

How to Create and Submit an Amendment – for student 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**. 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.

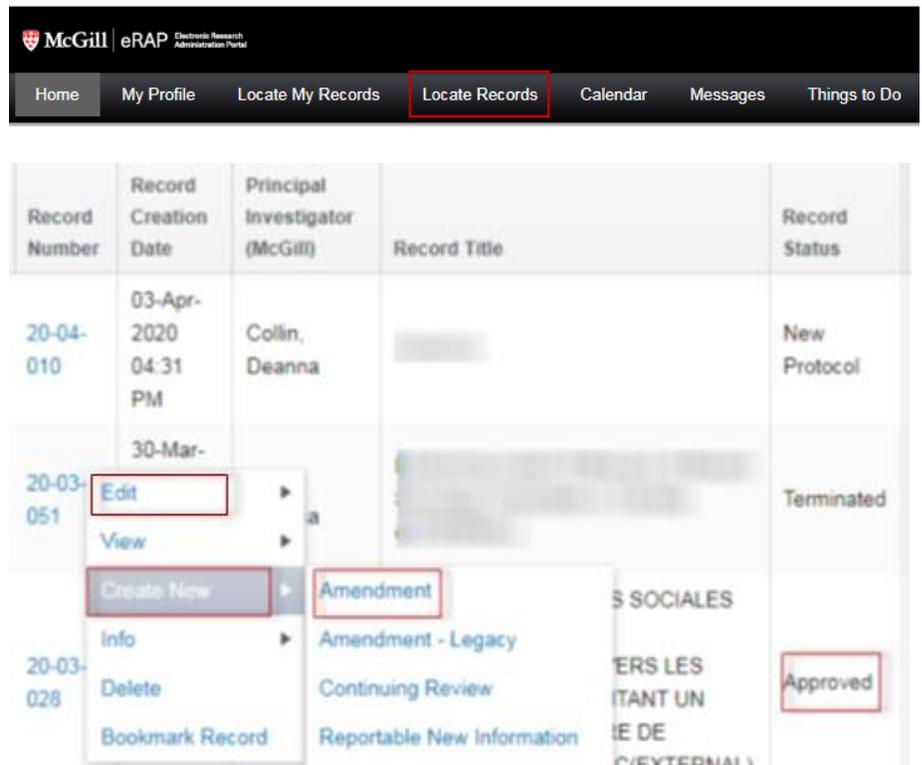
Note: Record Status should display as 'Approved'. An amendment can only be submitted if the initial application has received final approval.

3. Click **'Amendment'** from the second flyout menu. The amendment form opens.

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 columns: Record Number, Record Creation Date, Principal Investigator (McGill), Record Title, and Record Status. The table contains three rows of records. The second row, with record number 20-03-051, has a flyout menu open over it. The flyout menu includes 'Edit' (highlighted with a red box), 'View', 'Create New' (highlighted with a red box), 'Info', 'Delete', and 'Bookmark Record'. The 'Create New' sub-menu is open, showing options: 'Amendment' (highlighted with a red box), 'Amendment - Legacy', 'Continuing Review', and 'Reportable New Information'. The 'Record Status' for this record is 'Terminated'. The third row, with record number 20-03-028, has a status of 'Approved' (highlighted with a red box).

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

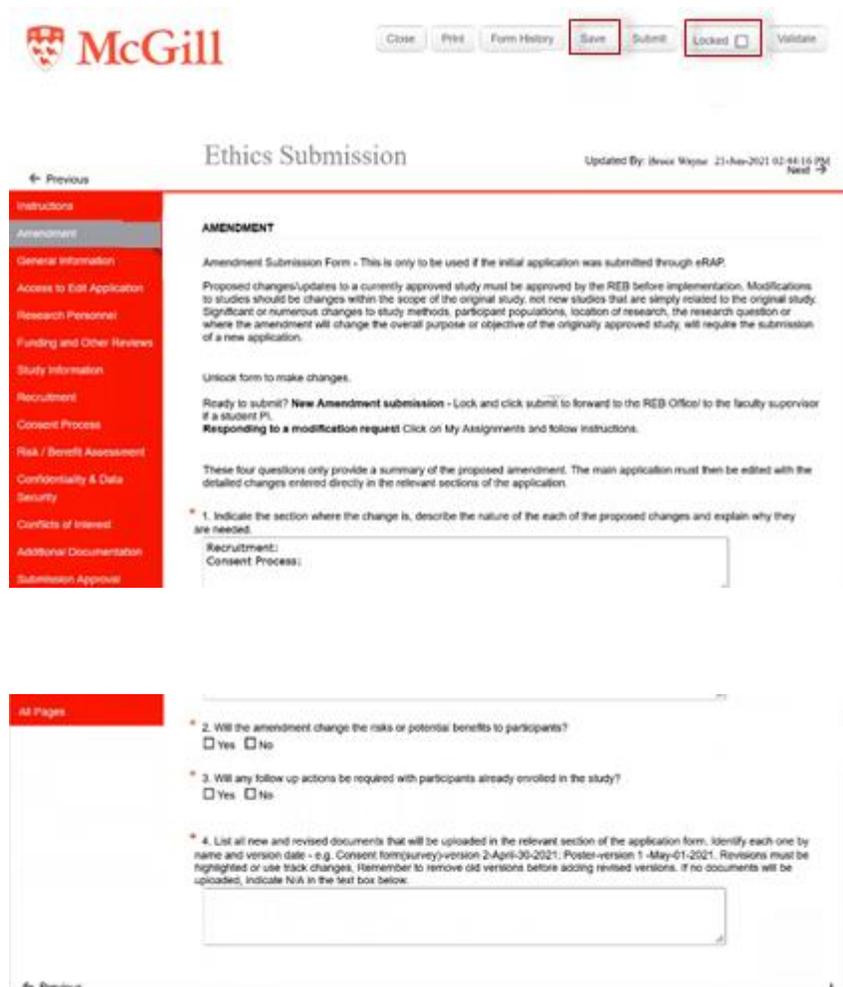
4. The Ethics Submission screen displays. You will be on the **Instructions** page.

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 main 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 the amendment request has been sent to your supervisor for approval. The supervisor has to then advance it to the REB for review.

They may decide changes are needed before sending to the REB. They may communicate the required revisions to you and the application stays with the supervisor in eRAP, but you can still go in, do the edits and then let them know it has been completed. The supervisor will then advance the submission to the REB.

They can also return the amendment to you through eRAP. You will receive an email "Student Modifications Required". Once you have made the required revisions (they will communicate these to you directly, you will need to send it back to your supervisor. Click on "My Assignments" tab and click "I am Done".

Once the REB Office receives the amendment it will be reviewed and you will be notified:

o That the amendment has been approved.

Or

That modifications/clarifications are required

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

