# How to Submit a Protocol as a Designate

RAS Training Documentation

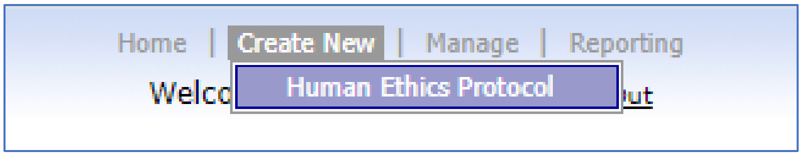
Last Modified: July 30, 2024

# Contents

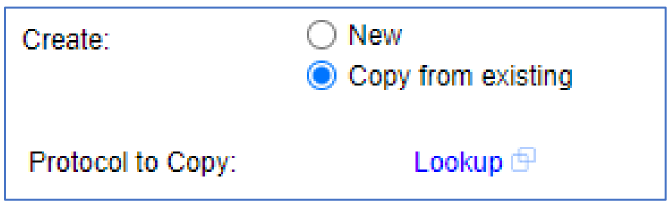
# Initial Application

To create a new Human Ethics Protocol as a Designate:

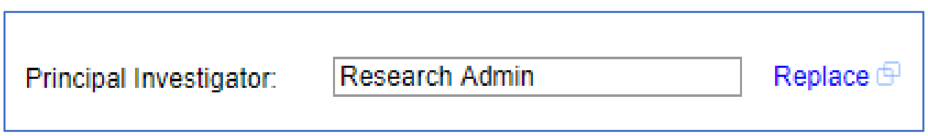
1. Under the **Create New** menu item select **Human Ethics Protocol**
   **Note**: The newly created protocol will receive a temporary protocol number while the application is in development.  Once the application is submitted, a final Human Ethics Protocol number will be assigned.



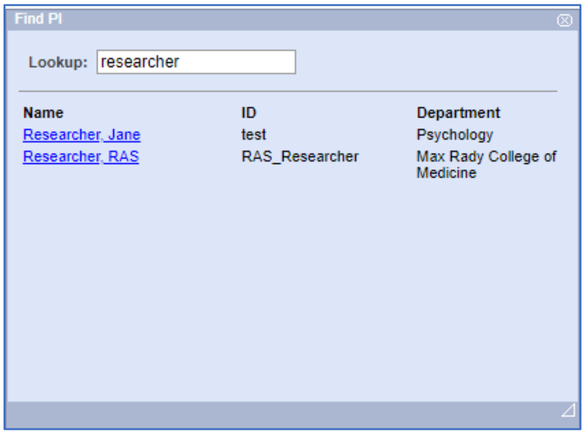

2. Start filling out the following information to start your new protocol:
   a. **Create** – New or Copy from Existing
      i. To **copy from existing** protocol, click the **Lookup** link the Lookup Protocol to Copy window will appear



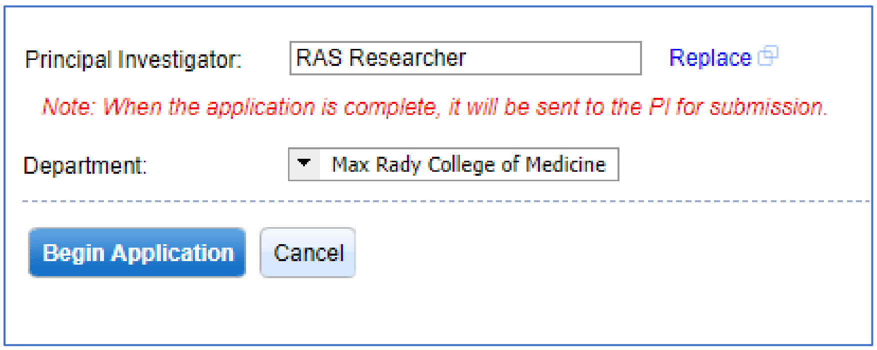

      ii. Search and select the protocol you wish to copy
      **Note**: You will only be able to copy protocols you have access to.
   b. **Protocol Title** – Enter the title of the protocol
   **Note**: The title must be unique per PI, this means it cannot be duplicated from another protocol under the same 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.




