ORE

Researcher Guide

for using Kuali

October 2018

Navigating the system

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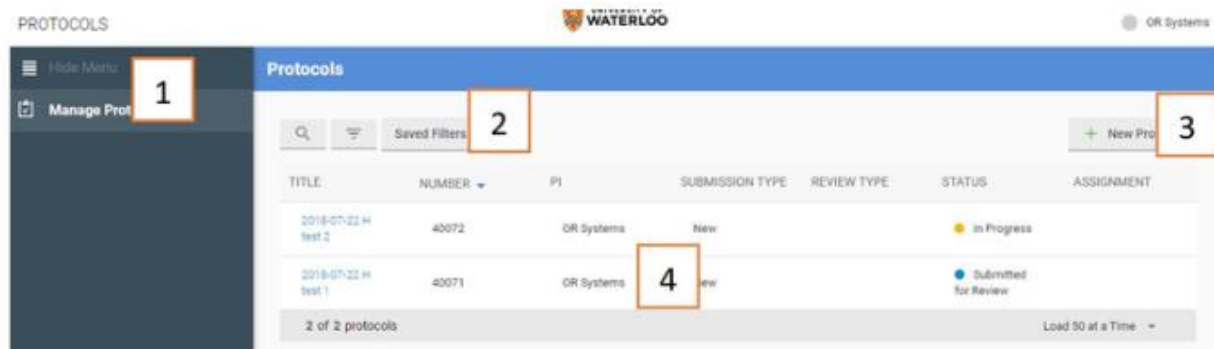
1. **Main navigation**
   - **Hide menu**
     - Reduces the size of this menu, giving you more area for the main content of the page.
   - **Manage protocols**
     - Displays existing ethics applications and allows you to begin a new application.
     - Allows you to view any applications shared with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

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" below the blue ribbon that contains your protocol number and title 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 <u>submit your application</u> once it has been completed.
- Print
  - Displays a version of your application with all <u>table questions</u> 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.
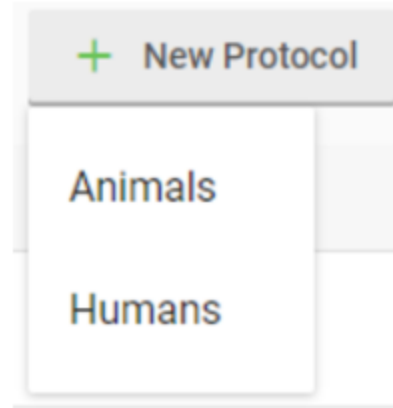
Applications

Beginning an application

You can begin a new application by selecting "New Protocol" then either "Animals" or "Humans" as appropriate.

General Information section

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
Make sure that you select 'Psychology' from the drop down list under 'Department'.

Study title

- Enter your study title.

Once you have completed these questions, select "Next" from the right menu.

General Questionnaire section

Choose an application type

In the 'General Questionnaire' section select the type of application you wish to complete. Most Psychology studies will be Standard Application.

This selection will determine many of the questions in the remainder of the application. Contact Research Ethics or Michelle Manios 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 under 'Please confirm' to acknowledge you have chosen the correct application type and select "Next" from the right menu.

Once you have selected the application type the left navigation field will display the different sections. You can click on the heading to jump to that section.

You will know that you have completed a section when the green arrow appears beside the section.

Jump to...

General Information   ✓

General Questionnaire   ✓

People

General details

Study description

Study sites

Funding

Conflict of interest

Benefits

Participants

Recruitment

Methods and procedures

Incidental and secondary ...

Equipment use

Deception

Risks and safeguards

Privacy

Data storage

Data Management

Consent & Withdrawal

Do you have any investigators external

General details

Is this new study related to any previou

What is the estimated start date and e

Start Date

End Date

Does this research require approval fro

What is the level of the research to be

Will this study involve Wilfrid Laurier U
(Cambridge Memorial Hospital, Grand

Has a version of this study been disap

Study description

State your research question(s)

The People Section

In the 'People' section you will list the Researchers on the protocol. You start with the person whom you selected as the Principal Investigator (PI) or Faculty Supervisor (FS).

For migrated records (protocols transferred from previous ethics system) this section will need to be updated. See the section on Amendments for further information.

Select ✏ the 'edit' icon to do so

Adding Researchers to the People section of 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 in this section. See below how to add Honours thesis students (or any undergraduate student) to the application.

Press 'Add Line' to add each Researcher to the 'People' section.

All Faculty members, graduate students, and staff identifications have been uploaded to the system and should be identifiable through a search of the name or user IDs.

