HOW TO SUBMIT AN INITIAL APPLICATION FOR ETHICAL REVIEW

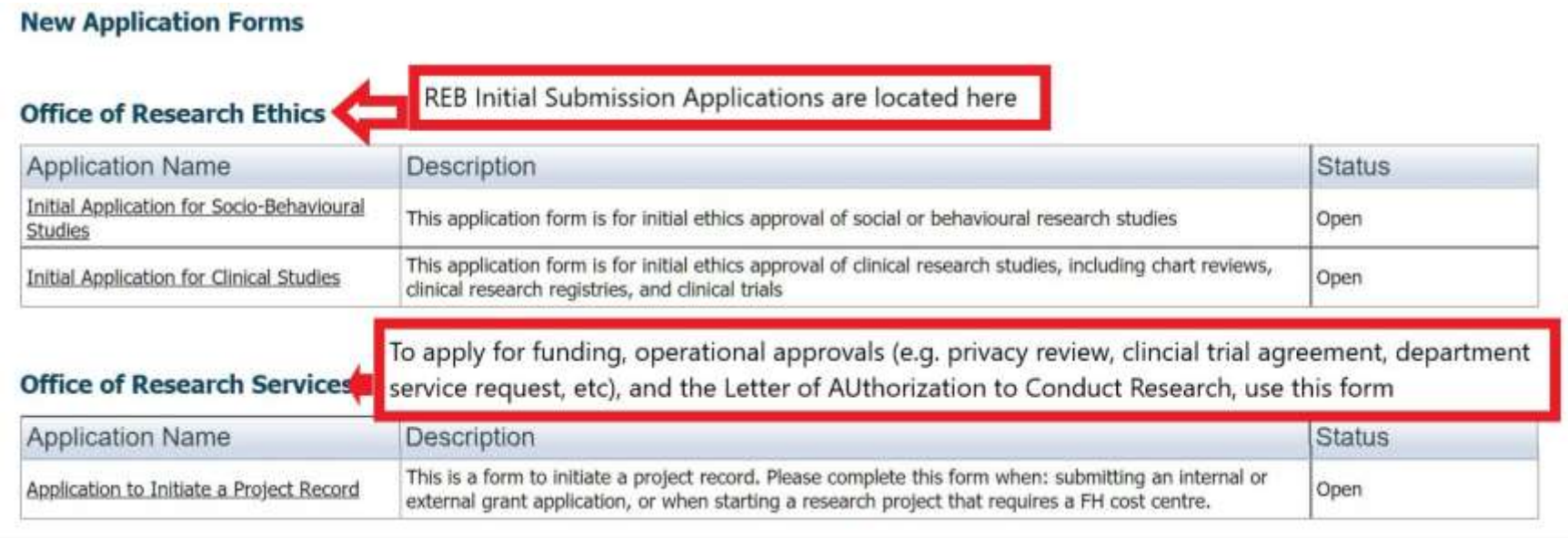
Log-in to the ROMEO Research Portal. If you are a first time user, you must click the Register button to create an account. Your username should be your primary email address. Once you have registered, you will receive an automatic email with instructions on setting up your password.

If you have already been an investigator or main contract on a previous submission to the Fraser Health Research Ethics Board (FHREB), you will likely already be registered. You can insert your primary email address in the Username and select "Reset Password" to create a new password.

Once logged in to the ROMEO System, you will see all applications in which you are involved, segregated by your role in the project (i.e. Principal Investigator or Other Team Member). You can also find existing applications using the Search function.

In order to apply for FHREB review for a new study, select "Apply New" and chose the appropriate application form.

SELECT THE APPROPRIATE APPLICATION FORM



New Application Forms

Office of Research Ethics ← REB Initial Submission Applications are located here

Application Name	Description	Status
Initial Application for Socio-Behavioural Studies	This application form is for initial ethics approval of social or behavioural research studies	Open
Initial Application for Clinical Studies	This application form is for initial ethics approval of clinical research studies, including chart reviews, clinical research registries, and clinical trials	Open

Office of Research Services ← To apply for funding, operational approvals (e.g. privacy review, clincial trial agreement, department service request, etc), and the Letter of AUthorization to Conduct Research, use this form

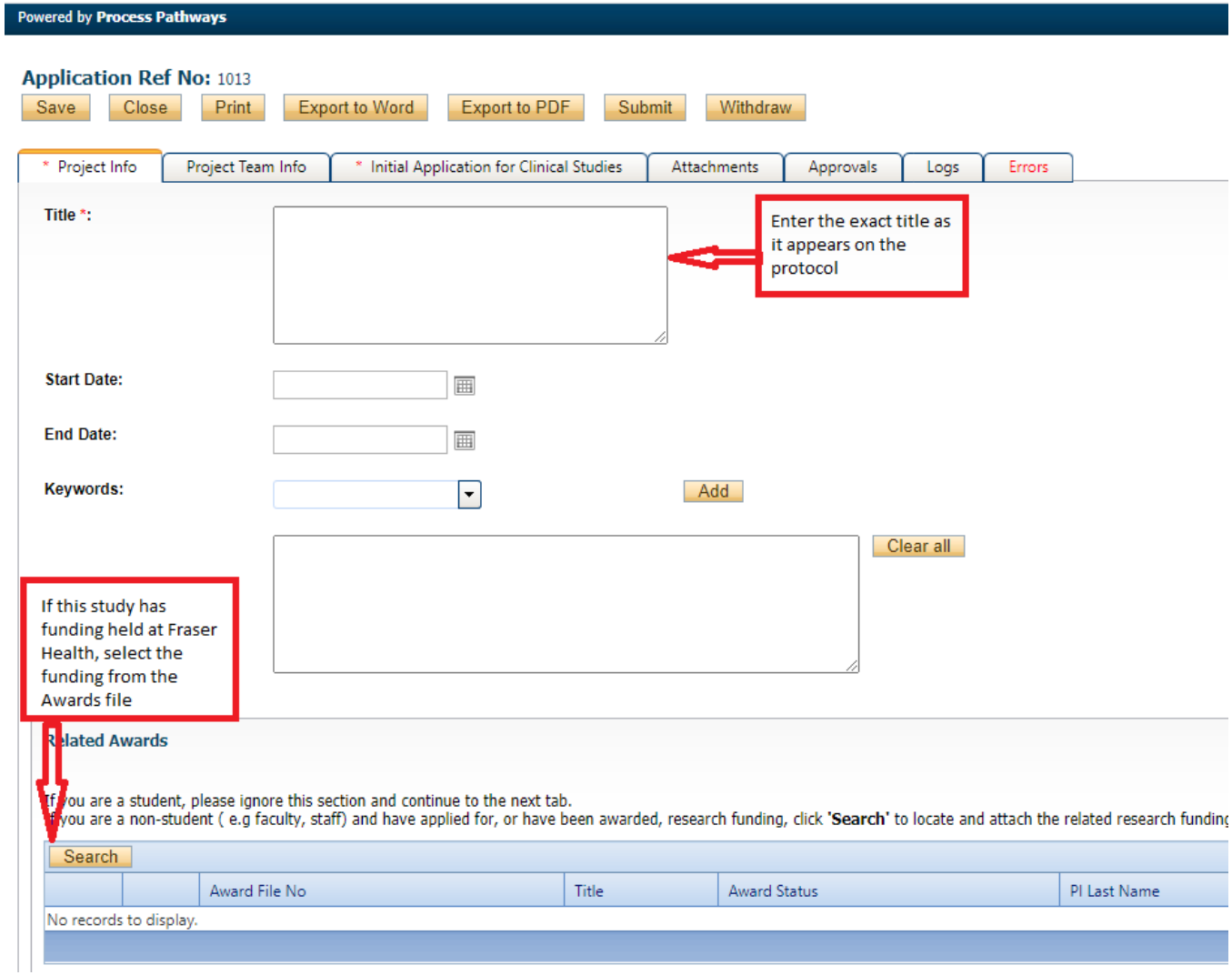
Application Name	Description	Status
Application to Initiate a Project Record	This is a form to initiate a project record. Please complete this form when: submitting an internal or external grant application, or when starting a research project that requires a FH cost centre.	Open

