

# Quick Reference

Research Administration System (RAS)

Last Modified: October 17, 2024



# Contents

Logging In
Certifications
Add Certifications
Protocol Management - Lifecycle Event Manager4
Search for a Protocol4
View Status of Submission
Reassign Submission
Delete Submission
Withdraw Submission
Submissions
Create New Initial Application6
Complete Initial Application7
Create Additional Follow-On Submissions7
Submit an Application/Follow-on Submission7
Sending an Application/Follow-on Submission back to the PI8
Team Changes Tab9
Save/Resume Submission9
Errors on Submission9
Application/Follow-on Submission Returned: Revisions Required10
Attachments: Marked-Up Versions12
Upload Clean & Marked-Up Version12
Review Process
Complete Review – Chair/REB Member14
Review Agenda14
Review Minutes15



## Logging In

- 1. Login to <u>RAS</u> using your UM email and password.
  - a. **Note**: If you see a blank screen this means you do not have a profile setup in RAS. Please contact IST and request a profile.

# Certifications

CORE certification is required for all research personnel submitting a Human Ethics protocol. PHIA certificate is only required for PIs and Advisors where PHIA is required for their Human Ethics protocol.

**Note:** All users must upload their own certificates to their profile prior to the submission of any Human Ethics protocols they are listed on.

#### Add Certifications

- 1. Click Manage > User Profile under the main menu
- 2. Click on the Certifications tab
- 3. Click on Add Certification
- 4. Enter data as follows:
  - a. Training Provider: Type in who provided the training i.e. TCPS-2
  - **b.** Attach Pledge: Click Attach Pledge > Choose File, find the file then and click Upload (Please ensure there are no characters in the file name).
  - c. Training Date: Enter in the certification date
  - d. Lookup Certification: Select the corresponding Certification from the list i.e. CORE

Add Certificat	tion				$\otimes$
Training Provide Attach P Training	r: ledge 🖻				
Lookup (	Certification:		<u>Go</u>	_	
Name <u>CORE</u> PHIA	<b>ID</b> 42 43				
					2

See video <u>"How to upload CORE and PHIA Certificates"</u> for more help.



# Protocol Management - Lifecycle Event Manager

## Search for a Protocol

To find and view a protocol:

- 1. From the LiveList page, select **Cases** from the Subject drop down
- 2. Click within the **Finder** textbox

	LiveList	тм	
Finder:	Go	Subject: 💌 Cases	Configure

- 3. Enter one of the following:
  - a. Protocol Number
  - b. PI First and/or Last Name
  - c. Partial string from the Title
- 4. Click Go, the LiveList will now filter based on the entered criteria
- 5. Click on the Protocol Number link to open the protocol to view the Lifecycle Event Manager
- 6. To go back to the LiveList click on the **Protocol Number** link again **Remember**: Do not use the Back button on your browser

#### View Status of Submission

- 1. Select the protocol from the LiveList
- View the status under the Lifecycle Event Manager tab
   Important: The data listed in this section is VIEW ONLY you cannot edit your submissions here.
   Ether create a new follow-on or navigate to the To Do List and access an active task to edit.
  - a. Actions: This drop down is used to create new follow-on submissions (i.e. Amendment).
  - b. Status: This section shows the current status of the selected protocol.
  - c. **Submissions**: This section allows the user to view each individual submission or withdraw the submission if it hasn't been approved yet.

VID Number F HE2020-0197	Title F Tuesday - Ame	ndment RAS	F Researcher	Status F Active	Type F Human Ethics
Lifecycle Event Communications Manager	Summary Research Personnel P	articipants Consent D	ata Risks/Benefits	Dissemination/Withdrawing	Attachments
Main		a	•	<b>G</b> 0	
Status: Active Approval E	Start: 08/24/2020 Risk L End: 08/20/2021 Assig	evel: ned REB: PSREB	Review Frequency Original Approval		
Submissions C	Receipt Date Summary	Status Decis	ion Lifecycle I	Details Actions	
3 Amendment 2 Personnel Change	08/25/2020 View 08/24/2020 View 08/21/2020 View	Admin Review Pend Completed Appro Completed Appro	ng <u>View</u> yed <u>View</u>	View Withdraw View	
			InterpriseWeb LLC, 2012-20	120	
		•	sinergenserved CDG, 2012-20	1214	



## **Reassign Submission**

A submission can be reassigned to any research member with **edit access**. Once reassigned, the submission can then be submitted back to the PI or reassigned to another research member with **edit access**.

