Nova Scotia Health

Research Ethics: The Path to Approval

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Sept 28th 2022

Overview

- Why do we have ethics boards?
- TCPS2 Core Principles
- REB approval process

What is 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, and includes, but is not limited to, the following methods:

- Interventional research, observational research
- Qualitative/quantitative research
- Social and behavioural, health services, public heath, or educational research
- Research involving existing human data or human biological materials and their derivatives

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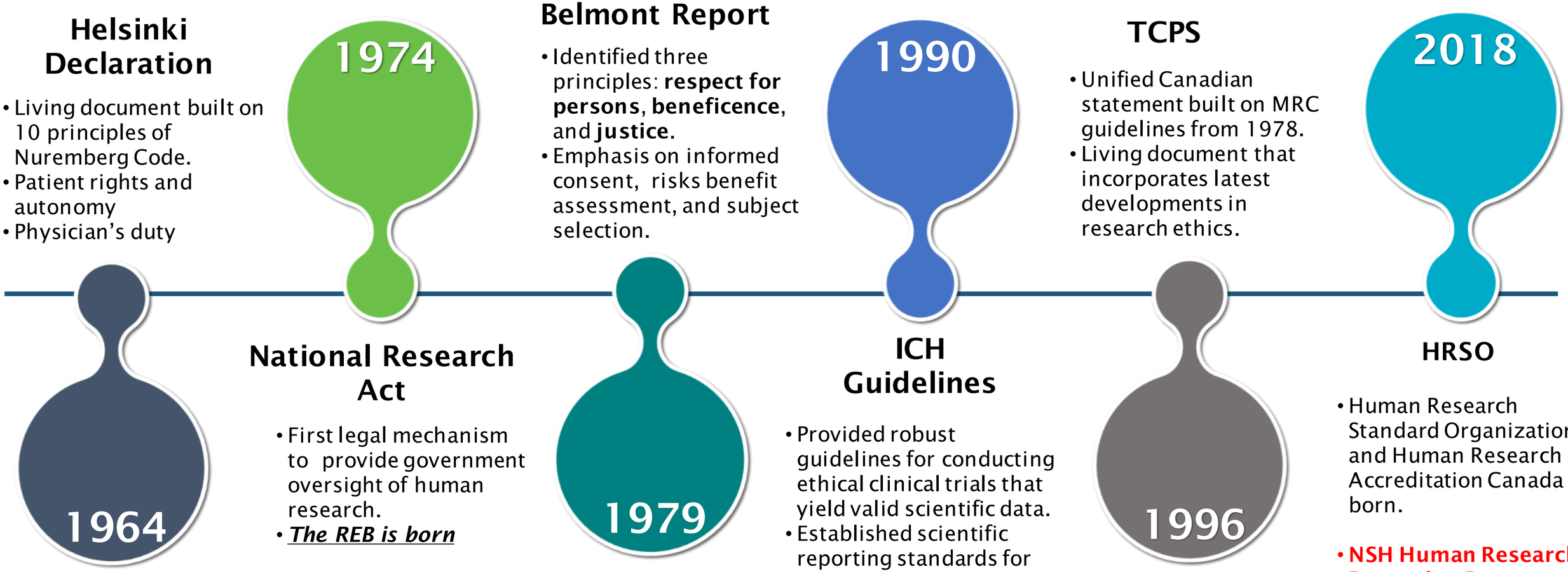
Ethical reform



Helsinki Declaration

- Living document built on 10 principles of Nuremberg Code.
- Patient rights and autonomy
- Physician's duty

National Research Act

- First legal mechanism to provide government oversight of human research.
- ***The REB is born***

Belmont Report

- Identified three principles: **respect for persons**, **beneficence**, and **justice**.
- Emphasis on informed consent, risks benefit assessment, and subject selection.

ICH Guidelines

- Provided robust guidelines for conducting ethical clinical trials that yield valid scientific data.
- Established scientific reporting standards for clinical trials.

TCPS

- Unified Canadian statement built on MRC guidelines from 1978.
- Living document that incorporates latest developments in research ethics.

