How to Submit a Protocol as a Student PI

RAS Training Documentation

Last Modified: August 25, 2023

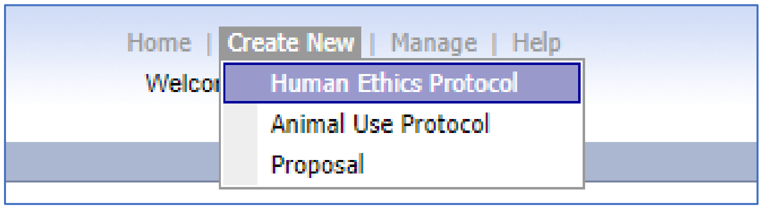
University of Manitoba

Contents

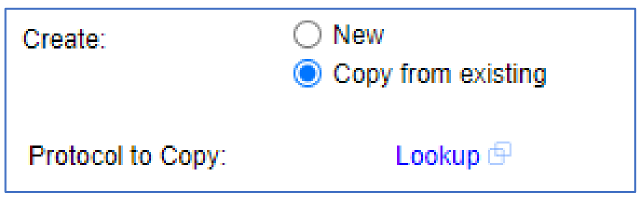
Initial Application

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

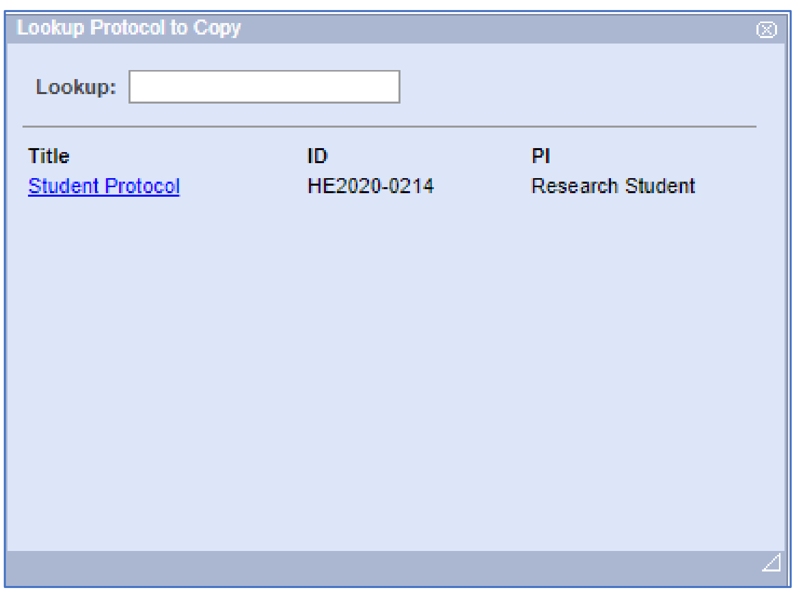
1. Under the Create New menu item select Human Ethics Protocol
   Note: The newly created protocol will receive a temporary protocol number while the application is in development. Once the application is submitted, a final Human Ethics Protocol number will be assigned.



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



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



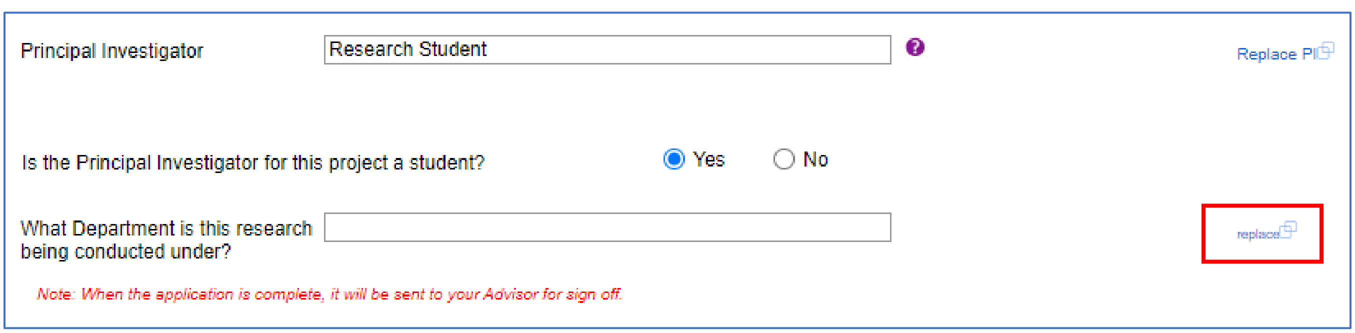
   b. **Protocol Title** – Enter the title of the protocol
      Note: The title must be unique per PI, this means it cannot be duplicated from another protocol under the same PI

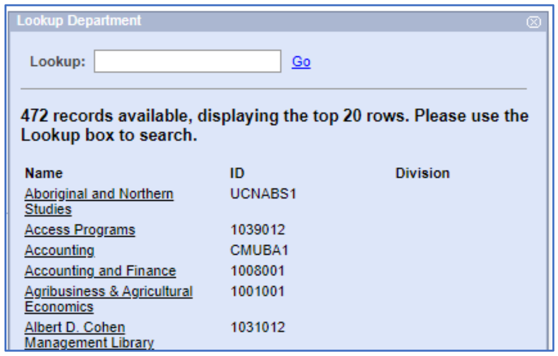
   c. **Principal Investigator** – Populated with name of the user who is logged in, this should be the PI
   d. **Department** – this drop down will auto populate based on the PI chosen
3. Click **Begin Application**

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.

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





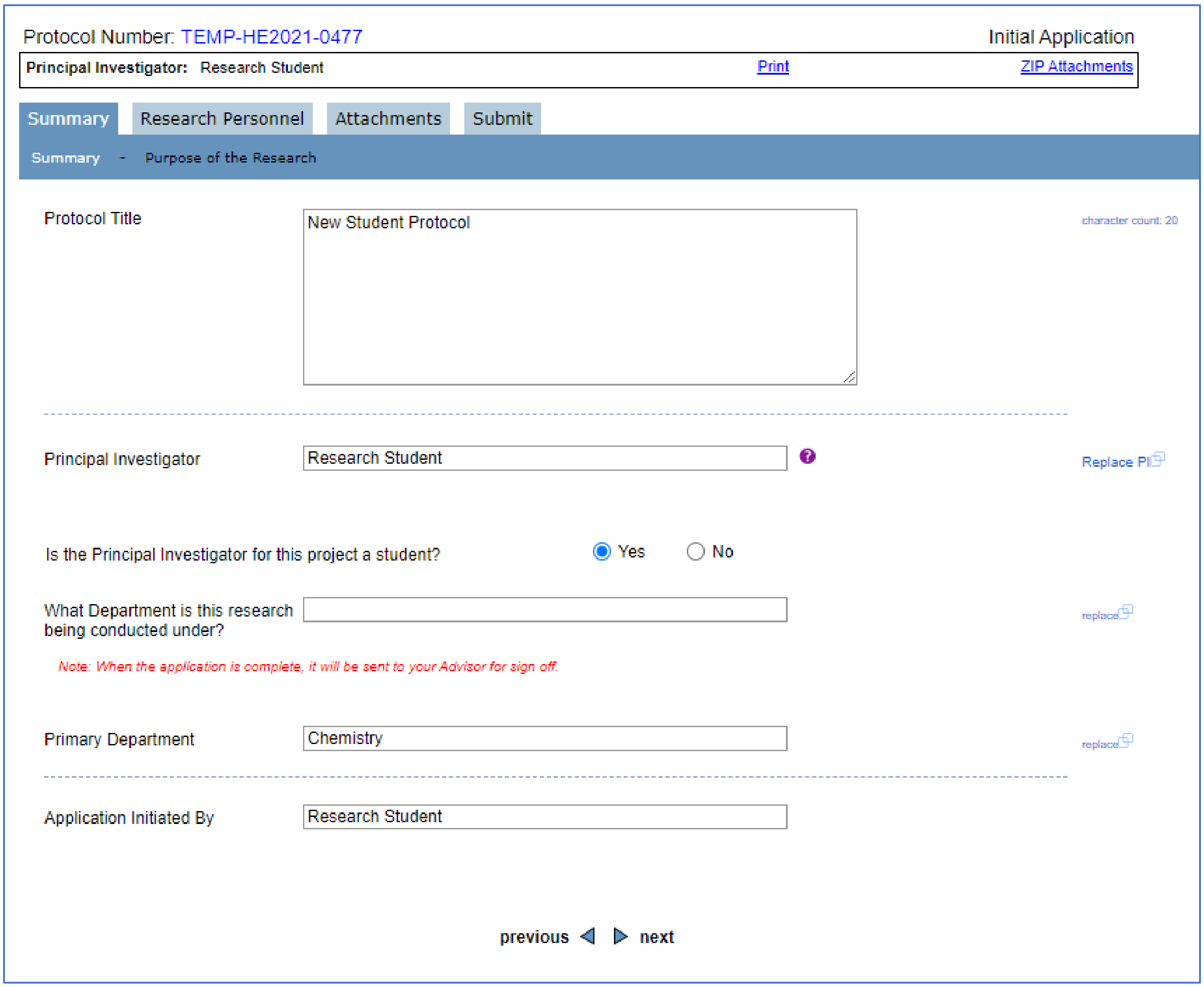
Lookup Department

Lookup: Go

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

Name	ID	Division
Aboriginal and Northern Studies	UCNABS1	
Access Programs	1039012	
Accounting	CMUBA1	
Accounting and Finance	1008001	
Agribusiness & Agricultural Economics	1001001	
Albert D. Cohen Management Library	1031012	

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



Protocol Number: TEMP-HE2021-0477 Initial Application

Principal Investigator: Research Student Print ZIP Attachments

Summary | Research Personnel | Attachments | Submit

Summary - Purpose of the Research

Protocol Title: New Student Protocol (character count: 20)

Principal Investigator: Research Student (Replace PI)

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

What Department is this research being conducted under? (replace)

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

Primary Department: Chemistry (replace)

Application Initiated By: Research Student

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Questions? Contact: RAS_Support@umanitoba.ca