Important: Only research members with Edit Access can be reassigned the submission.

 Under the Lifecycle Event Manager tab, select Reassign Task under actions Note: You can only reassign task prior to submission to the board.

Submissions							
Type 2 Personnel Change	Receipt Date	Summary <mark>View</mark>	<b>Status</b> In Development	Decision Pending	Lifecycle <u>View</u>	Details <u>View</u>	Actions Delete Reassign Task
1 Initial Application	06/15/2023	View	Completed	Approved	<u>View</u>	<u>View</u>	

- 2. Select the research member in the Person drop down list
- 3. Add any instructions to the Comments text area, optional

Reassign Task		8
Person:	<ul> <li>RAS Researcher</li> </ul>	
Comments:		
Please revise.		
	-	
	li.	
Reassign		
		Δ

Note: These notes will appear in the Lifecycle History view for all to view

Event #4: Submission Assigned
Result:
Currently with: RAS Researcher
Started: Thu Aug 24 2023 09:48:19
Comments: Please revise.

- 4. Click Reassign, then OK
- 5. Task is now reassigned and will be in this research members To Do List.



#### **Delete Submission**

**Important**: Deleting a submission removes it from the to do list and submission list. Use this function if the submission is not longer required.

 Under the Lifecycle Event Manager tab, select **Delete** under actions Note: You can only delete prior to submission to the board.

Submissions							
Type 2 Personnel Change	Receipt Date	Summary View	<b>Status</b> In Development	Decision Pending	Lifecycle <u>View</u>	Details <u>View</u>	Actions Delete Reassign Task
1 Initial Application	06/15/2023	View	Completed	Approved	<u>View</u>	<u>View</u>	

## Withdraw Submission

**Important**: Withdrawing a submission does not simply move it back to the to do list so it can be edited. It will remove it from the to do list and deactivate it so it cannot be edited/submitted further. Use this function only if a submission is and no longer require to be reviewed by the REB.

Under the Lifecycle Event Manager tab, select Withdraw under actions
 Note: You can only withdraw a submission after it has been submitted but prior to approval.

Submissions							
Type	Receipt Date	Summary	<b>Status</b>	Decision	Lifecycle	Details	Actions
1 Initial Application	06/10/2023	View	Admin Review	Pending	<u>View</u>	<u>View</u>	Withdraw

# Submissions

## Create New Initial Application

- 1. Navigate to the top menu bar and select Create New > Human Ethics Protocol
- 2. Enter the following:
  - a. Protocol Title
  - b. **Principal Investigator** if you are not the PI for this protocol, then click **Replace** to select the PI
- 3. Click Begin Application

Create a l	New Human Ethi	cs Protocol
Create:	New     Copy from existing	
Protocol Title:		
Principal Investigator:	RAS Researcher	Replace
Department:	<ul> <li>Max Rady College of Medicine</li> </ul>	
Begin Application	Cancel	



#### Complete Initial Application

- 1. Navigate through each tab and subtab of the application answering each question as it appears
- 2. Important to note:
  - a. If submitting a protocol as a Designate (i.e. Study Coordinator) the protocol will be sent to the PI for sign off once submitted.
  - b. If submitting a protocol as a Student PI, ensure you indicate this in the summary page and add your advisor in the **Research Personnel** tab. The application will be sent to the advisor for review once submitted.

Protocol Nu	mber: TEMP-	HE2020-0255					Initial App	lication		
Principal Inve	stigator: RAS F	Researcher						Print		
Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Indigenous Peoples	Attachments	Submit
Summary -	Purpose of th	e Research -	Research -	General Q	Questions					

## Create Additional Follow-On Submissions

Follow-on submissions can be submitted by anyone on the protocol that has **edit access** or **signature authority**.