HRSO

- Human Research Standard Organization and Human Research Accreditation Canada is born.
- **NSH Human Research Protection Program**

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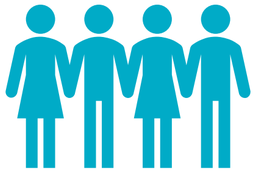
The modern Research Ethics Board



A board consists of

- At least 5 voting members
- Majority have to be Canadian citizens or permanent residents of Canada
- **Community Members**: At least one member whose primary role is to reflect the perspective of the research participant, and who is not affiliated with the organization either directly or indirectly.
- **Legal Member**: One member who has relevant expertise evidence through experience and/or training in the Canadian Law relevant to human research
- **Ethical expert:** one member who has relevant expertise evidenced through experience and/or training in the ethics relevant to human research.
- **Research Experts**: at least 2 members whose primary expertise evidenced through experience and/or training is in the relevant research discipline.

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From: Human Research Standards Organization; CAN.HRSO-200.01

The NS Health REB

- Independent board comprised of 90-100 volunteers that meet specific membership requirements
    - Executive Chair: **Dr. Chris MacKnight**
- All research projects involving patients, staff, resources or data must be **reviewed** and **approved** by the REB ***before*** human-related research begins.
- 300-400 projects approved annually
- 1350+ active studies

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The modern Research Ethics Board

- Lays out what is legitimate and what is not
- Moral research procedures
- Balance: the pursuit of knowledge and the rights of the research participants or others in society
- Professional obligation

Policies	Clinical Research	Clinical Trial	Regulated Clinical Trial
Tri-Council Policy Statement 2018 (TCPS):	✓	✓	✓
Human Research Standards Organization (NEW)	✓	✓	✓
Health Canada Division 5 Regulations			✓
International Council on Harmonization-Good Clinical Practice			✓
FDA Code of Federal Regulations (US studies only)			✓

TCPS2 2018

Health Canada

ICH

GOOD CLINICAL PRACTICES

FDA U.S. FOOD & DRUG ADMINISTRATION

Research is a privilege, not a right!
People first, data second

Tri-Council Policy Statement

Ethical Conduct for Research Involving Humans

TCPS2 2018

Canadian Institutes of Health Research
Natural Sciences and Engineering Research Council of Canada
Social Sciences and Humanities Research Council

TCPS CORE tutorial 2022 edition!

Core Principles

Respect for Persons

Concern for Welfare

Justice

Respect for persons

Respect for human dignity requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due.

- Respect autonomy, includes free, informed, safe and continuous consent
- Transparency and accountability of research (scientific validity, risk/benefit, COI, funding, qualifications for the undertaking)
- Protect and include those with developing, diminished or impaired autonomy, vulnerable or marginalized populations
- Protect participants' privacy and confidentiality (contracts, privacy impact assessments, legislation, data collection)
- Communicating and disseminating research results as broadly as possible (research registries, journals, etc)

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Concern for Welfare

- The welfare of a person is the quality of that person's experience of life in all its aspects.
  - The board needs to minimize foreseeable risk to that welfare – achieve most favourable balance of risks and benefits
  - Establish a plan and process for data safety monitoring (routine monitoring, reporting of negative impacts, establishment of a data safety monitoring board)
  - Also protect the welfare of groups or communities
- The concern about the welfare of a person extends to biological material obtained from that person, whether alive or deceased
  - Seek consent when practicable, either from participant or next of kin
  - Indigenous people/community data, OCAP principles

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Justice

Justice refers to the obligation to treat people fairly and equitably.

- Selecting and designing research topics/questions fairly and equitably with attention to diversity
- Distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it (i.e. detailed recruitment plan)
- Ensure proper compensation, insurance/funds for research-related injury
- Ensure appropriate community/collaborative partner involvement when applicable

Research Ethics Submission and Approvals

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NSH REB Decision Tree: Research vs QI, NSH vs IWK vs Dal REB?

NSH REB? Consult our Jurisdiction Policy on our website (NEW Oct 2022)

All human research involving Nova Scotia Health Authority (NSHA) affiliated physicians/scientists, patients, staff, resources and/or data is to be approved by the NSHA REB. Exceptions: recruiting staff in their professional abilities (physicians/nurse recruitment through professional associations).

Research

- Dal accepts NSH REB approvals but not the other way around.
- IWK and NSH are 2 institutions with their REBs. The REB you submit to will depend on participants and affiliations.

