

How to Submit a Protocol as a Student PI

RAS Training Documentation

Last Modified: June 10, 2022

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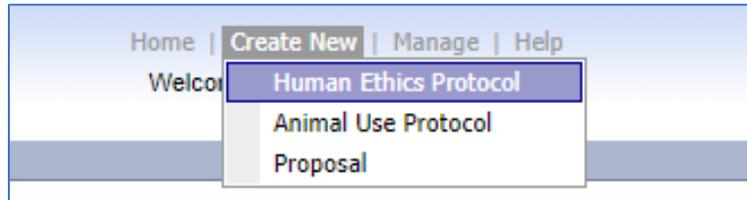
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Initial Application

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

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

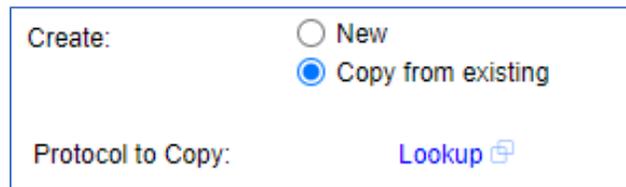
Note: The newly created protocol will receive a temporary protocol number while the application is in development. Once the application is submitted, a final Human Ethics Protocol number will be assigned.



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

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

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

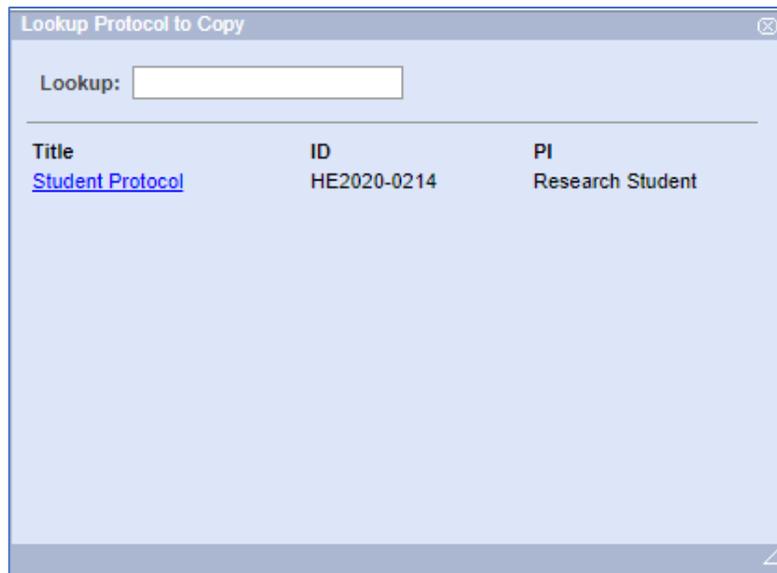


The screenshot shows a form with the following elements:

- Create:**
 - New
 - Copy from existing
- Protocol to Copy:** [Lookup](#) 

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

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



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

Title	ID	PI
Student Protocol	HE2020-0214	Research Student

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

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

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

Create a New Human Ethics Protocol

Create: New Copy from existing

Protocol Title:

Principal Investigator: [Replace](#)

Department:

Complete Initial Application

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

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

Principal Investigator [Replace PI](#)

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

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

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

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: character count: 20

Principal Investigator: Replace PI 

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

What Department is this research being conducted under? replace 

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

Primary Department: replace 

Application Initiated By:

previous   next

Adding Research Personnel

Add additional research personnel to the protocol.

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

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

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

Protocol Personnel

Name	Department	Role	CV	CORE	PHIA	Access	CC	Contact Details	Contact Level
Research Student	Chemistry	Principal Investigator		08/21/2020 Import	08/21/2020 Import	Signature Authority		Contact Details	Primary
<input type="button" value="Add"/>									

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

Find Person ✕

Lookup: [Go](#)

Name	ID	Department
Advisor, Research Student	RAS_Advisor	Chemistry
Advisor, Student	STDNT_ADV	Microbiology

4. Click on the users' name to add them to the protocol
5. Once they are added, complete the following:
 - a. Select **Department:** this default to the users' primary department
 - b. Select **Role:** this is the user's role for this specific protocol
 - c. Import **CV:** this is the user's CV, optional (not required for Human Ethics Fort Garry)
 - d. Import **CORE:** click **Import** to link the users CORE certificate
Note: all personnel must have CORE added to their user profile in the system. If they do not you must contact that person to get them to add it prior to submitting the protocol.
 - e. Import **PHIA:** click **Import** to link the users PHIA certificate
Note: this is only required for the PI & Advisor prior to **submission** for studies that involve personal health information, all other research personnel must have this added to their profile for import prior to **approval**.
 - f. Assign **Access:** this is the user's access to this protocol
 - i. **Edit Access:** Gives the user edit access to the protocol. Usually given to Study Coordinators.
 - ii. **No Access:** Given to users that do not need to access the protocol in the system.

