

For Faculty PI Applicants

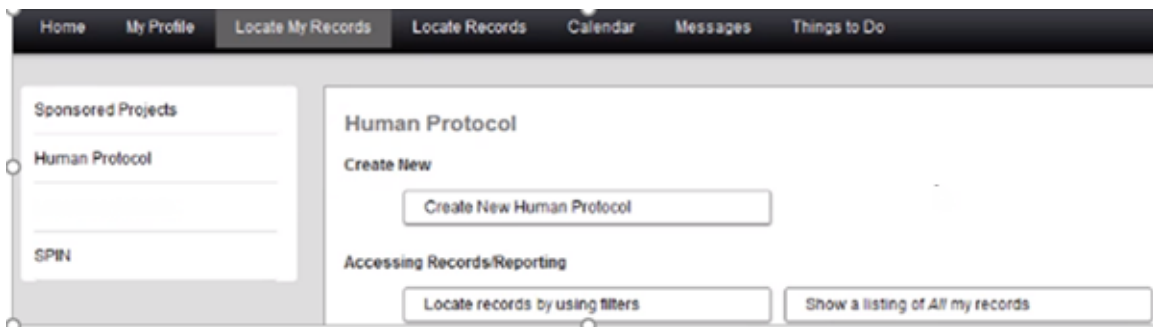
Getting started - how to create a new human research ethics application

Log into eRAP using your McGill credentials at <https://infoed.is.mcgill.ca>

1 Select Human Protocol.

2 Select **Create New Human Protocol**. Click **Continue**.

Note - If nothing happens when you click on the **Create New** button, confirm that your browser pop up blockers are turned off for this url. The form will have been created but blocked from appearing. Do not create a new form. Turn off the pop up blocker and find the form in Locate Records. It will be the one indicated as New Protocol with a title of "New Protocol created for (your name) created on (creation date)".



The Initial Application opens inside a new window.



Initial Application Updated By: **Your Name** 12-Dec-2019 08:48:24 AM

← **Grey color indicates which tab you are on**

INSTRUCTIONS

Welcome to the McGill Electronic Research Administration Portal (eRAP). Please read the following brief instructions before proceeding to fill out the application.

1. Save your work as you proceed through each section.
2. You **MUST** first complete the General Information page. Your response to the questions here determines the Research Ethics Board that will review your study, and the application form that you will complete.

If you are unsure of how to respond, contact the relevant REB office listed at the bottom of this page **BEFORE** filling out the rest 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.

Note - The study title is automatically populated. You **MUST** change this to the correct study title.

3. Identify all uploaded 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
4. To submit you must first check the Locked box. This will save the form and verifies all mandatory questions have been answered. If a message appears indicating the form is incomplete, provide the missing information. Once completed, you will get a "Form Complete Successful" message.
5. The last step is to then click on the "Submit" button.

The detailed user guides for submissions to the Faculty of Medicine ethics office can be found [here](#).

The detailed user guides for submissions to the Research Ethics Board Office (REBs-1,2,3,4) can be found [here](#).

Next →


As indicated in point 2 of the instructions, you **must complete the General Information section first**. This information determines which application form is presented.

Questions in the form with **asterisks** are **mandatory**.

Text boxes are for **text** only. Special characters and rich text will not work. Text boxes do not automatically expand. To make the text box bigger, drag the grey corner to the desired size.



A record number is automatically assigned. The Study Title is automatically populated and you **MUST** revise and put in your real title. Depending on your answers, new questions may appear. **Save your work often**.

 **Note:** You can save and close the application at any time to continue later, but you must remember the title or the record number in order to locate it in “Locate My Records” or in the “Quick Find” box.



Are you submitting to the IRB or REB?

IRB stands for Institutional Review Board. This board reviews projects in the scope of the Faculty of Medicine or Dentistry

REB stands for Research Ethics Board. This committee reviews all other research involving humans.

Answering “Yes” to the following question on the form will cause the IRB application form questions to appear:

Is the Principal Investigator’s primary affiliation with the Faculty of Medicine or Dentistry?

Answering “No” to the same question will make the following questions appear:

- Does the research involve invasive medical procedures or interventions, genetic testing, medical imaging or use of tissues (prospective or secondary use)?
- Is the research being funded by any U.S. federal agency (e.g. DHHA, DOD, NIH, NSF, FDA, etc.?)

