

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.



Enter email for your username

A login form with a light blue border. In the top right corner, it says "Login" with a blue circular arrow icon. Below this, there are two input fields: "Username" and "Password". A red box on the left contains the text "Enter email for your username" with a red arrow pointing to the Username field. Below the Password field, there is a section titled "Use your default language" with two radio buttons: "Yes" (which is selected) and "No". At the bottom of the form, there are three buttons: "Login", "Register", and "Reset 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 ROMEOSystem, 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.

The screenshot shows the Fraser Health ROMEOSystem interface. At the top, the Fraser Health logo is displayed with the tagline "Better health. Best in health care." Below the logo is a navigation bar containing a "BACK TO HOME" link, a search bar with a "File No" dropdown, and a search icon. On the right side of the navigation bar, there are links for "APPLY NEW", "News", and "Useful Links". A red callout box points to the "APPLY NEW" link with the text "Click here to find application forms for new submissions". Another red callout box points to the "Useful Links" link with the text "Click here for quick links to the FHREB consent form templates, guidance notes, meeting dates and more". Below the navigation bar, the main content area is titled "Role: Principal Investigator" and lists various application and event categories with their respective counts in parentheses:

Role: Principal Investigator	
Applications: Drafts	(0)
Applications: Requiring Attention	(0)
Applications: Under Review	(0)
Applications: Post-Review	(0)
Applications: Withdrawn	(0)
Events: Drafts	(0)
Events: Requiring Attention	(0)
Reminders	(0)

At the bottom of the main content area, there is a section titled "Role: Project Team Member" with a downward arrow.

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, clinical 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.

Powered by **Process Pathways**

Application Ref No: 1013

Save Close Print Export to Word Export to PDF Submit Withdraw

* Project Info Project Team Info * Initial Application for Clinical Studies Attachments Approvals Logs Errors

Title *: Enter the exact title as it appears on the protocol

Start Date:

End Date:

Keywords: Add

Clear all

If this study has funding held at Fraser Health, select the funding from the Awards file

Related Awards

If you are a student, please ignore this section and continue to the next tab.
If you are a non-student (e.g faculty, staff) and have applied for, or have been awarded, research funding, click 'Search' to locate and attach the related research funding

Search

Award File No	Title	Award Status	PI Last Name
No records to display.			

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.

Powered by PROCESS Pathways Welcome, Sara O'Shaughnessy

Application Ref No: 1012 **Application Form:** Initial Application for Clinical Studies

Project Info | **Project Team Info** | * Initial Application for Clinical Studies | Attachments | Approvals | Logs | Errors

Principal Investigator

Instructions : Do not hand type data for this section. The Principal Investigator (PI) section default populates with the researcher profile data for the project team member who creates the file. If you are not the PI, click the Change PI button to search for and select an alternate researcher profile. If you load an alternate researcher profile to the PI section, be sure to reload your researcher profile to the Other Project Team Info section below.

PI can be changed at any point by clicking here

Prefix: **Last Name*:** **First Name*:**

Affiliation*:

Position: Position can be left blank

Institution:

ADDING NEW TEAM MEMBERS

Other Project Member Info:
Do not hand type data for this section. To add more project team members to this application form, click Add New to search for and select from other researcher profiles. Click [?] for more info.

?

Last Name	First Name	Role In Project
No records to display.		

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 ROME portal database. Once the Team Member's profile is located, select the appropriate role in the project from the drop-down list.

The screenshot shows the 'Project Team Member Edit' window. At the top, there are 'Save' and 'Close' buttons. Below them is the 'Project Team Member Info' section with a 'Search Profiles' button. A dropdown menu is open over the 'Role In Project' field, listing various roles: Co-Investigator, Co-Supervisor, External Principal Investigator, Knowledge User, Patient Partner, Research Coordinator, Research Staff, Supervisor, and Undergraduate Researcher. The 'Co-Investigator' role is currently selected. Other fields include Prefix, Affiliation, Position, Email, Phone1, Country, Institution, Fax, and Phone2.

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.

Application Ref No: 1013

Save Close Print Export to Word Export to PDF Submit Withdraw

* Project Info Project Team Info * Initial Application for Clinical Studies Attachments Approvals Logs Errors

* Project Details * Conflict of Interest * Research Risks * Recruitment * Informed Consent Process * Data Security * Use of Study Results * Regulated Research

i 1.1) Project Nickname
Please provide a project nickname or short title, if applicable

i 1.2) * Study Purpose
Please summarize the purpose of the study using lay language.