- 1. In the LiveList select the protocol
- 2. Under the Lifecycle Event Manager tab select the submission under the Actions drop down

ifecycle Event Ma	nager Communications	Summary	Research Personnel	Secondary Us	e of Data At	tachments		
			A	Actions				
Stage: Protocol	Most Recent Approval Da	te:06/19/2021	Risk Lev	vel:	Review Freq	uency: 364 days		
Status: Active	Approval End: 06/18/2023		Assigne	d REB: REB2	Original Apr	oroval Date: 06/19/202		

- Amendment use this form to submit an amendment to the current protocol, you can include any personnel changes within this form.
   Note: Only one amendment or personnel change form may be submitted at a time.
  - Note: Only one amendment or personnel change form may be submitted at a time.
- b. **Personnel Change** use this form to submit a personnel change without having to submit a full amendment.
  - Note: Only one amendment or personnel change form may be submitted at a time.
- c. Renewal Request use this form to submit a renewal request to the current protocol.
- d. **REB Event** use this form to submit a REB event (formally adverse event form).
- e. **Protocol Closure** use this form to submit a study closure for the current protocol.
- 3. Navigate through each tab and subtab of the submission answering each question as it appears

## Submit an Application/Follow-on Submission

- 1. Navigate to the **Submit** tab
- 2. Read and check each of the Declaration Statements

**Remember**: If a Designate is submitting the application, they will not check off the declaration statements, the submission will be sent to the PI for them to sign off on these.



- 3. Check the I Agree checkbox to agree to the certification statement
- 4. Click Send for Review

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Indigenous Peoples	Attachments	Submit
Initial	Applica	tion Subi	missio	n						
Optional St	ubmission Note	S					//			
🗹 l have	reviewed the p	otocol contents a	ind confirm th	at the info	rmation provide	d in this application i	s complete and correct.			
	to abide by the rch Involving H		s and policies	of the RI	EB, including the	e Tri-Council Policy S	Statement and the University of Man	itoba Policy on t	he Ethics of	
🗹 I will er	nsure the study	does not comme	nce until the f	inal certifi	cate of approva	I has been issued by	the REB.			
🗹 I will er	nsure the study	does not comme	nce until appr	oval has l	been granted by	the appropriate org	anization, if applicable (e.g. chief an	d council, schoo	l board).	
🗹 l will er	nsure all resear	ch team members	s (e.g. faculty	students	, staff) handling	data will have the ap	propriate training (e.g. CORE, PHI/	A).		
🗹 I will er	nsure that study	r personnel are qu	ualified, appro	opriately tr	ained and will a	dhere to the REB-ap	proved application.			
🗹 I will no	otify the REB of	any protocol cha	nges and rep	ort advers	e events/experi	ences as soon as po	essible.			
🗹 l will su	ubmit any chan	ges to this study t	o the appropr	iate REB	for consideration	n before implementa	tion.			
🗹 l will su	ubmit a request	for annual approv	val to the REE	3 prior to t	he expiry date i	ndicated on the appr	oval certificate.			
🗹 l will su	ubmit a Study C	losure Form to th	e REB when	all study a	activity is comple	eted at the local site.				
	viding my signa ient (TCPS).	ture, I confirm tha	at I have read	the above	e terms and agre	ee to comply with this	s and other university policies, guide	elines and the Tri	i-Council Policy	
🗸 l Agree	(PI) (signed 10/09	2020, 3:37:22 PM by	y RAS Research	er)						
Send for	Review									

## Sending an Application/Follow-on Submission back to the PI

If you are a CoPI or Advisor, you will always have the option to send the submission back to the PI for review.

- 1. Navigate to the **Submit** tab
- Check the send this back to the PI
   Note: If you do not want to send this back to the PI but want to send it to the next person in the workflow/Office of Human Research Ethics, keep this box unchecked.

```
Send Initial Application back to the PI for review? (Select this option only if you have made changes to the Initial Application, and want the PI to review them)
```

- 3. Check the I Agree checkbox to agree to the certification statement
- 4. Click Send to PI

If you are a Designate/Edit Access research member when you navigate to the Submit tab the submission will always be sent to the PI.