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

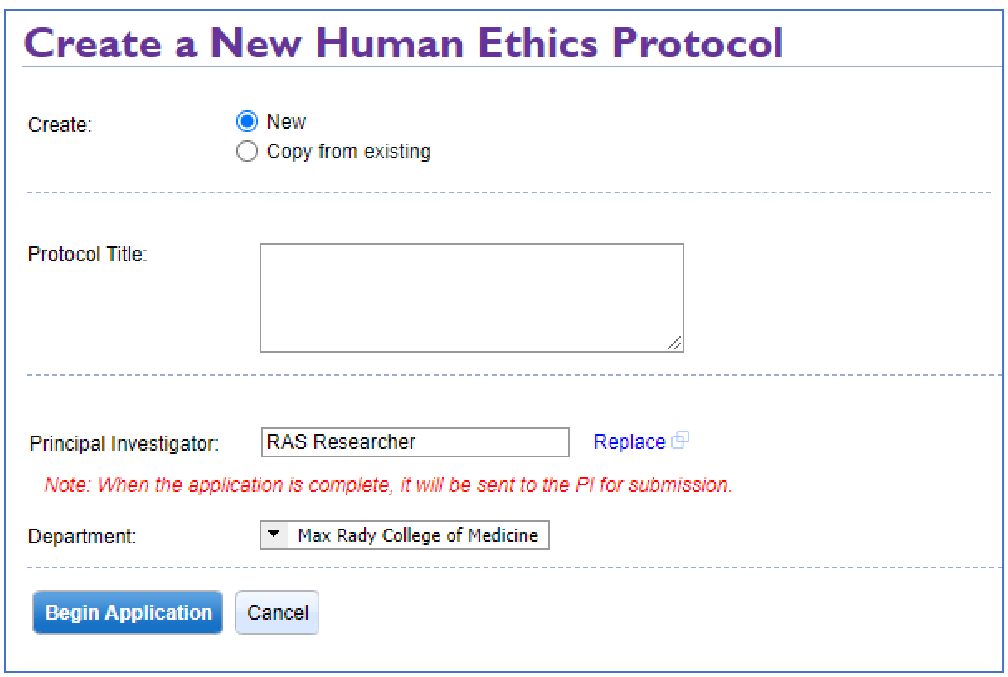



3. Once the application has been completed it will then be sent to the PI for submission.




d. **Department** – this drop down will auto populate based on the PI chosen

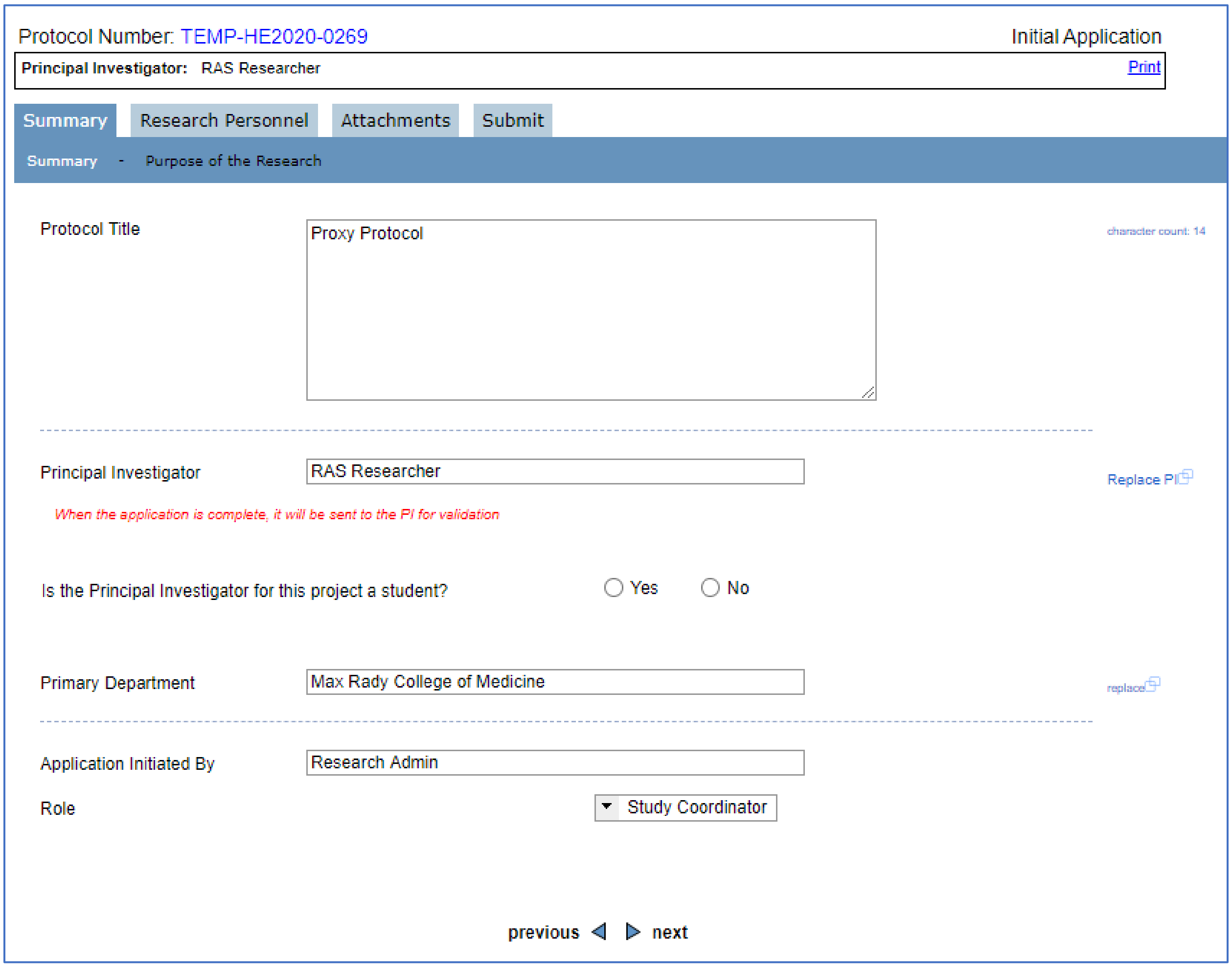
3. Click **Begin Application**



**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.

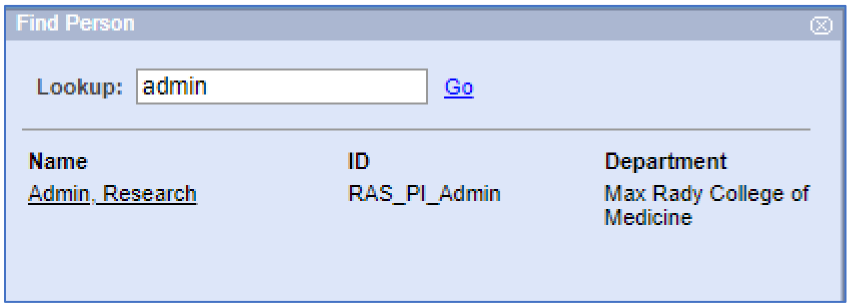



## Adding Research Personnel

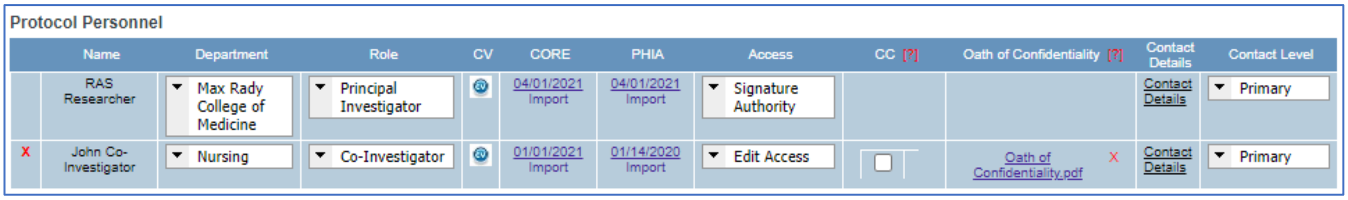
Add additional research personnel to the protocol including the Designates information.

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


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.




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


Protocol Personnel

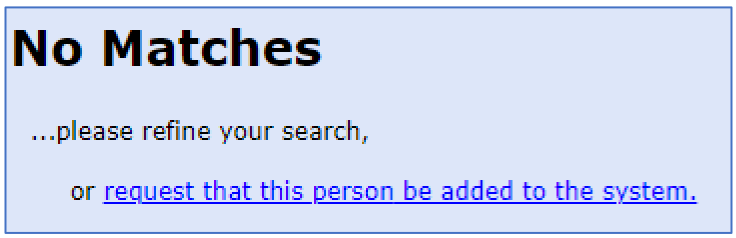
| | Name | Department | Role | CV | CORE | PHIA | Access | CC [?] | Oath of Confidentiality [?] | Contact Details | Contact Level |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | RAS Researcher | Max Rady College of Medicine | Principal Investigator | | 04/01/2021 Import | 04/01/2021 Import | Signature Authority | | | Contact Details | Primary |
| X | John Co-Investigator | Nursing | Co-Investigator | | 01/01/2021 Import | 01/14/2020 Import | Edit Access | | Oath of Confidentiality.pdf X | Contact Details | Primary |

## Add On-The-Fly User

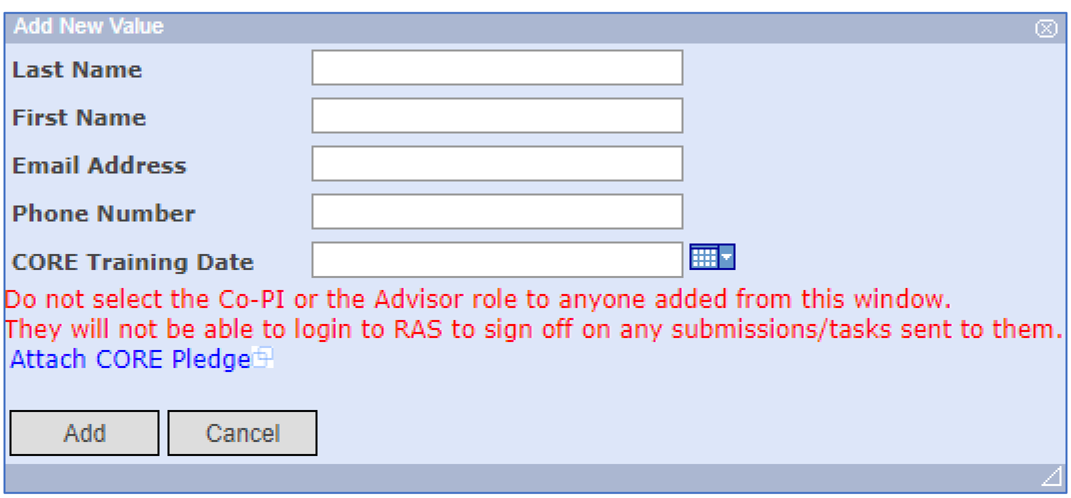
If you can't find someone in the Find Person lookup window when tying to add them to the research personnel table, you can add them on-the-fly.

**Important**: Most UM research personnel will be in the lookup. On-the-fly users are most likely external to the UM or students. Only <u>**one**</u> 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

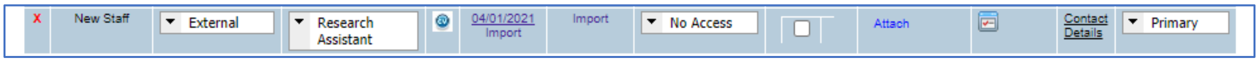



2. Complete the following (all fields are mandatory):
   a. Enter the **Last Name**
   b. Enter **First Name**
   c. Enter **Email Address**
   d. Enter **Phone Number**
   e. Select the **CORE Training Date**
   f. Click on **Attach CORE Pledge** to upload the users CORE certificate




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**



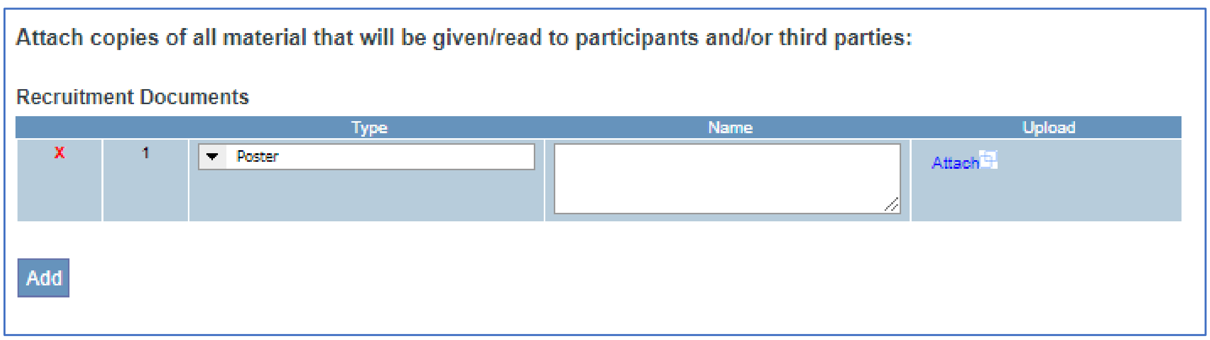

Once the application/submission has been submitted to the Ethics Office, a task will be sent to ORS to add this new user to the system.

## How to Add a Document

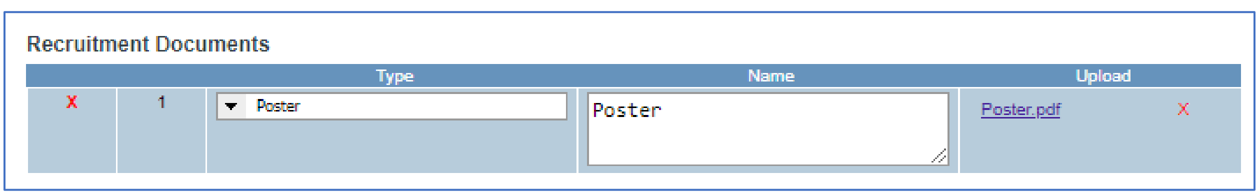
There are a few different areas within the initial application that allows you to upload documents.