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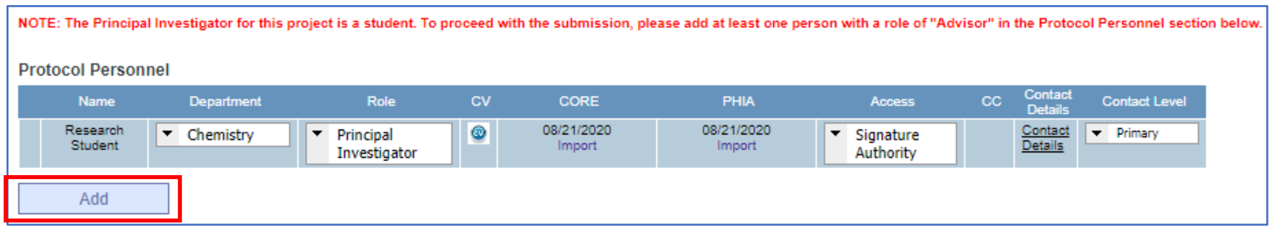
Adding Research Personnel

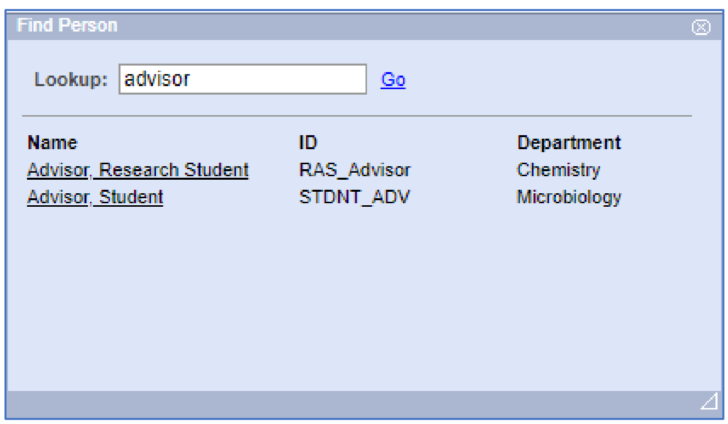
Add additional research personnel to the protocol.

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

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



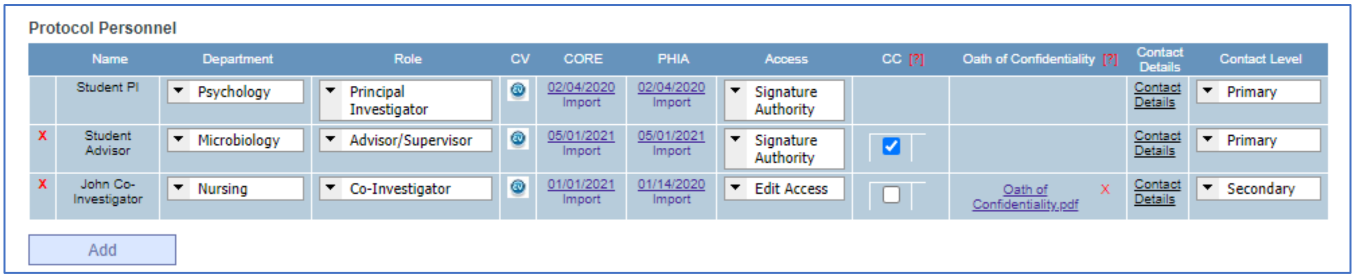
3. The Find Person window will appear, search for the user's name in the Lookup field
   Note: If the user you are trying to add does not appear in the list you can still add them to the protocol, see Add On-The-Fly User section.



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
	Student PI	Psychology	Principal Investigator		02/04/2020 Import	02/04/2020 Import	Signature Authority			Contact Details	Primary
X	Student Advisor	Microbiology	Advisor/Supervisor		05/01/2021 Import	05/01/2021 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	Secondary

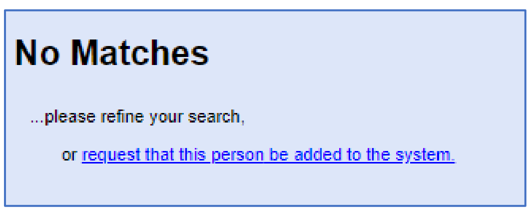
Add

Add On-The-Fly User

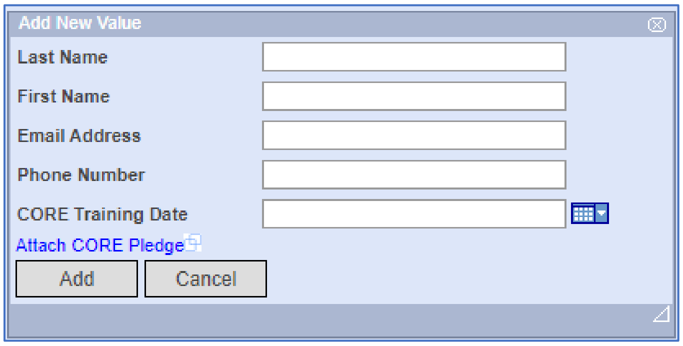
If you can't find someone in the Find Person lookup window when tying to add them to the research personnel table, you can add them on-the-fly.

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**

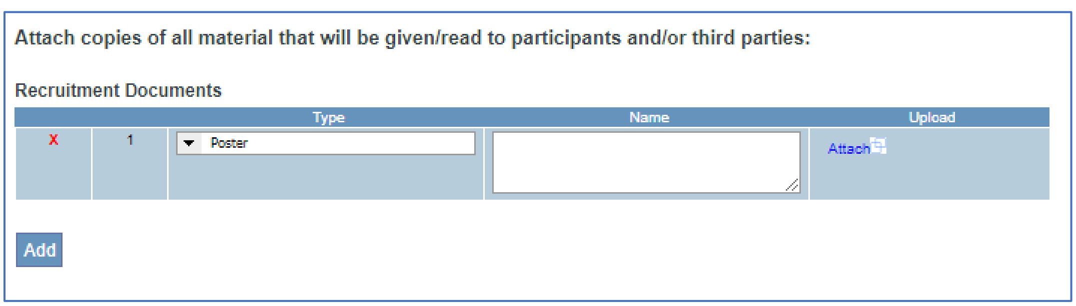
Once the application/submission has been submitted to the Ethics Office, a task will be sent to ORS to add this new user to the system.

How to Add a Document

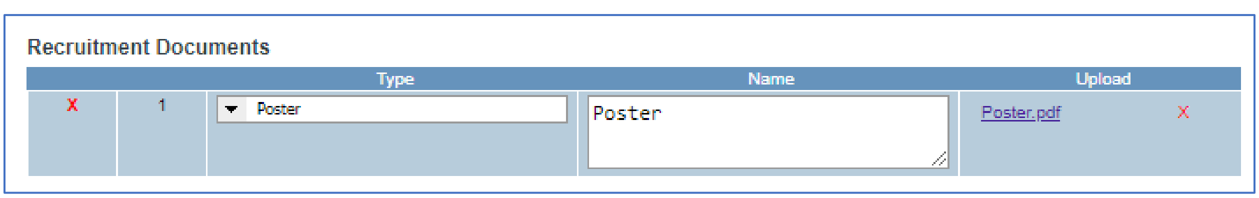
There are a few different areas within the initial application that allows you to upload documents.

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 instruction for an Initial Application, go to:

- Save Initial Application
- Submit Initial Application
- Advisor Review & Sign-Off
- After Submission
- Revisions Required from HEO

