



# **WesternREM (WREM) Applicant**

## **Online User Guide: Application Features**

**Helpdesk:** 519-661-3036

**Email:** [wrem@uwo.ca](mailto:wrem@uwo.ca)



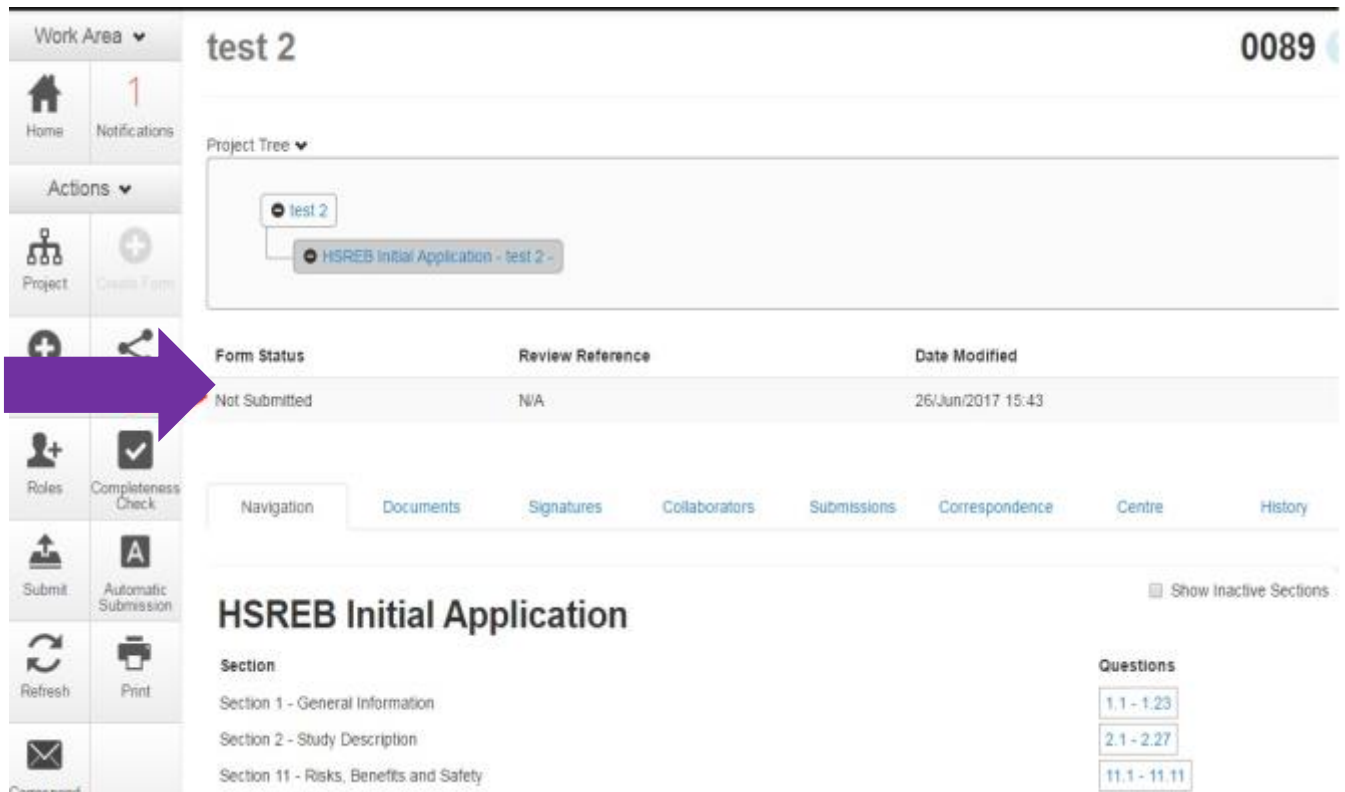
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## 1. Application Status

Every form within a project will have the following information associated with it:

- **Form Status** – current status of the form within the REB review process
- **Review Reference** – each form will receive a number once it has been submitted
- **Date Modified** – the last date the form was modified



