

ROMEO User Guide

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About ROMEO

ROMEO is a secure, web-based knowledge management system that is hosted at Western on dedicated servers maintained by Information Technology Services (ITS). REB applications and supporting documents submitted through ROMEO will be kept confidential and maintained by the Office of Research Ethics (ORE). Access to this information will only be permitted for necessary review and oversight of research involving human participants. Ethics applications for new studies and responses to Board recommendations must be submitted through ROMEO by the principal investigator.

ROMEO Help

If you encounter any problems or need help with ROMEO, please contact the Romeo helpdesk at ethics-romeo@uwo.ca or 519.661.3059.

You may also refer to the ROMEO resources section of the Office of Research Ethics website: <http://www.uwo.ca/research/ethics/romeo/>

ROMEO Resource Page



Fig.1

Logging into Romeo

Using current email addresses on file, the ORE has created default usernames for the majority of investigators and research support staff that have previously submitted to our Board. The first time that you login, you will need to set your password by selecting “reset password” and following the instructions provided.

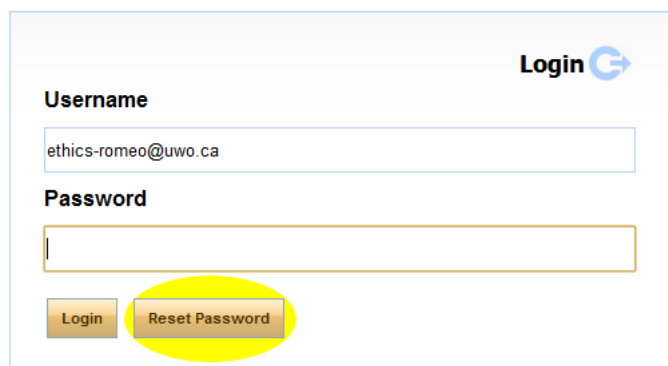
A screenshot of the ROMEO login interface. It features a 'Login' button with a circular arrow icon in the top right. Below it are two input fields: 'Username' containing 'ethics-romeo@uwo.ca' and 'Password' which is empty. At the bottom are two buttons: 'Login' and 'Reset Password'. The 'Reset Password' button is highlighted with a yellow oval.

Fig.2

ROMEO will send you an automated email with a confirmation code. Copy and paste the confirmation code into the space provided and create your new password.

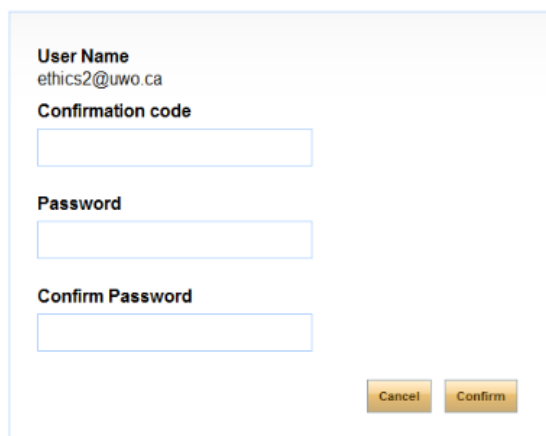
A screenshot of the ROMEO password reset interface. It contains four input fields: 'User Name' with 'ethics2@uwo.ca', 'Confirmation code', 'Password', and 'Confirm Password'. At the bottom right are two buttons: 'Cancel' and 'Confirm'.

Fig. 3

****If you do not have a valid username or are a new researcher, you will be presented with a red error message instructing you to contact the ORE for assistance.****

ROMEO Dashboard

Once you have successfully logged in to Romeo, you will be taken to the ROMEO dashboard. This page will differ slightly for every user. At anytime, selecting “Home” on the upper right-hand corner of the screen will bring you back to the ROMEO dashboard. You can also update your account information by selecting “My Profile”. Select “Apply New” to create a new protocol.