If the answer to either or both of these questions is “Yes”, you will be presented with the IRB form and the e-review will go through that ethics board. If the answer to all three questions is “No”, the REB application form will be presented and review will go through the REB Office that administers REB-1,2,3 and 4.

⚠ REMINDER: The following information only applies to applications being submitted to the REB Office and not the Medicine ethics board.

Once the General Information page is completed, you can proceed to the rest of the e-form.

Most questions are self-explanatory but please take note of the information for the following sections:

Access To Edit Application Section:

ACCESS TO EDIT APPLICATION

1 **2**

Name **3** Principal Investigator (PI) **4**

If this is not the PI, please click on the "Add" button to indicate the PI. You must then check off the "Principal Investigator (PI)" checkbox next to the appropriate name.

*There can only be one PI.
The PI is the person who is ultimately responsible for the conduct of the study.*

*Everyone listed in this section will have the ability to edit this application.
The PI assumes all responsibility for any changes to the application made by these people. The PI will NOT be notified when changes to the application are made by the people listed in this section.*

Email Communications: **5**

- 1 Add:** Click this button to add a new person. Search by last name. Repeat for each person to be listed. **⚠** Only McGill members can be listed. If you cannot locate a McGill member, contact eRAP support, eRAPsupport@mcgill.ca
Only list those who you wish to have **edit** access. At this point, an RA with edit access may be assigned to complete the form if you wish. As Principal Investigator, you will still have to review the content and then submit to the REB.
- 2 Delete:** Click this button to remove a person.
- 3 Name:** Name of a person who will have access to **edit** the application.
- 4 Principal Investigator (PI):** Only **one** PI may be selected.
- 5 Email Communications:**
The PI always receives the communications.
For each additional person, you can specify the communications preference. Choices are:

Email Communications: Do NOT cc in Communications
 cc in ALL Communications

You will be able to identify all co-investigators and other research team members, including externals, in the Research Personnel section.

Research Personnel Section:

Click [Add New](#) for each person to be listed.

List all co-investigators, collaborators, student researchers. For each, indicate their name, affiliation and their role in this project.

Example

Last Name: Doe
First Name: John
Affiliation: McGill University
Role on Project: Post-Doctoral Student - Co-Investigator - responsible for recruitment, interviews and analysis of data.

IMPORTANT:
The PI name will appear on the certificate. For other team members, you must check the appropriate box for their name to appear, if desired.

[Add New](#)

Last Name:	<input type="text"/>
First Name:	<input type="text"/>
Appear on Approval Certificate?	<input type="checkbox"/> ←
Affiliation:	<input type="text"/>
Role on Project:	<input type="text"/>
Remove	

Name and affiliation information will appear on the certificate. Write this as you wish it to appear.

Funding Section: Click [Add New](#) for each source of funding, if applicable.

Sources of Funding

Type of Fund:	Grant
Fund Status:	Awarded
Fund # (if applicable):	1234
Fund Title:	XYZ
Principal Investigator on Fund:	Prof. Wayne
Sponsor/Agency:	SSHRC
Comments:	

Sponsor/Agency – Write this as you wish it to appear on the certificate. Short form is recommended.

File Upload Information (for any area permitting upload of documents):

The file upload box on the form is an area where you upload the documents **relevant to that section of the application** e.g., consent documents are to be uploaded in the Consent Process section.

Upload all relevant documents:


[Add New](#)

To upload required documents, click [Add New](#). The file upload box will appear.


 Upload only one document at a time, clicking [Add New](#) to upload each additional document.


Upload all relevant documents:

[Add New](#)

File Name:	<input type="text"/>
File Upload:	 <input type="button" value="Choose File"/>
Remove	

1 File Name: Indicate a relevant description for the document being uploaded. e.g. Interview Consent version 1_ dd-mm-yyyy.

2 File Upload: Click the icon  to upload a file. A new window opens. Click on to select a file on your computer. Click .

The glasses icon  lets you view your uploaded document. If you selected the wrong document, you can delete it by clicking on the delete icon “X” or by selecting [Remove](#). “Remove” will delete the file **and** the file name.

IMPORTANT:

Documents stored on a cloud service or documents inside a file container are not accepted. The documents must be downloaded and attached **individually** to the application. Non-macro documents in any of Microsoft Office file formats and PDFs are accepted. The most common image file formats (jpg, png, bmp, gif) are accepted.

