



Documentation for Non-Medical Research Ethics Board Researchers – Full Board and Delegated Board Review

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Office of Research Ethics

If you run into any difficulties or have questions about Romeo, please contact the Romeo Helpdesk at 519-661-3059 or email ethics-romeo@uwo.ca

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Summary:

ROMEIO is the knowledge management system used by the Office of Research Ethics to manage Ethics protocols. Romeo has been available to the Non-Medical REB community since May 1st, 2012.

The purpose of this document is to provide information and instructions for using the Researcher Portal in Romeo. It will guide you through the life of the protocol from obtaining your user name and password, through the approval process to project close-out

Accessing Romeo:

To access Romeo, please go to <https://grant3.vm.its.uwo.ca/Romeo.Researcher>

If you have submitted an ethics application in the past, you may already have an account in Romeo. The easiest way to find out is to visit the Romeo link (listed above). Once you have reached this link, type in your email address as your username (i.e. jsmith@uwo.ca) and click the "Reset Password" button. If you have an existing account in the system, Romeo will send you an email on how to reset your password to access your account. This can also be done when you have forgotten your password and need it to be reset.

If you are a new member to the Non-Medical REB community, please complete this form to request an account: http://uwo.ca/research/services/ethics/romeo/romeo_new_investigator_form.html

It may take up to one full business day for your account to be created after you submit the form. You must provide an official Western, LHSC, or SJHC email address for account creation.

For further assistance, please contact the Romeo Helpdesk at ethics-romeo@uwo.ca or call us at 519-661-2111, extension 83059.

Helpful Tips:

1. Romeo does not accept characters such as " # % & * : < > ? \ / { | } ~ ☐ If you need to use any of these characters you will need to write out the word i.e. instead of using %, write out percent. If you include these characters in your answers in the form, you will lose your data when you go to save the file.

2. The role of the PI will default to the team member who is starting the application. thus this needs to be changed prior to the submission of Protocol. If this is not done following these steps, the file will not save, and any inputted data will be lost.

- A) Edit the file
- B) Click on Change PI on the second tab of the form
- C) Search for the name of the person who will be the PI and Select them into the file
- D) For the team members sections, click on Add New
- E) Next, click on Search Profiles and search for yourself. Select yourself into the file

Note: Do not type in your information as this does not link your account to the form

- F) Save the changes
- G) You can determine if the changes saved by closing the form and going back to the home screen – the file should now appear under the heading: Role Project Team Member

3. Western's server will not accept .zip files so do not upload anything in this format. MS Word and PDF attachments are preferred. Please ensure each document is uploaded with a version date.

4. Romeo is a web-based system. This means the system can time-out from inactivity. If you are going to be walking away from it, or work on something else, it is recommended that you save your changes, and close the file. This will ensure no data is lost.

Determining Review Level:

The Non-Medical Form is used for submissions for both the Non-Medical Full Board and the Non-Medical Delegated Board for social, behavioural and cultural research involving human participants.

For the purpose of this Policy, "minimal risk" research is defined as research in which the probability and magnitude of possible harms by participation in the research is no greater than those encountered by participants in those aspects of their everyday life (TCPS2). Research that is deemed "minimal risk" can be submitted to the Non-Medical Delegated Board for review.

Submissions that do not meet the criteria for Delegated Review are submitted to the Full Board. The deadlines for submissions are posted on the Research Ethics' website and are strictly enforced as the Board only meet once a month to review submissions.

Please note that the criterion for minimal risk research is only a general guideline and that the REB and its Chair will decide the level of review for each research proposal on a case-by-case basis. If you are unsure as to what board to submit to, please contact our office before the Full Board deadline to find out what board to submit to. Alternatively, you may submit your research proposal to the Full Board on or before the established deadline and if it is ascertained that your project is eligible for Delegated Review you will be notified within one week with your recommendations.

Late submissions and submissions that are submitted for Delegated Review but require Full Board review will be held over to the next Full Board deadline and meeting date.

Protocol Submission:

To submit your new protocol in Romeo, please follow the steps below:

Step 1: Log in to Romeo using your user name (email address) and password.

Step 2: Select "APPLY NEW" to begin creating a new protocol.

Step 3: After reading the description for “Non-Medical Form” and confirming that you are submitting to the correct board, click on “Non-Medical Form” to begin your protocol submission. If you are unsure at this point if this is the correct board, please contact our office at 519-661-3059. Please note that if the wrong form is selected, you will have to start a new submission on the correct form.

Step 4: Complete the form. All questions marked with an asterisk (*) are required. Any required question that is missed will appear in the Errors tab at the far right-hand side of the protocol form. You cannot submit your form with required questions left blank.