The screenshot shows the Romeo Research Portal interface. At the top, there is a navigation bar with links: Home, My Profile, Contact Us, Help, and Logout. Below this is a header with the Process Pathways logo and the Romeo Research Portal logo. A secondary navigation bar contains a yellow 'APPLY NEW' button, along with links for News, Useful Links, and Settings. The main content area is divided into two columns. The left column is titled 'Role: Principal Investigator' and lists application counts: Applications (Saved - Not Submitted) (4), Applications (Submitted - Under Review) (1), Applications (Submitted - Requiring My Attention) (0), Applications (Submitted - Post Review) (1), Applications (Withdrawn) (0), and My Reminders (1). The right column is titled 'Role: Project Team Member' and lists application counts: Applications (Saved - Not Submitted) (3), Applications (Submitted - Under Review) (0), Applications (Submitted - Requiring My Attention) (0), Applications (Submitted - Post Review) (0), Applications (Withdrawn) (0), and My Reminders (0).

Role: Principal Investigator		Role: Project Team Member	
Applications (Saved - Not Submitted)	(4)	Applications (Saved - Not Submitted)	(3)
Applications (Submitted - Under Review)	(1)	Applications (Submitted - Under Review)	(0)
Applications (Submitted - Requiring My Attention)	(0)	Applications (Submitted - Requiring My Attention)	(0)
Applications (Submitted - Post Review)	(1)	Applications (Submitted - Post Review)	(0)
Applications (Withdrawn)	(0)	Applications (Withdrawn)	(0)
My Reminders	(1)	My Reminders	(0)

Fig. 4

Choosing the Correct Form

Health Sciences ethics applications are reviewed at an appropriate level (Delegated or Full Board) based on the nature of the proposed research. Please read the form descriptions provided and refer to our [Categories of Review Guideline](#) and [REB Decision Tree](#).

If you still cannot determine to which REB you should submit, or what type of review you require, please contact one of the Ethics Officers:

- ❖ Full Board – Janice Sutherland, 519-661-2111 ext. 86764 jsutherl@uwo.ca
- ❖ Full Board – Shantel Walcott, 519-661-2111 ext. 87437 swalcot@uwo.ca
- ❖ Delegated – Grace Kelly, 519-661-2111 ext. 84692 grace.kelly@uwo.ca

****Please note** that if the incorrect form is submitted, you will be asked to create and submit a new application on the correct form.**

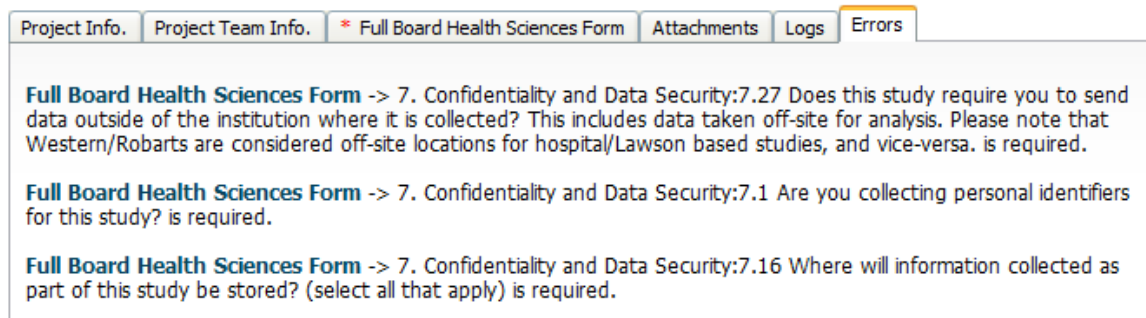
Research Ethics

Application Name	Description
Full Board Health Sciences Form	The Full Health Sciences Research Ethics Board reviews all research that involves a clinical trial for drugs, natural products, or devices. In addition this board reviews all research that involves the ingestion of any food or beverages or includes interventions that take place during surgery or that may interfere with the normal course of a patients standard care of treatment. In addition the Full Health Sciences Research Ethics Board reviews any research that is above minimal risk and research where there is an unknown, moderate or high physical or psychological risk for healthy volunteers or patients.
Non-Medical Form	The Non-Medical Research Ethics Board reviews all ethics applications involving human participants that include social, behavioral and cultural research in a non-clinical, non-patient-based population.
Delegated Health Sciences Form	The Delegated Health Sciences Research Ethics Board reviews all research that is deemed minimal risk or lower. Minimal risk research is research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.
Chart Review Form	The Delegated Health Sciences Research Ethics Board reviews all research that is deemed minimal risk or lower. Minimal risk research is research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

Fig. 5

Completing the Form

All questions marked with a red asterisk (*) are required. Any required question that is missed will appear in the Errors tab at the far right-hand side of the form. You will be unable to submit the form unless all of the required fields have been completed.