- iii. **Read-Only Access:** Given to user that can access the protocol but only have read-only access, meaning they cannot edit the protocol.
- iv. **Signature Authority:** This gives the user signing authority on the protocol
Note: Only the PI, Co-PI and Advisor roles can receive signing authority.
- g. Check the **CC** checkbox to have the user cc'd on all email notifications
- h. **Oath of Confidentiality:** click attach to upload the user's oath of confidentiality
Note: this is required to be uploaded for each protocol personnel except for the PI, CO-PI and Advisor
- i. Choose the **Contact Level:** Primary or Secondary

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	<input checked="" type="checkbox"/>		Contact Details	Primary
X	John Co-Investigator	Nursing	Co-Investigator		01/01/2021 Import	01/14/2020 Import	Edit Access	<input type="checkbox"/>	Oath of Confidentiality.pdf X	Contact Details	Secondary

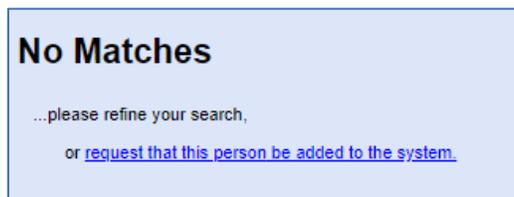
[Add](#)

Add On-The-Fly User

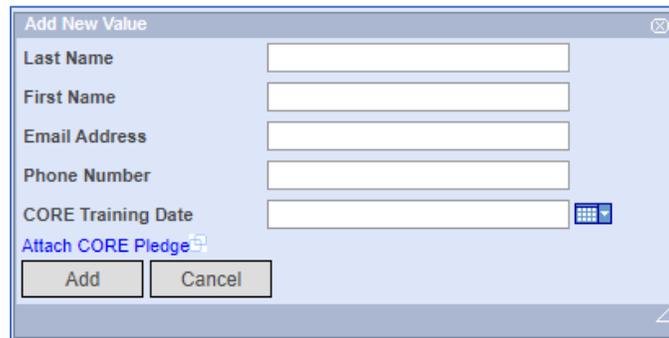
If you can't find someone in the Find Person lookup window when trying to add them to the research personnel table, you can add them on-the-fly.

Important: Most UM research personnel will be in the lookup. On-the-fly users are most likely external to the UM or students. Only **one** external research personnel is allowed **edit** or **view only** access to a protocol. Multiple no access external personnel may be added to the protocol. All on-the-fly personnel are reviewed by the Ethics Office at submission. If this rule is violated the protocol will be sent back to the PI to adjust.

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



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



Add New Value

Last Name

First Name

Email Address

Phone Number

CORE Training Date 

Attach CORE Pledge 

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**



X New Staff External Research Assistant 04/01/2021 Import No Access Attach Contact Details Primary

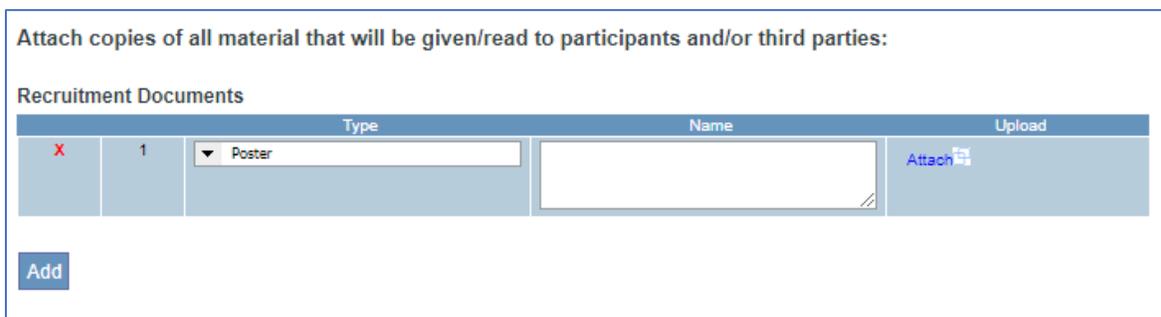
Once the application/submission has been submitted to the Ethics Office, a task will be sent to ORS to add this new user to the system.

How to Add a Document

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

Here is the Participants > Recruitment subtab

1. Click **Add**



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

Recruitment Documents

	Type	Name	Upload
X 1	Poster	<input type="text"/>	Attach 

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

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

View All Documents

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

Here you can view and/or add additional documents.

