How to Submit a Protocol as a PI

RAS Training Documentation

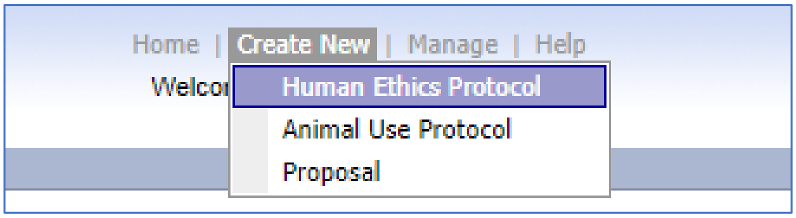
Last Modified: August 25, 2023

Contents

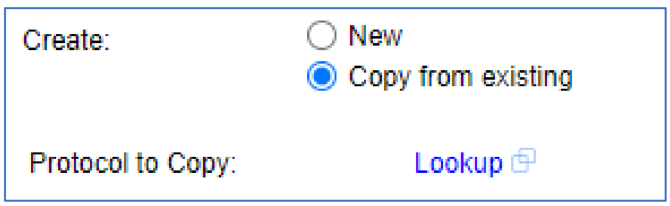
Initial Application

To create a new Human Ethics Protocol as a PI:

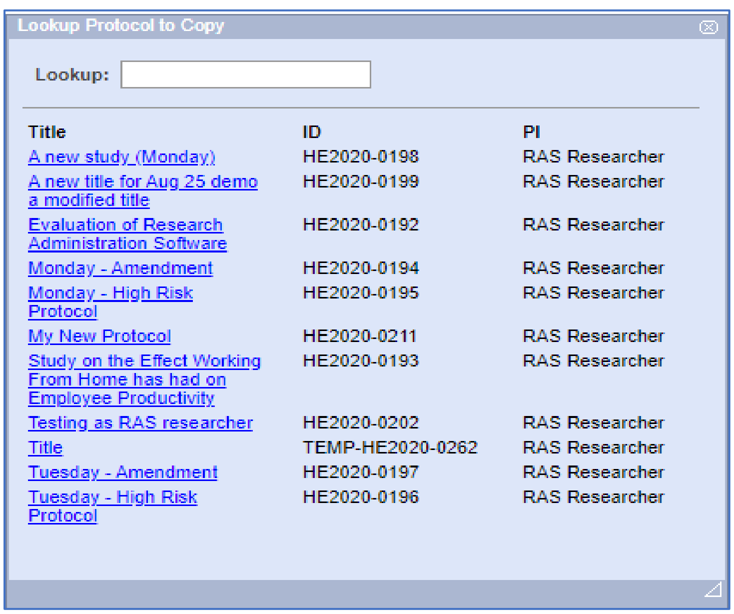
1. Under the **Create New** menu item select **Human Ethics Protocol**
   Note: The newly created protocol will receive a temporary protocol number while the application is in development. Once the application is submitted, a final Human Ethics Protocol number will be assigned.



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



      ii. Search and select the protocol you wish to copy
      Note: You will only be able to copy protocols you have access to.

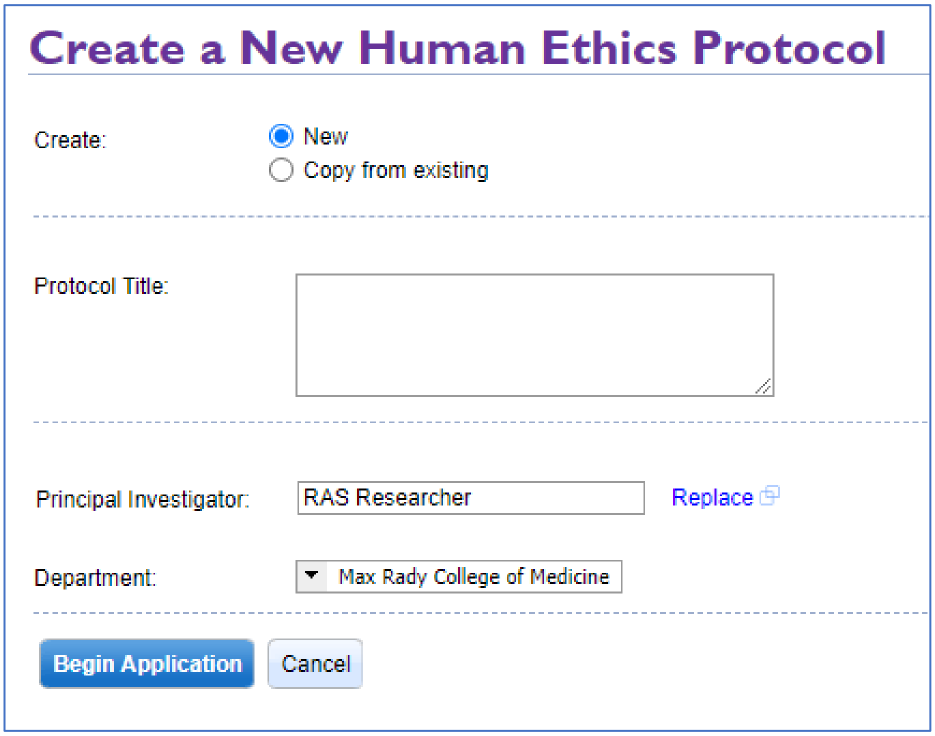


   b. **Protocol Title** – Enter the title of the protocol

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

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

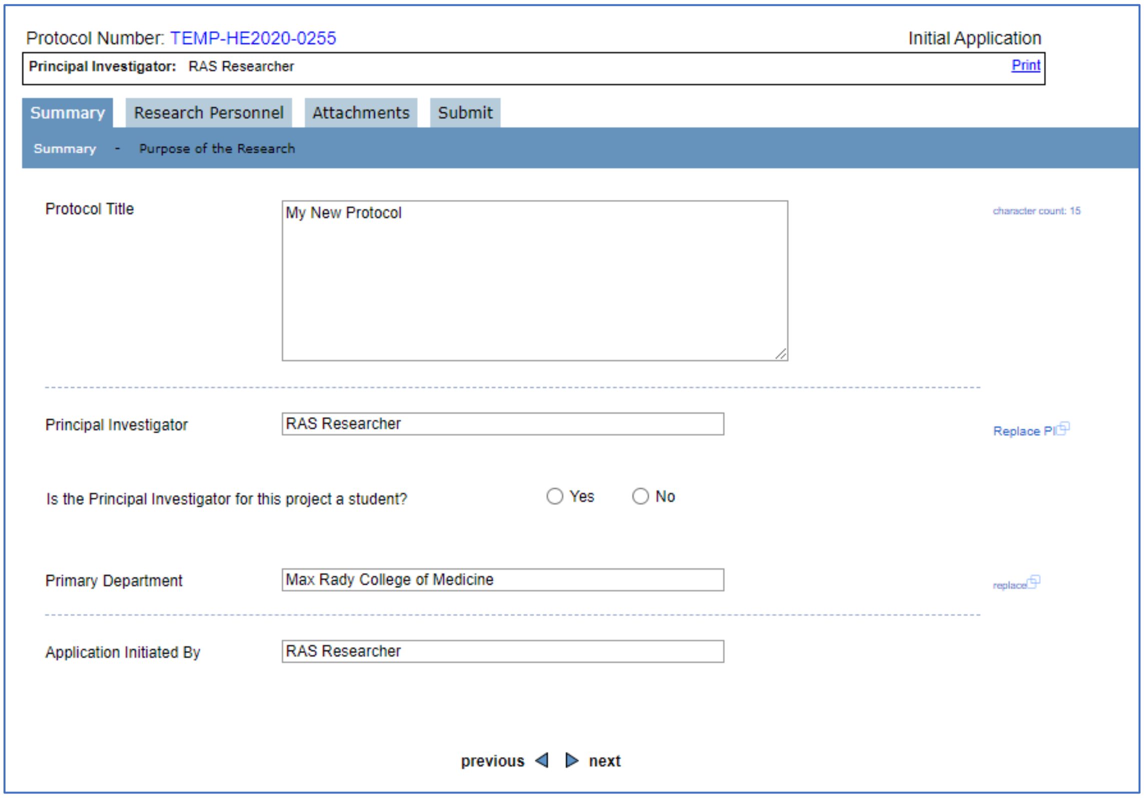
3. Click **Begin Application**



Complete Initial Application

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

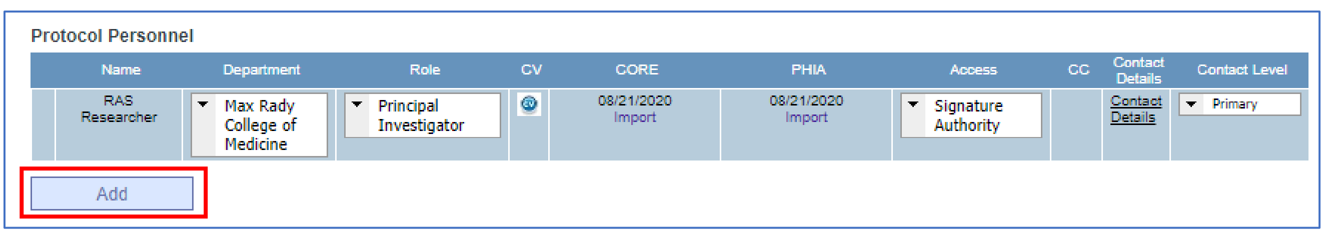
Navigate through each tab and answer each question as they appear within the form.