a. Initial Ethical Application for Clinical Research: Use this form if you are conducting clinical research, including clinical drug, device or natural product trials, clinical observational studies, chart reviews, clinical research registries/databanks or biobanks, etc.
b. Initial Ethical Application for Socio-Behavioural Research: Use this form if you are conducting behavioural or social sciences/humanities research. Such research that may involve the study of patients or health care providers, or access to medical records, but are not clinical in nature and do not involve any invasive procedures. Such studies may involve interviews, observations, or the administration of questionnaires or tests.
c. Application to Initiate a Project Record: All studies running at Fraser Health must submit this application to initiate operational and institutional approval in addition to the ethics review. Once a project record is initiated with the Office of Research Services, the application forms for the Department Agreement for Providing Research Related Services, Contracts & Agreements intake, the Data Access Agreement, and the Letter of Authorization to Conduct Research in Fraser Health can be accessed and submitted. This application may be submitted concurrent to the ethics review application.

If you are unsure which form to use, please contact REB@fraserhealth.ca.

PROJECT INFO TAB

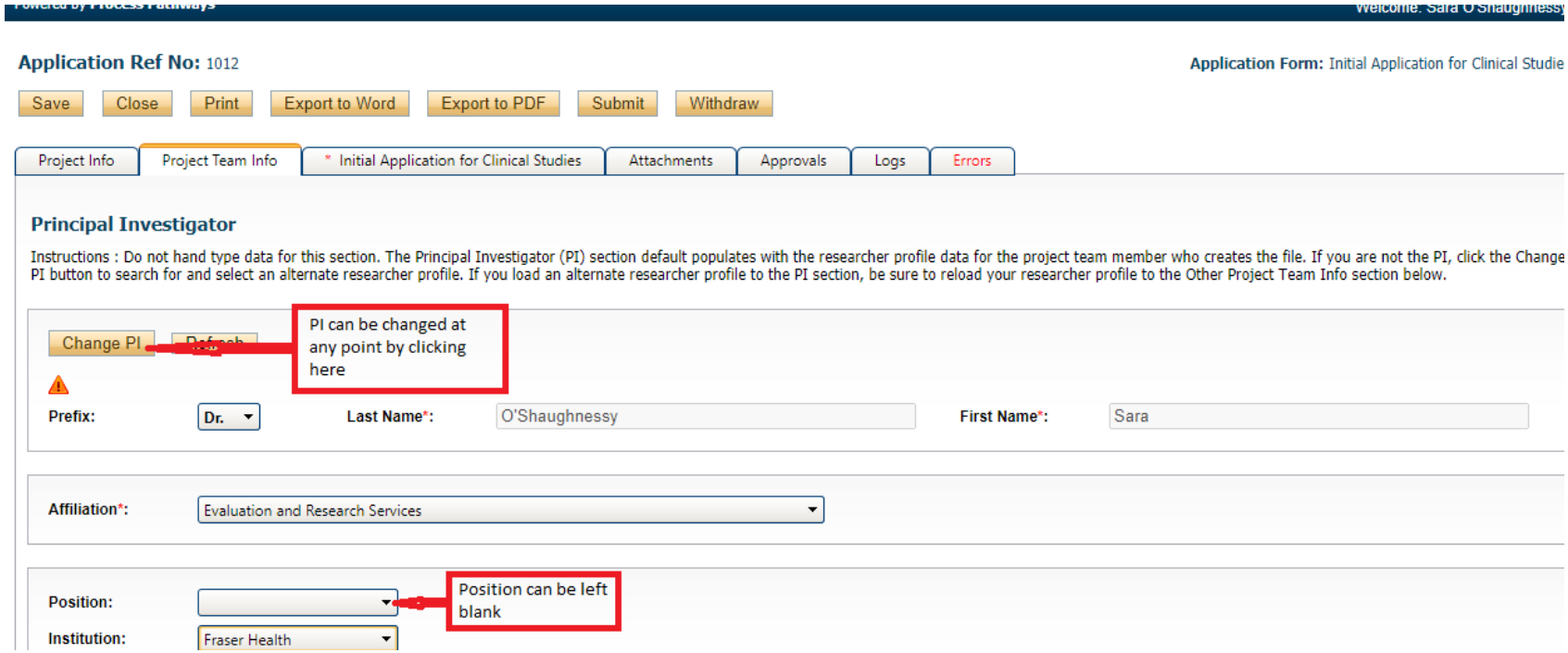
Once you have selected the appropriate application form, complete the section tabs. Make sure to **SAVE your work frequently**. If you close the application or browser without saving, all changes will be lost. Complete the Project Info Tab. Note that questions with a ***red asterisk** are required. If there is an award or funding associated with the study that is held at Fraser Health, you must search for it in Related Awards and link it to the ethics submission file.