Here is the Participants > Recruitment subtab

1. Click **Add**




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




## 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:

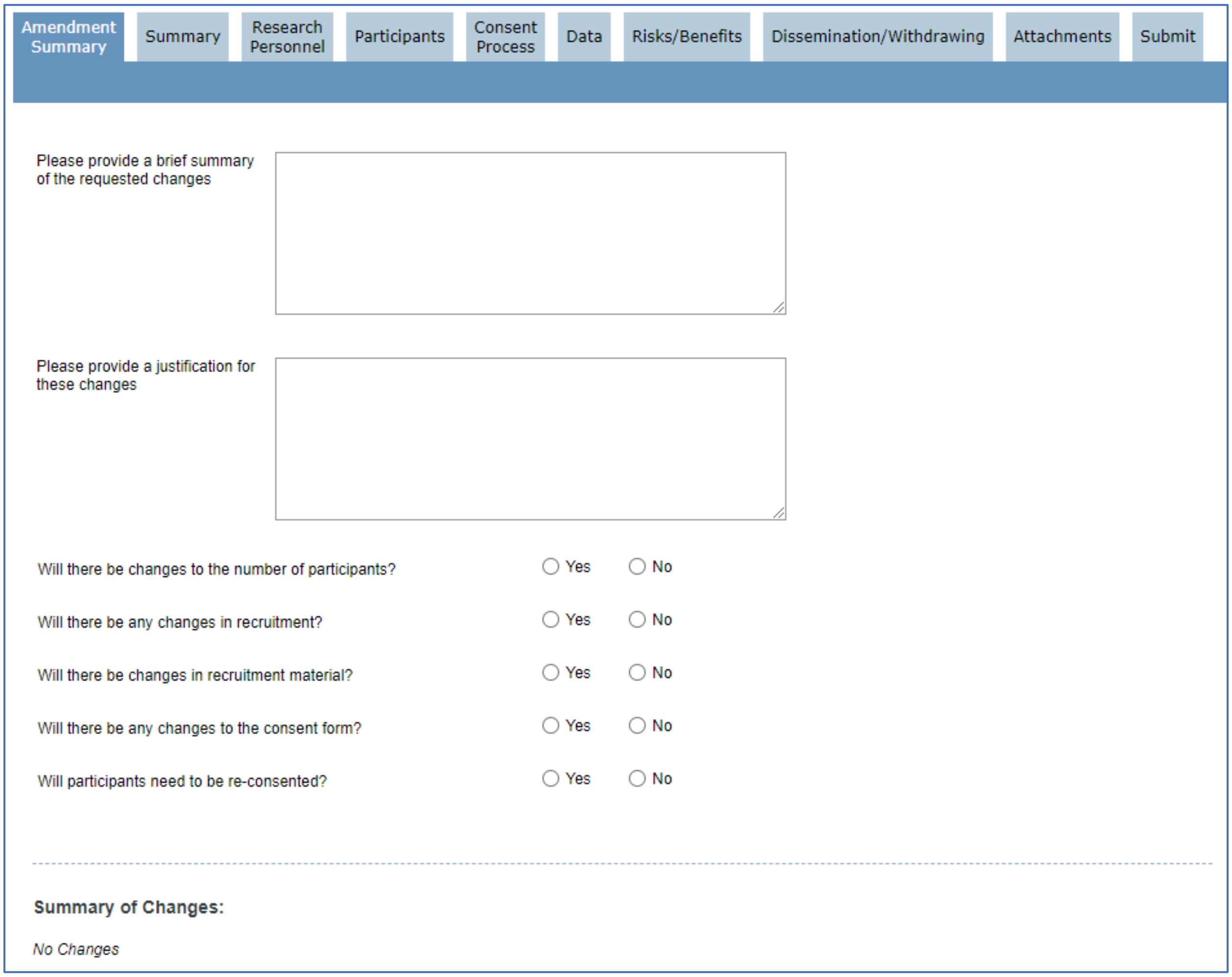
- Save Initial Application
- Submit Initial Application
- After Submission

# Follow-On Submissions

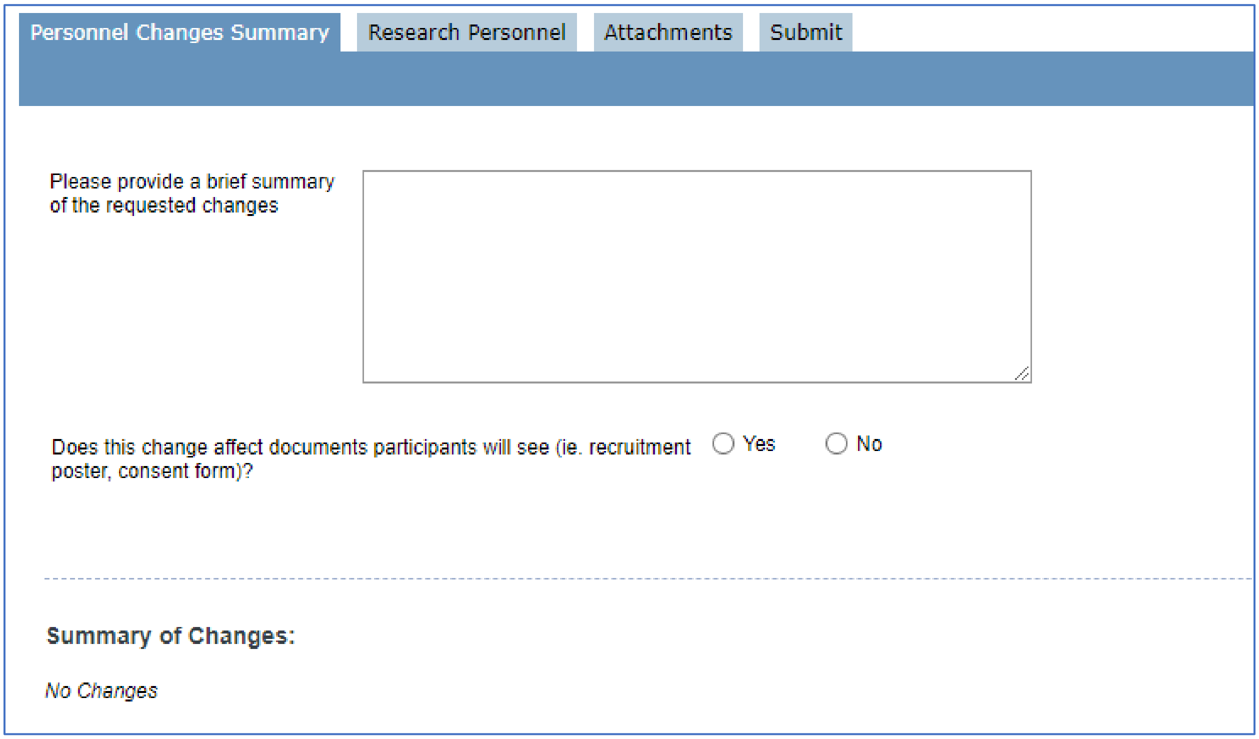
## Amendment/Personnel Change

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

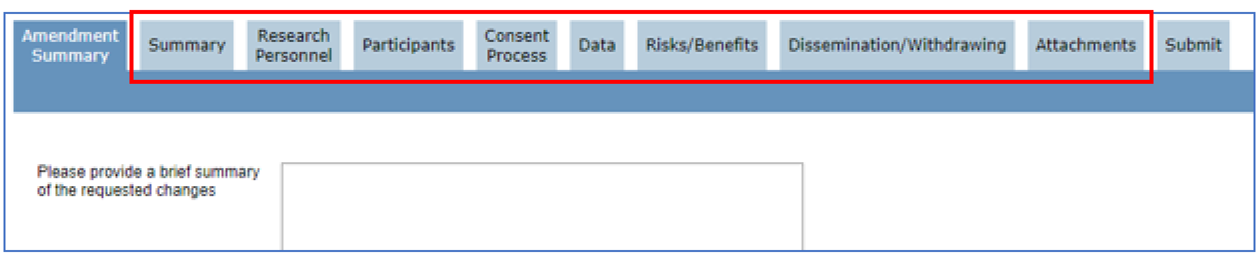
1. Select the protocol link from the **LiveList**
2. Under **Actions** select **Create Amendment** or **Create Personnel Change**, click **Go**
    a. **Amendment** – Complete all questions under Amendment Summary



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



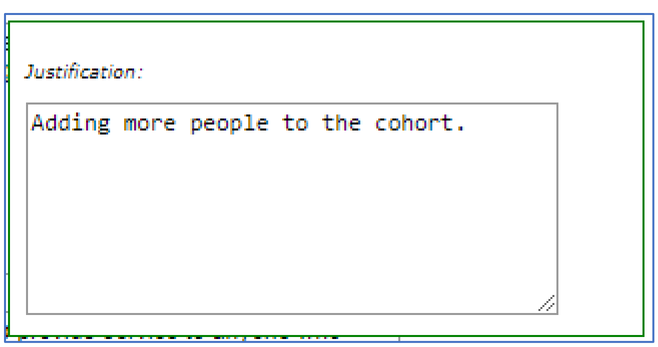

3. Navigate throughout the application and make your changes. As this is a living document, when you make a change to questions within the initial application section you will need to justify each change.




a. When you make a change to any question throughout the application it's tagged with

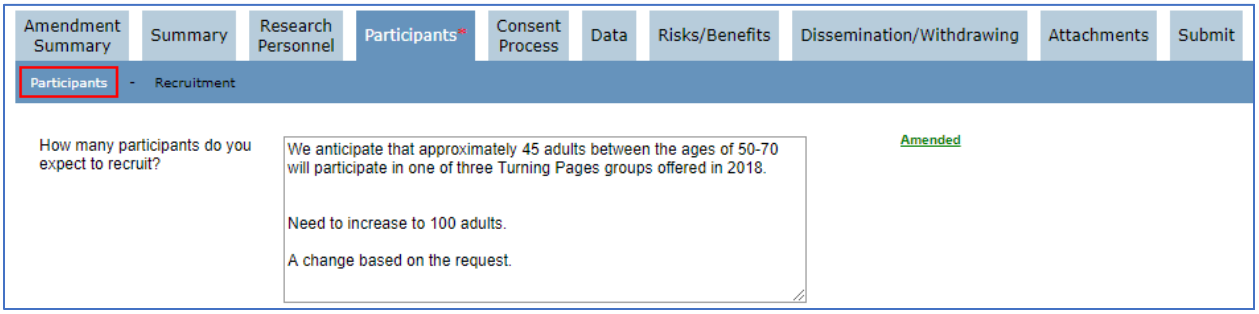
Amended (Please Justify)

b. Add your justification for the change to that specific question in the text box