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.

[Print](#) [Export to Word](#) [Export to PDF](#)

* Project Info	* Project Team Info	* Initial Application for Clinical Studies	Attachments	Approvals	Logs
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[Administrative Supervisor's Signature for Initial REB Application.docx](#)

[Add Attachment](#)

NOTE : The maximum individual attachment size is 5MB. All attachments larger than 5MB will stall the system, and your data may be lost. However, you may upload multiple attachments, provided that each is no larger than 5MB.

This form must be downloaded and signed by the PI's Administrative Supervisor and re-attached prior to submission.

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.

Powered by Process Pathways

Application Ref No: 1012

Save Close Print Export to Word Export

Project Info Project Team Info * Initial Application for C

Add Attachment

NOTE : The maximum individual attachment size is 5MB. All attachments must be labeled. However, you may upload multiple attachments, provided that each is

Upload Attachment

Description:

A brief description of the document or other contextual information can be provided here. Please also list version number here, if applicable

Upload Attachment:

Browse

Allowed File Types:

.jpeg,.jpg,.png,.doc,.docx,.xls,.xlsx,.txt,.pdf,.ppt,.odt

Allowed File Size: 5 MB

Version Date:

Doc Agreement

--Select One--

Add Attachment Cancel

Select the corresponding document type from the drop-down list (e.g. protocol, consent form, etc.)

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.

Application Ref No: 1012

[Save](#) [Close](#) [Print](#) [Export to Word](#) [Export to PDF](#) [Submit](#) [Withdraw](#)

Project Info	Project Team Info	* Initial Application for Clinical Studies	Attachments	Approvals	Logs	Errors
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Initial Application for Clinical Studies -> Project Details:1.2 Study Purpose is required.

Initial Application for Clinical Studies -> Project Details:1.3 External Peer Review is required.

Initial Application for Clinical Studies -> Project Details:1.6 How many participants are expected to take part in the entire study? is required.

Initial Application for Clinical Studies -> Project Details:1.7 How many participants are expected to take part in the study at Fraser Health sites? is required.

Initial Application for Clinical Studies -> Project Details:1.8 Will participants be compensated for their participation? is required.

Initial Application for Clinical Studies -> Project Details:1.9 Have all research team members completed the TCPS Core Tutorial? is required.

Initial Application for Clinical Studies -> Project Details:1.10 Is the researcher or research group paid by the funder for each participant enrolled? is required.

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.

File No: 2020535 Project Title: Training project part 2 Project Work Flow State: ORS Review

Application Form: Initial Application for Clinical Studies

Close Print Export to Word Export to PDF

View mode. Changes cannot be saved.

Timestamp	Activity Log	Workflow State	Workflow Message	User	Role/Group
2021/03/09 10:02	New File Submitted By Researcher Project Work Flow State has been changed from Pre Submission to ORS Review	Pre Submission -> ORS Review	Test for training [Action: Submit]	Vicky King (su)	Principal Investigator

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

File No: 2020535 Project Title: Training project part 2 Project Work Flow State: ORS Review

Application Form: Initial Application for Clinical Studies

Close Print Export to Word Export to PDF

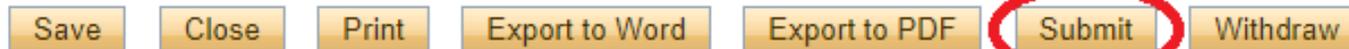
View mode. Changes cannot be saved.

Timestamp	Log Activity	User
2021/03/09 10:39	Renewal Request (2020535-3426) is created	vicky_user
2021/03/09 10:02	Project Work Flow State has been changed from Pre Submission to ORS Review	Vicky King (su)
	Project Title has been changed from "" to 'Training project part 2' Project Start Date has been changed from "" to '2021/09/01' Project End Date has been changed from "" to '2022/08/31' Related Award with File No '2020533' And Title 'TEST Training Proposal 2' has been Added For Investigator: Vicky King -> Use Of Address has been changed from "" to 'Primary Address' Initial Application for Clinical Studies: Recruitment -> Recruitment process has been changed from "" to 'recruitment' Regulated Research -> Is there a requirement for this research to comply with United States regulations under 45CFR46? (i.e. any U.S. government funded research) has been changed from "" to 'No' Use of Study Results -> Are there plans to make the study data publicly available? If yes, provide details: has been changed from "" to 'public availability' Use of Study Results -> Describe how the research results will be disseminated to the individual participants/communities/groups involved in the research in a culturally relevant and meaningful way: has been changed from "" to 'participant dissemination' Use of Study Results -> Describe the plans for using and disseminating the results of the research: has been changed from "" to 'dissemination' Data Security -> Retention and Destruction of Data has been changed from "" to 'retention'	