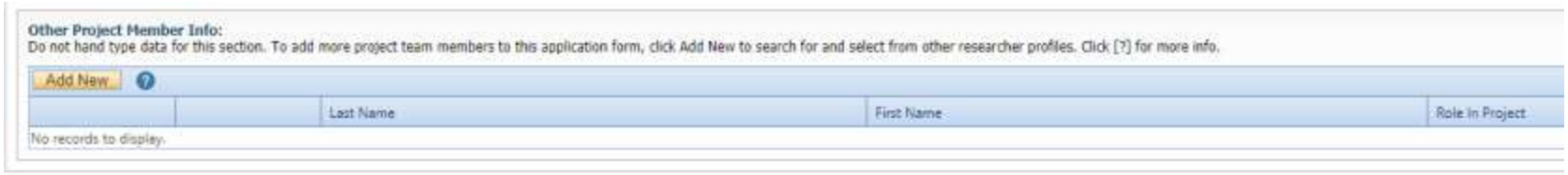
PROJECT TEAM INFO TAB

The Principal Investigator's information will automatically populate with the information of the individual making the application.

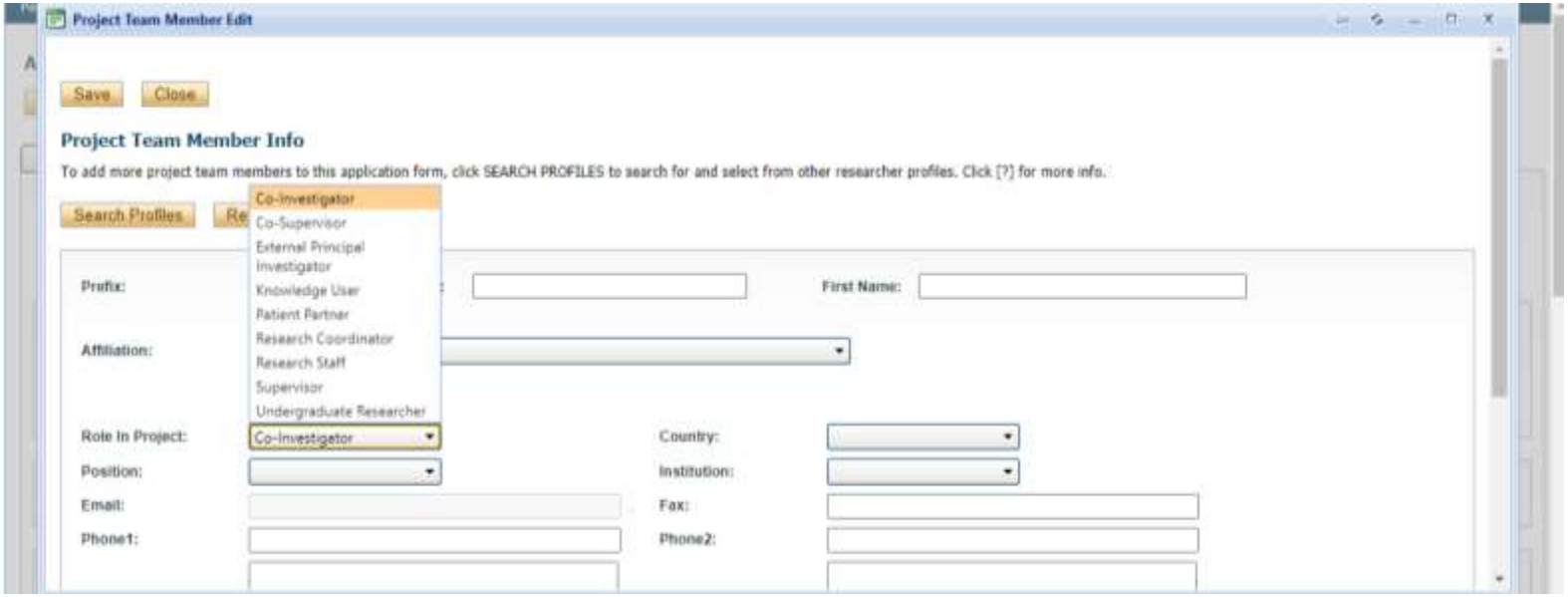
All identified project team members can contribute to an application form pre-submission, but only the PI can submit an application form. If the application form has been initiated by a team member or research coordinator, the role of Principal Investigator will automatically be populated with that individual's information. This can be switched at any time using the "Change PI" function. Do not manually type in the PI's name. Once this is complete, remember to re-add yourself to the application as a team member.



ADDING NEW TEAM MEMBERS



Use the Add New button to find and team members to the submission. Use the Search Profiles button to find and select team members from the ROMEO portal database. Once the Team Member's profile is located, select the appropriate role in the project from the drop-down list.

