

# How to Submit a Protocol as a Student PI

RAS Training Documentation

Last Modified: July 30, 2024

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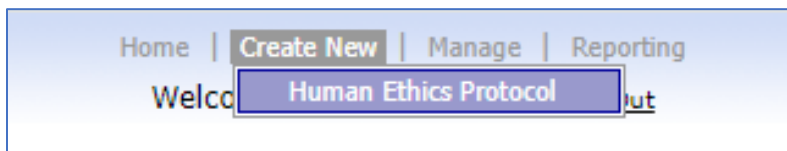
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## Initial Application

To create a new Human Ethics Protocol as a Student PI:

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

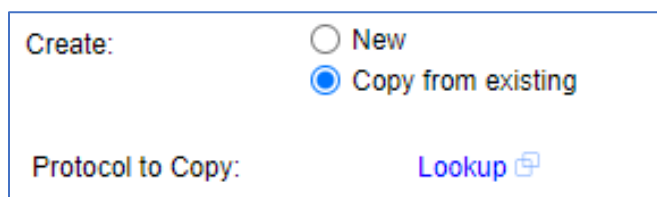
**Note:** The newly created protocol will receive a temporary protocol number while the application is in development. Once the application is submitted, a final Human Ethics Protocol number will be assigned.



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

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

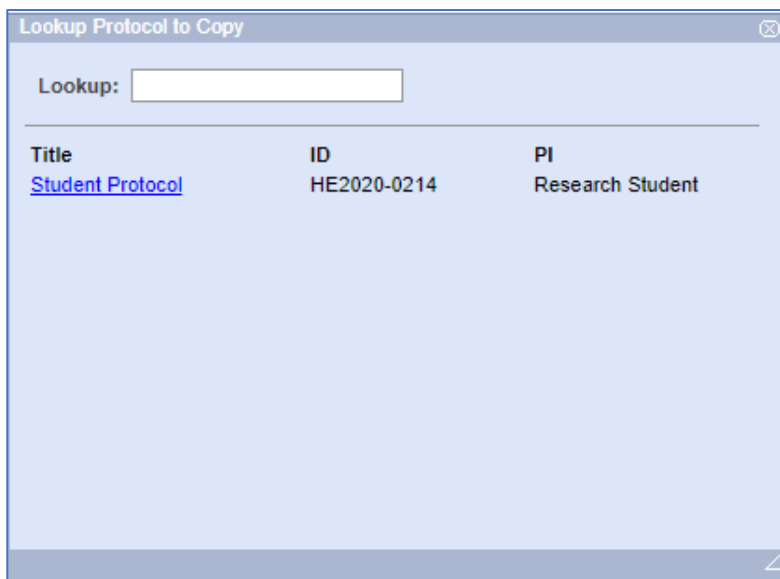
- i. To **copy from existing** protocol, click the **Lookup** link the Lookup Protocol to Copy window will appear



The screenshot shows a form with the label 'Create:'. There are two radio buttons: 'New' (unselected) and 'Copy from existing' (selected). Below this, there is a label 'Protocol to Copy:' and a blue 'Lookup' button with a magnifying glass icon.

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

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



The screenshot shows a window titled 'Lookup Protocol to Copy'. It has a search bar labeled 'Lookup:'. Below the search bar is a table with the following data:

Title	ID	PI
<a href="#">Student Protocol</a>	HE2020-0214	Research Student

- 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](#)

Department: ▼ Chemistry

---

### 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.

1. Check off **Yes** for the question 'Is the Principal Investigator for this project a student?'. This will ensure you need to also include the student's advisor in the Research Personnel tab.
2. Indicate the Department the research will be conducted by clicking the replace link beside the question

Principal Investigator

[Replace PI](#)

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

What Department is this research being conducted under?

[replace](#)

Note: When the application is complete, it will be sent to your Advisor for sign off.

Lookup Department

Lookup:  [Go](#)

472 records available, displaying the top 20 rows. Please use the Lookup box to search.