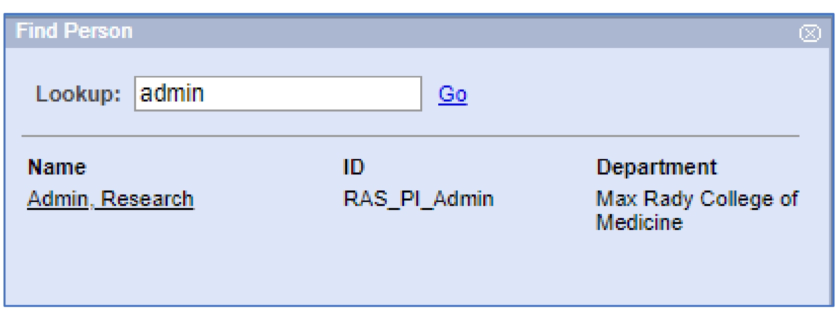
Adding Research Personnel

Add additional research personnel to the protocol.

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



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 user's 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.
        Note: A user with Edit Access can be reassigned a submission task to complete, see Reassign a Task section.
        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

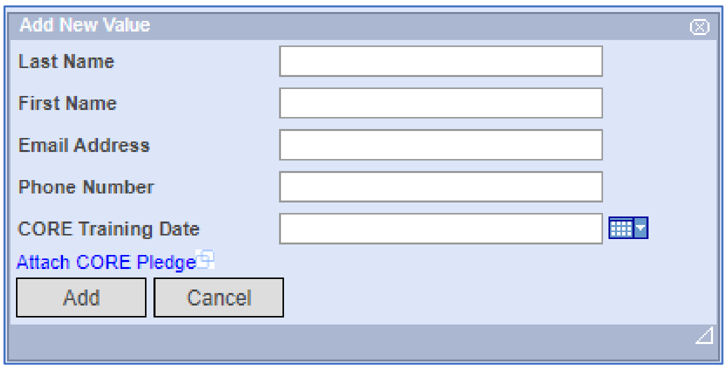
Add On-The-Fly User

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

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

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



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**

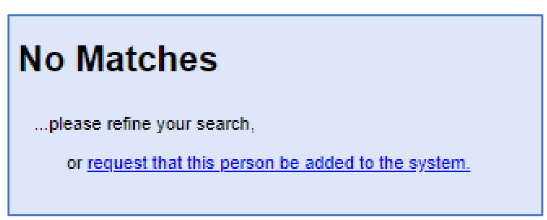
Once the application/submission has been submitted to the Ethics Office, a task will be sent to ORS to add this new user to the system.

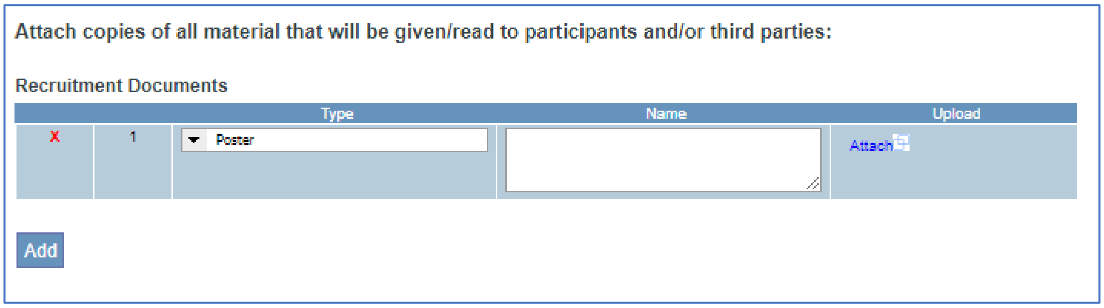
How to Add a Document

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

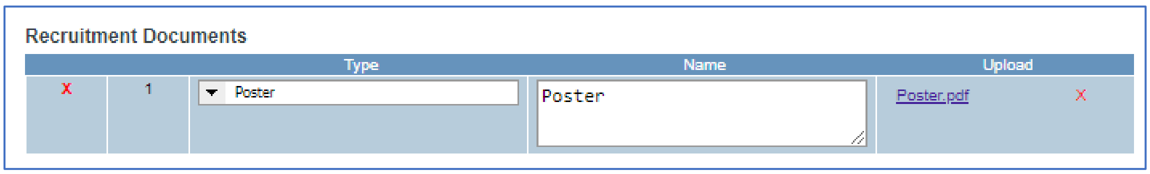
Here is the Participants > Recruitment subtab

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

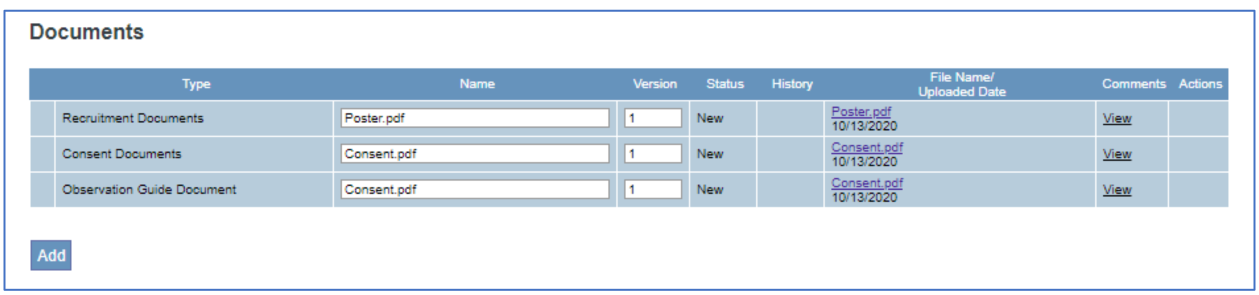


View All Documents

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

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

Here you can view and/or add additional documents.



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

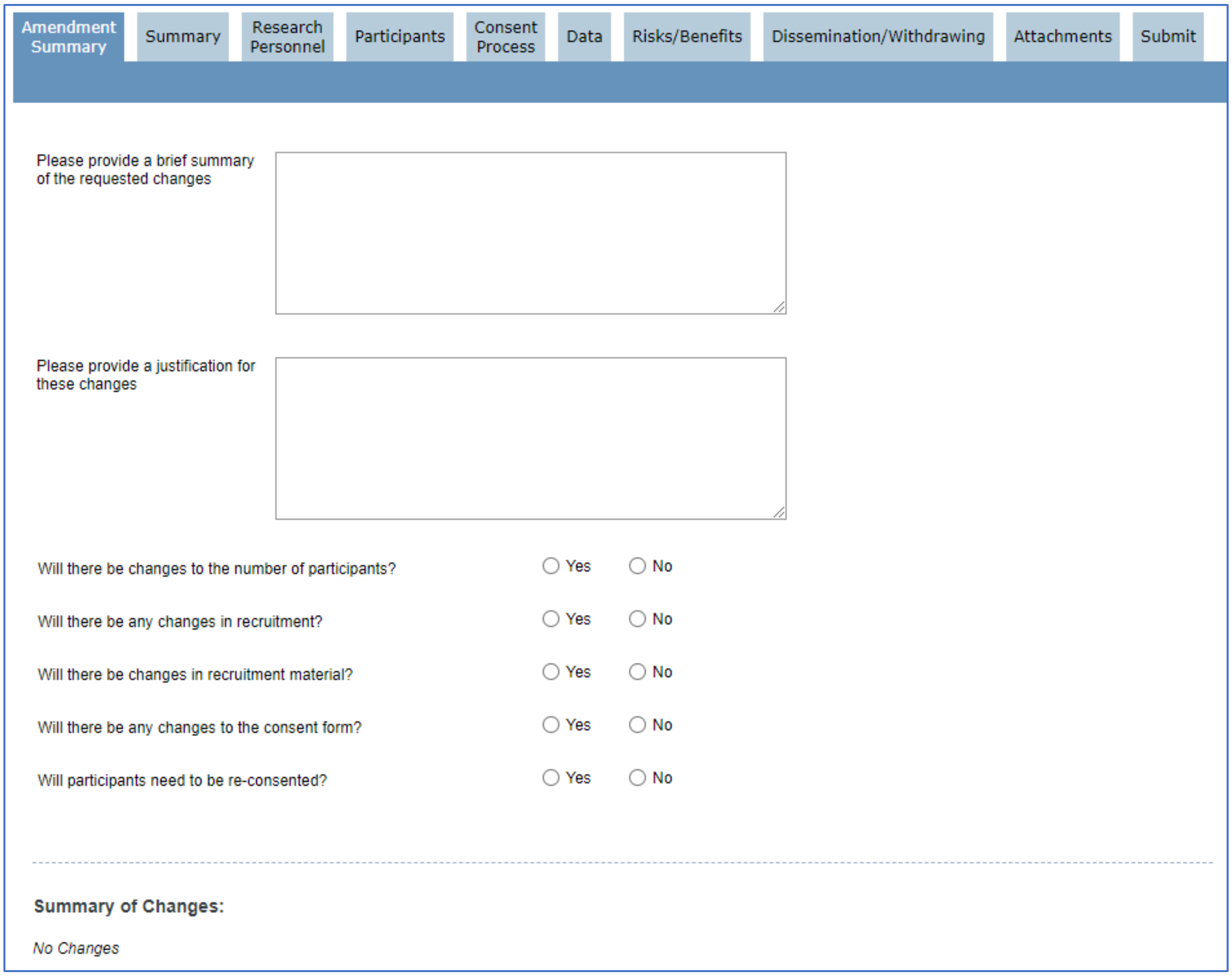
- Save Initial Application
- Submit Initial Application
- After Submission