Documents								
Type	Name	Version	Status	History	File Name/ Uploaded Date	Comments	Actions	
Recruitment Documents	Poster.pdf	1	New		Poster.pdf 10/13/2020		View	
Consent Documents	Consent.pdf	1	New		Consent.pdf 10/13/2020		View	
Observation Guide Document	Consent.pdf	1	New		Consent.pdf 10/13/2020		View	

[Add](#)

To continue the instruction 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 Student PI:

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

Amendment Summary	Summary	Research Personnel	Participants	Consent Process	Data	Risks/Benefits	Dissemination/Withdrawing	Attachments	Submit
<p>Please provide a brief summary of the requested changes</p> <div style="border: 1px solid black; height: 60px;"></div>									
<p>Please provide a justification for these changes</p> <div style="border: 1px solid black; height: 60px;"></div>									
<p>Will there be changes to the number of participants? <input type="radio"/> Yes <input type="radio"/> No</p>									
<p>Will there be any changes in recruitment? <input type="radio"/> Yes <input type="radio"/> No</p>									
<p>Will there be changes in recruitment material? <input type="radio"/> Yes <input type="radio"/> No</p>									
<p>Will there be any changes to the consent form? <input type="radio"/> Yes <input type="radio"/> No</p>									
<p>Will participants need to be re-consented? <input type="radio"/> Yes <input type="radio"/> No</p>									
<hr/>									
<p>Summary of Changes:</p> <p><i>No Changes</i></p>									

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

Personnel Changes Summary Research Personnel Attachments Submit

Please provide a brief summary of the requested changes

Does this change affect documents participants will see (ie. recruitment poster, consent form)? Yes No

Summary of Changes:

No Changes

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

Amendment Summary Summary Research Personnel Participants Consent Process Data Risks/Benefits Dissemination/Withdrawing Attachments Submit

Please provide a brief summary of the requested changes

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

Justification:

Adding more people to the cohort.

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

Amendment Summary	Summary	Research Personnel	Participants*	Consent Process	Data	Risks/Benefits	Dissemination/Withdrawing	Attachments	Submit
Participants - Recruitment									
How many participants do you expect to recruit?		<p>We anticipate that approximately 45 adults between the ages of 50-70 will participate in one of three Turning Pages groups offered in 2018.</p> <p>Need to increase to 100 adults.</p> <p>A change based on the request.</p>					Amended		

- e. A summary of changes will appear in the **Amendment Summary** tab or **Personnel Change Summary** tab. This will include the previous value and the new value as well as the justification that was added

Summary of Changes:

Location	Field	Original Value	New Value	Action	Justification
Participants >> Participants	How many participants do you expect to recruit?	We anticipate that approximately 45 adults between the ages of 50-70 will participate in one of three Turning Pages groups offered in 2018. Need to increase to 85 adults. A change based on the request.	We anticipate that approximately 45 adults between the ages of 50-70 will participate in one of three Turning Pages groups offered in 2018. Need to increase to 100 adults. A change based on the request.	Using New Value	Adding more people to the cohort.

Renewal Request

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

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

Renewal Request Attachments Submit

Have there been changes to the protocol design that have not been approved by the REB? Yes No

Provide a brief summary of the progress of the study.

Please brief justification for the renewal request.

previous ◀ ▶ next

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REB Event

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

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

Protocol Number: HE2021-0015 REB Event

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

REB Event Attachments Submit

Description of Event ?

What actions will be taken to rectify this event?

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

Please explain:

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

previous ◀ ▶ next

Protocol Closure

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

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

Protocol Number: HE2021-0015 Protocol Closure

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

Protocol Closure Attachments Submit

Is communication with participants complete (ex. recruitment, data collection, summary of findings, member checking)? Yes No [?](#)

Please provide a brief summary of the outcome of the study and progress in meeting the study objectives.

Were there any problems encountered in this study? Yes No

previous ◀ ▶ next

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Save Initial Application or Follow-On Submission

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

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



Continue Saved Initial Application or Follow-On Submission

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

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



Submit an Initial Application or Follow-On Submission

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

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

To Submit an Initial Application or Follow-On Submission:

1. Complete each question contained within each of the tabs and sub tabs of the form
2. When all questions have been addressed navigate to the **Submit** tab
3. Enter any desired **Submission Notes** in the field provided
4. Read and check each of the **Declaration Statements**