Name	ID	Division
<a href="#">Aboriginal and Northern Studies</a>	UCNABS1	
<a href="#">Access Programs</a>	1039012	
<a href="#">Accounting</a>	CMUBA1	
<a href="#">Accounting and Finance</a>	1008001	
<a href="#">Agribusiness &amp; Agricultural Economics</a>	1001001	
<a href="#">Albert D. Cohen Management Library</a>	1031012	

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

Protocol Number: **TEMP-HE2021-0477**
Initial Application

Principal Investigator: Research Student
[Print](#)
[ZIP Attachments](#)

Summary
Research Personnel
Attachments
Submit

Summary - Purpose of the Research

Protocol Title

New Student Protocol

character count: 20

Principal Investigator

Research Student

?

Replace PI

Is the Principal Investigator for this project a student?

☒ Yes
☐ No

What Department is this research being conducted under?

replace

Note: When the application is complete, it will be sent to your Advisor for sign off.

Primary Department

Chemistry

replace

Application Initiated By

Research Student

previous
next

## Adding Research Personnel

Add additional research personnel to the protocol.

**Remember:** when a student is filling in the form, they will need to also add their Advisor here. Once the submission has been completed it will be sent to the Advisor for final sign-off.

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

**NOTE:** The Principal Investigator for this project is a student. To proceed with the submission, please add at least one person with a role of "Advisor" in the Protocol Personnel section below.

Name	Department	Role	CV	CORE	PHIA	Access	CC	Contact Details	Contact Level
Research Student	Chemistry	Principal Investigator		08/21/2020 Import	08/21/2020 Import	Signature Authority		Contact Details	Primary

**Add**

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="#">Advisor, Research Student</a>	RAS_Advisor	Chemistry
<a href="#">Advisor, Student</a>	STDNT_ADV	Microbiology

4. Click on the users' name to add them to the protocol
5. Once they are added, complete the following:
  - a. Select **Department**: this default to the users' primary department
  - b. Select **Role**: this is the user's role for this specific protocol
  - c. Import **CV**: this is the user's CV, optional (not required for Human Ethics Fort Garry)
  - d. 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.
  - e. 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**.
  - f. Assign **Access**: this is the user's access to this protocol

- i. **Edit Access:** Gives the user edit access to the protocol. Usually given to Study Coordinators.
- ii. **No Access:** Given to users that do not need to access the protocol in the system.
- iii. **Read-Only Access:** Given to user that can access the protocol but only have read-only access, meaning they cannot edit the protocol.
- iv. **Signature Authority:** This gives the user signing authority on the protocol  
**Note:** Only the PI, Co-PI and Advisor roles can receive signing authority.
- g. Check the **CC** checkbox to have the user cc'd on all email notifications
- h. **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
- i. Choose the **Contact Level:** Primary or Secondary

	Name	Department	Role	CV	CORE	PHIA	Access	CC (?)	Oath of Confidentiality (?)	Contact Details	Contact Level
	Student PI	Psychology	Principal Investigator		<a href="#">02/04/2020 Import</a>	<a href="#">02/04/2020 Import</a>	Signature Authority			<a href="#">Contact Details</a>	Primary
X	Student Advisor	Microbiology	Advisor/Supervisor		<a href="#">05/01/2021 Import</a>	<a href="#">05/01/2021 Import</a>	Signature Authority	<input checked="" type="checkbox"/>		<a href="#">Contact Details</a>	Primary
X	John Co-Investigator	Nursing	Co-Investigator		<a href="#">01/01/2021 Import</a>	<a href="#">01/14/2020 Import</a>	Edit Access	<input type="checkbox"/>	<a href="#">Oath of Confidentiality.pdf</a> X	<a href="#">Contact Details</a>	Secondary
<a href="#">Add</a>											

### 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 is 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

## No Matches

...please refine your search,

or [request that this person be added to the system.](#)

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

First Name

Email Address

Phone Number

CORE Training Date  

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](#)

- Click **Add**
- 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.
- 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.
- Attach the **Oath of Confidentiality**
- Select the **Contact Level**

New Staff

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

- 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="button" value="X"/> 1 <input type="button" value="Poster"/>	<input type="text"/>	<input type="button" value="Attach"/>

- Select the **Type** of document
- Type in the **Name** of the document
- Click **Attach**, find and **Upload** the document



Recruitment Documents			
	Type	Name	Upload
X	1	Poster	Poster.pdf 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.