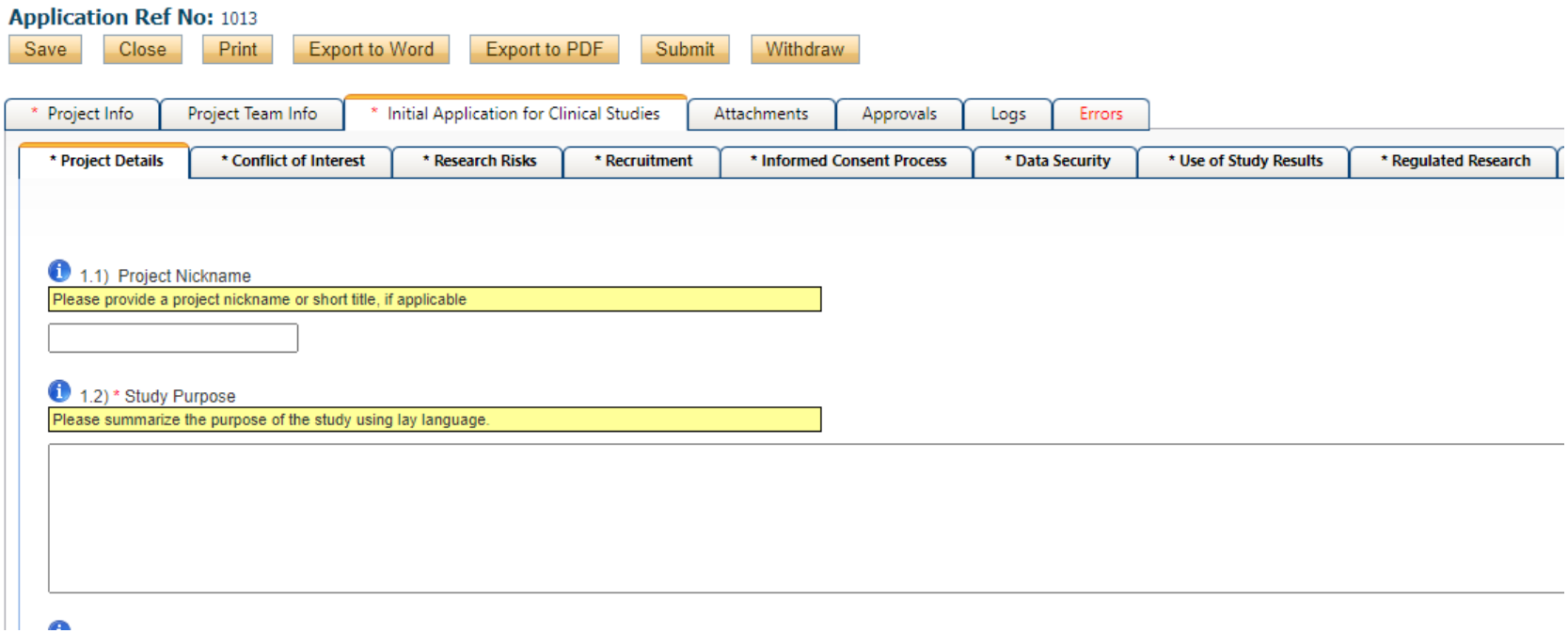


What Happens If I Can't Find My Team Members?

If you cannot find this person in the database, please have them register an account. All team members conducting research activities must be listed on the REB submission.

APPLICATION SPECIFIC QUESTIONS

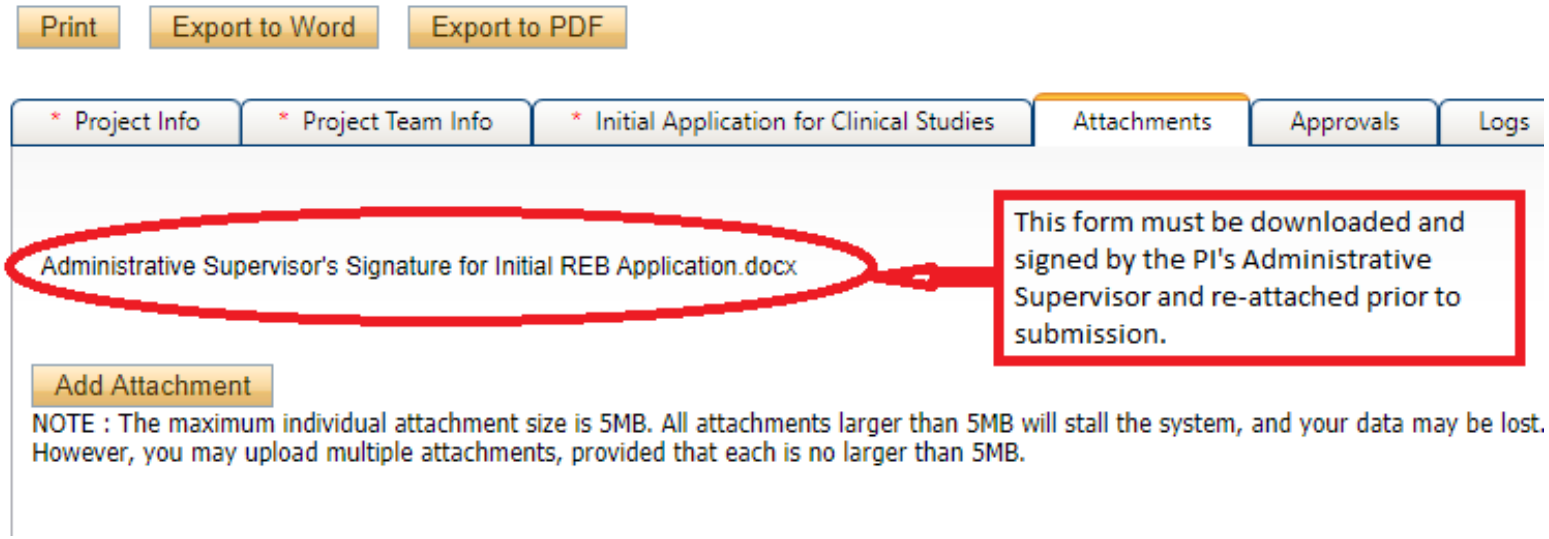
Complete all the questions in the application form. The application form has several tabs with different types of questions. Tabs with an * are required.



Use the blue "i" buttons for additional instructions on answering the questions. If a required question is not applicable to your study, insert "n/a" rather than leaving it blank. If you are uncertain how to answer a question after reviewing the information button and the FHREB Guidance Notes, please contact REB@fraserhealth.ca.

