How to Submit a Protocol as a PI

RAS Training Documentation

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Questions? Contact: RAS_Support@umanitoba.ca
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Questions? Contact: [RAS_Support@umanitoba.ca](mailto:RAS_Support@umanitoba.ca)
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
      
      ![Lookup Protocol to Copy](image)
      
      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

Create a New Human Ethics Protocol

Create:  
- New
- Copy from existing

Protocol Title: 

Principal Investigator:  RAS Researcher  Replace

Department:  Max Rady College of Medicine

Begin Application  Cancel

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

---

**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 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.

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Questions? Contact: **RAS_Support@umanitoba.ca**
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](image)

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**

![Participants Recruitment](image)

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**

![No Matches](image)

Questions? Contact: [RAS_Support@umanitoba.ca](mailto:RAS_Support@umanitoba.ca)
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

   Please provide a brief summary of the requested changes:

   Please provide a justification for these changes:

   Will there be changes to the number of participants?  
   - [ ] Yes  
   - [ ] No

   Will there be any changes in recruitment?  
   - [ ] Yes  
   - [ ] No

   Will there be changes in recruitment material?  
   - [ ] Yes  
   - [ ] No

   Will there be any changes to the consent form?  
   - [ ] Yes  
   - [ ] No

   Will participants need to be re-consented?  
   - [ ] Yes  
   - [ ] No

   Summary of Changes:

   No Changes

   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.

<table>
<thead>
<tr>
<th>Amendment Summary</th>
<th>Summary</th>
<th>Research Personnel</th>
<th>Participants</th>
<th>Consent Process</th>
<th>Data</th>
<th>Risks/Benefits</th>
<th>Dissemination/Withdrawing</th>
<th>Attachments</th>
<th>Submit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please provide a brief summary of the requested changes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Summary of Changes:**

*No 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**

Questions? Contact: RAS_Support@umanitoba.ca
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.

![Image of interface showing tab and subtab changes]

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.

![Image of summary of changes table]

### Summary of Changes:

<table>
<thead>
<tr>
<th>Location</th>
<th>Field</th>
<th>Original Value</th>
<th>New Value</th>
<th>Action</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>How many participants do you expect to recruit?</td>
<td>We anticipate that approximately 45 adults between the ages of 50-70 will participate in one of three Turning Pages groups offered in 2010. Need to increase to 100 adults. A change based on the request.</td>
<td>We anticipate that approximately 45 adults between the ages of 50-70 will participate in one of three Turning Pages groups offered in 2010. Need to increase to 100 adults. A change based on the request.</td>
<td>Using New Value</td>
<td>Adding more people to the cohort</td>
</tr>
</tbody>
</table>
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
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 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.

![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**

<table>
<thead>
<tr>
<th>Submissions</th>
<th>Type</th>
<th>Receipt Date</th>
<th>Summary</th>
<th>Status</th>
<th>Decision</th>
<th>Lifecycle</th>
<th>Details</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Initial Application</td>
<td>08/23/2023</td>
<td>View</td>
<td>Revisions</td>
<td>Pending</td>
<td>View</td>
<td>View</td>
<td>Withdraw</td>
<td>Reassign Task</td>
</tr>
</tbody>
</table>

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

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

Questions? Contact: [RAS_Support@umanitoba.ca](mailto:RAS_Support@umanitoba.ca)
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 the link within the task

Questions? Contact: RAS_Support@umanitoba.ca
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

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**Figure 4: Example of the Initial Application**
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

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.

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.

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

Questions? Contact: RAS_Support@umanitoba.ca
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**

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

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

Questions? Contact: [RAS_Support@umanitoba.ca](mailto:RAS_Support@umanitoba.ca)
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

![To Do List](image)

**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.

![Revise Initial Application](image)

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

Questions? Contact: [RAS_Support@umanitoba.ca](mailto:RAS_Support@umanitoba.ca)
Note: Any comments made will also be indicated with an * 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

![Investigator Response](image)

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

The revision has now been 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 slightly different. The example below is of an Initial Application returned to the PI for after a pre-review.

![Initial Application](image)

Questions? Contact: [RAS_Support@umanitoba.ca](mailto:RAS_Support@umanitoba.ca)
Upload Clean & Marked-Up Version
To upload the marked-up version you must replace/upload a new “clean” version of the document then the marked-up version.

There are two ways to upload the clean version: Under the designated tab (i.e. Consent Process for a consent form) or under the Attachments tab.

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

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

Questions? Contact: RAS_Support@umanitoba.ca
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