MacREM Guides for Researchers

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Helpdesk: 905-525-9140 ext. 23142
Email: ethicsoffice@mcmaster.ca
Getting Started

1. ABOUT MacREM

The new system was purchased from Infonetica Ltd, which specializes in research management, ethics management, ethics approval and compliance training solutions. It is the same system currently in use by the Hamilton Integrated Research Ethics Board (HiREB), but there is currently no shared login access. The system we are calling McMaster Research Ethics Manager (MacREM) is a web-based electronic platform for conducting research ethics reviews and is built using modern infrastructure that exhibits a vast set of features, while maintaining an easy-to-use interface.

HiREB has been using this system since 2014. They also use the same system for multi-centre clinical trial studies submitted through Clinical Trials Ontario (CTO), for which HiREB acts as the REB of record. CTO’s system CTO Stream has been developed in partnership with Infonetica. An Ontario wide group of users of the Infonetica system meet to share and discuss issues that has resulted in ongoing improvements.

1.1. Target Audience

This guide is intended for all MacREM Users and will provide useful information on how to create an account and navigate the online application system.

1.2. Internet Settings

MacREM supports the latest versions of the following browsers:
- Microsoft Edge
- Mozilla Firefox
- Google Chrome
- Apple’s Safari

MacREM uses pop-ups. You will need to configure your browser to ensure MacREM pop-ups are allowed. MacREM does not support the Epic browser and the TOR browser has not received extensive testing.

1.3. Technical Support

Email – ethicsoffice@mcmaster.ca
Phone – 905-525-9140 ext. 23142

2. GETTING STARTED

2.1. Access the System
To access the system go to: https://macrem.mcmaster.ca. You can also login from the MREB MacREM website: https://reo.mcmaster.ca/macrem

2.2. Accounts
MacREM accounts are setup to be compliant MacIDs, so you should be able to login with your MacID. Logging out will return you to the MREB MacREM website.

2.3. How to Log In

Once you have arrived at the login page, enter your MacID coordinates - email address and password, and click Log in.

3. NAVIGATING the MacREM System

Upon logging into MacREM, you will be directed to the Work Area. The Work Area is your home page where you will create new projects and find all current pending notifications.

3.2. Navigation Menu

The Navigation Menu will always be visible at the top of the page no matter where you are in the system, and includes links to:
1. **Home** – takes you to the Work are / Home page
2. **Contacts** – takes you to the Contacts page. For more information please refer to section 3.3
3. **Help** – The Help bar links to:
   a) **Contact Information** – Provides contact information for the MREB Research Ethics Office
   b) **Help** – Provides training materials for quick reference
   c) **FAQ** – Links to Frequently Asked Questions
   d) **Templates** – Links to REB Guidance Templates and Sample Documents
   e) **About** – Provides information about the McMaster Research Ethics Board (MREB)
4. **Account Settings** – clicking on your name on the right-hand side of the Navigation Menu allows you to:
   a) **Change Password** (no need as you will use MacID)
   b) **Update Personal Information**
   c) **Logout**

### 3.3. Contacts

This page lists all of the contacts you have saved to your personal address book in MacREM.

### 3.4. Actions Toolbar

The **Actions Toolbar** will display all actions available in MacREM. 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.

#### 3.4.1. Create Folder

Creating folders will help you easily organize your applications within MacREM. Whether you are working with several PIs, many research students or just simply want to organize between Full Board and Delegated, you can use the **Create Folder** function to do this.

1. Click the ‘Create Folder’ tile
2. Add a folder title (no more than 40 characters)
3. Drag and drop the files from your list of Projects into the folder
4. To move files out of the folder, click on the folder
5. Click the ‘Move project’ tile and select the Project and Destination you wish for that file to move
6. Click ‘Move’

#### 3.4.2. Delete Folder

1. Once the folder is empty (see section 3.4.1 on how to ‘Move’ a project), you can delete the folder
2. From the Home page, click on the 'Delete Folder' tile
3. Select the folder you wish to delete
4. Click 'Delete' and confirm with 'Yes'

3.4.3. Create Project

Clicking the ‘Create Project’ tile will bring up the Create Project dialog box.

**Create Project**

- **Project Title**
  - Enter your short title (fewer than 200 characters). This title will be used to access your file from the Project Menu, so ensure it is something unique.

- **Main Form**
  - Select the appropriate form
    - MREB Application Form or
    - Transfer Basic Data to MacREM form
  - *NOTE*: all new applications should use the MREB Application Form. The Transfer form is used only by the Ethics Office transferring an active application from the old system.

For more information about how to Create a Project, review the: MacREM Applicant – QuickGuide: Creating a Project

3.3.3. Delete Project

Clicking the ‘Delete Project’ tile in the Action Toolbar will bring up the Delete Project pop up window.

1. Select from the drop-down list the project you want to delete and click the ‘Delete’ button.

*NOTE*: Projects that have been submitted for review cannot be deleted.

3.4.5. Duplicate Project

Clicking the 'Duplicate Project' tile will bring up the Duplicate Project dialog box.
1. Select the project from the drop-down list you want to duplicate and click the ‘Duplicate’ button.
2. The duplicated project will appear in your Projects Menu.

