# Visual User Guide for Navigating ROMEO

## 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:

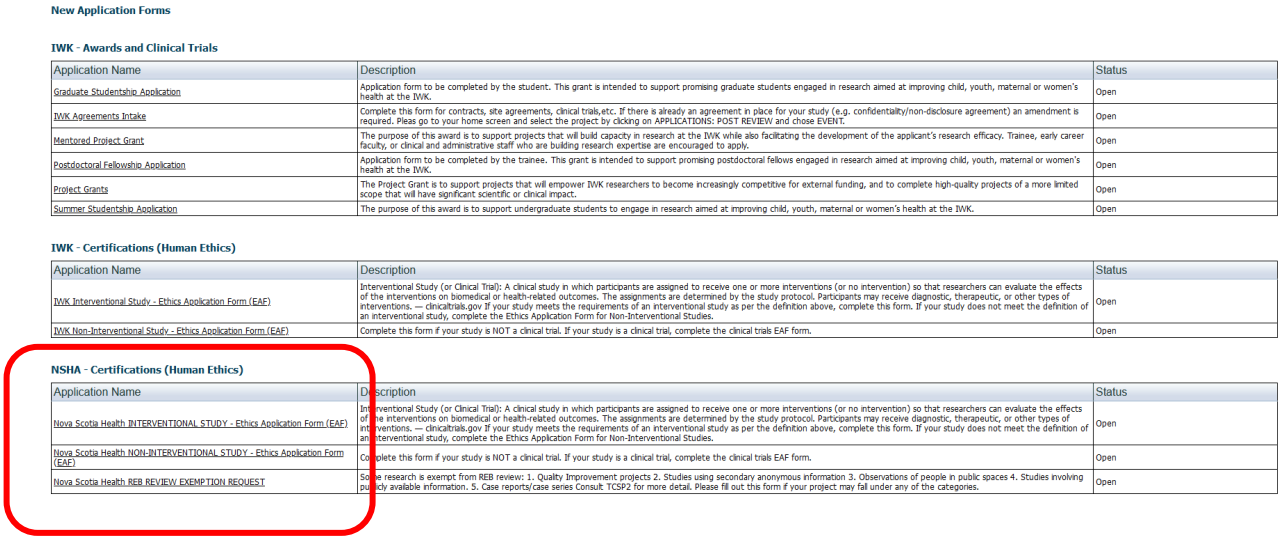
| | |
|---|---|
| *Applications: Draft* | View your list of applications in development. These are accessible for edit purposes by all listed team members. Detailed study log is maintained to facilitate collaborative edits and application development. These projects are not yet visible to the research office or REB. |
| *Applications: Requiring Attention* | 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 *REB Review Summary*). Notification is received by email. |
| *Applications: Under Review* | All new submissions that are in the review process. Includes those in reviewers hands |

| | |
|---|---|
| | awaiting comments, and those noted above as "Requiring My Attention". |
| *Applications: Post Review* | All previously approved, active or closed submissions. These records are locked. Changes or revisions may only be done through submission of an Event application. |
| *Applications: Withdrawn* | Applications that never achieved approval |
| *Events: Draft* | 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. |
| *Events: Requiring Attention* | 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. |
| *Reminders* | Previously approved studies with routine continuing review activities outstanding, such as Annual Renewals due. |

## 2. Creating a new Study

Click on apply new


For NS Health users make sure you scroll to the 3rd 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. confidentailty/non-disclosure agreement) an amendment is required. Pleas 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 particpants 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 particpants 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 |

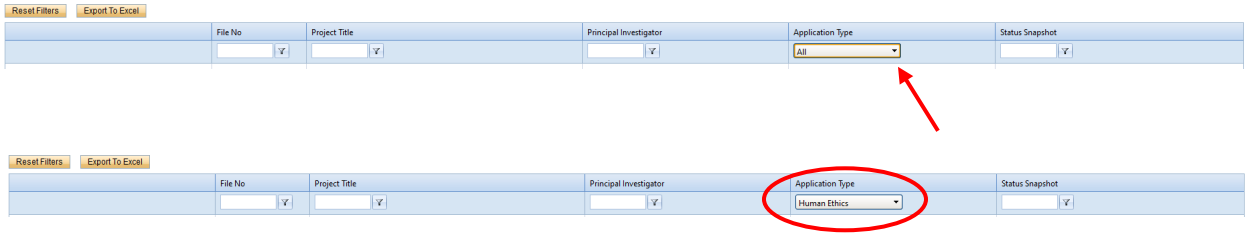
3. Searching for an active study

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

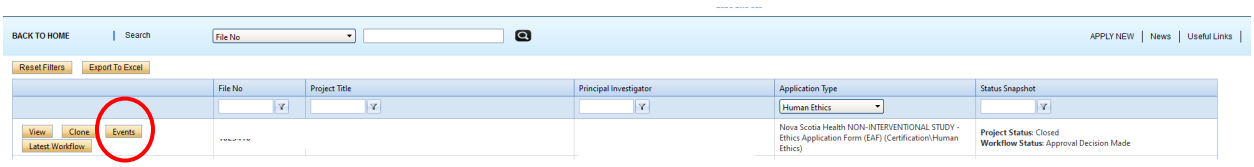

If you search using the Post Review button you will get a list of all your studies (active and closed) and you will also see both the Human Ethics and Awards file for each study. You can narrow down the search by clicking on the application type to filter out the Awards files (click on application type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