ATTACHMENTS

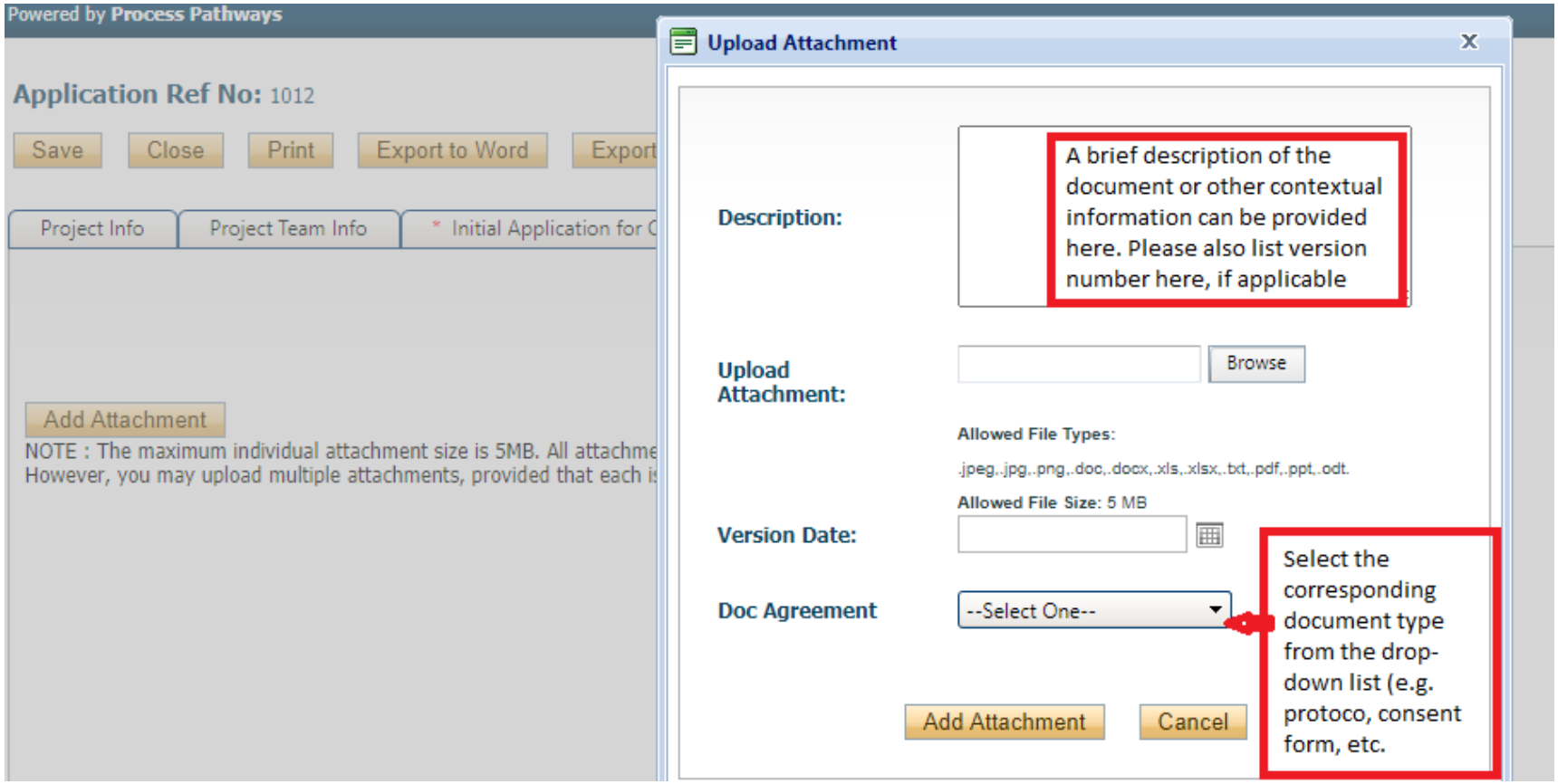
The Attachments Tab is where all supporting documentation are located, including study documents, modification memos, certificates of initial approval, etc. Each application is required to download the Administrative Supervisor's Signature for Initial REB Application form and re-upload once the PI's Administrative Supervisor's signature has been obtained to authorize the study. The FHREB Certificate of Initial Approval will not be released until this signature is obtained and submitted.



In addition to the Administrative Supervisor's signature form, upload all study documents (protocol, consent, etc.) in the Attachments tab. Attachments may be Word documents, Excel spreadsheets, PDFs, jpeg files, etc. The maximum size ROMEO allows is 5MB. For larger files, compress the file or simply break the file into pieces equal to or less than the maximum size allowable, and clearly label each piece (e.g., Part 1 of 5 – IB).

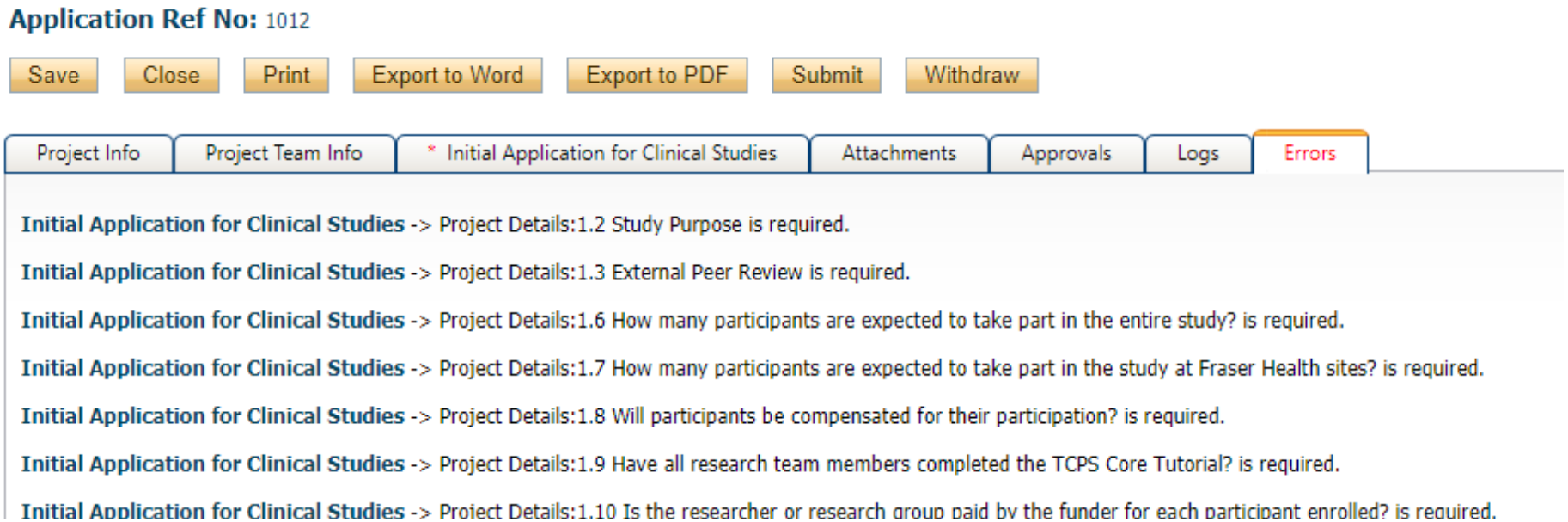
1. Do not attach files that include the following characters in the file name: ", # % & * : < > ? / [] | ~
2. Do not use the period character in the middle of a file name, or at either the start or end of a file name
3. File names should not exceed 128 characters

PLEASE CLEARLY LABEL FILES AS THE STUDY DOCUMENTS WILL APPEAR ON THE APPROVAL CERTIFICATE AS TITLED ON THE ATTACHMENT.