*NOTE: Duplicating a project will create an exact replica of the project, including all of the applications associated with the project – but excludes any documents uploaded in the original project (e.g., protocols, consent forms, etc.).

3.4.6. Transfer Project

MacREM facilitates transferring the ownership of a project from one person to another. Only the current Project Owner / Form Owner (the user who created the project) has the ability to initiate a transfer.

Once the project is transferred to another individual, it will no longer be listed on your project list and you will no longer have access to it unless the new owner shares the project with you.

1. Click the ‘Transfer’ tile – this will bring up the Transfer Projects dialog box.
2. Select the project you want to transfer from the list by clicking on the checkbox next to the User Project ID, or search for the project you want to transfer.
3. Input the email address of the person to whom you are transferring the project.
   a) You can also enter a message to accompany the transfer.
4. Once the transfer request is complete, the transfer recipient will receive a notification through MacREM and his/her personal email. The transfer recipient can then accept or reject the transfer.

3.5 General Menu

The General Menu is the main hub for all notifications and is based on four distinct categories. The number listed in the corresponding title is the number of unread notifications.
The General Menu tiles will only appear on the Work Area / Home page.

3.5.1. Notifications

Users will receive notifications whenever an event occurs on an application form within a Project. Clicking the Notification tile will bring you to the Notification page, which is similar to an email inbox.

1. You can search through the available notifications by keywords
2. You can search through the available notifications by start and end date
3. The display slider can be used to change the number of notifications returned as results once a search is completed

4. The check box to the left of each message can be used to select one or more messages at one time. You can select all messages at once by clicking the check box at the top left-hand side of the page.
5. Selected messages can be marked as unread, marked as flagged, or deleted.
   - Delete a single notification using the X on the right side
   - Delete multiple notifications by clicking the boxes on the right and selecting an action

*NOTE: Deleted notifications cannot be recovered.*
3.5.2. Signatures

Clicking the **Signatures** tile will bring you to the Signatures page. Here, users can view Signatures that have been collected on the form, or Signature Requests, along with the status of the Signature or Signature Request (Valid, Invalid or Requested).

Signatures

You can search through your pending and previous signature requests using the following criteria: Project Title, Requesting User Name and Requested Date.

![For more information about how to Sign an Application, review the: MacREM Applicant – QuickGuide: Signing an Application](image)

3.5.3. Transfers

Clicking the **Transfers** tile will bring you to the Transfers page. You can search through the pending/completed transfer requests using the following criteria: Transfer ID, Project Title, User Name and Date.

Transfers

3.5.4. Shared

Clicking the **Shared** tile will bring you to the Shared Forms page. You will be presented with a list of forms that have been shared with you, along with related information.

*NOTE:* These projects will only be ones that have been shared with you as an external team member (i.e., you are not the Project Owner / Form Owner or have a Role in the project.)
To view the form that has been shared with you, click the ‘View Form’ button. The share can be rejected should you no longer wish to be a collaborator on an application form. Shared projects will also be available under the Project Menu in the Work Area.

3.6. 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.
Application Features

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, such as Not Submitted, Submitted, Under Review, etc.
- **Review Reference** – each form will receive a number once it has been submitted. This is also the MREB#
- **Date Modified** – the last date the form was modified

<table>
<thead>
<tr>
<th>Form Status</th>
<th>Review Reference</th>
<th>Application Type</th>
<th>Date Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under Review</td>
<td>2018-0421</td>
<td>MREB Application</td>
<td>Nov/05/2018 15:17</td>
</tr>
</tbody>
</table>

- TEST reviewers unassign TEST Form Comments Token
- MREB Application Form
2. Actions Toolbar – Within a Project

The Actions Toolbar will display all actions available in MacREM. 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 the Projects to which you currently have access. You can easily search this project menu by using the ‘Search Projects’ search bar.

2.2 Collaborating on a Project

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

2.2.1 Roles

In order for a team member to contribute to a project or any forms within a project, the Project Owner / Form Owner (the user who created the project) can assign a Role in the project to that team member. This however does not make the form accessible to the person with the role. It is better to Share the project, which is explained next.

For more information about how to Assign a Role in a Project review see: MacREM Application – QuickGuide: Adding Study Team Members
2.2.2 Individual Form Sharing

The Project Owner and/or Form Owner can share have access to the application and forms. The **Share** tile allows you to share the currently selected form with an individual on 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 (MacID). If the collaborator has not previously logged into MacREM they will not be recognized on the system. All anyone has to do to be recognized is to login just once:

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 MacREM, the system will display the following message: **User does not exist in the system**
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 MacREM.

The process may involve an outside researcher in which case they will have to apply for a guest MacID. All users of the systems will need a MacID.

The Ethics Office will assist outside guest researchers with obtaining a MacID. Usually this process can be turned around quickly.

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. The Ethics Office has a blank copy, but at 75 pages long, it is probably better to negotiate the online version.

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 from the home page or by clicking the **Documents tile** within a selection of the application form:
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 selection of the application form:
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.
3.5 Signatures

*NOTE: Only the Principal Investigator has the authority to sign off on a project. Therefore, when requesting a signature, only the PIs 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:
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 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.

