Research Ethics System
Training guide
About these instructions
This document describes how to complete tasks in the Research Ethics System.

View the Human Research Ethics documentation and/or Animal Research Ethics documentation for information on the ethics process.

Records imported from the previous system
If you have an active record from the previous ethics system (Form 101 or AUPP) it has been brought into the new Research Ethics System. See the Imported records guide for additional information on working with imported records.

Logging in
Sign into the Research Ethics System with your Waterloo (Nexus/WatIAM) credentials.

Please use current versions of Chrome, Firefox, Safari, and Microsoft Edge when using the system.

Note: If you are working in the system for longer than 4 hours at a time, you will be asked to sign in again. If this happens, you will not lose anything you have done. Simply sign in again and keep working.
Navigating the system
Manage protocols page

1. Main navigation
   - Hide menu
     o Reduces the size of this menu, giving you more area for the main content of the page.
   - Manage protocols
     o Displays existing ethics applications and allows you to begin a new application.
     o Allows you to view any applications shared with you by another researcher.

2. Search and filters
   - Allows you to search through your application(s) and filter the display of applications.

3. New Protocol
   - Begins the process for creating a new application.

4. Existing protocols
   - Displays your existing protocols, with any filters applied. If you have more than the current page limit, there will be a “Load more” option at the bottom of the list. Selecting the title of a protocol will open it.
   - Displays both the original approved version and the in progress version if you have an application with a renewal or amendment in progress.
Creating an application
You can begin a new application by selecting “New Protocol” then either “Animals” or “Humans” as appropriate.

Beginning the application

Click between the question and the line to start typing. You will find that many questions provide additional information to guide you through the process.

Principal Investigator/Faculty supervisor

- Begin typing and the system will automatically search for the user, bringing up a list of results. You can then select the appropriate user.
  - You can search by name or username. Username will be quickest method to find the user.

Note: Students cannot serve as Principal Investigator. Submitting an application with a student in this field will result in your application being returned to you.

Department

- Select your department from the drop down list.
Study title

- Enter your study title.

Lay Summary (Animal application only)

- Enter your lay summary.

Once you complete these questions, select “Next” from the right menu.

Choosing an application type

You can now select the type of application wish to complete.

This selection will determine many of the questions in the remainder of the application. Contact Research Ethics to verify your selection if you are unsure. An incorrect selection may require you to redo large portions of the application.

After selecting your application type, check the box below to acknowledge you have chosen the correct application type and select “Next” from the right menu.
Viewing the full application
You are now presented with the full application and your application will appear on the “Manage Protocols” screen.

The full application screen has the following areas:

1. Back
   - Returns you to the “Manage Protocols” screen.

2. Left-hand navigation
   - Allows you to select an item from the list to move you to that section.
     - Green checkmarks will appear if all questions in that section have an answer. If an optional question isn’t answered, you will not get a green checkmark. A green checkmark is not required to submit your application.

3. Activity log
   - Stores all actions and notifications that have occurred on the application.

Note: Select “Protocol” to return to your application.
4. Version

- Records all versions of your application. Each time it is returned to you and any time you begin an amendment or renewal your application will create a new version.
  - If you have multiple versions, this drop-down will let you go between versions to see them at that state.

5. Protocol status

- Displays the status of your application.

Note: Once submitted to Research Ethics, the status will become “Submitted for Review.”

6. Right-hand menu

- View admin attachments
  - Displays any documents Research Ethics provides to you. This will include the clearance certificate within 24 hours of the application being approved.
- Abandon
  - Allows you to abandon an application you have no intention of proceeding with.
    - This cannot be undone. Only abandon an application if you are truly done with the record. There is no harm in leaving a record in progress indefinitely.
- Submit
  - Allows you to submit your application once it has been completed.
- Print
  - Displays a version of your application with all table questions shown in full. This is ideal for reviewing your application before submitting it.

7. Application form

- Displays your application form.

Continue completing the application. Certain questions will appear based on the answers provided to previous questions.

Note: Your application will be saved automatically, shortly after you make changes or additions. This happens every time you see the “Save complete” notification appear at the bottom of your screen.
Answering application questions
Most questions require you to provide a text response or select an item from a list of options. However, there are some question types are not as intuitive or need to be completed in a specific way. Please review the specific instructions for the sections below.

Completing the people section
The people section will start with the person who you selected as the Principal Investigator (PI) or Faculty Supervisor (FS). If you are not the PI/FS, you will also be listed here.

These initial people will need to be updated. Select the icon to do so.

<table>
<thead>
<tr>
<th>PERSON</th>
<th>WATERLOO DEPARTMENT</th>
<th>RESEARCHER ROLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR Systems</td>
<td>Kinesiology</td>
<td></td>
</tr>
</tbody>
</table>

Adding additional people to the application
People can be added as either University of Waterloo research team members or as external investigators. If you have any external investigators, the table for adding them is opened after answering ‘yes’ to the question below.

Do you have any investigators external to the University of Waterloo

- Yes
- No

All faculty members and staff have been added to the system. Students are added to the system either by logging in, or by sending a request to Research Ethics. Until this happens, you can't add a student to the application.