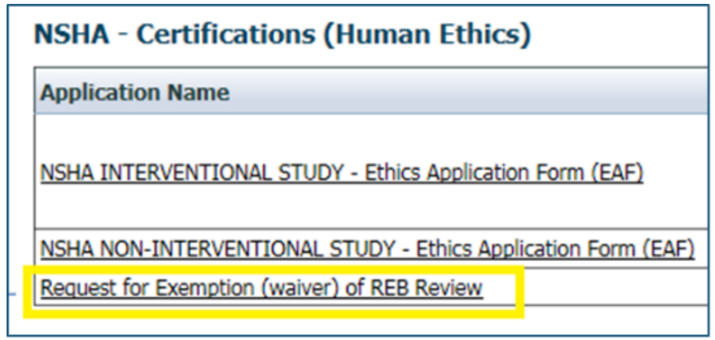
- Obtain a ROMEO account (sign up form on NSH REB website)
- Templates: all templates are inside REB forms.
- Consult the checklist for all submission requirements

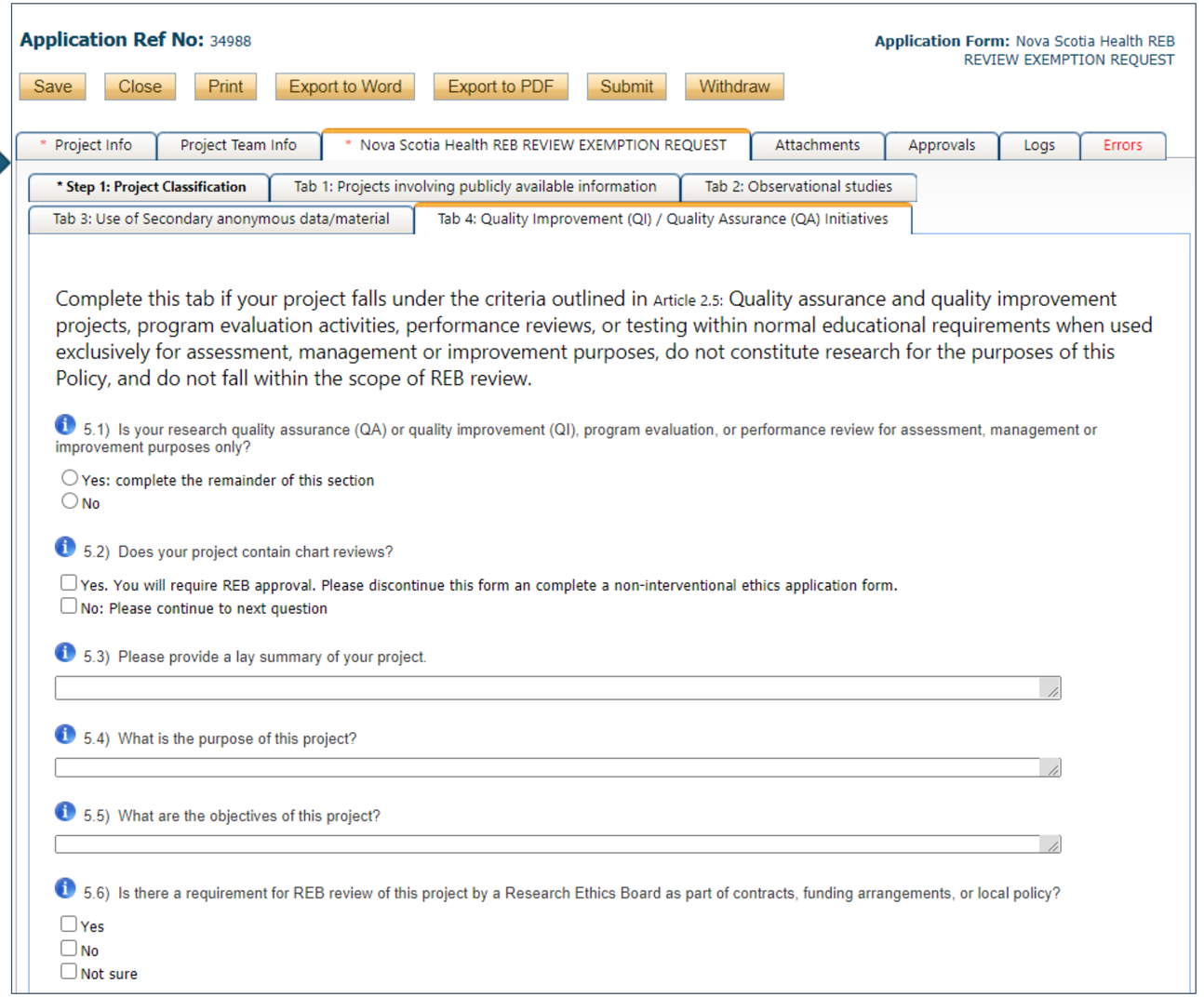
Quality Improvement

- ARECCI tool from Alberta Innovates
- *REB Exemption Review Form* in ROMEO (Consultation tool from NSH REB)
- Consult TCPS2 Chapter 2 for more details.