**Signature of Faculty, Staff Researcher, Principal Investigator**

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.
3.6 How to Submit an Application

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

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

Once all unanswered questions have been completed, your application will be submitted. You will be returned to a splash page that will inform you that your application is in the review process:
If you go back to your application, which is now locked until it you receive comments from the Ethics Office or Chair, you will see that the system has recorded the time of the signature:

Signature of Faculty, Staff Researcher, Principal Investigator

Signed: This form was signed by Mr Michael Wilson (mwilson@mcmaster.ca) on May/09/2018 11:01 AM

3.7 Submissions

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

4. Completing an Application Form

4.1 Smart questions

The application forms used in MacREM 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 the 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** for other users. To add a comment, click on the icon highlighted in the picture below.
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.

**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 MacREM have associated help texts. To view the help text click on the icon (a white ‘i’ with a blue circle around it) as illustrated below:

Is your grant title different from above? (If your research is not funded or you don’t have a grant just select NO)

- **Yes**
- **No**

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

With few exceptions, most questions on the form will be mandatory and must be answered in order to submit the application. There are no questions where a “not applicable” will be an appropriate answer. Based on your Yes or No selection to some questions, entire sections of the form will be skipped.

### 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.
Upload research agreement(s).

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 - Agreements

Please attach your Agreements here:

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Version Date</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Browse</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

All documents should be uploaded with a proper name (the file name) that will help the REB to identify it.

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 and Autosave

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, when you click the Navigate icon, submit an application or run the 'Completeness Check'. It is advisable to click the Save icon if you are staying on a page for a long time to edit in case of internet interruption or other unforeseeable events.
QuickGuide: Adding Study Team Members & Sharing the Form

When a user creates a new project in MacREM she/he becomes the ‘Project Owner’ and has exclusive access to the project and all of the forms within.

In order for other members of the study team, to access the application forms in the project, they can be given a Role by the Project Owner, but they must be shared on the application through the Share tile. Once a user has shared permissions, they will be granted access to previously created forms and all forms created in the future for the project. Just assigning a Role may not give them the necessary permissions to access and work with the form.

To add a study team member within the application form itself:

1. Log in to MacREM https://macrem.mcmaster.ca
2. Click on the project in the list of Projects at the bottom of the screen that you wish to update.
3. Make sure that the application you wish to update is highlighted in grey in the Project tree.
4. In Section 2 of the Application Form, you can add study team members to your list of Contacts inside the application form, and then ‘Load’ them into the contact form to fill it automatically.
5. Click on the Roles tile in the Actions Toolbar on the left hand side of the screen.

6. Enter the email address of the person you wish to add. Study team members must have MacID. If they don’t have MacID, please contact the Ethics Office and they will apply for a guest MacID account. Choose a role for that person by clicking the dropdown menu beside their email address. Click ‘Share Role’.

   a) If needed, you can edit the permissions of the person added by clicking on the Collaborator tab in the Actions Toolbar after they are added through the Share tile.

**Roles**

In order for a team member to contribute to a project or any forms within a project, the **Project Owner / Form Owner** (the user who created the project) can assign a **Role** in the project to that team member. This however does not make the form accessible to the person with the role. It is better to **Share** the project, which is explained next.

**Individual Form Sharing**

The Project Owner and/or Form Owner, and anyone who has been given a role (or not) in the project, will have access to the application and forms within that application, but only if it is shared. The **Share** tile allows you to share the currently selected form with an individual 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 (MacID). If they collaborator has not previously logged into MacREM they will not be recognized on the system. All anyone has to do to be recognized is login:
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 MacREM, the system will display the following message: **User does not exist in the system**

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 MacREM.

The process may involve an outside researcher in which case they will have to apply for a guest MacID. All users of the systems will need a MacID.

The Ethics Office will assist outside guest researchers with obtaining a MacID. Usually this process can be turned around quickly.
QuickGuide: Creating a New Project

This QuickGuide outlines steps for creating a new project within MacREM.

To create a new project:

Getting Started:

1. Log into MacREM: https://macrem.mcmaster.ca

2. Click on ‘Create Project’ from the Actions Toolbar and enter the following information:

   a) Project Title (less than 200 characters or about 28 average length words).
      *NOTE: on the form you will be asked to enter a short title or acronym to save ‘real estate’ on the system screens.
      • This title will be used to access your file from the Project Menu
   b) Main Form
      • Select the appropriate application: in almost all case, this is the MREB Application Form
      • The Transfer Basic Data to MacREM temporary form and procedure to migrate applications to the new system and is used by the Ethics Office only.

   c) The MREB Application Form will ask you if you want to create one of four projects – an MREB Standard Application, a Conditional Release of Funds Application, a Course-Based Application, Application for an External REB Clearance.

3. Click ‘Create’

4. In the Navigation tab under Section 1 begin by answering the first screening questions:
*NOTE: The first screening question are to establish that the applicant is applying to the right REB. There are two REBs at McMaster, the Hamilton Integrated Research Ethics Board, or HiREB which reviews clinical trials and all research from the Faculty of Sciences, and MREB, which is the board of record using the MacREM system – all research on campus that is not medical or from the Health Sciences.

