

How to Submit a Protocol as a Designate

RAS Training Documentation

Last Modified: August 25, 2023

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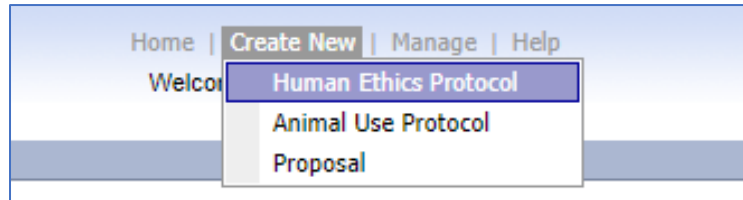
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Initial Application

To create a new Human Ethics Protocol as a Designate:

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

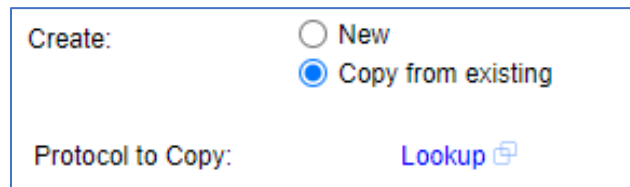
Note: The newly created protocol will receive a temporary protocol number while the application is in development. Once the application is submitted, a final Human Ethics Protocol number will be assigned.




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 following elements:
 Create: New Copy from existing
 Protocol to Copy: [Lookup](#) 

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

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

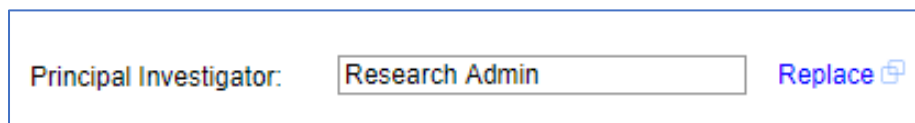
- b. **Protocol Title** – Enter the title of the protocol


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

- i. When a Designate (i.e. Study Coordinator) is filling out the form for the PI you must replace the Principal Investigator name with the PI's name.

1. Click **Replace** to choose the correct PI for this protocol.



The screenshot shows a form with the following elements:
 Principal Investigator: [Replace](#) 

2. The **Find PI** search box will appear, type into the lookup field to find the PI's name.

Find PI

Lookup:

Name	ID	Department
Researcher_Jane	test	Psychology
Researcher_RAS	RAS_Researcher	Max Rady College of Medicine

- Once the application has been completed it will then be sent to the PI for submission.

Principal Investigator: [Replace](#)

Note: When the application is complete, it will be sent to the PI for submission.

Department:

- Department** – this drop down will auto populate based on the PI chosen
- Click **Begin Application**

Create a New Human Ethics Protocol

Create: New Copy from existing

Protocol Title:

Principal Investigator: [Replace](#)

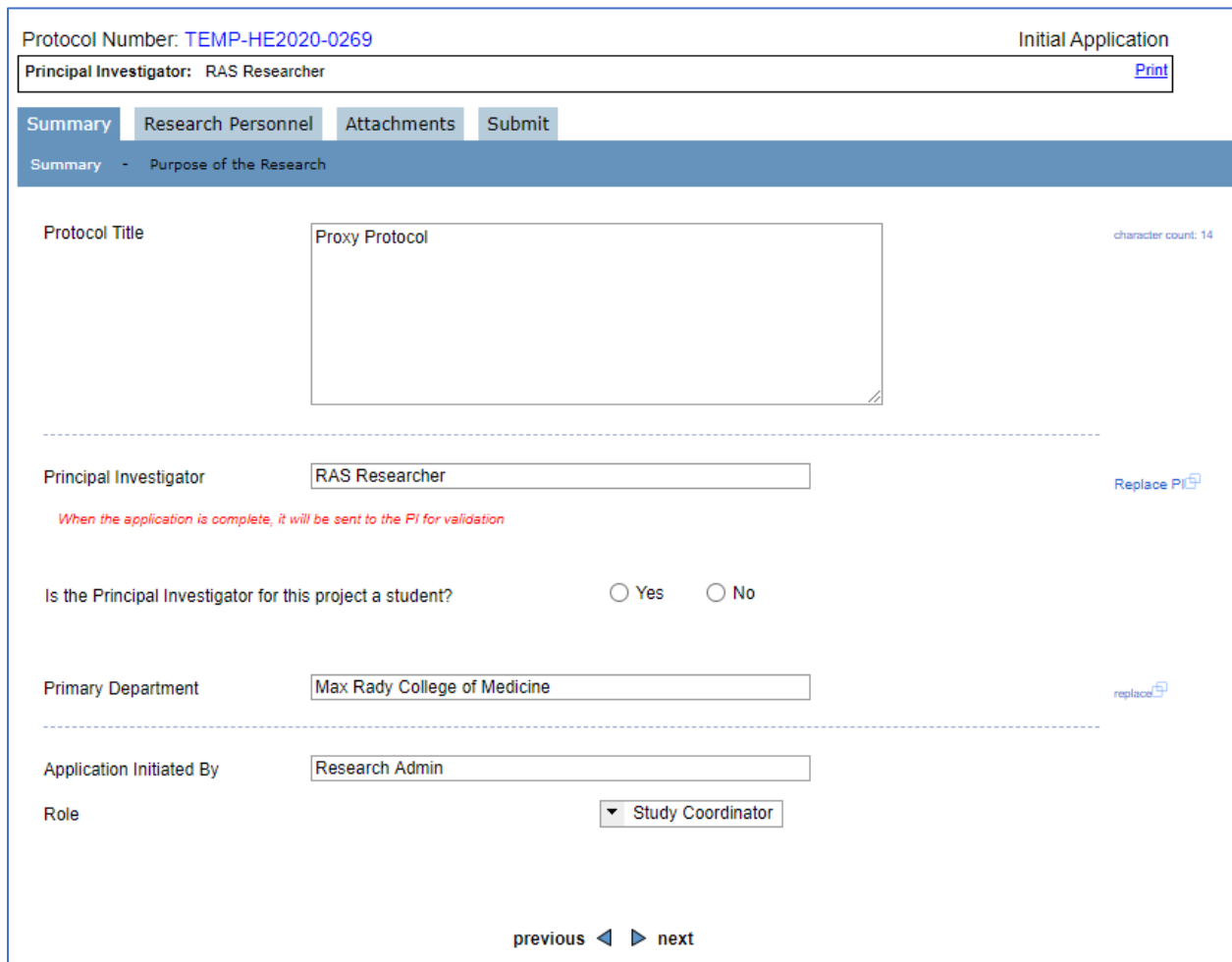
Note: When the application is complete, it will be sent to the PI for submission.

