



## IWK Research & Innovation Advancement - Research Ethics

### Registering in the ROMEO Researcher Portal & Introduction to Managing Study Review Activities

The ROMEO Researcher Portal is a web based system established to provide electronic submission, review and approval processes for research ethics board (REB) and grant/award applications. It may be accessed by research team members and supports collaborative editing and development of applications, REB submission, review and approval processes, and ongoing oversight of REB related activities. This is meant to get you started. Further information and training events will be provided through the [IWK website](#).

#### Website address

To log in into the ROMEO Researcher Portal visit:

<https://nsha-iwk.researchservicesoffice.com/Romeo.Researcher/>

#### Login

Registration is required the first time the ROMEO Researcher Portal is accessed.

EXISTING RESEARCHERS: All study team members (Principal Investigators, Research Coordinators, etc.) named on existing projects, are already registered in Romeo. *Reset Password* is all that is required. Enter Romeo using the website address above, using your email address as your Username and click Reset Password. You'll receive an automated email with a Confirmation Code and web link to reset your password. If your Username (email address) is not recognized, please contact [Joanne Street](#). We will verify the address recorded in Romeo and make any necessary corrections.

NEW RESEARCHERS: To register click on the Register button on the login page.

IMPORTANT: Researchers must maintain only one login in order to ensure access to all relevant studies. Multiple logins will interfere with study notifications and may result in lost records. Your email address is used as the Login ID.

#### Homepage:

The homepage displays a number of sections depending on various roles you may be involved in, for example:

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

Role : Principal Investigator

- Applications (Saved - Not Submitted) (7)
- Applications (Submitted - Requiring My Attention) (0)
- My Reminders (0)
- Applications (Submitted - Under Review) [Click here...]
- Applications (Submitted - Post Review) [Click here...]
- Applications (Withdrawn) [Click here...]

Role: Project Team Member

- Applications (Saved - Not Submitted) (0)
- Applications (Submitted - Requiring My Attention) (0)
- My Reminders (0)
- Applications (Submitted - Under Review) [Click here...]
- Applications (Submitted - Post Review) [Click here...]
- Applications (Withdrawn) [Click here...]

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, for example: projects due for Annual Renewal.

#### Quick Link Descriptions:

<i>Applications (Saved – Not Submitted) (7)</i>	View your list of applications in development. These are accessible for edit purposes by all identified team members. Detailed study log is maintained to facilitate collaborative edits and application development. These projects are not yet visible to RIA or REB.
<i>Applications (Submitted – Requiring My Attention) (1)</i>	Applications that have been subject to initial research office review or completed REB review, that have outstanding issues will be listed here. Eg. missing or inaccurate application detail or documents necessary for review, or issues to be addressed before approval may be finalized (i.e. the <i>REB Review Summary</i> ).
<i>My Reminders</i>	Previously approved studies with routine continuing review activities outstanding, such as Annual Renewals due.
<i>Applications (Submitted – Under Review) [Click here...]</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 (Submitted – Post Review) [Click here...]</i>	All previously approved, now active or closed submissions. These records are locked. Changes or revisions may only be done through submission of an Event application (see below).
<i>Applications (Withdrawn) [Click here...]</i>	Applications that never achieved approval

It's recommended you review the list(s) on first sign in, to ensure studies are appropriately linked to your individual User ID. These lists will include details of recorded Grant/Awards and NSHA (or previous MREB and CDHA) studies. If it appears IWK REB studies are missing from the list please contact [Joanne Street](#) for assistance in identifying the problem.

### New Applications:

To submit a new application, select the 'APPLY NEW' link in the light blue area, top right of the Home Page. This will begin the application process and guide you through a series of tabs and questions that replace the paper EAS form application process. Additional study documents are uploaded on the Attachments tab.

### Ongoing Study Management:

Use the quick links to monitor or submit ongoing study activity as either the 'Principal Investigator' or 'Project Team Member'. For example, to submit a new Event (i.e. an Annual, Amendment, Safety or SAE report, etc.), enter:

- Applications (Submitted – Post Review) [**Click here...**]

All related ethics and awards files will be displayed with the option to *View* or create an *Event*.

**Click Events** - The following event activities are available. Click the *Event Form Name* to initiate the process and access the necessary electronic forms:

Event Form Name	Description
<a href="#">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. Can also be used to submit external SAE Summary Tables.
<a href="#">Amendment Request</a>	This includes research protocols, ethics application forms, consent forms/addendums, research team contact pages, supporting materials, and product information.
<a href="#">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="#">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="#">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="#">Safety related events reporting (PSUR, DSMB, Safety Alerts)</a>	PSUR: Periodic Safety Update Reports, DSMB: Data & Safety Monitoring Board updates, sponsor issued safety alerts or other sponsor provided safety information.
<a href="#">Study Closure</a>	If there are any unreported minor study deviations, please attach a completed report (see template)
<a href="#">Study Personnel Change Notification</a>	Use this form to notify the REB of changes to your project team for this study.

### My Reminders Quick Link:

This link shows when researchers need to take action on a study. E.g. review response might be due or the study is in need for annual renewal. Email notifications of items requiring attention will also be forwarded to the Principal Investigator and team members.

Role : Principal Investigator

Applications (Saved - Not Submitted)	(7)
Applications (Submitted - Requiring My Attention)	(0)
My Reminders	(0)
Applications (Submitted - Under Review) [Click here...]	
Applications (Submitted - Post Review) [Click here...]	
Applications (Withdrawn) [Click here...]	

Role: Project Team Member

Applications (Saved - Not Submitted)	(0)
Applications (Submitted - Requiring My Attention)	(0)
My Reminders	(0)
Applications (Submitted - Under Review) [Click here...]	
Applications (Submitted - Post Review) [Click here...]	
Applications (Withdrawn) [Click here...]	

On the Home Page, *Settings* must be set and saved in order to receive routine system notifications, Annual Renewal notices for example.

I would like to receive notifications regarding due/expired dates reminders :  
 (e.g. : Progress Report Reminder, Certification Expiration Reminder)

Tips to ensure efficient review of your application:

- Include full study title
- Ensure the correct Investigator is listed on study documents for multi-site studies
- Ensure proper logos are on consents, assents, and other relevant study documents
- Include all study documents (protocol, consents, data collection sheets, letters of support, etc.)
- Provide sufficient information, in lay terms, in section 4 of the EAF
- Include team members TCPS2 certification