

## Visual User Guide for Navigating ROMEO

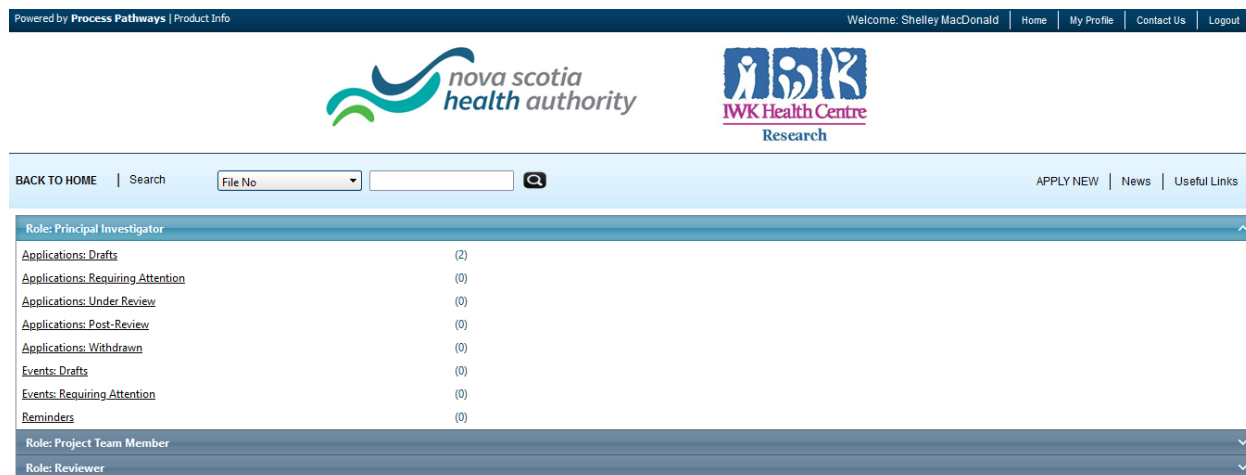
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## 1. Homepage

The homepage is your starting point in Romeo and displays several sections depending on the roles you may be involved in:

- Role: Principal Investigator
- Role: Project Team Member
- Role: Reviewer (if you serve on the REB or other review committees)
- Role: Signing Authority (for those authorized to provide institutional or Departmental signoff)

Click the bar to expand the section you need to use.



The homepage allows researchers and team members' access to all new and ongoing studies, including both REB and Grant/Award records. This page provides quick links for managing research review activities, viewing current project status, and specifying items requiring attention.

Quick Link Descriptions:

<i>Applications: Draft</i>	View your list of applications in development. These are accessible for edit purposes by all listed team members. Detailed study log is maintained to facilitate collaborative edits and application development. These projects are not yet visible to the research office or REB.
<i>Applications: Requiring Attention</i>	Applications that have been subject to initial or completed REB review, that have outstanding issues will be listed here. Eg. missing or inaccurate application detail or documents, or issues to be addressed before approval may be finalized (i.e. the <i>REB Review Summary</i> ). Notification is received by email.
<i>Applications: Under Review</i>	All new submissions that are in the review process. Includes those in reviewers hands



	awaiting comments, and those noted above as “Requiring My Attention”.
<i>Applications: Post Review</i>	All previously approved, active or closed submissions. These records are locked. Changes or revisions may only be done through submission of an Event application.
<i>Applications: Withdrawn</i>	Applications that never achieved approval
<i>Events: Draft</i>	Annual Renewals, Amendments, Safety or SAE report, etc. in development. As above, these Draft items are visible to the team but are not yet visible to the research office.
<i>Events: Requiring Attention</i>	For example, Amendments that have had initial REB review but have outstanding issues such as missing documents or inaccurate details. Researchers are notified via email of the necessary revisions required for resubmission.
<i>Reminders</i>	Previously approved studies with routine continuing review activities outstanding, such as Annual Renewals due.