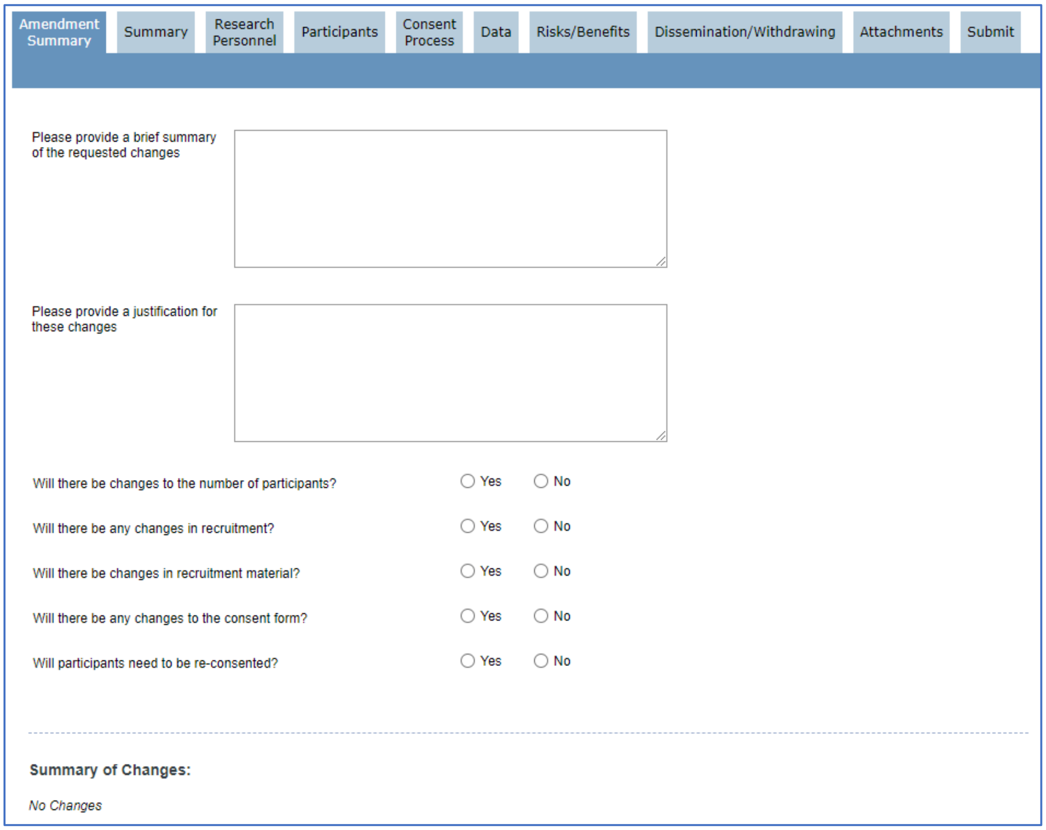
Follow-On Submissions

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

Amendment/Personnel Change

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

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



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

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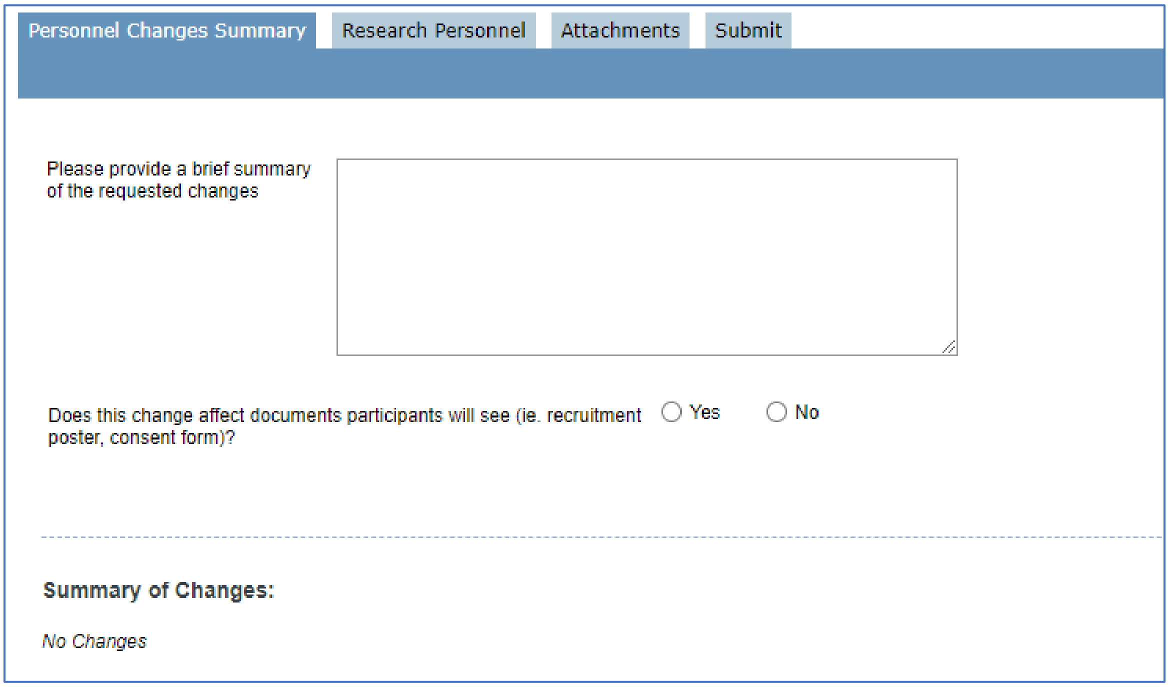
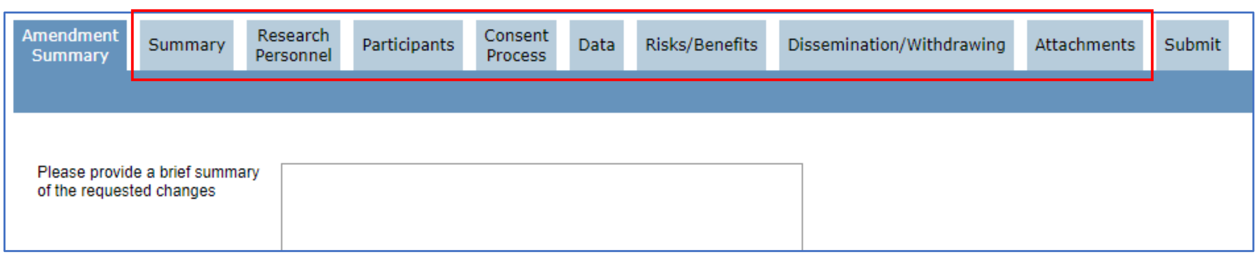
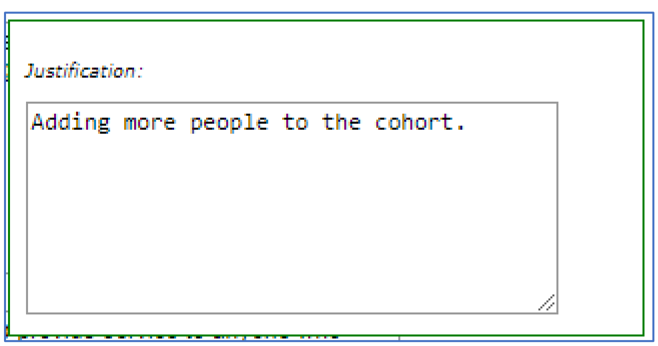


3. Navigate throughout the application and make your changes. As this is a living document, when you make a change to questions within the initial application section you will need to justify each change.

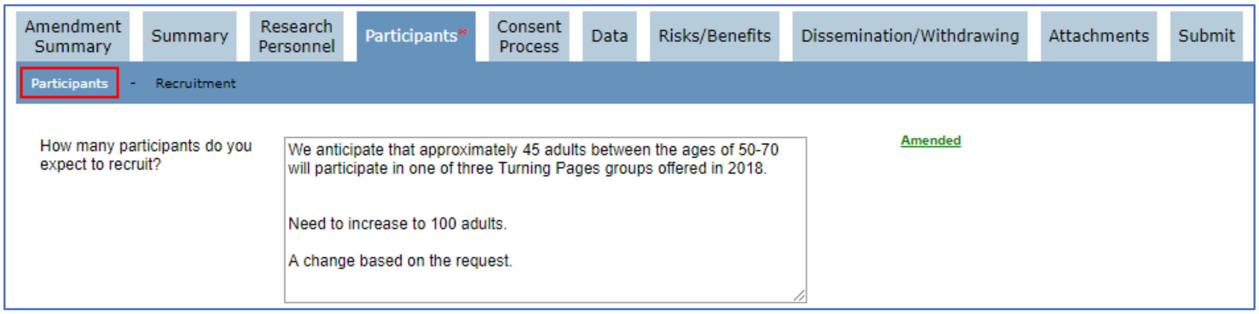


   a. When you make a change to any question throughout the application it's tagged with
      Amended (Please Justify)
   b. Add your justification for the change to that specific question in the text box

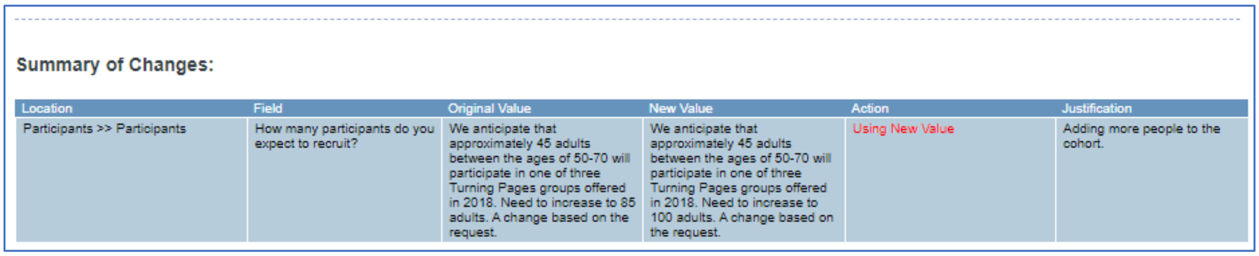


   c. Once you have included the justification the question will now state Amended
   d. A red asterisk will be added to each tab and a red box around the subtab to easily locate any changes to the application

Questions? Contact: RAS_Support@umanitoba.ca



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:

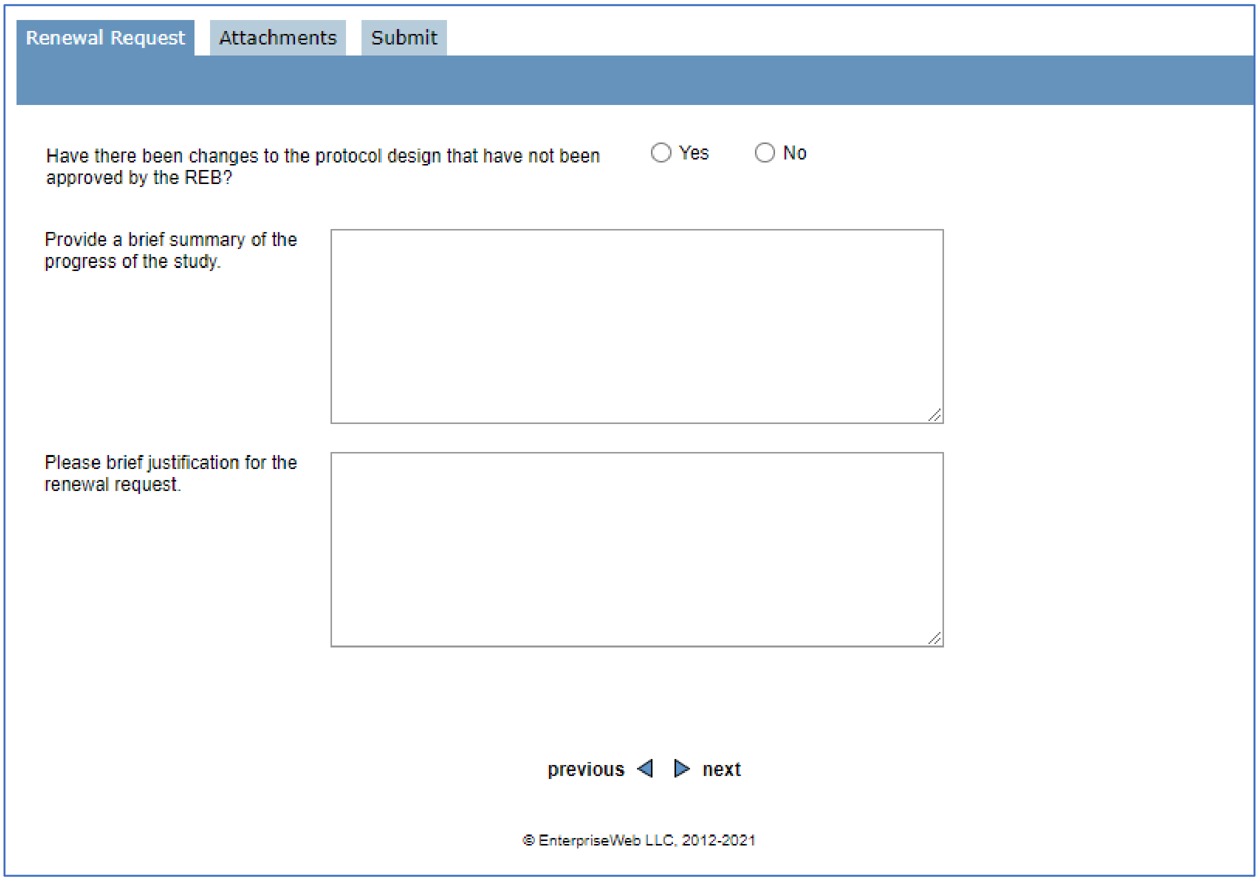
Location	Field	Original Value	New Value	Action	Justification
Participants >> Participants	How many participants do you expect to recruit?	We anticipate that approximately 45 adults between the ages of 50-70 will participate in one of three Turning Pages groups offered in 2018. Need to increase to 85 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.