- Submit project to the Quality Improvement Program at NSH (Sharepoint form)
- Once approved by QI, you may require input from the Privacy Office
- Questions? Contact QualityImprovement@nshealth.ca

Not sure if you need REB review?





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What does not require ethics review?

TCPS2, Article 2.2: Publicly available information:

a. publicly available through a mechanism set out by legislation or regulation and that is protected by law (i.e. death registries, court judgements); or

b. in the public domain and the individuals to whom the information refers have no reasonable expectation of privacy (i.e. press releases, film or audio recordings, podcasts).

TCPS2, Article 2.3: Research involving the observation of people in public places where:

a. it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;

b. individuals or groups targeted for observation have no reasonable expectation of privacy; and

c. any dissemination of research results does not allow identification of specific individuals.

TCPS2, Article 2.4: Secondary use of information or biological samples

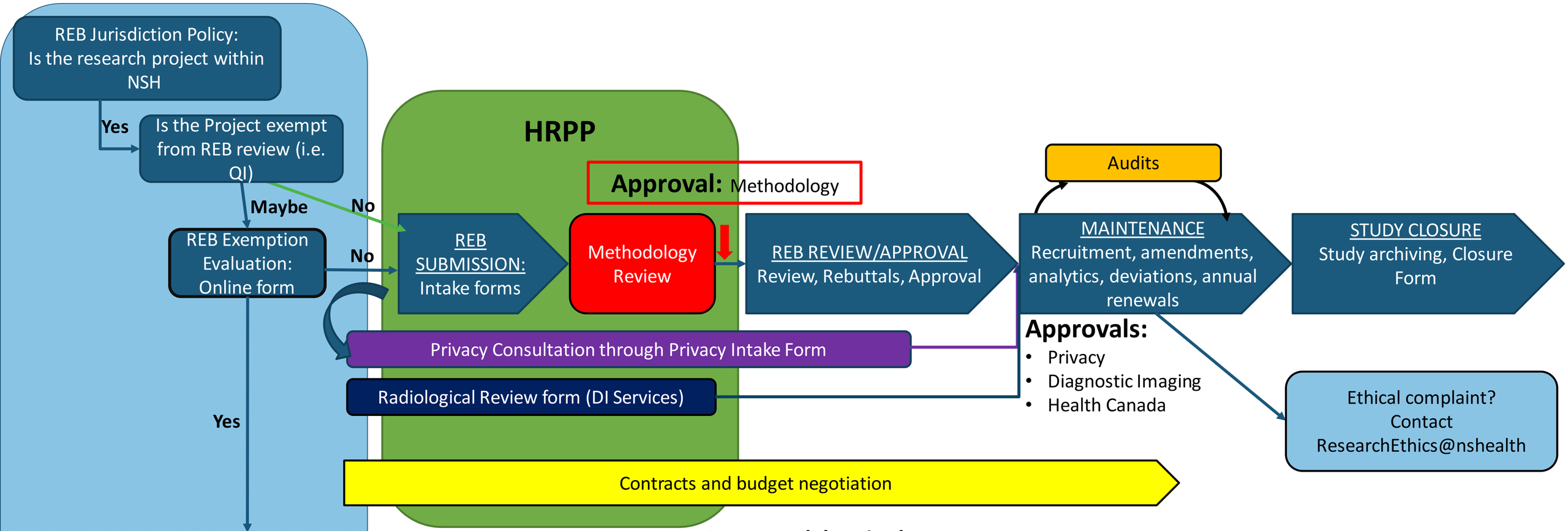
Research that relies exclusively on the secondary use of **anonymous** information, or **anonymous** human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

TCPS2, Article 2.5: Quality Assurance Initiatives

Quality assurance and quality improvement studies, 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.

More information: https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html

NSH REB Decision Tree: Research Process



Layers of Approvals

- **Ethics**
- **Radiology Review**
- **Privacy**
- **Methodology (non-CT)**
- **Contracts/Budgets**

Common delays in the process

- REB reviewer is late with the return of the review.
- PI is late submitting the changes.
- If you have not received a response from the REB in 3 weeks from your submission date, email ResearchEthics@nshealth.ca for a status update. Include the ROMEO# in your email.