Honours thesis (or Directed Studies) students

To add an Undergraduate student (eg. Honours thesis, Directed Studies) to an application, the student must first log into the system. This acknowledges them in the system and then you will be able to add them to the application. **Do not add them as external invetigators**.
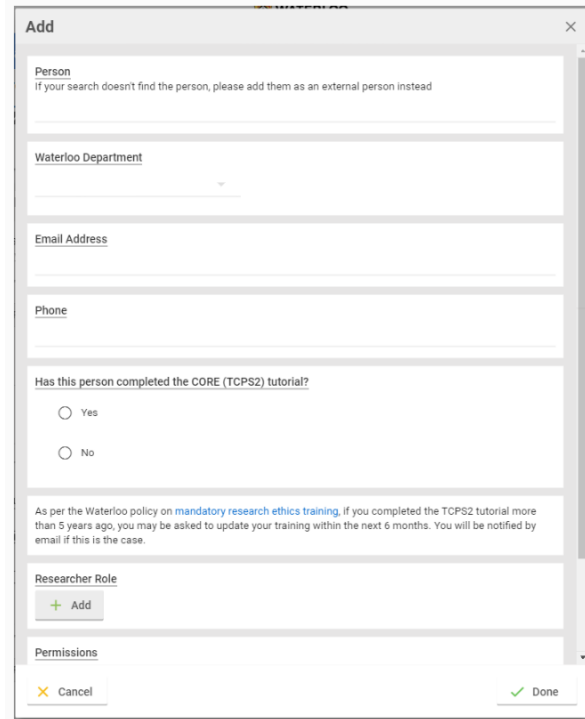
Answer all questions in the pop-up window.

Only one internal researcher can be selected as 'Principal Investigator'. This is the University of 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.

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

Answer all questions in the pop-up window.

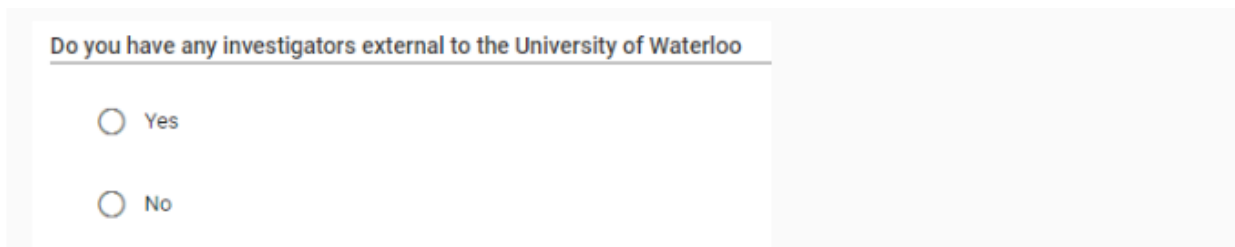Please provide the accurate date of the TCPS2 CORE tutorial completion.

Note: A copy of the TCPS2 certificate will become a requirement in the future. At this time it is only a recommendation to include the document (in pdf format).

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.

To include additional internal or external investigators (researchers outside the department or university), select the line button next to the appropriate list.

Other University of Waterloo researchers can be provided access to the application to allow for collaboration on the protocol. Granting access will not allow the Researcher to submit. Only the Researcher listed as 'Principal Investigator' in the **General Information** section can submit the application.

Granting Permissions

All Researchers need to have been granted access to be able to view the application in their account.

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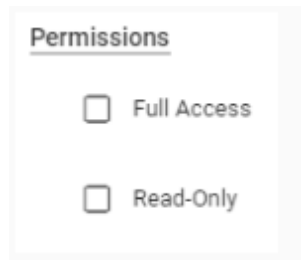
- The Researcher will be able to complete any part of the application.
- If someone other than the PI/FS is completing the application, this person must provide the PI/FS with 'Full Access' so they are able to view and submit the protocol.

Read-only

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

Tip:

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

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.

Section Questions

Most questions in the sections require you to provide a text response or select an item from a list of options. However, there are some question types that are not as intuitive or need to be completed in a specific way.
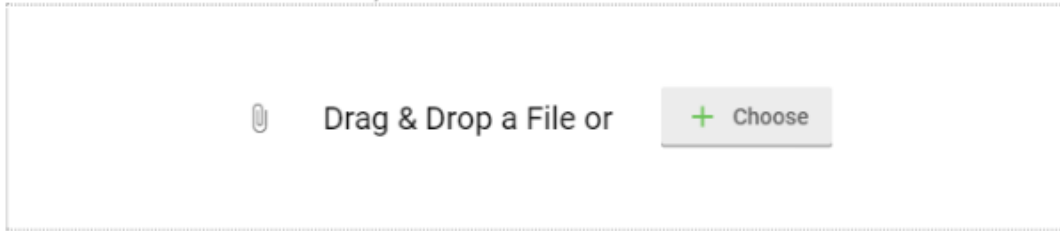
Tables

When answer a question in a table format, you can add multiple response or a single response. The set up for the 'People' section is an example of a table format (see the 'People' section for further information).

