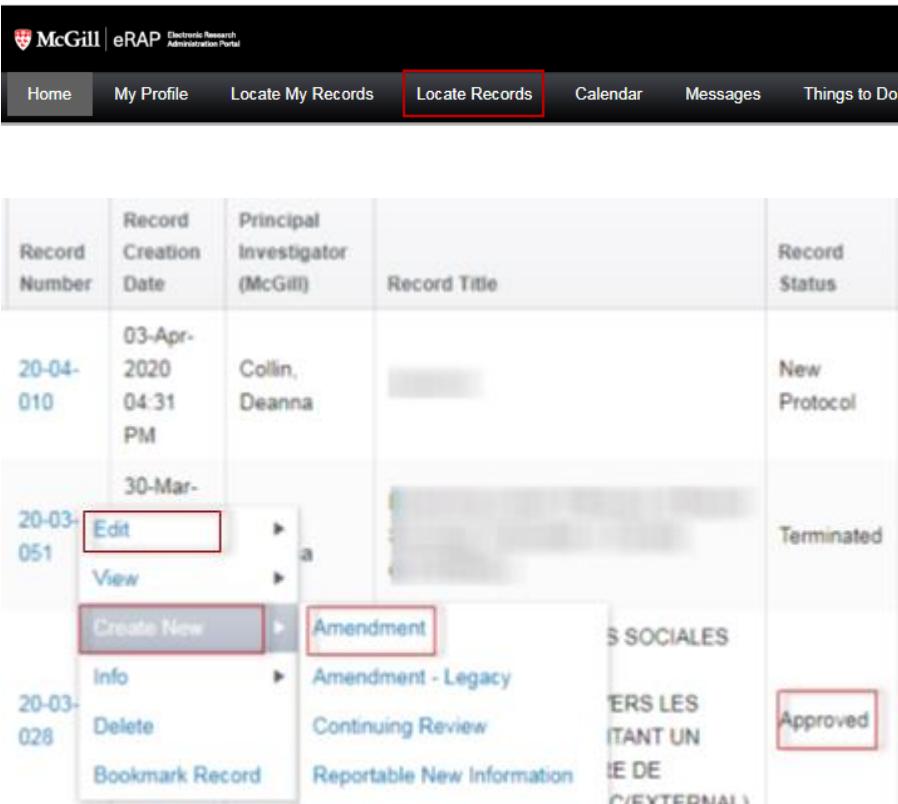


How to Create and Submit an Amendment – for RA creating on behalf of Faculty PI

Note: ensure that the popup blocker is disabled for this URL (see FAQ for help)

IMPORTANT -Select **Amendment** option **only** if the initial application was submitted through eRAP, using the eRAP application form. If you used the pre-eRAP Word application version, you must use the **Amendment-Legacy** form.