## 2. Creating a new Study

Click on apply new

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BACK TO HOME | Search | File No |  

**APPLY NEW** | News | Useful Links

**Role: Principal Investigator** ^

- Applications: Drafts (2)
- Applications: Requiring Attention (0)
- Applications: Under Review (0)
- Applications: Post-Review (0)
- Applications: Withdrawn (0)
- Events: Drafts (0)
- Events: Requiring Attention (0)
- Reminders (0)

**Role: Project Team Member** v

**Role: Reviewer** v

For NS Health users make sure you scroll to the 3<sup>rd</sup> block (NSHA Certifications) and pick the appropriate application type.

### New Application Forms

#### IWK - Awards and Clinical Trials

Application Name	Description	Status
Graduate Studentship Application	Application form to be completed by the student. This grant is intended to support promising graduate students engaged in research aimed at improving child, youth, maternal or women's health at the IWK.	Open
IWK Agreements Intake	Complete this form for contracts, site agreements, clinical trials, etc. If there is already an agreement in place for your study (e.g., confidentiality/non-disclosure agreement) an amendment is required. Please go to your home screen and select the project by clicking on APPLICATIONS: POST REVIEW and chose EVENT.	Open
Mentored Project Grant	The purpose of this award is to support projects that will build capacity in research at the IWK while also facilitating the development of the applicant's research efficacy. Trainee, early career faculty, or clinical and administrative staff who are building research expertise are encouraged to apply.	Open
Postdoctoral Fellowship Application	Application form to be completed by the trainee. This grant is intended to support promising postdoctoral fellows engaged in research aimed at improving child, youth, maternal or women's health at the IWK.	Open
Project Grants	The Project Grant is to support projects that will empower IWK researchers to become increasingly competitive for external funding, and to complete high-quality projects of a more limited scope that will have significant scientific or clinical impact.	Open
Summer Studentship Application	The purpose of this award is to support undergraduate students to engage in research aimed at improving child, youth, maternal or women's health at the IWK.	Open

#### IWK - Certifications (Human Ethics)

Application Name	Description	Status
IWK Interventional Study - Ethics Application Form (EAF)	Interventional Study (or Clinical Trial): A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. — clinicaltrials.gov If your study meets the requirements of an interventional study as per the definition above, complete this form. If your study does not meet the definition of an interventional study, complete the Ethics Application Form for Non-Interventional Studies.	Open
IWK Non-Interventional Study - Ethics Application Form (EAF)	Complete this form if your study is NOT a clinical trial. If your study is a clinical trial, complete the clinical trials EAF form.	Open

#### NSHA - Certifications (Human Ethics)

Application Name	Description	Status
Nova Scotia Health INTERVENTIONAL STUDY - Ethics Application Form (EAF)	Interventional Study (or Clinical Trial): A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. — clinicaltrials.gov If your study meets the requirements of an interventional study as per the definition above, complete this form. If your study does not meet the definition of an interventional study, complete the Ethics Application Form for Non-Interventional Studies.	Open
Nova Scotia Health NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)	Complete this form if your study is NOT a clinical trial. If your study is a clinical trial, complete the clinical trials EAF form.	Open
Nova Scotia Health REB REVIEW EXEMPTION REQUEST	Some research is exempt from REB review: 1. Quality Improvement projects 2. Studies using secondary anonymous information 3. Observations of people in public spaces 4. Studies involving publicly available information. 5. Case reports/case series Consult TCSP2 for more detail. Please fill out this form if your project may fall under any of the categories.	Open

### 3. Searching for an active study

There are two ways to search for a study.

1. You can type the Romeo number in the search bar
2. You can click on Applications: Post-Review

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BACK TO HOME | Search | File No.

