

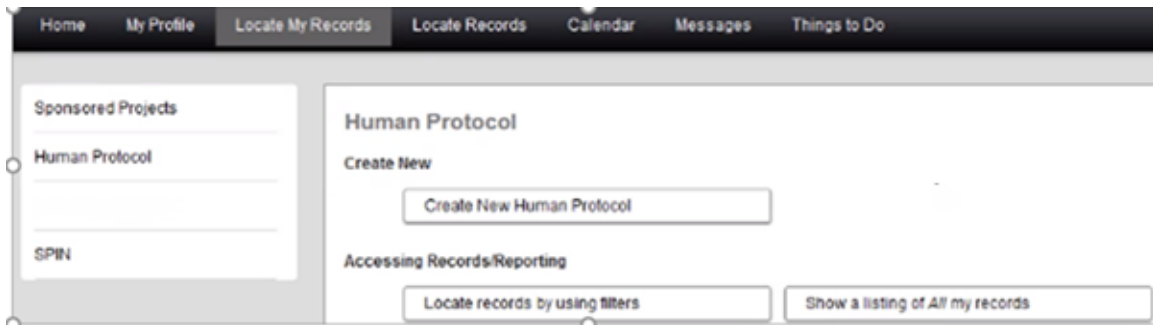
For RA completing an application on behalf of a Faculty PI

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

Login 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)".



3. The Initial Application form opens.

A screenshot of the 'Initial Application' form in the eRAP system. The top left features the McGill logo. The top right has a row of buttons: 'Close', 'Print', 'Form History', 'Save' (highlighted in yellow), 'Submit', 'Locked' (with a checkbox), and 'Validate'. Below the buttons, it says 'Updated By: [redacted] Your Name' and '12-Dec-2019 08:48:24 AM' with a 'Next' arrow. On the left, a red sidebar contains a list of tabs: 'Instructions' (highlighted in grey), 'General Information', 'Research Personnel', 'Study Information', 'Recruitment', 'Confidentiality & Data Security', 'Conflicts of Interest', 'Submission Approval', and 'All Pages'. A red arrow points to the 'Instructions' tab with the text 'Grey color indicates which tab you are on'. The main content area is titled 'INSTRUCTIONS' and contains a welcome message and a list of five steps for completing the application. Step 2 is highlighted in yellow. At the bottom right, there is a yellow 'Next' button with a right-pointing arrow.

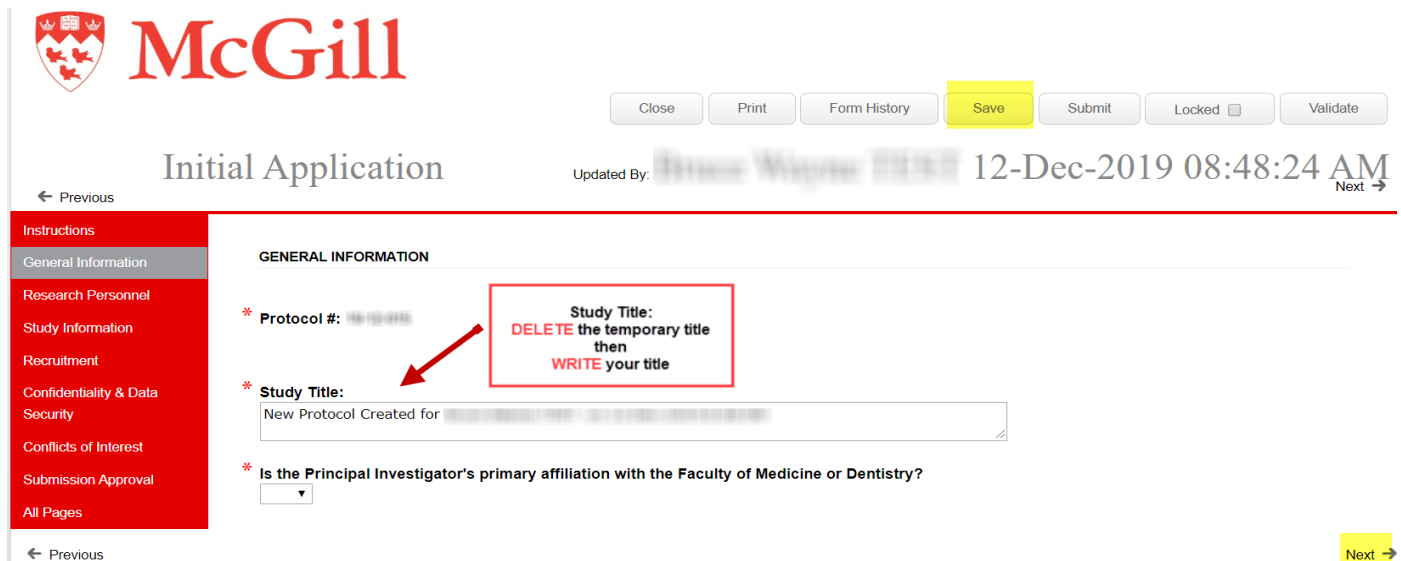
4. As indicated in point 2 of the instructions, you **must complete the General Information section first**. This information determines which application form is presented.

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.



5. A record number is automatically assigned. The Study Title is automatically populated. 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 Records” .

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:

- **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:

7. 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 the PI wants to have edit access. you wish to have **edit** access.

⚠️ At this point, be sure that the PI has been added and the PI box checked next to the PI's name..

- 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.

8. 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 approval 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.

9. **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.

10. **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="text"/>
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 [Choose File](#) to select a file on your computer. Click [Upload](#).

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.

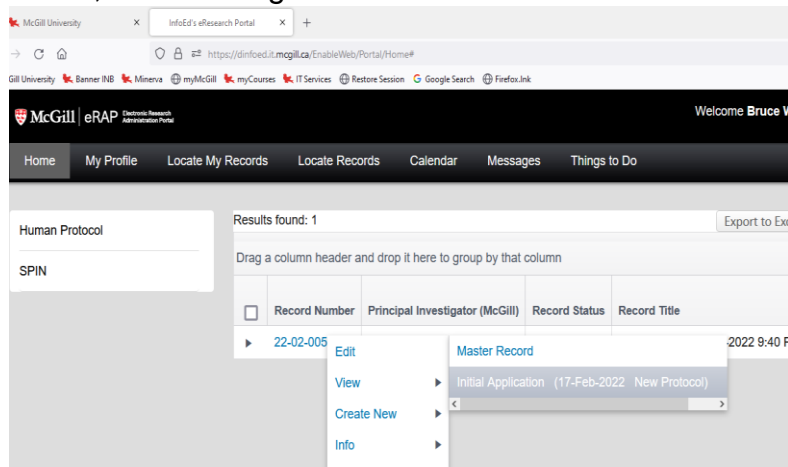
Here is a list of the sections where documents can be uploaded:

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

11. Submission Approval Section

In order to submit, there are two options.

- A. Recommended – Simply **Save and Close**, and inform the Faculty PI that the application is ready for their review. The PI will log in, find the record a, hover over the record number, select **Edit**, then **Initial Application-New Protocol**. The application will open up and they can review, make changes and then submit to the REB.



The remaining instructions apply only if not following the above procedure.

B. Not recommended – You may choose to forward the application to the faculty PI through eRAP. In the Submission approval section, select “I am not the PI” from the drop-down.

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

Follow the steps below once you are ready to forward the application to the faculty PI.



- 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 PI.

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

The PI will receive an email notifying them that their approval is needed. They will then have to log in to eRAP, review, make any changes if needed, and then they must submit it to the REB.

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.