Follow-On Submissions

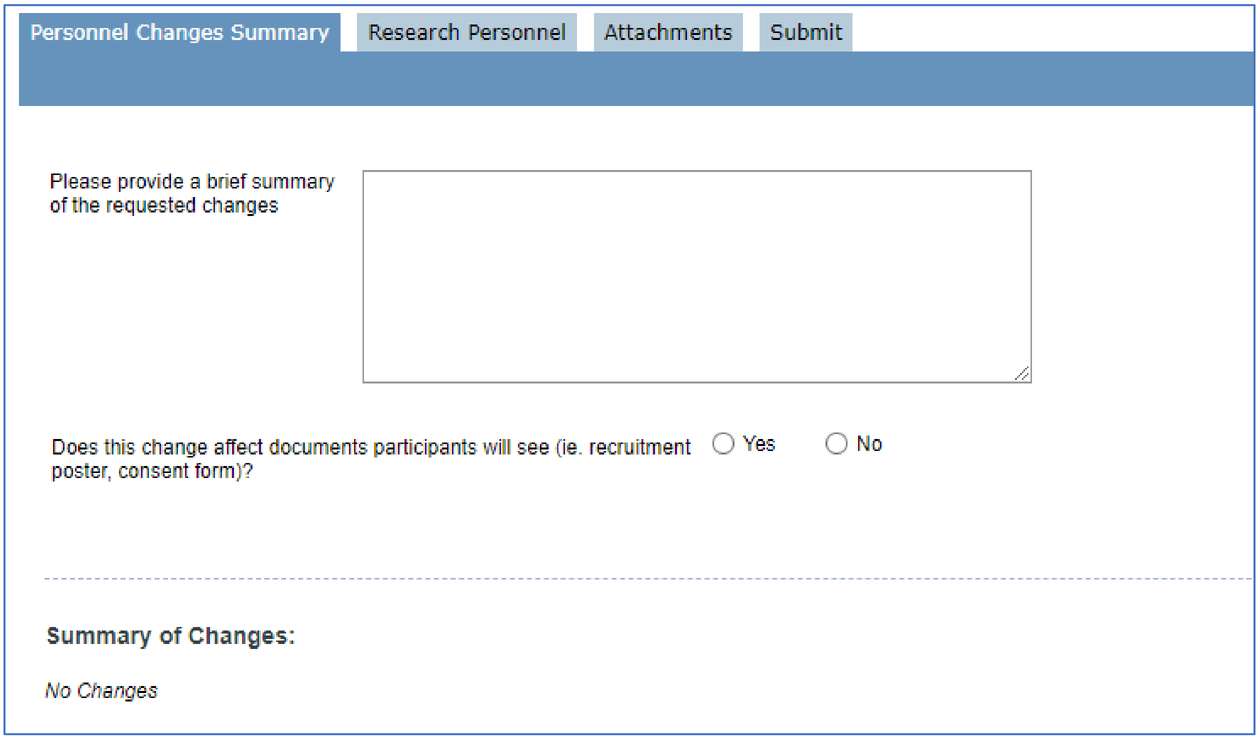
Amendment/Personnel Change

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

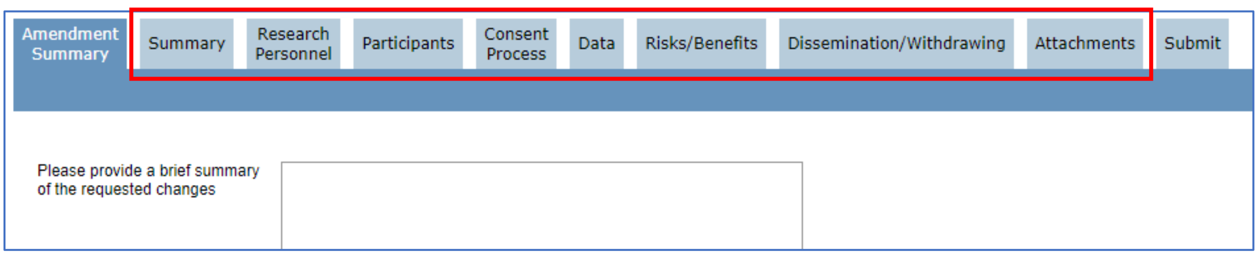
1. Select the protocol link from the **LiveList**
2. Under **Actions** select **Create Amendment** or **Create Personnel Change**, click **Go**
    a. **Amendment** – Complete all questions under Amendment Summary



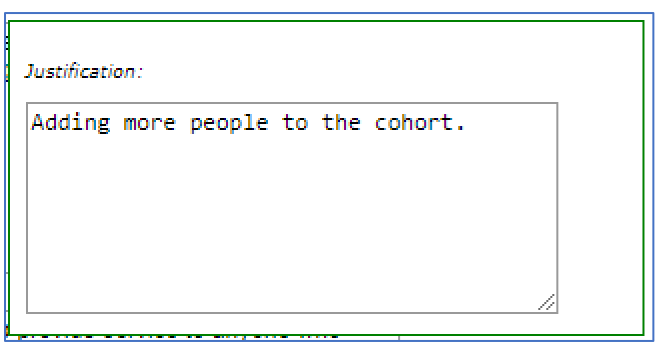
    b. **Personnel Change** – Complete all questions under Personnel Summary



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.

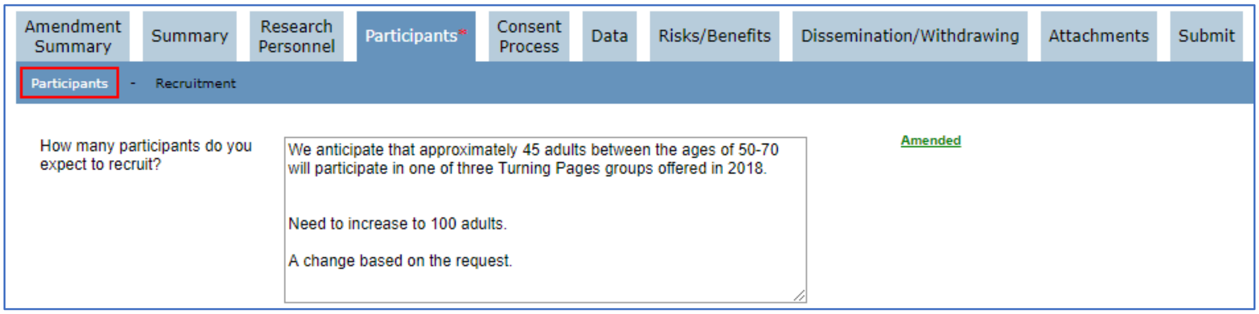


   a. When you make a change to any question throughout the application it's tagged with **Amended (Please Justify)**
   b. Add your justification for the change to that specific question in the text box

