How to Apply for a Letter of Authorization to Conduct Research

All studies running at Fraser Health must submit an application to Initiate a Project Record in addition to the REB review. This application form is located in new application forms section of the awards module of the ROMEO research portal. The purpose of this form is to ensure all necessary approvals are in place for the study to begin. Additional applications for operational approvals, such as a Privacy review, may be required depending on the nature of the study.

The application to Initiate a Project Record in Fraser Health may be submitted concurrent to the ethics review application on ROMEO for studies applying for approval in Fraser Health only, or concurrent to the ethics review application on the Provincial Research Ethics Platform hosted on the UBC RISe system for multi-jurisdictional research.

1. 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.



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Enter email for your	Login 🕞
username	Password
	Use your default language ● Yes ◯ No
	Login Register 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.

2. Select "Apply New"

BACK TO Search File No	Better health. Best in health care.	Click here to find application forms for new submissions APPLY NEW News Useful Links
Role: Principal Investigator		~
Applications: Drafts	(0)	
Applications: Requiring Attention	(0)	Click have for swick
Applications: Under Review	(0)	links to the FHREB
Applications: Post-Review	(0)	consent form
Applications: Withdrawn	(0)	templates, guidance
Events: Drafts	(0)	and more
Events: Requiring Attention	(0)	
Reminders	(0)	
Role: Project Team Member		~

3. Select "Application to Initiate a Project Record"

	Better health. Best in health care.	
BACK TO Search File No.	@	APPLY NEW News Useful Links
New Application Forms		
Office of Research Ethics		
Application Name	Description	Status
Application Name Initial Application for Socio-Behavioural Studies	Description This application form is for initial ethics approval of social or behavioural research studies	Status Open
Application Name Initial Application for Socio-Behavioural Studies Initial Application for Clinical Studies	Description This application form is for initial ethics approval of social or behavioural research studies This application form is for initial ethics approval of clinical research studies, including chart redinical research registries, and clinical trials	Open views, Open
Application Name Initial Application for Socio-Behavioural Studies Initial Application for Clinical Studies Office of Research Services	Description This application form is for initial ethics approval of social or behavioural research studies This application form is for initial ethics approval of clinical research studies, including chart re clinical research registries, and clinical trials	Open views, Open
Application Name Initial Application for Socio-Behavioural Studies Initial Application for Clinical Studies Office of Research Services Application Name	Description This application form is for initial ethics approval of social or behavioural research studies This application form is for initial ethics approval of clinical research studies, including chart re clinical research registries, and clinical trials Description	Status Open views, Open

Once you select the appropriate application form, you will be assigned a temporary Application Reference Number will the application is in draft format. This will be replaced with a permanent File Number once the application form is submitted. Please note the File Number will be different from the File Number associated with the FHREB application (if applicable).

Note that if you have already submitted an Application to Initiate a Project Record for this study, skip to step 9

4. Complete the Project Info Tab

Enter the study title, start & end dates and keywords.

The Related Certifications section of this tab allows you to connect the operational and institutional approvals with the REB application in the ROMEO Research Portal.

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Click Search Click Add M	h to attach an existing certification	ad to a realistic control has		
 Click Search Click Add N 	h to attach an existing certification iew to attach a certification not yet submitt	ted to a review committee		
Click Search Click Add N Add New	h to attach an existing certification lew to attach a certification not yet submit Bearch	ted to a review committee		

For studies with an existing REB application on ROMEO: Select "SEARCH". This will generate a list of your existing REB applications. Select the appropriate study.

ptions	Filo #	Certification Category	Title	Status	Expiry Date
	Y	Y	Y	X I	1
electj	2020548	Human Ethics	Test 4	Active	2022/08/09
electj	2020544	Human Ethics	Test 2	Active	
elect	2020539	Human Ethics	TEST	Active	

For studies that have not yet applied for REB review on ROMEO: Select "ADD NEW". This will generate an open text box in which you can indicate you have not yet submitted for REB review.

For multi-jurisdictional studies that have applied for harmonized REB review on the Provincial Research Ethics Platform hosted on the UBC RISe portal: Select "ADD NEW". This will generate an open text box in which you must indicate the H-Number for the study.

1/08/13		
1/12/24		
ogics	Project Certification	×
logics	Certification Category	
	Human Ethics	
	Notes	
	Use this space to provide relative information, e.g., RISe	
	number for multi-jurisdictional files	-10
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5. Complete the Project Team Member Tab

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

pplication Ref	No: 1012							Application I	Form: Initial Application for Clinical Studie
Save Close	Print	Export to Word	et to PDFSubmi	E. Withd	T in se				
Project Info	Project Team Info	* Initial Application fo	Clinical Studies A	tlachments.	Approvals	Logi	trun		
Principal Inve	stigator								
Instructions : Do not PI button to search f	t hand type data fo for and select an a	or this section. The Principal itemate researcher profile. I	Dwestigator (PE) section Fyou load an alternate re	default popula esearcher prof	stes with the resi lie to the PL secti	earcher profi	le data for the project to reload your research	team member who creates the ner profile to the Other Project 1	file. If you are not the PL, click the Chang Feam Info section below.
Change Pl	Detech	Pi can be changed at any point by clicking							
*	-	nere	_						
Profix:	Dr. •	Last Name":	O'Shaughnessy				First Name*:	Sara	
Affiliation':	Evaluation an	nd Research Services			٠				
Position:		• B	sition can be left ank						

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. <u>Do not manually type in the PI's name</u>. Once this is complete, remember to re-add yourself to the application as a team member.

