

# How to Submit a Protocol as a PI

## RAS Training Documentation

Last Modified: July 30, 2024

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## Initial Application

To create a new Human Ethics Protocol as a PI:

1. Under the **Create New** menu item select **Human Ethics Protocol**

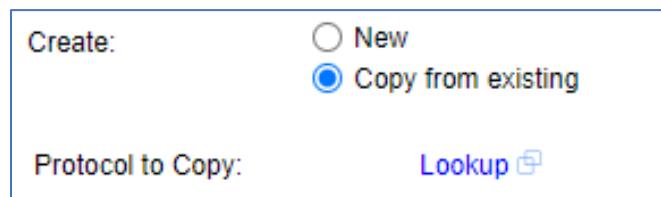
**Note:** The newly created protocol will receive a temporary protocol number while the application is in development. Once the application is submitted, a final Human Ethics Protocol number will be assigned.



2. Start filling out the following information to start your new protocol:

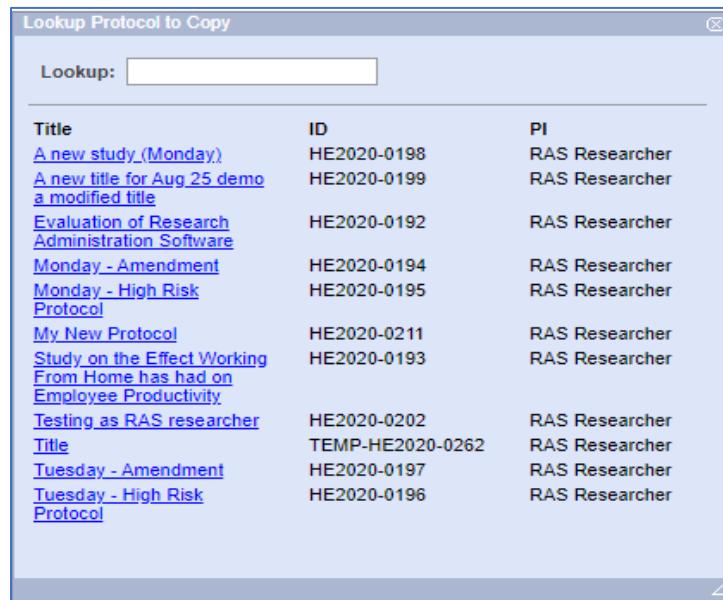
- a. **Create** – New or Copy from Existing

- i. To **copy from existing** protocol, click the **Lookup** link the Lookup Protocol to Copy window will appear



- ii. Search and select the protocol you wish to copy

**Note:** You will only be able to copy protocols you have access to.



- b. **Protocol Title** – Enter the title of the protocol

**Note:** The title must be unique per PI, this means it cannot be duplicated from another protocol under the same PI

- c. **Principal Investigator** – Populated with name of the user who is logged in, this should be the PI
- d. **Department** – this drop down will auto populate based on the PI chosen

3. Click **Begin Application**

### Create a New Human Ethics Protocol

Create:  New  Copy from existing

Protocol Title:

Principal Investigator:  [Replace !\[\]\(269fd4c0b49557f7ba83ac4867465274\_img.jpg\)](#)

Department:

[Begin Application](#) [Cancel](#)

#### Complete Initial Application

The initial application form employs a feature that displays relevant questions and tabs based upon the responses provided throughout the application form. This means you will only see questions that are required for you to answer as you are completing the form.

Navigate through each tab and answer each question as they appear within the form.

Protocol Number: [TEMP-HE2020-0255](#) Initial Application

Principal Investigator: [RAS Researcher](#) [Print](#)

[Summary](#) [Research Personnel](#) [Attachments](#) [Submit](#)

Summary - Purpose of the Research

Protocol Title  character count: 15

Principal Investigator  [Replace PI](#)

Is the Principal Investigator for this project a student?  Yes  No

Primary Department  [replace](#)

Application Initiated By

[previous](#) [next](#)

## Adding Research Personnel

Add additional research personnel to the protocol.

1. Navigate to the Research Personnel tab
2. Click **Add** under the Protocol Personnel table

Protocol Personnel									
Name	Department	Role	CV	CORE	PHIA	Access	CC	Contact Details	Contact Level
RAS Researcher	Max Rady College of Medicine	Principal Investigator		08/21/2020 Import	08/21/2020 Import				
<a href="#">Add</a>									

3. The Find Person window will appear, search for the user's name in the Lookup field

**Note:** If the user you are trying to add does not appear in the list you can still add them to the protocol, see [Add On-The-Fly User](#) section.

**Find Person**

Lookup:  [Go](#)

Name	ID	Department
<a href="#">Admin, Research</a>	RAS_PI_Admin	Max Rady College of Medicine

4. Click on the user's name to add them to the protocol

5. Once they are added, complete the following:

- Select **Department**: this default to the users' primary department
- Select **Role**: this is the user's role for this specific protocol
- Import **CV**: this is the user's CV, optional (not required for Human Ethics Fort Garry)
- Import **CORE**: click **Import** to link the users CORE certificate

**Note:** all personnel must have CORE added to their user profile in the system. If they do not, you must contact that person to get them to add it prior to submitting the protocol.

- Import **PHIA**: click **Import** to link the users PHIA certificate

**Note:** this is only required for the PI & Advisor prior to **submission** for studies that involve personal health information, all other research personnel must have this added to their profile for import prior to **approval**.

- Assign **Access**: this is the user's access to this protocol

- Edit Access**: Gives the user edit access to the protocol. Usually given to Study Coordinators.