Department:

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. If the designate is filling out this form for a Student PI, check off **Yes** for the question 'Is the Principal Investigator for this project a student?'. This will ensure they need to also include the student's advisor in the Research Personnel tab. See the Student PI Submission process for more details on student PIs.
2. Select the role of the Designate under the **Role** drop down.
3. Navigate through each page and answer each question as they appear within the form.



Protocol Number: [TEMP-HE2020-0269](#) Initial Application

Principal Investigator: RAS Researcher [Print](#)

Summary Research Personnel Attachments Submit

Summary - Purpose of the Research

Protocol Title character count: 14

Principal Investigator [Replace PI](#)

When the application is complete, it will be sent to the PI for validation

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

Primary Department [replace](#)

Application Initiated By


Role

previous ◀ ▶ next

Adding Research Personnel

Add additional research personnel to the protocol including the Designates information.

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	Signature Authority		Contact Details	Primary
<input type="button" value="Add"/>									

- 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
Admin_Research	RAS_PI_Admin	Max Rady College of Medicine

- Click on the users' name to add them to the protocol
- 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.
 - 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

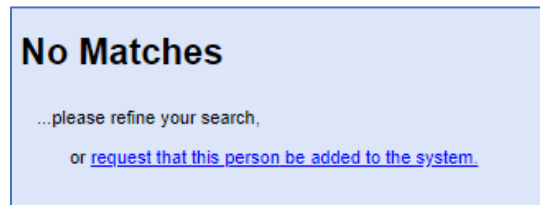
Protocol Personnel											
	Name	Department	Role	CV	CORE	PHIA	Access	CC (?)	Oath of Confidentiality (?)	Contact Details	Contact Level
	RAS Researcher	Max Rady College of Medicine	Principal Investigator		04/01/2021 Import	04/01/2021 Import	Signature Authority			Contact Details	Primary
X	John Co-Investigator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

Add On-The-Fly User

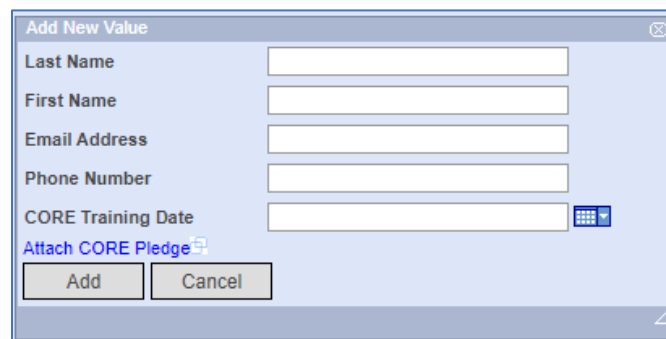
If you can't find someone in the Find Person lookup window when trying to add them to the research personnel table, you can add them on-the-fly.

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 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

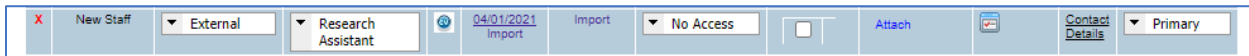


2. Complete the following (all fields are mandatory):
 - a. Enter the **Last Name**
 - b. Enter **First Name**
 - c. Enter **Email Address**
 - d. Enter **Phone Number**
 - e. Select the **CORE Training Date**
 - f. Click on **Attach CORE Pledge** to upload the users CORE certificate



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**



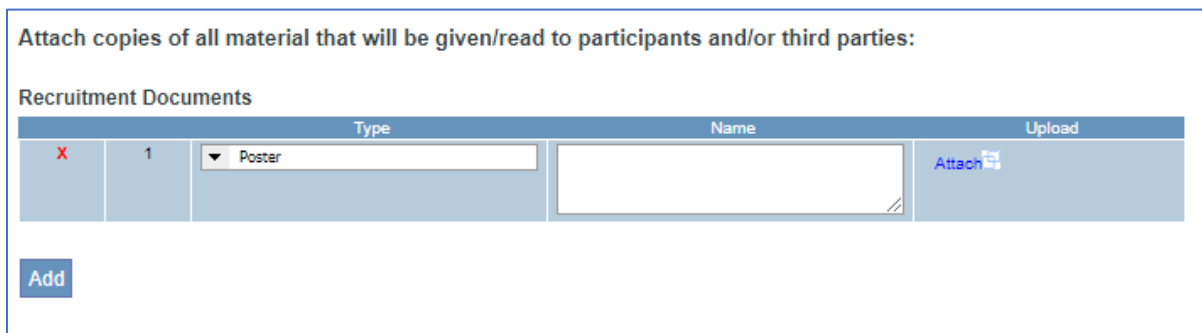
Once the application/submission has been submitted to the Ethics Office, a task will be sent to ORS to add this new user to the system.