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		Poster.pdf 10/13/2020	<a href="#">View</a>		
Consent Documents	Consent.pdf	1	New		Consent.pdf 10/13/2020	<a href="#">View</a>		
Observation Guide Document	Consent.pdf	1	New		Consent.pdf 10/13/2020	<a href="#">View</a>		

[Add](#)

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

- [Save Initial Application](#)
- [Submit Initial Application](#)
- [Advisor Review & Sign-Off](#)
- [After Submission](#)
- [Revisions Required from OHRE](#)

## Follow-On Submissions

A follow-on submission can be initiated by the Student PI, the Advisor or anyone with Edit Access on the protocol. It's important to note that for all Student PI protocols a submission will always have to go back to the Advisor before being submitted to the Humane Ethics Office for sign-off regardless of who initiated it.

### Amendment/Personnel Change

To create a new Amendment or Personnel Change form as a Student 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/Withdrawing	Attachments	Submit
<p>Please provide a brief summary of the requested changes</p> <div></div>									
<p>Please provide a justification for these changes</p> <div></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>									
<p><b>Summary of Changes:</b></p> <p>No Changes</p>									

- b. **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/Withdrawing   Attachments   Submit

Please provide a brief summary of the requested changes

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

Justification:

Adding more people to the cohort.

- c. 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/Withdrawing	Attachments	Submit
-------------------	---------	--------------------	---------------	-----------------	------	----------------	---------------------------	-------------	--------

Participants

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.

Need to increase to 100 adults.

A change based on the request.

Amended

- 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 Student 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 Student 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

previous
next

## Protocol Closure

To create a new Protocol Closure form as a Student 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

previous ◀ ▶ next

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## Reassign a Task

The reassign 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)

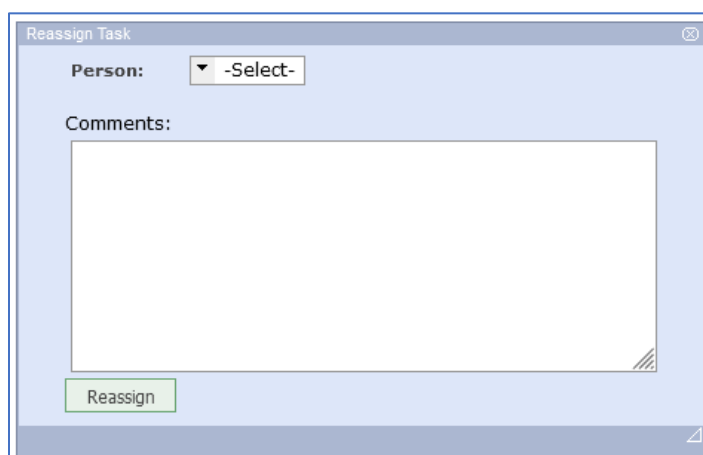
### How to Reassign

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.

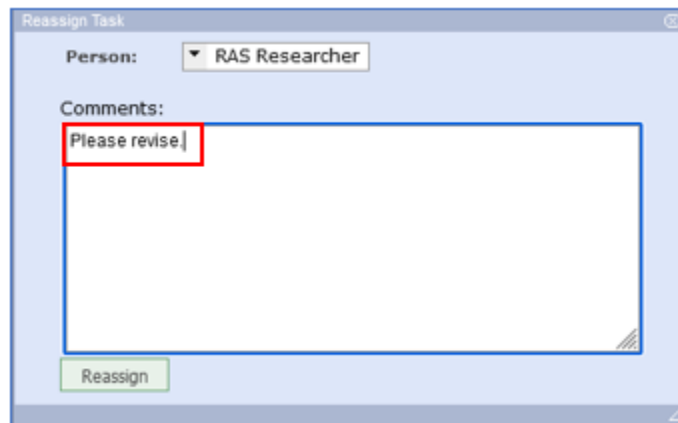


The dialog box titled "Reassign Task" contains a "Person:" dropdown menu currently set to "-Select-". Below it is a "Comments:" text area. At the bottom left is a green "Reassign" button. The dialog has a close button in the top right corner.