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



## 4. Where to find events

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

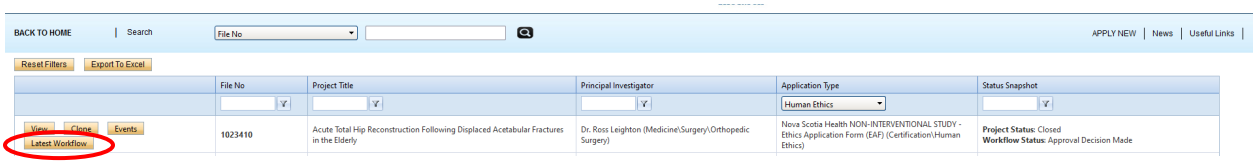



Make sure you choose your event from the NS Health Research Ethics list of events

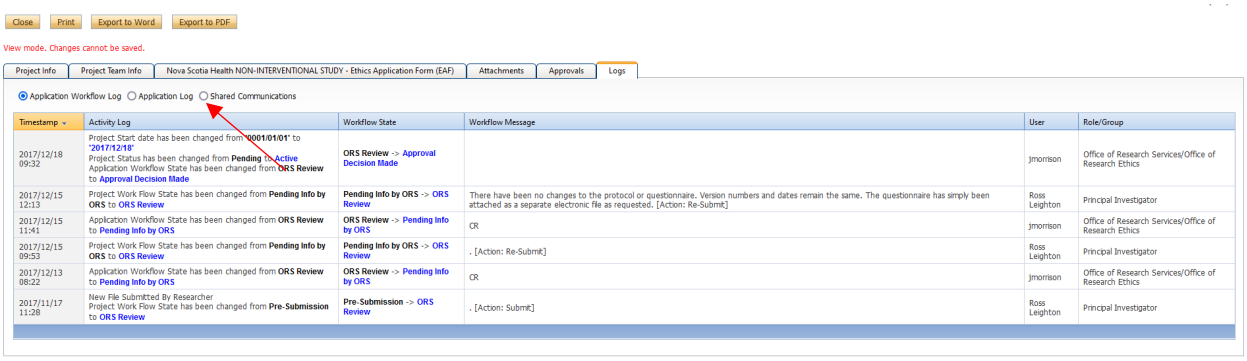
| Event Form Name | Description |
|---|---|
| IWK Acknowledgement Request | Letters/notifications from the study team, sponsor, etc. that require an acknowledgement that the REB has received specific information. Examples would include: studies on placed hold, or reactivated; studies closed to accrual/enrollment, status updates, etc. |
| IWK Amendment Request | This includes amendments to research protocols, consent forms, supporting materials and product information |
| IWK Annual Renewal Request | 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. |
| IWK Major Study Violation | 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. |
| IWK SAE/SUSAR - for local SAE/SUSAR Reporting | 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. |
| IWK Safety Related Event Reporting (External SAEs, Minor Protocol Deviations, PSUR, DSMB, Safety Alerts) | 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. |
| IWK Study Closure | If there are any unreported minor study deviations, please attach a completed report (see template) |
| IWK Study Personnel Change Notification | Use this form to notify the REB of changes to your project team for this study. |
| NS Health Research Ethics | |
| Nova Scotia Health Acknowledgement Request | 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. |
| Nova Scotia Health Amendment Request | This includes research protocols, consent forms/addendums, research team contact pages, supporting materials, and product information. |
| Nova Scotia Health Annual Renewal Request | 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. |
| Nova Scotia Health Local Suspected Unexpected Serious Adverse Reaction (SUSAR) Reporting Form | 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. |
| Nova Scotia Health Major Study Violation | 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. |
| Nova Scotia Health Change in Principal/Supervising Investigator (PI/SI) form | 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." |
| Nova Scotia Health Change in Study Personnel | 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. |
| Nova Scotia Health Safety related events reporting (PSUR, DSMB, Safety Alerts) | (Periodic Safety Update Reporting (PSUR), Data & Safety Monitoring Board (DSMB) updates, sponsor issued safety alerts and/or sponsor provided safety information. |
| Nova Scotia Health Study Closure | |