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**



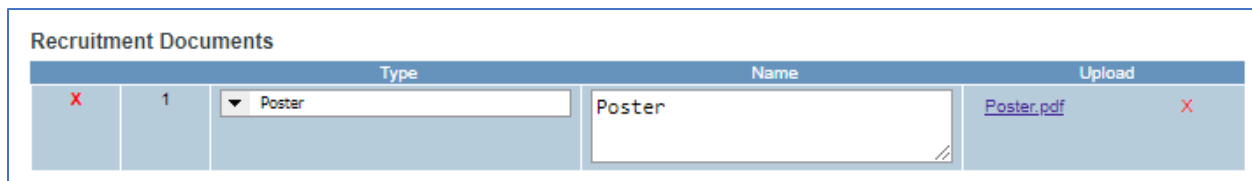
Attach copies of all material that will be given/read to participants and/or third parties:

Recruitment Documents

Type	Name	Upload
X 1 Poster		Attach

Add

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



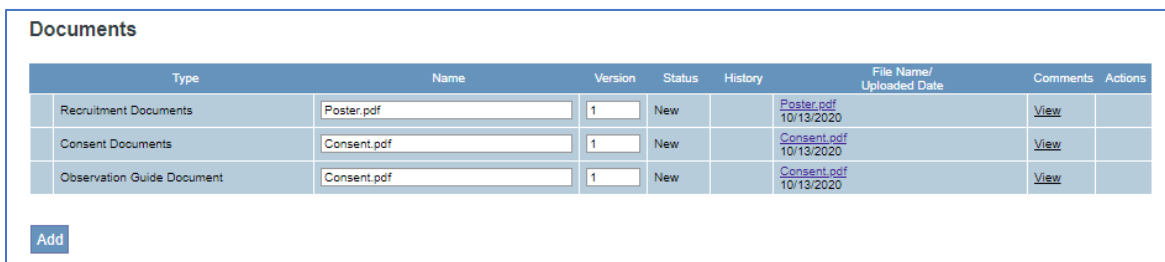
Recruitment Documents

Type	Name	Upload
X 1 Poster	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		View
Consent Documents	Consent.pdf	1	New		Consent.pdf 10/13/2020		View
Observation Guide Document	Consent.pdf	1	New		Consent.pdf 10/13/2020		View

Add

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

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

Follow-On Submissions

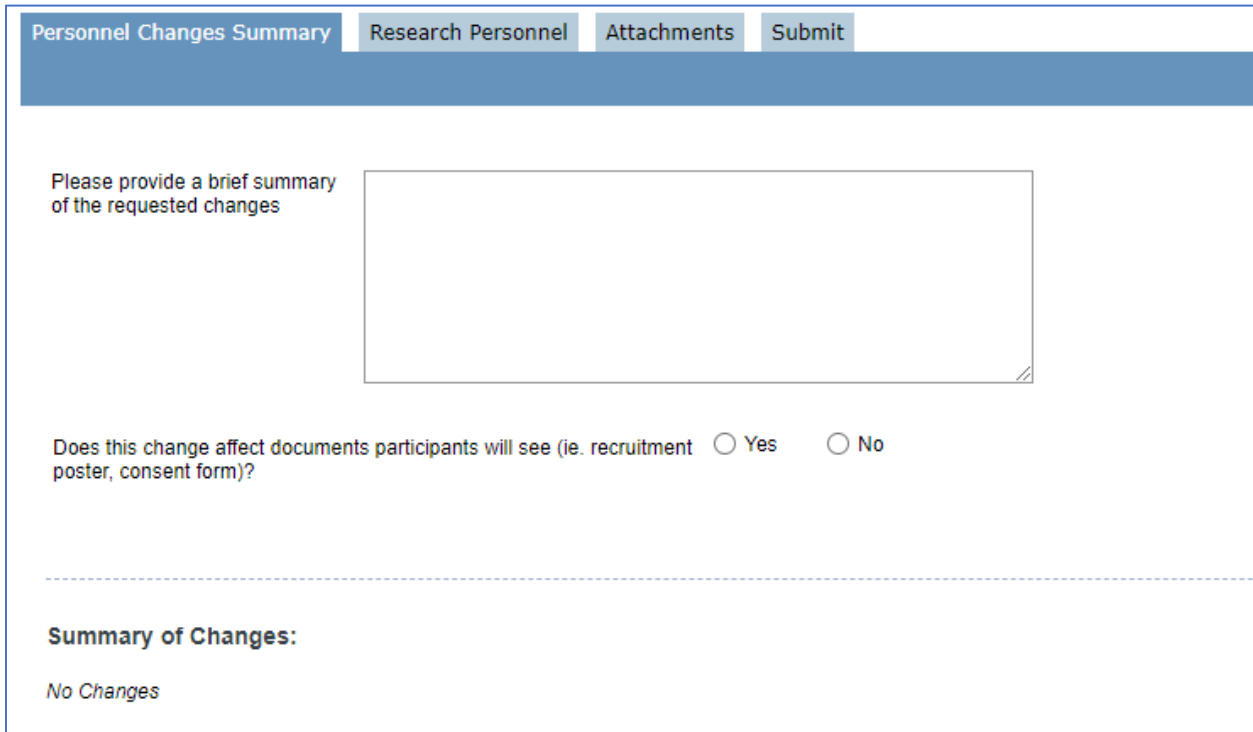
Amendment/Personnel Change

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

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 style="border: 1px solid #ccc; height: 70px; width: 100%;"></div>									
<p>Please provide a justification for these changes</p> <div style="border: 1px solid #ccc; height: 70px; 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 style="border-top: 1px dashed #ccc;"/> <p>Summary of Changes:</p> <p><i>No Changes</i></p>									

b. **Personnel Change** – Complete all questions under Personnel Summary



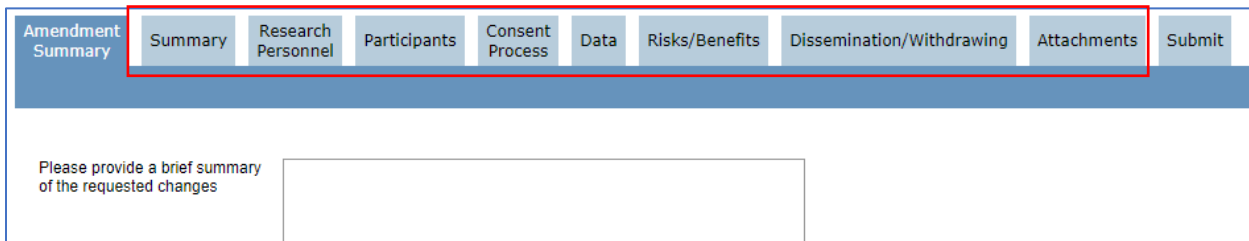
Personnel Changes Summary | Research Personnel | Attachments | Submit