Project Info Tab: This is where you indicate the Protocol Title and the Start and End dates for the protocol. Please ignore the Related Awards section.

Project Team Info Tab: This is where you list the members who are involved with the research study. The Principal Investigator’s (PI) information will auto-populate at the top section of this tab. If the PI is not the person who is completing the submission, the information will default to the person who is starting the form and the role of the PI will need to be changed back to the Principal Investigator prior to submission following these steps (if you miss a step below, your changes and work within the form will not save):

1. Edit the file
2. Click on Change PI on the second tab of the form
3. Search for the name of the person who will be the PI and Select them into the file
4. For the team members sections, click on Add New
5. Next, click on Search Profiles and search for yourself. Select yourself into the file

Note: Do not type in your information as this does not link your account to the form

6. Save the changes
7. You can determine if the changes saved by closing the form and going back to the home screen – the file should now appear under the heading: Role Project Team Member

To add team members, select “Add New” under Other Project Member Info and then select Search Profiles where you can search for them by name. If they do not appear in the list under Search Profiles, please direct those individuals to complete the New Investigator Account form so that we can create an account for them. After they have an account they can be added to the file. You will also need to select the “Role In Project” for any staff added. Please note that all staff members listed as Research Support Staff will be copied on correspondence from the Office of Research Ethics. All team members will receive notification when the study is initially submitted for review.

Non-Medical Form Tab: This tab is the bulk of the form. Please go through each section, completing the questions with the required information. If you are unsure what the question is asking, select the “i” next to the question for more information.

Attachments tab: Use this tab to upload instruments, letters of information, scripts and any other documentation that is required for review. Please add the title of the instrument in the “Description” box when uploading documents. Please be sure to include a version date on all your uploaded documentation.

Step 5: Save the form using the save button at the top left hand corner. You can also do this at any point during the process of filling it out and return to fill it out at a later time. Please note that Romeo is a web-based environment and as such runs like all other websites – it can time out from inactivity, and if you lose your internet connection, you will lose your unsaved work. It is recommended that you save your work often to avoid loss of data.

Step 6: Submit the form for review. This can only be done by the Principal Investigator from their Romeo account. You will not be able to make changes after the form has been submitted, until it has been reviewed by the Office of Research Ethics (ORE) staff and the Non-Medical REB. All team members will receive an email notifying you that the protocol has been submitted. .

Board Recommendations:

After the board has reviewed your protocol, the Principal Investigator and anyone listed as Research Support Staff will be notified by email that the file has been returned to you for editing, and that the recommendations are available to you in the Attachments tab of the form.

Note: You may only make changes as requested by the recommendations. Any additional changes you want to make must be submitted as a revision after the study receives its initial approval.

There are three options for your recommendations:

1. Approved – no changes required and you will receive the approval notice for the study
2. Pending Approval with Changes – minor changes required to be submitted for review, after which approval will be granted for the study
3. Tabled – major changes required to be made. Must be re-submitted according to posted deadlines and will need to be re-reviewed by the reviewers/board.

Below are instructions to respond to the Board’s recommendations:

Step 1: Login to Romeo.

Step 2: Select Applications – Requiring My Attention on your Romeo homepage. You should see the protocol listed, as well as a message saying “Please see the recommendations in the Attachments tab”.

Step 3: Select Edit and download the PDF of your recommendations from the Attachments tab. Please modify your protocol as required using CAPITAL LETTERS for all sections within the Romeo form itself. Please track your changes in your attached documents and upload a copy with your changes tracked, and a clean copy for review. You will not see the versions you originally submitted – please edit the copies you have saved and upload them to the Attachments tab with a new version date.

Step 4: Save your changes.

Step 5: Re-Submit the protocol. It can only be re-submitted by the Principal Investigator from their Romeo account. It is now locked and available for review by the ORE staff. Please note that once you hit Re-Submit you will be unable to access your file again until it is released back to you for further changes (if needed) or until it is approved. Therefore, please ensure that all changes have been made and you are ready to Re-Submit before hitting this button.

Once your response has been reviewed, it will either be returned to you for additional information or be approved. The turnaround time for review of responses is one business week. There are no deadlines to re-submit your response unless your file was tabled. If it was tabled, it must be submitted in time for a deadline for an upcoming meeting. The recommendations will inform you of this if this is the case.

If it is returned for additional information, an email will be sent, directing you to log in and address the concerns in the email. The same steps would be followed as above.