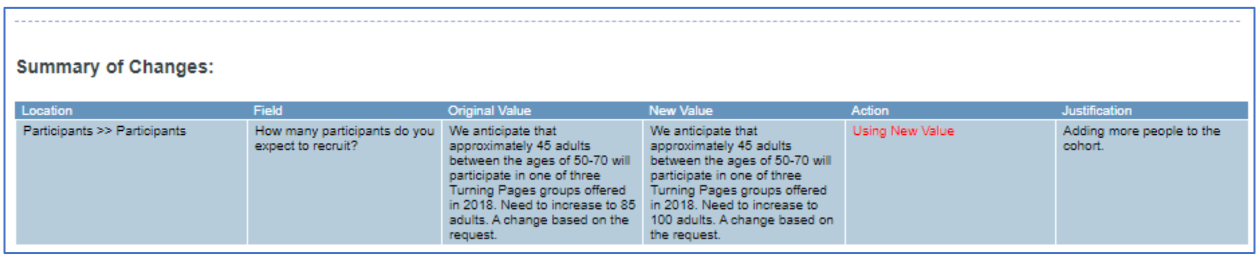


c. Once you have included the justification the question will now state Amended

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




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



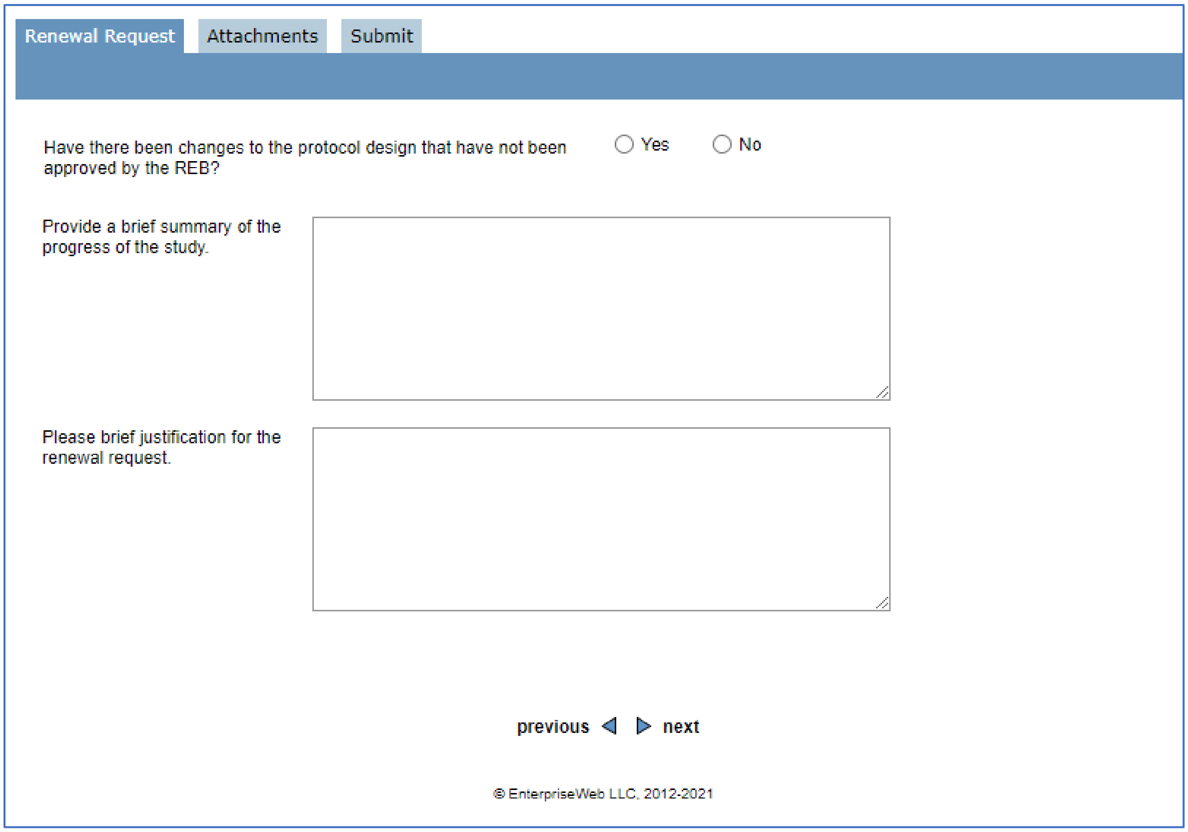
**Summary of Changes:**

| 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:

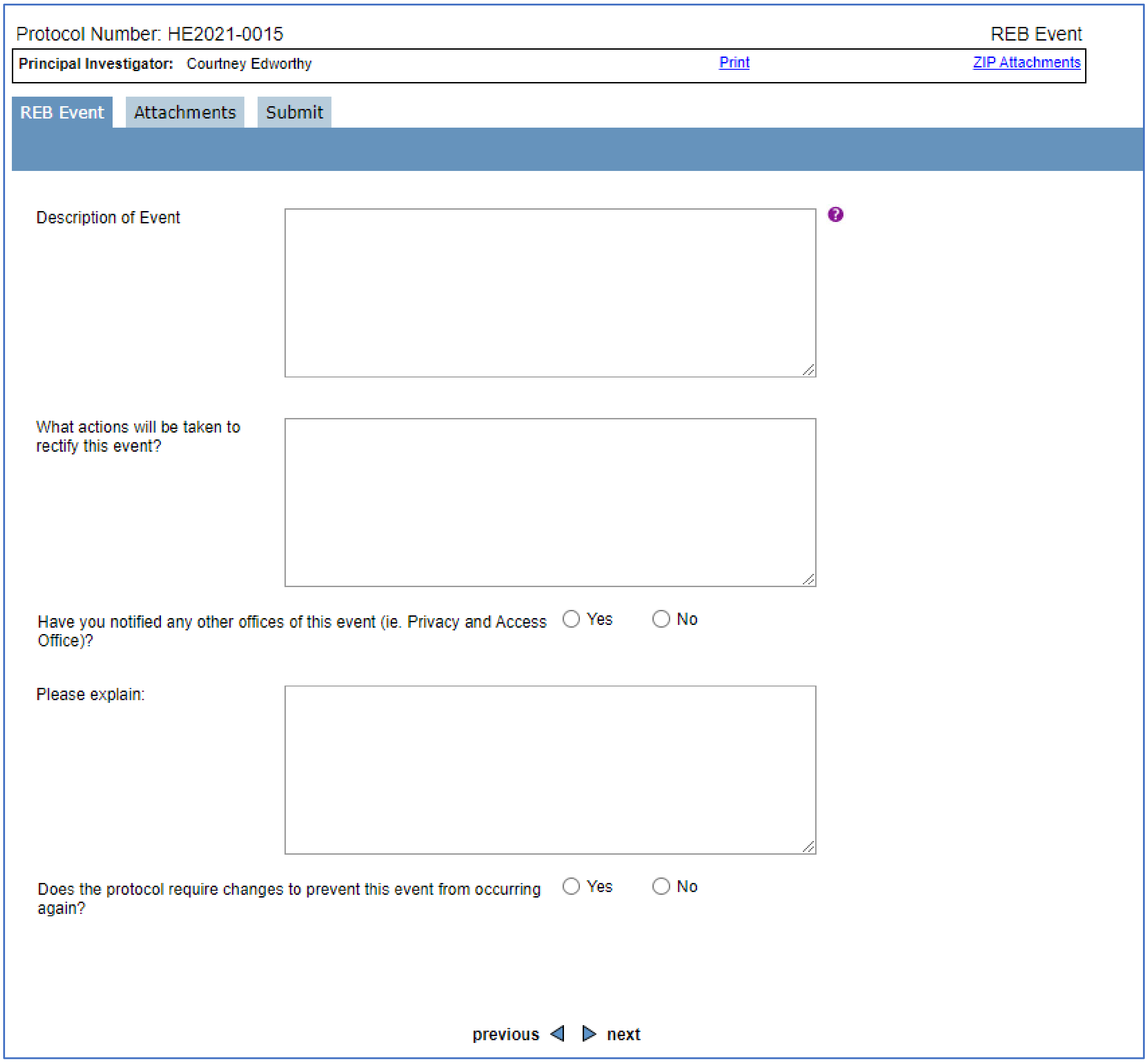
1. Select the protocol link from the **LiveList**
2. Under **Actions** select **Create Renewal Request**, click **Go**
3. Navigate through each tab and answer each question as they appear within the form



## REB Event

To create a new REB Event form as a Designate:

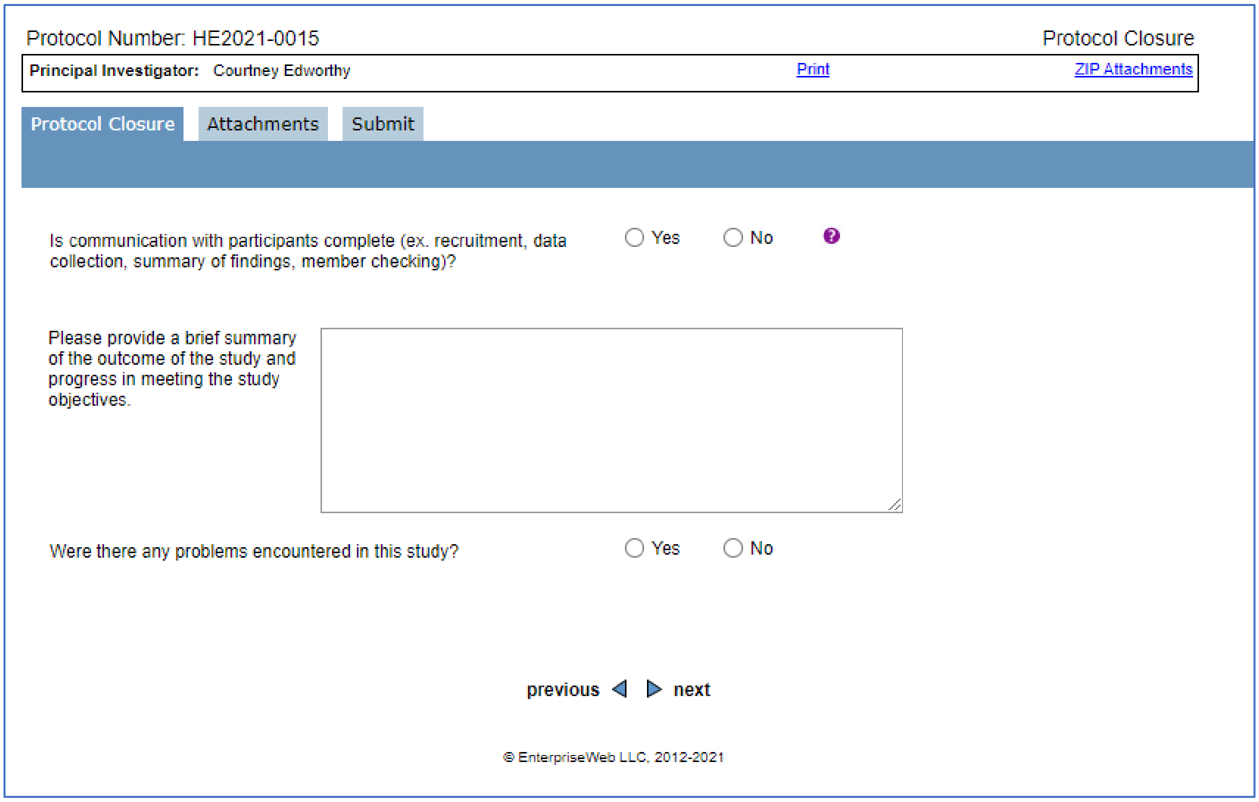
1. Select the protocol link from the **LiveList**
2. Under **Actions** select **Create REB Event**, click **Go**
3. Navigate through each tab and answer each question as they appear within the form