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

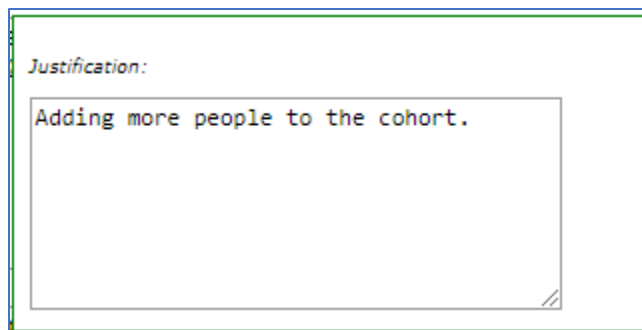
3. Navigate throughout the application and make your changes. As this is a living document, when you make a change to questions within the initial application section you will need to justify each change.



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
<div style="border: 1px solid blue; padding: 5px;"> Participants - Recruitment </div>									
<p>How many participants do you expect to recruit?</p> <div style="border: 1px solid gray; padding: 5px; margin-top: 10px;"> <p>We anticipate that approximately 45 adults between the ages of 50-70 will participate in one of three Turning Pages groups offered in 2018.</p> <p>Need to increase to 100 adults.</p> <p>A change based on the request.</p> </div> <p style="text-align: right; margin-top: 10px;">Amended</p>									

- 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 Designate:

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.

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REB Event

To create a new REB Event form as a Designate:

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 Designate:

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 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, there are rules as to who can be reassigned a task and where the task can go after it's been reassigned.

Reassign Rules

A task can only be reassigned to a research team member who has edit access to a protocol. Any research team member with signature authority (PI, CoPI or Advisor) or edit access can reassign to someone with edit access. Tasks cannot be reassigned to signature authority research team members.

When a task is with a research team member with edit access, they have 2 options to move the task forward:

1. **Submit to the PI:** to send the task back to the PI they must navigate to the Submit tab within the task and to submit it back to the PI
2. **Reassign to another user with edit access:** to reassign to another research team member with edit access, navigate to the LiveList, select the protocol. Beside the current submission under Action click Reassign and choose their name.

Important: A research team member with edit access cannot reassign or submit a task to a CoPI or Advisor. They also cannot reassign a task to a PI, they must submit it using the Submit tab in the submission.

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 HEO depending on who is listed in the protocol), or they can reassign it to a research team member with edit access.

Remember: A CoPI and Advisor can always send a task back to the PI by navigating to the Submit tab, checking off all declarations and 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

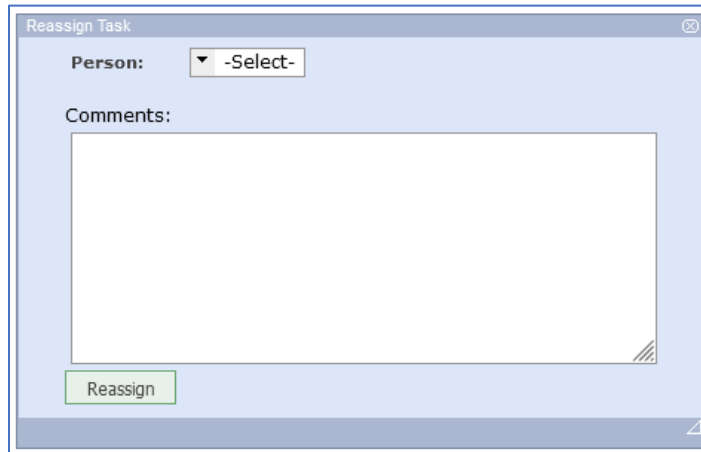
1. Select the protocol link from the **LiveList**
2. Under **Submissions > Actions** click **Reassign Task**

Submissions

Type	Receipt Date	Summary	Status	Decision	Lifecycle	Details	Actions
1 Initial Application	08/23/2023	View	Revisions	Pending	View	View	Withdraw Reassign Task

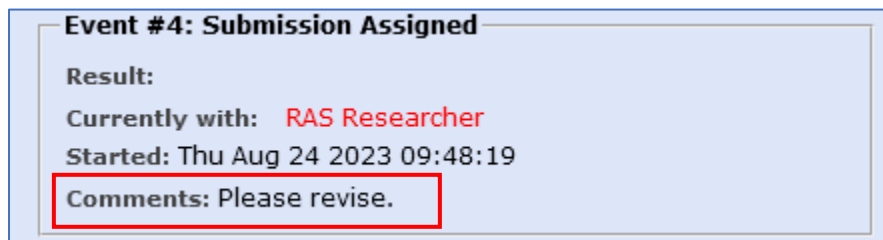
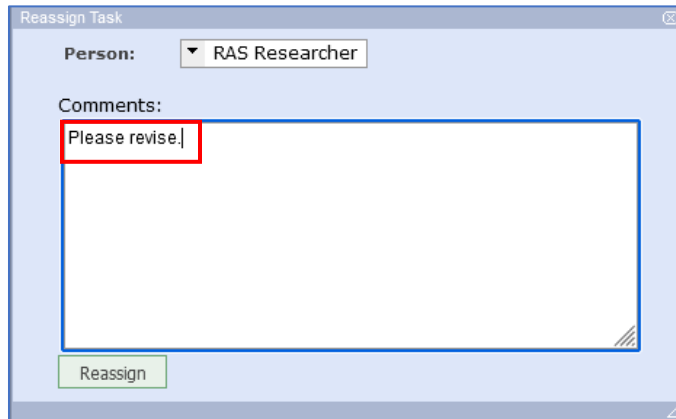
3. Select the **Person** to reassign the submission to

Remember: Only research personnel with Edit Access will appear here.