The screenshot shows the WesternREM interface for a project named 'test 2'. The top navigation bar includes 'Work Area', 'test 2', and a user ID '0089'. The left sidebar contains various action buttons like Home, Notifications, Project, Create Form, Roles, Completeness Check, Submit, Automatic Submission, Refresh, Print, and Correspondence. The main content area displays a 'Project Tree' with 'test 2' and 'HSREB Initial Application - test 2'. Below this is a table with the following data:

Form Status	Review Reference	Date Modified
Not Submitted	N/A	26/Jun/2017 15:43

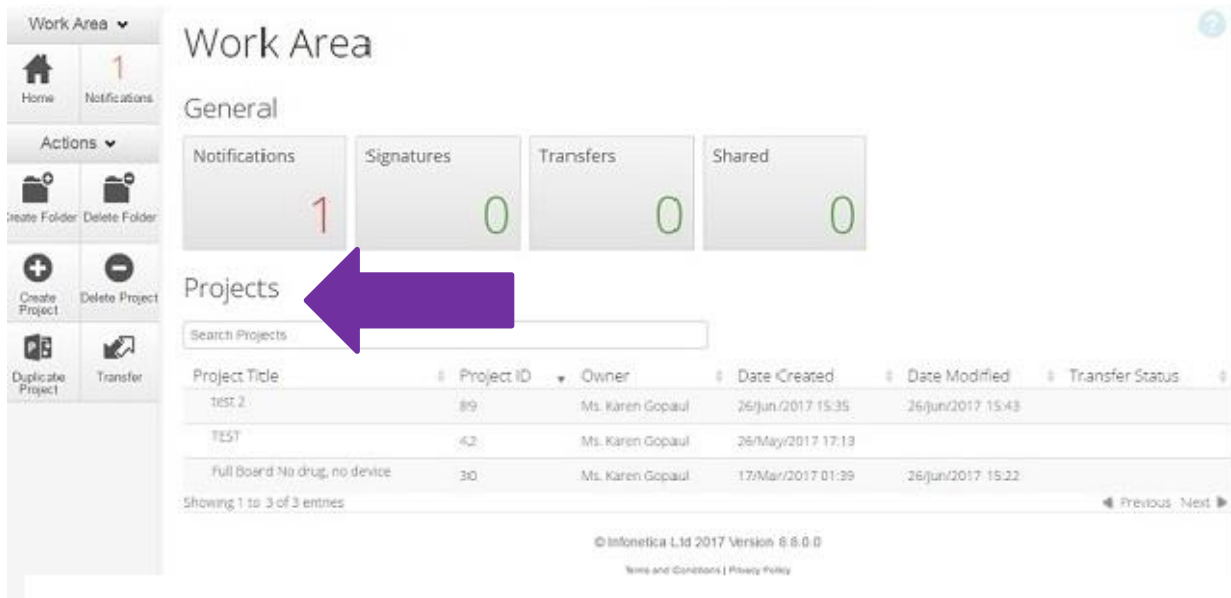
Below the table is a navigation bar with tabs for 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', 'Centre', and 'History'. The main content area is titled 'HSREB Initial Application' and shows a list of sections: 'Section 1 - General Information', 'Section 2 - Study Description', and 'Section 11 - Risks, Benefits and Safety'. On the right, there is a 'Questions' section with three items: '1.1 - 1.23', '2.1 - 2.27', and '11.1 - 11.11'. A purple arrow points to the 'Form Status' column in the table.

## 2. Actions Toolbar – Within a Project

The **Actions Toolbar** will display all actions available in WesternREM. The Actions Toolbar is dynamic and will only display the actions currently available to the user depending on what stage you're at in the system.

### 2.1 Project Menu

The **Project Menu** contains a list of all of the Projects to which you currently have access. You can easily search this project menu by using the '**Search Projects**' search bar.



Work Area

Home Notifications 1

Actions

Create Folder Delete Folder

Create Project Delete Project

Duplicate Project Transfer

General

Notifications 1 Signatures 0 Transfers 0 Shared 0

Projects

Search Projects

Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
TEST 2	89	Ms. Karen Gopaul	26/Jun/2017 15:35	26/Jun/2017 15:43	
TEST	42	Ms. Karen Gopaul	28/May/2017 17:13		
Full Board No drug, no device	30	Ms. Karen Gopaul	17/Mar/2017 01:39	26/Jun/2017 15:22	

Showing 1 to 3 of 3 entries

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### 2.2.1 Roles

In order for a team member to view a project or any forms within a project, the **Project Owner / Form Owner** (the user who created the project) must assign a **Role** in the project to that team member.

