following:

- Purpose of the audit/inspection
- Scheduled audit/inspection date, plan, procedures and exit interview
- Determination of the areas that the auditor/inspector will want to see and ensure appropriate personnel availability
- Audit/inspection reporting: documented observations and findings of the auditors
- Follow-up requirements
- Procedures for non-compliance

Upon confirmation of the audit/inspection date and time the REB Office will:

- Notify all relevant staff members of the audit/ inspection
- Review audit/inspection procedures with appropriate REB Office staff and conduct a thorough review of relevant documentation
- Ensure that original relevant documents are available and that the information is complete and up-to-date
- Prepare the logistic aspects of the audit/inspection visit for example:
    - Access to a photocopier, telephone and internet connection
    - Reserved work space
    - Availability of appropriate personnel for interviews

## 3.2 Participating in an Audit/Inspection

Prior to being granted access to REB documentation, auditors/ inspectors must present identification and proof of their authority or authorization to conduct an audit/inspection and access REB documents.

No entity other than those listed on the relevant consent forms may have access to any document that includes participant identifiers. The REB Office will be responsible for the preparation of such information from relevant files prior to the audit/ inspection as required.

The REB Chair and/or designated staff will accompany the

auditor/inspector at all times while in the Research Ethics Office.

The REB Chair and/or designated staff will attend the exit interview and ensure that all audit/inspection observations are understood and determine whether a written response is required.

### 3.3 Follow-up After an Audit/Inspection

Written reports listing the observations/deviations noted during the audit/inspection will be addressed by the REB Chair and staff as soon as possible following the audit/inspection.

Reports of the audit/inspection shall be shared with the Vice-President of Research and the Research, Teaching & Learning Advisory Committee at Holland Bloorview as soon as possible.

When applicable, the REB shall address any deficiencies noted, describe the intended corrective actions and the timeframe for implementation, and submit to the Research, Teaching & Learning Advisory Committee for approval. Following approval, a response letter and action plan will be forwarded to the auditor/inspector.

Revision History

V2/July2014: changed Research Advisory Committee to Research, Teaching & Learning Advisory Committee.