4. Add **Comments**, optional

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




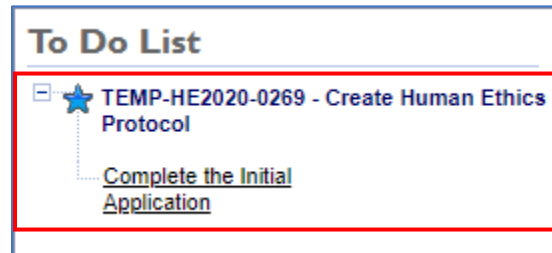
5. Click **Reassign**
6. Task is now reassigned

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:

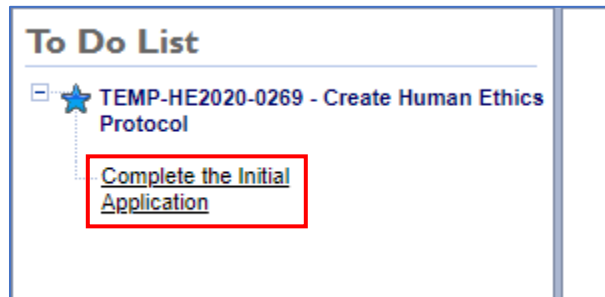
1. Click Save at the  top left-hand side of the screen
2. Click the **Home** menu item to return to the LiveList
3. The protocol is now listed in your **To Do List**



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 link within the task



The PI will also see the new temporary protocol in their LiveList.

ID Number	Title	PI	Status	Type
TEMP-HE2020-0269	Proxy Protocol	RAS Researcher	Under Development	Human Ethics

Remember: The PI can reassign this saved application to themselves to complete at any time as well. See **Delete or Reassign Task** section of the Lifecycle Event Manager for more information.

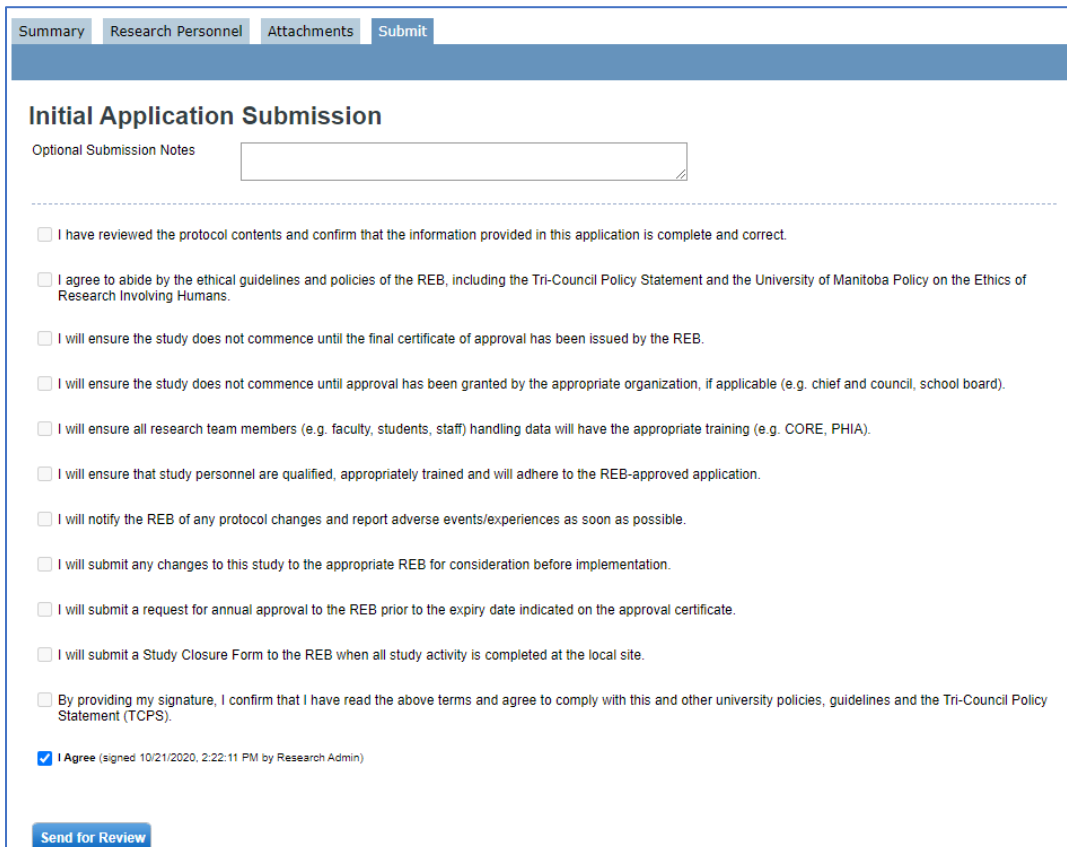
Submit an Initial Application or Follow-On Submission

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. When a Designate is submitting the application, the **Declaration Statements** will be greyed out, these must be completed by the PI



Summary Research Personnel 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.

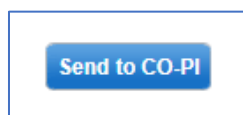
I will submit a request for annual approval to the REB prior to the expiry date indicated on the approval certificate.