Initial Application Submission

Optional Submission Notes

- I have reviewed the protocol contents and confirm that the information provided in this application is complete and correct.
- I agree to abide by the ethical guidelines and policies of the REB, including the Tri-Council Policy Statement and the University of Manitoba Policy on the Ethics of Research Involving Humans.
- I will ensure the study does not commence until the final certificate of approval has been issued by the REB.
- I will ensure the study does not commence until approval has been granted by the appropriate organization, if applicable (e.g. chief and council, school board).
- I will ensure all research team members (e.g. faculty, students, staff) handling data will have the appropriate training (e.g. CORE, PHIA).
- I will ensure that study personnel are qualified, appropriately trained and will adhere to the REB-approved application.
- I will notify the REB of any protocol changes and report adverse events/experiences as soon as possible.
- I will submit any changes to this study to the appropriate REB for consideration before implementation.
- I will submit a request for annual approval to the REB prior to the expiry date indicated on the approval certificate.
- I will submit a Study Closure Form to the REB when all study activity is completed at the local site.
- By providing my signature, I confirm that I have read the above terms and agree to comply with this and other university policies, guidelines and the Tri-Council Policy Statement (TCPS).
- I Agree (PI) (signed 10/16/2020, 11:59:02 AM by Research Student)

[Send for Review](#)

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

[Send to CO-PI](#)

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

- Send Initial Application back to the PI for review? (Select this option only if you have made changes to the Initial Application, and want the PI to review them)
- I Agree (CO-PI)

6. Click **Send for Review**

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

Errors on the Initial Application or Follow-On Submission

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

Incomplete Application

The Initial Application submission is incomplete.

Please address the errors highlighted throughout the application form and resubmit.

[Return](#)

Click **Return**

The form will return to the first error on your form. Errors are indicated by a red asterisk on the tab along with a red box around the subtab. Once you select the location of the error, the individual question will be marked with Required beside it.

Correct Errors

Protocol Number: TEMP-HE2020-0255My New ProtocolInitial Application

Principal Investigator: RAS ResearcherStatus: Correcting Errors/Omissions [Print](#)

SummaryResearch PersonnelParticipantsConsent ProcessDataRisks/BenefitsDissemination/Withdrawing *AttachmentsSubmit

Feedback - Withdrawing

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

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

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

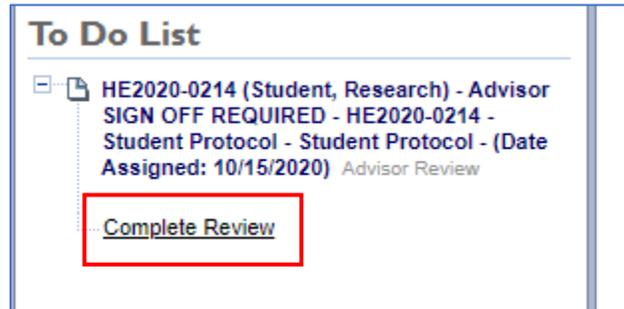
The application has now been sent to the Advisor for review and final sign-off.

Advisor Sign-Off

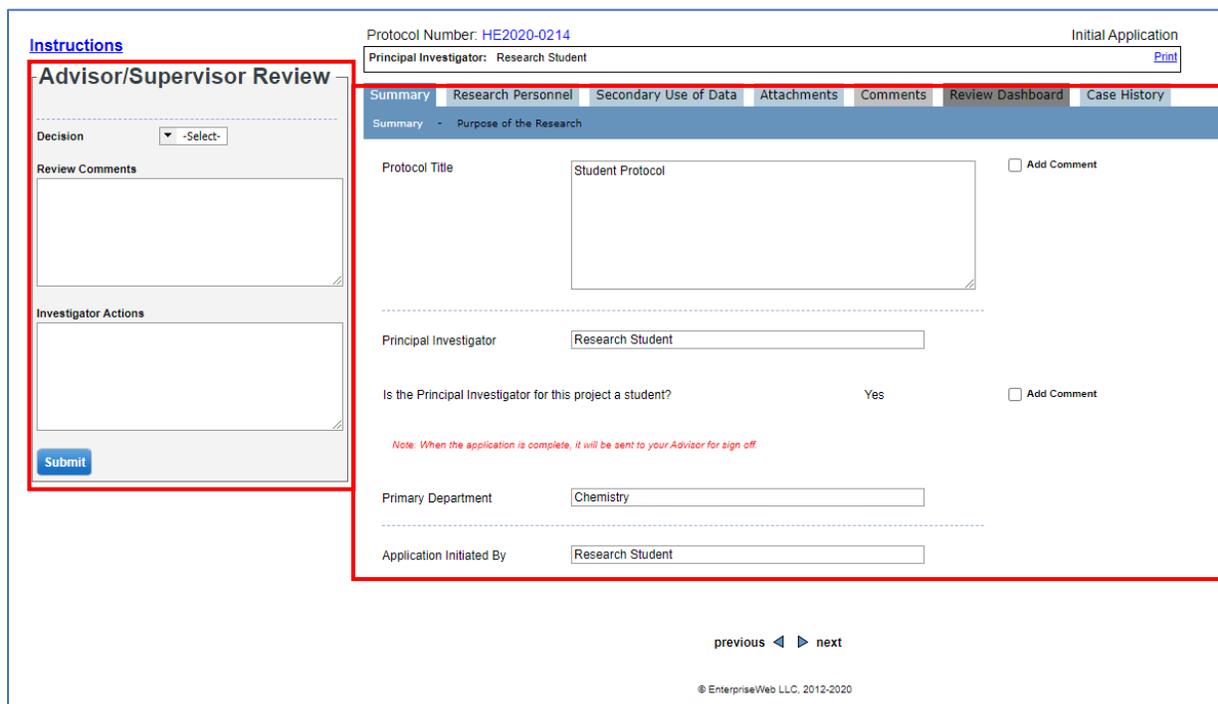
The Advisor will receive an email notification along with a **To Do List** task to sign off on the initial application or follow-on submission.

