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 (<u>https://infoed.is.mcgill.ca</u>). | # MeC | | warch | | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------------------------------------------|--------------------------------------------|----------------------------------------------------------------|-----------------------------------------------------------|------------------|
| 1.Click Locate My Records. . The Quick Find box can also be used entering either record number, study title, PI name. | Home | My Profile | Locate My Records | Locate Records | Calendar Message | s Things to Do |
| 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. | Record | 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- Edit |] <u>}</u> a | | | Terminated |
| 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 | 20-03- 028 | Create New Info Delete Bookmark Re | Amend Amend Continue ecord Report | Iment Iment - Legacy uing Review able New Information | S SOCIALES ERS LES ITANT UN IE DE C/EXTERNALI | Approved |

McGill University Research and Innovation | Ethics and Compliance

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.

| | Ethics Submission | Updated By: Brace Wayne 28-Aps-2021 09:32:00 Aps Next 1 | | | |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| ndment | INSTRUCTIONS | | | | |
| ral information In to Edit Application | Welcome to the McGill Electronic Research Administr instructions before proceeding to fill out the applicatio | ation Portal (eRAP). Please read the following brief n. | | | |
| arch Personnel | 1. Save your work as you proceed through each section. | | | | |
| ng and Other | 2 You MUST first complete the General information page. Board that will review your study, and the application for | four response to the questions here determines the Research Ethics in that you will complete. | | | |
| Information | If you are unsure of how to respond, contact the relevant REB office listed at the bottom of this page BEFORE filling out the reat 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. | | | | |
| Arount | Note - The study title is automatically populated. You MU | ST change this to the correct study title. | | | |
| ant Process | Identify all upbaded 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 | | | | |
| denilality & Data | To submit you must first check the Locked box. This will answered, if a message appears indicating the form is in get a "Form Complete Successful" message. | save the form and verifies all mandatory questions have been complete, provide the missing information. Once completed, you will | | | |
| icts of Interest | 5. The last step is to then click on the "Submit" button. | | | | |
| onal Documentation | The detailed user outles for submissions to the Faculty of Madicine and Health Sciences athirs office can be found here | | | | |
| nsion Approval | The detailed user suides for submissions to the Research | h Ethics Board Office (REBs. 1.2.3.4) can be found have | | | |
| | | | | | |

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

| | Ethics Submission |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Previous | DUITOS CONDITISSION Operated by these weps 21-ten-Jul 0.54(10.0) Next -9 |
| itructions | |
| eronant | AMENDMENT |
| neral information | Amendment Submission Form - This is only to be used if the initial application was submitted through eRAP. |
| cess to Edit Application | Proposed changes/updates to a currently approved study must be approved by the REB before implementation. Modifications |
| exarch Personnel | 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 |
| nding and Other Haviews | where the amendment will change the overall purpose or objective of the originally approved study, will regulae the submission of a new application. |
| aty information | |
| cruitment | Unlock form to make changes. |
| reset Process | Hearty to submit? New Amendment submittation - Lock and close submit to forward to the HEB Office to the faculty supervisor if a student PI. |
| A / Deverts Assessment | Responding to a modelication requires take on by Assignments and token instructions. |
| enformating & Data | 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. |
| enflicts of trainingt | * 1. Indicate the section where the change is, describe the nature of the each of the proposed changes and explain why they |
| attuna Documentation | Recruitment: Consent Process: |
| | |
| Pages | 2. Will the amendment change the risks or potential benefits to participants? |
| | Times INO |
| | * 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 2/4pri-30-2021. Poster-version 1-May-01-2021. Revealers must be highlighted or use track changes, literative to remove did versions before adding revised versions. If no documents will be uploaded, indicate N/s in the value to be takey. |
| | |
| | |
| | |

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: • 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