Research St. Joseph's – Hamilton (RSJ-H)		**Pages** 1 of 4	**Number** 016-RSJ-H
Policy Title Quality Assurance and Compliance Program		**Date** 06 March 2019	
Supersedes 01 November 2015	**Cross Reference** **008-RSJ-H**	**Issuing Authority** RSJ-H Scientific Director	
☑ Charlton Campus	☑ West 5th Campus	☑ King Campus	

Position responsible *for developing and maintaining the policy: RSJ-H Scientific Director*

1.0 PURPOSE

Research studies within Research St. Joseph's – Hamilton (RSJ-H) are expected to be conducted in accordance with applicable territorial regulations (e.g. Health Canada, U.S. Food and Drug Administration, etc.) , The International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) and institutional policies, and any revisions thereto, in order to ensure the protection of study subjects' safety and maintain the highest levels of scientific integrity. Research St. Joseph's - Hamilton supports an internal quality assurance and compliance program to ensure these expectations are met and to provide study auditing and monitoring services and educational opportunities to the research community.

2.0 SCOPE

This policy is applicable to all research studies being conducted within Research St. Joseph's - Hamilton.

3.0 RESPONSIBILITIES

The, main investigator for the study at RSJ-H (Principal Investigator (PI) or Local Principal Investigator (LPI) is responsible for ensuring that the study site and all study team members are conducting research activities to the highest quality standards outlined in the applicable territorial regulations, ICH guidelines, TCPS and institutional policies. It is the responsibility of the investigator to request monitoring services from RSJ-H and to determine, in agreement with the monitor, the frequency of monitoring visits based on risk-assessment.

RSJ-H is responsible for appointing a qualified individual, or individuals, to participate in regulatory inspections. RSJ-H is responsible for ensuring that a trained auditor, or auditors, is/are conducting the audit on its behalf and is/are independent of the audited study. RSJ-H is responsible for ensuring the monitoring service is provided by trained and qualified individuals.

The auditor is responsible for objectively conducting the audit of the research study to ensure its compliance with the protocol, Standard Operating Procedures (SOPs), site policies, GCP, TCPS and all applicable regulatory requirements, and to verify that the data is recorded and accurately reported according to these same directives. The auditor is responsible for creating an audit report following the audit to describe all observed findings and will provide this report to the PI/LPI, Vice President Research,

RSJ-H Executive Director, Chair(s) of the Hamilton Integrated Research Ethics Board (HiREB) and the PI/LPI's RSJ-H Research Program Lead.

The monitor is responsible for objectively conducting the review of the research study to ensure its compliance with the protocol, SOPs, site policies, GCP, all applicable regulatory requirements, and to verify that the data is recorded and accurately reported according to these same directives. The monitor is responsible for conducting reviews according to the monitoring plan established in cooperation with the PI or LPI and is responsible for creating monitoring reports after each visit describing findings and providing corrective direction. This monitoring report will be provided to the PI or LPI.

4.0 PROCEDURE – REGULATORY INSPECTIONS

Upon receipt of an inspection notice from a regulatory authority it is the responsibility of the individual who has received the notice to immediately notify the study sponsor/CRO and/or PI/LPI and/or Research Administration.

It is the responsibility of the PI/LPI to ensure that all study staff are aware of the inspection and to delegate their specific roles and responsibilities during the inspection. The PI/LPI will be required to attend the opening interview and exit meeting.

Research Administration will be responsible for delegating a qualified individual or individuals to assist the study team at the inspection site and work alongside the sponsor/CRO in preparing for the inspection. The delegated individual(s) is/are responsible for ensuring all RSJH-specific items are addressed during the inspection.

Upon receipt of the final inspection report it is the responsibility of the sponsor/CRO, PI/LPI and RSJH to address all findings related to their specific role in the study and to respond to the finding(s) with supporting documentation and/or corrective measures as required.

5.0 PROCEDURE – AUDITS

5.1 Selection

The PI or LPI may volunteer a study for an audit. The PI or LPI should contact Research Administration to volunteer a study at least one (1) week in advance.