Questions? Contact: RAS_Support@umanitoba.ca

Renewal Request

To create a new Renewal Request form as a Student PI:

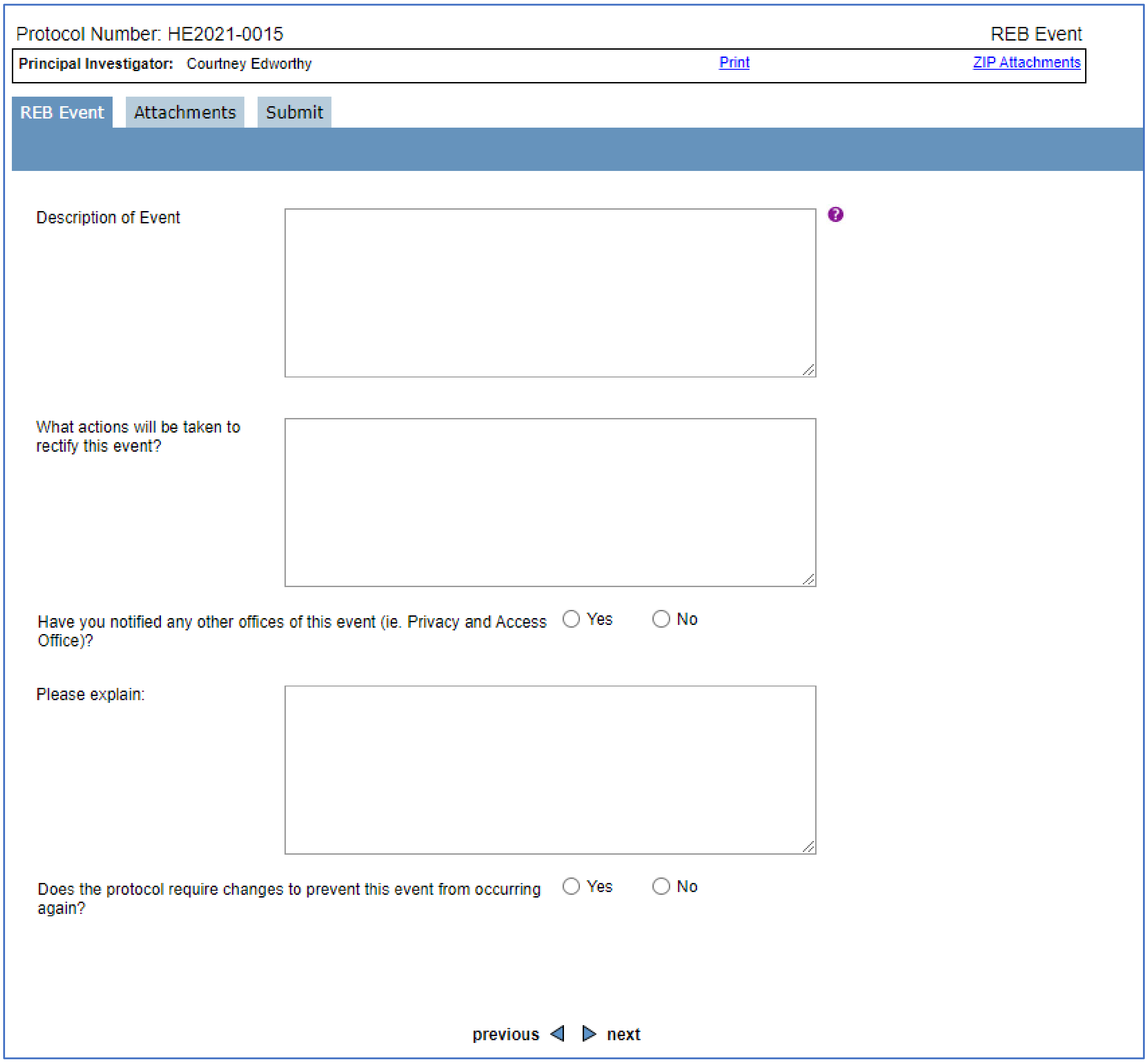
1. Select the protocol link from the **LiveList**
2. Under **Actions** select **Create Renewal Request**, click **Go**
3. Navigate through each tab and answer each question as they appear within the form



REB Event

To create a new REB Event form as a Student PI:

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


Protocol Number: HE2021-0015 REB Event

Principal Investigator: Courtney Edworthy Print ZIP Attachments

REB Event | Attachments | Submit

Description of Event

What actions will be taken to rectify this event?

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

Please explain:

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

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Protocol Closure

To create a new Protocol Closure form as a Student PI:

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

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)**

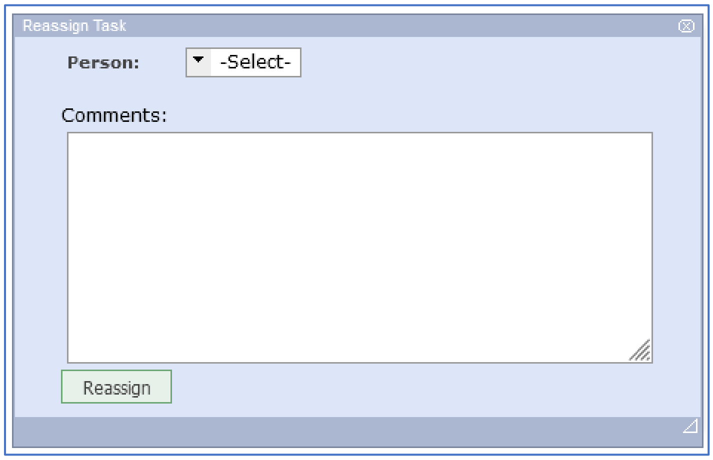
How to Reassign

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

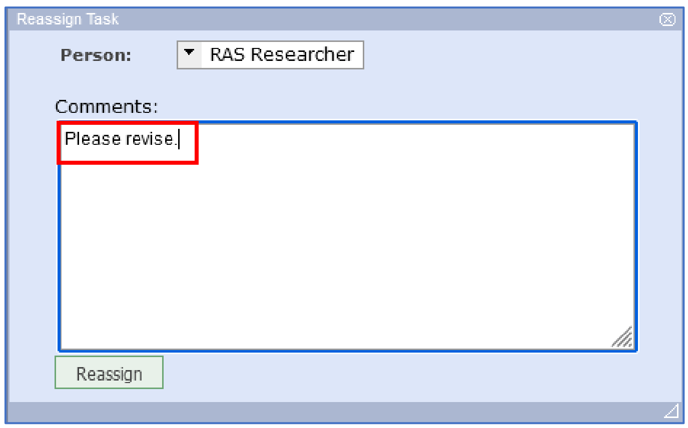
Submissions

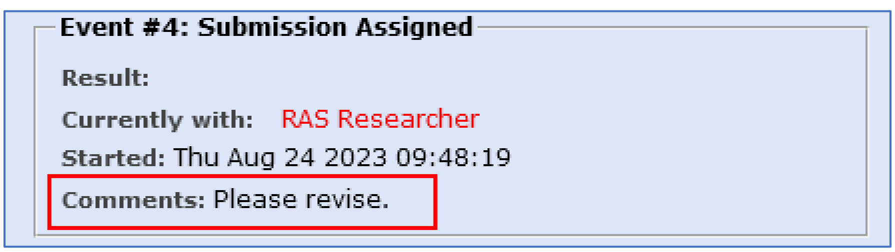
Type	Receipt Date	Summary	Status	Decision	Lifecycle	Details	Actions	
1 Initial Application	08/23/2023	View	Revisions	Pending	View	View	Withdraw	Reassign Task

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.



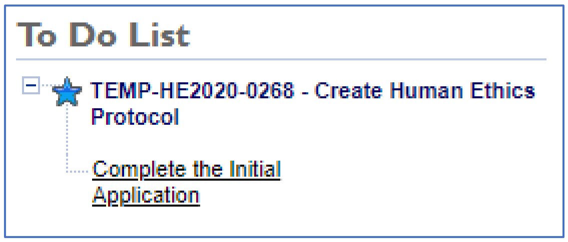


5. Click **Reassign**
6. Task is now reassigned
   Note: The task will be located in the reassigned users to do list, an email is not sent notifying the user of the task.