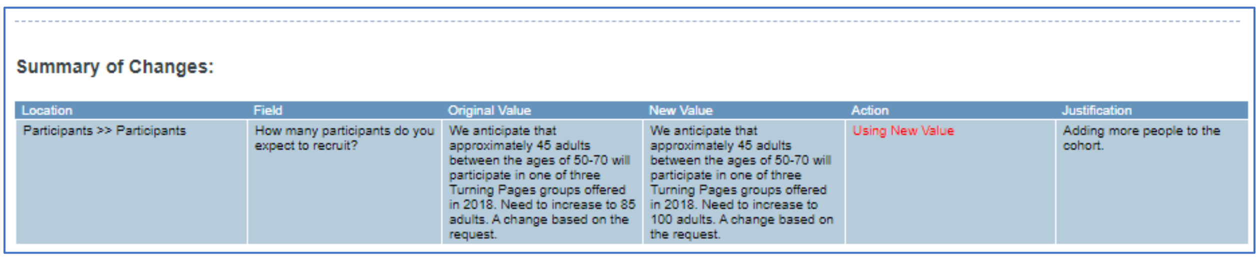


   c. Once you have included the justification the question will now state **Amended**

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



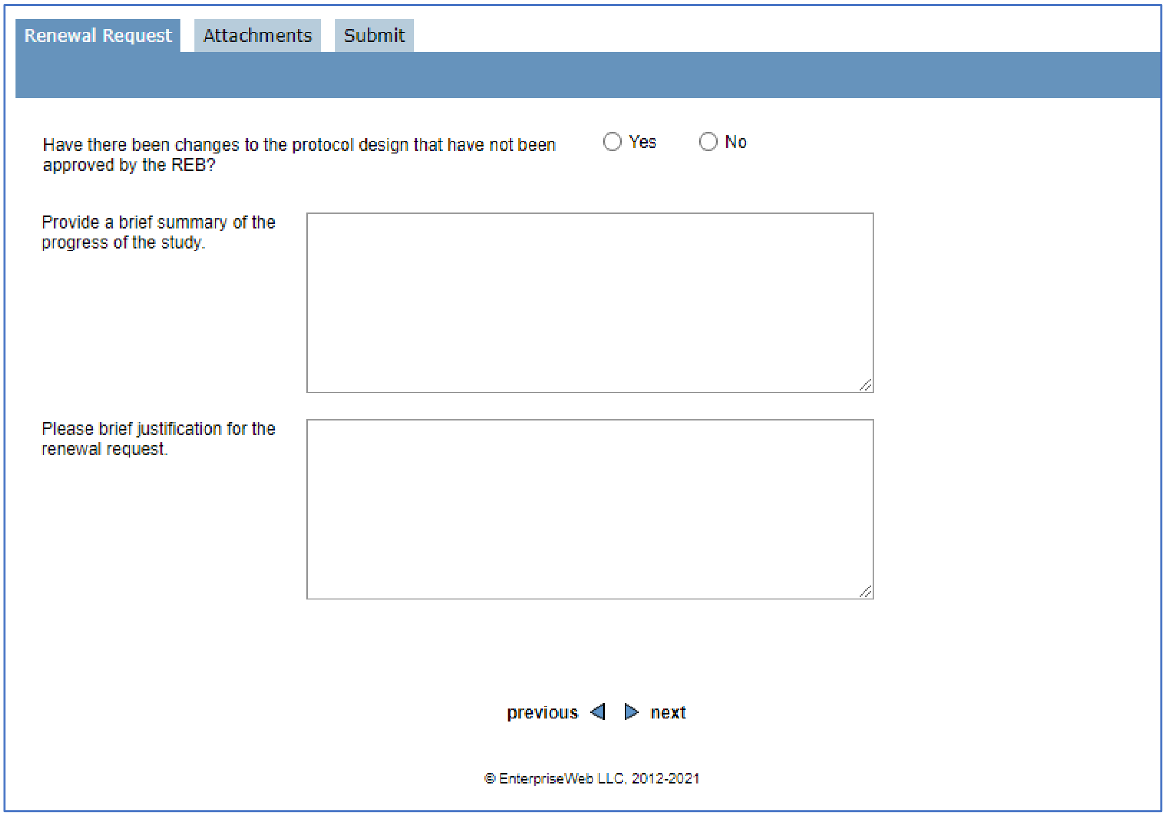
Summary of Changes:

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 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



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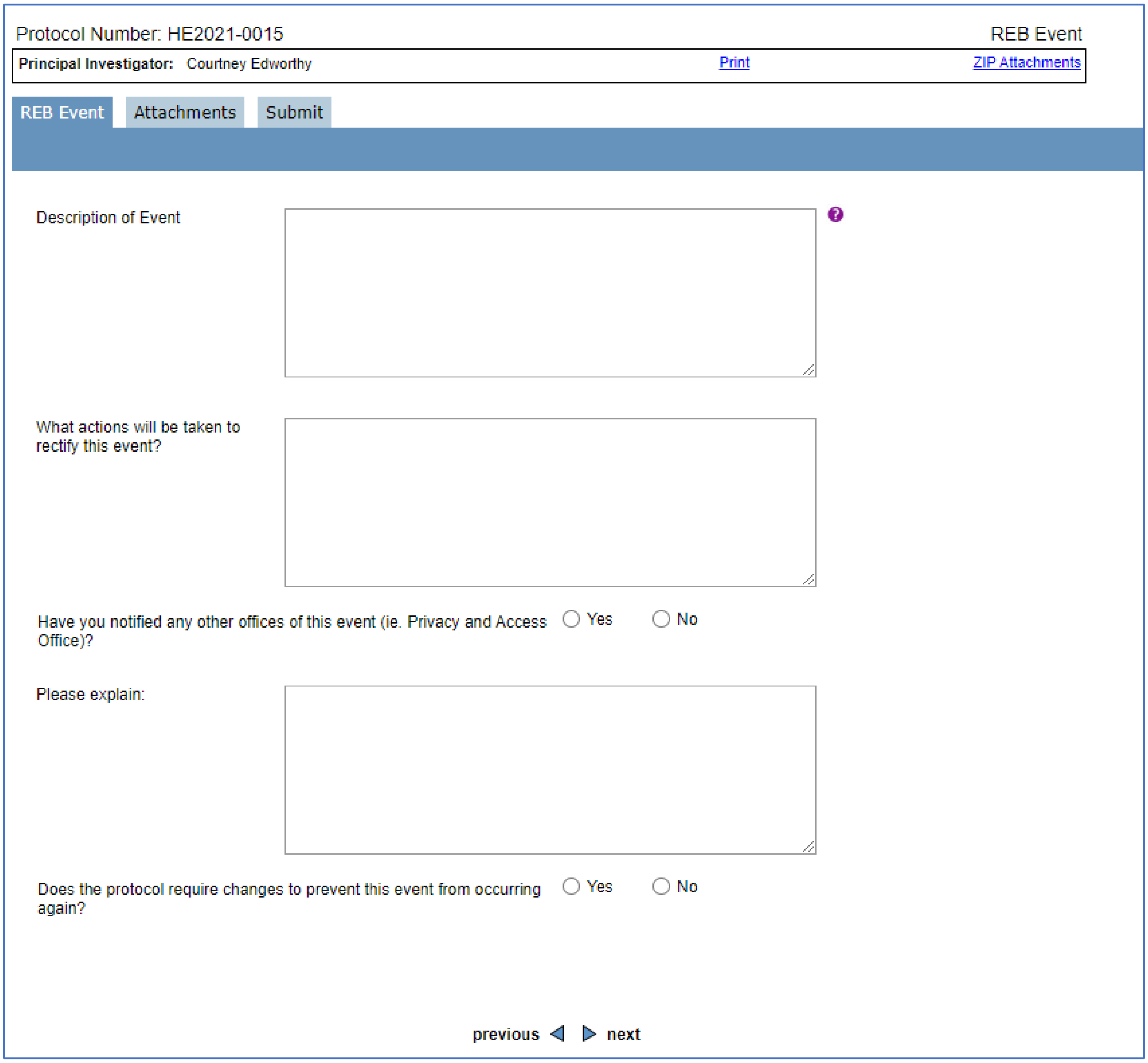
REB Event

To create a new REB Event form as a PI:

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


Protocol Number: HE2021-0015

REB Event

Principal Investigator: Courtney Edworthy

Print

ZIP Attachments

REB Event | Attachments | Submit

Description of Event

What actions will be taken to rectify this event?

