How to Submit a Protocol as a Designate

RAS Training Documentation

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Questions? Contact: RAS_Support@umanitoba.ca
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Initial Application
To create a new Human Ethics Protocol as a Designate:

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

   ![Create New Menu](image)

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

      ![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
      
      i. When a Designate (i.e. Study Coordinator) is filling out the form for the PI you must replace the Principal Investigator name with the PI’s name.

      1. Click **Replace** to choose the correct PI for this protocol.

      ![Principal Investigator](image)

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

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

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

3. Click **Begin Application**
Complete Initial Application

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

1. If the designate is filling out this form for a Student PI, check off Yes for the question ‘Is the Principal Investigator for this project a student?’. This will ensure they need to also include the student’s advisor in the Research Personnel tab. See the Student PI Submission process for more details on student PIs.
2. Select the role of the Designate under the Role drop down.
3. Navigate through each page and answer each question as they appear within the form.

Adding Research Personnel

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

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

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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 Window](image)

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 user’s 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
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

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.

Questions? Contact: RAS_Support@umanitoba.ca
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**

![Add](image1)

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

![Upload](image2)

**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.

![View All Documents](image3)

Questions? Contact: [RAS_Support@umanitoba.ca](mailto:RAS_Support@umanitoba.ca)
To continue the instructions for an Initial Application, go to:

- [Save Initial Application](#)
- [Submit Initial Application](#)
- [After Submission](#)
Follow-On Submissions

Amendment/Personnel Change

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

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

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

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
```

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

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

   a. When you make a change to any question throughout the application it’s tagged with **Amended (Please Justify)**

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

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

d. A red asterisk will be added to each tab and a red box around the subtab to easily locate any changes to the application

e. A summary of changes will appear in the **Amendment Summary** tab or **Personnel Change Summary** tab. This will include the previous value and the new value as well as the justification that was added.
Renewal Request
To create a new Renewal Request form as a Designate:

1. Select the protocol link from the LiveList
2. Under Actions select Create Renewal Request, click Go
3. Navigate through each tab and answer each question as they appear within the form
REB Event
To create a new REB Event form as a Designate:

1. Select the protocol link from the LiveList
2. Under Actions select Create REB Event, click Go
3. Navigate through each tab and answer each question as they appear within the form
Protocol Closure
To create a new Protocol Closure form as a Designate:

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

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

**Submissions**

<table>
<thead>
<tr>
<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>
</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
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.

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

<table>
<thead>
<tr>
<th>To Do List</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEMP-HE2020-0269 - Create Human Ethics Protocol</td>
</tr>
<tr>
<td>Complete the Initial Application</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>To Do List</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEMP-HE2020-0269 - Create Human Ethics Protocol</td>
</tr>
<tr>
<td>Complete the Initial Application</td>
</tr>
</tbody>
</table>

The PI will also see the new temporary protocol in their LiveList.

<table>
<thead>
<tr>
<th>ID Number</th>
<th>Title</th>
<th>PI</th>
<th>Status</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEMP-HE2020-0269</td>
<td>Proxy Protocol</td>
<td>RAS Researcher</td>
<td>Under Development</td>
<td>Human Ethics</td>
</tr>
</tbody>
</table>

Remember: The PI can reassign this saved application to themselves to complete at any time as well. See Delete or Reassign Task section of the Lifecycle Event Manager for more information.

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. When a Designate is submitting the application, the Declaration Statements will be greyed out, these must be completed by the PI
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 after the PI signs 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 PI for review and signature.

Errors on the Initial Application or Follow-On Submission

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

Click Return

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

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

After the submission has gone through, you can view the protocol in the LiveList.
Investigator Sign-Off

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

To review the initial application or follow-on submission:

1. Click the link in the To Do List

   ![To Do List](image)

2. Click Review/Submit Protocol

3. Navigate and review the whole submission, the PI can add additional information to any questions within the submission at this time as well

4. When all questions have been addressed navigate to the Submit tab

5. Enter any desired Submission Notes in the field provided, optional

6. Read and check each of the Declaration Statements
7. Check the I Agree checkbox to agree to the certification statement
8. Click Send for Review

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

Questions? Contact: RAS_Support@umanitoba.ca
After Submission

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

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

![LiveList Image]

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

![Lifecycle History Image]

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**

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

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

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

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

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

Questions? Contact: RAS_Support@umanitoba.ca
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 PI for review and signature.

**Attachments: Marked-Up Versions**

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

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

**Note:** Depending on where you are in the submission process or what type of submission you are revising, the Marked-Up Version section in the Attachments tab may look slightly 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 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