**Note:** A user with Edit Access can be reassigned a submission task to complete, see [Reassign a Task](#) section.

- No Access**: Given to users that do not need to access the protocol in the system.
- Read-Only Access**: Given to user that can access the protocol but only have read-only access, meaning they cannot edit the protocol.
- Signature Authority**: This gives the user signing authority on the protocol

**Note:** Only the PI, Co-PI and Advisor roles can receive signing authority.

- Check the **CC** checkbox to have the user cc'd on all email notifications

- Oath of Confidentiality**: click attach to upload the user's oath of confidentiality

**Note:** this is required to be uploaded for each protocol personnel except for the PI, CO-PI and Advisor

- Choose the **Contact Level**: Primary or Secondary

Protocol Personnel											
	Name	Department	Role	CV	CORE	PHIA	Access	CC <a href="#">[?]</a>	Oath of Confidentiality <a href="#">[?]</a>	Contact Details	Contact Level
	RAS Researcher	Max Rady College of Medicine	Principal Investigator	 04/01/2021 Import	 04/01/2021 Import		Signature Authority			Contact Details	Primary
	John Co-Investigator	Nursing	Co-Investigator	 01/01/2021 Import	 01/14/2020 Import		Edit Access	<input type="checkbox"/>	Oath of Confidentiality.pdf 	Contact Details	Primary

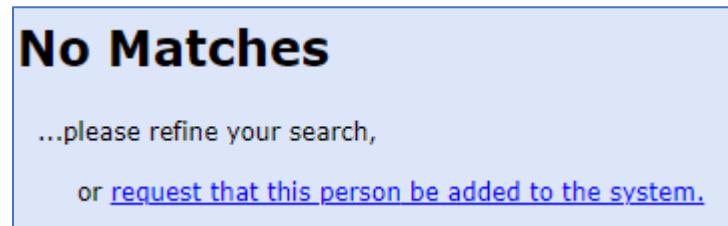
## Add On-The-Fly User

If you can't find someone in the Find Person lookup window when trying to add them to the research personnel table, you can add them on-the-fly.

**Important:** Most UM research personnel will be in the lookup. On-the-fly users are most likely external to the UM or students. Only one external research personnel are allowed **edit** or **view only** access to a protocol.

Multiple no access external personnel may be added to the protocol. All on-the-fly personnel are reviewed by the Ethics Office at submission. If this rule is violated the protocol will be sent back to the PI to adjust.

1. Click on the **request that this person be added to the system** link



2. Complete the following (all fields are mandatory):

- a. Enter the **Last Name**
- b. Enter **First Name**
- c. Enter **Email Address**
- d. Enter **Phone Number**
- e. Select the **CORE Training Date**
- f. Click on **Attach CORE Pledge** to upload the users CORE certificate

**Add New Value**

Last Name	<input type="text"/>
First Name	<input type="text"/>
Email Address	<input type="text"/>
Phone Number	<input type="text"/>
CORE Training Date	<input type="text"/>

**Do not select the Co-PI or the Advisor role to anyone added from this window.  
They will not be able to login to RAS to sign off on any submissions/tasks sent to them.**

[Attach CORE Pledge](#)

**Add** **Cancel**

3. Click **Add**
4. The user's **Department** will default to the PIs department. Make sure to update this to **External** if adding someone external to the UM, If adding a student add the PIs department.
5. Select the **Role** and **Access** for this user  
**Note:** If this user does not require access to this protocol, they will not be given a profile in the system.
6. Attach the **Oath of Confidentiality**
7. Select the **Contact Level**

<input type="checkbox"/> <b>New Staff</b>	<input type="checkbox"/> <b>External</b>	<input type="checkbox"/> <b>Research Assistant</b>	 <b>04/01/2021 Import</b>	<b>Import</b>	<input type="checkbox"/> <b>No Access</b>	<input type="checkbox"/>	<b>Attach</b>		<b>Contact Details</b>	<input type="checkbox"/> <b>Primary</b>
---	--	--	--	---------------	---	--------------------------	---------------	---	------------------------	---

Once the application/submission has been submitted to the Ethics Office, a task will be sent to ORS to add this new user to the system.

## How to Add a Document

There are a few different areas within the initial application that allows you to upload documents.

Here is the Participants > Recruitment subtab

1. Click **Add**

Attach copies of all material that will be given/read to participants and/or third parties:

Recruitment Documents

Type	Name	Upload
<input type="checkbox"/> 1 <input type="button" value="Poster"/>		<input type="button" value="Attach"/>

**Add**

2. Select the **Type** of document
3. Type in the **Name** of the document
4. Click **Attach**, find and **Upload** the document

Recruitment Documents

Type	Name	Upload
<input type="checkbox"/> 1 <input type="button" value="Poster"/>	Poster	<a href="#">Poster.pdf</a> <input type="button" value="X"/>

## View All Documents

Throughout the initial application there are a few different places to add documents. You can view all uploaded documents under the **Attachments** tab.

**Note:** You can only delete Attachments from the location they were added (If a document was added under Recruitment tab, you can only delete from the Recruitment tab).

Here you can view and/or add additional documents.