Adding the PI and Additional Study Personnel

5. Anyone who creates a project is consider the Applicant. The applicant may or may not be the Principal Investigator. There are several ways to add the PI if the applicant is creating the project on their behalf:

   1. In the top Menu – go to Contacts and click Add Contact. Fill the form for the PI. Not all these fields may be used on the actual application.
   2. In the actual application form in the Contact section for Principal Investigator, you can now click Load, which will prompt you to select from your list of Contacts. This list of contacts will be available for all future applications that you create.
   3. Click on the Roles tile in the Actions Toolbar. Enter the email address of the person you wish to add. Choose a role for that person by clicking the dropdown menu beside their email address. Click ‘Share Role’.

   *NOTE: You can change the permissions of those who have a Role in the project by clicking on the Collaborator tab in the Actions Toolbar.

Documents

6. When you come to a question in the form which has a blue ‘Upload Document’ button within the question, you can then upload the document associated with that section.

Clicking on the ‘Upload Document’ button will prompt you to upload your documents:
   I. Browse your computer for the document you wish to upload
   II. Provide a version date
   III. Provide a version number
   IV. Click ‘Upload’

   *NOTE: In some questions this will not appear until you are prompted by answering the question. Please be sure to work through the form in sequential order to ensure that no questions are missed.

Submitting and Signing

7. Once you have completed all of the required questions for your application you can then check to ensure that your project is complete by clicking the Completeness Check tile in
the Actions Toolbar.

8. If the application is complete you can then do one of the following:

   a) If you are the PI you can sign the application by clicking the blue Sign button on the last page of the application. You will be prompted to enter your Username and Password and click Sign.

   b) If you are not the PI you can request the signature of the PI by clicking the Request Signature button on the last page of the application. You will be prompted to enter the PI’s Email Address and click Sign.

   c) If you are a student and this is your project, you will have to request the signature of your Supervisor.

   *NOTE: Once all of the signatures have been signed the application is enabled to be automatically submitted.

Additional Information

1. **Comments** – any user who has access to the application forms can add comments to other users. To add a comment, click on the comment bubble icon at the top right hand corner of each question. These comments are only viewable to applicants, not the REB.

2. **Help Text** – some questions within MacREM have associated help texts. To view the help text click on (i) icon in the top right hand corner of each question.

3. **Previous / Next / Navigate** – these three tiles on the left hand side in the Actions Toolbar will navigate you through the project and auto-save when pressed.

4. **Mandatory Questions** – most questions are mandatory but entire sections are skipped depending on your Yes or No answers.

5. **Smart Form** – it is advised to work through the form in chronological order as it is a smart form and questions may appear or disappear depending on the answers you provide.

QuickGuide: Creating a Sub-Form

This QuickGuide outlines steps for creating a Sub-Form within MacREM.

1. A **Sub-Form** refers to the following:
   - Amendment Form
   - Annual Report Form
   - For Information Only Form
   - Program of Research
   - Reportable Events Form
   - Privacy Breach
- Study Participant Complaint
- Protocol Violation / Deviation
- Serious Adverse Events

There are also Sub-Forms for the transitional and temporary Transfer Basic Data to MacREM Form:
  - Transfer Amendment Form
  - Transfer Annual Report Form
  - Transfer Program of Research
  - Transfer Reportable Events / For Information Only Form
    - For Information Only
    - Privacy Breach
    - Study Participant Complaint
    - Protocol Violation / Deviation
    - Serious Adverse Events

2. Log into MacREM:  https://macrem.mcmaster.ca

3. Click on the project in the list of Projects at the bottom of the screen that you wish to create the sub-form for.

   ![Projects](https://example.com/Projects.png)

4. Make sure that the application you wish to update is highlighted in grey in the Project tree.

   ![Project Tree](https://example.com/Project_Tre.png)

5. Click on ‘Create Sub-form’ from the Actions Toolbar.
6. Select the Sub-Form that you wish to create from the drop down menu and click ‘Create’.

7. Complete the application and upload your documents (if applicable).

   *NOTE: In some questions the ‘Upload Document’ button will not appear until you prompt it by answering the question. Please be sure to work through the form in sequential order to ensure no questions or uploads are missed.

8. Sign and Submit

Once you have completed all of the required questions for your application you can check to ensure that your project is complete by clicking the Submit tile or the Completeness Check tile in the Actions Toolbar.

If the application is complete you can then do one of the following:
a. If you are the PI you can sign the application by clicking the blue Sign button on the last page of the application. You will be prompted to enter your Username and Password and click Sign.

b. If you are not the PI you can request the signature of the PI by clicking the Request Signature button on the last page of the application. You will be prompted to enter the PI’s Email Address and click Sign.

QuickGuide: Creating an Annual Report Sub-Form

This QuickGuide outlines steps for creating an Annual Report (or Transfer Annual Report) Sub-Form within MacREM.