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

Please explain:

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

previous **next**

Protocol Closure

To create a new Protocol Closure form as a PI:

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

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)**

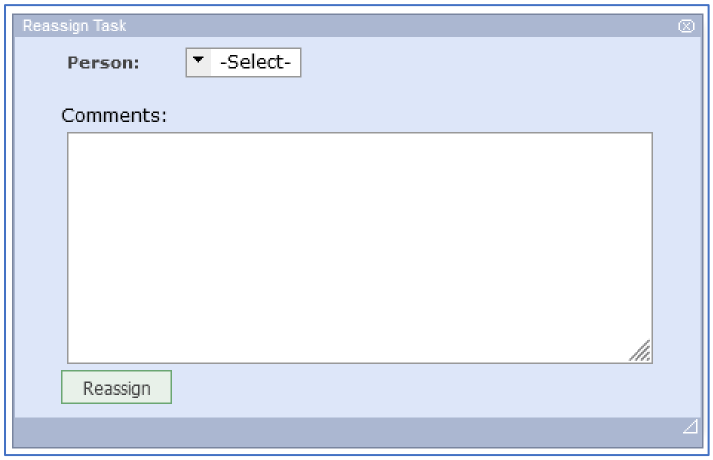
How to Reassign

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

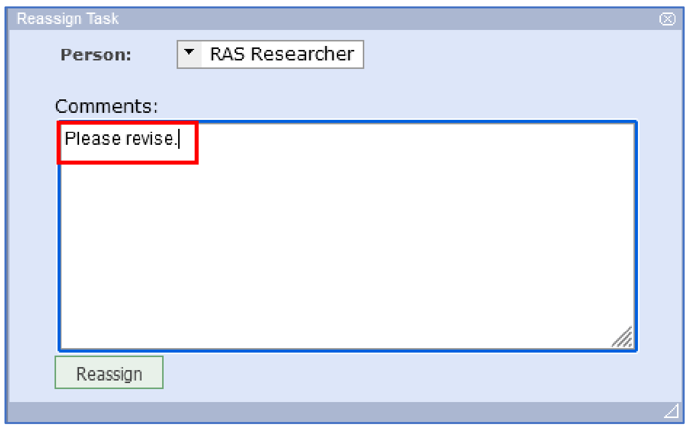
Submissions

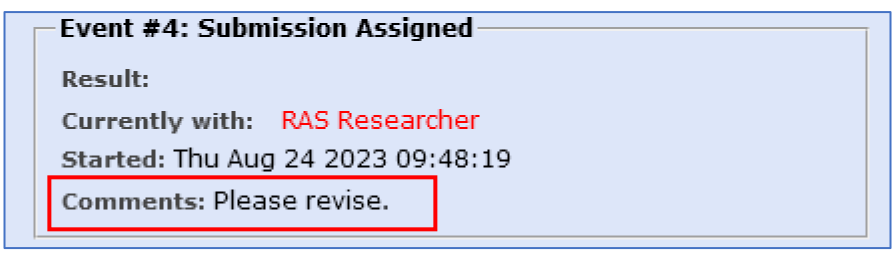
Type	Receipt Date	Summary	Status	Decision	Lifecycle	Details	Actions	
1 Initial Application	08/23/2023	View	Revisions	Pending	View	View	Withdraw	Reassign Task

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 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

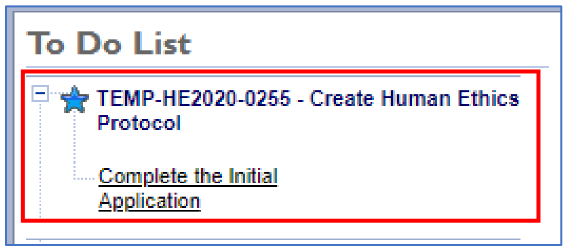


Figure 1: Example of the Saved Initial Application

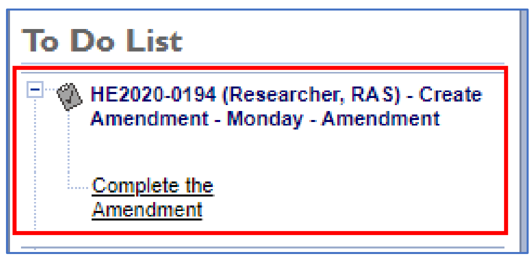


Figure 2: Example of the Saved Amendment

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

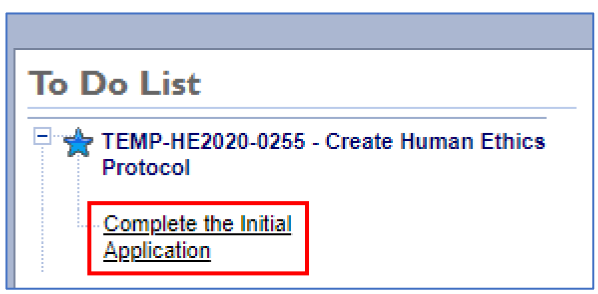


Figure 3: Example of the Saved Initial Application

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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**