Documents

Type	Name	Version	Status	History	File Name/ Uploaded Date	Comments	Actions
Recruitment Documents	Poster.pdf	1	New		<a href="#">Poster.pdf</a> 10/13/2020	<a href="#">View</a>	
Consent Documents	Consent.pdf	1	New		<a href="#">Consent.pdf</a> 10/13/2020	<a href="#">View</a>	
Observation Guide Document	Consent.pdf	1	New		<a href="#">Consent.pdf</a> 10/13/2020	<a href="#">View</a>	

**Add**

To continue the instructions for an Initial Application, go to:

- [Save Initial Application](#)
- [Submit Initial Application](#)
- [After Submission](#)

## Follow-On Submissions

### Amendment/Personnel Change

To create a new Amendment or Personnel Change form as a PI:

1. Select the protocol link from the **LiveList**
2. Under **Actions** select **Create Amendment** or **Create Personnel Change**, click **Go**
  - a. **Amendment** – Complete all questions under Amendment Summary

Amendment Summary	Summary	Research Personnel	Participants	Consent Process	Data	Risks/Benefits	Dissemination/Withdrawal	Attachments	Submit
<p>Please provide a brief summary of the requested changes</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>									
<p>Please provide a justification for these changes</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>									
<p>Will there be changes to the number of participants? <input type="radio"/> Yes <input type="radio"/> No</p> <p>Will there be any changes in recruitment? <input type="radio"/> Yes <input type="radio"/> No</p> <p>Will there be changes in recruitment material? <input type="radio"/> Yes <input type="radio"/> No</p> <p>Will there be any changes to the consent form? <input type="radio"/> Yes <input type="radio"/> No</p> <p>Will participants need to be re-consented? <input type="radio"/> Yes <input type="radio"/> No</p>									
<hr/> <p><b>Summary of Changes:</b></p> <p>No Changes</p>									

- a. **Personnel Change** – Complete all questions under Personnel Summary

Personnel Changes Summary   [Research Personnel](#)   [Attachments](#)   [Submit](#)

Please provide a brief summary of the requested changes

Does this change affect documents participants will see (ie. recruitment poster, consent form)?  Yes  No

---

**Summary of Changes:**

No Changes

3. Navigate throughout the application and make your changes. As this is a living document, when you make a change to questions within the initial application section you will need to justify each change.

Amendment Summary   [Summary](#)   [Research Personnel](#)   [Participants](#)   [Consent Process](#)   [Data](#)   [Risks/Benefits](#)   [Dissemination/Withdrawal](#)   [Attachments](#)   [Submit](#)

Please provide a brief summary of the requested changes

- When you make a change to any question throughout the application it's tagged with **Amended (Please Justify)**
- Add your justification for the change to that specific question in the text box

*Justification:*

Adding more people to the cohort.

- Once you have included the justification the question will now state **Amended**

d. A red asterisk will be added to each tab and a red box around the subtab to easily locate any changes to the application

Amendment Summary	Summary	Research Personnel	Participants*	Consent Process	Data	Risks/Benefits	Dissemination/Withdrawal	Attachments	Submit
<b>Participants</b> - Recruitment									
How many participants do you expect to recruit?		We anticipate that approximately 45 adults between the ages of 50-70 will participate in one of three Turning Pages groups offered in 2018.			<u>Amended</u>				
		Need to increase to 100 adults. A change based on the request.							

e. A summary of changes will appear in the **Amendment Summary** tab or **Personnel Change Summary** tab. This will include the previous value and the new value as well as the justification that was added

Summary of Changes:					
Location	Field	Original Value	New Value	Action	Justification
Participants >> Participants	How many participants do you expect to recruit?	We anticipate that approximately 45 adults between the ages of 50-70 will participate in one of three Turning Pages groups offered in 2018. Need to increase to 85 adults. A change based on the request.	We anticipate that approximately 45 adults between the ages of 50-70 will participate in one of three Turning Pages groups offered in 2018. Need to increase to 100 adults. A change based on the request.	Using New Value	Adding more people to the cohort.

## Renewal Request

To create a new Renewal Request form as a PI:

1. Select the protocol link from the **LiveList**
2. Under **Actions** select **Create Renewal Request**, click **Go**
3. Navigate through each tab and answer each question as they appear within the form

Renewal Request   [Attachments](#)   [Submit](#)

Have there been changes to the protocol design that have not been approved by the REB?  Yes  No

Provide a brief summary of the progress of the study.

Please brief justification for the renewal request.

previous   next

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## REB Event

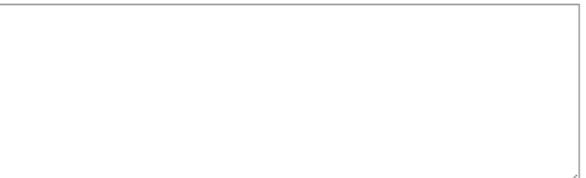
To create a new REB Event form as a PI:

1. Select the protocol link from the **LiveList**
2. Under **Actions** select **Create REB Event**, click **Go**
3. Navigate through each tab and answer each question as they appear within the form

Protocol Number: HE2021-0015 REB Event

Principal Investigator: Courtney Edworthy [Print](#) [ZIP Attachments](#)

[REB Event](#) [Attachments](#) [Submit](#)

Description of Event  [?](#)

What actions will be taken to rectify this event? 

Have you notified any other offices of this event (ie. Privacy and Access Office)?  Yes  No

Please explain: 

Does the protocol require changes to prevent this event from occurring again?  Yes  No

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## Protocol Closure

To create a new Protocol Closure form as a PI:

1. Select the protocol link from the **LiveList**
2. Under **Actions** select **Create Protocol Closure**, click **Go**
3. Navigate through each tab and answer each question as they appear within the form

Protocol Number: HE2021-0015 Protocol Closure

Principal Investigator: Courtney Edworthy [Print](#) [ZIP Attachments](#)

[Protocol Closure](#) [Attachments](#) [Submit](#)

Is communication with participants complete (ex. recruitment, data collection, summary of findings, member checking)?  Yes  No [?](#)

Please provide a brief summary of the outcome of the study and progress in meeting the study objectives.

Were there any problems encountered in this study?  Yes  No

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## Reassign a Task

The reassigned feature is used to assign a task (current working submission) to another research team member to continue editing or to complete the task on the PI's behalf. Due to the system workflow to ensure submissions are reviewed and signed off properly, when the reassigned task is submitted it will proceed in the workflow. This means that the submission will also go to the PI, CoPI(s), then Advisor(s) regardless of who is submitting the task.