<p>Login to eRAP https://infoed.is.mcgill.ca .</p> <ol style="list-style-type: none">1. Click Locate Records and apply filters as needed to locate the protocol which will be amended.2. Protocols on which you have edit access will display. Find and hover over the Record Number of the protocol that requires an amendment.3. Note: Record Status should display as 'Approved'. Only approved protocols may be amended.4. A-If the PI has already created the new amendment for you to complete, select 'Edit' from the flyout menu. B-If you, and not the PI, will start the amendment, select 'Create New' from the flyout menu. In either of these scenarios, a new, second flyout menu will appear.5. Select 'Amendment (date created, new protocol) for situation A, or 'Amendment' for situation B	 <p>The screenshot shows the McGill eRAP interface. At the top, there is a navigation bar with the following items: Home, My Profile, Locate My Records, Locate Records (highlighted with a red box), Calendar, Messages, and Things to Do. Below the navigation bar is a table of records. The table has columns for Record Number, Record Creation Date, Principal Investigator (McGill), Record Title, and Record Status. The records shown are:</p> <table border="1"><thead><tr><th>Record Number</th><th>Record Creation Date</th><th>Principal Investigator (McGill)</th><th>Record Title</th><th>Record Status</th></tr></thead><tbody><tr><td>20-04-010</td><td>03-Apr-2020 04:31 PM</td><td>Collin, Deanna</td><td>[Redacted]</td><td>New Protocol</td></tr><tr><td>20-03-051</td><td>30-Mar-</td><td>[Redacted]</td><td>[Redacted]</td><td>Terminated</td></tr><tr><td>20-03-028</td><td></td><td></td><td></td><td>Approved</td></tr></tbody></table> <p>A flyout menu is open for record 20-03-051, showing the following options: Edit (highlighted with a red box), View, Create New (highlighted with a red box), Info, Delete, and Bookmark Record. A secondary flyout menu is open for the 'Create New' option, showing the following options: Amendment (highlighted with a red box), Amendment - Legacy, Continuing Review, and Reportable New Information. The 'Approved' status of record 20-03-028 is also highlighted with a red box.</p>	Record Number	Record Creation Date	Principal Investigator (McGill)	Record Title	Record Status	20-04-010	03-Apr-2020 04:31 PM	Collin, Deanna	[Redacted]	New Protocol	20-03-051	30-Mar-	[Redacted]	[Redacted]	Terminated	20-03-028				Approved
Record Number	Record Creation Date	Principal Investigator (McGill)	Record Title	Record Status																	
20-04-010	03-Apr-2020 04:31 PM	Collin, Deanna	[Redacted]	New Protocol																	
20-03-051	30-Mar-	[Redacted]	[Redacted]	Terminated																	
20-03-028				Approved																	
<p>NOTE:</p> <ol style="list-style-type: none">a. If the amendment form does not appear in a new window, it is because of the popup issue. Do not create another new continuing review. It has been created. You can access it by hovering over the Record Number and clicking Edit and Amendment (new protocol) from the flyout menu.b. Be sure to disable popup blockers for this																					

6. The Ethics Submission screen displays. You will be on the **Instructions** page.

Note: these instructions do not apply to the amendment; they apply to an initial application. Please ignore.

McGill

Close Print Form History Save Submit Locked Validate

Ethics Submission Updated By: Bruce Wayne 28-Apr-2021 09:32:00 AM Next

Instructions

INSTRUCTIONS

Welcome to the McGill Electronic Research Administration Portal (eRAP). Please read the following brief instructions before proceeding to fill out the application.

1. Save your work as you proceed through each section.
2. You MUST first complete the General Information page. Your response to the questions here determines the Research Ethics Board that will review your study, and the application form that you will complete.

If you are unsure of how to respond, contact the relevant REB office listed at the bottom of this page BEFORE filling out the rest of the form. Submitting to the wrong ethics office will result in your submission not being accepted and it will be sent back to you.

Note - The study title is automatically populated. You MUST change this to the correct study title.
3. Identify all uploaded documents such as advertisements, consent forms, assent forms, surveys, questionnaires etc. with a clear filename description and version date e.g. Survey Consent Form --version1 July-24-2019
4. To submit you must first check the Locked box. This will save the form and verifies all mandatory questions have been answered. If a message appears indicating the form is incomplete, provide the missing information. Once completed, you will get a "Form Complete Successful" message.
5. The last step is to then click on the "Submit" button.

The detailed user guides for submissions to the Faculty of Medicine and Health Sciences ethics office can be found [here](#).

The detailed user guides for submissions to the Research Ethics Board Office (REBs-1,2,3,4) can be found [here](#).

7. From the menu on the left, click **Amendment**. The new amendment form opens in a new window.
8. If you do not see the **Amendment** tab, unlock the protocol by unchecking the **Locked** field. Once unlocked, the **Amendment** tab will appear in the left menu.
9. The first step is to complete the Amendment form which summarizes the changes to be made.
For question 4- this is only to **list** the documents for which new versions are being supplied. The revised documents must be uploaded in the application itself. **Note** that you must delete the current versions which are being revised, and then add the revised documents.
10. Based on your described amendments, revise all the relevant sections of the initial application from the menu on the left. You must **delete** (not strike through or highlight) all existing content that will no longer apply, as well as adding the new content.