4. Add **Comments**, optional

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





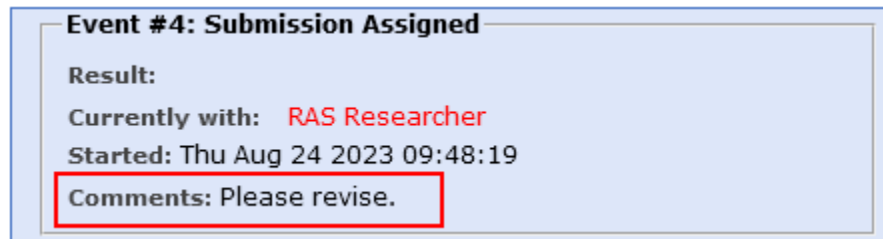
Reassign Task

Person: ▼ RAS Researcher

Comments:

Please revise.

Reassign



**Event #4: Submission Assigned**

Result:

Currently with: RAS Researcher

Started: Thu Aug 24 2023 09:48:19

Comments: Please revise.


5. Click **Reassign**

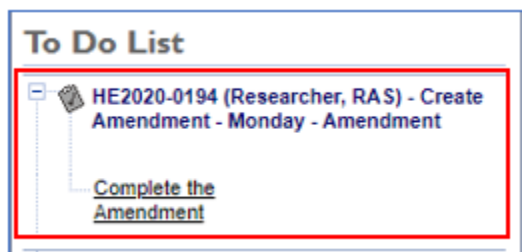
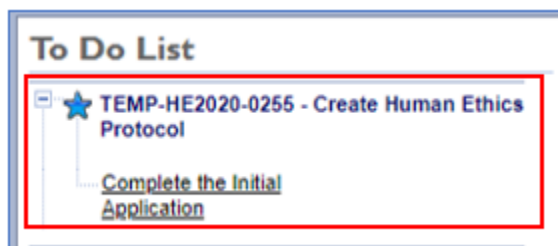
6. Task is now reassigned

**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:

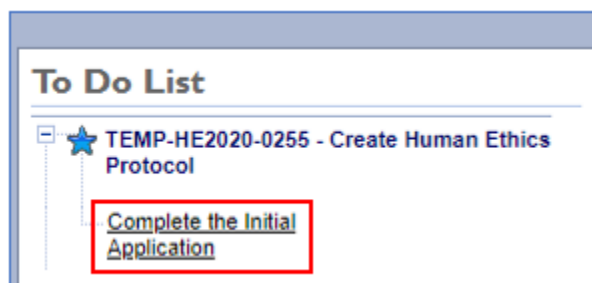
1. Click Save at the  **Save** top left-hand side of the screen
2. Click the Home menu item to return to the LiveList
3. The protocol is now listed in your To Do List



## 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 Statements**

### 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.

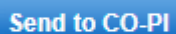
☒ I will submit a Study Closure Form to the REB when all study activity is completed at the local site.

☒ 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 10/16/2020, 11:59:02 AM by Research Student)

[Send for Review](#)

1. 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



- 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**
2. Click **Send for Review**

The application/submission has now been sent to the Advisor for review and final sign-off.

### 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.



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 [Print](#)

Summary

Research Personnel

Participants

Consent Process

Data

Risks/Benefits

Dissemination/Withdrawing \*

Attachments

Submit

Feedback - Withdrawing

Will you be providing participants with the opportunity to review their data? ☐ Yes ☒ No

How will information from or about your participants be presented (e.g., summary statistics for the whole group, direct quotations from their interviews)?

Required

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

The application has now been sent to the Advisor for review and final sign-off.