- 1. Navigate to the **Submit** tab
- 2. Check the I Agree the submission is complete checkbox
- 3. Click Send to PI

I Agree the submission is complete



## Team Changes Tab

When a submission is moving between research members, each member will see changes since the last time they had it. This tab will appear when any initial application or follow-on submission is sent to another research team member listed. This also includes when you reassign to someone with **edit access**.

Protocol Numbe	SI. HE2025-0151							
Principal Investigator:	RAS Researcher				Print		ZIP Attac	hments
Team Changes	Personnel Changes	Summary	Research Per	sonnel**	Attachments*	Submit		
New Change	25							
New Change		ield		Original Va	lue	Current Value		Action

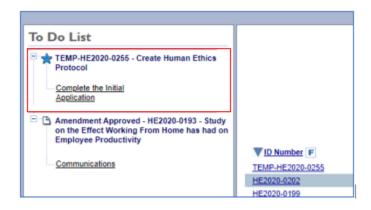
## Save/Resume Submission

1. All submissions are saved automatically when you navigate to another tab within your

submission. You can click at the top left-hand side of the screen though to ensure it has saved fully.

**Important**: Do not exit your submission before navigating to another tab or manually saving.

- 2. Click the Home menu item at the top of the screen to return to the LiveList
- 3. The submission is now listed in your **To Do List**
- 4. To return to the submission, click the task under the To Do List



#### Errors on Submission

- 1. If you get an error stating Incomplete Application, this means there are missed questions that need to be addressed, Click **Return**
- 2. Errors are indicated by a red asterisk on the tab and red box on the subtab



Protocol Nu	mber: TEMP-	HE2020-0255		My I	New Protocol		Initial Applic	ation
Principal Inve	stigator: RAS I	Researcher				Status: 0	Correcting Errors/Omis	sions Print
Gummary	Research Personnel	Participants	Consent Process	Data	Risks/Benefits	Dissemination/Withdrawing *	Attachments	Submi
data? How will in about your presented statistics fo	formation from o participants be (e.g., summary r the whole grou ations from their	up,	pportunity to r	eview the	ir () Yes	• No	Required	

3. Fix each error indicated, return to the **Submit** tab and submit the application again

#### Application/Follow-on Submission Returned: Revisions Required

After an application or submission has been reviewed and it is sent back from the OHRE for revisions (either from pre-review or REB review), the PI will receive an email notification and task to be completed in their To Do List.

- 1. Under the **To Do List**, find the Revise task
- 2. Click the link within the task



Note: You can click the link in the Email notification, this will bring you to the task as well.

- 3. The Comments tab provides a summary of all comments made
- 4. Click on the link under Location to bring you to each comment to review

PI Response	:					
Location		leid	Original Value	Current Value	Comment	Action
Summary >> Pure Research		Describe the research question(s) and objectives for his research study.	Objectives	Objectives	add more detail	No Change
Participants >> P		fow many participants do rou expect to recruit?	Recruit	Recruit	please add more specific	No Change



**Note**: Any comments made will also be indicated with a red \* on the tab within the Application section.

- Make the appropriate changes to each question based on comments provided Important: For information on how to upload a marked-up version of a document, please see <u>Attachment: Marked-Up Versions</u>
- 6. If Justification is required, add your justification to the popup box that appears beside the question

Note: Justification is mandatory, you must fill in a response.

Requirement: Confirm and justify participants.	
Justification:	
la l	

7. Any additional changes to the application/submission, will be added to the **Comments** tab

omments Summary*	Research Personnel* Participants	Consent Process Data	Risks/Benefits Disse	mination/Withdrawing	Attachments Subr
PI Response:					
Location	Field	Original Value	Current Value	Convent	Adion
Summary ** <u>Purcos of the</u> Baseach	Describe the research question(s) and objectives for this research study:	Objectives	Objectives - there are many objectives which are included in the attachment.	add more detail	Using New Yolke
Participants >> Participants	How many participants do you exceed to receive?	Reput	100 participants.	please add more specific	Using New Yolke
Research Description	What type of data (e.g. directly identifiable, anonymized) will each individual have ecoses to?	Cata	Data - data will be anonymized.		Using New Yolue
	▶ ne				

8. Add any additional comments in Investigator Response under the Review section

Instructions
Response to Chair Review
Review Comments
Investigator Response (to the Administrator)

9. Navigate to the **Submit** tab and resubmit the application/submission

The revision has now bene sent to the OHRE.