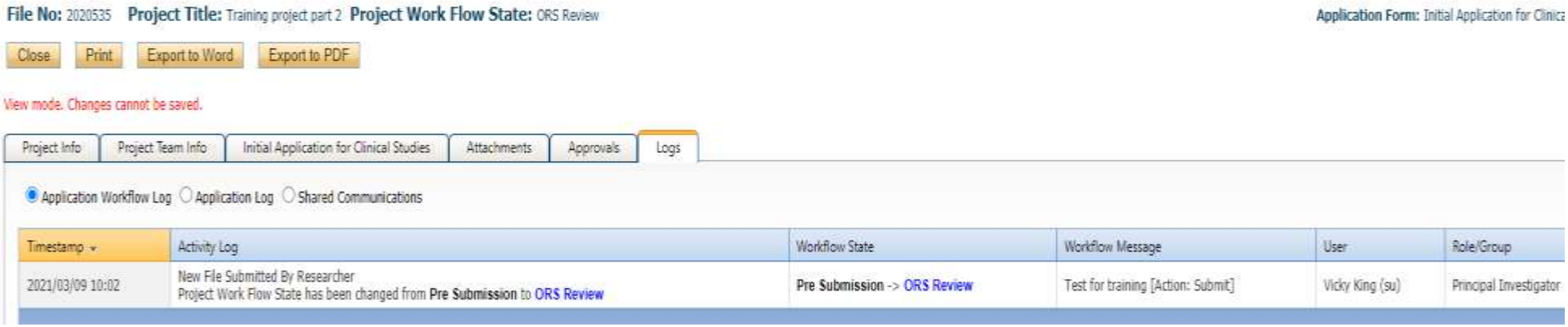
ERRORS TAB

The Errors tab keeps a log of all unanswered required question and will only appear if you have missed a required question. If all questions have been responded to, this tab will disappear from view.

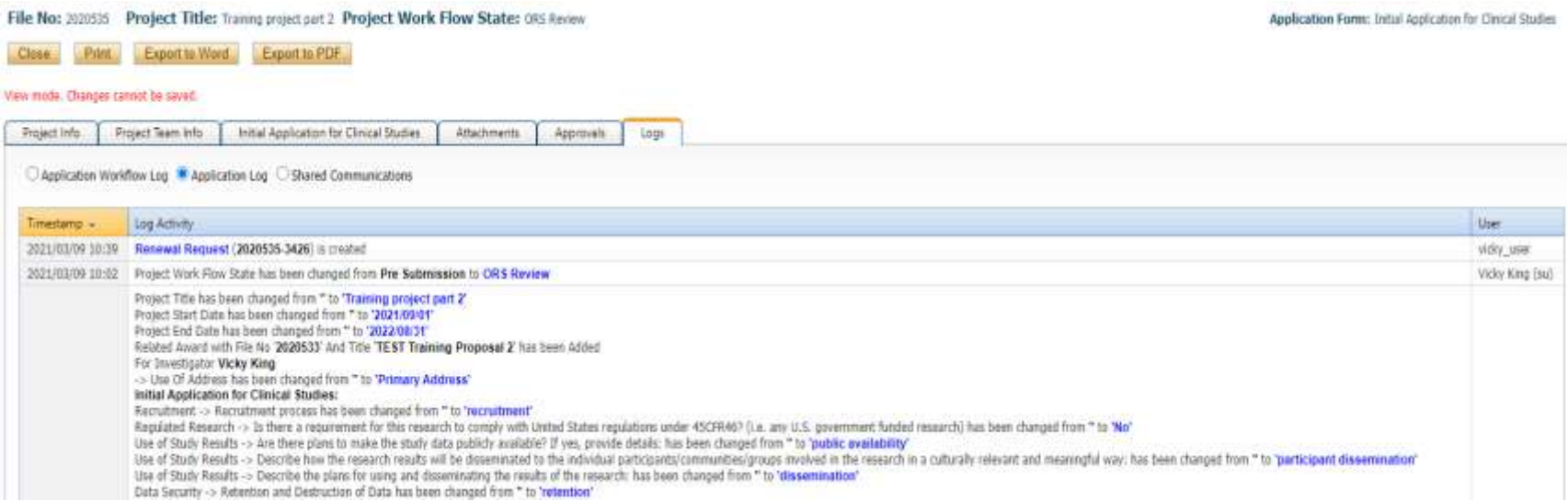


LOG TAB

The Application Workflow Log allows you to track the status of the application and view any actions taken on the file by the project team members and the Research Ethics Office.

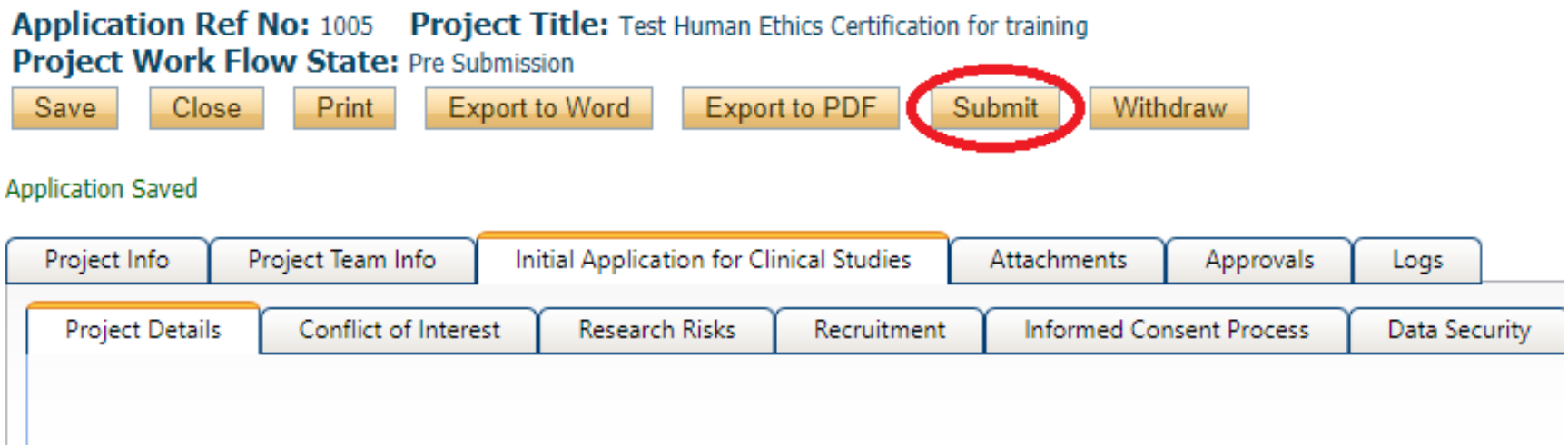


The Application Log shows all changes made to the application by research team members.