## Protocol 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



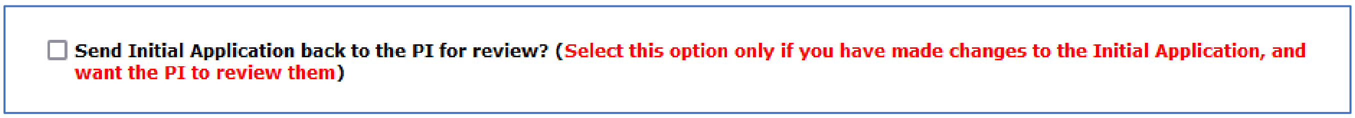
![University of Manitoba]

# 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.

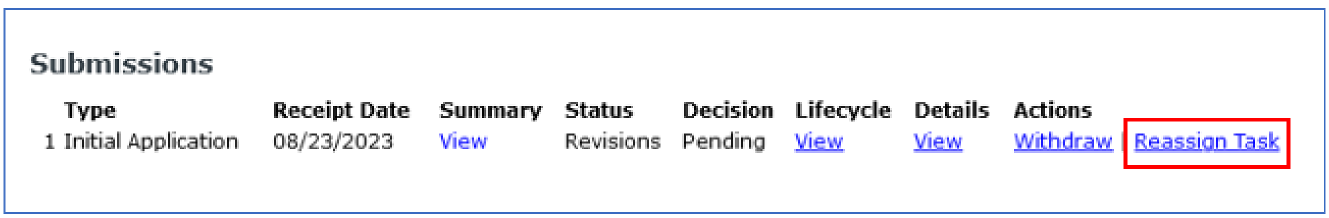
When a task is with a PI, they can submit it to the next research team member in the workflow (e.g., CoPI, Advisor or OHRE depending on who is listed in the protocol), or they can reassign it to a research team member with edit access or signature authority.

**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.

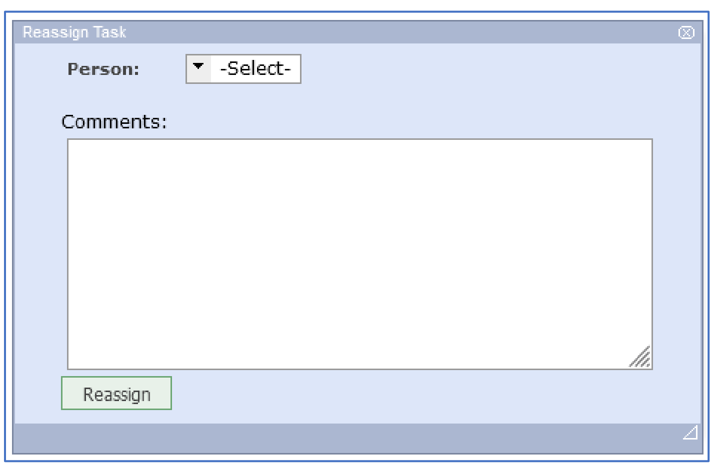



## How to Reassign

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



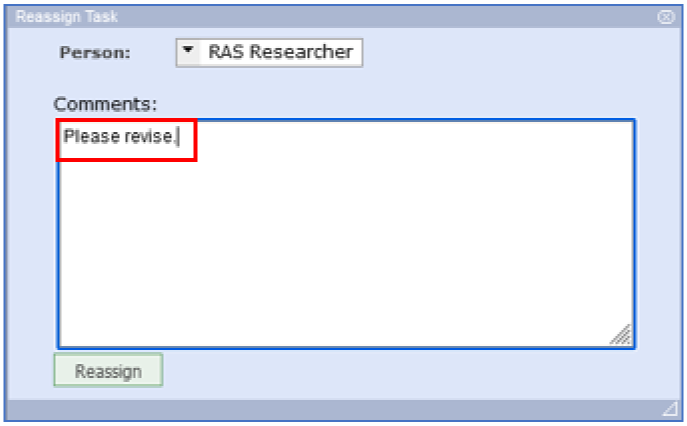

3. Select the **Person** to reassign the submission to
   **Remember**: Only research personnel with Edit Access or Signature Authority will appear here.

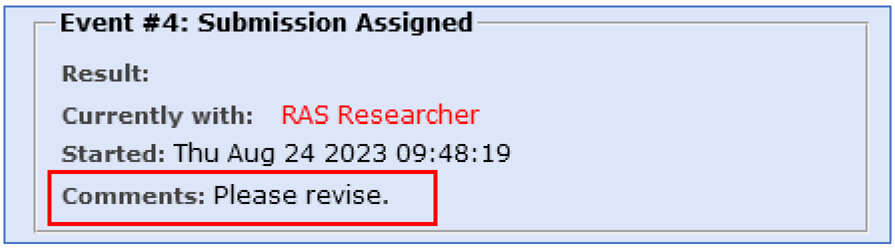



4. Add **Comments**, optional
   **Note**: Comments will appear in the Lifecycle View once reassigned.



Questions? Contact: RAS_Support@umanitoba.ca



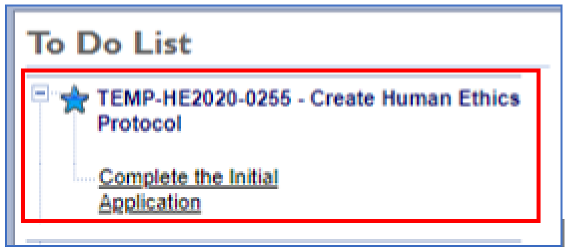

5. Click **Reassign**
6. Task is now reassigned
   **Note**: The task will be located in the reassigned users to do list, an email is not sent notifying the user of the task.

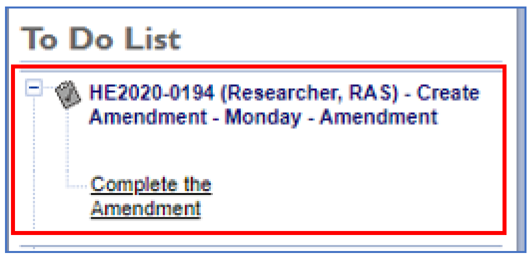
## Save Initial Application or Follow-On Submission

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

1. Click Save at the 

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




### Continue Saved Initial Application or Follow-On Submission

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

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

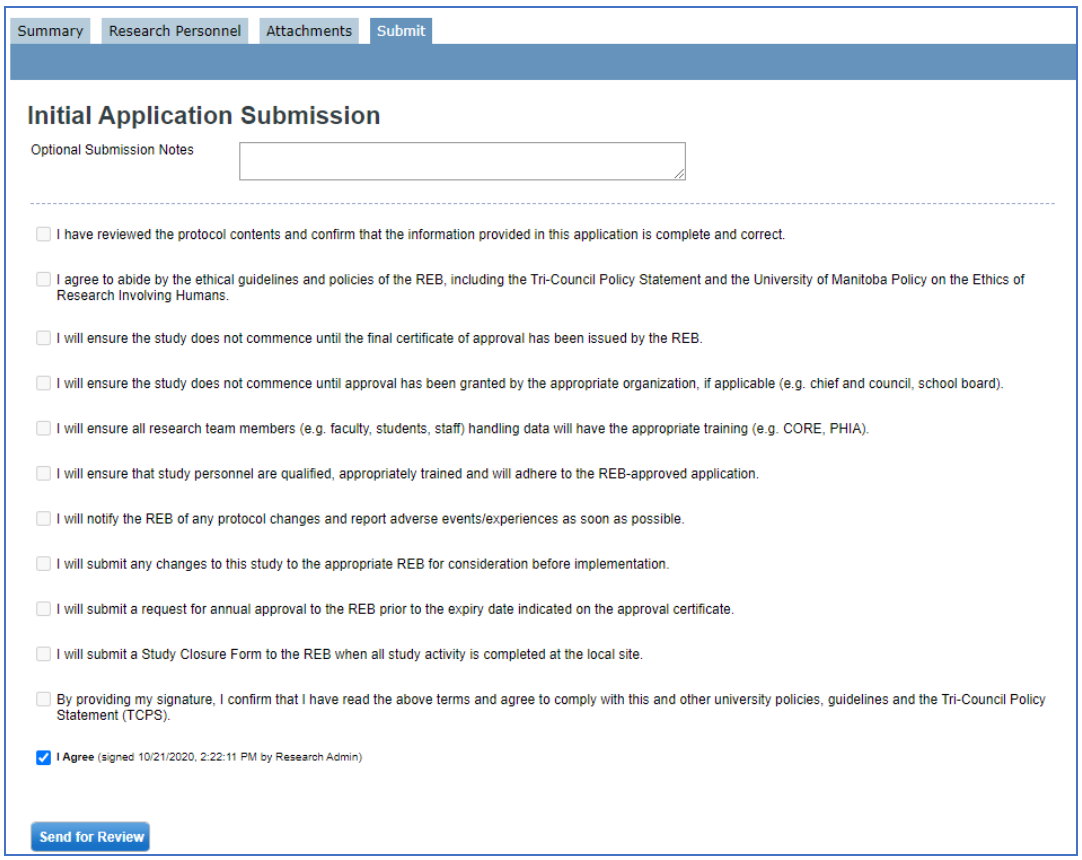
# Submit an Initial Application or Follow-On Submission

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

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

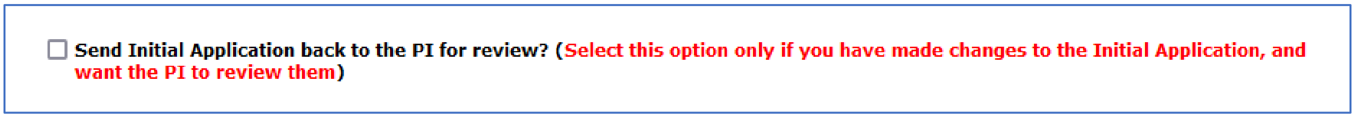
To Submit an Initial Application or Follow-On Submission:

1. Complete each question contained within each of the tabs and sub tabs of the form
2. When all questions have been addressed navigate to the **Submit** tab
3. Enter any desired **Submission Notes** in the field provided
4. When a Designate is submitting the application, the **Declaration Statements** will be greyed out, these must be completed by the PI




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.