Methodology Review

All Non-Interventional studies that have not been externally reviewed prior to submission are sent for a methodology review

- You may submit your protocol to the Research Methods Unit prior to submission to have this review done first
  - RMU@nshealth.ca

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Research ethics review process

Type of Review	
Full Board Review (Interventional)	Reviewed on Mondays at board meetings
Delegated Review (Non-Interventional)	Reviewed on a first come, first serve basis
Request for Exemption	Reviewed within 2 weeks

Who can be a Principal Investigator?

- Non-Interventional studies: PI can be a student or trainee provided;
  - A Supervising Investigator (SI) with an NS Health affiliation takes responsibility for the study.
  - The student/trainee obtains a letter of support from their department.
  - The student/trainee signs the Researcher's Commitments form
- Regulated Interventional Studies: Cannot be a trainee

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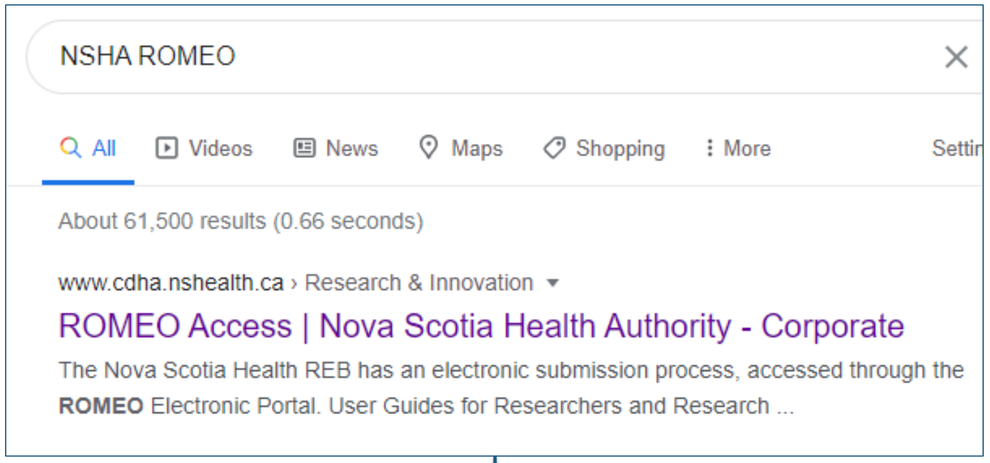
Accessing ROMEO

Google NSHA ROMEO: cdha.nshealth.ca



ROMEO Access

The Nova Scotia Health REB has an electronic submission process, accessed through the ROMEO Electronic Portal

ROMEO PORTAL ← ROMEO portal Link

User Guides for Researchers and Research Coordinators on how to use to the electronic portal:

- ROMEO Research Portal Users Guide
- Jurisdiction Policy Link
- ROMEO New User Form

Forms/Guides for ROMEO

- Procedures for Obtaining Access to HDNS Data
- Access to NS Department of Health and Wellness Application Form

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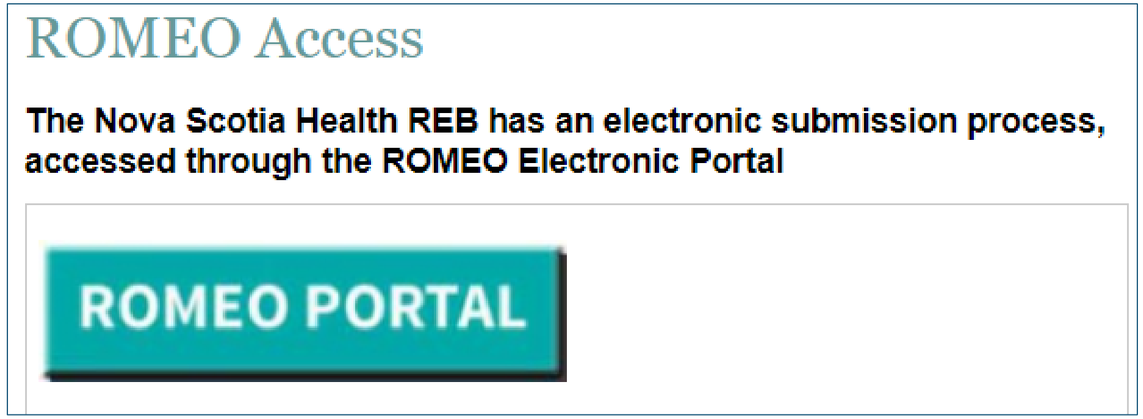
Reciprocity for REB review