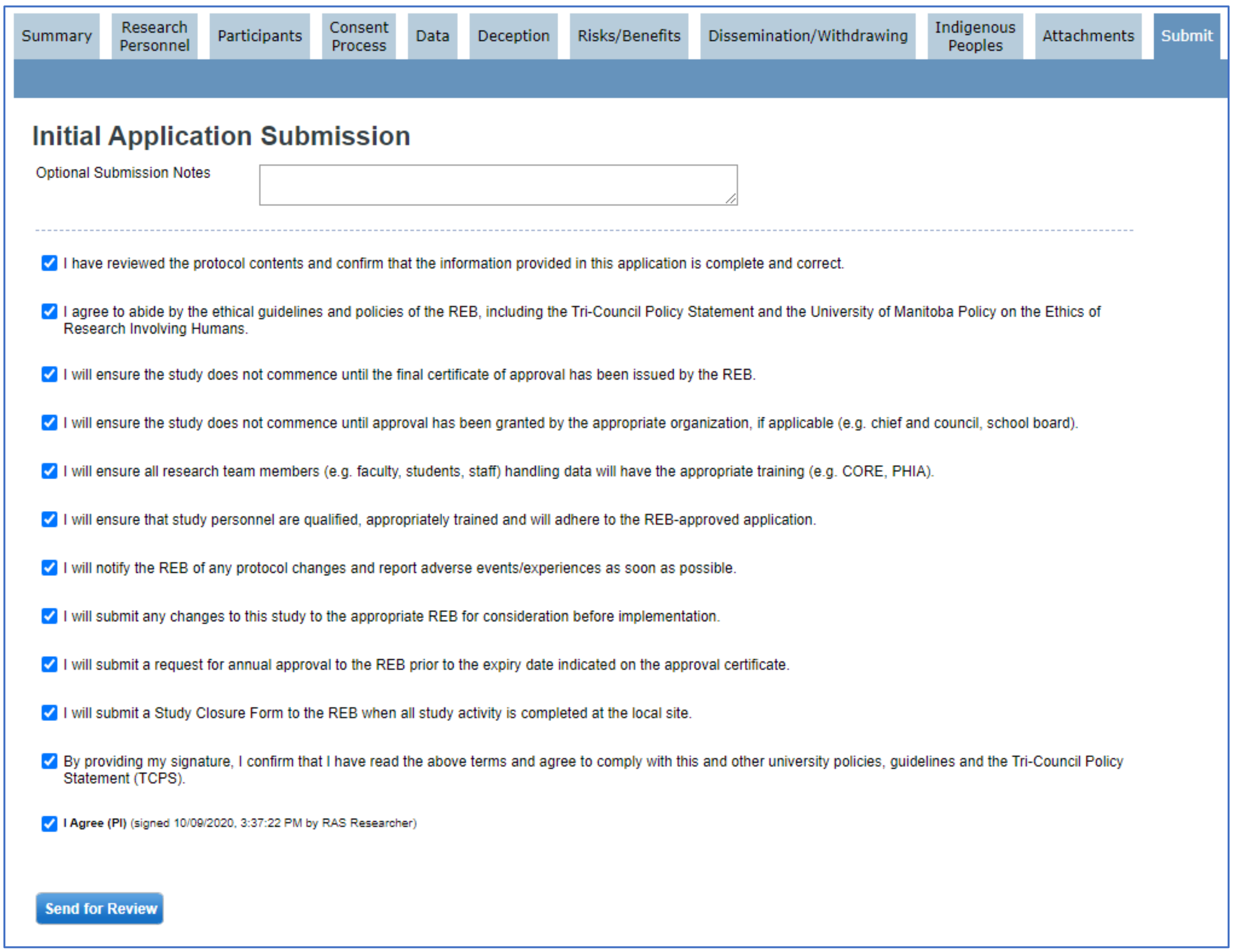


Figure 4: Example of the Initial Application

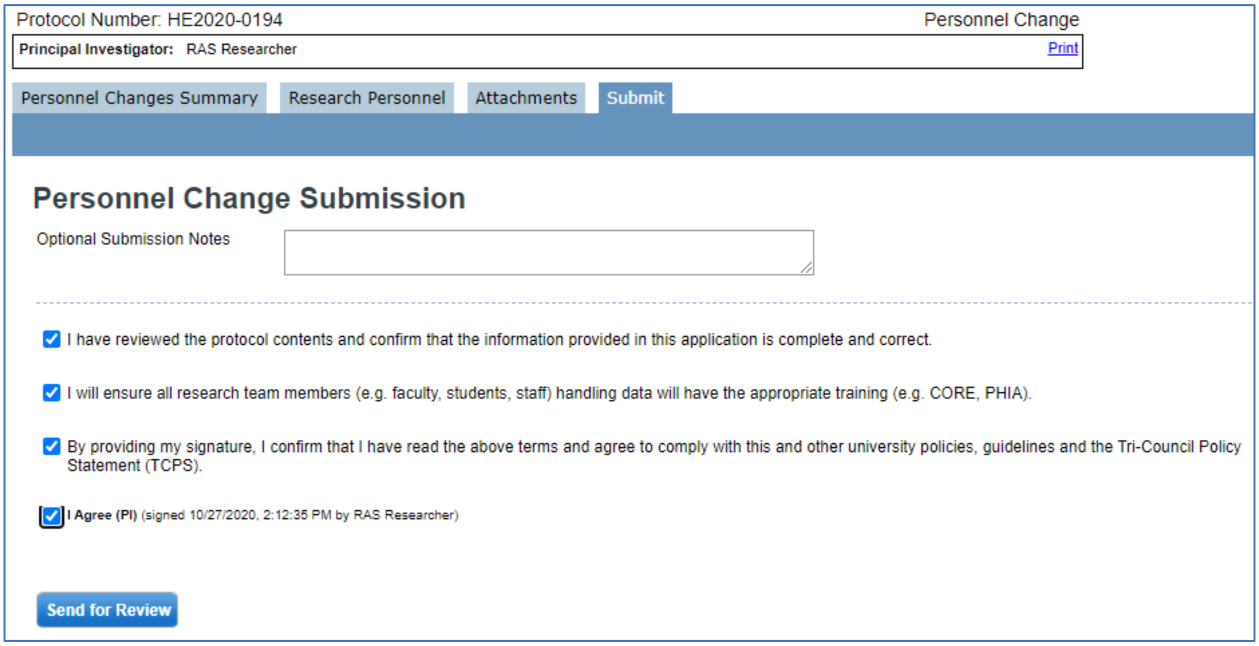
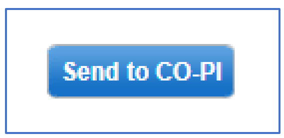


Figure 5: Example of the Personnel Change form

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



        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

6. Click **Send for Review**

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

Errors on the Initial Application or Follow-On Submission

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

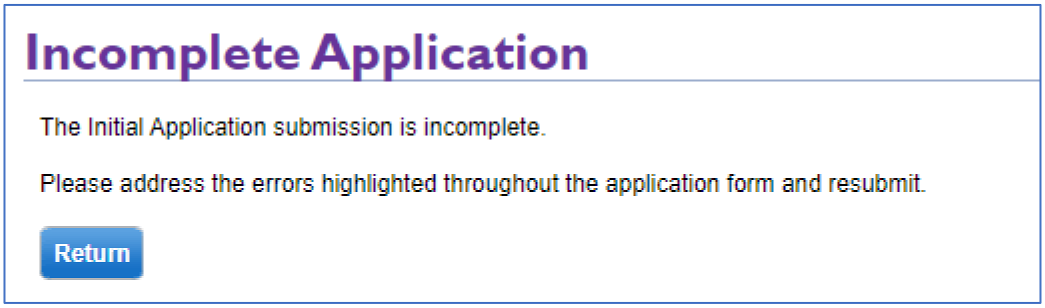


Figure 6: Example of an incomplete Initial Application

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.

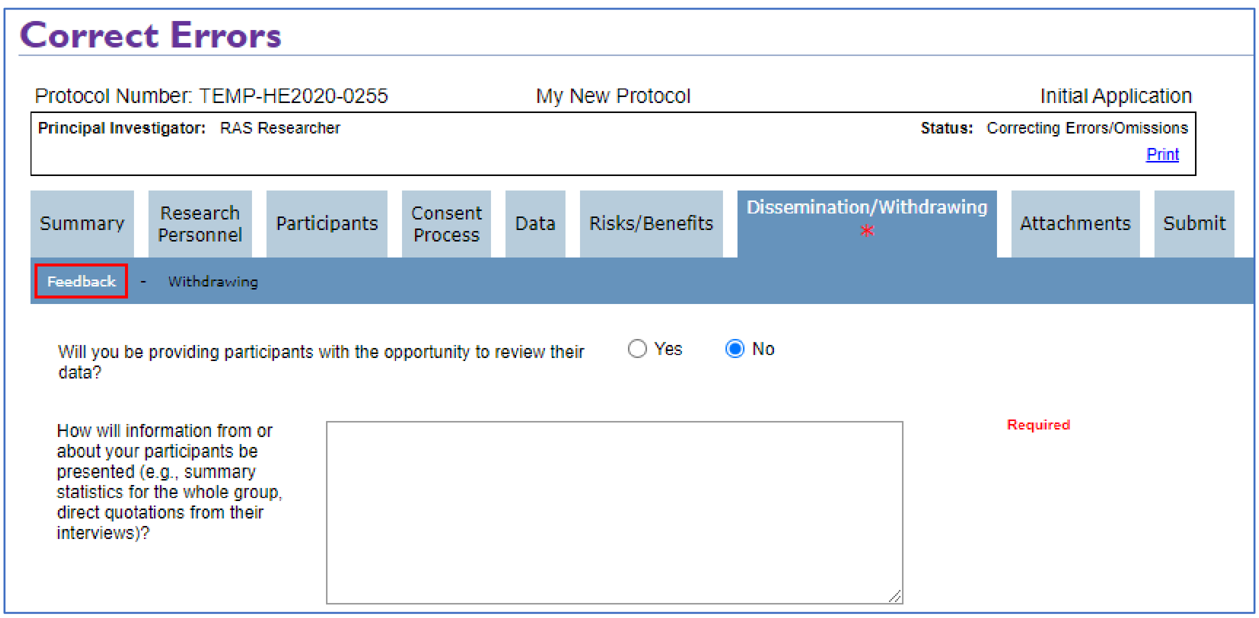


Figure 7: Example of errors on the Initial Application

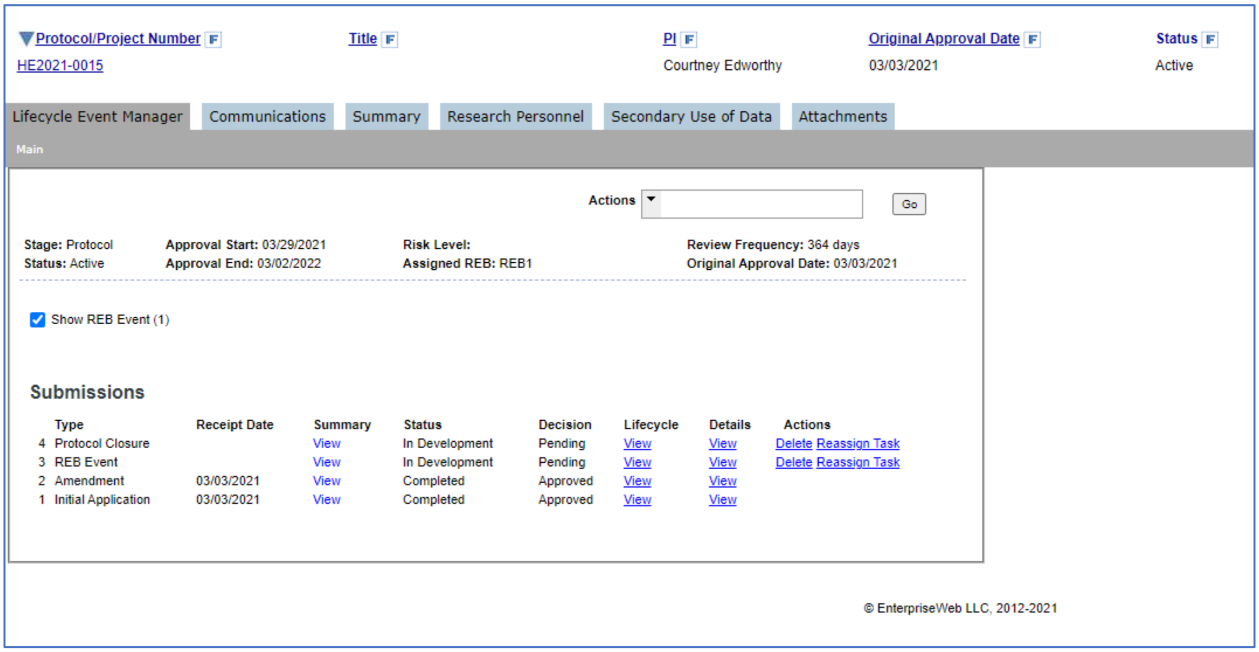
Once you complete all errors indicated, click the **Submit** tab and resubmit the application.