Approval:

After the board has approved your protocol the Principal Investigator will receive the official approval notice in the mail. The Principal Investigator and Research Support Staff will also be emailed notifying them that the approval notice has been posted to the Attachments tab in Romeo. It can be downloaded by clicking on Applications Submitted – Post Review and then by going in to the file in View mode. **Note that you cannot begin your research until you your official approval notice in Romeo.**

Once your study is approved it will then move to the “Applications (Submitted – Post Review)” section of your Romeo dashboard. Once the study is approved you may submit other, post-approval documents to the ORE for review and approval, such as Revisions.

Post-Approval Processes

Revisions:

Revisions are also handled through Romeo. Revisions are minor modifications to an existing study.

To submit a revision, please follow the steps below:

Step 1: Login to Romeo

Step 2: Click on Applications (Submitted – Post Review) to see all your approved protocols.

Step 3: Select Events for the protocol you wish to revise.

Step 4: Select “Non-Medical Revision Form” and complete the form. This includes answering the questions on the form, and uploading to the attachments tab a copy of your revised documentation.

If you submitted your study originally in Romeo you can obtain a MS Word copy of your protocol to revise by “View”ing your submission and hitting Export to Word to make a copy. You can then track your changes in this copy to upload to the attachments tab of the Revision Form.

If you submitted the revision in hard copy, you need to revise the copy of the protocol you have and track your changes. Each site should have a copy of what was originally submitted for approval in hard copy. Please revise your copy of what you submitted in hard copy and proceed as outlined below.

Any other documentation (letters of information, posters, etc) must also be revised and uploaded to the attachments tab of the form. All documentation must be submitted with an updated version date. If any of this is missing, the revision will not be processed until it is provided.

Step 5 Submit the Revision Form. This form can be submitted in one of the following ways:

- A) The Principal Investigator completes and submits the form for review.
- B) A Team Member (not the PI) completes and submits the form. ORE staff will then send an email to the PI asking for them to authorize the information on the revision form as correct. The revision form will not be processed until this email authorization is received.
- C) A Team Member (not the PI) completes and saves the form. The PI then logs in to their account, selects Events for the study and Edits the saved Revision under My Saved Events. The PI then submits the revision for processing.

Step 6: If any follow up is required on the revision, an email will be sent. Responses to the requested information for the Revision can be submitted via the Revision Response form, located in Romeo under Events for the study. If it is acceptable as is, an email will be sent notifying the PI and the Research Support Staff that the approval notice is available in Romeo under the Attachments tab, and the hard copy will be sent out in the mail.

You may not implement any of the requested revisions into your study until you have received your official approval. This process can take a few weeks, depending on volume.

Continuing Ethics Review (CER) Form:

This summary must be submitted once a year for all active studies. ORE staff will email a reminder one month before the form is required to be submitted. The email reminder will also be sent out one month prior to your study expiring, to allow for the option to extend the end date if required.

To submit the form:

You can follow the instructions sent by email, or:

Step 1: Login to Romeo

Step 2: Look at Applications Submitted Post Review or My Reminders to locate the file.

Step 3: Select Events next to the protocol you want to submit the CER for and then select Non-Medical Continuing Ethics Review under the New Event Forms table at the top of the screen.

Step 4: Complete the form and submit it for review using one of the methods for submission below:

- A) The Principal Investigator completes and submits the form for review.
- B) A Team Member (not the PI) completes and submits the form. ORE staff will then send an email to the PI asking for them to authorize the information on the CER form as correct. The CER form will not be processed until this email authorization is received.
- C) A Team Member (not the PI) completes and saves the form. The PI then logs in to their account, selects Events for the study and Edits the saved CER under My Saved Events. The PI then submits the CER for processing.

If the form is accepted as is and you are not requesting an end-date extension, you will not hear back from the ORE staff. You can check the status of the form in Romeo – if it is set to Active, it has been processed. If an end-date extension is requested, an approval email will be sent once it is processed and approved.

End of Study Report:

You need to inform the ORE once your study is completed, so that the file may be closed. To do this, follow the steps below:

Step 1: Login to Romeo.

Step 2: Select Applications (Submitted – Post Review) and then select Events next to the study you wish to close.

Step 3: Select Non-Medical End of Study Report and complete the form. Once completed, click Submit to send in the form using one of the below methods:

- A) The Principal Investigator completes and submits the form for review.
- B) A Team Member (not the PI) completes and submits the form. ORE staff will then send an email to the PI asking for them to authorize the information on the end of study form as correct. The end of study form will not be processed until this email authorization is received.
- C) A Team Member (not the PI) completes and saves the form. The PI then logs in to their account, selects Events for the study and Edits the saved end of study under My Saved Events. The PI then submits the end of study for processing.

If there is no-follow up by the ORE staff, the file will be closed and the status of the study in Romeo will change from Active to Closed. If there is follow-up an email will be sent out with instructions.