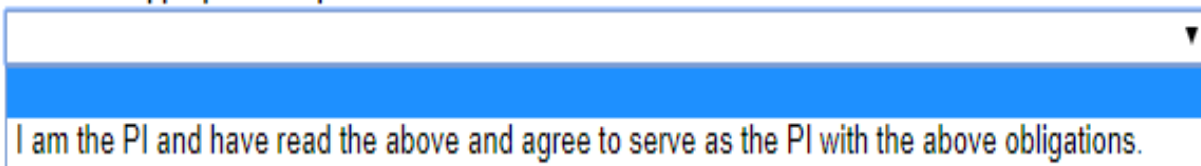
Here is a list of the sections where documents can be uploaded:

- ✓ Funding and Other Reviews
- ✓ Study Information
- ✓ Recruitment
- ✓ Consent process
- ✓ Confidentiality & Data Security
- ✓ Additional Documentation

Submission Approval Section

A. If you are the Faculty PI and submitting on your own behalf, select the option below:

* Select the appropriate response below:



I am the PI and have read the above and agree to serve as the PI with the above obligations.

Follow the steps below once you are ready to submit to the REB Office.



- 1 Save: Click to save your application.
- 2 Validate: Click to make sure that you have answered all the mandatory questions. This step is optional; validation occurs automatically at the “Submit” step.
- 3 Locked: Click to lock the application.
- 4 Submit: Validation occurs automatically at this step.

If mandatory questions have not been answered, a window will appear with information on which section(s) are incomplete. You can click on the section to navigate directly to the question. Once all incomplete sections have been completed and the changes saved, clicking “Submit” sends the application to the REB Office.

This is what the pop-up window looks like when there are incomplete sections. Ignore page numbers in the Validation window, these are a software artifact, and are meaningless for this form.

PageQuestion

- 9 2. Describe the anticipated value and potential benefits of the study and explain how the results will be disseminated (e.g. thesis, academic presentations/publications, websites, community organization, etc.).
- 13 1. Describe how the identity of research participants will be protected during recruitment and data collection and after the research, including how participants will be identified on data collection instruments and in publications. Indicate if participants may be identified by name or otherwise (e.g. organization, job title) in any reports and indicate why this would be an appropriate option for participants to agree to. Explain if participant confidentiality is not applicable (e.g. anonymous survey).

You will receive a submission confirmation by email. **Note** that this is the only step at which you will receive such a confirmation.

B. While not recommended, an RA can also begin the form and submit through eRAP to you as the PI, for submission to the REB. Instructions for the RA to begin the form are found in the **RA guide**. If a Research Assistant has completed the form on your behalf and sent it to you through the system (not just by going in and editing it after you started it) to review and then to submit to the REB, you will receive an email informing you of this. The email subject line will read “PI Approval Required”. The steps for submission are slightly different. **NOTE: This is not the recommended route.** It will be easier for you if you begin the application and the RA simply fills in the sections and informs you when it is ready for your review. You will then submit to the REB.

Once you receive the “PI Approval Required” email, you login to eRAP and locate the application under the “Things to Do” heading at the top of the page. Click on the blue file number to open the application

Module	Record Number	Principal Investigator (McGill)	Object	Record Status	Subject	Assigned
Human Subjects	20-01-014	Colin Thomas	Initial Application	PI Approval Required (REB)	PI Approval Required	15-Jan-2020 11:12:30 AM

Review the content. If satisfactory, you can submit to the REB. If not satisfactory, you have the option to either send it back to the RA by routing it back to their workflow, or ask the RA to login and edit the application while it remains in your workflow (communicate required changes directly), **or make the edits yourself (recommended)**. To send either to the REB or to the RA’s workflow, you then go to the “My Assignments” tab in the left side menu and choose the desired route in the Next Step/Decision drop down list. Then click “I am done”.

MY ASSIGNMENTS

All Pages

Comments:

Next Step/Decision:

Assign to:

I submitted my application. What next?

The REB Office will conduct a pre-review of your submission. The REB Office could return the application to you for missing information or clarifications required prior to REB review. You will receive an email from the REB Office with the subject line: Pre-review Modifications Required.

The REB Office will send the application for REB review. If the REB review requires modifications/clarifications, you will receive an email with the subject line Modifications Required.

If there are no revisions required following review, or once you have satisfactorily revised the application following a Notice of Review, you will receive a **Certificate of Approval**.

Need help?

For technical support contact:

erapsupport@mcgill.ca

or

514-398-7394

For ethics related questions:

<https://mcgill.ca/research/research/compliance/human/reb-i-ii-iii>

for ethics advisor contact information.