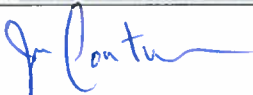




Section 900:	Quality Management
Title:	External Audits or Inspections
SOP Code:	901.001
Effective Date:	2015MAY25

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		2015MAY22 Date
	Name: Jennifer Couture	
Approval Authority:		
Chair, HSREB		May 22, 2015 Date
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		May 22, 2015 Date
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the procedures to be followed before, during and following an external inspection or audit.

2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

All HSREB members, HSREB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Health Canada has the authority to inspect Researcher sites conducting clinical trials that fall under the Regulations to assess compliance with relevant regulations and guidelines.

The US Food and Drug Administration (FDA) has the authority to audit Researcher sites involved in studies conducted under a US Investigated New Drug Application (IND) or Investigational Device Exemption (IDE) to assess compliance with relevant regulations and guidelines. The US Office for Human Research Protection (OHRP) has the authority to audit Canadian REBs that oversee studies that are supported by the US federal government.

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

These audits or inspections may involve the HSREB; therefore, the HSREB must have policies in place for dealing with external audits or inspections. The Researcher is responsible for notifying the HSREB of any planned audits or inspections of research projects overseen by the HSREB.

5.1 Preparing for an Inspection or Audit

- 5.1.1 The Ethics Compliance Advisor or designee will confirm with the Sponsor and/or the Researcher (or inspector/auditor, as applicable) regarding the agreed dates and times of the inspection/audit, and verify the purpose of the inspection/audit, the applicable project(s) undergoing inspection/audit and the inspection/audit plan and procedures;
- 5.1.2 The Ethics Compliance Advisor or designee will notify the HSREB members and the HSREB Office Personnel of the inspection/audit;
- 5.1.3 The Ethics Compliance Advisor or designee will review the inspection/audit procedures with the HSREB members and HSREB Office Personnel and conduct a thorough review of the required documentation;
- 5.1.4 The Ethics Compliance Advisor or designee will arrange for access to the appropriate documents for the inspector/auditor;
- 5.1.5 The Ethics Compliance Advisor or designee will confirm that the HSREB members and HSREB Office Personnel are available for interviews or to assist the inspector/auditor;
- 5.1.6 The Ethics Compliance Advisor or designee will arrange for 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 Ethics Compliance Advisor or designee will meet with the inspector/auditor as scheduled. Prior to being granted access to the

research-specific HSREB documentation, the inspector/auditor must exhibit proof of authority or authorization to conduct the inspection/audit;

- 5.2.2 The Ethics Compliance Advisor or designee will record the name, contact information and title of the inspector/auditor and retain any written notices of inspection/audit for the HSREB files;
- 5.2.3 The Ethics Compliance Advisor or designee will provide a brief orientation to the inspector/auditor of HSREB procedures;
- 5.2.4 The Ethics Compliance Advisor or designee will provide access to the research-specific documents requested by the inspector/auditor and maintain a list of the documents reviewed;
- 5.2.5 The Ethics Compliance Advisor or designee will accompany the inspector/auditor at all times while in confidential areas of the HSREB office and/or Queen's University and Affiliated teaching Hospital(s);
- 5.2.6 The Ethics Compliance Advisor or designee will ensure that the inspector/auditor's questions are answered by the most appropriate personnel. The HSREB Chair or designee, HSREB Office Personnel and HSREB members must make every reasonable effort to be available and to accommodate the requests of the inspector/auditor;
- 5.2.7 The Ethics Compliance Advisor or designee will request meetings with the inspector/auditor at the end of each day, as needed, to discuss any observations. If questions are asked or observations are made during the daily meetings, the HSREB Chair or designee will research the issues and provide the inspector/auditor with clarification as soon as possible once the information is available;
- 5.2.8 The Ethics Compliance Advisor or designee will ensure that the required personnel are present at the exit interview and that observations are understood before the inspector/auditors leave the facility;
- 5.2.9 The Ethics Compliance Advisor or designee will record any observations of the inspector/auditor and any discussion and ascertain when/if a written response is required.

5.3 Follow-up after an Inspection or Audit

- 5.3.1 The Ethics Compliance Advisor or designee will request a copy of the report from the Researcher if applicable;
- 5.3.2 The Ethics Compliance Advisor or designee and any other designated individuals will review any findings relevant to the HSREB and prepare a written response to each item or observation, including any clarification or corrective action that will be taken. The response to the inspector/auditor should be

- coordinated through the appropriate channels (e.g., the sponsor via the Researcher);
- 5.3.3 The Ethics Compliance Advisor or designee and any other designated individuals will institute any correction actions as applicable and revise the HSREB SOPs as needed;
 - 5.3.4 The Ethics Compliance Advisor or designee will file the original inspection/audit and response documents in the Office of Research Ethics.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
External Audits or Inspections	v.901.001 2015MAY25	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.