For more information about how to Assign a Role in a Project review the:  
**WREM Applicant – QuickGuide: Adding Study Team Members**

### 2.2 Collaborating on a Project

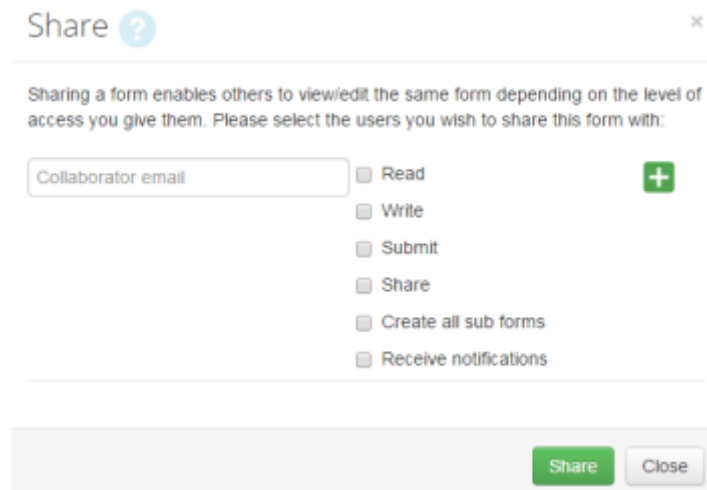
By clicking on the **Collaborators** tile, you can change the permissions that a person has for the study.

### 2.2.2 Individual Form Sharing

The Project Owner and/or Form Owner, and anyone who has been given a role in the project, will have access to the application and forms within that application. The **Share** tile allows you to share the currently selected form with an individual **external** to the study team. This action will only share the form you have selected. It will not share any other forms associated with the project.

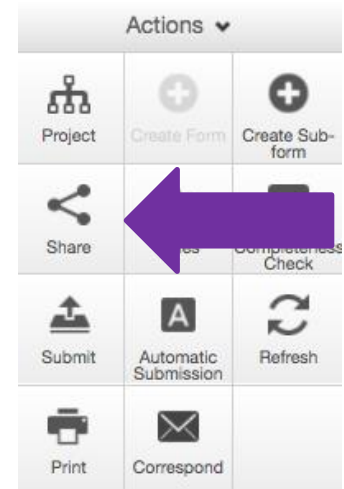
To complete the action, click the **Share** tile within the **Actions Toolbar**.

You will be presented with a dialog box where you can enter the collaborator's email address:



When adding a collaborator, you can select one of the six sharing options available:

- **Read** – The collaborator will be allowed to read the application
- **Write** – The collaborator will be able to make changes to the application
- **Submit** – The collaborator will be able to submit the application to the REB
- **Share** – The collaborator will be able to share the application with other study staff
- **Create all sub forms** – The collaborator will be able to create all sub forms for that application and have full permissions to edit and submit those applications
- **Receive notifications** – The collaborator will receive system notifications related to the shared application form

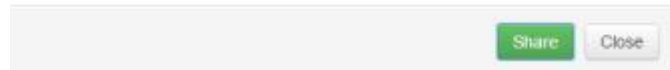
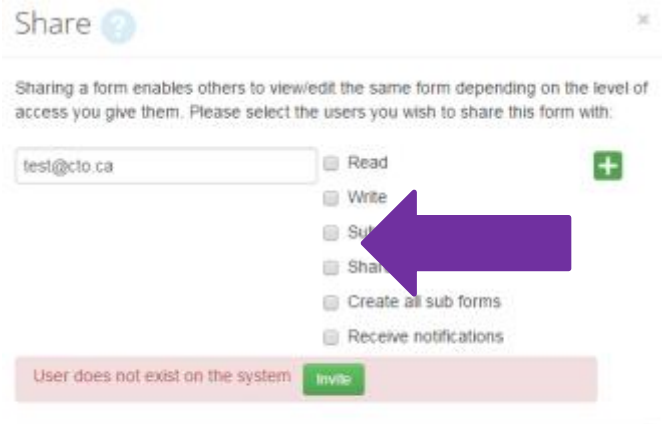


If the email address entered is not registered to a user within WesternREM, the system will display the following message:

You will have an option to send an invite to the individual, which will initiate a notification email to them, along with the instructions about how to register with WesternREM.