## Advisor Review & Sign-Off

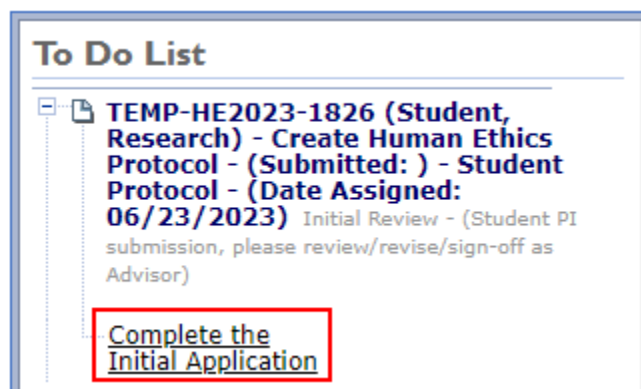
The Advisor will receive an Advisor Sign-Off email notification along with a **To Do List** task to sign off on the initial application or follow-on submission.

**New:** The Advisor can now edit the submission. The commenting function has been removed to allow for better collaboration between research members. Research members will also see the new Team Changes tab that will collect changes made. This tab will display all changes made

To review the initial application or follow-on submission:

1. Click on the **Complete the Initial Application** link in the To Do List

**Note:** If this is a follow-on submission the type of submission being completed would replace “Initial Application”



2. **Team Changes** tab will display no new changes if this is the first time the Advisor is getting the submission. If the submission is sent back to the PI or other research members and changes are made, the Advisor will see those new changes here when they receive the task again.

Protocol Number: **TEMP-HE2023-1826** Initial Application

Principal Investigator: Research Student [Print](#) [ZIP Attachments](#)

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

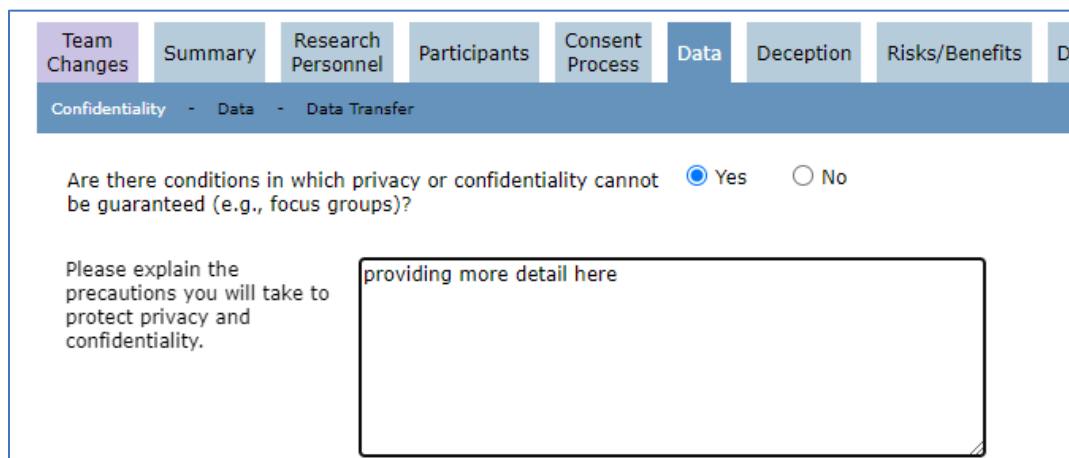
**New Changes**

Location	Field	Original Value	Current Value	Action
None				

[next](#)

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3. Navigate through the tabs and subtabs of the application section and review the answers to each question
4. Changes made to the submission will start collecting in the **Team Changes** tab, this ensures the if this is sent back to the PI, they can see all changes made.



Team Changes Summary Research Personnel Participants Consent Process **Data** Deception Risks/Benefits Di

Confidentiality - Data - Data Transfer

Are there conditions in which privacy or confidentiality cannot be guaranteed (e.g., focus groups)? ☒ Yes ☐ No

Please explain the precautions you will take to protect privacy and confidentiality.

providing more detail here



Location	Field	Original Value	Current Value	Action
Data >> Confidentiality	Please explain the precautions you will take to protect privacy and confidentiality.	x	providing more detail here	Using New Value

5. Once the submission has been reviewed, the Advisor can either send it back to the PI or to the Office of Human Research Ethics for review.
  - a. To send back to PI
    - i. Navigate to the **Submit** tab, check off all declarations
    - ii. Check off **"Send Initial Application back to the PI for review?"**
    - iii. Click **Send to PI**

Team Changes	Summary*	Research Personnel*	Secondary Use of Data	Attachments	Submit
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## Initial Application Submission