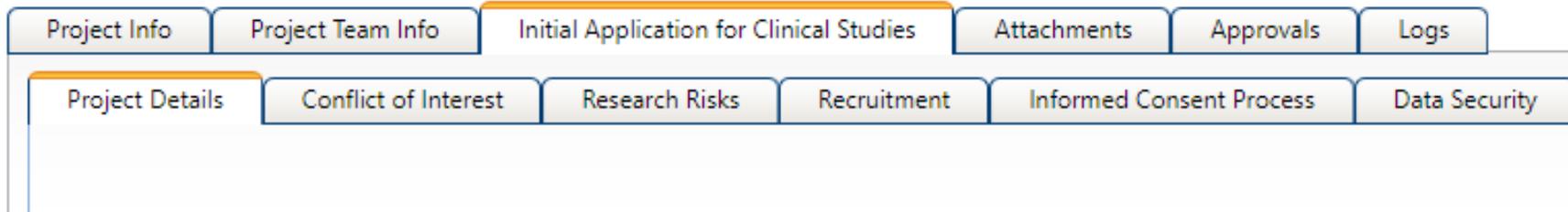
SUBMITTING YOUR APPLICATION

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.

Application Ref No: 1005 **Project Title:** Test Human Ethics Certification for training
Project Work Flow State: Pre Submission



Application Saved



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 ROME0 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.



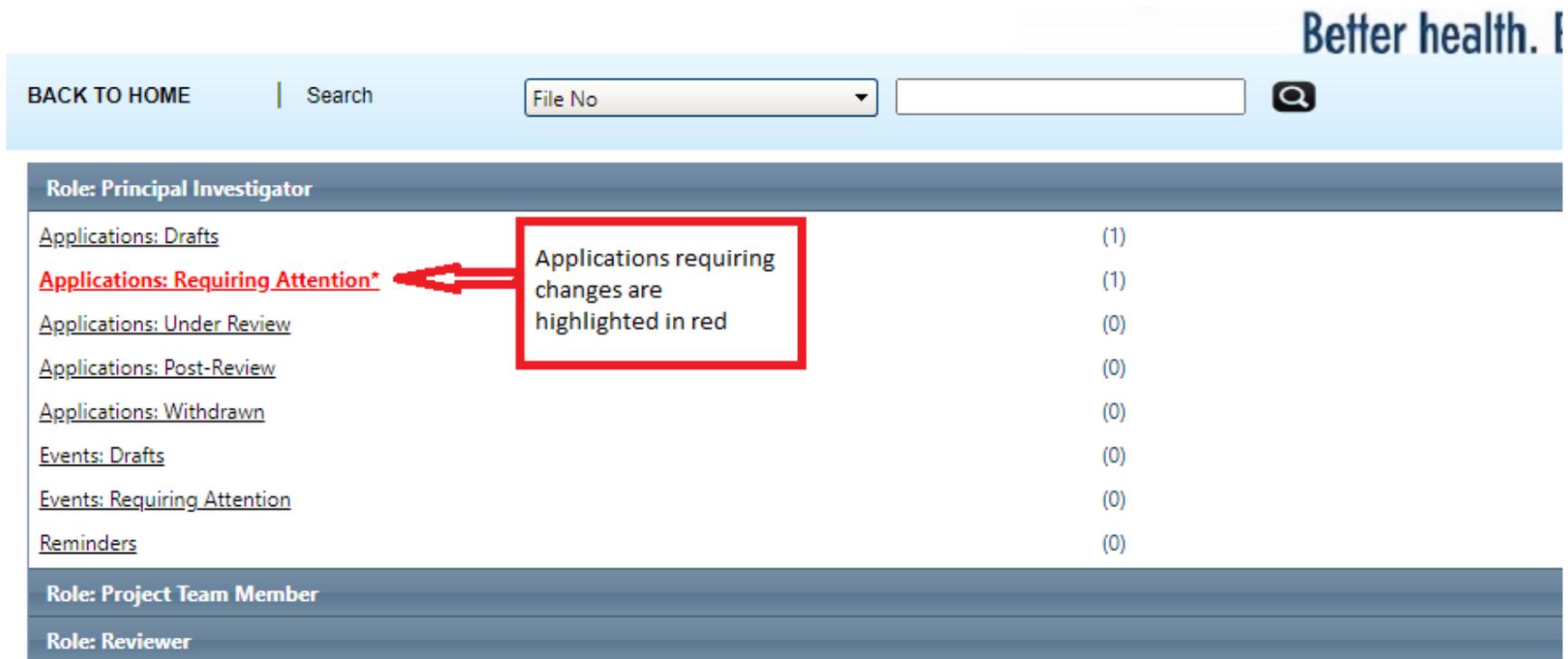
BACK TO HOME | Search | File No: [dropdown] [input] [icon] | APPLY NEW | News | Useful Links | Settings