To review the initial application or follow-on submission:

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



2. There are 2 main sections in this view: **Advisor/Supervisor Review** and **Application** section



3. Navigate through the tabs and subtabs of the application section and review the answers to each question
4. To add additional comments to a specific question, check the box next to **Add Comment**, a text box will appear where you can add comments

Protocol Number: [HE2020-0214](#) Initial Application

Principal Investigator: Research Student [Print](#)

Summary | Research Personnel | Secondary Use of Data | Attachments | Comments | Review Dashboard | Case History

Who currently has custody of the records/database/materials to be used? qwerty

Add Comment
add more detail

5. After you add comments, they will be summarized in the **Comments** tab of the submission

Protocol Number: [HE2020-0214](#) Initial Application

Principal Investigator: Research Student [Print](#)

Summary | Research Personnel | Secondary Use of Data* | Attachments | Comments | Review Dashboard | Case History

Summary of New Comments:

Location	Field	Current Value	Comment
Secondary Use of Data	Who currently has custody of the records/database/materials to be used?	qwerty	add more detail

6. In the Advisor/Supervisor Review section add the following information:
- Decision – select either [Revisions Required](#) or [Approved](#)
 - Review Comments – enter general comments regarding the review, if applicable
 - Investigator Actions – enter any actions you wish the Student PI to take, if applicable

[Instructions](#)

Advisor/Supervisor Review

Decision

Review Comments
Looks good so far, please add more detail where noted.

Investigator Actions

7. Click **Submit** to complete the review of the application

Revisions Required

If there are Revisions Required, the application/submission will be sent back to the PI to address the protocol comments the advisor provided.

The PI will receive an email notification and a **To Do List** task.

1. Click on the Revise link in the To Do List

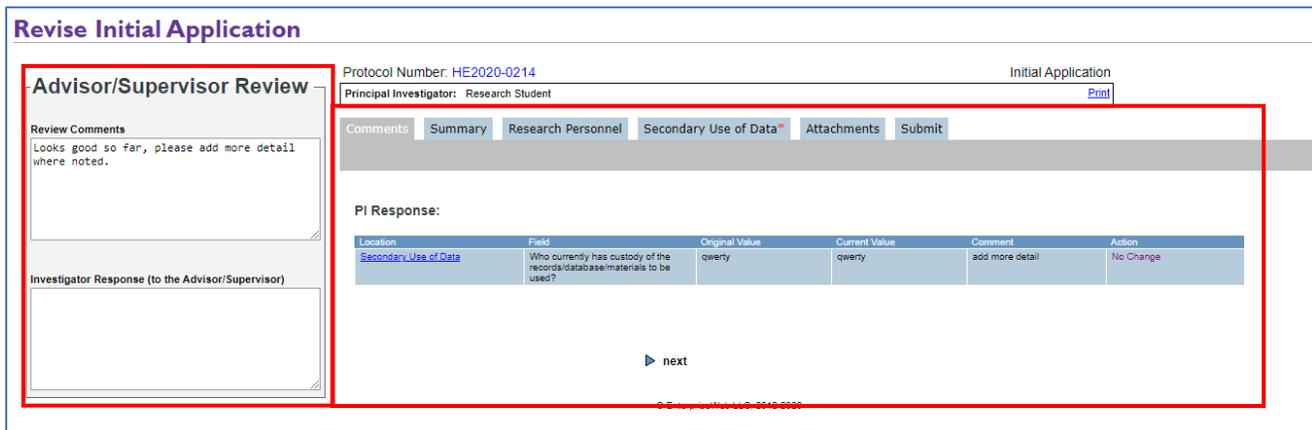


To Do List

HE2020-0214 (Student, Research) - Revise Initial Application (HE2020-0214) - (Submitted:) - Student Protocol - (Date Assigned: 10/15/2020) Revisions Required

[Revise Initial Application](#)

2. There are 2 main sections in this view: **Advisor/Supervisor Review** and **Application** section



Revise Initial Application

Protocol Number: [HE2020-0214](#) Initial Application

Principal Investigator: Research Student [Print](#)

Comments Summary Research Personnel **Secondary Use of Data*** Attachments Submit

Review Comments
Looks good so far, please add more detail where noted.