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 (signed 10/21/2020, 2:22:11 PM by Research Admin)

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 after the PI signs off



- ii. After the Co-PI has reviewed the application/submission, navigate to the **Submit** tab
- iii. Read and check each of the **Declaration Statements**
- iv. The Co-PI has the option of sending the application back to the PI if changes have been made or they can click I Agree to send for review

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)

I Agree (CO-PI)

6. Click **Send for Review**

The application/submission has now been sent to the PI for review and signature.

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 [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 initial application or follow-on submission.

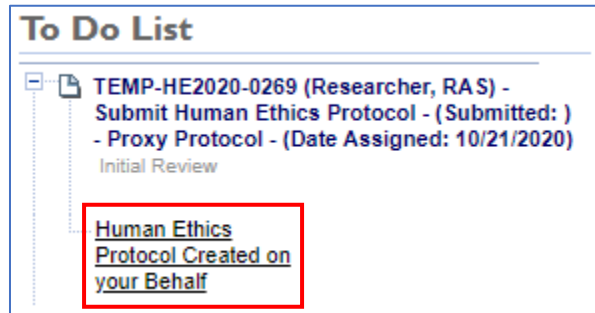
After the submission has gone through, you can view the protocol in the LiveList.

Investigator Sign-Off

The PI will receive an email notification along with a **To Do List** task to sign off on the submission.

To review the initial application or follow-on submission:

1. Click the link in the To Do List



2. Click **Review/Submit Protocol**

Protocol Number: TEMP-HE2020-0269	Human Ethics Application
Principal Investigator: RAS Researcher	Status: In Development

The following Human Ethics application was created on your behalf:

Title: Proxy Protocol

Created by: Research Admin

[Review/Submit Protocol](#)

3. Navigate and review the whole submission, the PI can add additional information to any questions within the submission at this time as well
4. When all questions have been addressed navigate to the **Submit** tab
5. Enter any desired **Submission Notes** in the field provided, optional
6. Read and check each of the **Declaration Statements**

Summary Research Personnel Secondary Use of Data 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 10/21/2020, 2:32:40 PM by RAS Researcher)

Send for Review

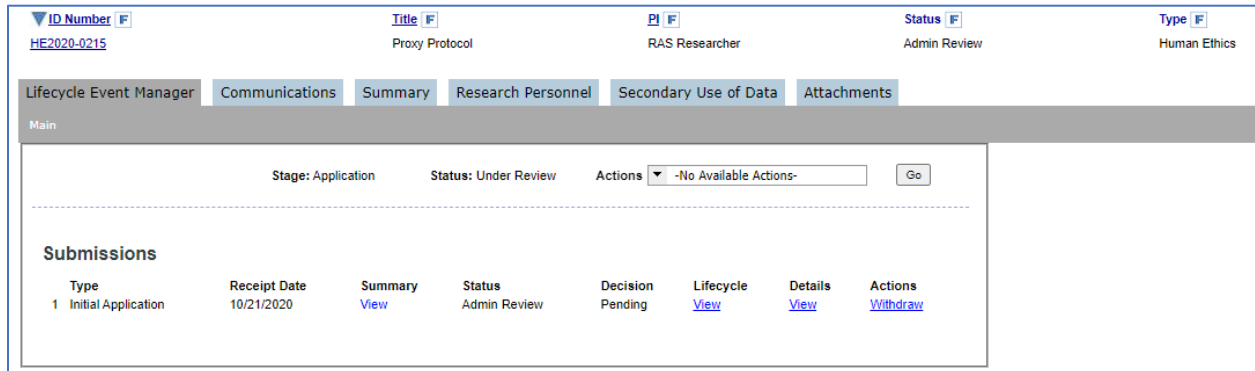
7. Check the **I Agree** checkbox to agree to the certification statement
8. Click **Send for Review**

The submission is now sent to the Ethics Office for review.

After Submission

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

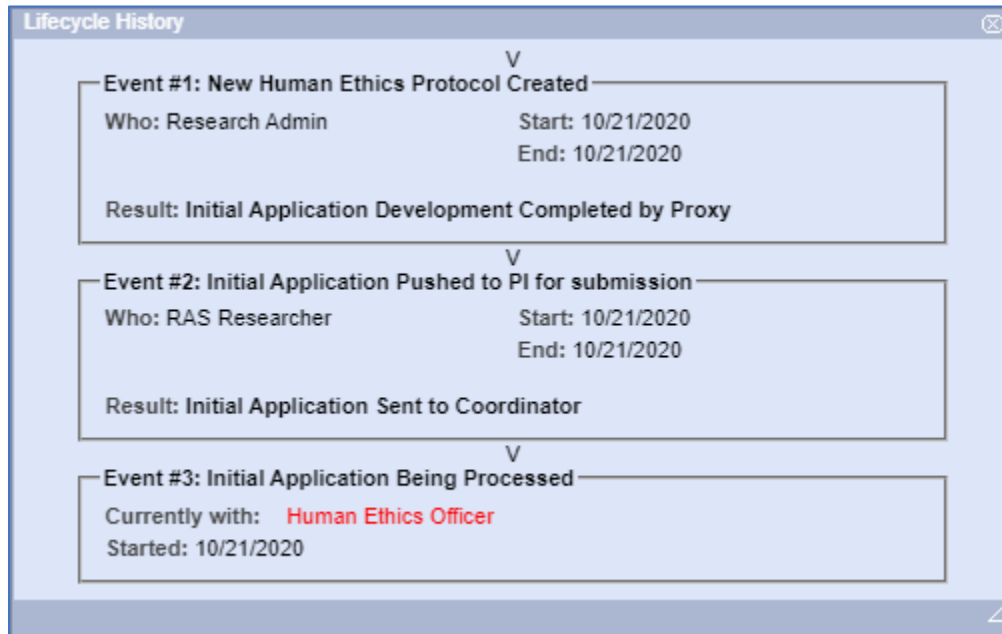
1. Navigate to the **LiveList**
2. Select the protocol from the list by clicking on the protocol number link under the Protocol/Project Number column