When a task is with a PI, they can submit it to the next research team member in the workflow (e.g., CoPI, Advisor or OHRE depending on who is listed in the protocol), or they can reassign it to a research team member with edit access or signature authority.

**Remember:** A CoPI and Advisor can always send a task back to the PI by navigating to the Submit tab, checking off the "Send *Initial Application* back to the PI for Review" check box.

**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)**

### How to Reassign

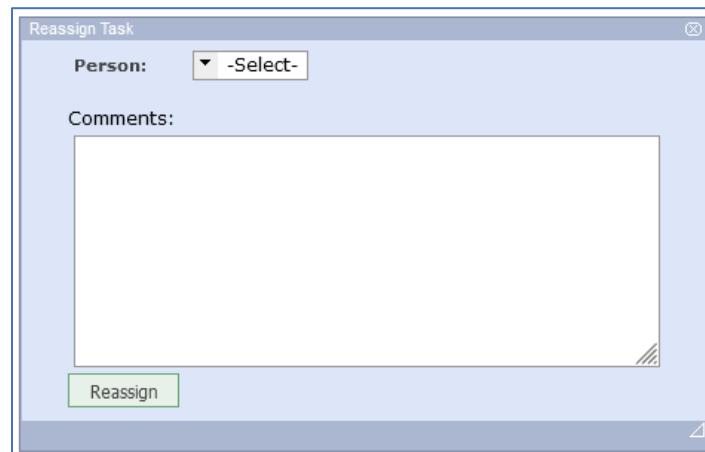
1. Select the protocol link from the **LiveList**
2. Under **Submissions > Actions** click **Reassign Task**

#### Submissions

Type	Receipt Date	Summary	Status	Decision	Lifecycle	Details	Actions
1 Initial Application	08/23/2023	<a href="#">View</a>	Revisions	Pending	<a href="#">View</a>	<a href="#">View</a>	<a href="#">Withdraw</a> <a href="#">Reassign Task</a>

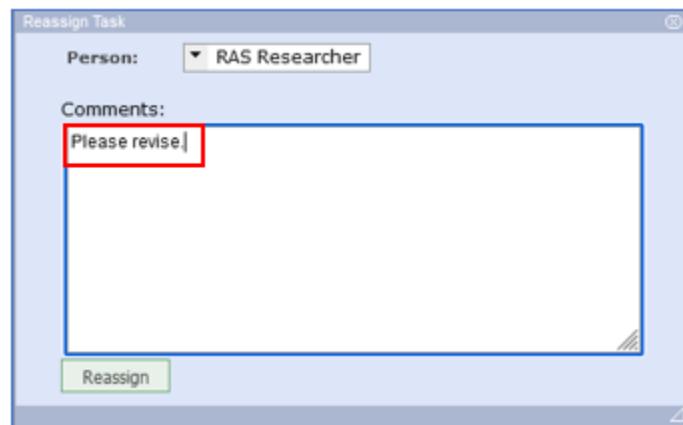
3. Select the **Person** to reassign the submission to

**Remember:** Only research personnel with Edit Access or Signature Authority will appear here.



4. Add **Comments**, optional

**Note:** Comments will appear in the Lifecycle View once reassigned.

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

5. Click **Reassign**

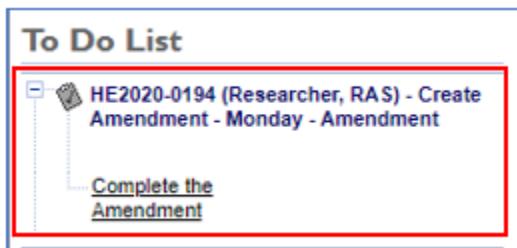
6. Task is now reassigned

**Note:** The task will be located in the reassigned users to do list, an email is not sent notifying the user of the task.

## Save Initial Application or Follow-On Submission

The system will automatically save your progress when you navigate to a new tab within your submission. Do not exit your submission before navigating to a new tab or manually saving. To save an initial application or follow-on submission to complete it at a later date:

1. Click Save at the  top left-hand side of the screen
2. Click the Home menu item to return to the LiveList
3. The protocol is now listed in your To Do List



## Continue Saved Initial Application or Follow-On Submission

To continue working on a saved initial application or follow-on submission:

1. Under the **To Do List**, find the saved initial application or follow-on submission task
2. Click the link within the task



## Submit an Initial Application or Follow-On Submission

Each application/submission form contains mandatory questions and logic to help ensure completeness.

When you attempt to submit the initial application or follow-on submission, the system will validate the completeness of the application. If a required field has not been completed, the submission will be stopped, and the user will be prompted to complete the incomplete fields. See [Errors on the Application](#) for more information.

To Submit an Initial Application or Follow-On Submission:

1. Complete each question contained within each of the tabs and sub tabs of the form
2. When all questions have been addressed navigate to the **Submit** tab
3. Enter any desired **Submission Notes** in the field provided
4. Read and check each of the **Declaration Statement**

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Indigenous Peoples	Attachments	Submit
---------	--------------------	--------------	-----------------	------	-----------	----------------	---------------------------	--------------------	-------------	--------

**Initial Application Submission**

Optional Submission Notes

I have reviewed the protocol contents and confirm that the information provided in this application is complete and correct.

I agree to abide by the ethical guidelines and policies of the REB, including the Tri-Council Policy Statement and the University of Manitoba Policy on the Ethics of Research Involving Humans.

I will ensure the study does not commence until the final certificate of approval has been issued by the REB.

I will ensure the study does not commence until approval has been granted by the appropriate organization, if applicable (e.g. chief and council, school board).