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:

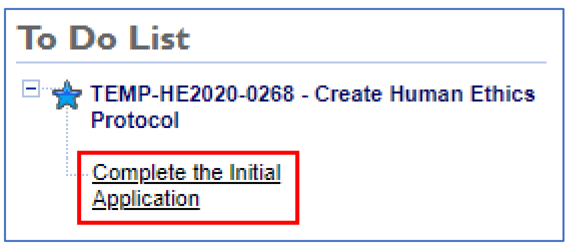
1. Click Save at the  top left-hand side of the screen
2. Click the Home menu item to return to the LiveList
3. The protocol is now listed in your To Do List



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



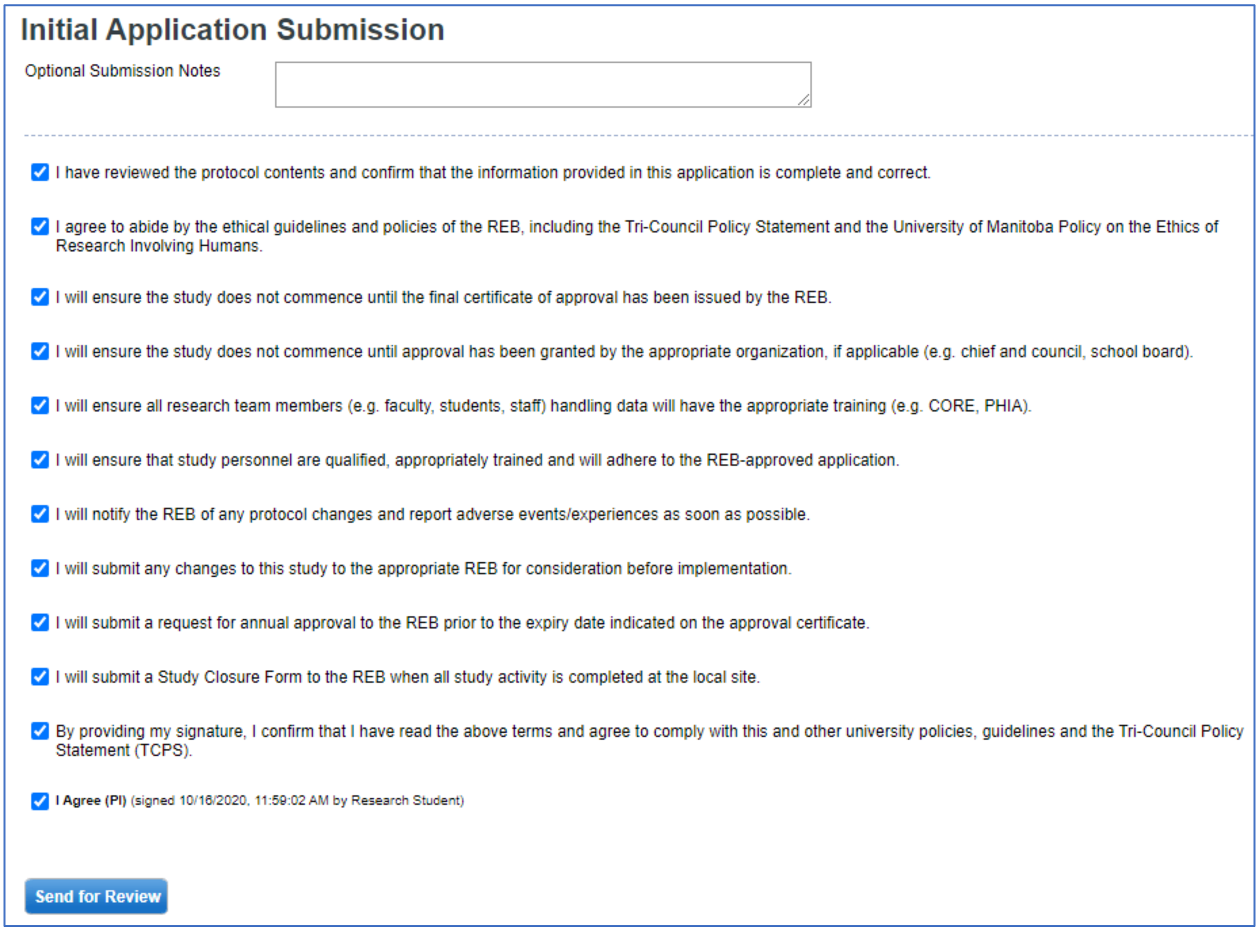
Submit an Initial Application or Follow-On Submission

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**



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

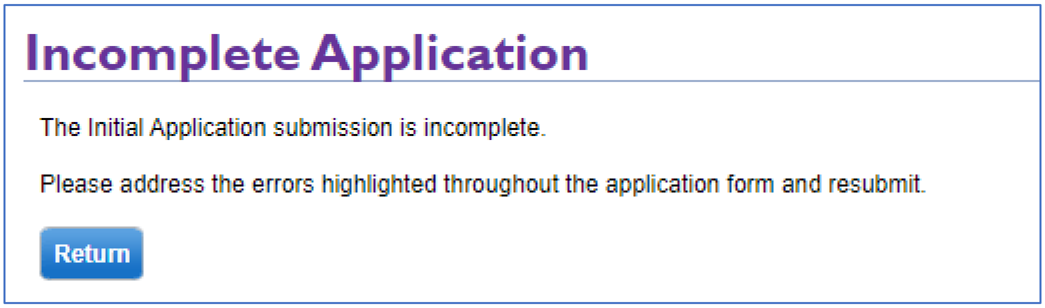
        ii. After the Co-PI has reviewed the application/submission, navigate to the **Submit** tab
        iii. Read and check each of the **Declaration Statements**
        iv. The Co-PI has the option of sending the application back to the PI if changes have been made or they can click I Agree to send for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

6. Click **Send for Review**

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

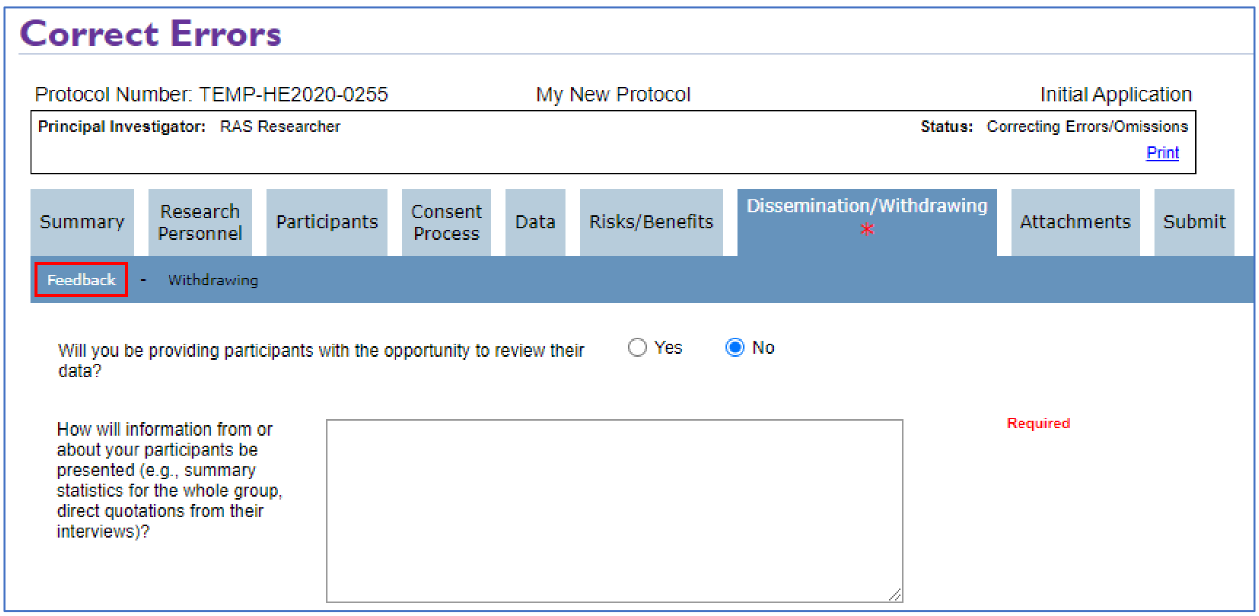
Errors on the Initial Application or Follow-On Submission

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



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 application.

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

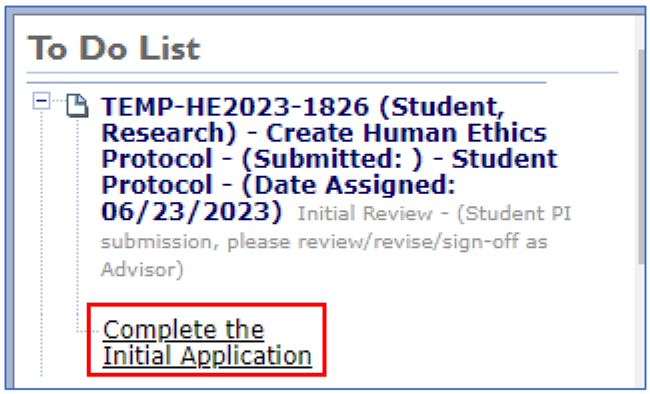
Advisor Review & Sign-Off

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

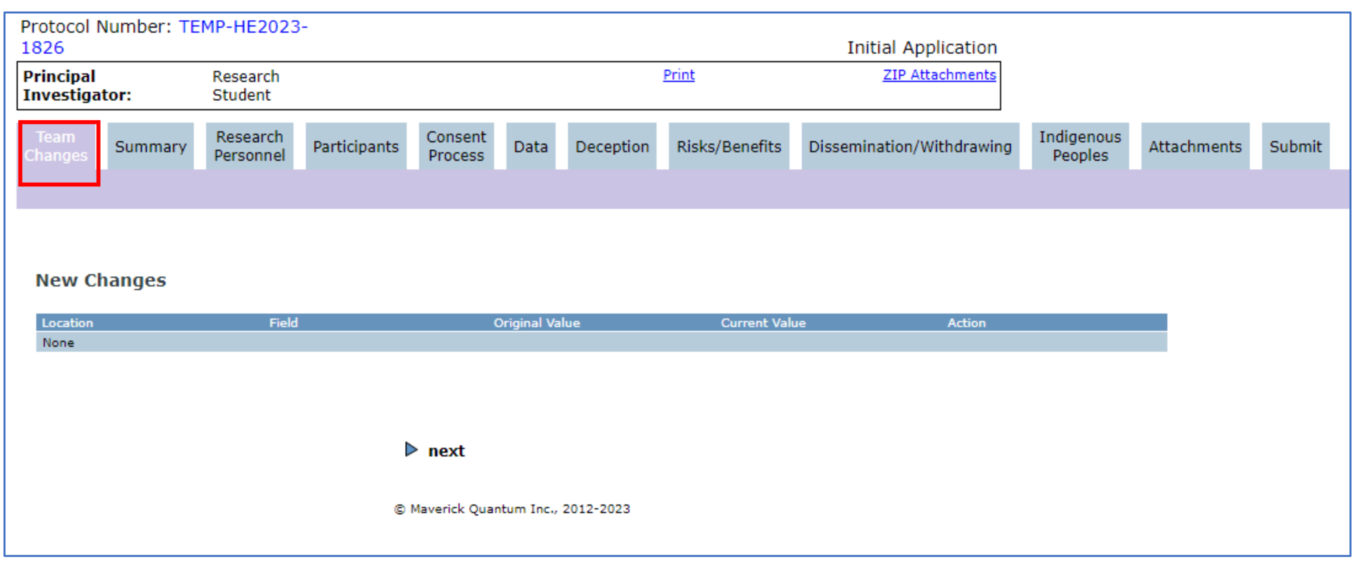
New: The Advisor can now edit the submission. The commenting function has been removed to allow for better collaboration between research members. Research members will also see the new Team Changes tab that will collect changes made. This tab will display all changes made