1. A Sub-Form refers to the following:
   - Amendment
   - Annual Report
   - For Information Only
   - Program of Research
   - Reportable Events
     - Privacy Breach

McMasterREM (Researcher)
MacREM Applicant Training Manual (Version 3.0)
There are also Sub-Forms for the transitional and temporary Transfer Basic Data to MacREM application:

- Transfer Amendment
- Transfer Annual Report
- Transfer For Information Only
- Transfer Program of Research
- Transfer Reportable Events

- Privacy Breach
- Study Participant Complaint
- Protocol Violation / Deviation
- Serious Adverse Events

2. Log into MacREM: [https://macrem.mcmaster.ca](https://macrem.mcmaster.ca)

3. Click on the project in the list of Projects at the bottom of the screen that you wish to create the sub-form for.

4. Make sure that the application you wish to update is highlighted in grey in the Project tree.

5. Click on ‘Create Sub-form’ from the Actions Toolbar.
6. Select the **Annual Report** or **Transfer Annual Report** that you wish to create from the drop down menu and click ‘Create’.

![Create Sub-form](image)

- Please Select...
  - Amendment
  - Annual Report
  - For Information Only
  - Reportable Events
  - Program of Research

[Create]  [Close]
7. Complete the application. There are no upload documents for annual reports.

8. Sign and Submit

Once you have completed all of the required questions for your application you can check to ensure that you have answered them all by clicking the Completeness Check tile in the Actions Toolbar.

If the application is complete you can then do one of the following:

- If you are the PI or Supervisor, you can sign the application by clicking the blue Sign button on the last page of the application, which is enabled to submit once signed.
- If you are not the PI or Supervisor, you can request their signature by clicking the Request Signature button. You will be prompted to enter their Email Address. They must have a MacID and be already registered on MacREM.
1.27 Signature of Faculty Supervisor of Student Research

I certify that the information provided in this Annual Report is correct and that I continue to be bound by the terms of the assurance provided by me on the original application for research ethics approval.

You will receive a system notification and an automatic email acknowledging receipt of the report. Once processed by the Ethics Office you will receive a confirmation email if your research is renewed stating that you have active clearance for that project. If the research is complete, you will receive a notification through the system, and an email stating that it has been completed.

Questions?
T. 905-525-9140 ext. 23142
E. ethicsoffice@mcmaster.ca
QuickGuide: Creating an Amendment Sub-Form

This QuickGuide outlines steps for creating an Amendment (or Transfer Amendment) Sub-Form within MacREM.

1. A **Sub-Form** refers to the following:
   - Amendment
   - Annual Report
   - For Information Only
   - Program of Research
   - Reportable Events
     - Privacy Breach
     - Study Participant Complaint
     - Protocol Violation / Deviation
     - Serious Adverse Events

   There are also Sub-Forms for the transitional and temporary Transfer Basic Data to MacREM application:
   - Transfer Amendment
   - Transfer Annual Report
   - Transfer For Information Only
   - Transfer Program of Research
   - Transfer Reportable Events
     - Privacy Breach
     - Study Participant Complaint
     - Protocol Violation / Deviation
     - Serious Adverse Events

2. Log into MacREM:  [https://macrem.mcmaster.ca](https://macrem.mcmaster.ca)

3. Click on the project in the list of Projects at the bottom of the screen that you wish to create the amendment sub-form for.
4. Make sure that the application you wish to update is highlighted in grey in the **Project tree**. You can only create an Amendment after the original application has been cleared. You can only create one amendment at a time. You cannot create a second amendment until the first one has been cleared.

5. Click on 'Create Sub-form' from the **Actions Toolbar**.

6. Select the **Amendent or Transfer Amendment** that you wish to create from the drop down menu and click 'Create'.
7. Complete the application. If there are documents to upload you will be prompted only if the questions you select asked for uploads. Upload documents in PDF only.
8. The Amendment Checklist Questions

Check the box or boxes for the areas where you are making changes in the amendment. This will determine which pages you should answer later in the application. The next page after the checklist has existing questions shared from the original application.

1.7 Check if you are making changes to any of the following General Information:

☐ Yes
- Title
- Contact information
- Changes to Investigators
- Funding status
- Timelines
- Location of research
- Other REB review or clearances
- Level of Project
- Research Involving Indigenous Peoples
- Conflict of Interest

1.8 Check this box if you are making changes to any of the following like Project Description, Purpose, Recoding, Methodology and Incentives:

☐ Yes
- Project Description
- Participants
- Recruitment
- Methods to collect data
- Secondary use of data
- Experience of researchers
- Incentives or reimbursement
- Test instruments and interview guides
- Research database

9. Sign and Submit
Once you have completed all of the required questions for your application you can check to ensure that you have answered them all by clicking the Completeness Check tile in the Actions Toolbar.

If the application is complete you can then do one of the following:

   e. If you are the PI or Supervisor, you can sign the application by clicking the blue Sign button on the last page of the application, which is enabled to submit once signed.

   f. If you are not the PI or Supervisor, you can request their signature by clicking the Request Signature button. You will be prompted to enter their Email Address. They must have a MacID and be already registered on MacREM.