I will ensure all research team members (e.g. faculty, students, staff) handling data will have the appropriate training (e.g. CORE, PHIA).

I will ensure that study personnel are qualified, appropriately trained and will adhere to the REB-approved application.

I will notify the REB of any protocol changes and report adverse events/experiences as soon as possible.

I will submit any changes to this study to the appropriate REB for consideration before implementation.

I will submit a request for annual approval to the REB prior to the expiry date indicated on the approval certificate.

I will submit a Study Closure Form to the REB when all study activity is completed at the local site.

By providing my signature, I confirm that I have read the above terms and agree to comply with this and other university policies, guidelines and the Tri-Council Policy Statement (TCPS).

I Agree (PI) (signed 10/09/2020, 3:37:22 PM by RAS Researcher)

**Send for Review**

5. Check the **I Agree** checkbox to agree to the certification statement
  - a. If a Co-PI is listed on the protocol under Research Personnel
    - i. The protocol will be sent to them for sign-off

**Send to CO-PI**

- ii. After the Co-PI has reviewed the application/submission, navigate to the **Submit** tab

**Note:** The Co-PI has the option of sending the application back to the PI if changes have been made, click the Send back to Pi for review first check box then checkoff I Agree.

**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)**

- iii. Read and check each of the **Declaration Statements**

- iv. Check off **I Agree**

6. Click **Send for Review**

The submission has now been sent to the Ethics Office for review.

#### Errors on the Initial Application or Follow-On Submission

If you get an error stating Incomplete Application, this means there are missed questions that need to be addressed.

## Incomplete Application

The Initial Application submission is incomplete.

Please address the errors highlighted throughout the application form and resubmit.

**Return**

Click **Return**

The form will return to the first error on your form. Errors are indicated by a red asterisk on the tab along with a red box around the subtab. Once you select the location of the error, the individual question will be marked with

Required beside it.

## Correct Errors

Protocol Number: TEMP-HE2020-0255	My New Protocol					Initial Application
Principal Investigator: RAS Researcher						Status: Correcting Errors/Omissions <a href="#">Print</a>
Summary	Research Personnel	Participants	Consent Process	Data	Risks/Benefits	Dissemination/Withdrawning *
						Attachments
<a href="#">Feedback</a> - <a href="#">Withdrawning</a>						
<p>Will you be providing participants with the opportunity to review their data?</p> <p><input type="radio"/> Yes   <input checked="" type="radio"/> No</p> <p>How will information from or about your participants be presented (e.g., summary statistics for the whole group, direct quotations from their interviews)?</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p style="color: red; margin-left: 10px;">Required</p>						

Once you complete all errors indicated, click the **Submit** tab and resubmit the application.

After the submission has gone through, you can view the protocol in the LiveList.

## After Submission

Once you have submitted the initial application or follow-on submission, you can view its progress in the LiveList.

1. Navigate to the LiveList
2. Select the protocol from the list by clicking on the protocol number link under the **Protocol/Project Number** column

Protocol/Project Number <a href="#">#</a>	Title <a href="#">#</a>	PI <a href="#">#</a>	Original Approval Date <a href="#">#</a>	Status <a href="#">#</a>																																																									
HE2021-0015	Courtney Edworthy	03/03/2021	Active																																																										
<a href="#">Lifecycle Event Manager</a> <a href="#">Communications</a> <a href="#">Summary</a> <a href="#">Research Personnel</a> <a href="#">Secondary Use of Data</a> <a href="#">Attachments</a>																																																													
<p><b>Main</b></p> <table border="1"> <tr> <td>Stage: Protocol</td> <td>Approval Start: 03/29/2021</td> <td>Risk Level:</td> <td>Review Frequency: 364 days</td> </tr> <tr> <td>Status: Active</td> <td>Approval End: 03/02/2022</td> <td>Assigned REB: REB1</td> <td>Original Approval Date: 03/03/2021</td> </tr> <tr> <td colspan="4"> <input checked="" type="checkbox"/> Show REB Event (1)         </td> </tr> <tr> <td colspan="5"> <p><b>Submissions</b></p> <table border="1"> <thead> <tr> <th>Type</th> <th>Receipt Date</th> <th>Summary</th> <th>Status</th> <th>Decision</th> <th>Lifecycle</th> <th>Details</th> <th>Actions</th> </tr> </thead> <tbody> <tr> <td>4 Protocol Closure</td> <td></td> <td><a href="#">View</a></td> <td>In Development</td> <td>Pending</td> <td><a href="#">View</a></td> <td><a href="#">View</a></td> <td><a href="#">Delete Reassess Task</a></td> </tr> <tr> <td>3 REB Event</td> <td></td> <td><a href="#">View</a></td> <td>In Development</td> <td>Pending</td> <td><a href="#">View</a></td> <td><a href="#">View</a></td> <td><a href="#">Delete Reassess Task</a></td> </tr> <tr> <td>2 Amendment</td> <td>03/03/2021</td> <td><a href="#">View</a></td> <td>Completed</td> <td>Approved</td> <td><a href="#">View</a></td> <td><a href="#">View</a></td> <td><a href="#">Delete Reassess Task</a></td> </tr> <tr> <td>1 Initial Application</td> <td>03/03/2021</td> <td><a href="#">View</a></td> <td>Completed</td> <td>Approved</td> <td><a href="#">View</a></td> <td><a href="#">View</a></td> <td></td> </tr> </tbody> </table> </td> </tr> </table>					Stage: Protocol	Approval Start: 03/29/2021	Risk Level:	Review Frequency: 364 days	Status: Active	Approval End: 03/02/2022	Assigned REB: REB1	Original Approval Date: 03/03/2021	<input checked="" type="checkbox"/> Show REB Event (1)				<p><b>Submissions</b></p> <table border="1"> <thead> <tr> <th>Type</th> <th>Receipt Date</th> <th>Summary</th> <th>Status</th> <th>Decision</th> <th>Lifecycle</th> <th>Details</th> <th>Actions</th> </tr> </thead> <tbody> <tr> <td>4 Protocol Closure</td> <td></td> <td><a href="#">View</a></td> <td>In Development</td> <td>Pending</td> <td><a href="#">View</a></td> <td><a href="#">View</a></td> <td><a href="#">Delete Reassess Task</a></td> </tr> <tr> <td>3 REB Event</td> <td></td> <td><a href="#">View</a></td> <td>In Development</td> <td>Pending</td> <td><a href="#">View</a></td> <td><a href="#">View</a></td> <td><a href="#">Delete Reassess Task</a></td> </tr> <tr> <td>2 Amendment</td> <td>03/03/2021</td> <td><a href="#">View</a></td> <td>Completed</td> <td>Approved</td> <td><a href="#">View</a></td> <td><a href="#">View</a></td> <td><a href="#">Delete Reassess Task</a></td> </tr> <tr> <td>1 Initial Application</td> <td>03/03/2021</td> <td><a href="#">View</a></td> <td>Completed</td> <td>Approved</td> <td><a href="#">View</a></td> <td><a href="#">View</a></td> <td></td> </tr> </tbody> </table>					Type	Receipt Date	Summary	Status	Decision	Lifecycle	Details	Actions	4 Protocol Closure		<a href="#">View</a>	In Development	Pending	<a href="#">View</a>	<a href="#">View</a>	<a href="#">Delete Reassess Task</a>	3 REB Event		<a href="#">View</a>	In Development	Pending	<a href="#">View</a>	<a href="#">View</a>	<a href="#">Delete Reassess Task</a>	2 Amendment	03/03/2021	<a href="#">View</a>	Completed	Approved	<a href="#">View</a>	<a href="#">View</a>	<a href="#">Delete Reassess Task</a>	1 Initial Application	03/03/2021	<a href="#">View</a>	Completed	Approved	<a href="#">View</a>	<a href="#">View</a>	
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3. To view the current Lifecycle History of this submission, click on the **View** link under Lifecycle