To review the initial application or follow-on submission:

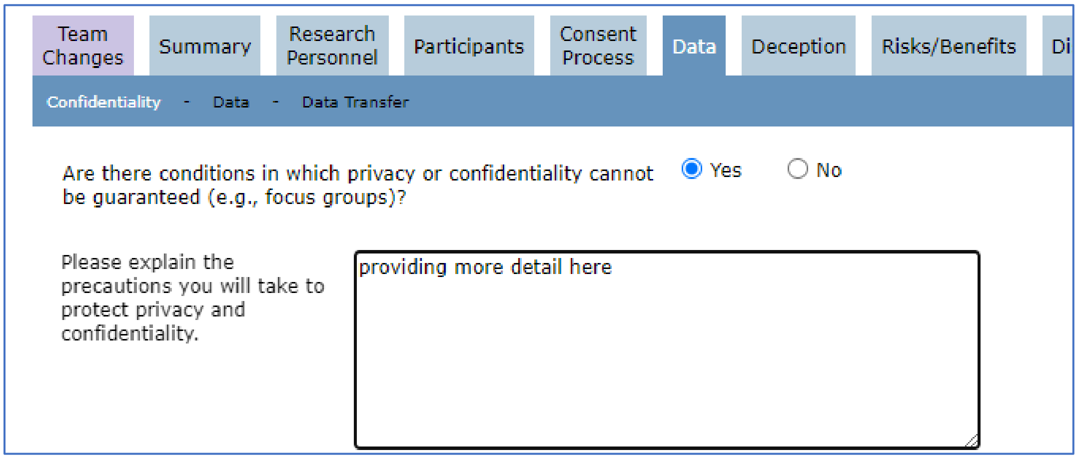
1. Click on the **Complete the Initial Application** link in the To Do List
   Note: If this is a follow-on submission the type of submission being completed would replace "Initial Application"

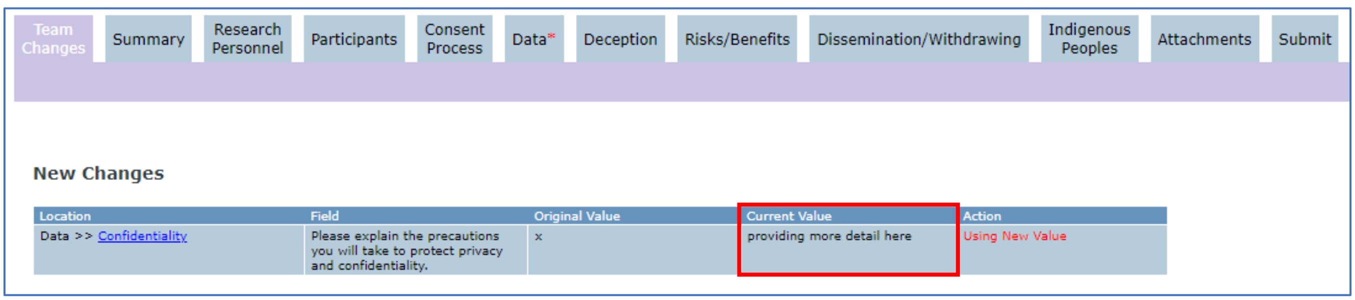


2. **Team Changes** tab will display no new changes if this is the fist time the Advisor is getting the submission. If the submission is sent back to the PI or other research members and changes are made, the Advisor will see those new changes here when they receive the task again.



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





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

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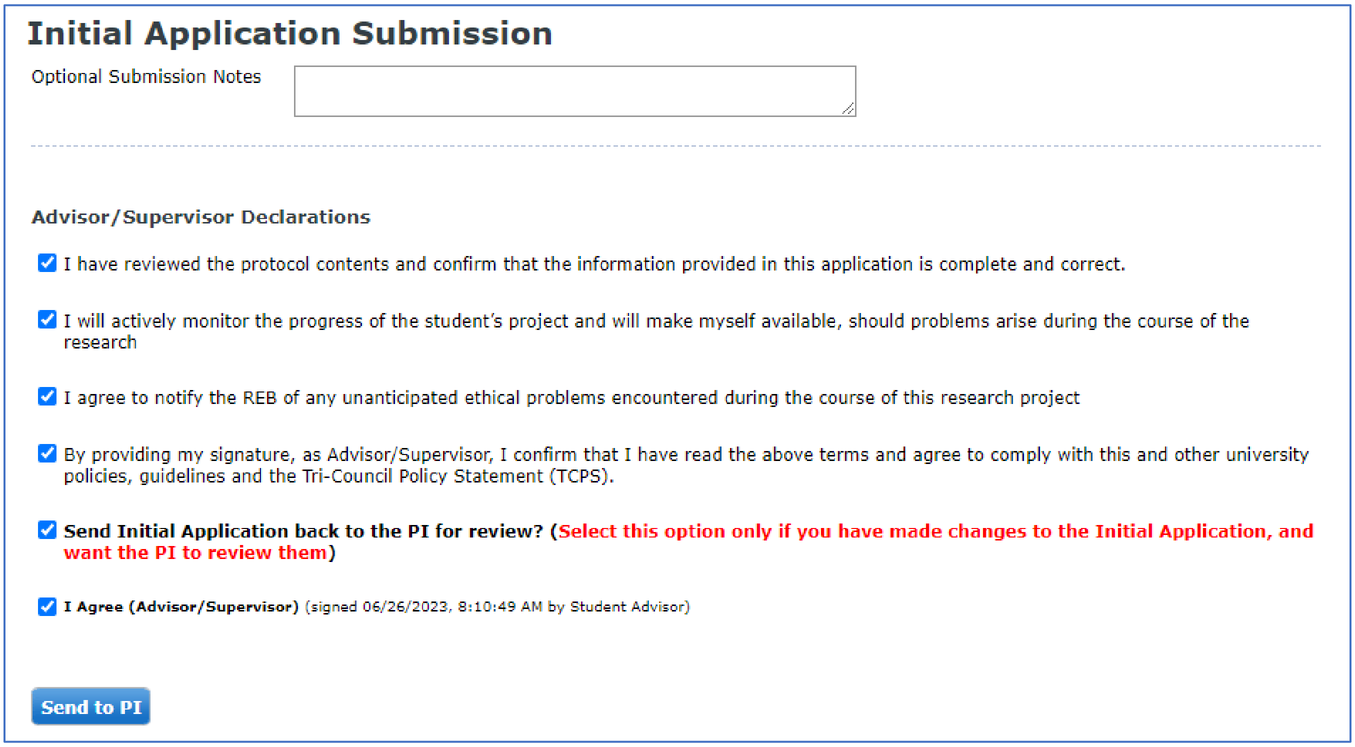


Initial Application Submission

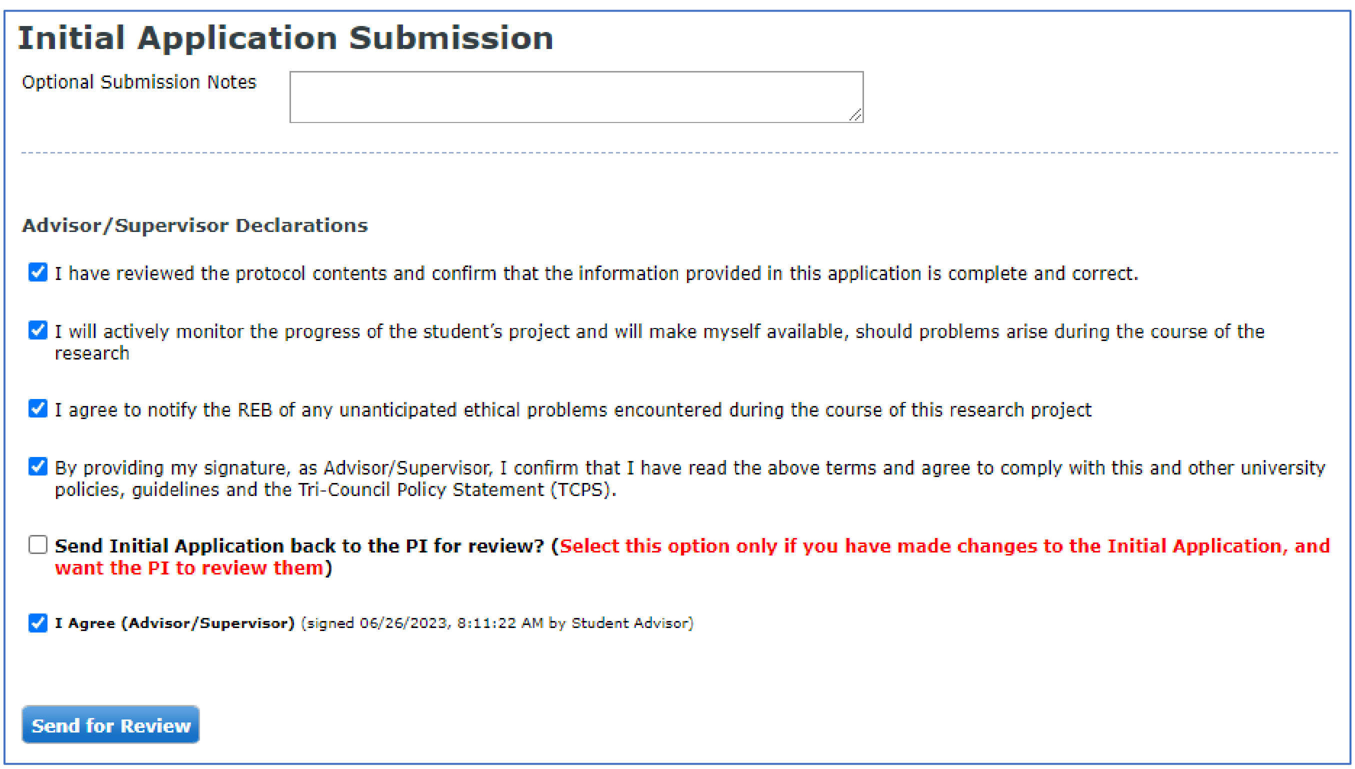
Optional Submission Notes

Advisor/Supervisor Declarations

- [x] I have reviewed the protocol contents and confirm that the information provided in this application is complete and correct.
- [x] I will actively monitor the progress of the student's project and will make myself available, should problems arise during the course of the research
- [x] I agree to notify the REB of any unanticipated ethical problems encountered during the course of this research project
- [x] By providing my signature, as Advisor/Supervisor, I confirm that I have read the above terms and agree to comply with this and other university policies, guidelines and the Tri-Council Policy Statement (TCPS).
- [x] **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)**
- [x] **I Agree (Advisor/Supervisor)** (signed 06/26/2023, 8:10:49 AM by Student Advisor)