Uploading files

To upload a document you can drag a file onto the box, or click 'Choose' to select a 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)

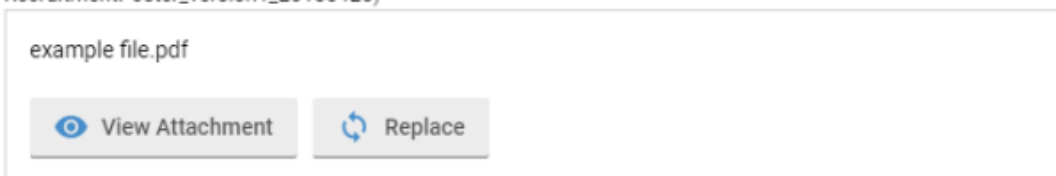📎   Drag & Drop a File or   + Choose

Documents are to be in PDF format only.

The 'View Attachment' button will show the attachment within the browser if it is a pdf or image.

The 'Replace' button will reset the field to allow for a different file to be uploaded.

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

example file.pdf

👁 View Attachment   🔃 Replace
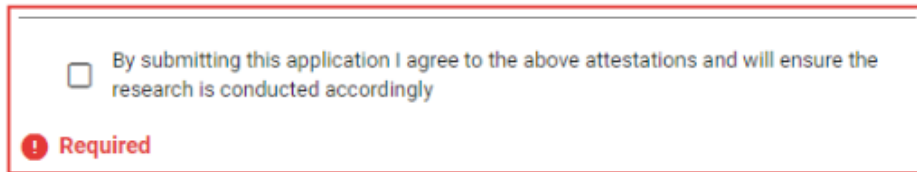
Submitting an application

An application can only be submitted by the person listed as Principal Investigator in the 'General Information' section. Begin by reviewing the application and when it is ready agree to the attestation in the last section and press the 'Submit' button in the right menu.
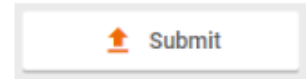
⬆ Submit

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

> ❗ **Incomplete**   ✕
> 2 of the required fields are empty.

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

> ☐ By submitting this application I agree to the above attestations and will ensure the research is conducted accordingly
>
> ❗ **Required**

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

❗	OR Systems	Kinesiology		✏	🗑

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

Submission Type	Review Type	Status	Time in Current Status
New		Submitted for Review	Since July 22 – a few seconds

The status on the 'Manage Protocols' screen will also change.

Amendments

How to Begin

The amendment process involves updating the application with the changes to the study. After the amendment is approved, the new version incorporates the original and all approved amendments.
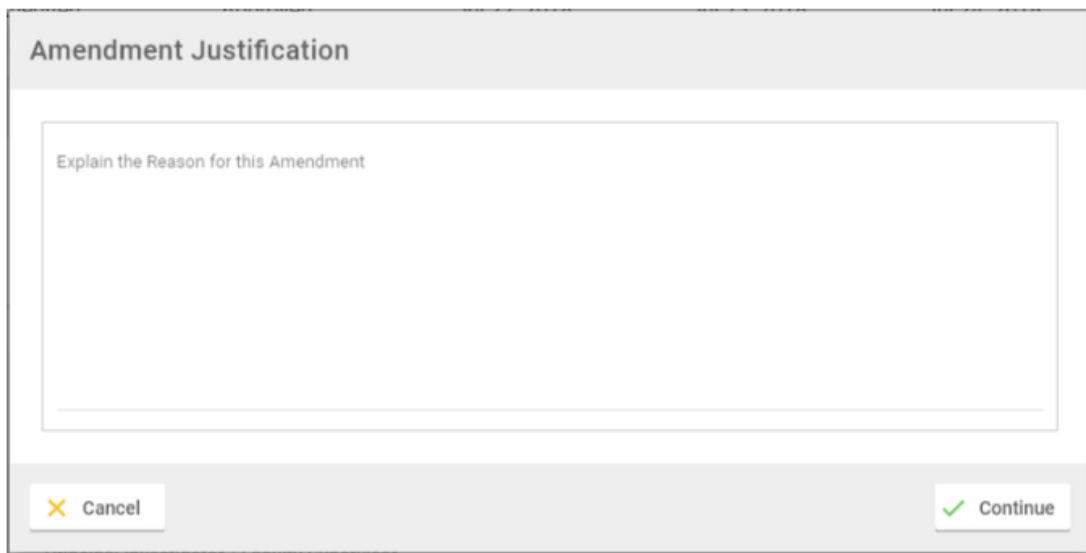
A protocol can only have one amendment or one renewal in progress at a time.

From the 'Manage Protocols' screen, open the protocol that you want to amend.

Select the 'Amend' button from the right menu.
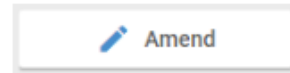
The 'Amendment Justification' text box will appear. Enter the reason for the amendment in the box and select 'Continue'.