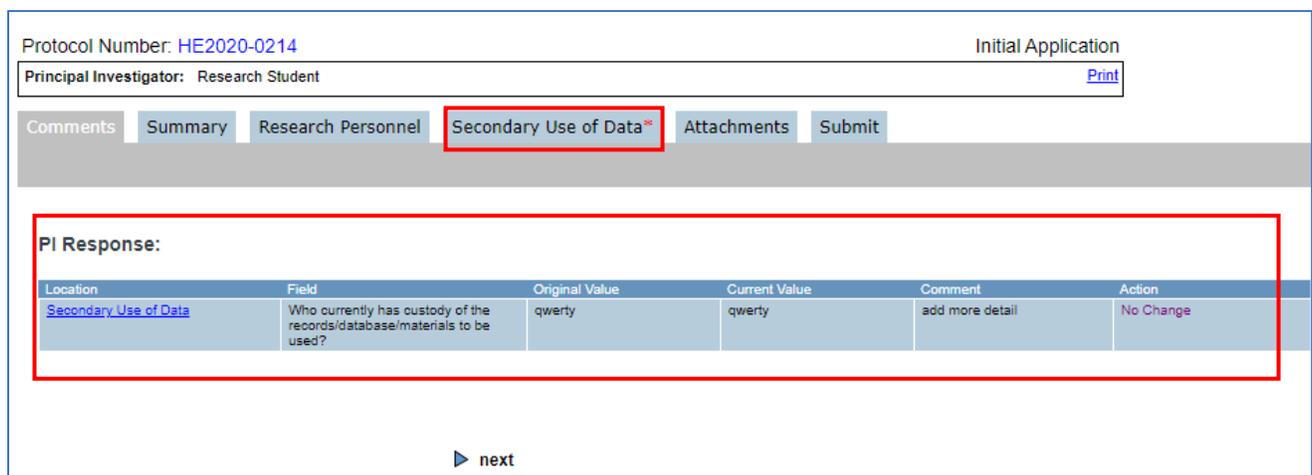
Investigator Response (to the Advisor/Supervisor)

PI Response:

Location	Field	Original Value	Current Value	Comment	Action
Secondary Use of Data	Who currently has custody of the records/database/materials to be used?	qwerty	qwerty	add more detail	No Change

▶ next

3. Comments are marked with a red asterisk, or you can click on the link in the Comments tab of the Application section



Protocol Number: [HE2020-0214](#) Initial Application

Principal Investigator: Research Student [Print](#)

Comments Summary Research Personnel **Secondary Use of Data*** Attachments Submit

PI Response:

Location	Field	Original Value	Current Value	Comment	Action
Secondary Use of Data	Who currently has custody of the records/database/materials to be used?	qwerty	qwerty	add more detail	No Change

▶ next

4. Hover over the Comment to view what the advisor has said.
5. After you have made a change to the field in questions, you will see Using New Value

Who currently has custody of the records/database/materials to be used?	Records are the property of the <u>UofM</u> .	Comment Using New Value
---	---	--

6. Once all comments have been addressed navigate to the Advisor/Supervisor Review section, add additional information back to the Advisor in **Investigator Response**

Advisor/Supervisor Review

Review Comments

Looks good so far, please add more detail where noted.

Investigator Response (to the Advisor/Supervisor)

Thank you for your comments, I have updated that answer.

7. Submit the form again by going to the Submit tab and click **I Agree**

Comments Summary Research Personnel Secondary Use of Data* Attachments Submit

Initial Application Submission

Optional Submission Notes

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

I agree to abide by the ethical guidelines and policies of the REB, including the Tri-Council Policy Statement and the University of Manitoba Policy on the Ethics of Research Involving Humans.

I will ensure the study does not commence until the final certificate of approval has been issued by the REB.

I will ensure the study does not commence until approval has been granted by the appropriate organization, if applicable (e.g. chief and council, school board).

I will ensure all research team members (e.g. faculty, students, staff) handling data will have the appropriate training (e.g. CORE, PHIA).

I will ensure that study personnel are qualified, appropriately trained and will adhere to the REB-approved application.

I will notify the REB of any protocol changes and report adverse events/experiences as soon as possible.

I will submit any changes to this study to the appropriate REB for consideration before implementation.

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

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

By providing my signature, I confirm that I have read the above terms and agree to comply with this and other university policies, guidelines and the Tri-Council Policy Statement (TCPS).