APPLY NEW | News | Useful Links

**Role: Principal Investigator**

- Applications: Drafts (2)
- Applications: Requiring Attention (0)
- Applications: Under Review (0)
- Applications: Post-Review (0)
- Applications: Withdrawn (0)
- Events: Drafts (0)
- Events: Requiring Attention (0)
- Reminders (0)

**Role: Project Team Member**

- Applications: Drafts (0)
- Applications: Requiring Attention (0)
- Applications: Under Review (0)
- Applications: Post-Review (48)**
- Applications: Withdrawn (0)
- Events: Drafts (0)
- Events: Requiring Attention (0)
- Reminders (0)

**Role: Reviewer**

- Applications: Chair (0)
- Applications: Reviewer (New) (0)
- Applications: Reviewer (In Progress) (0)
- Events: Chair (0)
- Events: Reviewer (New) (0)
- Events: Reviewer (In Progress) (0)

If you search using the Post Review button you will get a list of all your studies (active and closed) and you will also see both the Human Ethics and Awards file for each study. You can narrow down the search by clicking on the application type to filter out the Awards files (click on application type and choose Human Ethics):

\*You will only need the Human Ethics file to submit any event to ethics.

Reset Filters | Export To Excel

File No	Project Title	Principal Investigator	Application Type	Status Snapshot
<input type="text"/>	<input type="text"/>	<input type="text"/>	All	<input type="text"/>

Application Type dropdown arrow

Reset Filters | Export To Excel

File No	Project Title	Principal Investigator	Application Type	Status Snapshot
<input type="text"/>	<input type="text"/>	<input type="text"/>	Human Ethics	<input type="text"/>

## 4. Where to find events

After you have found your study click on the events button:

The screenshot shows a web application interface. At the top, there is a navigation bar with 'BACK TO HOME', a search bar, and 'APPLY NEW | News | Useful Links'. Below this is a toolbar with 'Reset Filters' and 'Export To Excel'. The main area contains a table with columns: File No, Project Title, Principal Investigator, Application Type, and Status Snapshot. The 'Application Type' dropdown is set to 'Human Ethics'. Below the table, there are buttons for 'View', 'Clone', 'Latest Workflow', and 'Events'. The 'Events' button is circled in red.

Make sure you choose your event from the NS Health Research Ethics list of events

