Policy

Policy Title:	Research Ethics Board Jurisdiction, Auspices, and Oversight	
Applies To:	Nova Scotia Health Research Ethics Board and Office Nova Scotia Health Principal Investigators Principal Investigators applying to the Nova Scotia Health Research Ethics Board	
Approved: October 13, 2022	**Effective:** October 18, 2022	**Next Review:** October 13, 2026
Sponsor:	Nova Scotia Health Research Ethics Board Executive Committee	
Approval Authority:	VP Research, Innovation, and Discovery	
Number: RS-RE-001		**Manual:** Research

PURPOSE

This policy provides direction to Principal Investigators to determine whether their Research requires ethical and institutional oversight by Nova Scotia Health's Research Ethics Board and Human Research Protection Program to conduct Research with(in) the organization.

DEFINITIONS

Auspices	Under the protection, endorsement, or support of an individual or an organization and as used herein only as such responsibilities fall within the mandate of the Research Ethics Board.
Human Biological Specimens	Any specimen from a human, including blood, urine, tissues, organs, saliva, DNA/RNA, hair, nail clippings, or any other cells or fluids, whether collected for Research purposes, or as residual specimens from diagnostic, therapeutic, or surgical procedures.
Human Research	A systematic, rigorous investigation involving human beings that includes, but is not limited to, the following disciplines: health Research, social sciences and humanities Research, creative and arts-based Research, and engineering Research. The investigation includes, but is not limited to, the following methodologies: interventional Research, observational Research, qualitative Research, social and behavioural Research, health

	services Research, public health Research, educational Research, Research involving existing human data, deceased individuals, and human biological materials and their derivatives.
Jurisdiction	The limits or territory within which the authority may be exercised.
Nova Scotia Health Human Research Protection Program (HRPP)	An organization-wide program composed of a network of interdependent entities and programs that share the responsibility for Research participant protection and interact in a system that promotes a culture of Research integrity, quality, efficiency, accountability, and evidenced-based practices.
Nova Scotia Health Research Ethics Board (REB)	A body of researchers, physicians, community members, lawyers, and others with specific expertise (e.g., ethics or relevant Research disciplines) that reviews the ethical acceptability of all Research involving humans conducted within the organization's Jurisdiction or under the organization's Auspices.
Nova Scotia Health Patients (Research Context)	All individuals including clients, residents, and members of the public who receive or have requested health care or services from Nova Scotia Health and its health care providers.
Nova Scotia Health Team Members	Refers to all employees, physicians, learners, volunteers, board members, contractors, contract workers, franchise employees, and those with affiliated appointments and other individuals performing activities within Nova Scotia Health.
Principal Investigator (PI)	The leader of a Research team who is responsible for the conduct of the Research and for the actions of any member of the Research team.
Research	An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.
Rigorous Scientific Peer Review	A panel of experts in the field that has formally reviewed the protocol. National or provincial funding competitions are considered Rigorous Scientific external Peer Reviews.

PRINICIPLES AND VALUES

Human Research seeks to understand something that is not yet known, so participation in Human Research is not without risks. As an institution, Nova Scotia Health is accountable for the Research carried out in its Jurisdiction and under its Auspices. Nova Scotia Health's Human Research Protection Program (HRPP) and Research Ethics Board (REB) provide the institutional leadership and oversight for the protection, rights, and wellbeing of Human Research participants.

Together, the Human Research Protection Program and Research Ethics Board promote and ensure a culture of Research safety, privacy, integrity, quality, efficiency, and accountability through policy and practice.

POLICY STATEMENTS

1. Human Research falls within the Nova Scotia Health REB's Jurisdiction and under its Auspices if one or more of the following criteria is met:

    1.1. The Principal Investigator (PI) wishes to recruit Nova Scotia Health Patients, Team Members, and/or their data or Human Biological Specimens for their Research project.

    1.2. The Human Research is to be conducted at a Nova Scotia Health facility, outside of Service Departments.

        - For example, Research where participants are entering Nova Scotia Health facilities (i.e., hospital sites, Nova Scotia Health owned clinics) outside the clinical standard of care may trigger an agreement, contract, or a collaborative letter of support from the department where the Research is taking place.