## 5. Viewing study documents and correspondence

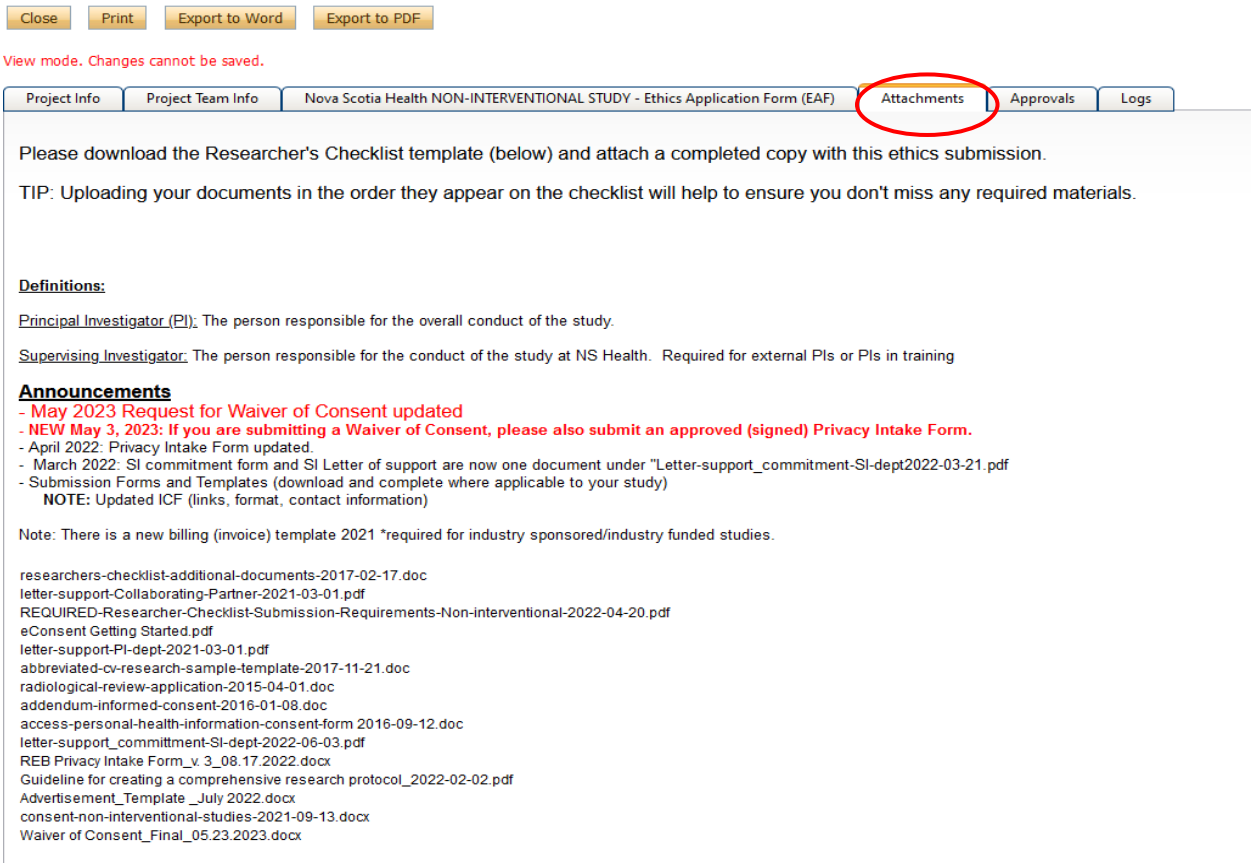
If you would like to review you study documents or see any emails that have been sent through Romeo, enter your study by clicking the Latest Workflow button:

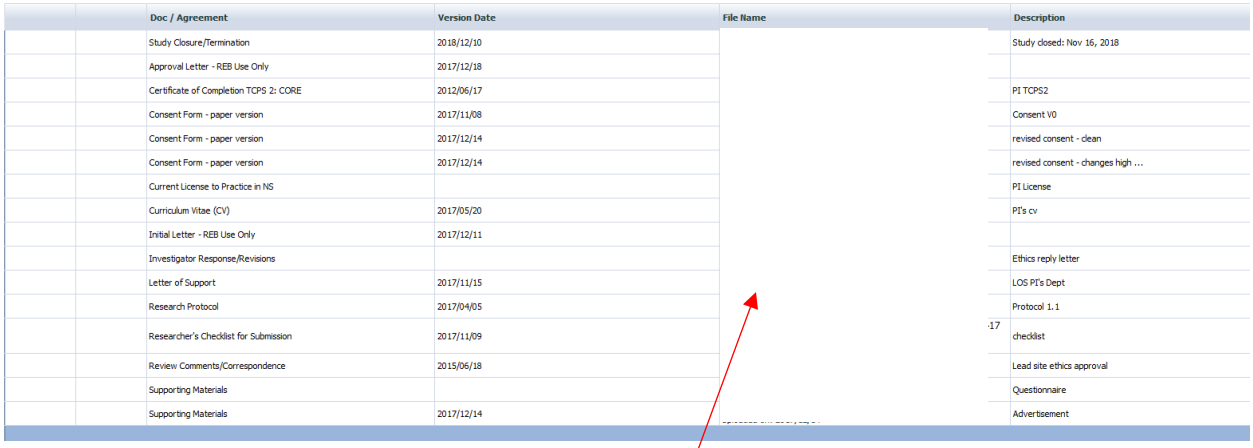



This will open your study on the logs tab. To view the emails, click on the shared communications button:




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





| | | 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 | .17 | 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.