Send to PI

b. To send for review:
   i. Navigate to the **Submit** tab, check off all declarations
   ii. Ensure that "**Send Initial Application back to the PI for review?**" is not checked off
   iii. Click **Send for Review**



Initial Application Submission

Optional Submission Notes

Advisor/Supervisor Declarations

- [x] I have reviewed the protocol contents and confirm that the information provided in this application is complete and correct.
- [x] I will actively monitor the progress of the student's project and will make myself available, should problems arise during the course of the research
- [x] I agree to notify the REB of any unanticipated ethical problems encountered during the course of this research project
- [x] By providing my signature, as Advisor/Supervisor, I confirm that I have read the above terms and agree to comply with this and other university policies, guidelines and the Tri-Council Policy Statement (TCPS).
- [ ] **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)**
- [x] **I Agree (Advisor/Supervisor)** (signed 06/26/2023, 8:11:22 AM by Student Advisor)

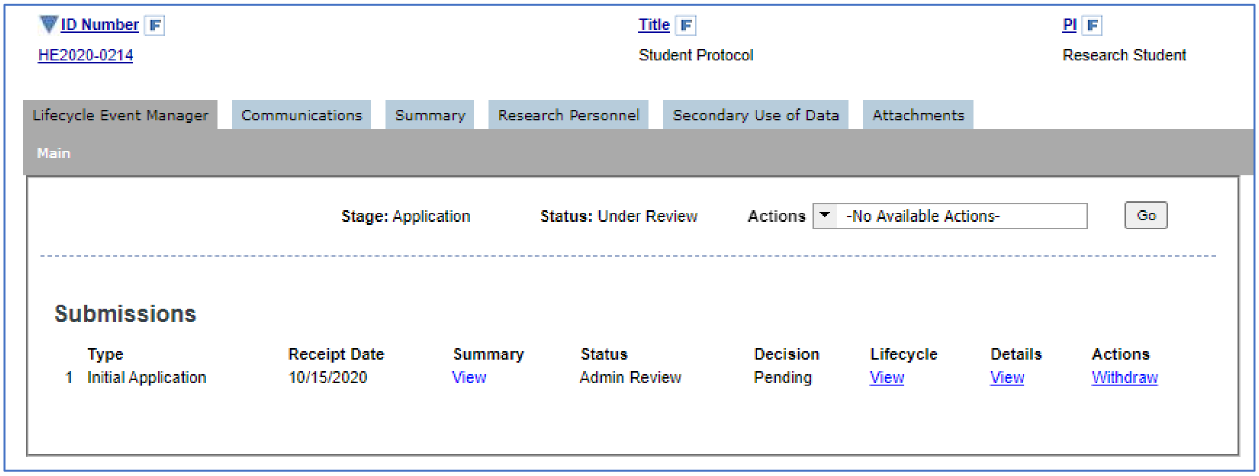
Send for Review

![University of Manitoba]

After Submission

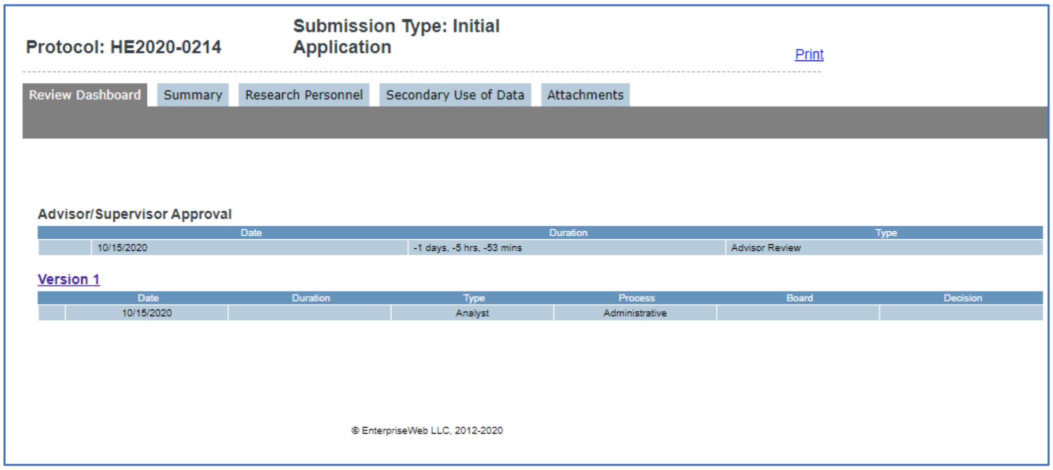
Once you have submitted the initial application or follow-on submission, you can view its progress in the LiveList.

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

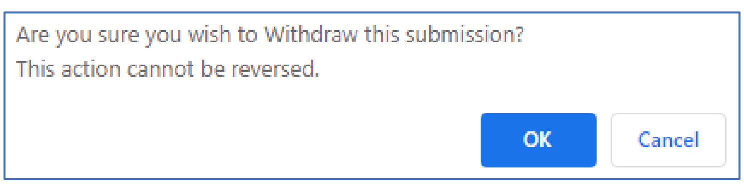
An initial application or follow-on submission can be withdrawn after you have submitted a submission but before it has been approved.

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	

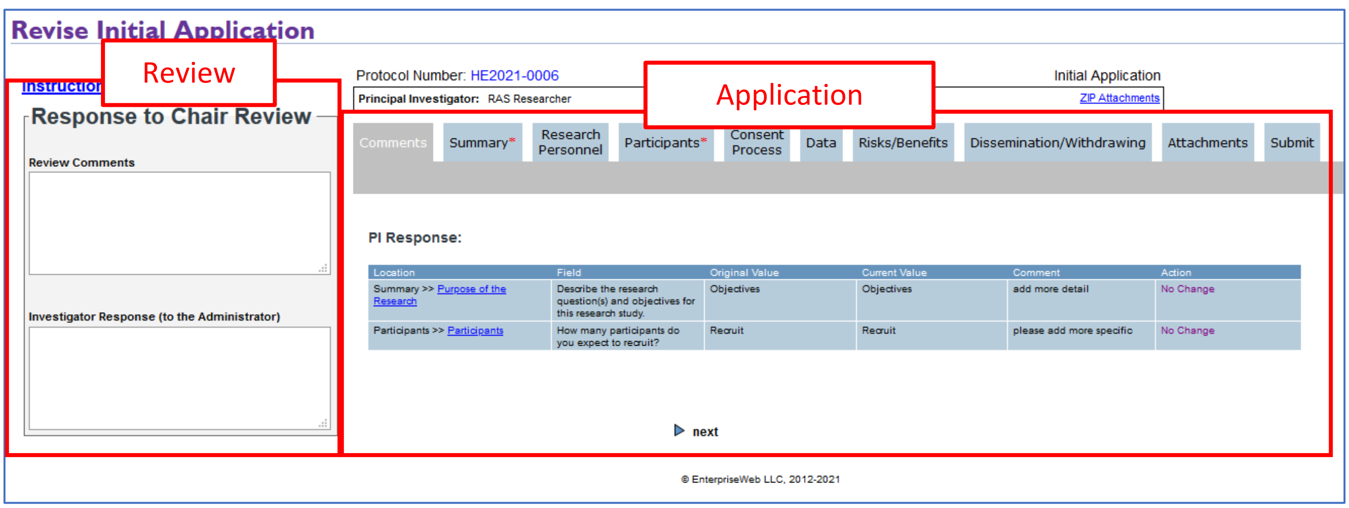
Revisions Required

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

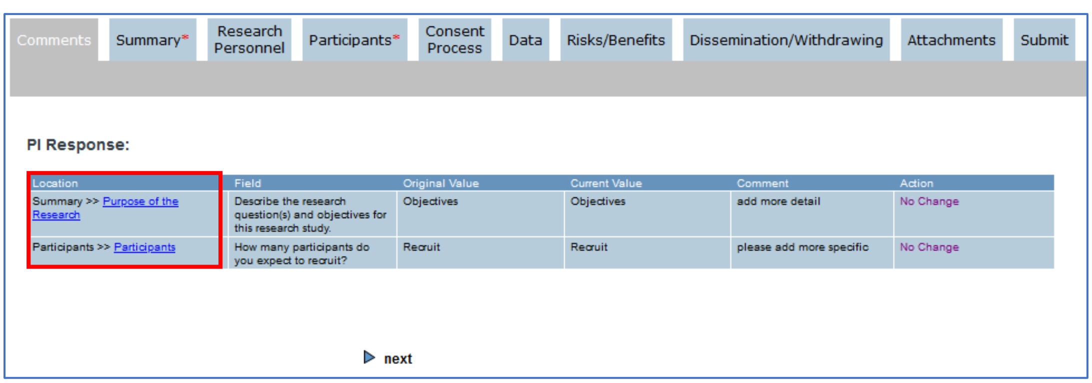
1. Under the **To Do List**, find the Revise task
2. Click the link within the task

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.