8.5 Signature of Faculty Supervisor of Student Research

I am the supervisor for this proposed student research and have read this ethics application and supporting documents and deem the project to be valid and worthwhile, and I will/continue to provide the necessary supervision of the student researcher(s) throughout the project including ensuring that the project will be conducted as cleared and to make myself available should problems arise during the course of the research.

This form is enabled to auto-submit after all signatures have been obtained.

Before signing, please make sure that all uploaded documents are in PDF format. If you have a unique document type that will not properly convert to PDF, please contact the ethics office for assistance.

After signing please check to make sure the green confirmation bar appears before logging out or closing your browser. If you do not receive email confirmation of the submission within 24 hours, please notify us at ethicsoffice@mcmaster.ca

You will receive a system notification and an automatic email acknowledging receipt of the amendment.

Questions?
T. 905-525-9140 ext. 23142
E. ethicsoffice@mcmaster.ca
QuickGuide: Creating a For Information Only Sub-Form

This QuickGuide outlines steps for creating a For Information Only (or Transfer For Information Only) Sub-Form within MacREM.

1. A **Sub-Form** refers to the following:
   - Amendment
   - Annual Report
   - For Information Only
   - Program of Research
   - Reportable Events
     - Privacy Breach
     - Study Participant Complaint
     - Protocol Violation / Deviation
     - Serious Adverse Events

   There are also continuing and ongoing Sub-Forms for the transitional and temporary Transfer Basic Data to MacREM application:
   - Transfer Amendment
   - Transfer Annual Report
   - Transfer For Information Only
   - Transfer Program of Research
   - Transfer Reportable Events
     - Privacy Breach
     - Study Participant Complaint
     - Protocol Violation / Deviation
     - Serious Adverse Events

2. Log into MacREM: [https://macrem.mcmaster.ca](https://macrem.mcmaster.ca)

3. Click on the project in the list of Projects at the bottom of the screen that you wish to create the amendment sub-form for.
4. Make sure that the application you wish to update is highlighted in grey in the **Project tree**. You can only create a For Information Only form after the original application has been cleared. However, unlike Amendment forms, you can create many For Information Only forms at a time. This will not always be necessary, but some larger research studies have such a need. These forms can also be submitted before the one of them is cleared.

5. Click on **Create Sub-form** from the **Actions Toolbar**.
6. Select the **Amendent or Transfer Amendment** that you wish to create from the drop down menu and click ‘Create’.

7. Complete the application. If there are documents to upload you will be prompted only if the questions you select asked for uploads. Upload documents in PDF only.
8. What qualifies as a For Information Only Application?

There is an explanation on the top of the form about what kinds of changes can be submitted on the For Information Only form as opposed to an Amendment form. If it is not clear, contact the Ethics Office.

For Information Only - -

Screening

If you are ONLY making administrative or other minor changes that do not substantively alter the currently approved protocol and documents, then you may be able to submit a For Information Only form to document the change, instead of an Amendment form. The For Information Only form is only reviewed by the Ethics Secretariat staff to confirm the change does not require an Amendment form and ethics review. If you are unsure which form to use, please contact ethicsoffice@mcmaster.ca or ext. 23142.

Some examples of changes that may only require a For Information Only form include:

- Change to study title
- Change to investigator information
- Update of funding status
- Location of research (in some cases)
- Reporting clearance from other REBs
- Change to level of project
- Notifying MREB of an update to an open-ended interview guide (in certain cases, see TCPS, Art. 10.5)
- Minor or administrative changes to the Letter of Information or other study documents (e.g. new contact information, changing wording for clarity or to address typos/grammar, removing a survey question)
9. Sign and Submit

Once you have completed all of the required questions for your application you can check to ensure that you have answered them all by clicking the Completeness Check tile in the Actions Toolbar.

If the application is complete you can then do one of the following:

- If you are the PI or Supervisor, you can sign the application by clicking the blue Sign button on the last page of the application, which is enabled to submit once signed.
- If you are not the PI or Supervisor, you can request their signature by clicking the Request Signature button. You will be prompted to enter their Email Address. They must have a MacID and be already registered on MacREM.

Submission Signatures

This form is enabled to auto-submit after all signatures have been obtained.

After signing please check to make sure the green confirmation bar appears before logging out or closing your browser. If you do not receive email confirmation of the submission within 24 hours, please notify us at ethicsoffice@mcmaster.ca

4.2 Signature of Faculty Supervisor of Student Research

I certify that the information provided in this For Information Only form is correct.

Request Signature  Sign

Supervisors will receive the signature request via an email from MacREM, but we recommend that you follow up personally with your supervisor to ensure they sign and the form is submitted.

You will receive a system notification and an automatic email acknowledging receipt of the For Information Only application.

Questions?
T. 905-525-9140 ext. 23142
E. ethicsoffice@mcmaster.ca
QuickGuide: How to Delete a Form

This QuickGuide outlines steps for a **Project Owner** and/or **Form Owner** to delete an unused form within a project.

*NOTE:* This excludes the main MREB Application Form as it has been submitted and cleared.