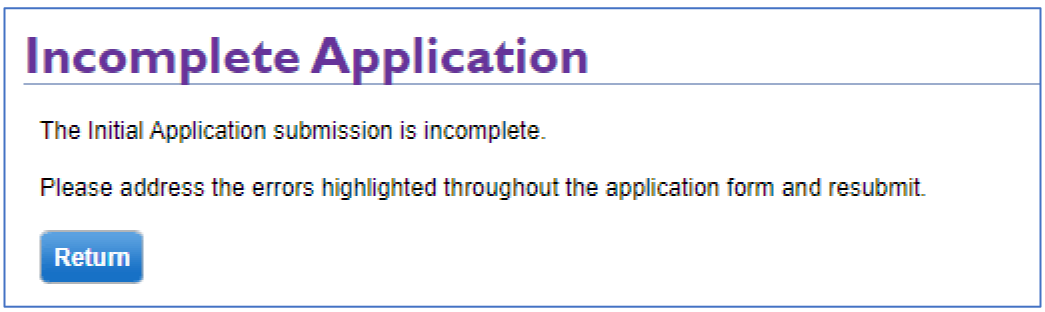

iii. Read and check each of the **Declaration Statements**
iv. Check off **I Agree**

2. Click **Send for Review**

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

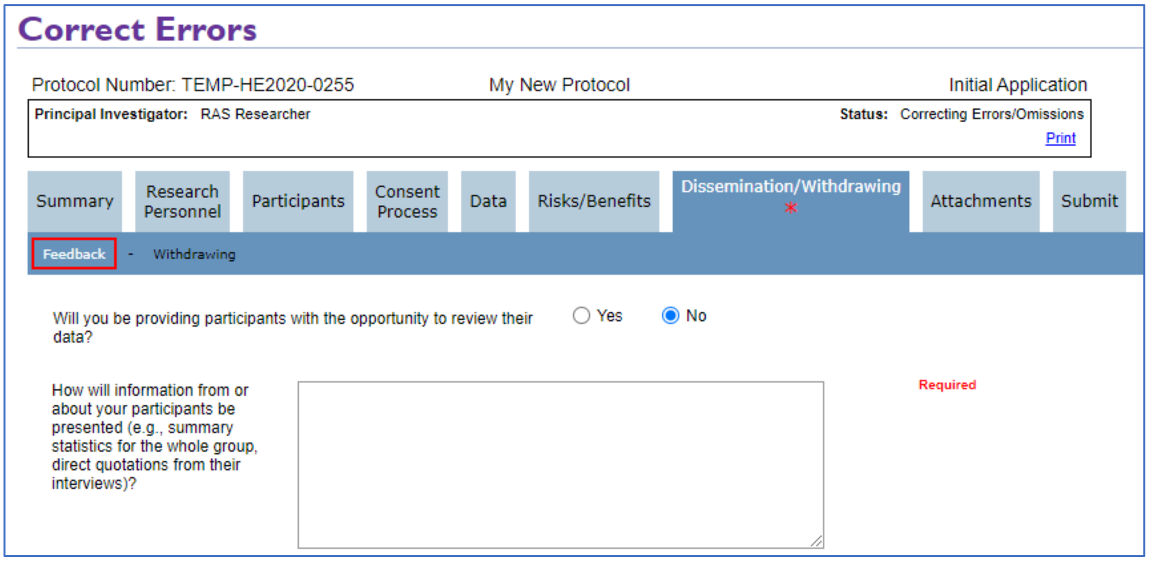
## Errors on the Initial Application or Follow-On Submission

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




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.




Once you complete all errors indicated, click the **Submit** tab and resubmit the initial application or follow-on submission.

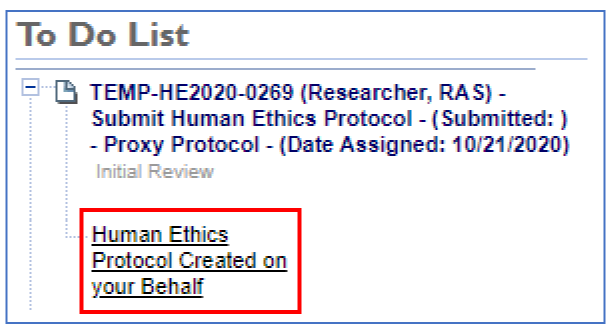
After the submission has gone through, you can view the protocol in the LiveList.

## PI Sign-Off

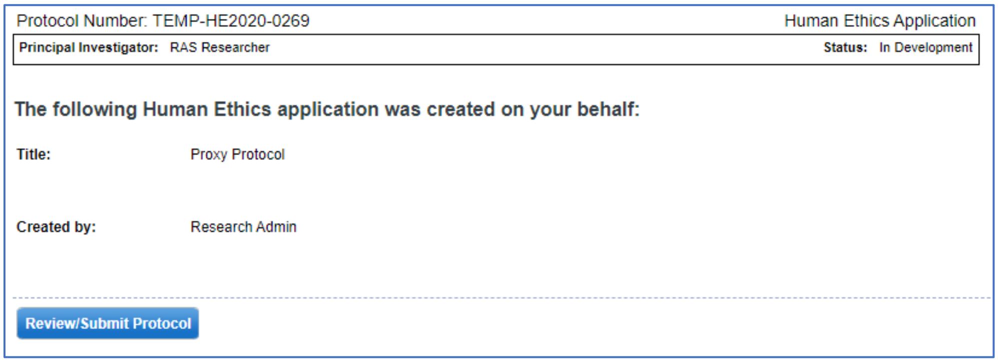
The PI will receive an email notification along with a **To Do List** task to sign off on the submission.

To review the initial application or follow-on submission:

