

How to revise and resubmit an application in response to a request for modifications from the REB -for RA making modifications on behalf of a Faculty PI

The PI and anyone indicated to be cc'd on communications, will receive an email indicating modifications are required. If you are an RA with edit access to this protocol you will be able to access the application to draft any revisions.

Next Steps:

1. Log in to eRAP (<https://infoed.is.mcgill.ca>) with your McGill username and McGill password.
2. Locate the record using **Locate Records** tab. Search by Human Protocol, and PI name, file number, and/or title.
3. Items requiring an action will be listed. Look for "Pre-Review Modifications" or "Modifications Required". Click on the record link to open the application.
4. The Initial Application will appear. Click the check box next to "Locked" to unlock the application. You can now make revisions as indicated in the email from the REB.

Click to unlock



Revisions must be made directly in the section of the application as indicated in the REB comments. To add a general comment that doesn't belong to any specific section you can create and add it as an upload at the end of the application in the tab section 'Additional Documents'.

Note 1: For revisions to information in text boxes, new text can be added and previous text can be deleted. There is no need to indicate what the revised text is. This can be seen when looking at the Form History function. This function will allow you to compare versions before submitting the revised clean version to the REB.

Note 2: If you need to upload revised documents, you **MUST first delete the old one** from the application.

5. You can click Form History at the top of the form to compare versions. A window similar to the following will appear:

Initial Application

COMPLETED ON	COMPLETED BY	SUBMISSION NUMBER	SIGNATURE SUBMISSION TYPE	VIEW	COMPARE FROM TO
19-Jun-2019 10:55:49 AM					<input checked="" type="radio"/> <input type="radio"/>
19-Jun-2019 11:13:22 AM					<input type="radio"/> <input checked="" type="radio"/>
				Go	

Example 1: In this example, clarifying text has been added in the revised application and is indicated in blue.

CONFLICTS OF INTEREST

1. Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits, financial or otherwise (outside of expected standard salary/conference expenses) directly related to this study?
No

2. Are there any restrictions regarding access to or disclosure of information (during or at the end of the study) that have been placed on the researcher(s) including any publication restrictions by any third parties.
No

3. Does any member of the research team have a dual role or any other relationship, financial or non-financial, that may be, or could be seen to be, a conflict of interest in relation to the study participants or any aspect of the research (e.g. teaching or clinical relationship, family member, supervisory relationship)?
No

ADDITIONAL DOCUMENTATION

Are there any other issues or information that need to be considered by the Research Ethics Board in the review of this application?
No

Please upload any additional documentation relevant to the study. If more than one, upload as separate documents, identifying by title and version date in file name and on each document.

CONFLICTS OF INTEREST

1. Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits, financial or otherwise (outside of expected standard salary/conference expenses) directly related to this study?
Yes

1a. Please describe:
Submit a Research Ethics Application Submit a Research Ethics Application Submit a Research Ethics Application

2. Are there any restrictions regarding access to or disclosure of information (during or at the end of the study) that have been placed on the researcher(s) including any publication restrictions by any third parties.
Yes

2a. Please describe:
Submit a Research Ethics Application Submit a Research Ethics Application Submit a Research Ethics Application

3. Does any member of the research team have a dual role or any other relationship, financial or non-financial, that may be, or could be seen to be, a conflict of interest in relation to the study participants or any aspect of the research (e.g. teaching or clinical relationship, family member, supervisory relationship)?
Yes

3a. Please describe and address how these conflicts will be managed.
Submit a Research Ethics Application Submit a Research Ethics Application Submit a Research Ethics Application

Example 2: In this example, the content of the original application has been removed and is highlighted in red. The new content stays highlighted in blue. The deleted content does not show in the revised application that will be submitted.

Methodology / Procedures

6. Answer all the points below for each method and procedure used to obtain data:

a. Describe in detail what data is needed to answer the research questions/objectives and what activities and/or procedures will be used to collect the data.

b. For each activity/procedure specify where it will be done, the approximate time commitment and frequency (as applicable).

c. For each activity/procedure, describe the methods to be used (e.g. paper/online surveys, interviews, focus groups, questionnaires, video-recording etc.). List and attach all measures that will be used such as surveys, interview guides, observation guides. If a published scale, the link can be provided.

d. Identify who will do the data collection if not the Principal Investigator.
Terezaire [REDACTED]

8e. Please upload all relevant methodology documents (eg: measures to be used, surveys, interview guides). If more than one, upload as separate documents, identifying by title and version date in file name and on each document.

Methodology / Procedures

8. Answer all the points below for each method and procedure used to obtain data:

a. Describe in detail what data is needed to answer the research questions/objectives and what activities and/or procedures will be used to collect the data.


b. For each activity/procedure specify where it will be done, the approximate time commitment and frequency (as applicable).

c. For each activity/procedure, describe the methods to be used (e.g. paper/online surveys, interviews, focus groups, questionnaires, video-recording etc.). List or

d. Identify who will do the data collection if not the Principal Investigator.
Terezaire [REDACTED]

8e. Please upload all relevant methodology documents (eg: measures to be used, surveys, interview guides). If more than one, upload as separate documents, identifying by title and version date in file name and on each document.



6. When done with the modifications, click . Inform the PI that the modifications are made and ready for them to review and submit. These modifications cannot be forwarded to the PI through eRAP. The faculty PI will have to go into the record to advance to the REB.