To delete a form:

1. Ensure the sub-form you wish to delete is highlighted as illustrated below (1); and determine the Project Owner and/or Form Owner by selecting the **Collaborators** tab (2):
2. Once determined you are the Project Owner and/or Form Owner, delete an unused form by selecting the form from the tree view and click the 'Delete Form' button in the Actions Toolbar.

3. Click the green ‘Delete’ button to permanently delete the form.

*NOTE: This action CANNOT be undone once finalized. Please ensure you are deleting the appropriate forms in your project.
QuickGuide: How to Find a Clearance Letter

This QuickGuide outlines steps for finding a clearance letter within MacREM.

To find a clearance letter:

1. Login to MacREM: https://macrem.mcmaster.ca

2. Click on the study from your Work Area, under ‘Project Title’

3. Ensure the application form for which you wish to find your clearance letter is highlighted, as illustrated below (1)

4. Click on the History tab (2)

5. Find the approval notification in the form history and click ‘Download’ (3)

*NOTE: You can also search for “Approved” in the search bar to narrow results
### Form History

<table>
<thead>
<tr>
<th>Date</th>
<th>User</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:06 PM</td>
<td>Review user</td>
<td>Notification received: You are cleared to begin your research. Here is your certificate of approval.</td>
</tr>
<tr>
<td>1:09 PM</td>
<td>Review user</td>
<td>Form status changed from MREB Cleared to Cleared</td>
</tr>
</tbody>
</table>
QuickGuide: How to Respond to Recommendations from the REB

This QuickGuide outlines steps for responding to comments from the REB within MacREM.

To respond to REB recommendations:

*NOTE:* There may be recommendations for changes by the Ethics Office and by the MREB Chair. The Ethics Office will ask for recommendations for example if your application is not complete when submitted. The MREB Chair will ask for changes based on the review outcome from reviewers on the board.

1. When you receive notification (by email and through your Notification tile in MacREM) from the REB requesting modifications you will need to submit your response.

2. Login using the link in the email (which will open the project if you are currently logged in) or go to MacREM: https://macrem.mcmaster.ca

**Responding to the Ethics Office Recommendations**

3. When receiving recommendations from the Ethics Office from the Notification tile, click on the notification you wish to address, it will read “Notification received: Application returned to Applicant”.

4. When prompted click ‘View Form’.

5. Locate the notification letter in the History tab
You can download the letter to read the comments from the Ethics Office. You should also review your application to see if there are any **Reviewer Comments** that you need to respond to. You can’t resubmit your application unless you make the required changes.

If you open the application and click on the review comments you can go directly to the panel where the comment was made. Alternatively you can navigate through the application to find the number in a blue bubble on the panel where the comment was made.

A feature of the software is that all changes that you make to comments will show up in Track Changes for the Chair to easily see. If you add new text, it will show up in green. If you delete text, it will appear in red with strike throughs. The Chair will be able to see any changes or new additions. Some of the changes that you will be requested to make are specific changes requested while others are more like responding to comments or concerns. When you have finished addressing the comments and making changes, submit your application again. You will have to obtain signatures once more.

**NOTE:** You could SHARE your application with the Ethics Office (with their permission) if you would like some initial consultation on the completeness of your application. Please contact the ethics office at ethicsoffice@mcmaster.ca or ext. 23142 for more information. The Ethics staff can also remotely connect with your application to walk you through the process.

**Responding to the MREB Chair Recommendations**
6. You will receive an email with attached PDF letter and a notification when changes are requested following the review process. The review letter can also be accessed by clicking on the Notification or looking in the History tab of the project.

The Chair will be notified when you have responded or made revisions.

Question 1.4 asks if you are creating an Initial Submission or Responding to MREB Recommendations. In MacREM version V.04 this is a mandatory question when responding to the MREB concerns and review. You will be asked to upload a PDF document with responses to the Chairs’ concerns clearly outlined. Instructions on how to respond to comments are as follows:

**Steps to Respond to MREB Comments**

1) **Revise the MREB Form**

- Refer to reviewer comments in the PDF sent via email by the Chair.
- Navigate to applicable questions within the online form and make the revisions.
- Edits to the main form should be made within the online interface so the system can track the changes (as opposed to making changes in a Word document and then pasting back into MacREM).

2) **Revise Supporting Documents if Required (e.g. Letter of Information, Questionnaire, etc.)**

- Use grey highlighting or track changes so the Chair can easily see revisions.
- Upload a PDF version of the revised document(s), with a new version number, to the appropriate question within the application.
- Delete the old version of the document(s) from the application.

3) **Summarize the Revisions for the Chair**

- Create a document that lists each reviewer comment (and question number), along with your response to the comment. You may want to copy the questions and comments from the Chair’s PDF letter.
- In many cases the response may simply refer to changes made within the online application, (e.g. “Revised the consent process, see changes in 15.1”).
- Use italics, or some other visible formatting, to distinguish your response from the reviewer comments.
- Any changes you make to the application that are in addition to responding to reviewer comments should be explained in the document as well.
- Refer to the Sample Summary of Revisions document if needed (See Help/Templates in the top menu).
- Upload the summary of revisions document below.
*** Once everything is done you can sign the form to resubmit to the Chair ***

Following the above steps will make it easier, and therefore faster, for the Chair to review the revisions. A more comprehensive guide to responding to reviewer comments using MacREM is available (See MacREM Quick Guide Respond to REB in Help/Templates).