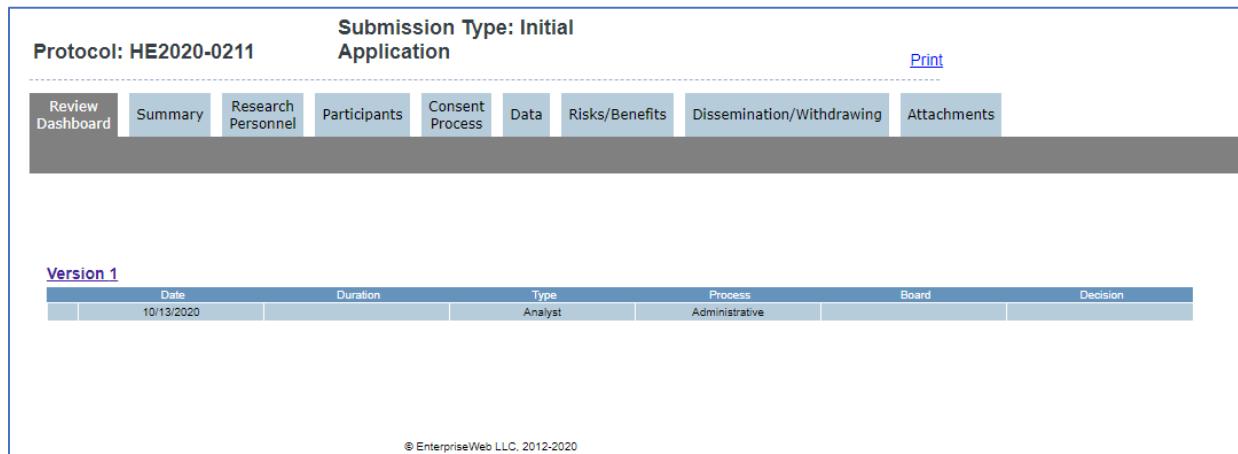
a. The Lifecycle History window will appear, this tells you where the submission is



The Lifecycle History window displays two events:

- Event #1: New Human Ethics Protocol Created**
  - Who: RAS Researcher
  - Start: 09/16/2020
  - End: 10/13/2020
  - Result: Initial Application Sent to Coordinator
- Event #2: Initial Application Being Processed**
  - Currently with: Human Ethics Officer
  - Started: 10/13/2020

4. To view the protocol and the submission status in more detail, click on the **View** link under Details



Protocol: HE2020-0211      Submission Type: Initial Application      [Print](#)

Review Dashboard    Summary    Research Personnel    Participants    Consent Process    Data    Risks/Benefits    Dissemination/Withdrawing    Attachments

**Version 1**

Date	Duration	Type	Process	Board	Decision
10/13/2020		Analyst	Administrative		

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5. To return to the LiveList

- Click the **Home** button under the Menu Bar or;
- Click on the Protocol Number link above the **Lifecycle Event Manager** tab

### Withdraw Initial Application or Follow-On Submission

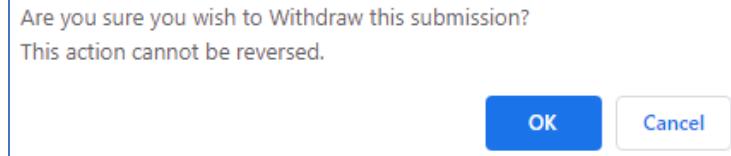
An initial application or follow-on submission can be withdrawn after you have submitted a submission but before it has been approved. This function is only meant to be used if you no longer wish to submit. Once withdrawn you cannot re-submit to the Office of Human Research Ethics.