Once the individual completes and submits a Registration Form in WREM, the new user will receive a confirmation in WREM and by email indicating the Registration Form has been received.

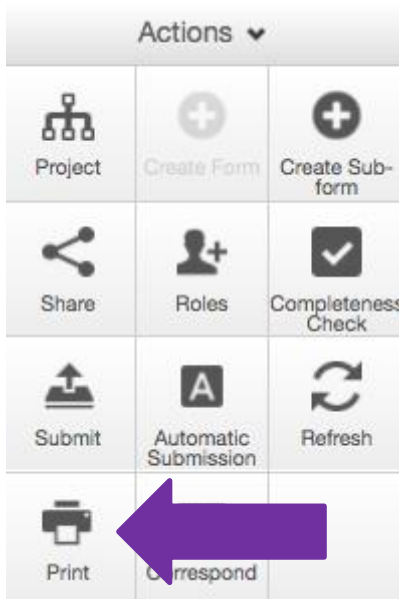
The Office of Human Research Ethics will vet the information on the form and the new user will receive a user account within 24 hours and be able to access WREM at that time.



### 2.3 Print

By clicking the Print tile, a PDF version of the currently selected form can be printed. This PDF file can also be saved directly to your computer.

**\*NOTE:** You cannot print a blank copy of the form; only the sections you have completed will print.

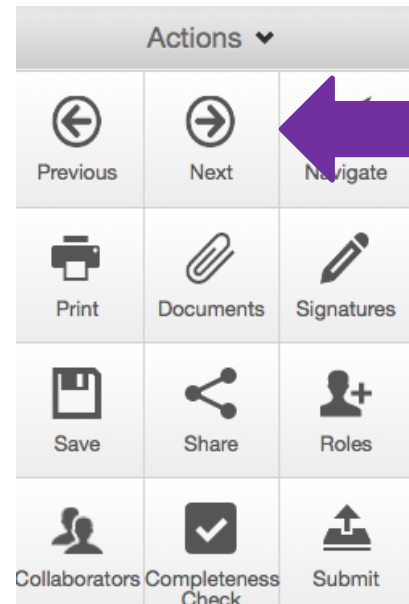


### 3. Actions Toolbar – Within an Application

#### 3.1 Previous/Next

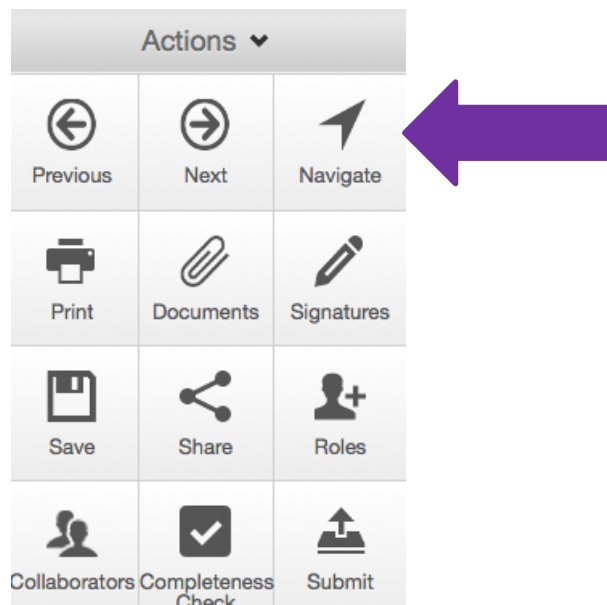
The two tiles highlighted in the image to the right, **Previous** and **Next**, are displayed once you have begun entering information into an application form. By clicking on the Previous/Next tiles, you will be directed to the Previous/Next section within the application form and all of your progress within the form to that point will be saved.