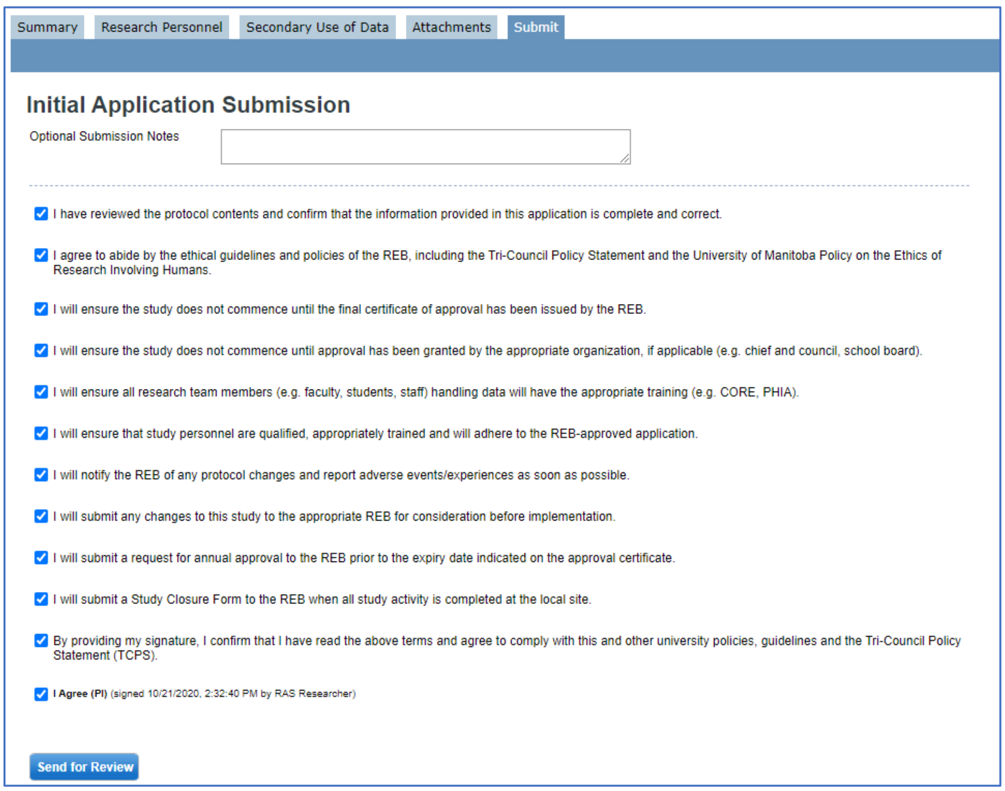
1. Click the link in the To Do List




2. Click **Review/Submit Protocol**




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**



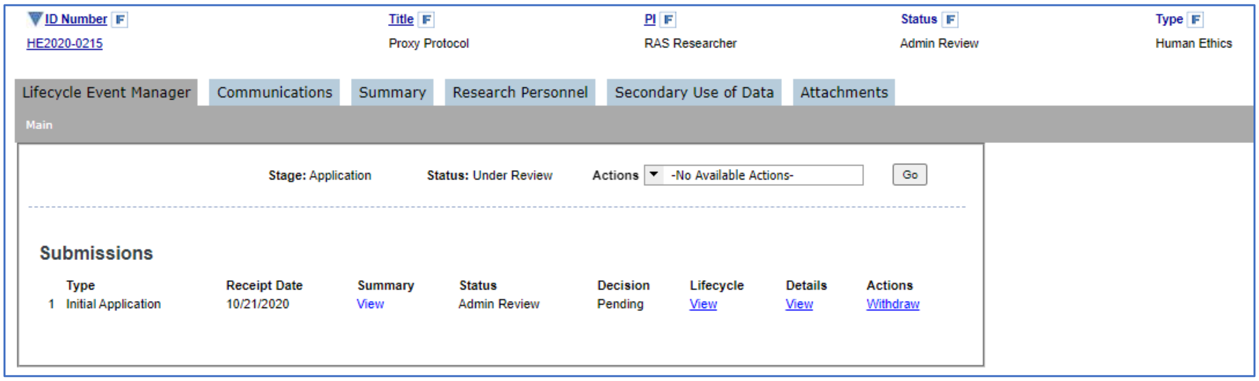

7. Check the **I Agree** checkbox to agree to the certification statement
8. Click **Send for Review**

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

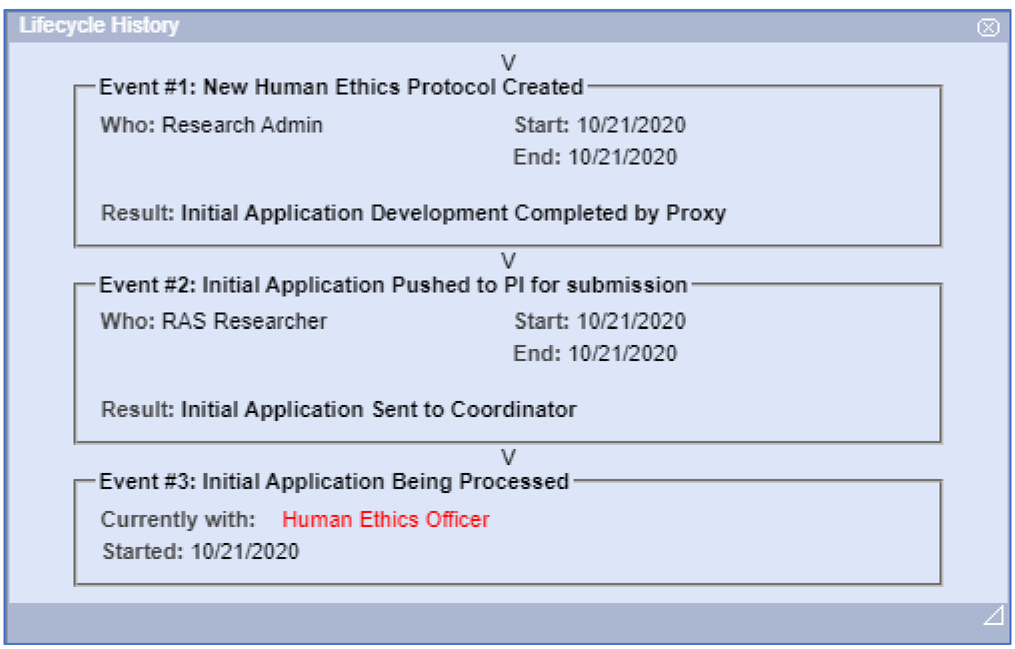
# After Submission

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

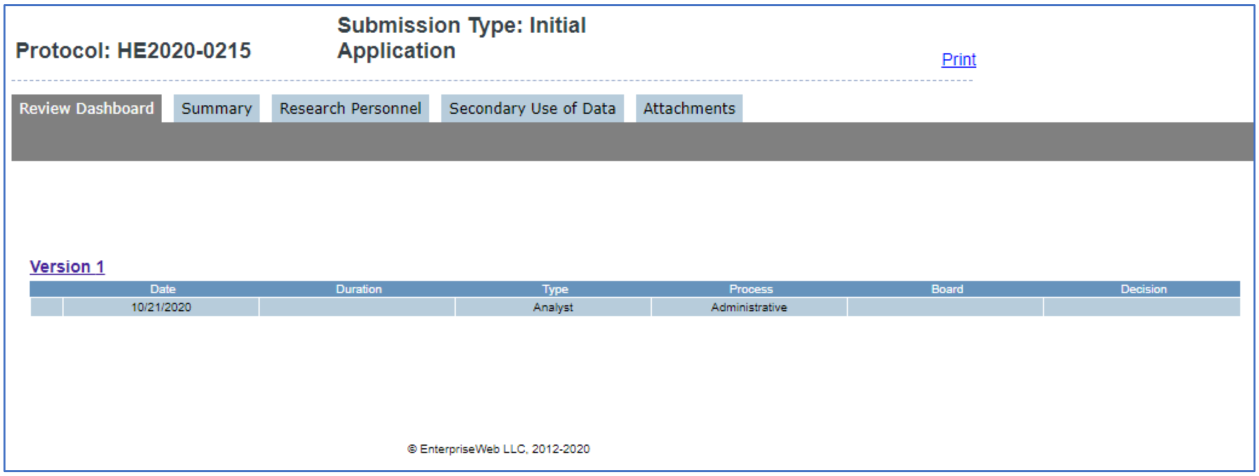
1. Navigate to the **LiveList**
2. Select the protocol from the list by clicking on the protocol number link under the Protocol/Project Number column




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

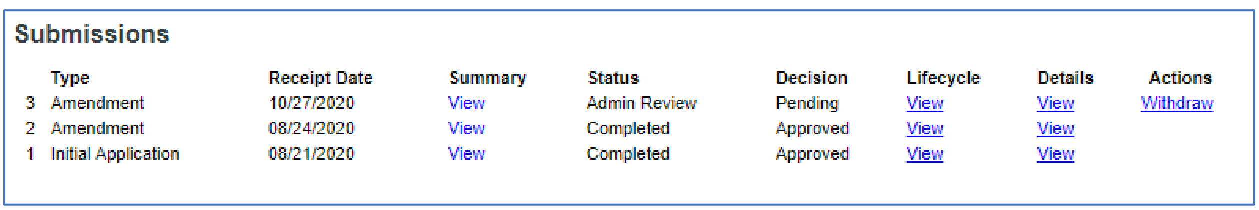



5. To return to the **LiveList**
    a. Click the **Home** button under the Menu Bar or;
    b. Click on the Protocol Number link above the **Lifecycle Event Manager** tab

## 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.

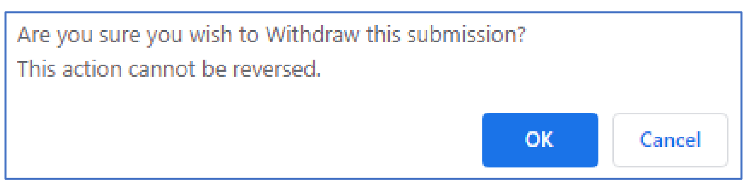
1. In the **LiveList**, select the protocol link under Protocol/Project Number to view the Lifecycle Event Manager
2. Under Submissions > Actions click **Withdraw**



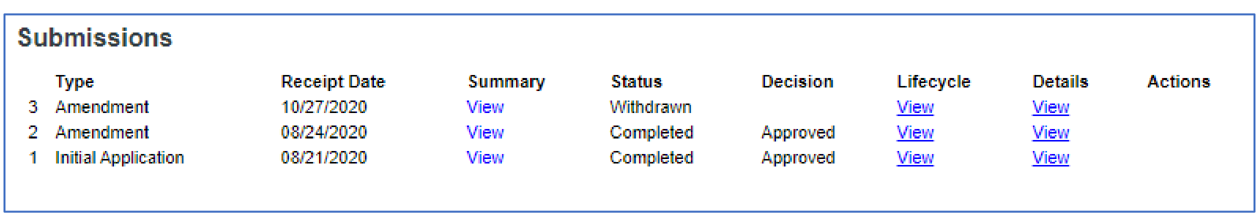
**Submissions**

| | 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




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 | |

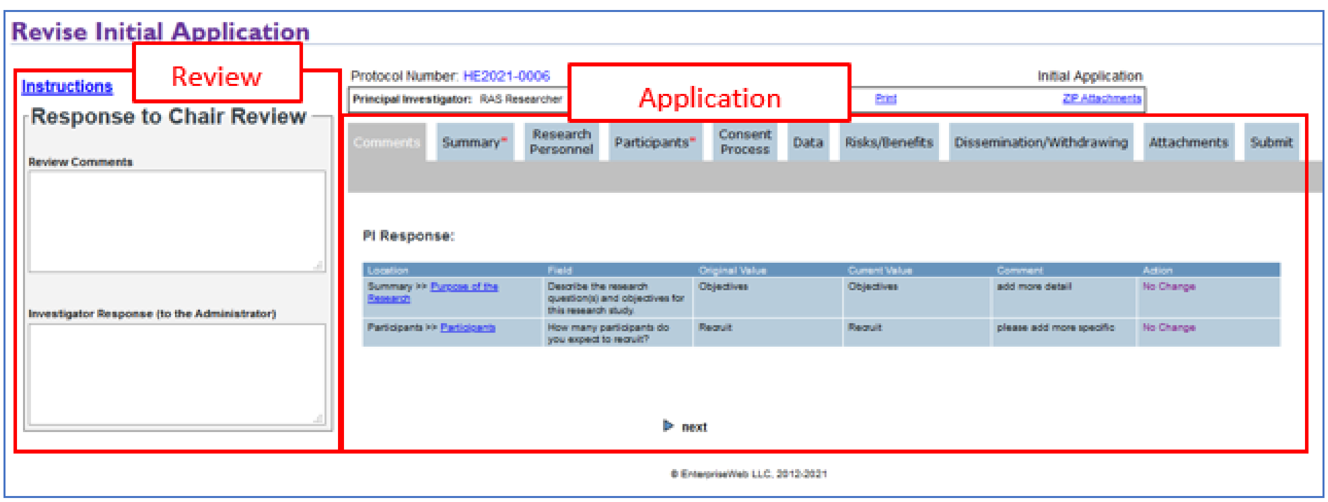
# Revisions Required

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

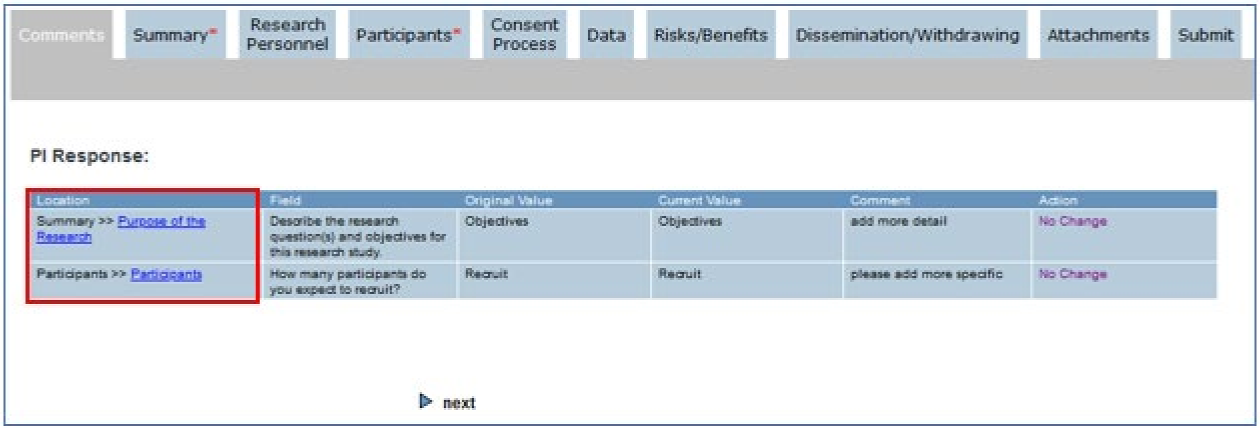
The designate (or Study Coordinator) will also receive an email notification if they were cc'd under the Research Personnel section of the protocol. If the designate is to complete the revision task they can reassign the task to themselves. See **Delete or Reassign Task** section of the Lifecycle Event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

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


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.