- In the **LiveList**, select the protocol link under Protocol/Project Number to view the Lifecycle Event Manager
- Under Submissions > Actions click **Withdraw**

## Submissions

Type	Receipt Date	Summary	Status	Decision	Lifecycle	Details	Actions
3 Amendment	10/27/2020	<a href="#">View</a>	Admin Review	Pending	<a href="#">View</a>	<a href="#">View</a>	<a href="#">Withdraw</a>
2 Amendment	08/24/2020	<a href="#">View</a>	Completed	Approved	<a href="#">View</a>	<a href="#">View</a>	
1 Initial Application	08/21/2020	<a href="#">View</a>	Completed	Approved	<a href="#">View</a>	<a href="#">View</a>	

3. A confirmation window will appear, Click **OK** to continue



4. The submission will still be listed under **Submissions** for audit trail purposes

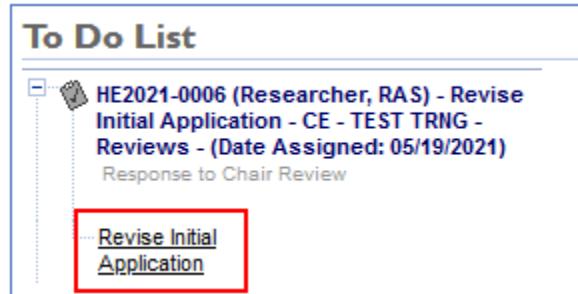
## Submissions

Type	Receipt Date	Summary	Status	Decision	Lifecycle	Details	Actions
3 Amendment	10/27/2020	<a href="#">View</a>	Withdrawn		<a href="#">View</a>	<a href="#">View</a>	
2 Amendment	08/24/2020	<a href="#">View</a>	Completed	Approved	<a href="#">View</a>	<a href="#">View</a>	
1 Initial Application	08/21/2020	<a href="#">View</a>	Completed	Approved	<a href="#">View</a>	<a href="#">View</a>	

## Revisions Required

After an application or submission has been reviewed and it is sent back from the OHRE for revisions, 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. There are 2 main sections in this view: **Review** and **Application** section

**Remember:** The Review section can change based on who has provided the review. The example below is a Chair Review, you may also see OHRE Review or Member Review.

**Revise Initial Application**

<b>Instructions</b>	<b>Review</b>	<b>Protocol Number: HE2021-0006</b>	<b>Principal Investigator: RAS Researcher</b>	<b>Application</b>	<b>Print</b>	<b>Initial Application</b>	<b>ZIP Attachments</b>																						
<b>Response to Chair Review</b>		<b>Comments</b>	<b>Summary*</b>	<b>Research Personnel</b>	<b>Participants*</b>	<b>Consent Process</b>	<b>Data</b>	<b>Risks/Benefits</b>	<b>Dissemination/Withdrawal</b>	<b>Attachments</b>	<b>Submit</b>																		
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4. The **Comments** tab provides a summary of all comments made
5. Click on the link under **Location** to bring you to each comment to review

<b>Comments</b>	<b>Summary*</b>	<b>Research Personnel</b>	<b>Participants*</b>	<b>Consent Process</b>	<b>Data</b>	<b>Risks/Benefits</b>	<b>Dissemination/Withdrawal</b>	<b>Attachments</b>	<b>Submit</b>																		
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Location	Field	Original Value	Current Value	Comment	Action																						
Summary >> <a href="#">Purpose of the Research</a>	Describe the research question(s) and objectives for this research study.	Objectives	Objectives	add more detail	No Change																						
Participants >> <a href="#">Participants</a>	How many participants do you 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.

6. 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 [Attachment: Marked-Up Versions](#)

7. 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.

<b>Requirement:</b> Confirm and justify participants.
<b>Justification:</b>

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

Comments	Summary*	Research Personnel*	Participants*	Consent Process	Data	Risks/Benefits	Dissemination/Withdrawal	Attachments	Submit																								
<p><b>PI Response:</b></p> <table border="1"> <thead> <tr> <th>Location</th> <th>Field</th> <th>Original Value</th> <th>Current Value</th> <th>Comment</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td>Summary &gt;&gt; <a href="#">Purpose of the Research</a></td> <td>Describe the research question(s) and objectives for this research study.</td> <td>Objectives</td> <td>Objectives - there are many objectives which are included in the attachment.</td> <td>add more detail</td> <td><a href="#">Using New Value</a></td> </tr> <tr> <td>Participants &gt;&gt; <a href="#">Participants</a></td> <td>How many participants do you expect to recruit?</td> <td>Recruit</td> <td>100 participants.</td> <td>please add more specific</td> <td><a href="#">Using New Value</a></td> </tr> <tr> <td><a href="#">Research Personnel</a></td> <td>What type of data (e.g. directly identifiable, anonymized) will each individual have access to?</td> <td>Data</td> <td>Data - data will be anonymized.</td> <td></td> <td><a href="#">Using New Value</a></td> </tr> </tbody> </table> <p>► next</p>										Location	Field	Original Value	Current Value	Comment	Action	Summary >> <a href="#">Purpose of the Research</a>	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	<a href="#">Using New Value</a>	Participants >> <a href="#">Participants</a>	How many participants do you expect to recruit?	Recruit	100 participants.	please add more specific	<a href="#">Using New Value</a>	<a href="#">Research Personnel</a>	What type of data (e.g. directly identifiable, anonymized) will each individual have access to?	Data	Data - data will be anonymized.		<a href="#">Using New Value</a>
Location	Field	Original Value	Current Value	Comment	Action																												
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Participants >> <a href="#">Participants</a>	How many participants do you expect to recruit?	Recruit	100 participants.	please add more specific	<a href="#">Using New Value</a>																												
<a href="#">Research Personnel</a>	What type of data (e.g. directly identifiable, anonymized) will each individual have access to?	Data	Data - data will be anonymized.		<a href="#">Using New Value</a>																												

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

Instructions

**Response to Chair Review**

Review Comments
<b>Investigator Response (to the Administrator)</b>

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

The revision has now been 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 slightly different. The example below is of an Initial Application returned to the PI for after a pre-review.