**\*NOTE: Clicking the Backspace or Delete button on your keyboard when you are not in a selected field will result in moving to the previous page and your work will NOT be saved.**



#### 3.2 Navigate

By clicking the **Navigate** tile, you will be directed back to the main page of the currently selected form. When you click on the Navigate tile, all of your progress within the form to that point will be saved.



### 3.3 Documents

You can view all Documents uploaded in the currently selected application form by clicking the **Documents tab** from the application form home page or by clicking the **Documents tile** within a section of the application form:

Project Tree ▼

- HC-Drug #1
  - HSREB Initial Application - HC-Drug #1 - Khan
  - HSREB Amendment Form - HC-Drug #1 - Gopalul
  - HSREB Amendment Form - HC-Drug #1 - Khan
  - HSREB Amendment Form - Basile
  - HSREB Amendment Form - Basile













Form Status	Review Reference	Application Type	Date Modified
Not Submitted	N/A	N/A	20/Aug/2017 20:28

Navigation **Documents** Submissions Correspondence Centre History

Collaborators

Name	Access	Edit Permissions
------	--------	------------------

Actions ▼

 Previous	 Next	 Navigate
 Print	 Documents	
 Save	 Share	 Roles
 Collaborators	 Completeness Check	 Submit

Clicking either of these links will present you with a list of all documents attached to the currently selected form, along with related information.



### 3.4 Collaborators

You can view a list of all collaborators in the currently selected application form by clicking the **Collaborators tab** from the application form home page or by clicking the **Collaborators tile** within a section of the application form:

Project Tree ▼

- HC-Drug #1
  - HGREB Initial Application - HC-Drug #1 - Khan
  - HGREB Amendment Form - HC-Drug #1 - Gopalul
  - HGREB Amendment Form - HC-Drug #1 - Khan
  - HGREB Amendment Form - Basile
  - HGREB Amendment Form - Basile

Form Status	Review Reference	Application Type	Date Modified
Not Submitted	N/A	N/A	20/Aug/2017 20:28

Navigation Documents Signatures **Collaborators** Evidence Centre History

Collaborators

Name	Access	Edit Permissions
------	--------	------------------

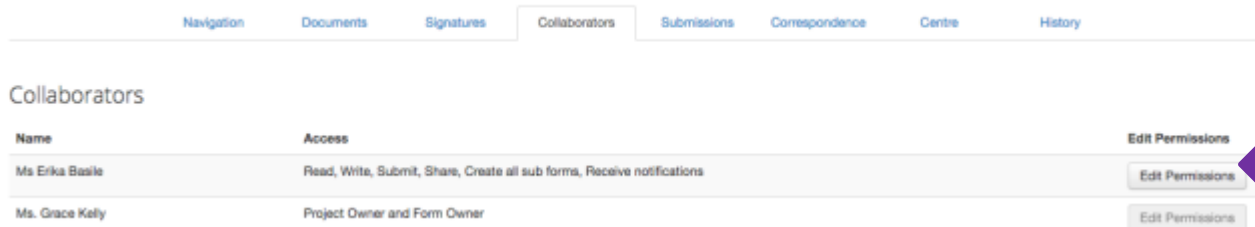
Actions ▼

Previous	Next	Navigate
Print	Sign	Reject
Documents	Signatures	Unlock
Share	Roles	Collaborators
Completeness Check	Submit	

Clicking either of these links will present you with a list of all collaborators currently listed on the project, along with related information.

You are also able to Edit Permissions from this list (without having to go into the form).

Click **Edit Permissions** and you will be presented with a dialog box, enabling you to edit that collaborator's access level.



Name	Access	Edit Permissions
Ms Erika Basile	Read, Write, Submit, Share, Create all sub forms, Receive notifications	<a href="#">Edit Permissions</a>
Ms. Grace Kelly	Project Owner and Form Owner	<a href="#">Edit Permissions</a>

### Edit Permissions - Ms. Nicole Holme ×

- Read (Applicant Role)
- Write (Applicant Role)
- Submit (Applicant Role)
- Share (Applicant Role)
- Create all sub forms (Applicant Role)
- Receive notifications (Applicant Role)

Save

Close

### 3.5 Signatures


**\*NOTE:** Only the Principal Investigator has the authority to sign off on a project. Therefore, when requesting a signature, only the PI's signature should be requested.