If you think it will be insufficient to use the summary document to address a concern you have with a specific reviewer comment, and that a discussion with the Chair may be necessary, please directly contact the reviewing Chair via email or phone.

----- End of Instructions ----

When you send a document through this question, the attachment will stick to this question for downloading, but it can also be found in the History list. The attachment should be in PDF format.

7. Sample Summary of Revisions Document

In top Menu of MacREM in Help/Templates there is a sample document on how to respond to the MREB comments.

8. Receiving Clearance

If your response is satisfactory, you will receive an email and letter of clearance which means you can start your research. The “official” letter of clearance will arrive later sent by the Ethics Office, once they have set an expiry date for annual reporting purposes. Both documents will be saved in your project.

If your response still requires more clarification, the Chair will return it to you again with additional comments. You will need to sign the application again to resubmit it.
QuickGuide: How to Sign an Application

This QuickGuide outlines steps for signing an application form when you have received an email or notification for a signature request.

*NOTE: This guide can be used for Principal Investigators or Faculty Supervisors

To sign an application:

1. Locate the application by logging into MacREM: https://macrem.mcmaster.ca

2. Click on the ‘Signature’ tile in the Work Area

3. From the list, find the signature request with the status ‘Requested’ and click ‘View Form.’ This will take you to the application form you have been asked to sign.
4. After you have reviewed the application, click the ‘Sign’ button in the Actions Toolbar (illustrated below).

- Enter your username (full email address – you need MacID authorization to do this) and password into the pop-up window, and press the green ‘Sign’ button to sign-off on the application.

*NOTE: although there is a ‘Sign’ button on the last page of the application, this will be disabled and you will not be able to sign the form.

*NOTE: a signature request can also be rejected by clicking the Reject tile. You will be presented with an entry dialog box where you can begin entering your username and password.

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**QuickGuide: How to Submit an Application – Auto-Submit Enabled**

This QuickGuide outlines steps for submitting an application form when Auto-Submit is enabled.

*NOTE: This guide can be used for whomever has permission to submit an application on MacREM.

To Submit an application with Auto-Submit Enabled by the system:

1. When Auto-Submit is enabled, a Submit button does not appear in the Navigation area.

2. Signatures must first be obtained before the application can be submitted. A Principal Investigator has only one signature to be obtained. The application will automatically submit after entering your
If the Supervisor and the Student Principal Investigator need to sign, the application will automatically be submitted once the last signature is obtained. Typically, a student will sign first for themselves then request a signature from their Supervisor. Supervisors need a MacID email address and then must have logged into MacREM at least once in advance of the request to be recognized by the system for signing purposes.

8.5 Signature of Faculty Supervisor of Student Research

I am the supervisor for this proposed student research and have read this ethics application and supporting documents and deem the project to be valid and worthwhile, and I will /continue to provide the necessary supervision of the student researcher(s) throughout the project including ensuring that the project will be conducted as cleared and to make myself available should problems arise during the course of the research.

3. Open the project or sub-form (amendment, annual report etc..) that needs to be signed.
4. Complete the application to the last section on Researcher Assurances. Signatures and signature requests can later be found in the Signature tab of the project.

5. If you share an application with Collaborators, you can give them a permission to Submit forms. Without that permission, only the applicant or Project Owner – the person who created the form - can submit the application. Once the form is signed, it is locked into the system. You can make no further changes unless it is returned to you by the Ethics Office. You should always receive some form of notification that you have submitted your form successfully after signing, by form messages, notifications, or emails.
6. Since there is no submit button to click after signing the application, there is no waiting around after signing. You may only need to wait for someone you requested to sign. You can send them more requests or reminders.

**QuickGuide: Transfer and Duplicate Sub-forms**

This QuickGuide outlines steps for transferring or duplicating sub-forms on MacREM.

Applicants can transfer applications to other registered users on the MacREM system. **Transferring completely removes the protocol from the transferrer.** Duplicate copies of applications can also be made. This duplicates the data and questions, but not the document attachments.

A new vendor release now allows applicants to transfer individual sub-forms, such as amendments, for information only, annual reports and program of research. Duplicates of sub-forms can now also be made.

Examples of this use:
- **A)** Research Assistant created an amendment but not the original application. RA leaves their position but transfers the amendment to the new RA
- **B)** Researcher makes a duplicate of an amendment in order to reuse the data and questions for a new amendment. The new amendment will have modifications to previous questions
- **C)** A student is creating the third amendment on a project but was not involved in the first and second amendment. The previous students involved in the first and second amendment, who are no longer involved in the project, transfer the amendments to the new student for reference.

You will see the Duplicate Form and Transfer Form tiles when you open a project:
Duplicate Form

Duplicate the current sub form with data.

Number of duplicates required: 1

Warning! This process can take a while.

Duplicate Close
Questions?
T. 905-525-9140 ext. 23142
E. ethicsoffice@mcmaster.ca