Section 900:	**QUALITY ASSURANCE**		
Standard Operating Procedure (SOP):	**902 AUDITS BY REGULATORY AGENCIES**		
This SOP pertains to:	All Research submitted to the REBs		
Responsibility for executing this SOP:	Research Ethics Staff, the Chairs and Members of the U of S Research Ethics Boards, the Vice President Research and the Director, Research Ethics		
Approval Authority	The Vice-President Research		
Effective Date:	July 1, 2012	**Superseded documents dated:**	

1. PURPOSE: This SOP states the procedures for preparation for regulatory audits of the REB and appropriate behaviour toward regulators.	**REFERENCES**
2. POLICY: Quality assurance and quality control of the daily operations of the REB ensure that they effectively support the REB's mandate. Therefore, the REB must have in place mechanisms and policies for dealing with external auditing and accrediting bodies.	
3. SPECIFIC PROCEDURES: **3.1. Preparing for an audit** Certain regulatory and/or accrediting bodies have the authority to audit the operations of REBs. These include Health Canada, the federal granting agencies (CIHR, NSERC and SSHRC), the U.S. Food and Drug Administration (FDA), the U.S. Office of Human Research Protections (OHRP), Sponsors, or funding entities of research, or others who may also be authorized by regulations or agreement with the Institution to audit specific documents and procedures. For external audits involving Health Canada, the federal granting agencies, the FDA, or OHRP, the following must be notified immediately: • Vice President, Research, • Director, Research Ethics • Relevant REB Chair • Relevant Hospital Administration, if applicable • Relevant Health Records, if applicable	
3.2. Participating in an audit Prior to being granted access to REB documentation, inspectors or auditors must exhibit proof of their authority or authorization to conduct an audit and access REB documents. No entity other than	

those listed on the consent forms may have access to any document that includes participant identifiers. The REB shall be responsible for the preparation of such information from files prior to the audit as may be required. Auditors will be provided with adequate working area to conduct an audit and REB staff and members must make every reasonable effort to be available and to accommodate and expedite the requests of such auditors. Documents may be copied and taken off-site by individuals only when authorized in writing by the Director, Research Ethics or Vice-President, Research.	
3.3. Follow-up after an audit Reports of the audit, either verbal or written, should be addressed by the principal investigator, the REB Chair or other appropriate individuals or offices, as soon as possible after site-specific audits. Reports of the audit either verbal or written and directed to the operation of the REB should be presented to the Vice-President Research, the Director, Research Ethics and the applicable REB Chair(s) and the findings of the audit addressed as soon as possible.	