Research St. Joseph's – Hamilton (RSJ-H)		Pages 1 of 3	Number 019-RSJ-H
Policy Title Research Contracts		**Date** February 27, 2020	
Supersedes New Policy	**Cross Reference** 002-RSJ-H; 006-RSJ-H; 013-RSJ-H; 036-RSJ-H; 051-RSJ-H; 043-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 Executive Director.

1.0   PURPOSE

This policy is intended to describe the processes for the upload, drafting, review, negotiation, and/or approval of all research related contracts to be entered into by RSJ-H and to ensure oversight, tracking and management of the research contracts process.

2.0   DEFINITIONS

"RSJ-H" means Research St. Joseph's – Hamilton operating as The Research Institute of St. Joe's Hamilton.

"Affiliated Researcher" means an individual who meets one of the categories of affiliation and has completed the annual affiliation and workplace training requirements with RSJ-H pursuant to the *Research Affiliation with Research St. Joseph's – Hamilton Policy* (002-RSJ-H) and the *Workplace Training Requirements Policy* (013-RSJ-H).

"Research Contract(s)" means any and all contracts related to scientific research and experimental development being conducted at an affiliated healthcare provider (including but not limited to, St. Joseph's Healthcare Hamilton) under the administration and oversight of RSJ-H, including but not limited to, clinical trial agreements, research collaboration agreements, site agreements, research service agreements, confidentiality or non-disclosure agreements, research funding or grant agreements, data transfer agreements, and material transfer agreements.

"Study Personnel" means all individuals involved in the performance of the research activity under the direction and supervision of an Affiliated Researcher.

3.0   POLICY

3.1 General Principles

All Research Contracts require the institutional review, negotiation and authorization of RSJ-H. All Research Contracts must be signed by the RSJ-H Scientific Director or RSJ-H Executive Director on behalf of RSJ-H and, if applicable, by the Affiliated Researcher. Affiliated Researchers must not sign or request or permit anyone else to sign a Research Contract on behalf of RSJ-H as they are not authorized to do so.

Any investigator who wishes or is required to enter into a Research Contract must: (a) be an Affiliated Researcher of, and in good standing with, RSJ-H and (b) follow all processes and procedures with respect to the oversight, tracking, and management of Research Contracts.

3.2 Responsibilities of Affiliated Researcher

An Affiliated Researcher will:

- Upload or request Research Contracts for required RSJ-H institutional review, drafting, negotiation, and authorization using the RSJ-H secure contracts portal.

- Provide to RSJ-H all relevant and supporting documentation and information related to the proposed research activity and verify the completeness and correctness of all related documentation prior to submission to RSJ-H.

- Determine if institution(s), investigator(s), and Study Personnel have the capacity to effectively undertake and complete the proposed research activity, including ensuring sufficient and appropriate resources are available and required training has been completed.

- Ensure she/he understands and agrees to comply with all contractual rights, responsibilities, obligations, and liabilities set forth in the Research Contract.

- Review and sign the Research Contract in her/his personal capacity as the investigator for the research activity.

- Ensure all Study Personnel understand, abide by, and are bound by the contractual obligations that pertain to them in the Research Contract.

- Immediately notify RSJ-H of any material changes that may impact any Research Contract.

- Retain a copy of any and all Research Contracts in a secure location for her/his records.

- Ensure the timely and proper management of any account(s) related to the Research Contract.

3.3 Responsibilities of RSJ-H

RSJ-H will:

- Decide, in its sole discretion, to review, negotiate, and/or enter into or not enter into any Research Contract.

- Review and negotiate Research Contracts on its own institutional behalf, and if applicable, other related documentation.

- If required, provide reasonable assistance to Affiliated Researcher to resolve any Research Contract related issue(s).

- Maintain a secure electronic database for uploading, managing, and tracking Research Contracts, and retain a hardcopy or electronic copy of fully executed Research Contracts where RSJ-H is a party thereto.

4.0   PROCEDURE

- Any request for a Research Contract to be drafted must be made to RSJ-H using the RSJ-H contract template request portal found at https://rsjh.ca/contracts/template/, along with all relevant and supporting documentation and sufficient information and details about the research activity. The draft contract can be used as a starting point but is not one-size fits all, and RSJ-H will tailor such drafts in alignment with the circumstances of the research activity.

- All Research Contracts received from an external party require RSJ-H institutional review, negotiation, and authorization, and therefore, must be uploaded, along with all relevant and supporting documentation (such as the protocol and budget), using the RSJ-H contract upload portal found at https://rsjh.ca/contracts/.

- Once a Research Contract has been successfully uploaded or requested using the contract portal, each contract is issued a unique 5-digit contract order identification number which will be used as a reference in all future correspondence and for archiving purposes.

- The status of a Research Contract can be checked using the contract status report, updated weekly by RSJ-H, which is available via the same contract portal found at https://rsjh.ca/contracts/Contract_Status.pdf.