

How to Create and Submit an Amendment – for Faculty PI

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

Note: ensure that the popup blocker is disabled for this URL.

Login to eRAP (<https://infoed.is.mcgill.ca>).

1. Click **Locate My Records**. You can also click **Locate Records** to filter selections for those with a large amount of records. The **Quick Find** box can also be used entering either record number, study title, PI name.

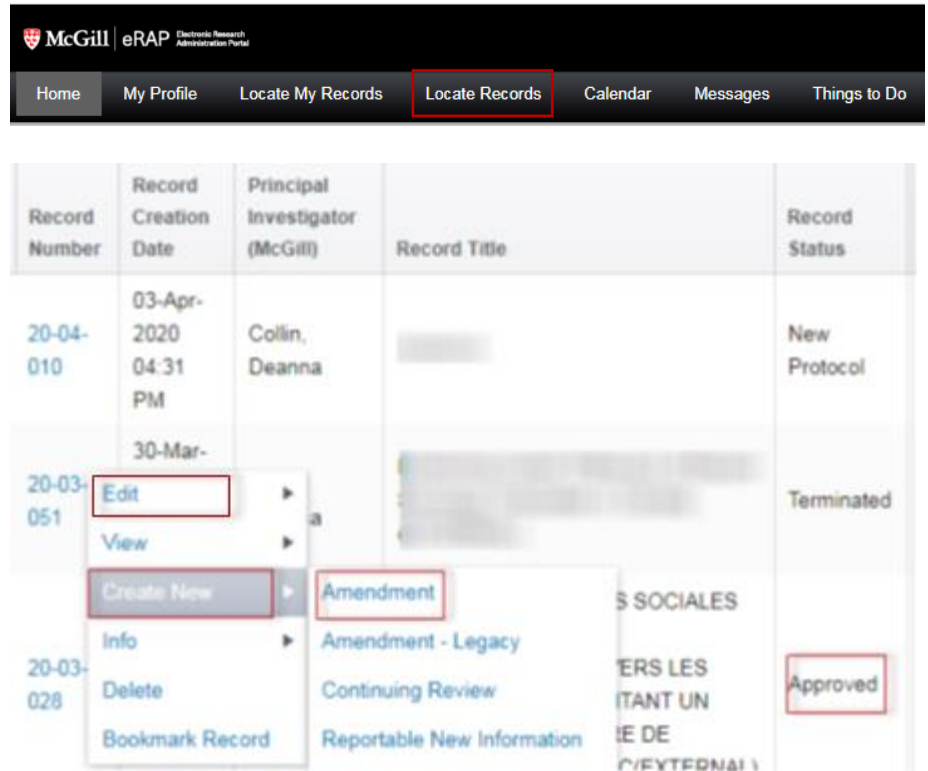
2. Hover over the record number and select **'Create New'** from the flyout menu.
Note: Record Status should display as 'Approved'. An amendment can only be submitted if the initial application has received final approval.

3. Click **'Amendment'** from the second flyout menu. The amendment form opens. If an RA has already started an amendment for you, you will select **'Edit'** and **'Amendment (dat new protocol.'**

 **NOTE:**

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.

Be sure to disable popup blockers for this URL



The screenshot shows the McGill eRAP interface. The top navigation bar includes '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 with the following columns: Record Number, Record Creation Date, Principal Investigator (McGill), Record Title, and Record Status.

| Record Number | Record Creation Date | Principal Investigator (McGill) | Record Title | Record Status |
|---------------|----------------------|---------------------------------|--------------|---------------|
| 20-04-010 | 03-Apr-2020 04:31 PM | Collin, Deanna | | New Protocol |
| 20-03-051 | 30-Mar- | | | Terminated |
| 20-03-028 | | | | Approved |

A flyout menu is open for record 20-03-051, showing options: Edit (highlighted with a red box), View, Create New (highlighted with a red box), Info, Delete, and Bookmark Record. A second flyout menu is open for 'Create New', showing options: Amendment (highlighted with a red box), Amendment - Legacy, Continuing Review, and Reportable New Information.

4. 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.

5. From the menu on the left, click **Amendment**. The amendment form opens in a new window.

6. 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.

7. 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 in the relevant sections. Note that you **must delete** the current approved versions and then add the additional or revised documents.

8. Based on your described amendments in Question 1, revise all the relevant sections of the initial application from the Tab-Section Menu on the left. You must **delete** (not strike through or highlight) all existing content that will no longer apply, as well indicating new content. New content does not need to be highlighted. 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 the current approved protocol to

the proposed revised protocol. You can also use Form History to compare for yourself.

9.If you are changing existing uploaded documents, you **must** remove the current version of the documents and replace with a new version.

10.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.

11.In the **SUBMISSION APPROVAL** section, click on the down-arrow to select "I am the PI".

13. Check the **Locked** field.

14. Click **Submit**.

You will receive an email indicating that your Amendment request has been submitted to the REB Office.

SUBMISSION APPROVAL

Submission Approval

As the Principal Investigator (PI) of this study, I confirm that I have reviewed the McGill University Policy on the Ethical Conduct of Research Involving Human Participants, and I agree to comply with this and any other relevant University policies, as well as the Tri-Council Policy Statement Ethical Conduct of Research Involving Humans (TCPS2), and those of my profession or discipline regarding the ethical conduct of research.

I have read and approved the content of this application.
I allow release of my nominative information as required by these policies and procedures.

* Select the appropriate response below:

I am not the PI
I am the PI and have read the above and agree to serve as the PI with the above obligations