The screenshot shows the LiveList interface for protocol HE2020-0215. At the top, there are fields for ID Number (HE2020-0215), Title (Proxy Protocol), PI (RAS Researcher), Status (Admin Review), and Type (Human Ethics). Below this are navigation tabs: Lifecycle Event Manager, Communications, Summary, Research Personnel, Secondary Use of Data, and Attachments. The main content area shows the submission details:

Type	Receipt Date	Summary	Status	Decision	Lifecycle	Details	Actions
1 Initial Application	10/21/2020	View	Admin Review	Pending	View	View	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



The Lifecycle History window displays the following events:

- Event #1: New Human Ethics Protocol Created**
Who: Research Admin
Start: 10/21/2020
End: 10/21/2020
Result: Initial Application Development Completed by Proxy
- Event #2: Initial Application Pushed to PI for submission**
Who: RAS Researcher
Start: 10/21/2020
End: 10/21/2020
Result: Initial Application Sent to Coordinator
- Event #3: Initial Application Being Processed**
Currently with: **Human Ethics Officer**
Started: 10/21/2020

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

Protocol: HE2020-0215 **Submission Type: Initial Application** [Print](#)

Review Dashboard Summary Research Personnel Secondary Use of Data Attachments

Version 1

Date	Duration	Type	Process	Board	Decision
10/21/2020		Analyst	Administrative		

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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	View	Admin Review	Pending	View	View	Withdraw
2 Amendment	08/24/2020	View	Completed	Approved	View	View	
1 Initial Application	08/21/2020	View	Completed	Approved	View	View	

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

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

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

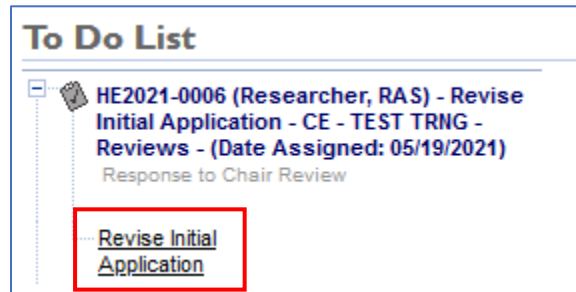
Submissions							
Type	Receipt Date	Summary	Status	Decision	Lifecycle	Details	Actions
3 Amendment	10/27/2020	View	Withdrawn		View	View	
2 Amendment	08/24/2020	View	Completed	Approved	View	View	
1 Initial Application	08/21/2020	View	Completed	Approved	View	View	

Revisions Required

After an application or submission has been reviewed and it is sent back from the HEO for revisions, the PI will receive an email notification and task to be completed in their To Do List.

The designate (or Study Coordinator) will also receive an email notification if they were cc'd under the Research Personnel section of the protocol. If the designate is to complete the revision task they can reassign the task to themselves. See **Delete or Reassign Task** section of the Lifecycle Event Manager.

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

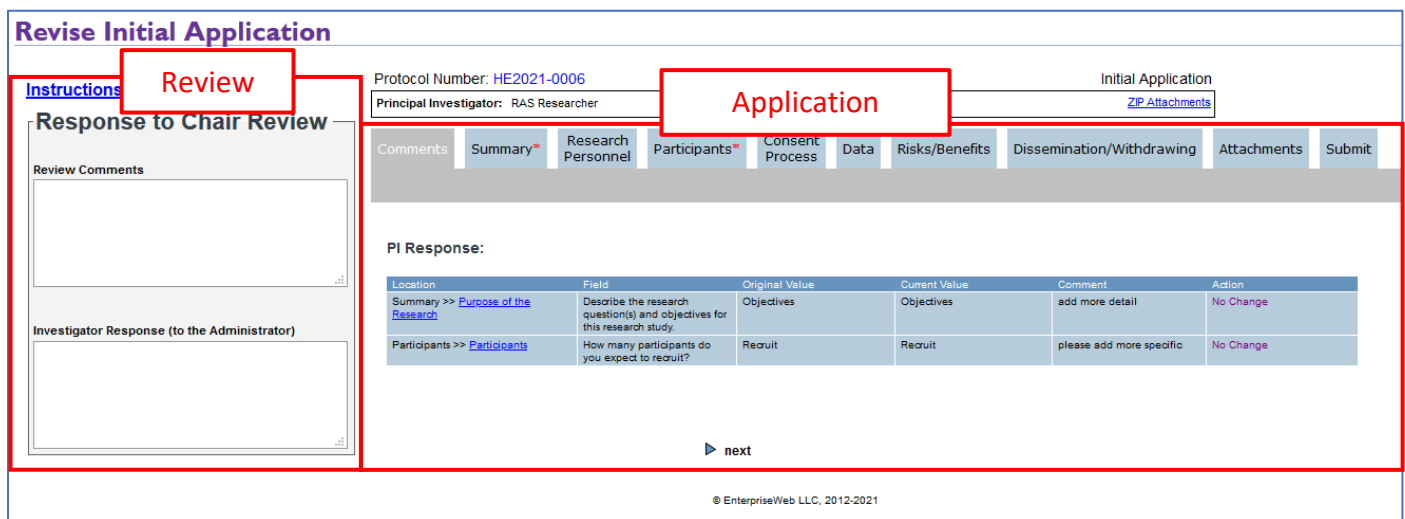


To Do List

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

[Revise Initial Application](#)

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 HEO Review or Member Review.



Revise Initial Application

Protocol Number: HE2021-0006 Initial Application
Principal Investigator: RAS Researcher [ZIP Attachments](#)

Review

Application

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 >> Purpose of the Research	Describe the research question(s) and objectives for this research study.	Objectives	Objectives	add more detail	No Change
Participants >> Participants	How many participants do you expect to recruit?	Recruit	Recruit	please add more specific	No Change

next

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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

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 >> Purpose of the Research	Describe the research question(s) and objectives for this research study.	Objectives	Objectives	add more detail	No Change
Participants >> Participants	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 * 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.