#### Attachments: Marked-Up Versions

A Marked-Up Version of a document is a copy that includes track changes to indicate changes made. These documents must be uploaded in the Attachments tab along with a copy of a clean version of the document.

**Important**: The marked-up version is not part of the final approval. This means you will not see this copy once the submission is approved only the clean version.

**Note**: Depending on where you are in the submission process or what type of submission you are revising, the Marked-Up Version section in the Attachments tab may look sightly different. The example below is of an Initial Application returned to the PI for after a pre-review.

	Protocol Number:	HE2023-0228			1	Initial Application	n		
nstructions Revisions	Principal Investigator:	Courtney Edworthy		Print		ZIP Attachment	_		
teview Comments	Comments Sum	nary Research Personnel P	Participants Consent Process*	Data Risks/Ben	efits Dissemination	n/Withdrawing	Indigenous Peoples	Attachments*	Submit
Please see comments. The document title names must be									
updated/changed and then uploaded as Marked Up Version' under the Attachments tab with track changes or highlighting. Please also upload a clean copy of documents in the appropriate tabs.	PI Response:								
appropriate tabs.	Location	Field	Original Value	Current Value	Comment	Action	Justification	n	
nvestigator Response (to the Analyst)	Attachments	Document type / Name	Consent Documents / Consent.pdf	Consent Documents / Consent.pdf	Please make the appropriate changes and upload a marked up version with track changes along with the updated Consent form.	New document required			
	Consent Process >:	> Consent Docume		Consent.pdf [View Page]	Please add dates.	No Change			
	Informed Consent Process		Page]	(age)					

#### Upload Clean & Marked-Up Version

To upload the marked-up version you must replace/upload a new "clean" version of the document then the marked-up version.

There are two ways to upload the clean version: Under the designated tab (i.e. Consent Process for a consent form) or under the Attachments tab.

#### Designated Tab

- 1. Navigate to the designated tab, in this example the Consent Process tab
- 2. Click Replace, find and Upload the clean version of the document

Summary	Research Personnel	Participants	Consent Process	Data	Risks/Benefits	Dissemination/Withdrawin	g Indigenous Peoples
nsent Process		13 - F					1979 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 -
where and ho							
	(s): <sub>Type</sub>			Name		Upload	
		ent (				sent.pdf Replace Comme	
	nsent Process he consent /here and ho nt be obtaine	Summary Personnel nsent Process the consent where and how the obtained? test	Summary Personnel Participants nsent Process the consent hybere and how to be obtained? test consent form(s): bocuments	Summary Personnel Participants Process nsent Process test test onsent form(s): bocuments	Summary Personnel Participants Process Data Insent Process Test Test Test Test Test Test Test T	Summary Personnel Participants process Data Risks/Benefits nsent Process test test test onsent form(s): roouments	Summary Personnel Participants Process Data Risks/Benefits Dissemination/Withdrawin nsent Process the consent h/ere and how to be obtained? test consent form(s): boouting to be added by the set of the set o



3. Once the new document has been uploaded navigate to the Attachments tab to upload the <u>marked-up version</u>

#### Attachments Tab

- 1. Navigate to the Attachments tab
- 2. Click **Upload** under New Version, find and **Upload** the <u>clean version</u> of the document
  - 3. Once the new document has been uploaded you can now upload the marked-up version