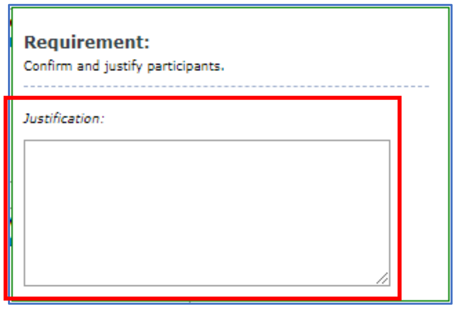


4. The **Comments** tab provides a summary of all comments made
5. Click on the link under **Location** to bring you to each comment to review

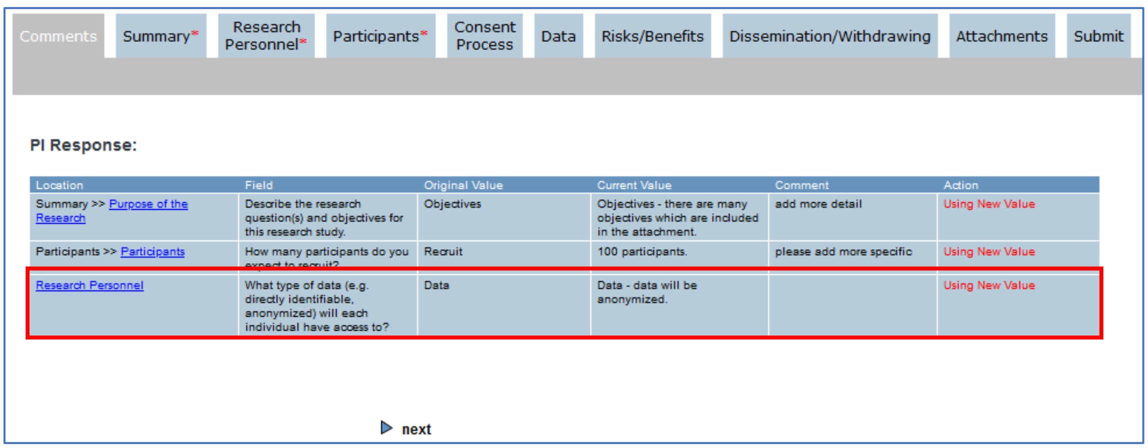


Note: Any comments made will also be indicated with a * on the tab within the Application section.

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

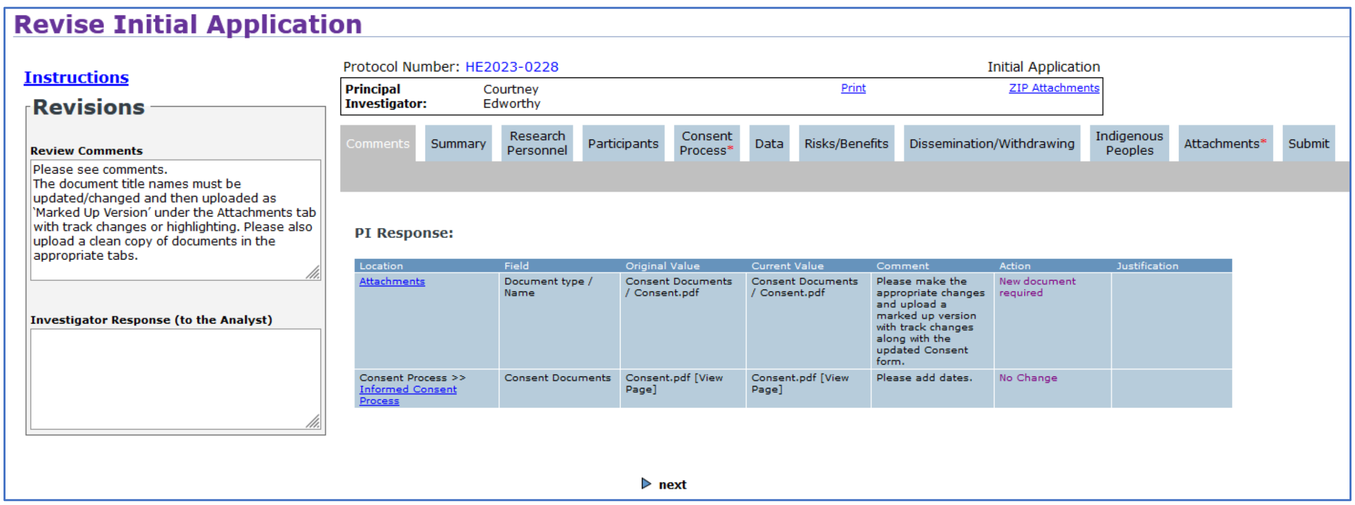
The revision has now been sent to the Advisor for review and final sign-off.

Attachments: Marked-Up Versions

A Marked-Up Version of a document is a copy that includes track changes to indicate changes made. These documents must be uploaded in the Attachments tab along with a copy of a clean version of the document.

Important: The marked-up version is not part of the final approval. This means you will not see this copy once the submission is approved only the clean version.

Note: Depending on where you are in the submission process or what type of submission you are revising, the Marked-Up Version section in the Attachments tab may look sightly different. The example below is of an Initial Application returned to the PI for after a pre-review.



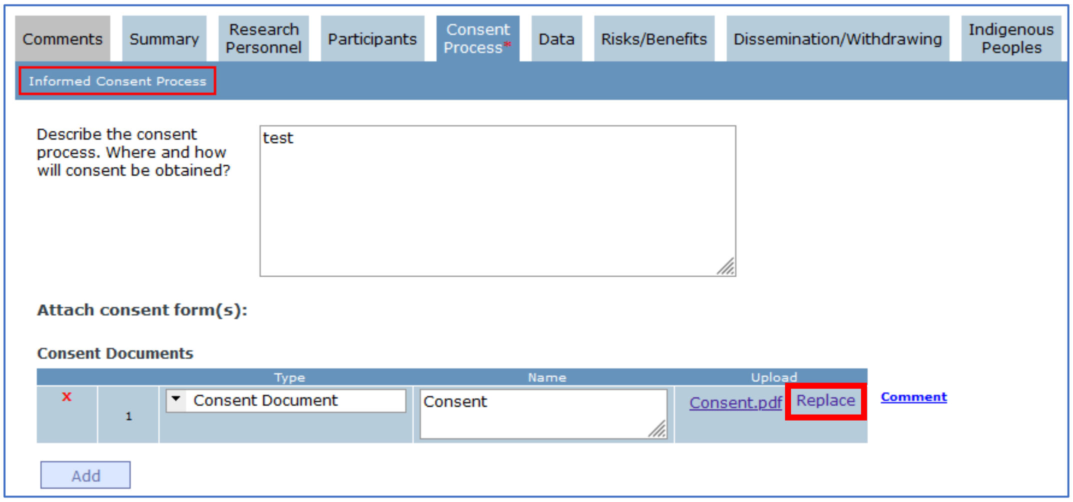
Upload Clean & Marked-Up Version

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

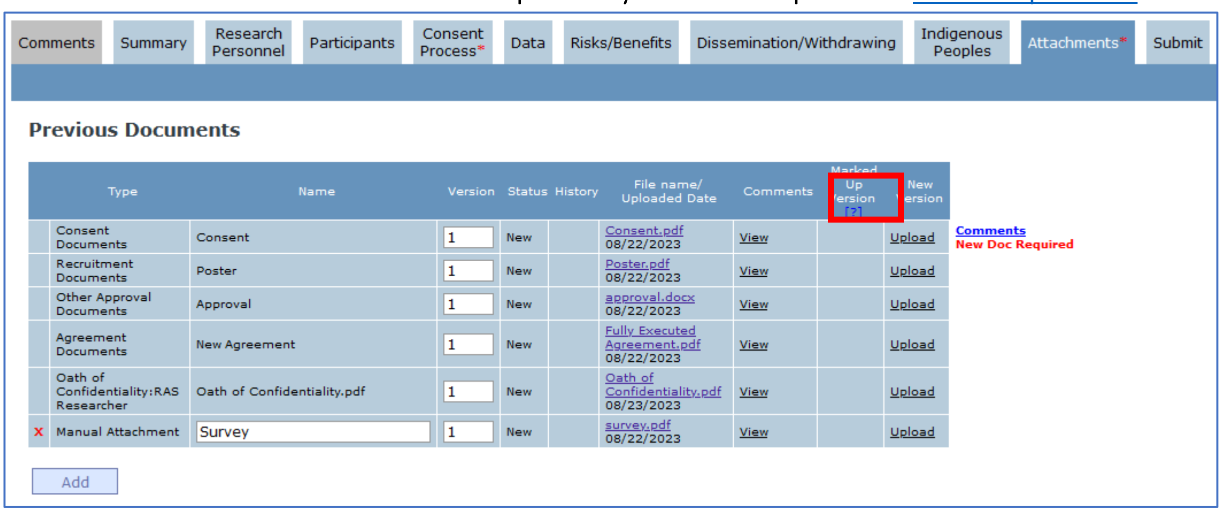
1. Navigate to the designated tab, in this example the **Consent Process** tab
2. Click **Replace**, find and **Upload** the <u>clean version</u> of the document



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

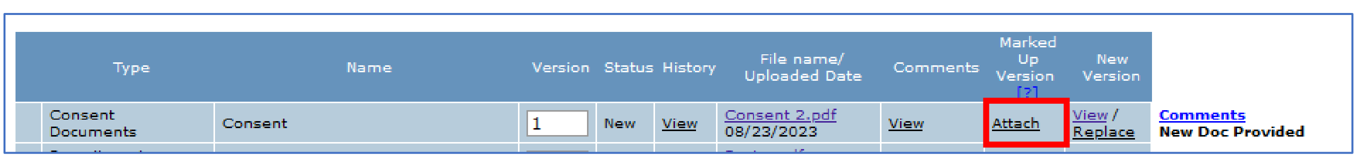
Attachments Tab

1. Navigate to the **Attachments** tab
2. Click **Upload** under New Version, find and **Upload** the clean version 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



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**