Researcher Qualifications Policy	**HREA-RCH01**
Issuing Authority	Health Research Ethics Authority
Signature of Administrative Authority Chairperson, HREA	Regina Coady
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Background: The Health Research Ethics Authority (HREA) was established by the HREA Act and came into effect on July 1, 2011. The HREA Act mandates that all health research conducted in Newfoundland and Labrador (NL) requires the approval of the Health Research Ethics Board (HREB) or a research ethics body that has been approved by the HREA. The HREB has the authority to ensure that all health research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants. Research Ethics Office (REO) Personnel provide administrative and other health research ethical review expertise and support to the HREA and HREB, as per Section 6 of the HREA Act. REO Personnel may also engage with researchers and students to provide education and consultation.

Scope: All Researchers, HREB members and REO Personnel are responsible for ensuring that the requirements of this policy are met.

Purpose: The purpose of this policy is to articulate the qualifications required for an individual to conduct research under the jurisdiction of the HREB and to outline the requirements for enrolling participants in compliance with the principles of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS2 (2018).

Policy Statements:

1. Research involving human participants will be conducted by individuals qualified by education, training and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants.

2. The Researcher will provide the HREB with their current CV outlining relevant training and experience in sufficient detail for the HREB to make an objective judgment regarding the Researcher's qualifications.

3. Student Researchers will provide the HREB with a signed Supervisor Attestation Form. The Supervisor will be qualified to conduct the research undertaken by the student.

4. Researchers will comply with the decisions and responsibilities set out by the HREB and will conduct the research in compliance with applicable regulations and guidelines. Researchers will comply with applicable HREB policies and Standard Operating Procedures.

RELATED DOCUMENTS

Standard Operating Procedure 801: *Researcher Qualifications and Responsibilities*

Health Research Ethics Authority Act: An act to establish a health research ethics authority for the province. (2011). Retrieved from: SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT (assembly.nl.ca)

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Retrieved from: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2

International Conference on Harmonization – Good Clinical Practice (ICH-GCP 4.1.1): ICH GCP - 4. INVESTIGATOR - ICH GCP