Once an application form is completed, it requires signatures before it can be submitted. You can view all active and pending Signatures in the currently selected application form by clicking the **Signatures tab** from the application form home page or by clicking the **Signatures tile** within a section of the application form:

Project Tree ▾

- HC-Drug #1
  - HSREB Initial Application - HC-Drug #1 - Khan
    - HSREB Amendment Form - HC-Drug #1 - Gopalul
    - HSREB Amendment Form - HC-Drug #1 - Khan
    - HSREB Amendment Form - Basile
    - HSREB Amendment Form - Basile
















Form Status	Review Reference	Application Type	Date Modified
Not Submitted	N/A	N/A	20/Aug/2017 20:28

Navigation Documents Signatures  Missions Correspondence Centre History

Collaborators

Name	Access	Edit Permissions

Actions ▾

 Previous	 Next	 Navigate
 Print	 Sign	 Reject
 Documents	 Signatures 	 Collaborators
 Share	 Roles	 Collaborators
 Completeness Check	 Submit	

Clicking either of these links will present you with all active signatures on this form and all pending signature requests on this form.

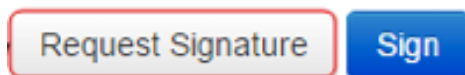
Signatures are sorted by the following columns:

1. **Type** – displays the role of the signatory
2. **Signatory Email** – displays the email of the person who signed the form
3. **Signed Date** – displays the date the person signed the form
4. **Validity** – all signatures will be labelled as valid and will lock the form to prevent further changes. Once a form is unlocked to make modifications, any previous signatures will be invalidated and will be labelled as invalid

### 3.5.1 Requesting a Signature

If you are a study staff member who has completed the application form but does not have signing authority, you can request the signature of the appropriate individual by clicking the **'Request Signature'** button.

#### *Please Sign*



This will bring up a pop-up window where signature recipient's email address can be entered, along with an optional message. Click the **'Request'** button to complete the signature request.



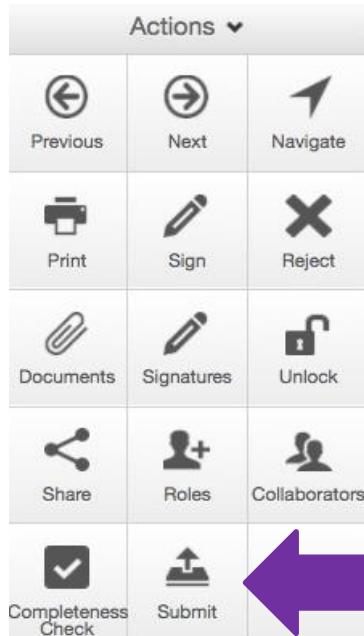
The person from whom you are requesting the signature will receive a notification email, and a WesternREM notification on the project.

For more information about how to Sign an Application, review the:  
**WREM Applicant – QuickGuide: Signing an Application**

### 3.6 How to Submit an Application

When the application is complete, to submit the application, you must click the **'Submit'** tile and the system will check the form for completeness.

**\*NOTE:** You can also check for completeness by clicking **'Completeness Check'** next to **'Submit'**.

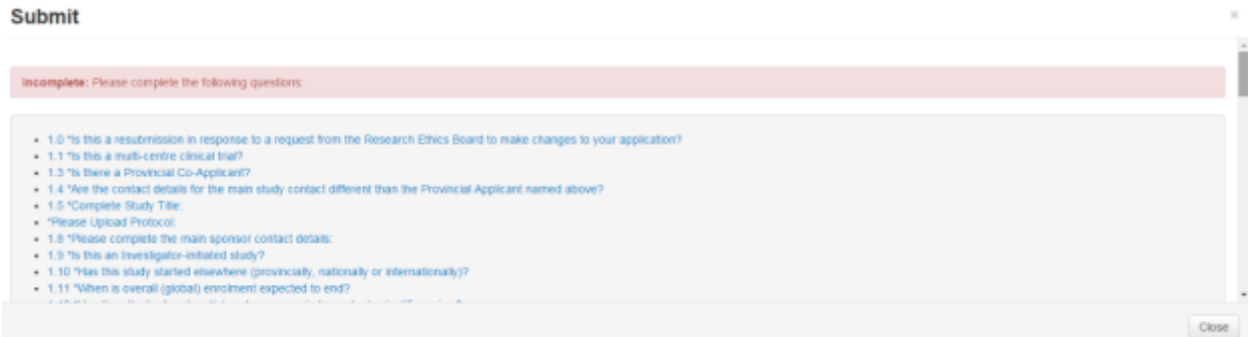


#### Submit

Loading: Checking form is complete...