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.

dve Close						
oject Team Memb	er Info					
add more project team m	embers to this application for	click SEARCH PROFI	ILES to search for and select fr	om other researcher profiles.	Click [?] for more info.	
inarch Dusfilas	Co-investigator					
PERIOD P TO IDER	Co-Supervisor					
	Investigator					
Prefix:	Knowledge User			First Name:		
	Patient Partner					
Athilation	Research Coordinator					
	Research Staff					
	Supervisor					
Bala in Departs	Undergraduate Researcher		Countrat	1	-	
inter in conject.	Continuescipition		Course y.		-	
Position:	5		institution:		-	
Email:			Fax:			
Phone1:	<u> </u>		Phone2:			
	<u></u>			A		

For this section, <u>it is not required to include all team members on the study</u>, only those you wish to grant online access to (e.g. those who have been designated to submit forms on behalf of the PI).

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.

6. Project Sponsor Tab

Insert information about the project sponsor or funder in this section, as applicable.

Application Project W	on Ref No: 1030 Pr fork Flow State: Pre	oject Title: Test Submission			Applicatio	an Form: Applica	tion for Lett	Econduct	ization to Research
Save	Close Print	Export to Word	Export to PDF St	ubmit Withdraw					
Froject In	o Froject Team Info	Project Sponsor	Info Application I	for Letter of Authorization to Conduct Resea	arch Attachments	Approvals	Logs	Errors	1
Click Add N	ew to add funder and per f	scal year budget detail	s for this project,						
Add Ner	#5.1								
	Investigator		Agency	Program			inte	tal Requests	ed Amourn
No records	to display.								

Use the "Add New" button to add sponsors/funders to the project record. Locate the sponsors/funders by selecting "Agency".

ponsor Info.					
Agency:	Agency				
Program:	0	•			
Investigator:	Dr. Sara O'Shaughnesy	y (Principal Investigator)			
Competition Date:		-			
Start Date:	0	100			
End Date:		100			
Currency Type:	CAD	•	 		
Comments:					

Use the search function to locate the appropriate Agency name. If the sponsor/funder is not listed, contact <u>Adriel.Orena@fraserhealth.ca</u> to add the sponsor/funder.

Agency List				×
	Start With ® Any part			
Agency Name: Abbreviation:				
Constant	Dent			
Search	Resel			
				- ñ
Options	Name	Abbreviation	Source	
Options	Name	Abbreviation	Source	
Select	Name	Abbreviation	Source	
Select Select	Name Fraser Health Professional Practice Heart & Stroke Foundation of Canada	Abbreviation V FH PP HSFOC	Source	

7. Complete the Application to Initiate a Project Record tab.

Physiotherapy Association of British Columbia

Ridge Meadows Hospital Foundation

Select

Select

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PT Assoc BC

RMH-F

Professional Association

EH Enundation

This section collects information about the nature of the project being submitted (e.g. a request to apply for external research funding, a request for a Letter of Authorization for an existing project), and will identify the necessary sub-approvals required before the Letter of Authorization can be issued.

8. Submit the application form

Once you select the appropriate application form, you will be assigned a temporary Application Reference Number will the application is in draft format. This will be replaced with a permanent File Number once the application form is submitted.

Complete the questions found in each tab. Make sure to **SAVE your work frequently**. If you close the application or browser without saving, all changes will be lost. Note that questions with a ***red asterisk** are required.

If no further sub-approvals are required, the Department of Evaluation and Research Services will issue the Letter of Authorization in the Attachments tab and mark the submission as "Active".

If further sub-approvals are required, the application will be marked as "Pending". Please follow the next steps.



9. Navigate to "Applications: Post-Review" from your home page

10. Locate the appropriate study from the list.

Select "Events" to access the intake forms for the sub-approvals.

ICK TO Search	File No	Better hea	lth. Best in healt	h care.	LY NEW News Useful Link
Reset Filters Expo	rt To Eace	Project Title	Principal Investigator	Application Type	Status Snapshot
	[x]	x	[x]	Al	[y]
View Clone Events Latest Workflow	2020561	Test for Run-Through #2	Dr. Sara O'Shaughnessy (Evaluation and Research Services)	Application to Initiate a Project Record (Awards)Awards)	Project Status: Active Workflow Status: Approval Decision Made
View Clone Events Latest Workflow	2020560	Test - operational approval run through	Dr. Sara O'Shuughnessy (Evaluation and Research Services)	Application to Initiate a Project Record (Awards)Awards)	Project Status: Pending Workflow Status: Approval Decition Made

11. Events Page

The events page will provide a list of applications related to the various sub-approvals that may be required. Complete each form as necessary. Multiple forms may be submitted concurrently. If you are unsure which forms are required for your study, please contact Research.Approvals@fraserhealth.ca for guidance.