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

After Submission

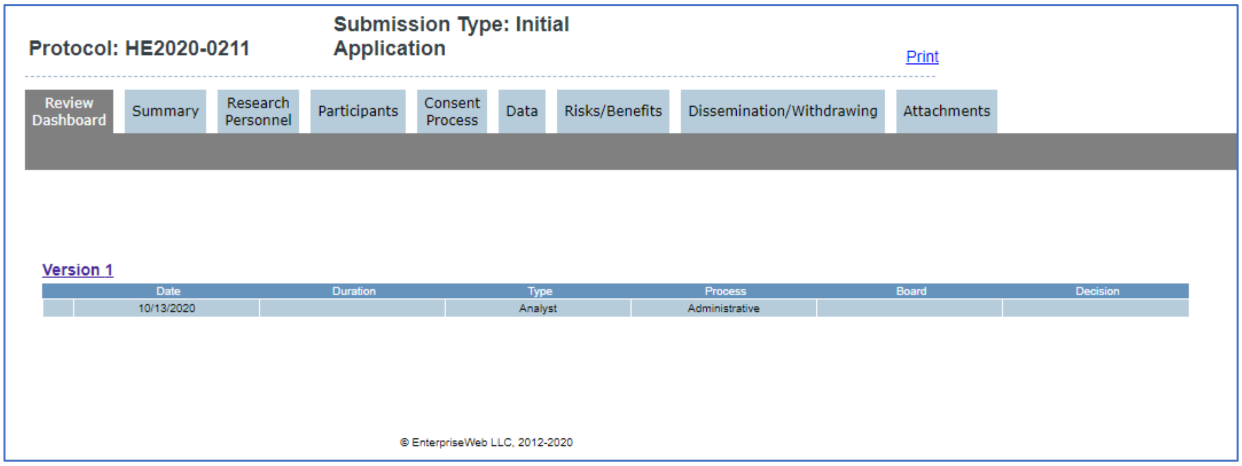
Once you have submitted the initial application or follow-on submission, you can view its progress in the LiveList.

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



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

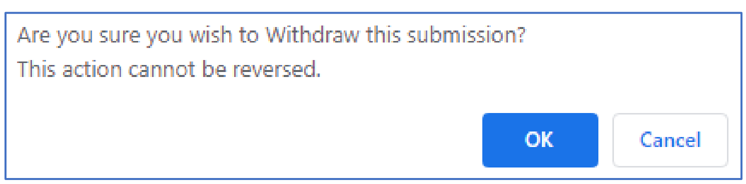
An initial application or follow-on submission can be withdrawn after you have submitted a submission but before it has been approved. This function is only meant to be used if you no longer wish to submit. Once withdrawn you cannot re-submit to the Human Ethics Office.

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	

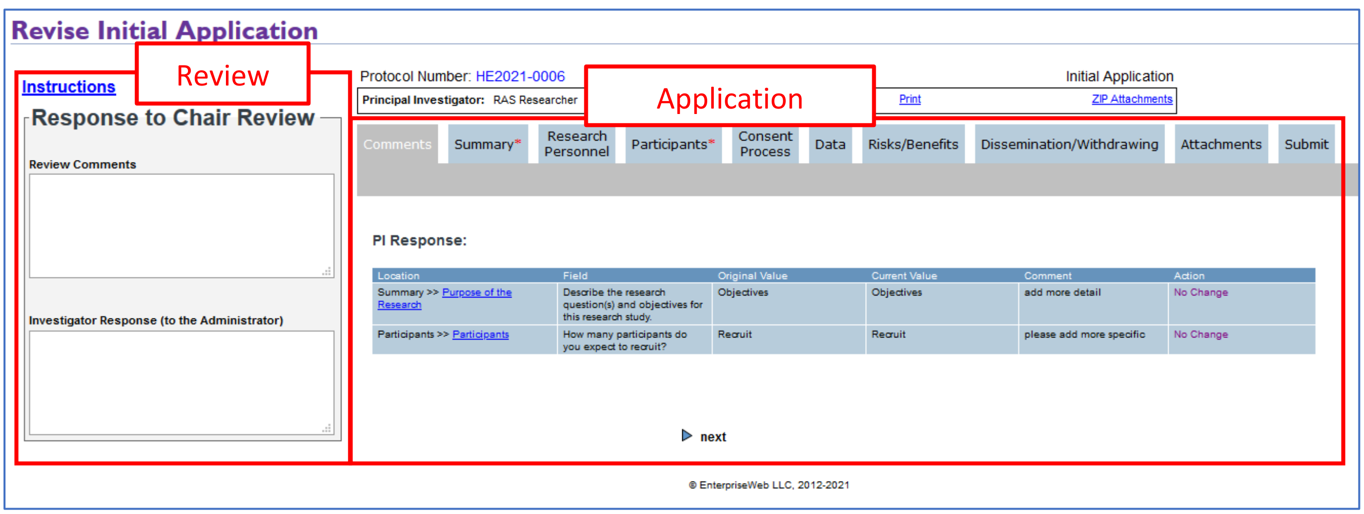
Revisions Required

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

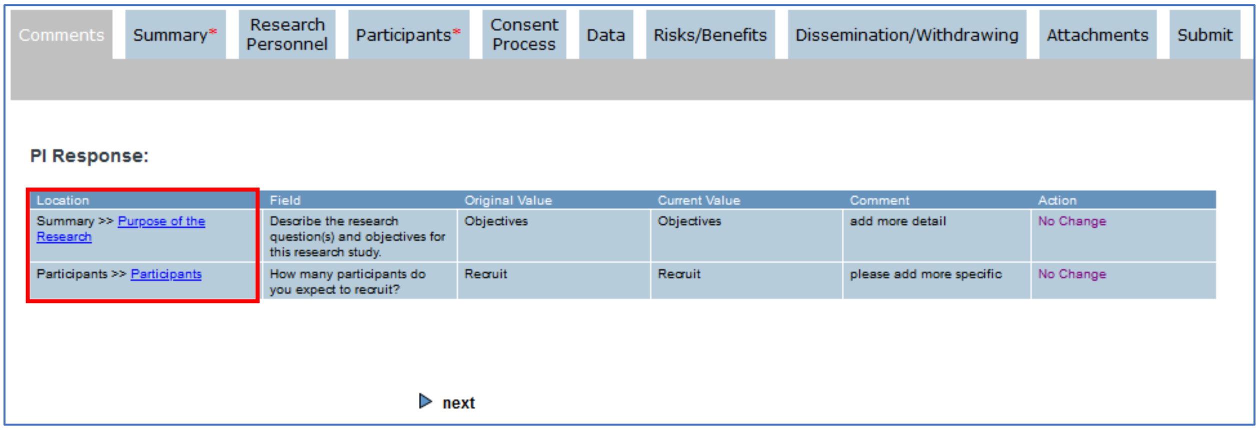
1. Under the **To Do List**, find the Revise task
2. Click the link within the task

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

3. There are 2 main sections in this view: **Review** and **Application** section
   Remember: The Review section can change based on who has provided the review. The example below is a Chair Review, you may also see HEO Review or Member Review.