Рге	evious Docun	nents									
	Туре		Name	Version	Status	History	File name/ Uploaded Date	Comments	Marked Up Version (7)	New Version	
	Consent Documents	Consent		1	New		Consent.odf 08/22/2023	View		Upload	Comments New Doc Required
	Recruitment Documenta	Poster		1	New		Poster.odf 08/22/2023	View	1	Upload	
	Other Approval Documents	Approval		1	New		acoroval.docx 08/22/2023	View		Upload	
	Agreement Documents	New Agreement		1	New		Fully Executed Agreement.odf 08/22/2023	View		Unioad	
	Oath of Confidentiality:RAS Researcher	Oath of Confide	ntiality.pdf	1	New		Oath of Confidentiality.odf 06/23/2023	View		Upload	
x	Manual Attachment	Survey		1	New		survey.odf 08/22/2023	Ximo		Upload	

Marked-Up Version

- 1. Navigate to the Attachments tab
- 2. Click Attach under Marked Up Version, find and Upload the marked-up version of the document

					File name/ Uploaded Date	Comments	Marked Up Version	New Version	
Consent Documents	Consent	1	New	View	Consent 2.odf 08/23/2023	View	Attach	View / Replace	Comments New Doc Provided

**Note:** The original document that was replaced in the designate tab and attachments tab can still be viewed by clicking **View** under History

Туре	Name	Version	Statu	s History	File name/ Uploaded Date	Comments	Marked Up Version [7]	New Version	
Consent Documents	Consent	1	New	View	Consent 2.pdf 08/23/2023	View	View X	View / Replace	Comments New Doc Provide



# **Review Process**

When an application has been submitted there will be a task listed in the Task view for the Office of Human Research Ethics (OHRE). The OHRE will then assign the application to the appropriate REB member(s)/Chair.

#### Complete Review – Chair/REB Member

- 1. Click on the **Complete Review** To Do List task
- Review the protocol in its entirety, add comments to each question within the submission by clicking the check box beside each question
   Note: Comments are summarized in the Comments tab.
- 3. Input the **Decision/Recommendation** for this review under the Chair/Member Review pane

Member Review
Recommendation  -Select-
Do you have a conflict of interest to report? Yes No
Review Comments
Investigator Actions
Submit

- 4. Indicate whether or not there is a conflict of interest
- 5. Add additional comments/actions if needed
- 6. Click Submit

#### **Review Agenda**

When the agenda is built/sent, members will receive an email and a task under the To Do List.

1. Click on the Agenda Communications To Do List task



- 2. To download the agenda, click the link beside Download Document
- 3. To access submissions, click the link beside Assess Submissions
- 4. Enter your response as to whether you will attend the meeting in the **Response** drop down
- 5. Add additional **Comments**, if applicable



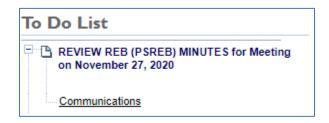
6. Click **Close** to close the task, Click **Delete** to remove the task from you list

REVIEW REB AGENDA	
Action Required: REVIEW REB AGENDA	
The PSREB Agenda and materials for our meeting on November 27, 2020 are now available for review.	
Thank you in advance for your attention to this matter. If you have any questions, please do not hesitate to contact me.	
Please login to the <u>Research Administration System (RAS)</u> to access any task or view your Projects/Protocols. Please ensure you are using a supported browser; Chrome, Firefox or Microsoft Edge.	
Download Document: here	
Access Submissions: here	
Please specify your response in the section below:	
Response:	Ŧ
Comments:	
Close	
Delete	

#### **Review Minutes**

When the minutes are built/sent members will receive an email and a task under the To Do List.

1. Click on the Minutes **Communications** To Do List task



- 2. To download the minutes, click the link beside Download Document
- 3. Click Close to close the task, Click Delete to remove the task from you list



#### **REVIEW REB MINUTES**

Action Required: REVIEW REB MINUTES

The PSREB Minutes and materials from our meeting on November 27, 2020 are now available for review.

Thank you in advance for your attention to this matter. If you have any questions, please do not hesitate to contact me.

Please login to the <u>Research Administration System (RAS)</u> to access any task or view your Projects/Protocols. Please ensure you are using a supported browser, Chrome, Firefox or Microsoft Edge.

Download Document: here