Optional Submission Notes

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☒ **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)**

**Advisor/Supervisor Declarations**

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

☐ I will actively monitor the progress of the student's project and will make myself available, should problems arise during the course of the research

☐ I agree to notify the REB of any unanticipated ethical problems encountered during the course of this research project

☐ By providing my signature, as Advisor/Supervisor, 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 (Advisor/Supervisor)** (signed 07/30/2024, 2:44:22 PM by RAS Researcher)

**Send to PI**

b. To send for review:

- i. Navigate to the **Submit** tab, check off all declarations
- ii. Click **Send for Review**

Team Changes	Summary*	Research Personnel*	Secondary Use of Data	Attachments	Submit
--------------	----------	---------------------	-----------------------	-------------	--------

## Initial Application Submission

Optional Submission Notes

---

☐ **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)**

**Advisor/Supervisor Declarations**

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

☒ I will actively monitor the progress of the student's project and will make myself available, should problems arise during the course of the research

☒ I agree to notify the REB of any unanticipated ethical problems encountered during the course of this research project

☒ By providing my signature, as Advisor/Supervisor, 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 (Advisor/Supervisor)** (signed 07/30/2024, 2:43:25 PM by RAS Researcher)

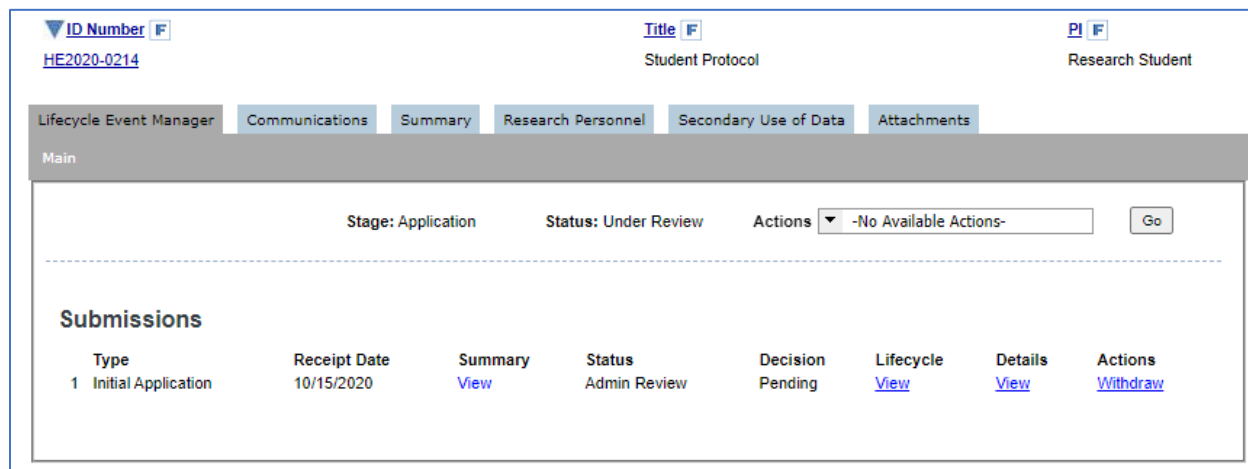
**Send for Review**



## After Submission

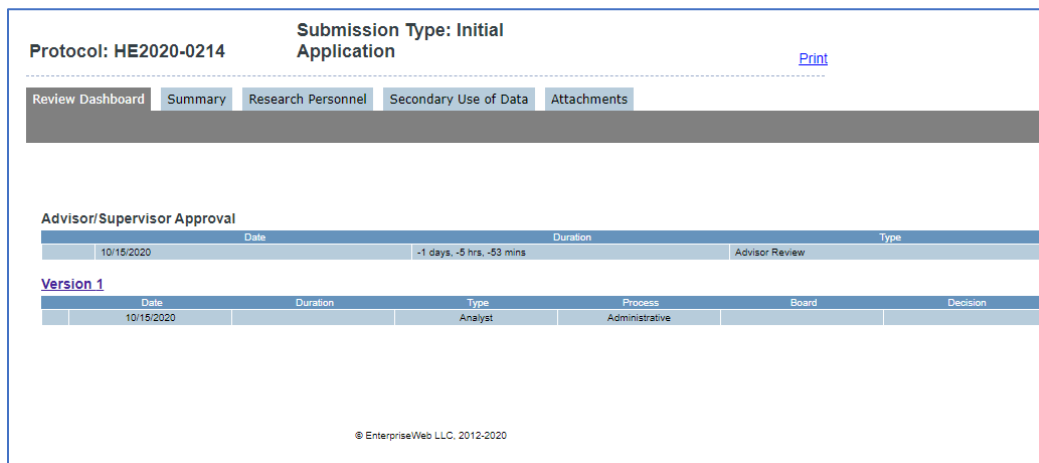
Once you have submitted the initial application or follow-on submission, you can view its progress in the LiveList.