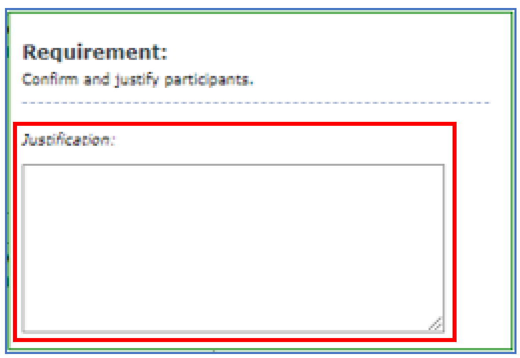



4. The **Comments** tab provides a summary of all comments made
5. Click on the link under **Location** to bring you to each comment to review

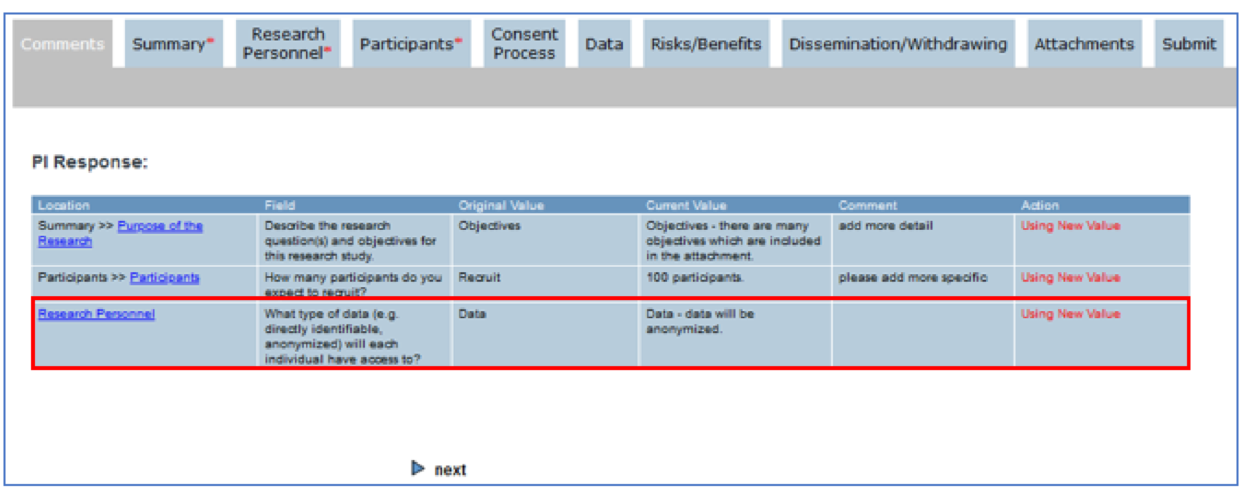



**Note**: Any comments made will also be indicated with a red * on the tab within the Application section.

6. Make the appropriate changes to each question based on comments provided
   **Important**: For information on how to upload a marked-up version of a document, please see [Attachment: Marked-Up Versions]()
7. If Justification is required, add your justification to the popup box that appears beside the question
   **Note**: Justification is mandatory, you must fill in a response.




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




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

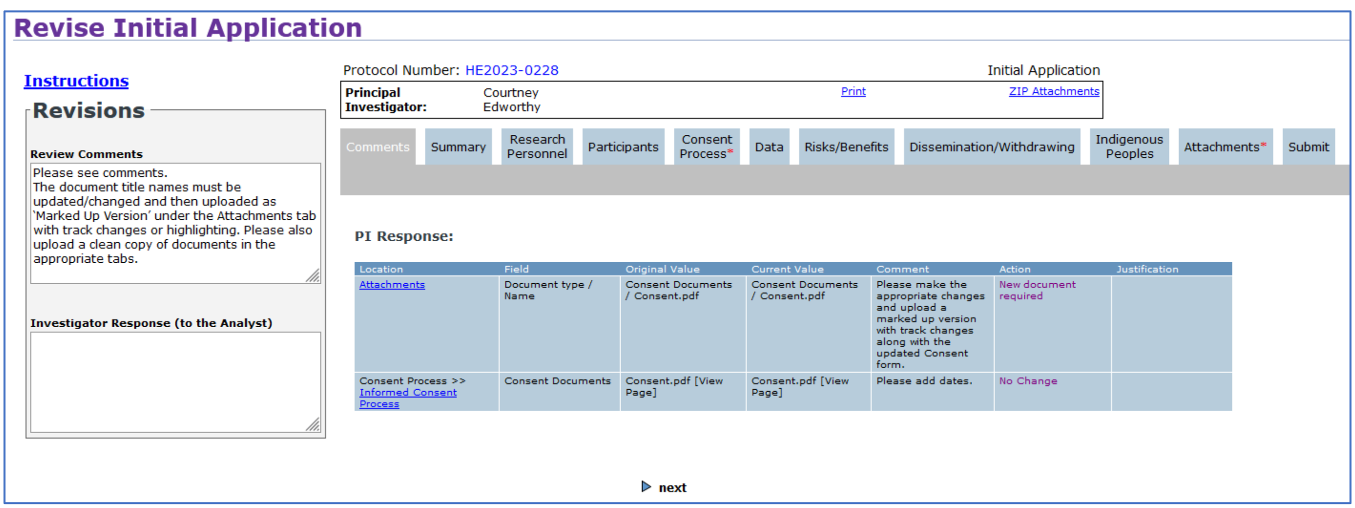
The revision has now been sent to the PI for review and signature.

## 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 sightly 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

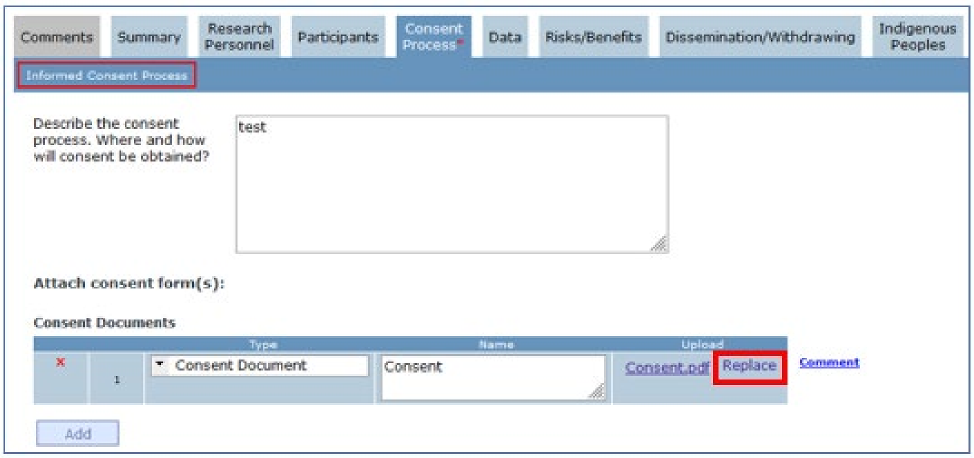
## Upload Clean & Marked-Up Version

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*

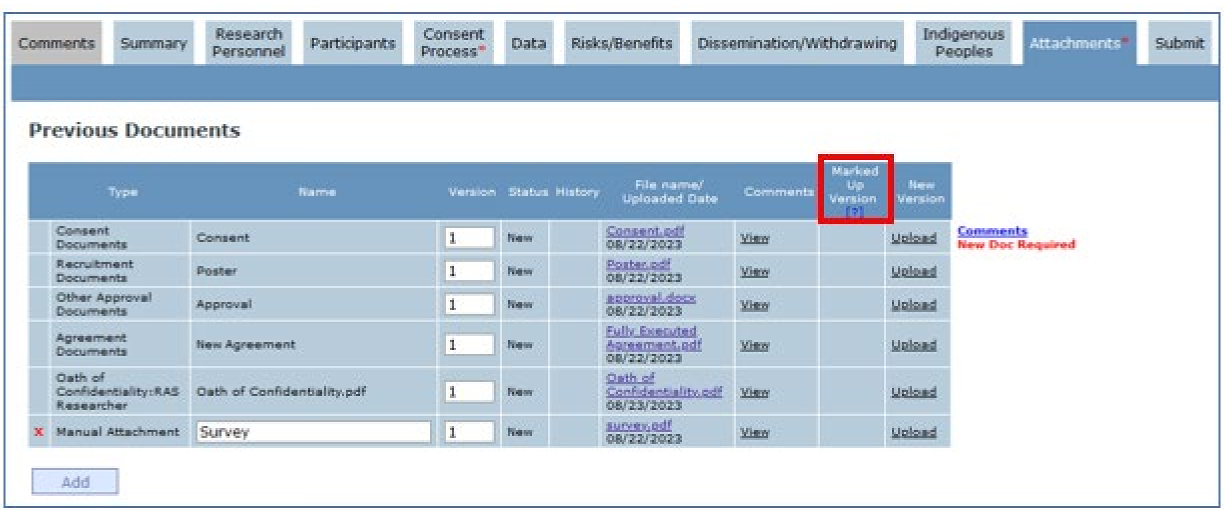
1. Navigate to the designated tab, in this example the **Consent Process** tab
2. Click **Replace**, find and **Upload** the <u>clean version</u> of the document




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 <u>clean version</u> of the document
3. Once the new document has been uploaded you can now upload the [marked-up version]()



## *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 |

3. **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 |