Research studies may also be randomly selected for an audit. Research Administration will randomly select a research study from a list of all studies currently approved and ongoing with the Hamilton Integrated Research Ethics Board (HiREB). Research Administration will provide this study to the auditor.

A research study may also be subject to a risk management audit. A risk management audit is carried out when there is reason to believe there are problems with the site's data and/or procedures. This can become apparent through risk analysis, which may identify weak compliance with the protocol, an overly low or high rate of adverse reactions/events compared to other sites, a high rate of recruitment

compared to other sites, etc. When a study has been selected for a risk management audit, Research Administration will provide this study to the auditor and immediately contact the PI/LPI.

5.2 Preparation

The auditor will contact the PI or LPI and provide written notice of the audit. The auditor and PI/LPI will agree on a date no sooner than one (1) week and no later than two (2) weeks from the date of notice to conduct the audit. The auditor may consider extenuating circumstances as a reason to postpone the start of an audit within a reasonable timeframe.

The auditor and PI/LPI will arrange a pre-audit meeting to discuss audit procedures and determine what study materials and areas will be inspected. The PI/LPI is required to attend this meeting; co-investigators and other study personnel are permitted to attend, but are not required to do so.

5.3 Audit

The auditor will conduct the audit in an efficient manner to avoid disruptions in progress of the research study. The PI/LPI or their delegate must remain available to the auditor throughout the audit to answer any questions or provide the auditor with materials upon request.

Audits may identify very significant safety or ethical concerns. Should such findings be made the auditor will contact the RSJ-H Scientific Director who will take steps to inform necessary parties or individuals, which may include, but are not limited to, the St. Joseph's Healthcare Hamilton administration, McMaster administration, funding agencies, HiREB or applicable territorial regulatory body. In exceptional circumstances the RSJ-H Scientific Director could issue a study stop order, or require immediate measures to address a serious concern, before further study work can proceed. The stop order may apply only to the study under audit, or could apply to all studies supervised by the PI/LPI or could extend to the entire research group or community, particularly if a process or intervention applies to study subjects across multiple studies.

5.4 Audit Close-Out

The auditor will provide a written copy of a preliminary report that summarizes audit findings and suggestions for corrective actions. A copy of this report will be given to the PI/LPI. The PI/LPI and auditor will agree on a date soon after the completion of the audit to discuss the preliminary report findings. The PI/LPI is required to attend this meeting and may clarify or address findings.

A final report of the audit will be provided to the PI/LPI, Vice President Research, RSJ-H Executive Director, Chair(s) of the Hamilton Integrated Research Ethics Board (HiREB) and the PI/LPI's RSJ-H Research Program Lead – if a response is required it will be noted in the final report with an anticipated timeline. The PI/LPI is required to respond to any noted findings with a plan for their correction within the specified timeline. RSJ-H may request a follow-up audit and/or a corrective action plan from the PI or LPI to ensure that audit findings have been addressed and corrected

6.0 PROCEDURE – MONITORING VISIT

6.1 Selection

The PI or LPI must contact Research Administration to request the monitoring service. Upon request, the monitor will meet with the PI/LPI to determine the frequency of monitoring visits based on risk-assessment.

6.2 Monitoring Visit

The monitor will carry out monitoring visits in accordance with the plan agreed upon with the PI/LPI. The monitor will access any study materials relevant to the monitoring visit and review for compliance with ICH-GCP guidelines, Health Canada regulations, protocol requirements, SOPs and any other pertinent guidelines. The PI/LPI does not need to be present during the monitoring visit, but should make plans to have any study materials available to the monitor upon request.

6.3 Monitoring Visit Close-out

After finalizing the review, the monitor will prepare a monitoring report outlining and findings, deficiencies and required corrective action and provide this to the PI/LPI. The PI/LPI can work with the monitor to ensure corrective actions have been implemented appropriately and will state these actions in a response letter to the monitoring visit report.