Event Form Name	Description
<a href="#">IWK Acknowledgement Request</a>	Letters/notifications from the study team, sponsor, etc. that require an acknowledgement that the REB has received specific information. Examples would include: studies on placed hold, or reactivated; studies closed to accrual/enrollment, status updates, etc.
<a href="#">IWK Amendment Request</a>	This includes amendments to research protocols, consent forms, supporting materials and product information
<a href="#">IWK Annual Renewal Request</a>	REB approval will expire on the last day of the specified approval period, normally effective for 1 year. To ensure continuing approval, an Annual Approval Request is required 4-6 weeks prior to the expiry date. If approval expires all study activities must cease immediately, and the REB may close your file.
<a href="#">IWK Major Study Violation</a>	Major study violations are deviations from regulatory requirements or REB-approved documents, policies, and/or processes that impact data integrity, participant safety, privacy/confidentiality or willingness to continue in the study. • Examples include: obtaining informed consent with an outdated or unapproved version of the consent; beginning study procedures before consent was obtained; enrolling participants who didn't meet eligibility criteria; omitting key protocol-required tests or procedures; medication errors, including prescribing a contraindicated medication; using the wrong survey instrument; or using or releasing personal information without the participant's consent. • CLINICAL TRIALS: Deviations that DO NOT meet the criteria of a Major Violation are to be submitted to the REB using the Minor Deviation Reporting Form as part of the Annual Renewal process. • Major study violations must be reported to the REB upon discovery.
<a href="#">IWK SAE/SUSAR - for local SAE/SUSAR Reporting</a>	Adverse event: Any untoward medical occurrence experienced by a research participant. SAE: Serious Adverse Event. SUSAR: Suspected Unexpected Serious Adverse Reaction. An adverse event that is 'serious' and 'unexpected' and related or possibly related to participation in the research. Adverse events that do not meet all three of these criteria should not be reported to the REB.
<a href="#">IWK Safety Related Event Reporting (External SAEs, Minor Protocol Deviations, PSUR, DSMB, Safety Alerts)</a>	External SAEs, Minor Protocol Deviation, PSUR: Periodic Safety Update Reports, DSMB: Data & Safety Monitoring Board updates, sponsor issued Safety Alerts or other sponsor provided safety information.
<a href="#">IWK Study Closure</a>	If there are any unreported minor study deviations, please attach a completed report (see template)
<a href="#">IWK Study Personnel Change Notification</a>	Use this form to notify the REB of changes to your project team for this study.
<b>NS Health Research Ethics</b>	
<a href="#">Nova Scotia Health Acknowledgement Request</a>	Letters/notifications from the study team, sponsor, etc. that require an acknowledgement that the REB has received specific information. Examples would include: studies on hold, off hold; studies closed to accrual/enrollment, etc.
<a href="#">Nova Scotia Health Amendment Request</a>	This includes research protocols, consent forms/addendums, research team contact pages, supporting materials, and product information.
<a href="#">Nova Scotia Health Annual Renewal Request</a>	REB approval for this study will expire on the last day of the specified approval period. To ensure continuing review, submit an Annual Approval Request 2-4 weeks prior to this date. If approval is not renewed on time, the Board will close your file and you must cease all study activities immediately.
<a href="#">Nova Scotia Health Local Suspected Unexpected Serious Adverse Reaction (SUSAR) Reporting Form</a>	Adverse event: Any untoward medical occurrence experienced by a research participant. Suspected Unexpected Serious Adverse Reaction (SUSAR): An adverse event that is 'serious' and 'unexpected' and related or possibly related to participation in the research. Adverse events that do not meet all three of these criteria are not SUSARs and should not be reported to the REB.
<a href="#">Nova Scotia Health Major Study Violation</a>	Major study violations are deviations from applicable regulatory requirements or REB approved documents, policies and/or processes that impact data integrity or participant safety, privacy/confidentiality, or willingness to continue in the study.
<a href="#">Nova Scotia Health Change in Principal/Supervising Investigator (PI/SI) form</a>	Use this form to submit a change in PI/SI only (changes to team members are to be submitted using the 'change in study personnel form.'
<a href="#">Nova Scotia Health Change in Study Personnel</a>	Use this form to notify the REB of changes to your project team for this study. New team members must already have a master profile before being added to the REB file.
<a href="#">Nova Scotia Health Safety related events reporting (PSUR, DSMB, Safety Alerts)</a>	(Periodic Safety Update Reporting (PSUR), Data & Safety Monitoring Board (DSMB) updates, sponsor issued safety alerts and/or sponsor provided safety information.
<a href="#">Nova Scotia Health Study Closure</a>	

## 5. Viewing study documents and correspondence

If you would like to review your study documents or see any emails that have been sent through Romeo, enter your study by clicking the Latest Workflow button:

BACK TO HOME | Search | File No. | APPLY NEW | News | Useful Links |

Reset Filters | Export To Excel

	File No	Project Title	Principal Investigator	Application Type	Status Snapshot
<div>View   Close   Events   Latest Workflow</div>	1023410	Acute Total Hip Reconstruction Following Displaced Acetabular Fractures in the Elderly	Dr. Ross Leighton (Medicine/Surgery/Orthopedic Surgery)	Nova Scotia Health NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) (Certification/Human Ethics)	Project Status: Closed Workflow Status: Approval Decision Made

This will open your study on the logs tab. To view the emails, click on the shared communications button:

Close | Print | Export to Word | Export to PDF

View mode. Changes cannot be saved.