SUBMITTING YOUR APPLICATION

Once you are ready to submit, hit "Submit". If you are not ready to submit, you can select "Save & Close" in order to continue working on it at another time.



While all team members can view and edit the application pre-submission, the PI is the only person who can submit the application. No other team member can do this on their behalf. The team member responsible for completing the application should notify the PI when the application is ready to be reviewed and submitted.

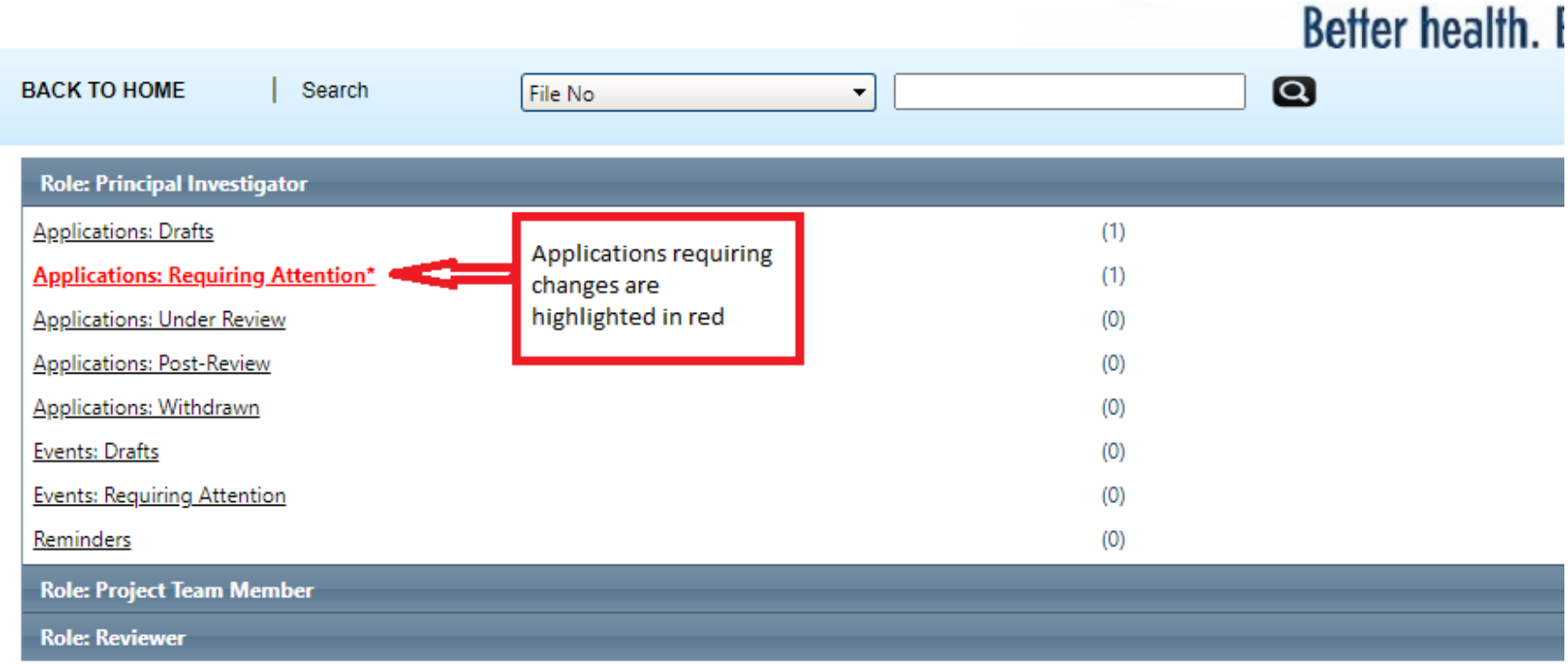
The submission will now be under review with the FHREB. At this stage, you will not be able to make edits or changes to the application. However, you will be able to view the application in the "Applications – Under Review" section of your profile's homepage.

FHREB NUMBER ASSIGNMENT

Once you submit, the ROMEO portal will assign you an FHREB Number (File No). This is different than the Application Reference Number assigned to the file pre-submission. The FHREB Number should be used for all correspondence on the file.

APPLICATIONS REQUIRING REVISIONS

If the FHREB review determines the application requires revision, it will be sent back to you and will be visible on your main dashboard under "Applications—Requiring Attention."



At this stage, you will be able to edit the application by clicking on this link: "Applications – Requiring Attention". Remember that if you are making the revisions on behalf of the PI, you will need to let them know when the revisions are completed so that they may re-submit the application.