I Agree (PI)

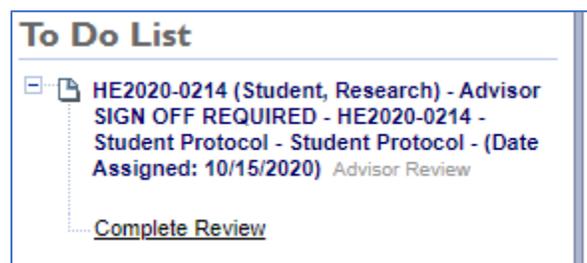
The submission will be sent back to the advisor for review and sign-off.

Review Investigator Response

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

To review the Investigators Response submission:

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



2. View the investigators responses and comments under **Results & Comments** tab

Protocol Number: HE2020-0214 Initial Application
Principal Investigator: Research Student [Print](#)

Results & Comments | Summary | Research Personnel | Secondary Use of Data* | Attachments | Review Dashboard | Case History

Advisor/Supervisor Review

Decision: -Select-

Review Comments

Investigator Actions

[Submit](#)

Advisor/Supervisor Review

Previous Review Comments:
Looks good so far, please add more detail where noted.

Investigator Response to Previous Comments:
Thank you for your comments, I have updated that answer.

PI Response:

Location	Field	Original Value	Current Value	Comment	Action
Secondary Use of Data	Who currently has custody of the records/database/materials to be used?	qwerty	Records are the property of the UofM.	add more detail	Using New Value

Summary of New Comments:
No Comments

- Navigate through the tabs and subtabs of the application section with the red asterisks to review each answer

Who currently has custody of the records/database/materials to be used?

Records are the property of the UofM.

Add Comment

[Previous Comments](#)
[Using New Value](#)

- View each of the initial advisor comment by hovering over **Previous Comments**

Comment:
Previous Review 1: add more detail

- View the previous answer before it was changes by the PI by hovering over **Using New Value**

Change History:
Prior Value qwerty

- In the Advisor/Supervisor Review section add the following information:
 - Decision:** select either Revisions Required or Approved
 - Review Comments:** enter general comments regarding the review, if applicable
 - Investigator Actions:** enter any actions you wish the Investigator to take, if applicable

Approve Submission

1. Under Decision select **Approve**
2. Check each of the declaration statements to provide your approval
3. Click **Submit**

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

Instructions

Advisor/Supervisor Review

Decision

The following declarations must be acknowledged. Once read and agreed to, please check them off.

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

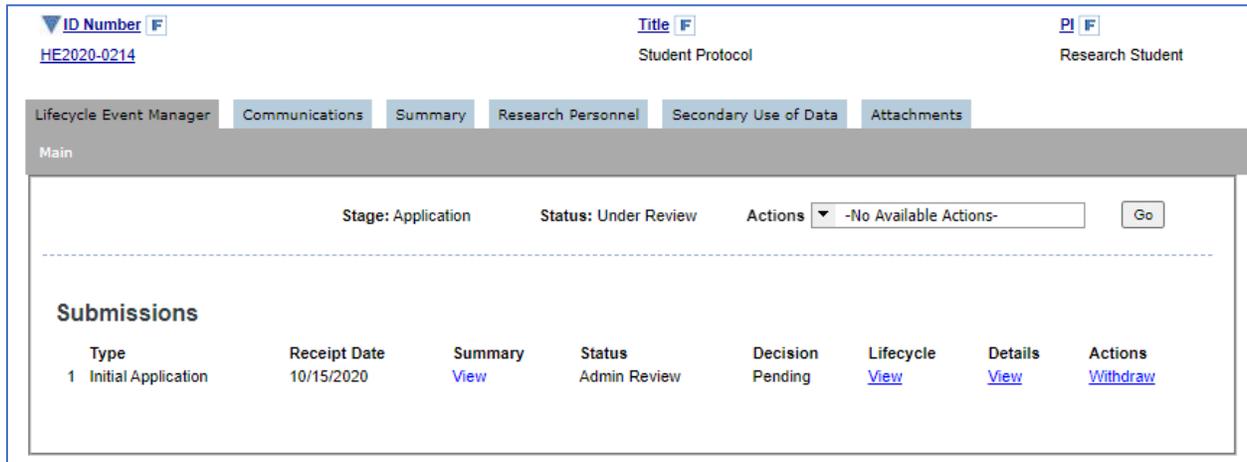
Review Comments

Investigator Actions

After Submission

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

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



The screenshot shows the 'LiveList' interface for a submission with ID HE2020-0214. The title is 'Student Protocol' and the user is 'Research Student'. The interface includes tabs for 'Lifecycle Event Manager', 'Communications', 'Summary', 'Research Personnel', 'Secondary Use of Data', and 'Attachments'. The 'Main' section displays the submission stage as 'Application' and status as 'Under Review'. Below this is a table of submissions:

Type	Receipt Date	Summary	Status	Decision	Lifecycle	Details	Actions
1 Initial Application	10/15/2020	View	Admin Review	Pending	View	View	Withdraw