Close

All unanswered mandatory questions will be highlighted by the system. Clicking an unanswered question link will direct you to that question within the application form.



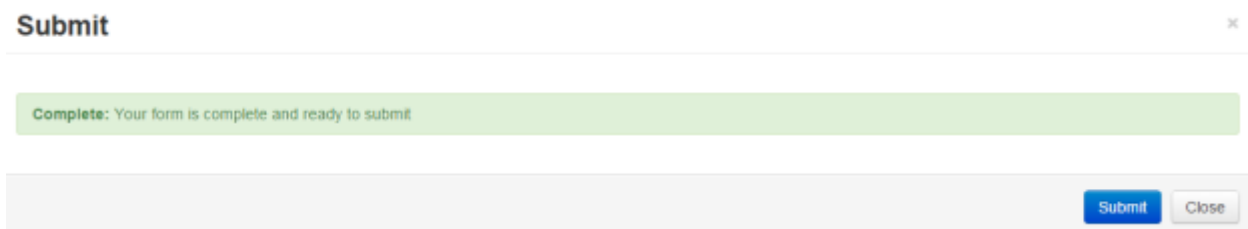
**Submit**

**Incomplete:** Please complete the following questions:

- 1.0 \*Is this a resubmission in response to a request from the Research Ethics Board to make changes to your application?
- 1.1 \*Is this a multi-centre clinical trial?
- 1.3 \*Is there a Provincial Co-Applicant?
- 1.4 \*Are the contact details for the main study contact different than the Provincial Applicant named above?
- 1.5 \*Complete Study Title:
- \*Please Upload Protocol:
- 1.8 \*Please complete the main sponsor contact details:
- 1.9 \*Is this an Investigator-initiated study?
- 1.10 \*Has this study started elsewhere (provincially, nationally or internationally)?
- 1.11 \*When is overall (global) enrolment expected to end?

Close

If the form passes the completeness test, clicking the blue **'Submit'** button will submit the form to the REB.



**Submit**

**Complete:** Your form is complete and ready to submit

Submit Close

Once the form has been successfully submitted, you will be presented with a confirmation screen. Press the Home button to return to the Work Area.

### 3.7 Submissions

The **Submissions** tab can be found on the main page of the currently selected application form.

Project Title ▾

- HC-Drug #1
  - HSREB Initial Application - HC-Drug #1 - Khan
  - HSREB Amendment Form - HC-Drug #1 - Gopaul
  - HSREB Amendment Form - HC-Drug #1 - Khan
  - HSREB Amendment Form - Basile
  - HSREB Amendment Form - Basile

Form Status	Review Reference	Application Type	Date Modified
Not Submitted	N/A	N/A	20/Aug/2017 20:28

Navigation Documents Signatures Collaborators **Submissions** Centre History

Collaborators

Name	Access	Edit Permissions
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Clicking the **Submission** tab will bring up a list of all previous submissions of the currently selected application form. Every time an application is submitted to the REB, a PDF snapshot is taken and a record of the submission is stored under the Submissions tab. When an application form is resubmitted to the REB due to required recommendations, previous submissions are archived. All Submissions can be downloaded in a PDF format.

For more information about how to Respond to Recommendations, review the:  
**WREM Applicant – QuickGuide: How to Respond to Recommendations**

### 3.8 History

The **History** tab can be found on the main page of the currently selected application form.