    > **EXCEPTION:** Principal Investigators operating on behalf of a private office or clinic, or Research studies administered or overseen by a Contract Research Organization that requires the use of Nova Scotia Health Service Departments or resources, Team Members, or facilities (e.g., Diagnostic Imaging or Pathology & Laboratory Services), are not within the scope of Nova Scotia Health REB's Jurisdiction.

    1.3. The Human Research is conducted by a Nova Scotia Health Team Member or those with a Nova Scotia Health appointment or affiliation.

    > **EXCEPTION:** Principal Investigators operating on behalf of a private office or clinic, or Research studies administered or overseen by a Contract Research Organization whose Research does not fall under statements 1.1 and 1.2, do not fall within the Nova Scotia Health REB's Jurisdiction.

2. All Research projects that require Nova Scotia Health REB approval, whether externally or internally driven, must have institutional privacy, administrative, and ethical oversight by the REB both prior to, and throughout, the Research study lifecycle.

    2.1. The institution and REB must review all submitted applications, ensuring the proposed Research complies with:

        2.1.1. Applicable ethical guidelines, policies, and standards,

        2.1.2. Privacy legislation,

        2.1.3. Laws and regulations.

    2.2. Must be continuously monitored and reviewed by the REB.

    2.3. May be suspended or terminated for cause at the discretion of the HRPP or REB. Examples of cause include, but are not limited to:

        - Non-compliance to Nova Scotia Health policies,

- □ Complaints or safety reports that affect patient safety or well-being,
- □ Moderate to high-risk privacy breach.

3. All internal investigator-driven Human Research protocols within the Jurisdiction and under the Auspices of the Nova Scotia Health REB that have not already undergone Rigorous Scientific Peer Review must receive an institutional methodology review.
    - The institutional methodology review is designed to evaluate the Research protocols for rigour and potential benefit while ensuring that the methodology and proposed variables to be collected support the Research question or hypothesis. Please refer to Procedures and Forms.

REFERENCES

Legislative Acts

Personal Health Information Act, Statutes of Nova Scotia. (2010, c. 41). Retrieved from the Nova Scotia Legislature website: https://nslegislature.ca/sites/default/files/legc/statutes/personal%20health%20information.pdf

Canadian Regulations

Health Canada Food and Drugs Regulations, Part C, Division 5. https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-drugs-clinical-trials-human-subjects-gui-0100.html

Health Canada Natural Health Products Regulations, Part 4. https://laws-lois.justice.gc.ca/eng/regulations/sor-2003-196/page-5.html#h-700807

Health Canada Medical Device Regulations, Part 3. https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/

Federal Policies, Standards, and Guidelines

Government of Canada. Panel on Research Ethics. Tri-council Policy Statement: Ethical Conduct for Research Involving Humans – TCSP2 (2018). https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

CAN/HRSO – 100.01 – 2020. Development of a Huma Research Protection Program. https://www.hrso-onrh.org/standards/published-national-standards/

CAN/HRSO – 200.01 – 2021. Ethical Review and Oversight of Human Research. https://www.hrso-onrh.org/standards/published-national-standards/

CAN/HRSO – 300.01 – 2022. Conduct of Human Research. https://www.hrso-onrh.org/standards/published-national-standards/

International Council for Harmonization (ICH) of Technical Requirements for Pharmaceuticals for Human Use Integrated Addendum to ICH E6(R1): Good Clinical Practice (GCP) E6(R2). March 2018. https://www.ich.org/page/efficacy-guidelines

RELATED DOCUMENTS

Policies

Responsible Conduct of Research - Policy and Procedure - NSHA RS-QI-001

Procedures

NSHA-REB-SOP-3-001 NSHA REB Submission Requirements & Administrative Review

NSHA-REB-SOP-4-001 Review of Research

ROMEO Research Portal User Guide

Other procedures can be found here.

Forms

NS Health New User Form for Nova Scotia Health REB's Electronic Management System

Reviewer Assessments - Checklist for Methodology Review 2021-10-12

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VERSION HISTORY

Version:	Effective:	Approved by:	What's changed:
Original	2015-07	VP Research, Innovation and Knowledge Translation	N/A
Minor Revision	2017-09-15	VP Research, Innovation and Knowledge Translation	Revised to reflect new NSHA RS-RA-001 Administration of Research Policy
Major Revision	2022-10-18	VP Research, Innovation and Knowledge Translation	○ Eliminate bureaucratic burdens. ○ Redirecting responsibilities to more applicable teams/departments. Alignment with the Human Research Protection Program.