To include additional internal or external investigators, select the add line button next to the appropriate list.
Answer all questions in the pop-up table.

The “Researcher Role” for internal people can only have a single “Principal Investigator.” This is the Waterloo person responsible for overseeing the study/record. If you need to change who the Principal Investigator is, do so in the General Information section instead of here in the People section.

There is a “Co-Principal Investigator” option for others considered principal investigators.

Note: There can be more than one Faculty Supervisor. If you are the main Faculty Supervisor, you should be listed as the Principal Investigator in this section.

Other Waterloo researchers can be provided access to the application to allow for collaboration on the protocol. Granting access will not allow the user to submit. Only the user listed as Principal Investigator/Faculty Supervisor can submit the application.

Full Access

- The user will be able to complete any part of the application.
- If someone other than the PI/FS is completing the application, this person must provide the PI/FS with “Full Access” so they are able to submit the protocol.

Read-Only

- The user can see the application, but will be unable to change any of the content.

Permissions

- [ ] Full Access
- [ ] Read-Only

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Tables
When answering a question in a table, you can add multiple responses or a single response.

<table>
<thead>
<tr>
<th>PERSON</th>
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<th>RESEARCHER ROLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chris Francis</td>
<td>Kinesiology</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>OR Systems</td>
<td>Kinesiology</td>
<td></td>
</tr>
</tbody>
</table>

Press “Add Line” to start each new response. A pop-up will appear with follow-up questions.

Not all of the questions associated with the item will display on the main page.

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Selecting will open that item up to edit all follow-up questions associated with that line.

Select to delete the line entirely.

Once finished, select “Done” to save, or “Cancel” if you do not want to save the changes.

**Uploading files**

File upload questions will look like this:

**Screening questionnaire file**
File name should include document purpose, version number, and date (e.g., RecruitmentPoster_version1_20180425)

You can either drag a file onto the box, or click the “Choose” to select the file. Once added, the question will appear with the file name.

Screening questionnaire file
File name should include document purpose, version number, and date (e.g., RecruitmentPoster_version1_20180425)

example file.pdf

View Attachment will show the attachment within the browser if it is a pdf or image. All file types will provide a download option.

Replace will reset the field to allow for a different file to be uploaded.
Submitting an application

An application can only be submitted by the person listed as Principal Investigator/Faculty Supervisor in the “General Information” section. Begin by reviewing and agreeing to the attestation in the last section. Next, press the “Submit” button in the right menu.

If you have any errors, you will be notified as you press submit.

A question with an error on the main form will appear with a red box around it.

A question in a table with an error will have an exclamation mark beside it.

Once submitted, you can confirm the status has changed to “Submitted for Review” at the top of the application.

The status on the “Manage Protocols” screen will also change.
Amending an application
The amendment process involves updating the application with the changes to the study. After the amendment is approved, this new version incorporates the original and all approved amendments.

An application can only have one amendment or one renewal in progress at a time.

Beginning an amendment
From the “Manage Protocols” screen, open the application you want to amend.

Select the “Amend” button from right-hand menu.

Enter the reason for the amendment in the Amendment Justification box and select “Continue.”

If the buttons are greyed out, there is likely another amendment or renewal in progress, or you are not on the latest approved version of the application.
Open the Version screen and check for an in progress version and the latest approved version to see the current state of the application.

Making an update
After starting the amendment, select “Edit” beside any question to modify the question.

Make your change to the question and select “Apply Changes” to make the change, or “Cancel” to undo the change.

To make a change to an item in a table use the same process as used in the initial application for adding, editing or deleting.

Submitting the amendment
An amendment can only be submitted by the Principal Investigator/Faculty Supervisor. When you are finished making changes, you can submit the amendment with the Submit button.

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Abandoning an amendment
If you no longer wish to amend an application, or need to submit a renewal immediately, you can cancel out of the amendment by selecting the “Abandon” option.

You are now able to go to the last approved version and start a renewal.

Renewing an application
The renewal process should only be initiated once you receive a notification that it is needed. If you need to renew early, contact Research Ethics before proceeding.

Beginning a renewal
From the “Manage Protocols” screen, open the application you want to renew.

In the right-hand menu, select the “Renew” button.

If the buttons are greyed out, there is likely another amendment or renewal in progress, or you are not on the latest approved version.

Open the Version screen and check for an in progress version and the latest approved version to see the current state of the application.
Completing the renewal
You will now be presented with the renewal form you need to complete. Answer all questions, then submit the renewal. Questions are answered similarly to how they are answered on the main application.

Abandoning a renewal
If you no longer wish to submit a renewal, or need to submit an amendment immediately, you can cancel out of the renewal by selecting the “Abandon” option.

Closing an application
Begin by clicking on the “Request Close” button.

Unique Animal application processes
Most processes between the human and animal application are identical. This section contains the process that are different for an animal application.

Renew/Amend
In addition to the “Amend” and “Renew” options, a “Renew/Amend” option exists. This option allows you to complete an amendment and renewal at the same time. See the amendment and renewal sections for instructions on completing each.
This combines both processes into a single action and the amendment and renewal will be submitted to a single committee meeting for review.