Project Tree ▼

- HC-Drug #1
  - HSREB Initial Application - HC-Drug #1 - Khan
    - HSREB Amendment Form - HC-Drug #1 - Gopalul
    - HSREB Amendment Form - HC-Drug #1 - Khan
    - HSREB Amendment Form - Basile
    - HSREB Amendment Form - Basile

Form Status	Review Reference	Application Type	Date Modified
Not Submitted	N/A	N/A	20/Aug/2017 20:28

Navigation Documents Signatures Collaborators Submissions Correspondence Centre **History**

Collaborators

Name	Access	Edit Permissions
------	--------	------------------

Clicking the **History** tab will open a complete listing of events that have occurred for the selected application form. This includes signatures, submissions, and status changes throughout the REB review process. Certain historical actions will also have an accompanying attachment that can be downloaded in PDF format.

For more information about how to Find an Approval Letter, review the:  
**WREM Applicant – QuickGuide: How to Find an Approval Letter**

## 4. Completing an Application Form

### 4.1 Smart questions

The application forms used in WesternREM are composed of smart questions. Depending on the answers you provide, certain questions may become available or remain hidden as they are not required. As you progress through the forms, you may notice the questions are not numbered sequentially. This is a result of smart question functionality.

**\*NOTE:** It is therefore advised to complete the form in order of how the questions apply. Skipping ahead may result in entering a response that is not needed, or in not entering enough information.



## 4.2 Comments

Any user who has access to the application forms can add **comments** to other users. To add a comment, click on the icon highlighted in the picture below:



1.1

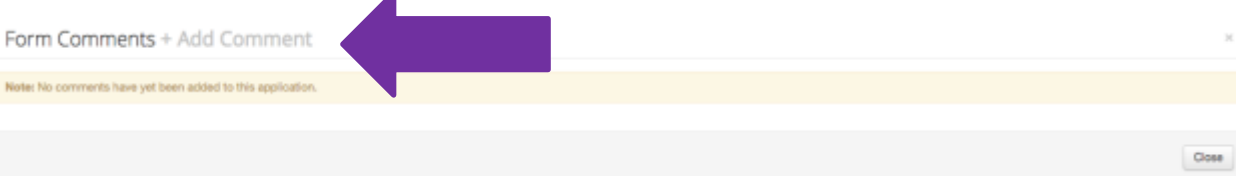
1.1 "Is this the initial submission or a response to REB recommendations?"

Initial Submission

Response to REB recommendations

A purple arrow points to a speech bubble icon in the top right corner of the question box.

You will be presented with all the comments related to that question. There is also a field where you can enter additional comments. By clicking the '+ Add Comment' button, the comment will be saved to the system.



Form Comments + Add Comment

Note: No comments have yet been added to this application.

Close

A purple arrow points to the '+ Add Comment' button.

**\*NOTE:** Only the person who adds the comments can edit and delete the comment and the comments are not submitted with the application.

## 4.3 Help Text

Some questions within WesternREM have associated **help** texts. To view the help text click on the icon highlighted below:



2.7

2.7 "Provide a summary of the study design AND methodology (it would also be helpful to submit a flow diagram if available):"

Upload a flow diagram (if applicable):

Upload Document

A purple arrow points to a question mark icon in the top right corner of the question box.

The help text will appear in a pop-up window. To close the help text, click anywhere outside the pop-up window.

#### 4.4 Mandatory questions


All questions labeled with an asterisk are mandatory questions and require an answer in order to sign and submit the application.

#### 4.5 Documents upload

You can upload documents by clicking the blue **'Upload Document'** button associated within certain questions.

**\*NOTE:** More opportunities to upload documents will appear as you complete the form.

**\*Please Upload Protocol:**



Upload Document

You can browse your computer for a file to upload. All major file types are supported, including Word documents, Excel documents, text files and PDFs.

#### Documents - Protocol

Please attach your Protocol here:

Document Name	Document Date	Version	
<input type="button" value="Browse"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Upload"/>

All documents should be uploaded with a proper name (the file name) that will help the REB in identifying it. Furthermore, the document name (file name) you provide will be reflected in the REB approval letter. All Product Monographs and Investigator Brochures should include the name of the drug in the document file name.

**\*NOTE:** Do not add any underscores or special characters into the document file name.

Once you have selected the file and inputted the Document Version Date and Version Number, to complete the upload process, click the **'Upload'** button.



#### 4.6 Save

You can save your progress at any time by clicking the **Save** tile in the **Actions Toolbar**. Your progress will also automatically save as you navigate from one page to the next.