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



The screenshot shows the 'LiveList' interface for protocol HE2020-0214. At the top, there are search filters for ID Number (HE2020-0214), Title (Student Protocol), and PI (Research Student). Below these are tabs for Lifecycle Event Manager, Communications, Summary, Research Personnel, Secondary Use of Data, and Attachments. The 'Main' section displays the submission details: Stage: Application, Status: Under Review, and Actions: -No Available Actions-. A 'Submissions' table lists one submission: Type: Initial Application, Receipt Date: 10/15/2020, Summary: View, Status: Admin Review, Decision: Pending, Lifecycle: View, Details: View, and Actions: Withdraw.

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



The screenshot shows the 'Lifecycle History' window for protocol HE2020-0214. It displays the submission type as 'Initial Application' and includes a 'Print' link. Below the submission type are tabs for Review Dashboard, Summary, Research Personnel, Secondary Use of Data, and Attachments. The 'Advisor/Supervisor Approval' section shows a table with columns: Date, Duration, and Type. The table contains one row: Date: 10/15/2020, Duration: ~1 days, ~5 hrs, ~53 mins, Type: Advisor Review. Below this is the 'Version 1' section, which shows a table with columns: Date, Duration, Type, Process, Board, and Decision. The table contains one row: Date: 10/15/2020, Duration: (blank), Type: Analyst, Process: Administrative, Board: (blank), Decision: (blank). At the bottom, there is a copyright notice: © EnterpriseWeb LLC, 2012-2020.

5. To return to the LiveList
  - a. Click the Home button under the Menu Bar or;
  - b. 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.

1. In the **LiveList**, select the protocol link under Protocol/Project Number to view the Lifecycle Event Manager
2. 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

Are you sure you wish to Withdraw this submission?  
This action cannot be reversed.

OK
Cancel

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 Student 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

### To Do List



**HE2021-0006 (Researcher, RAS) - Revise Initial Application - CE - TEST TRNG - Reviews - (Date Assigned: 05/19/2021)**  
Response to Chair Review

[Revise Initial Application](#)

**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**

Protocol Number: HE2021-0006 Initial Application

Principal Investigator: RAS Researcher **Application** [Print](#) [ZF Attachments](#)

[Instructions](#) **Review**

**Response to Chair Review**

Review Comments

Investigator Response (to the Administrator)

Comments Summary\* Research Personnel Participants\* Consent Process Data Risks/Benefits Dissemination/Withdrawing Attachments Submit

PI Response:

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

▶ next

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

Comments Summary\* Research Personnel Participants\* Consent Process Data Risks/Benefits Dissemination/Withdrawing Attachments Submit

PI Response:

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

▶ next

**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 [Attachment: Marked-Up Versions](#)
- 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:

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/Withdrawing	Attachments	Submit
<b>PI Response:</b>									
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	Using New Value				
Participants >> <a href="#">Participants</a>	How many participants do you expect to recruit?	Recruit	100 participants.	please add more specific	Using New Value				
<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.		Using New Value				

▶ next

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

[Instructions](#)

## Response to Chair Review

**Review Comments**

**Investigator Response (to the Administrator)**

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

The revision has now been sent to the Advisor for review and final sign-off.

### 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

#### Revisions

##### Review Comments

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.