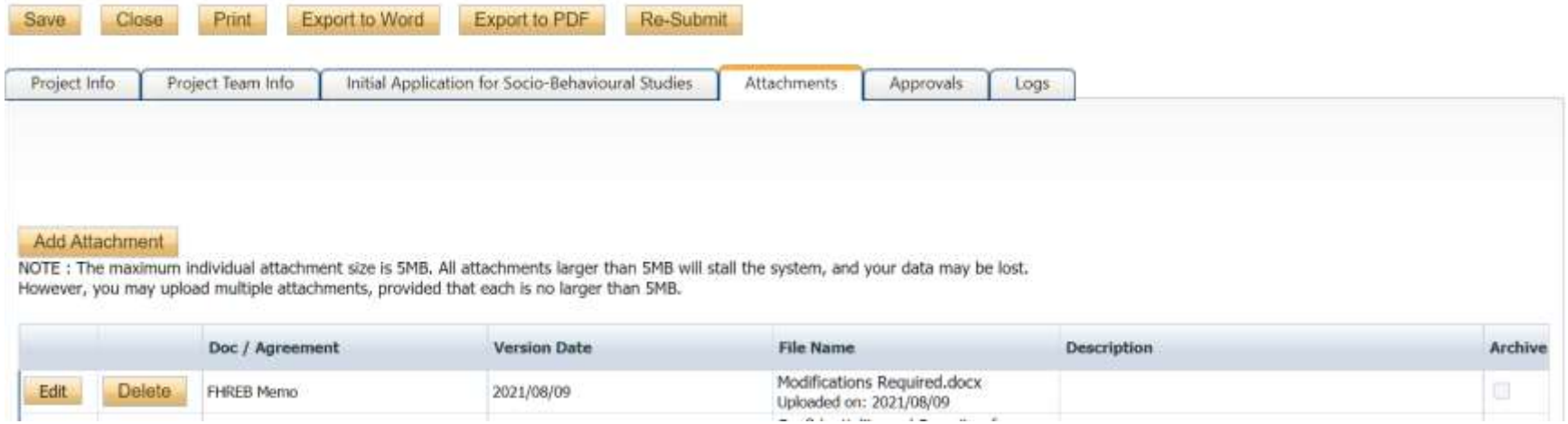
REQUIRED CHANGES

Administrative changes

If administrative changes (e.g. missing documents, etc.) are required by the FHREB Office, the application will be returned with the changes required indicated in the Latest Workflow section.

MODIFICATIONS/DEFERRAL

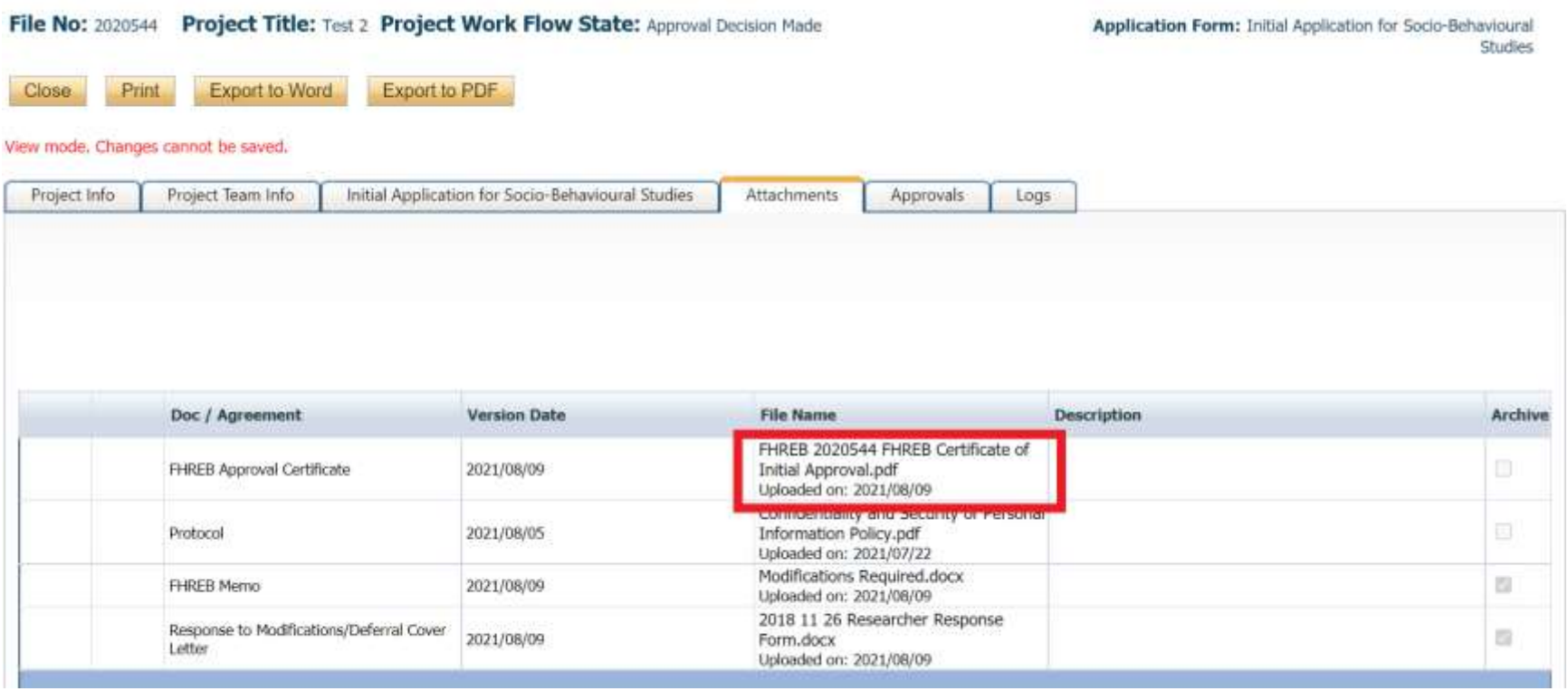
Following the FHREB review, the study team will be informed by the FHREB if modifications are required for the approval of the study. These changes can be found inside the ROMEO Research Portal by clicking on the Attachments tab. The Modification/Deferral memo will be uploaded to the attachments tab.



Use the "Edit" but to make any required changes to the application form. Ensure to attach a response to the modification/deferral memo in the attachments section of application. The response should be submitted as a Word document copying each change/question/clarification request from the memo and providing an answer directly below. Please also ensure to reattach any revised documents to the application with updated version numbers and dates. Revised documents should be submitted with changes highlighted or tracked.

APPROVED APPLICATIONS

Once the application has been approved, the study team will receive an automatic email the study has been approved. A formal approval certificate will be uploaded to the Attachments Tab. The application can no longer be modified but is available for viewing under "Applications – Post Review". Any future actions on this study (e.g. Amendment, Acknowledgement Request, etc.) must be submitted as an "Event" (please see Event Guidance for how to submit Event forms).



NEXT STEPS

FHREB Approval is only one step required for a study to commence at Fraser Health. No project may begin until the LETTER OF AUTHORIZATION TO CONDUCT RESEARCH (i.e. Fraser Health institutional approval) has been released. To obtain the Letter of Authorization to Conduct Research and apply for any other operational approvals, go to "APPLY NEW" and select "Application to Initiate a Project Record" (note that studies which have previously applied for funding through Fraser Health may already have a project record on file). Once this application is received by the Department of Evaluation and Research Services, you will be notified to apply for a Letter of Authorization to Conduct Research in the file Event forms. If other operational approvals or agreements are required (e.g. Privacy review, research contract, etc.), you will be prompted to submit separate Event forms for each of these.

The operational and institutional process is separate from the ethics submission process and can be done concurrent or sequentially.