Create New Event

	Event Form Name	Description			
+					
	Cost.Centre Réquest	Request a Franer Bealth cost centre for this research project			
*	Deanjuser				
	Deta Access Aqueement	The purpose of this form is to confirm that data transmission and storage procedures of your initiative meet Fraver Health and/or provencial requirements. Flease complete this section if the study requires access to personal information that is collected or maintained by Frazer Health. If you require asistance, please email our Research Privacy Advisor at dean.simmons@frazerhealth.ca. "Personal information include the following: Individual's name: all geographic subdivisors smaller than a province, including street address, oty, country, postal code birth date; home telephone numbers; home fax numbers; electronic mail addresses; SIN; MINI, PHN; device identifies and serial number; biosetric identifies; full face or identifiable photographic images and any comparable images; and any other unique identifying number; characteristic; or code, except a code to permit re-identifiable photographic images and any comparable images; and any other unique identifying number; characteristic; or code, except a code to permit re-identification of the de-identified data.			
	Octavia_user				
	Contracts Intake	Provide information to complete a contract: through Fraser Health			
	Affiliation Agreement Bestuest	Non-Fraser Health Principal Investigators conducting research in Fraser Health must apply for affiliated status prior to commencement of the research.			
	Putri_user				
	CIMS Intake	Clerical Trial Management System (CTMS) is a cloud-based software that helps maintain and manage the administrative aspects of clinical research operations, throughout the research lifecycle. It helps track petitient as well as study visits, and it improves the financial management and billing. All studies that are publicly registered on a clinical trial registry are strongly encouraged to be added to the CTMS. For more information, please visit the Fraser Health CTMS SharePoint site at http://ftworkspices/sites/RealTime-CTMS/default.avp.			
τ.	research_approvals				
	Desartment Agreement to Provide Research Related Services	Studies requiring the provision of services from Fraser Health departments/units to support the research must apply for operational approval using this form.			

12. Complete and submit each form, as applicable

If any changes are required, you will be directly notified, and the event forms will be visible as "Events: Requiring Attention" on your home page.

BACK TO Search File No +	0	APPLY NEW News Useful Links
Role: Principal Investigator		5
Applications: Drafts	(0)	
Applications: Requiring Attention	(0)	
Applications: Under Review	111	
Applications: Post-Review	(6)	
Applications: Withdrawn	101	
Events: Drafts	(1)	
Events: Requiring Attention*	421	
Reminders*	m	
Role: Project Team Member		
Role: Reviewer		

13. Click "Events: Requiring Attention"

This will show you the list of all submissions with Events Requiring Attention. Select "Events" from the file you wish to resubmit.

ACK TO Search	File No	• @		AP	PLY NEW News Useful Lin
Reset Filters Expo	rt To Excel				
	File No.	Project Title	Principal Investigator	Application Type	Status Snapshot
	(x)	Y	w	All •	[V]
View Clone Events Latest Workflow	2020560	Test - operational approval run through	Dr. Sara O'Shaughnessy (Evaluation and Research Services)	Application to initiate a Project Record (Awards)Awards)	Project Status: Pending Workflow Status: Approval Decision Made
View Clone Events Latest Workflow	2020548	Test 4	Dr. Saia O'Shaughnesiy (Evaluation and Research Services)	Initial Application for Clinical Studies (Certification/Human Ethics)	Project Status: Active Workflow Status: Approval Decision Made

14. Events Page

The Events Page is the same page where Event applications can be found. Scroll to the bottom of the page to find the Events Requiring Attention. Select "Latest Workflow" to see changes required.

File No: 2020560				
Principal Investigatori Dr. Sar Project Title: Test - operation	ra O'Shaughnesiy al approval run through			
Eventa: Drafts				•
Events: Requiring Attentio	h			*
	Territ No.	Event Category	Event Submission Date	Event Statue
Verw Event Edz Labert Wnikflow	2020560 - 3539	CTMS lenaise (CTMS initalie)	2021/08/20	Submitted by Researcher
Events: Under Basiew				4
Events: Pust Review				
Reminders				*

15. Latest Workflow

This section will provide instructions on what changes are needed to the event application.

O'Shaughnesi ject Title : Te	ke File No: 2020560 - 3539 sy Sara(Evaluation and Research Services) st - operational approvel run through				Event Form: CTMS I
ava Cio	se Print Export to Word Export to Pr	DF. Re-Submit			
Event Info	CTMS Intake Attachments Logs				
Timestamp	Activity Log	Workflow State	Workflow Message	User.	Role/Group
2021/08/20 09:22	Event Workflow State has been changed from ORS Review to Pending Info by ORS.	ORS Review -> Pending Info by ORS	test changes required	research_approvals	Office of Research Services/Office of Research Ethics
	Event Work Flow State has been changed from Pre-	Pre-Submission -> ORS	Borres	Sara	Balancin of Torrectformbox

16. Re-Submit.

Make any changes to the Event Application form and/or Attachments as required, and resubmit. Once all applicable Event forms are submitted and approved, the Letter of Authorization will be released in the Attachments tab and the study will be marked as "Active".