

## How to Create and Submit Legacy Amendments- for RA creating on behalf of faculty PI

**Important** – A legacy amendment is to be used if the initial ethics application was submitted prior to the launch of eRAP (the initial application was not created in eRAP, using the electronic eRAP application).

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

To amend studies created before eRAP, the following steps are required. Note that you will have to fill out the legacy amendment form and upload the required documents.

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

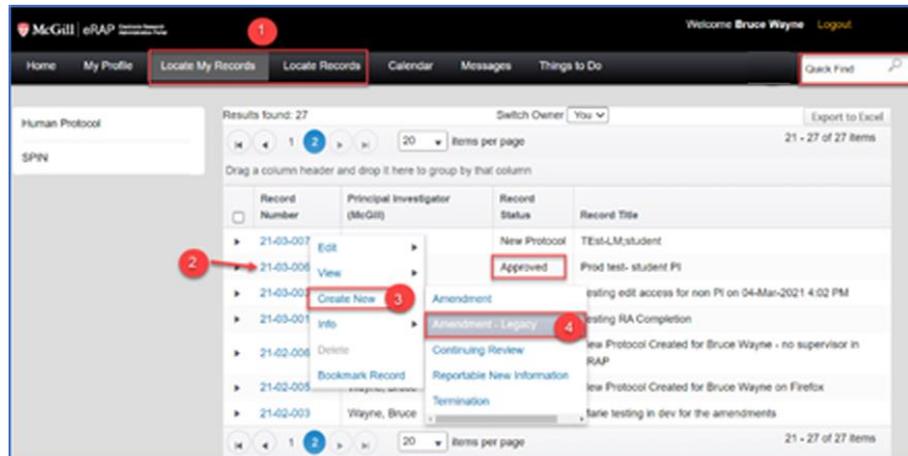
1. Click **Locate Records** tab, applying filters as needed- (file number, title, etc.) **Note** that you must be listed as having edit access on the application in order to create an amendment or even for the record to appear.
2. Find and hover over the desired Record Number of the protocol to be amended. **Note:** Record Status should display as 'Approved'. Only approved applications may be amended.
3. Select '**Create New**' from the flyout menu.
4. Click **Amendment – Legacy** from the second flyout menu. The legacy amendment form opens in a new window.

### **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-Legacy-new protocol** from the flyout menu.

Be sure to disable popup blockers for this URL

5. The **Locked** field must be unchecked.
6. Complete the form providing detailed information on the proposed revisions.
7. Fields with an asterisk are mandatory.
8. Click **Add New** on the amendment form to upload any revised appendices. Give each upload a descriptive file name e.g. 'Interview consent form dd/mm/yyyy'. If there are no documents to upload, write N/A in the text box. Click **Save**.



There are now 2 options.

9. You can inform the PI that the form is ready to submit (**recommended**). They can access the form by hovering over the record number, select **Edit**, then **Amendment Legacy-new protocol**, review, make any changes and they 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".

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 missing information.

11. Check the **Locked** field.
12. 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 and send it to the REB Office.

\* REB File # 21-06-004

\* 1. Please describe in detail each of the proposed changes and how these differ from currently approved procedures. Explain why the modifications are needed.

\* 2. Will any follow up actions be required with participants already enrolled in the study(e.g. re-consent)?

Yes  No

\* 3. Will the modifications change the risks or potential benefits to participants?

Yes  No

\* 4. In the text box below, identify all new and revised documents and then attach using the Add New button e.g. consent/assent forms; recruitment documentation; study measures. Identify each one by name and version date e.g. Consent form(survey)-version 2-April-30-2021; Poster-version 1-4-May-01-2021. Changes must be highlighted or track changed on revised documents. If there are no files to upload, indicate N/A in the box below.

Add New

File Upload: 

File Name:

Remove

## 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

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