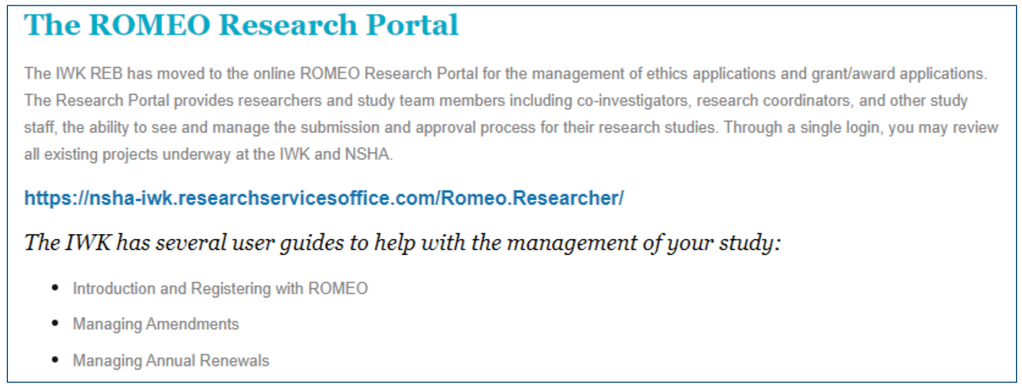
- Dalhousie University accepts REB approvals from NS Health and IWK
    - The submission/review process is completely electronic.
    - The link to the Researcher's Portal is on the NS Health Research Ethics website.
- NSH or IWK: Make sure you fill out the right form!

Shared Database

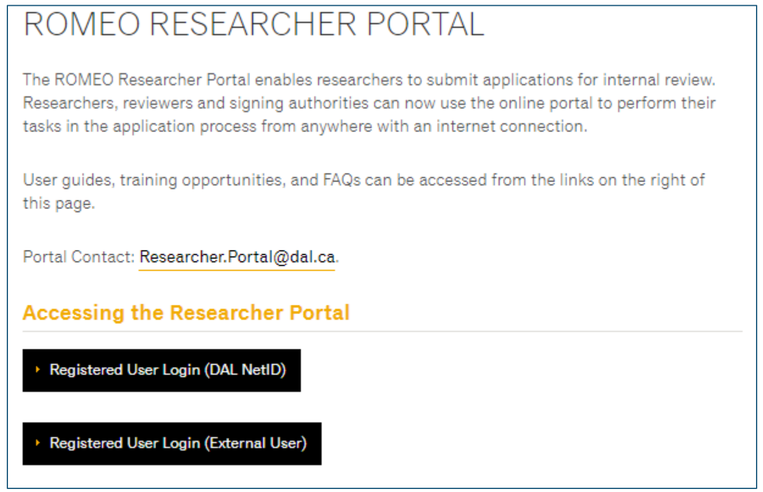
NS Health



IWK



Dalhousie



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Templates

Save | Close | Print | Export to Word | Export to PDF | Submit | Withdraw

* Project Info | Project Team Info | * Nova Scotia Health NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) | Attachments | Approvals | Logs | Errors

Please download the Researcher's Checklist template (below) and attach a completed copy with this ethics submission.

TIP: Uploading your documents in the order they appear on the checklist will help to ensure you don't miss any required materials.

Definitions:

Principal Investigator (PI): The person responsible for the overall conduct of the study.

Site Investigator: The person responsible for the conduct of the study at their institution(s) under the direction of the PI.

Submission Forms and Templates (download and complete where applicable to your study)
NOTE: Updated ICF (links, format, contact information)

Note: There is a new billing (invoice) template 2021 *required for industry sponsored/industry funded studies.

researchers-commitments-supervising-investigator-2020-04-30.doc
consent-non-interventional-studies-2021-09-13.docx
2021 REB Invoice template Billing Form Research.pdf
letter-support-PI-dept-2021-03-01.pdf
letter-support-SI-dept-2021-03-01.pdf
letter-support-Collaborating-Partner-2021-03-01.pdf
eConsent Getting Started.pdf
abbreviated-cv-research-sample-template-2017-11-21.doc
radiological-review-application-2015-04-01.doc
research-protocol-guidelines-2015-04-01.doc
addendum-informed-consent-2016-01-08.doc
access-personal-health-information-consent-form 2016-09-12.doc
researchers-checklist-submissions-non-interventional-2017-02-17.doc
researchers-checklist-additional-documents-2017-02-17.doc
Request for Waiver of Consent Addendum 2017-02-17.doc

Add Attachment

NOTE : The maximum individual attachment size is 5MB. All attachments larger than 5MB will stall the system, and your data may be lost.
However, you may upload multiple attachments, provided that each is no larger than 5MB.