**Revise Initial Application**

Instructions		Protocol Number: HE2023-0228								Initial Application																						
Revisions		Principal Investigator: Courtney Edworthy								Print	ZIP Attachments																					
		Comments	Summary	Research Personnel	Participants	Consent Process*	Data	Risks/Benefits	Dissemination/Withdrawing	Indigenous Peoples	Attachments*	Submit																				
<b>Review Comments</b> 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.		<b>PI Response:</b> <table border="1"> <thead> <tr> <th>Location</th> <th>Field</th> <th>Original Value</th> <th>Current Value</th> <th>Comment</th> <th>Action</th> <th>Justification</th> </tr> </thead> <tbody> <tr> <td>Attachments</td> <td>Document type / Name</td> <td>Consent Documents / Consent.pdf</td> <td>Consent Documents / Consent.pdf</td> <td>Please make the appropriate changes and upload a marked up version with track changes along with the updated Consent form.</td> <td>New document required</td> <td></td> </tr> <tr> <td>Consent Process &gt;&gt; Informed Consent Process</td> <td>Consent Documents</td> <td>Consent.pdf [View Page]</td> <td>Consent.pdf [View Page]</td> <td>Please add dates.</td> <td>No Change</td> <td></td> </tr> </tbody> </table>										Location	Field	Original Value	Current Value	Comment	Action	Justification	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 >> Informed Consent Process	Consent Documents	Consent.pdf [View Page]	Consent.pdf [View Page]	Please add dates.	No Change	
Location	Field	Original Value	Current Value	Comment	Action	Justification																										
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▶ next																																

## 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

Comments	Summary	Research Personnel	Participants	Consent Process*	Data	Risks/Benefits	Dissemination/Withdrawing	Indigenous Peoples						
<b>Informed Consent Process</b> <div style="border: 1px solid #ccc; padding: 10px;">           Describe the consent process. Where and how will consent be obtained?            test         </div>														
Attach consent form(s):														
Consent Documents														
<table border="1"> <thead> <tr> <th>Type</th> <th>Name</th> <th>Upload</th> </tr> </thead> <tbody> <tr> <td>Consent Document</td> <td>Consent</td> <td>Consent.pdf <b>Replace</b> <small>Comment</small></td> </tr> </tbody> </table>									Type	Name	Upload	Consent Document	Consent	Consent.pdf <b>Replace</b> <small>Comment</small>
Type	Name	Upload												
Consent Document	Consent	Consent.pdf <b>Replace</b> <small>Comment</small>												
<input type="button" value="Add"/>														

- Once the new document has been uploaded navigate to the **Attachments** tab to upload the [marked-up version](#)

#### Attachments Tab

- Navigate to the **Attachments** tab
- Click **Upload** under New Version, find and **Upload** the [clean version](#) of the document
- Once the new document has been uploaded navigate to the **Attachments** tab to upload the [marked-up version](#)

Comments	Summary	Research Personnel	Participants	Consent Process*	Data	Risks/Benefits	Dissemination/Withdrawing	Indigenous Peoples	Attachments*	Submit
<b>Previous Documents</b>										
Type	Name	Version	Status	History	File name/ Uploaded Date	Comments	Marked Up Version [?]	New Version	Comments	New Doc Required
Consent Documents	Consent	1	New		Consent.pdf 08/22/2023	<a href="#">View</a>		<a href="#">Upload</a>		
Recruitment Documents	Poster	1	New		Poster.pdf 08/22/2023	<a href="#">View</a>		<a href="#">Upload</a>		
Other Approval Documents	Approval	1	New		Approval.docx 08/23/2023	<a href="#">View</a>		<a href="#">Upload</a>		
Agreement Documents	New Agreement	1	New		Fully Executed Agreement.pdf 08/22/2023	<a href="#">View</a>		<a href="#">Upload</a>		
Oath of Confidentiality: RAS Researcher	Oath of Confidentiality.pdf	1	New		Oath of Confidentiality.pdf 08/23/2023	<a href="#">View</a>		<a href="#">Upload</a>		
<span style="color: red;">X</span> Manual Attachment	Survey	1	New		survey.pdf 08/22/2023	<a href="#">View</a>		<a href="#">Upload</a>		
<a href="#">Add</a>										

#### Marked-Up Version

- Navigate to the **Attachments** tab
- Click **Attach** under Marked Up Version, find and **Upload** the [marked-up version](#) of the document

Type	Name	Version	Status	History	File name/ Uploaded Date	Comments	Marked Up Version [?]	New Version	Comments	New Doc Provided
Consent Documents	Consent	1	New	<a href="#">View</a>	Consent_2.pdf 08/23/2023	<a href="#">View</a>	<a href="#">Attach</a>	<a href="#">View / Replace</a>		

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

Type	Name	Version	Status	History	File name/ Uploaded Date	Comments	Marked Up Version [?]	New Version	Comments	New Doc Provided
Consent Documents	Consent	1	New	<a href="#">View</a>	Consent_2.pdf 08/23/2023	<a href="#">View</a>	<a href="#">View X</a>	<a href="#">View / Replace</a>		