3. To view the current Lifecycle History of this submission, click on the **View** link under Lifecycle
 - a. The Lifecycle History window will appear, this tells you where the submission is



The 'Lifecycle History' window displays the following events:

- Event #1: New Human Ethics Protocol Created**
Who: Research Student | Start: 10/15/2020 | End: 10/15/2020
Result: Initial Application Completed
- Event #2: Advisor/Supervisor Review**
Who: Student Advisor | Start: 10/15/2020 | End: 10/15/2020
Result: Advisor/Supervisor Review Complete
- Event #3: Advisor/Supervisor Revisions Required**
Who: Research Student | Start: 10/15/2020 | End: 10/15/2020
Result: Submission Returned to Advisor
- Event #4: Advisor/Supervisor Review**
Who: Student Advisor | Start: 10/15/2020 | End: 10/15/2020
Result: Advisor/Supervisor Review Complete
- Event #5: Initial Application Being Processed**
Currently with: **Human Ethics Officer**
Started: 10/15/2020

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

Protocol: HE2020-0214 **Submission Type: Initial Application** [Print](#)

Review Dashboard Summary Research Personnel Secondary Use of Data Attachments

Advisor/Supervisor Approval

Date	Duration	Type
10/15/2020	-1 days, -5 hrs, -53 mins	Advisor Review

Version 1

Date	Duration	Type	Process	Board	Decision
10/15/2020		Analyst	Administrative		

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

Withdraw Initial Application or Follow-On Submission

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

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

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

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

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

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

Submissions

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

Revisions Required

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

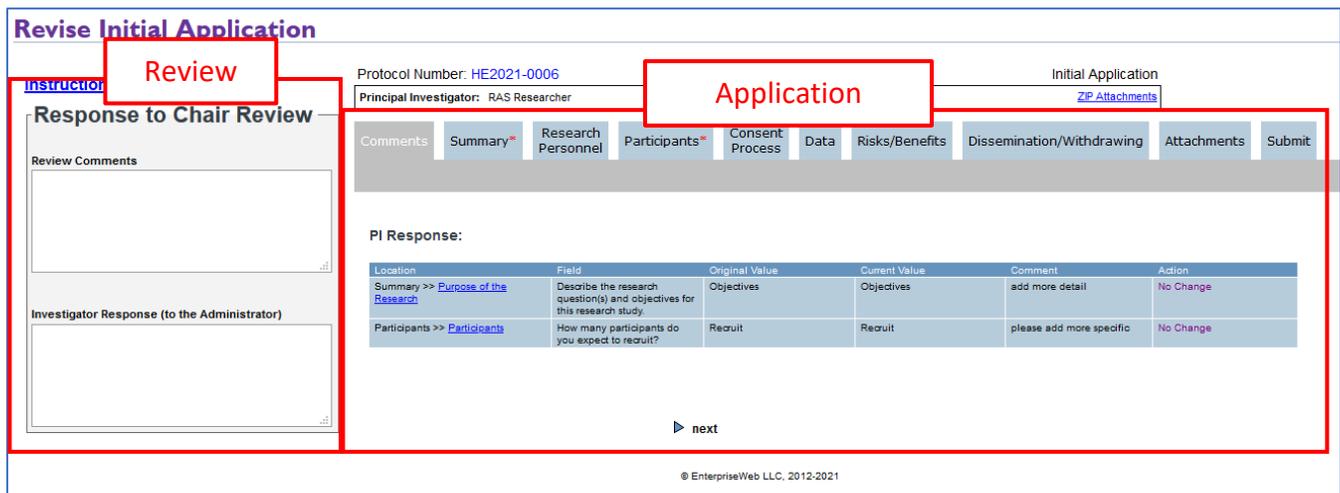
1. Under the **To Do List**, find the Revise task
2. Click the link within the task



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

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

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

▶ next

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

6. Make the appropriate changes to each question based on comments provided
7. If Justification is required, add your justification to the popup box that appears beside the question

Note: Justification is mandatory, you must fill in a response.

Requirement:
Confirm and justify participants.

Justification:

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

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

Location	Field	Original Value	Current Value	Comment	Action
Summary >> Purpose of the Research	Describe the research question(s) and objectives for this research study.	Objectives	Objectives - there are many objectives which are included in the attachment.	add more detail	Using New Value
Participants >> Participants	How many participants do you expect to recruit?	Recruit	100 participants.	please add more specific	Using New Value
Research Personnel	What type of data (e.g. directly identifiable, anonymized) will each individual have access to?	Data	Data - data will be anonymized.		Using New Value

▶ next

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

Instructions

Response to Chair Review

Review Comments

Investigator Response (to the Administrator)

10. Navigate to the **Submit** tab and resubmit the application/submission
The revision has now been sent to the Advisor for review and final sign-off.