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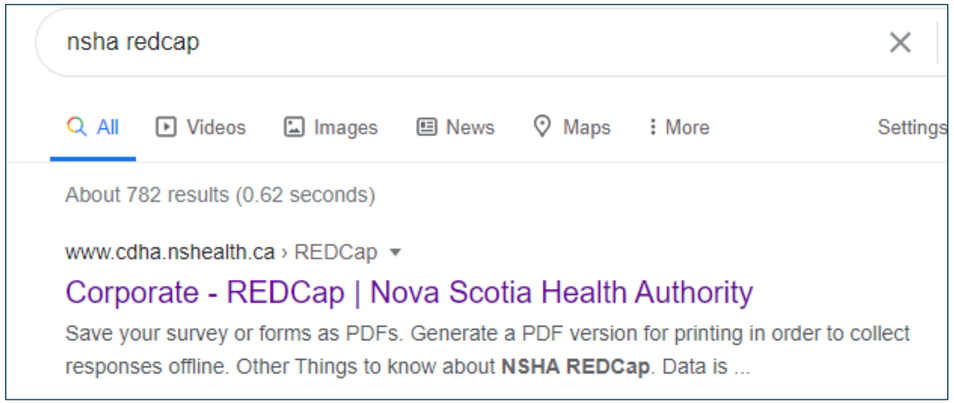
Decentralize your research via eConsent?

Google NSHA redcap: cdha.nshealth.ca



REDCap
Research Electronic Data Capture

At a Glance...

Key Features

- Free, web-based, and user-friendly electronic data capture tools (EDC) for research studies
- Databases can be quickly developed and customized for studies' needs

Useful for

- Collecting and tracking information and data from research studies
- Scheduling study events (e.g., patient visits)
- Conducting surveys

Available to

- Nova Scotia Health Authority affiliated investigators and research staff
- All others should contact their respective Institutions

Note: Please read the REDCap Terms of Service before applying for a REDCap account.

REDCap Project Initiation Form

REDCap Login Page

REDCap eConsent Training Guide

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REB submission and approval process

Nova Scotia Health Research Ethics Board
Centre for Clinical Research, Room 117
5790 University Ave., Halifax, NS B3H 1V7
email: ResearchEthics@nshealth.ca

REB's Researcher's Checklist for Submissions: Interventional Form

NOTE: 1. Please consult the ROMEO Attachment tab for templates and forms
2. Check when attached or Not Applicable (N/A) (if option is present)

Title of Protocol			
Principal Investigator		**Date:**	

Documents Required for Submission

Principal Investigator (PI) Qualifications

- ☐ **Letter of Support** from the PI's Department / Division / Program / Service
- ☐ **Copy of PI's current license to practice in Nova Scotia**
- ☐ **PI's completion certificate for the online tutorial *TCPS 2: CORE or CORE-2022*** Course on Research Ethics https://tcps2core.ca/welcome.
- ☐ **PI's current CV**
  Abbreviated version preferred. Must be signed and dated within the last 2 years.

Informed Consent Form(s) and Procedures *(i.e. main, pregnant partner, genetic, Access to PHI Form, etc.)*

	Informed Consent Form type	Version #	Date
☐	Title of Document		
☐			
☐			
☐			
☐			
☐			
☐ N/A	Waiver of Consent		

Standard Operating Procedures for obtaining consent
Refer to question 6.11 on Ethics Application Form

☐ N/A Attached SOP or described in section 6.11?

Screenshot

Submitting a Quality Initial REB Submission: EAF

No.	Question	Comment
2.2	Institutional Affiliation?	List Nova Scotia Health if applicable
3.1 – 3.6	**Research summary**	**Summarize, lay terminology, and do not copy & paste from protocol**. Imagine describing your project to a grade 8 class (age ~13).
4.3	Maximum number of participants globally	If only local, enter same as 4.2
6.2	Does your study include a cohort of First Nations etc.?	If so, must be submitted to Mi'kmaw Ethics Watch
6.6	Consent provided for recruitment purposes?	This question asks if consent has been gained for recruitment purposes, not how you will consent the participants into the study.
7.17	Where and how will personal health information and study data be stored?	Location of locked offices, electronic systems (One Content), central data repository or electronically on user terminals.
7.27	How long will records be stored?	Non-Interventional – 7 years Min. Interventional – 15 years min. (Health Canada clinical trials)
7.28	How will records be securely destroyed?	Simple deletion is not adequate. Provide info for both paper & electronic files and indicate as per Nova Scotia Health IT Services policy.

