

For Student PI Applicants

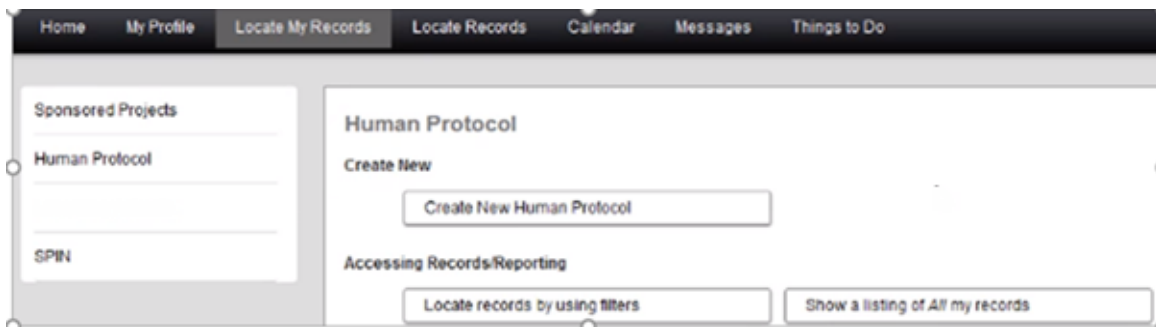
Getting started - How to create a new human research ethics application

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

Before you begin, ensure that your browser pop-up blockers are turned off for this URL.

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)".



3. The Initial Application opens inside a new window.

A screenshot of the McGill eRAP 'Initial Application' page. The page features the McGill logo and name in red. Below the logo, there is a navigation bar with buttons: Close, Print, Form History, Save (highlighted in yellow), Submit, Locked (with a checkbox), and Validate. The main content area is titled 'Initial Application' and includes a 'Next' button. Below the title, there is a section for 'INSTRUCTIONS' with a list of five steps. A red arrow points to the 'Instructions' tab in the left sidebar, which is highlighted in grey. The 'Save' button in the navigation bar is also highlighted in yellow. The page is updated by 'Your Name' on '12-Dec-2019 08:48:24 AM'.

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 →

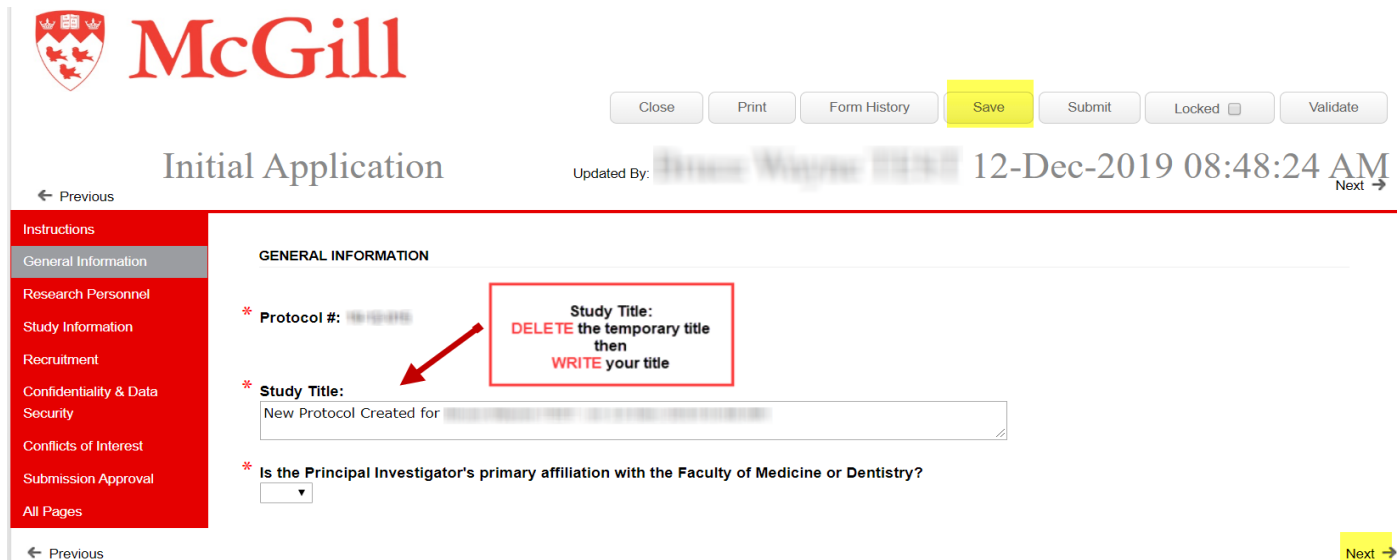
4. As indicated in point 2 of the instructions, you **must complete the General Information section first**. This information determines which application form is presented.

Sections 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.



5. A record number is automatically assigned. The Study Title is automatically populated and you **MUST** revise and put in your study 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 either the title or the record number to locate it in [“Locate My Records”](#) or using the Quick Find search box.

6. Are you submitting to the Research Ethics Office (REB1,2,3,4) or to the Medicine Ethics Office (IRB)?

There are different e-forms and routing based on your responses to the following questions in the General Information section:

Is the Principal Investigator’s primary affiliation with the Faculty of Medicine or Dentistry? If answering “Yes”, the IRB form will appear.