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

PI Response:

Location	Field	Original Value	Current Value	Comment	Action
Summary >> Purpose of the Research	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 >> Participants	How many participants do you expect to recruit?	Recruit	100 participants.	please add more specific	Using New Value
Research Personnel	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

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

Instructions

Response to Chair Review

Review Comments

Investigator Response (to the Administrator)

- Navigate to the **Submit** tab and resubmit the application/submission

The revision has now been sent to the PI for review and signature.

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
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	

▶ next

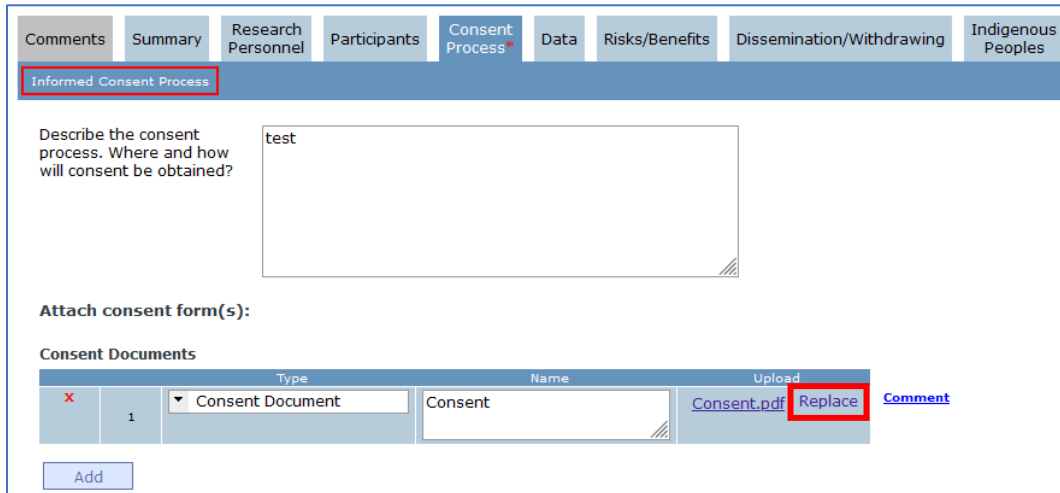
Upload Clean & Marked-Up Version

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

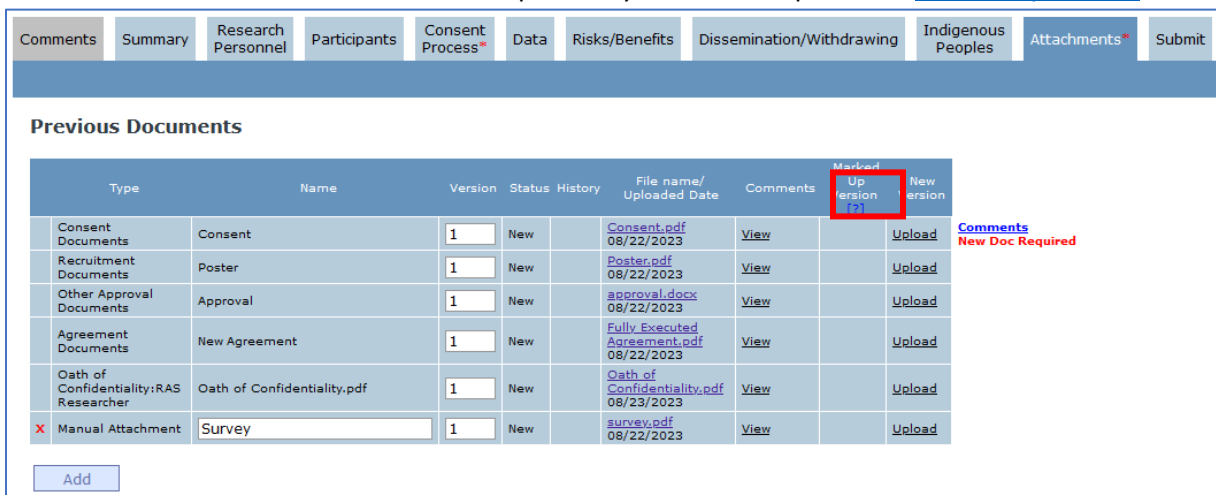


Type	Name	Upload
Consent Document	Consent	Consent.pdf Replace Comment

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
3. Once the new document has been uploaded you can now upload the [marked-up version](#)



Type	Name	Version	Status	History	File name/ Uploaded Date	Comments	Marked Up version (2)	New version
Consent Documents	Consent	1	New		Consent.pdf 08/22/2023	View		Upload
Recruitment Documents	Poster	1	New		Poster.pdf 08/22/2023	View		Upload
Other Approval Documents	Approval	1	New		approval.docx 08/22/2023	View		Upload
Agreement Documents	New Agreement	1	New		Fully Executed Agreement.pdf 08/22/2023	View		Upload
Oath of Confidentiality:RAS Researcher	Oath of Confidentiality.pdf	1	New		Oath of Confidentiality.pdf 08/23/2023	View		Upload
Manual Attachment	Survey	1	New		survey.pdf 08/22/2023	View		Upload

Marked-Up Version

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

Type	Name	Version	Status	History	File name/ Uploaded Date	Comments	Marked Up Version [?]	New Version
Consent Documents	Consent	1	New	View	Consent 2.pdf 08/23/2023	View	Attach	View / Replace

[Comments](#)
New Doc Provided

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

Type	Name	Version	Status	History	File name/ Uploaded Date	Comments	Marked Up Version [?]	New Version
Consent Documents	Consent	1	New	View	Consent 2.pdf 08/23/2023	View	View X	View / Replace

[Comments](#)
New Doc Provided