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Submitting a Quality Initial REB Submission: ICF

General Comments
Use the most current version of the REB's Consent Form template (on ROMEO)
Grade 8 Reading Comprehension Level (web-based software to evaluate)
Spelling / Grammar / Punctuation
Acronyms – Define Upon First Use
Header (Remove Template Headers & Instructions ("This section is standard as per TCPS2"))
Footer (Romeo File #, Version number & Date) – Update when making any Amendments
Standard Wording (Sections – Risks [Blood Samples, Breach of Confidentiality, Questionnaires, etc.], Compensation, Research Related Injury, Privacy and Confidentiality). If standard wording is not applicable to your study, please do not include.
If you remove or combine sections from the consent, please be sure to renumber the headings.
Avoid Repetition when using the REB template & Sponsor Template; Use REB wording whenever possible
Signature Page (use checkboxes if relevant). Please ensure all signature lines are on one page.

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A quality submission reflects quality of work elsewhere = trust

Submitting a Quality Initial REB Submission: General

General Comments
Letters of Support- The PI/SI cannot sign their own letters of support
NS Health Affiliation- Required- if you don't have an affiliation, you will require a Supervising Investigator
Supporting Material- Only submit documents that are being seen by the research participant (questionnaires, advertisements, etc.)
PI's license to practice- Do not submit the invoice; the certificate generally has an expiry date so make sure to submit the current license (This is not required for non-interventional studies)
CV- Needs to signed and dated within 2 years; please use abbreviated CV where possible
TCPS2: Core Certificate of Completion- Only required for PI and SI (not for sub-investigators or coordinators)
Use the Researchers Checklist to ensure you have all the necessary documents and upload a copy of the checklist with the submission.

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Submitting Responses to Initial Letter

Most Common Mistakes
Submit a detailed cover letter addressing each requested clarification (do not simply state “amended” or “revised”)
Do not delete any documents from Romeo (these will be archived by the ethics coordinator)
Update the version number and date on any revised documents you add
Highlight all changes on any revised documents

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After Approval

Continuing Review

- Annual approval request form – REB approval is valid for one year only.
  - ❖minor study deviation form
- Local Serious unexpected adverse reaction form, major study violation form, safety updates
- Amendment Forms – Any changes that you make to your study must be approved by the REB using the amendment form before you implement the change.
- Study Closure form - When the study is complete close your file with the REB Office
  - ❖Premature Study Closure form

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Please contact us if you ever have concerns about
your research.
We are here to help solve or troubleshoot any issues!

Consequences when failing to fulfill your ethical duties:

1) Loss of research privileges (no publication)
2) Directed audit
3) Mandate research ethics education before conducting any further research
4) Sanctions by your department
5) Complaint filed with College of Physicians and Surgeons

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Contact Information

NS Health Research Ethics Office: ResearchEthics@nshealth.ca

- REB Manager: Dr. Marie Tremblay, Marie-Laurence.Tremblay@nshealth.ca
- Senior Ethics Advisor: Joan Morrison, Joan.Morrison@nshealth.ca, C: (902) 476-9542
- Ethics Coordinators: Josie Leclair, josie.leclair@nshealth.ca, Shelley MacDonald, shelleyL.macdonald@nshealth.ca, Jennifer MacVicar, jennifer.macvicar@nshealth.ca
- Ethics Administrator: Michelle Roden Michelle.Roden@nshealth.ca

Check out our Webpage for more resources!

Navigating ROMEO without a headache

- ROMEO does not have an auto-save function. Press the Save button to save your work regularly!!
- The browser's 'back' button is your enemy: errors may occur and data might not save.
- To avoid system errors, do **NOT** use the symbols < or > in data entries.
- LOGOUT at the end of each session. Failure to logout before closing the browser may result in the file being locked and inaccessible to other team members, reviewers, and signatories.
- Questions?? Send an email with your to ResearchEthics@nshealth.ca
  - If you have received an initial letter, please send all correspondence to the Ethics Coordinator assigned to your file (include the Romeo # in all correspondence)

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