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

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 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-1,2,3,4.

 **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:

7. Access To Edit Application Section:

FACULTY SUPERVISOR & STUDENT PI ACCESS

▼ Add New

Delete

Name **TESTI Bruce Wayne**

Principal Investigator (PI)

*There can only be one PI.
If other researchers are involved, they must be listed on the Research Personnel section.
The PI is the person who has primary responsibility for the design and conduct of the study.*

**Please add your McGill Faculty Supervisor by clicking on the "Add" link at the top of this section.
Your supervisor will have access to edit this application.**

Your name appears and is automatically selected as study PI. You must add your McGill faculty supervisor by clicking on Add New. Search by last name and ‘Select’. **Only one supervisor** should be added, the one who will be approving this submission. Co-Supervisors and other team members can be added in the Research Personnel section.

8. Research Personnel Section:

← Previous next → 4

RESEARCH PERSONNEL

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.

[Add New](#)

← Previous Next →

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

IMPORTANT:

The PI name and that of the supervisor 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 it as you wish it to appear.

9. **Funding and Other Reviews Section:** Click [Add New](#) for each source of funding to be listed.

Sources of Funding

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

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


10. **File Upload (for any area permitting upload of documents):**

The file upload boxes on the form are areas where you should upload the documents relevant to that section of the form 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.


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


Upload all relevant documents:

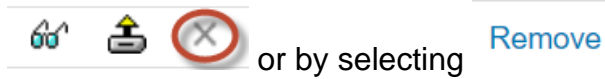
[Add New](#)

File Name:	<input type="text"/>
File Upload:	 <input type="file"/>
Remove	

1 File Name: Indicate a relevant description for the document e.g. interview consent document version 1_ dd-mm-yyyy

2 File Upload: Click the icon  to upload a file. A new window opens. Click on [Choose File](#) to select a file on your computer. Click [Upload](#).

The glasses icon  lets you view your document. If you picked the wrong document, you can delete it by clicking on the delete icon “X”



“Remove” will delete the file **and** the file name.

IMPORTANT:

Documents that are stored on a cloud service or documents inside a file container **are not accepted**. You must save those documents to your computer and attach them **individually** to the application. Non-macro documents in any of Microsoft Office file formats and PDFs are accepted. Accepted file formats are jpg, png, bmp, gif.

This 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

11. Submission Approval Section

In this section you will need to select the following statement from the dropdown.

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

Once completed, you will have to submit your application to your supervisor for approval. It is your supervisor who will then have to forward the application to the REB Office.

To submit the application to your supervisor for approval:



- 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: Click to submit your application to advance it to your supervisor. 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 your supervisor.

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.

These Mandatory Questions need to be completed ✕

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).

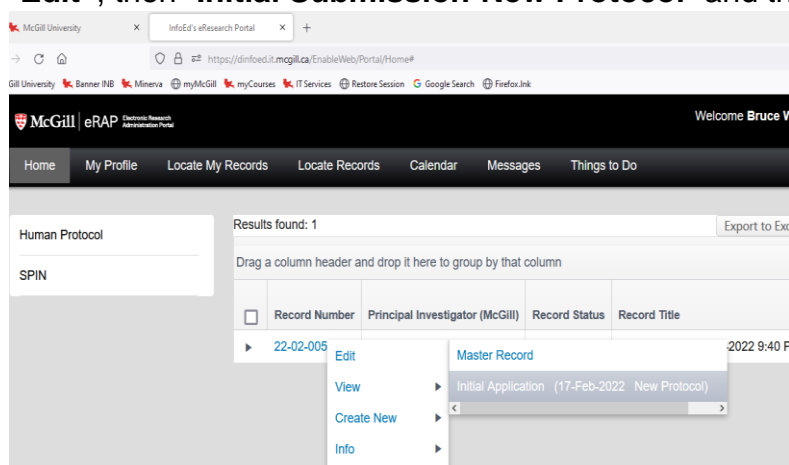
You will receive a submission confirmation email. **Note** that this is the only step at which you will receive such a confirmation.

I submitted my application to my supervisor. What next?

Your supervisor will receive an email informing them that an application requires their review. The supervisor must review the application. There are then two possible outcomes.

1. They approve the application and advance it to the REB for review.
2. They decide that changes are needed and:
 - a. They can communicate any required revisions to you (in person, via email, etc.), and the application remains with the supervisor in eRAP, but you can still do edits and let them know when these have been completed. **(Recommended process)**.
 - b. They can return the application to you by 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 the revised application back to your supervisor. Click on the **“My Assignments”** tab and click **“I am done”**.

You can access the application to further edit by hovering over the record number, selecting **“Edit”**, then **“Initial Submission-New Protocol”** and the application will open.



- c. The supervisor can make the changes directly themselves, as the supervisor has edit access. Once the required changes have been made, the supervisor will submit it to the REB. You can check in eRAP to see where the application is in the review process by checking in “Locate My Records”.

Your application has been submitted. 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 Ethics 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.