Reset Filters | Export To Excel

	File No	Project Title	Principal Investigator	Application Type	Status Snapshot
View Clone Latest Workflow	2020544	Test	Dr. Sara O'Shaughnessy (Evaluation and Research Services)	Initial Application for Clinical Studies (Certification)/Human Ethics	Project Status: Pending Workflow Status: ORS Review

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.”



Better health. I

BACK TO HOME | Search | File No [dropdown] [input] [search icon]

Role: Principal Investigator		
Applications: Drafts		(1)
Applications: Requiring Attention*	Applications requiring changes are highlighted in red	(1)
Applications: Under Review		(0)
Applications: Post-Review		(0)
Applications: Withdrawn		(0)
Events: Drafts		(0)
Events: Requiring Attention		(0)
Reminders		(0)

Role: Project Team Member

Role: Reviewer

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

Click "Edit" to make changes to the application and upload new documents

Click "Latest Workflow" to view changes required

File No	Project Title	Principal Investigator	Application Type	Status Snapshot
2020539	TEST	Dr. Sara O'Shaughnessy (Evaluation and Research Services)	Initial Application for Socio-Behavioural Studies (Certification)/Human Ethics	Project Status: Pending Workflow Status: Pending Info by ORS

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.

Application Ref No: 1015 Project Title: Test 4
Project Work Flow State: Pending Info by ORS

Application Form: Initial Application for Clinical Studies

Instructions visible in Latest Workflow Message

Timestamp	Activity Log	Workflow State	Workflow Message	User	Role/Group
2021/08/09 12:48	Application Workflow State has been changed from ORS Review to Pending Info by ORS	ORS Review -> Pending Info by ORS	Please attach consent forms to the application.	sara_user	Office of Research Services/Office of Research Ethics

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.

Save Close Print Export to Word Export to PDF Re-Submit

Project Info Project Team Info Initial Application for Socio-Behavioural Studies Attachments Approvals Logs

Add Attachment

NOTE : The maximum individual attachment size is 5MB. All attachments larger than 5MB will stall the system, and your data may be lost. However, you may upload multiple attachments, provided that each is no larger than 5MB.

	Doc / Agreement	Version Date	File Name	Description	Archive
Edit Delete	FHREB Memo	2021/08/09	Modifications Required.docx Uploaded on: 2021/08/09		<input type="checkbox"/>

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).

File No: 2020544 **Project Title:** Test 2 **Project Work Flow State:** Approval Decision Made

Application Form: Initial Application for Socio-Behavioural Studies

[Close](#) [Print](#) [Export to Word](#) [Export to PDF](#)

View mode. Changes cannot be saved.

Project Info	Project Team Info	Initial Application for Socio-Behavioural Studies	Attachments	Approvals	Logs
Doc / Agreement	Version Date	File Name	Description	Archive	
FHREB Approval Certificate	2021/08/09	FHREB 2020544 FHREB Certificate of Initial Approval.pdf Uploaded on: 2021/08/09		<input type="checkbox"/>	
Protocol	2021/08/05	Confidentiality and Security of Personal Information Policy.pdf Uploaded on: 2021/07/22		<input type="checkbox"/>	
FHREB Memo	2021/08/09	Modifications Required.docx Uploaded on: 2021/08/09		<input checked="" type="checkbox"/>	
Response to Modifications/Deferral Cover Letter	2021/08/09	2018 11 26 Researcher Response Form.docx Uploaded on: 2021/08/09		<input checked="" type="checkbox"/>	

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.