niagarahealth
Research Office

The Research Institute of St. Joe's Hamilton

New Niagara Health Researcher Guidance Document

PART I: AFFILIATION

Affiliation with the Research Institute of St. Joes Hamilton (RSJ-H):

Researchers performing work at Niagara Health (NH) are required to Affiliate with Research St. Joseph's – Hamilton. Researchers with an Affiliate relationship with RSJ-H will be given full eligibility to access the following services, free of charge:

- Access to on-line research training (Good Clinical Practice [GCP], lab training, Collaborative Institutional Training Initiatives [CITI]) etc.;
- Access to RSJ-H compliant research standard operating procedures;
- Consultation with Research Administration regarding research resources, conduct and /or procedures;
- Contract Review and negotiations support where applicable

RESPONSIBILITIES of Niagara Health Affiliated Researchers:

- Must have, and maintain, a common curriculum vitae (CCV) prepared to Research St. Joseph's – Hamilton guidelines, to be submitted to Research St. Joseph's - Hamilton annually on April 1st;
- Must ensure they and their staff are appropriately trained (with documentation) and supervised

How to Affiliate

1) Please log in to the CCV WEBSITE and SELECT THE RSJ-H, VALIDATE AND SUBMIT YOUR CV. Do not send the actual PDF of your CV to Research Administration – we will automatically be notified when the submit button is selected.

Guidelines for uploading your CCV:

- **Common CV login**: https://ccv-cvc.ca/loginresearcher-eng.frm
- **CV Select:** Funding
- **Funding Source:** RSJH
- **CV Type:** RSJH Affiliation

1) New affiliates are required to complete a single-page form for their initial appointment, RSJ-H Affiliate Application, to capture information not available in the CCV in order to meet additional reporting requirements. Please send the completed RSJ-H Affiliate Application form to aweerden@stjoes.ca.

PART II: TRAINING

Research Training Requirements

Human subjects are essential to the conduct of research intended to increase our scientific knowledge and improve human health. Research at Niagara Health must be conducted with the highest ethical and clinical research standards since protection of research subjects is fundamental to all research involving humans. Additionally, clinical research operations must be carried out in a safe environment for both research subjects and staff. The key to effective conduct of research is education and training of all people involved in research.

All individuals working in ANY research capacity at Niagara Health must complete or provide documentation of up-to-date training. The Research Institute will assign any training module to those individuals who have not yet completed the training at an outside institution or who have training certificates that are expired.

Mandatory Research Training

Individuals can be involved in a variety of research studies, and are thus expected to comply with certain regulations or guidelines that depend on the type of research they are conducting. A listing of various research study types and the associated mandatory research training can be found in the table below:

The following research training modules are required, at a minimum, based on the type of study that is being conducted. Investigators and study team members are advised to consult with Research Administration if there are any questions or ambiguities about the necessity of any research training modules:

Type of Study*	Required Training	Duration
Clinical studies that require approval from a research ethics board and require the use of patient chart(s) (e.g. Dovetale) and/or identifiable information	• ICH GCP • CITI Privacy Training • Dovetale research training (if applicable)	• Every two (2) years • Every two (2) years • One time
Clinical studies that require approval from a research ethics board ***and*** are regulated by Health Canada	• ICH GCP • Division 5 of the Canadian Food and Drug regulations	• Every two (2) years • Every two (2) years
Retrospective studies not involving human subjects	• CITI Privacy Training	• Every two (2) years
Studies involving humans sponsored by any of the Tri-Council Agencies of Canada (CIHR, NSERC, SSHRC)	• Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)	• Every two (2) years
Laboratory-based procedures conducted in the wet labs. This list is a minimum, other department specific training may be required.	• Laboratory Core WHMIS • BSLTRA • SJHH Fire Safety • Wet Lab Orientation	• Every five (5) years • Annual • Annual • One time
Those working in the wet labs or packing/receiving samples in dry ice	• Transportation of Dangerous Goods/International Air Transport Association training (TDG/IATA)	• Every two (2) years

PART III: CONTRACT REVIEW

The Research Institute of St. Joe's Hamilton reviews, drafts and negotiates research agreements on behalf of affiliated Researchers, including:

- Non-Disclosure Agreements (Confidentiality Agreements)
- Data Transfer Agreements
- Material Transfer Agreements
- Research Study Agreements
- Clinical Trial Agreements
- Service Agreements

If you require an agreement to be drawn up, contact researchcontracts@stjoes.ca
If you have received a contract from an outside party, you must submit it for review using the instructions below.

How to submit a contract for review:

RSJ-H has a secure web-based portal where parties to a contract (or agreement) can submit the contract for review. The contract reviewer will review the submission and will negotiate directly with the other party on behalf of Niagara Health (NH) and the NH Researcher. Any correspondence between the parties during the negotiation will include the NH Researcher.

To upload a contract for review please use the following link: https://rsjh.ca/contracts/

Any queries may be directed to: researchcontracts@stjoes.ca

Canadian Institutes of Health Research (CIHR)
Definition of an independent researcher:
An individual who:

- is autonomous regarding their research activities; and
- has an academic or research appointment which:
  - must commence by the effective date of funding; and
  - allows the individual to pursue the proposed research project, to engage in independent research activities for the entire duration of the funding, to supervise trainees (if applicable, as per their institution's policy), and to publish the research results; and
  - obliges the individual to conform to institutional regulations concerning the conduct of research, the supervision of trainees (if applicable), and the employment conditions of staff paid with CIHR funding.

Note: An individual, who meets the above requirements but is also a "trainee" as defined in this glossary, is considered an "independent researcher" by CIHR provided that:

- the research proposal covers only areas of investigation for which they are an independent researcher and not areas of research in which they are a trainee; and
- they can demonstrate in their application to CIHR that they will have sufficient time to devote to the proposed research.