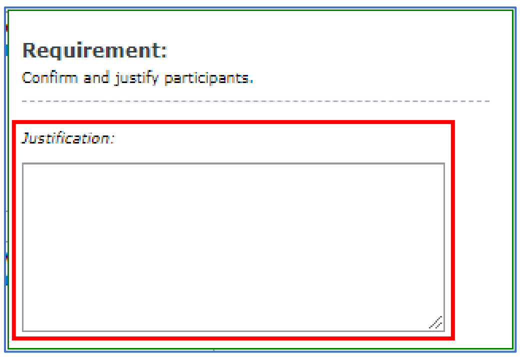


4. The **Comments** tab provides a summary of all comments made
5. Click on the link under **Location** to bring you to each comment to review

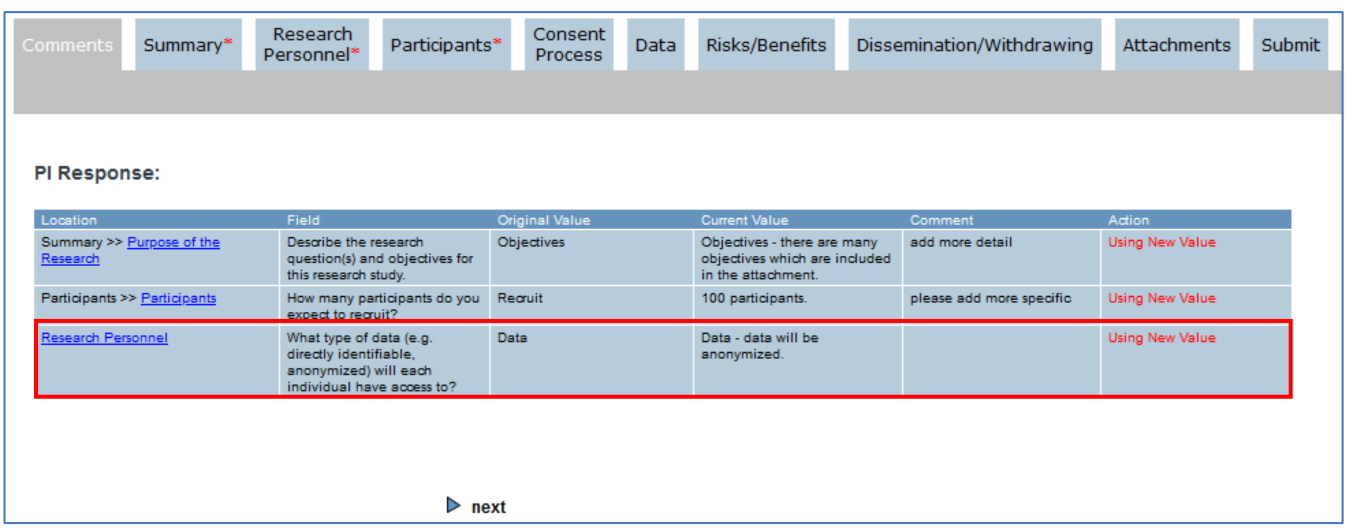


Note: Any comments made will also be indicated with a * on the tab within the Application section.

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

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

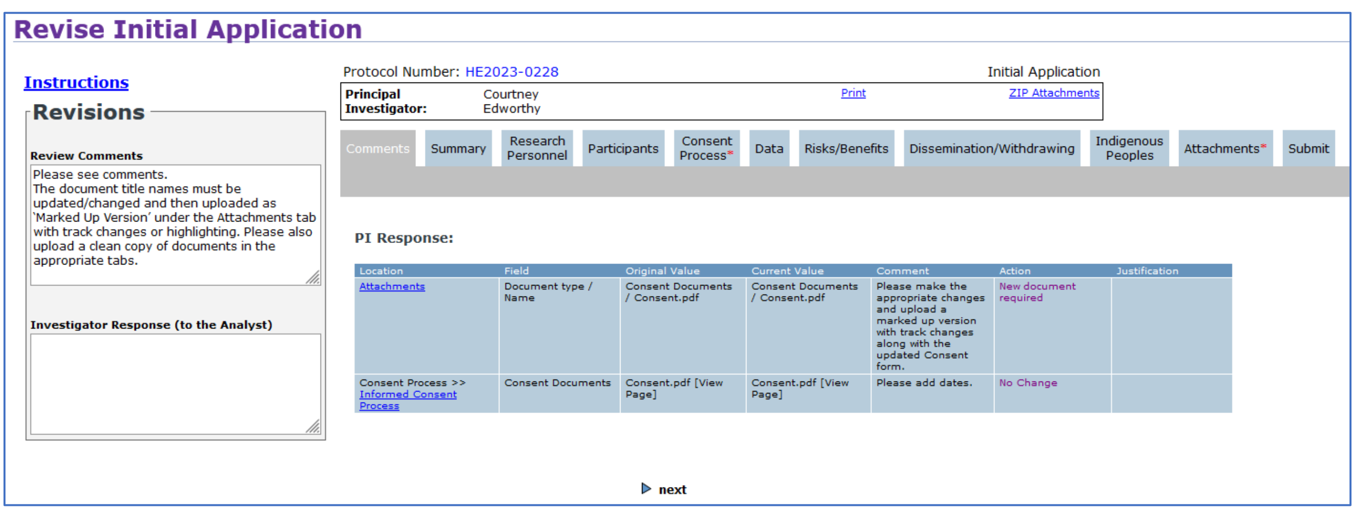
The revision has now bene sent to the HEO.

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.



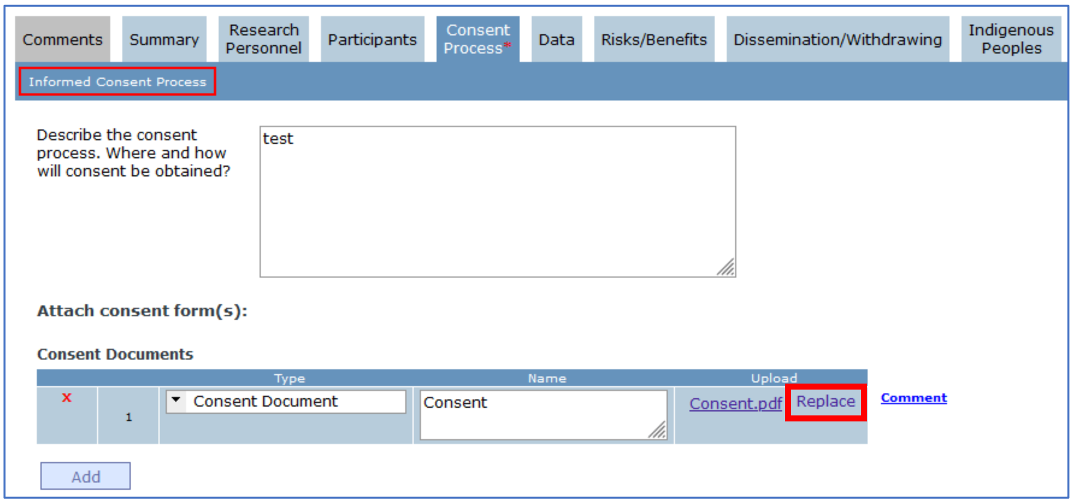
Upload Clean & Marked-Up Version

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

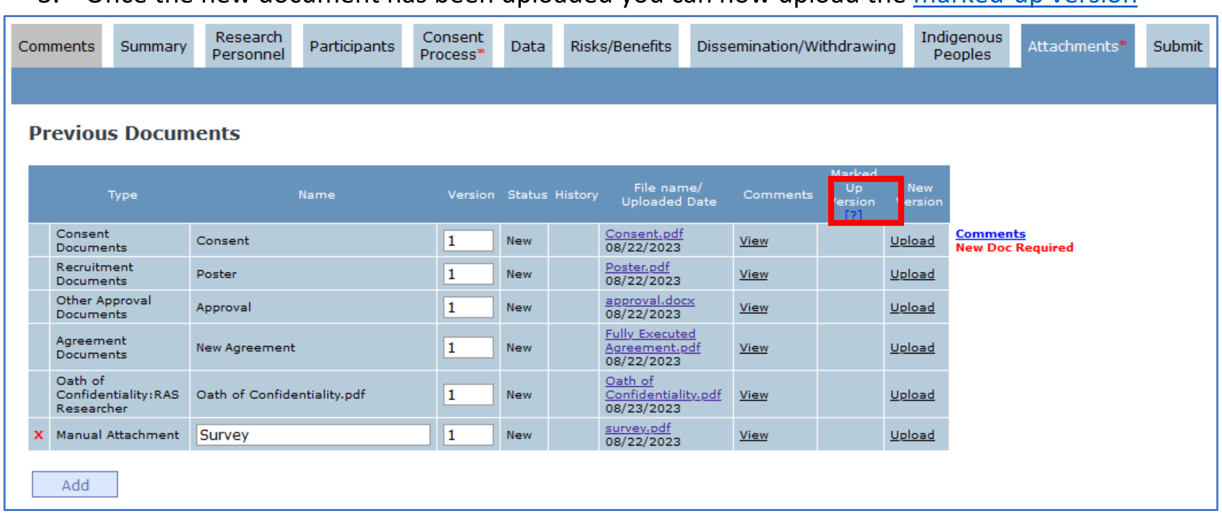
1. Navigate to the designated tab, in this example the **Consent Process** tab
2. Click **Replace**, find and **Upload** the <u>clean version</u> of the document



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](#)



	Type	Name	Version	Status	History	File name/ Uploaded Date	Comments	Marked Up Version [?]	New Version	
	Consent Documents	Consent	1	New		Consent.pdf 08/22/2023	View		Upload	Comments New Doc Required
	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	
x	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**