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Close Print Form History Save Submit Locked Validate

Ethics Submission Updated By: Bruce Wayne 21-Nov-2021 02:46:16 PM Next

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Amendment

AMENDMENT

Amendment Submission Form - This is only to be used if the initial application was submitted through eRAP.

Proposed changes/updates to a currently approved study must be approved by the REB before implementation. Modifications to studies should be changes within the scope of the original study, not new studies that are simply related to the original study. Significant or numerous changes to study methods, participant populations, location of research, the research question or where the amendment will change the overall purpose or objective of the originally approved study, will require the submission of a new application.

Unlock form to make changes.

Ready to submit? **New Amendment submission** - Lock and click submit to forward to the REB Office/ to the faculty supervisor if a student PI.
Responding to a modification request Click on My Assignments and follow instructions.

These four questions only provide a summary of the proposed amendment. The main application must then be edited with the detailed changes entered directly in the relevant sections of the application.

- * 1. Indicate the section where the change is, describe the nature of the each of the proposed changes and explain why they are needed.
 Recruitment:
 Consent Process:
- * 2. Will the amendment change the risks or potential benefits to participants?
 Yes No
- * 3. Will any follow up actions be required with participants already enrolled in the study?
 Yes No
- * 4. List all new and revised documents that will be uploaded in the relevant section of the application form. Identify each one by name and version date - e.g. Consent form(survey)-version 2-April-30-2021. Poster-version 1 -May-01-2021. Revisions must be highlighted or use track changes. Remember to remove old versions before adding revised versions. If no documents will be uploaded, indicate N/A in the text box below.

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The content in each section must reflect the study as it will now be conducted.
Note: There is no need to highlight deletions or additions made in each section. The REB will use **Form History** to compare (see FAQ to see instructions for how to do this yourself).

- If you are changing existing uploaded documents, you **must** remove the current version of the documents being revised and replace with a new version.
- Click **Save**. If there are mandatory questions that you have not filled in, a pop-up appears. Clicking on the question will bring you to that section. Fill in the question and click **Save** again

There are now 2 options.

- You can contact the PI and let them know the form is ready to submit(recommended).They access the form by hovering over the record number, select **Edit**, then **Amendment-new protocol**, review, make any changes, and select 'I am the PI' and submit to the REB.

If the RA chooses to submit the amendment to the PI for approval through eRAP, click **Submission Approval**, click on the down-arrow and select "I am not the PI".

Click **Save**

- Check the **Locked** field.
- Click **Submit**.

You will get an email indicating that your amendment application has been submitted to the faculty PI. The faculty PI will review it, make further changes if needed, and send it to the REB Office.

Once the REB Office receives the amendment it will be reviewed, and the PI and RA will be notified:

- That the amendment has been approved.
Or
- That modifications/clarifications are required.

The screenshot shows the McGill Ethics Submission interface. At the top, the McGill logo is on the left, and navigation buttons (Close, Print, Form History, Save, Submit, Locked, Update) are on the right. The page title is 'Ethics Submission' and it shows 'Updated by Bruce Wayne 28-Apr-2021 10:10:01 AM'. A red sidebar on the left contains a list of sections: Instructions, Amendment, General Information, Access to Full Application, Research Personnel, Funding and Other, Reviews, Study Information, Recruitment, Consent Process, Risk / Benefit Assessment, Confidentiality & Data, Security, Conflict of Interest, Additional Documentation, Submission Approval, and All Pages. The 'Submission Approval' section is highlighted. The main content area is titled 'SUBMISSION APPROVAL' and contains a declaration from the PI. A dropdown menu is open, showing 'I am not the PI' as the selected option. A red arrow points to this dropdown menu.