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

Application Workflow Log | Application Log | Shared Communications

Timestamp	Activity Log	Workflow State	Workflow Message	User	Role/Group
2017/12/18 09:32	Project Start date has been changed from "2017/12/18" to "2017/12/18" Project Status has been changed from Pending to Active Application Workflow State has been changed from ORS Review to Approval Decision Made	ORS Review -> Approval Decision Made		jmorison	Office of Research Services/Office of Research Ethics
2017/12/15 12:13	Project Work Flow State has been changed from Pending Info by ORS to ORS Review	Pending Info by ORS -> ORS Review	There have been no changes to the protocol or questionnaire. Version numbers and dates remain the same. The questionnaire has simply been attached as a separate electronic file as requested. [Action: Re-Submit]	Ross Leighton	Principal Investigator
2017/12/15 11:41	Application Workflow State has been changed from ORS Review to Pending Info by ORS	ORS Review -> Pending Info by ORS		jmorison	Office of Research Services/Office of Research Ethics
2017/12/15 09:53	Project Work Flow State has been changed from Pending Info by ORS to ORS Review	Pending Info by ORS -> ORS Review	[Action: Re-Submit]	Ross Leighton	Principal Investigator
2017/12/13 08:22	Application Workflow State has been changed from ORS Review to Pending Info by ORS	ORS Review -> Pending Info by ORS		jmorison	Office of Research Services/Office of Research Ethics
2017/11/17 11:28	New File Submitted by Researcher Project Work Flow State has been changed from Pre-Submission to ORS Review	Pre-Submission -> ORS Review	[Action: Submit]	Ross Leighton	Principal Investigator

To view your attachments, click on the attachments tab and scroll to the bottom of the page:

Close | Print | Export to Word | Export to PDF

View mode. Changes cannot be saved.

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

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.

Supervising Investigator: The person responsible for the conduct of the study at NS Health. Required for external PIs or PIs in training

**Announcements**

- May 2023 Request for Waiver of Consent updated
- NEW May 3, 2023: If you are submitting a Waiver of Consent, please also submit an approved (signed) Privacy Intake Form.
- April 2022: Privacy Intake Form updated.
- March 2022: SI commitment form and SI Letter of support are now one document under "Letter-support\_commitment-SI-dept2022-03-21.pdf"
- 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-checklist-additional-documents-2017-02-17.doc  
letter-support-Collaborating-Partner-2021-03-01.pdf  
REQUIRED-Researcher-Checklist-Submission-Requirements-Non-interventional-2022-04-20.pdf  
eConsent Getting Started.pdf  
letter-support-PI-dept-2021-03-01.pdf  
abbreviated-cv-research-sample-template-2017-11-21.doc  
radiological-review-application-2015-04-01.doc  
addendum-informed-consent-2016-01-08.doc  
access-personal-health-information-consent-form 2016-09-12.doc  
letter-support\_commitment-SI-dept-2022-06-03.pdf  
REB Privacy Intake Form\_v\_3\_08.17.2022.docx  
Guideline for creating a comprehensive research protocol\_2022-02-02.pdf  
Advertisement\_Template\_July 2022.docx  
consent-non-interventional-studies-2021-09-13.docx  
Waiver of Consent\_Final\_05.23.2023.docx

	Doc / Agreement	Version Date	File Name	Description
	Study Closure/Termination	2018/12/10		Study closed: Nov 16, 2018
	Approval Letter - REB Use Only	2017/12/18		
	Certificate of Completion TCPS 2: CORE	2012/06/17		PI TCPS2
	Consent Form - paper version	2017/11/08		Consent V0
	Consent Form - paper version	2017/12/14		revised consent - clean
	Consent Form - paper version	2017/12/14		revised consent - changes high ...
	Current License to Practice in NS			PI License
	Curriculum Vitae (CV)	2017/05/20		PI's cv
	Initial Letter - REB Use Only	2017/12/11		
	Investigator Response/Revisions			Ethics reply letter
	Letter of Support	2017/11/15		LOS PI's Dept
	Research Protocol	2017/04/05		Protocol 1.1
	Researcher's Checklist for Submission	2017/11/09		checklist
	Review Comments/Correspondence	2015/06/18		Lead site ethics approval
	Supporting Materials			Questionnaire
	Supporting Materials	2017/12/14		Advertisement

Files will show here, and you can click to open them.