RESEARCH
Policy and Procedure

TITLE:	Research Ethics Board Jurisdiction	**NUMBER:**	RS-RE-001
Sponsor:	VP Research, Innovation and Knowledge Translation	Page:	1of 6
Approved by:	Executive Leadership Team	Approval Date: Effective Date:	July 20, 2015 Sept 9, 2015
Applies To:	NSHA - Researchers and Research Ethics Board		

POLICY STATEMENTS

1. All human subjects research involving Nova Scotia Health Authority (NSHA) affiliated physicians/scientists, patients, staff, resources and/or data:
   1.1. is to be approved by the NSHA Research Ethics Board (REB) before the research begins.
   1.2. is subject to continuing review and monitoring by the REB.
   1.3. may be suspended or terminated for cause at the discretion of the REB.
2. Quality assurance and quality improvement projects, program evaluation activities, and performance reviews or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this policy and do not fall within the scope of REB review. Please see Appendix B for information on quality.

GUIDING PRINCIPLES AND VALUES

1. The REB's mandate is to protect the rights, safety and wellbeing of research participants. Research, by its nature, carries an inherent risk to research participants. To minimize this risk, proposed research is reviewed by the REB to ensure ethical acceptability. The scope of this review includes scientific, legal and financial aspects of the research.
   1.1. Scientific review is performed to determine the ethical implications of the methods and design of the research and to ensure the publication rights of the investigator.

1.2. Legal review is necessary to ensure that appropriate protections for the participants, investigators and institution are maintained.

1.3. Financial review is required to ensure research studies can be conducted successfully without undue financial incentives.

PROCEDURE

1. Determine whether the proposed activity constitutes research.
2. Determine whether the proposed activity involves patients, staff, resources or data.
3. Consult the Research Ethics Office if there is any doubt whether the proposed activity falls within the jurisdiction of the REB.
4. If it falls within the REB's jurisdiction, submit the proposed study to the Research Ethics Office using the link to the Researcher's Portal which is posted on the NSHA Research Ethics Website.
5. Await full REB approval before beginning the research and abide by all applicable REB policies, procedures and directives.

REFERENCES

Canadian Institute of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. (2014). *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.*

RELATED DOCUMENTS

Policies

RS-RA-001 Administration of Research

Forms

Research Ethics Board forms and templates located within the Researcher's Portal (link found on the NSHA Research Ethics Website)

Appendices

Appendix A – Definitions

Appendix B - Navigation Tool for Quality Improvement Project Review and Personal Health Information Act (PHIA) Compliance

Version History

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Appendix A – Definitions

Nova Scotia Health Authority Research Ethics Board	A body of researchers, community members, lawyers and others with specific expertise (e.g., in ethics, relevant research disciplines) established by the NSHA to review the ethical acceptability of all research involving humans conducted within its jurisdiction or under its auspices.
Research	An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.
NSHA Patient	All clients, inpatients, outpatients, residents and veterans who are recruited from any of the NSHA facilities, programs or services.
NSHA Staff	Physicians and dentists who hold NSHA appointments, all NSHA employees and those who hold courtesy or other affiliated appointments at NSHA.
NSHA Researcher	Any person conducting research within the NSHA or any person conducting research within the NSHA who has an affiliation with the NSHA.
Human Subjects Research	• Research involving human participants • Research involving human biological materials as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.
Research Participants	Individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering a research question.

Appendix B

Navigation Tool for Quality Improvement Project Review and Personal Health Information Act (PHIA) Compliance

Under the Personal Health Information Act, access to information for the purposes of "ensuring quality or standards of care within a quality review program within the custodians' organization" does not need specific patient consent. It is necessary to ensure that the work is being done with a "quality review program". There will be established quality programs which are explicitly part of the Nova Scotia Health Authority (NSHA) quality program which will qualify and if there is any question on this, they can be directed to Performance Excellence at Central Zone. The Terms of Reference Template for a Quality & Patient Safety Team (or Council) can be found here.

Projects must meet ethical requirements and ensure Personal Health Information Act (PHIA) compliance. Information about PHIA can be found here. All employees, physicians and students must complete mandatory PHIA education and sign a pledge of confidentiality.

To access the NSHA systems, you will need to be an employee (set up through Human resources), physician or student (set up through Affiliate Placement).

Is Your Project Research vs. Quality Improvement?

Sometimes the starting question is "is this research or is this quality". This ARECCI screening tool helps to distinguish if your project is a quality improvement or research project and print or electronically save your output for your files:

If the assessment shows that your project falls under:

- Research, submit a Research Ethics Board (REB) submission
- Quality Improvement – see next section

Quality Improvement

In relation to quality improvement, a starting question is "can the project be accomplished through use of de-identified data". An option may be a summary of data through Decision Support or you can discuss if they can de-identify the data through use of a patient ID code. If you require patient identified data, ask the question about "what is the minimum amount of identified data required" (e.g., consider use of encounter number without the name)?

For Quality Improvement projects, please complete the Quality Improvement Project request. You will need to insert the link for your completed ARECCI tool. Please allow time for the review process. You will be contacted with direction regarding your project.

Please note that some quality improvement projects will still require an ethical/Research Ethics Committee Review and/or a Privacy Impact Analysis (PIA).

Access to Horizon Patient Folder (HPF) or the Patient Record
Once the Quality Improvement Project Review process is complete, and if you require access to the Horizon patient Folder (HPF) or the patient record for your quality improvement project, please contact Health Information Services at **902-473-6318.** They will assist you with this process. Your project should have approval of your administrative and Departmental co-leads.

Decision Support Data for Quality Improvement or Quality Review
If you require data from Decision Support for a quality improvement project, submit your request through this link: http://ch-cdhaweb03/intranetforms/reportRequest.aspx or send a high level overview of your request to decision.support@nshealth.ca . Once received, someone will contact you for more details.

Learning from Quality Improvement
Quality improvement project results will be shared within your formalized quality review program. Additionally, be prepared to provide a brief report upon completion of your quality improvement project, upon request.

There will be an annual call for oral and poster presentations for the Quality Summit (held in late May or early June each year). More information may be found at http://www.cdha.nshealth.ca/performance-excellence/quality-summit

There are annual submissions for Capital Health Quality Team Awards (the deadline is generally the first Monday in December). More information can be found at http://www.cdha.nshealth.ca/performance-excellence-program/quality-awards

Quality Reviews
Quality Review recommendations for improvement in the future and action plans will be shared within your formalized quality review program.

If the Quality Review reveals broader Central Zone issues (e.g., touching on any other sites or with the potential to impact any other services in the Central Zone), the case or subject of review shall be referred to the Department's Leadership Team with a report of the review, and recommendations for follow-up to ZMAC – Quality Committee and Zone Quality & Patient Safety Council.

Additional information will be available in the upcoming Quality & Patient Safety Review Policy & Procedure.

Navigation Tool for Quality Improvement Project Review and Personal Health Information Act (PHIA) Compliance: Updated May 29, 2015

Version History

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
July, 2015 – Transititioned to a NSHA policy	2017-09-15 Revised to reflect new NSHA RS-RA-001 Administration of Research Policy