IMPORTANT: the 'Amendment Justification' only appears at the onset of beginning an amendment. Complete this field with all the modifications that are being submitted.

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.
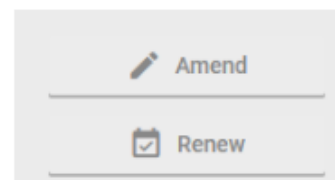
Open the Version screen and check for an in progress version and the latest approved version to see the current state of the application.

Each amendment/change will initiate a new 'version'. To see previous versions click the drop down arrow and select the version you would like to view. You will be able to view the submitted versions for your protocol.

Making an update

After starting the amendment, select 'Edit' beside any question to modify the question.

For migrated files (records that were in the previous ethics system) you may need to update the research team. Click 'amend' and update the 'General Information' section for the Principal Investigator. You should then update the 'General description' section with the study type. Migrated files will show as 'imported'. Change this to 'Standard Application' (or whatever type is appropriate to your study) and then all the sections will appear on the screen. Only provide information to the sections that have changes. Do not fill in all the sections with the information from your previous Form 101.

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.

Amendments for Imported records (from previous ethics system)

When changing an imported record, you are only required to update the section of the application that are being changed. Do not update or fill in the entire application.

If you are only changing the personnel on a record, you can do this directly on the imported version of the application. All imported records should be switched for the 'imported record' type to the appropriate type for your application (eg. Standard Application).

Changing only the personnel/researchers on the record

For all changes to an imported record, start an amendment as normal.

Next, edit the type of application to the appropriate type (eg. 'Standard Application') instead of 'Imported Record'.

This will open all the sections in the left navigation field for your type of application. ONLY CHANGE/UPDATE THE SECTIONS OF THE APPLICATION THAT ARE CHANGING.

It may be helpful to open your old application to help fill out the new changing sections. The old application can be found in pdf format in the 'Other Attachments' section at the bottom of the application.

If you are substantially changing a record there might be other options that would be easier for working with an imported record. Contact Research Ethics or Michelle Manios if you are unsure.

Other Attachments

Upload any additional study documents

Attachments

ATTACHMENT	≡	NAME
1APPLICATION.PDF		
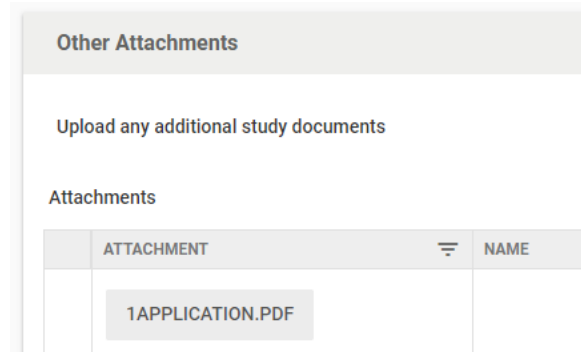
Submitting an Amendment
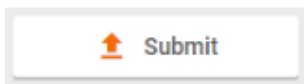
Any Researcher listed in the 'People' section can create an amendment for a protocol if they have been granted 'Full access' permissions. The Principal Investigator listed in the 'General Information' section is the only Researcher than can submit the amendment.

When responding to revisions requested by the Reviewer, any Researcher listed on the protocol can submit the changes with the 'Submit' button.

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 of the application and start a renewal.
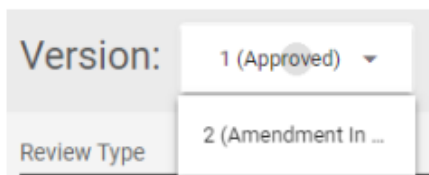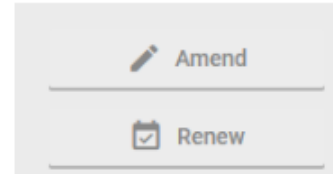
Renewals

Beginning a Renewal

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

From the 'Manage Protocols' screen, open the application you want to renew.
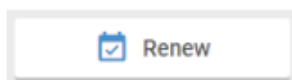
In the right menu, select the 'Renew' button.

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

Open the Version screen and check for an in progress version and the latest approved version to see the current state of the protocol.

Completing a 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.
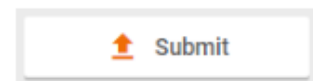
The protocol you are renewing is shown below the renewal application form/questions.
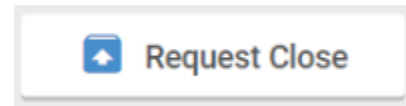
Abondoning a Renewal

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 in the right hand menu.

You are now able to go to the last approved version and start an amendment.

Closing an Application

Begin by clicking on the 'Request Close' button in the right hand menu.

You can now follow the same process as a renewal.