Project Info. Project Team Info. * Full Board Health Sciences Form Attachments Logs Errors

Full Board Health Sciences Form -> 7. Confidentiality and Data Security:7.27 Does this study require you to send data outside of the institution where it is collected? This includes data taken off-site for analysis. Please note that Western/Robarts are considered off-site locations for hospital/Lawson based studies, and vice-versa. is required.

Full Board Health Sciences Form -> 7. Confidentiality and Data Security:7.1 Are you collecting personal identifiers for this study? is required.

Full Board Health Sciences Form -> 7. Confidentiality and Data Security:7.16 Where will information collected as part of this study be stored? (select all that apply) is required.

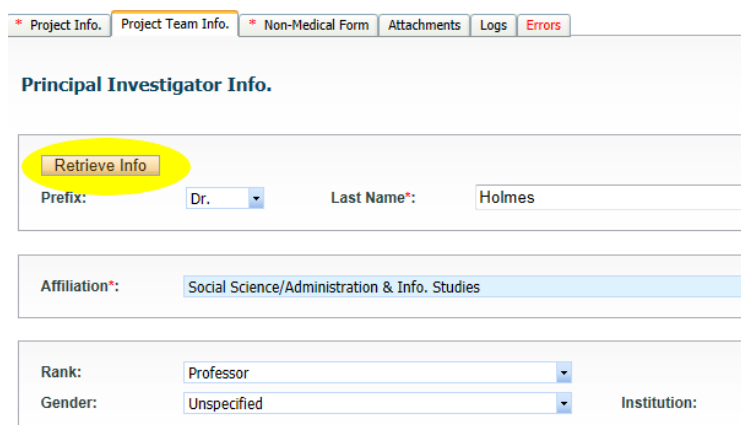
Fig.6

Project Info Tab: In this section, indicate the protocol title as well as the expected start and end date. Also, provide key words associated with the project.

Project Team Info Tab: Initially, ROMEO will auto fill the Principal Investigator (PI) section so that it corresponds with the individual that created the file or started the application. As stated above, the ORE will only except new study applications submitted from the PI's account. Therefore, if you are a study coordinator or research support staff that has created the application you must assign the protocol to the appropriate PI.

Please see the example below in which the study coordinator “Ms. Jane Watson” must assign the protocol to the PI “Dr. Sherlock Holmes”.

Step 1 - Select “Retrieve Info”:



* Project Info. Project Team Info. * Non-Medical Form Attachments Logs Errors

Principal Investigator Info.

Retrieve Info

Prefix: Dr. Last Name*: Holmes

Affiliation*: Social Science/Administration & Info. Studies

Rank: Professor Gender: Unspecified Institution:

Fig.7

Step 2 - Enter the PI's name and select "Search". Click on the "Select" button to assign the PI to the protocol.

Options	Last Name	First Name	Primary Affiliation
select	Holmes	Sherlock	Social Science\Administration & Info. Studies

Fig. 8

The PI's information will self populate:

Principal Investigator Info.

Retrieve Info

Prefix: Dr. Last Name*: Holmes First Name*: Sherlock

Affiliation*: Social Science/Administration & Info. Studies

Rank: Professor Gender: Unspecified Institution:

Phone 1: 555-1234 ext 1111 Phone 2: Email*: ethics1@uwo.ca Fax:

Fig.9

NOTE – If you cannot find your PI, please contact the Romeo Helpdesk ethics-romeo@uwo.ca 519-661-3049.

Step 3 - Add yourself as a team member in the "Other Project Member Info" section at the bottom of the screen:

Other Project Member Info:


Add New

Last Name	First Name	Role In Project
Watson	Jane	Research Support Staff

Edit Delete

Ready

Fig. 10

Full Health Sciences Form Tab: This is the bulk of the application and will contain all of the required information necessary for review by the Health Sciences REB. Please go through each section and complete all of the questions that apply to your study. Descriptive text at the top of each section will highlight the questions with important notifications provided in the blue information icons .

Project Info. Project Team Info. **Full Board Health Sciences Form** Attachments Logs

1. Registration Information 2. Background, Methodology and Analysis 3. Drugs and Natural Products 4. Clinical Trials 5. Risks and Benefits 6. Recruitment and Informed Consent 7. Confidentiality and Data Security 8. Conflict of Interest 9. Industry Sponsored Protocols 10. Confirmation of Responsibility

Please note that important notifications have been added to the information icons above questions 2.1, 2.2, 2.3, 2.4, 2.7 and 2.9 .