##### Investigator Response (to the Analyst)

Protocol Number: [HE2023-0228](#)

Initial Application

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

Comments Summary Research Personnel Participants Consent Process\* Data Risks/Benefits Dissemination/Withdrawing Indigenous Peoples Attachments\* Submit

#### PI Response:

Location	Field	Original Value	Current Value	Comment	Action	Justification
<a href="#">Attachments</a>	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 >> <a href="#">Informed Consent Process</a>	Consent Documents	Consent.pdf [View Page]	Consent.pdf [View Page]	Please add dates.	No Change	

▶ next

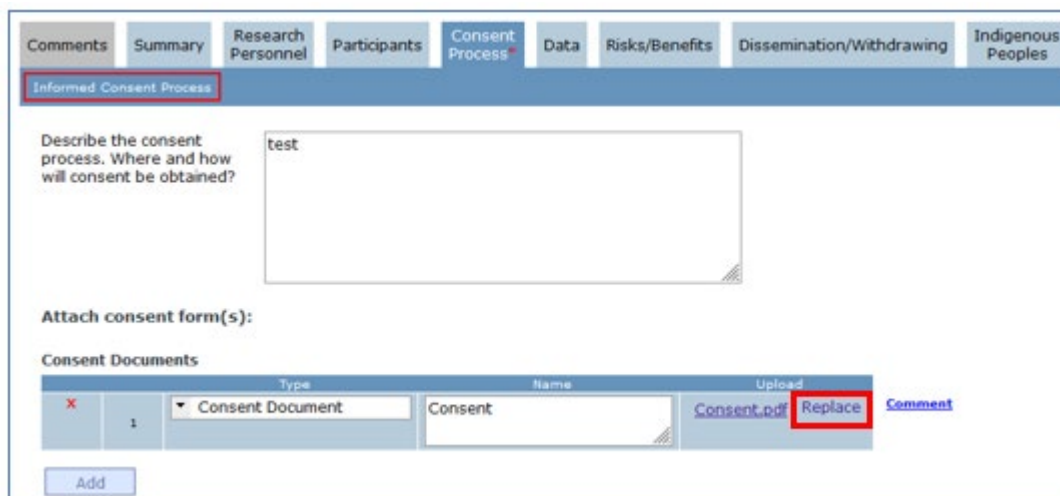
### Upload Clean & Marked-Up Version

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



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

#### Attachments Tab

1. Navigate to the **Attachments** tab
2. 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		
Consent Documents	Consent	1	New		<a href="#">Consent.pdf</a> 08/22/2023	<a href="#">View</a>		<a href="#">Upload</a>	<a href="#">Comments</a> New Doc Required	
Recruitment Documents	Poster	1	New		<a href="#">Poster.pdf</a> 08/22/2023	<a href="#">View</a>		<a href="#">Upload</a>		
Other Approval Documents	Approval	1	New		<a href="#">approval.docx</a> 08/22/2023	<a href="#">View</a>		<a href="#">Upload</a>		
Agreement Documents	New Agreement	1	New		<a href="#">Fully Executed Agreement.pdf</a> 08/22/2023	<a href="#">View</a>		<a href="#">Upload</a>		
Oath of Confidentiality:RAS Researcher	Oath of Confidentiality.pdf	1	New		<a href="#">Oath of Confidentiality.pdf</a> 08/22/2023	<a href="#">View</a>		<a href="#">Upload</a>		
Manual Attachment	<input type="text" value="Survey"/>	1	New		<a href="#">survey.pdf</a> 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	
Consent Documents	Consent	1	New	<a href="#">View</a>	<a href="#">Consent 2.pdf</a> 08/23/2023	<a href="#">View</a>	<a href="#">Attach</a>	<a href="#">View / Replace</a>	<a href="#">Comments</a> 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

Type	Name	Version	Status	History	File name/ Uploaded Date	Comments	Marked Up Version [?]	New Version	
Consent Documents	Consent	1	New	<a href="#">View</a>	<a href="#">Consent 2.pdf</a> 08/23/2023	<a href="#">View</a>	<a href="#">View X</a>	<a href="#">View / Replace</a>	<a href="#">Comments</a> New Doc Provided

3.