 2.1) *Has the study undergone a formal scientific or peer review (i.e. CIHR, NSERC, NIH)? If yes, please attach the approval letter (or relevant correspondence). Relevant correspondences can be added to the attachments tab.

☐ Yes ☐ No

Fig.11

Attachments Tab: upload all relevant study documents to the attachments tab including the letters of information, sponsor protocols, investigator brochures, online CT registry information, advertisements, Health Canada/FDA correspondences patient diaries etc. Please ensure that all documents are in Word, PDF or text format. Compressed files (i.e. ZIP files) will not be accepted.

If you do not have an electronic copy of a required study document such as the sponsor protocol, investigator brochure or product monograph please contact the ORE prior to submitting your application online. Becky Ament bament@uwo.ca will assist in making the necessary arrangements; hard copies will still be accepted.

Fig. 12

Attachment	Description	Version Date	Doc / Agreement
Letter of Information.docx Uploaded on: 2012/07/23		2012/07/01	Letter of Information & Consent
Study Advertisement.docx Uploaded on: 2012/07/23	Poster	2012/07/01	Advertisement
NIH Online Registry- summary.pdf Uploaded on: 2012/07/23	CT.gov		Other
Protocol Amendment 1-Drug Company.pdf Uploaded on: 2012/07/23		2012/05/01	Protocol
Health Canada NOL - Amendment 1.pdf Uploaded on: 2012/07/23			Other
FDA Notification Letter.pdf Uploaded on: 2012/07/23		2012/06/01	Other
Investigator Brochure.pdf Uploaded on: 2012/07/23		2012/05/01	Investigator Brochure
QOL Questionnaire.pdf Uploaded on: 2012/07/23		2012/07/01	Other

Save any changes that you have made to the protocol by selecting the “Save” button at the top left-hand corner. You can save the application at any point during the process of completing the form. Once you have completed the application, save your changes and export a copy of the protocol in Word format.

Save this document in a safe place as you will no longer have access to your original application once it has been submitted to the ORE for review.

Fig. 13

You will receive a confirmation email stating that your protocol has been submitted. Once your protocol has been reviewed you will receive an email with Board Recommendations. The Full Health Sciences REB will only accept new protocol submissions from the PI’s ROMEO account.

Post Review

Once you have received the recommendations from the REB you now need to go back in to Romeo to make the changes requested by the REB to the Western Protocol. Your application can be found under the heading **“Applications (Submitted- Requiring My Attention)”**.

Once you have found the study in your list of studies requiring attention click the edit button and you can now revise the sections of the Western protocol form.

If you click on the “project log” button you will see that the changes you made are listed in this log.

Be sure to save the changes you make and save a copy of this newest version of the Western protocol form to your own computer (you will need this newest version if you need to submit hard copy amendments in the future).

Once you have made all the required changes you need to upload any revised study documentation under the attachments tab (i.e. revised letters of information, advertisements etc.) These are documents that you would be editing and revising on your local computer.

Once you have ensured all necessary attachments have been uploaded you need to click on resubmit. This will lock the application again so that the modifications returned can be reviewed.

If the modifications submitted are correct you will then receive an automated email notice from Romeo informing you that your study has been approved. You will also receive the approval notice by email and hardcopy. If further changes are required you will receive an email notification from Romeo informing you that you need to logon to Romeo as additional information is required. You would then follow the same procedure that you did the first time you responded to changes required.

Submission of Updated Approvals

Step 1

Login to Romeo and select the study you need to submit an updated approval form for (please remember to follow the deadline dates for these requests).

Step 2

On the left hand side click the “events” button. From the list of event forms that are available select the “Updated Approval form”.

Complete the form, once the form is completed hit save and then submit.

After the REB meeting you will receive the updated approval by email and hard copy.

PLEASE NOTE THAT CURRENTLY ONLY UPDATED APPROVALS MAY BE SUBMITTED IN ROMEO. WE ANTICIPATE THAT ALL OTHER POST APPROVAL FORMS (REVISIONS, PROTOCOL DEVIATIONS ETC.) WILL BE ABLE TO BE SUBMITTED ELECTRONICALLY STARTING TUESDAY SEPTEMBER 4, 2012.