Human Ethics Submissions

RAS Training Documentation

Last Modified: July 30, 2024

Contents

Questions? Contact: RAS_Support@umanitoba.ca

Navigating the Application Forms

All application forms employ a feature that displays relevant questions and tabs based upon the responses provided throughout the application form. This feature helps to ensure complete application forms.

Its important to note this software uses branching, meaning that some questions or tabs may appear based on answers to previous questions. If you later change an answer to one of the branching questions, some questions/tabs may disappear. If you change your answer back, those questions/tabs will reappear. However, your responses to those questions are not saved so they will be lost.

To navigate throughout the application, you can use the previous and next button at the bottom of the page.
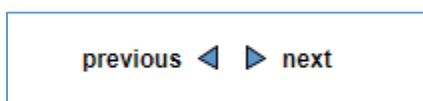
Or you can also click on the tab or subtab to jump to that page as well.

Important: Do not use the back button on your browser, use the Home Button.

Initial Application

An initial application can be submitted by either the PI, Designate or a Student PI.

Important notes about the transition from paper/PDF form to the new system:

- The **Checklist for New Studies** form is no longer required. These questions have been incorporated into the new electronic Initial Application within the system.
- The **Schedule A** form is no longer required. These questions have been incorporated into the new electronic Initial Application within the system.

Application Layout

The application form is composed of tabs and sub tabs. There are tabs and subtabs that are dynamically displayed based upon responses provided within the application form.

You can see the below 2 examples have different requirements as an example of what tabs may appear while filling out the form.

Protocol Number: TEMP-HE2020-0255   Initial Application
Principal Investigator: RAS Researcher   Print

| Summary | Research Personnel | Secondary Use of Data | Attachments | Submit |

Summary -   Purpose of the Research

Protocol Number: TEMP-HE2020-0255   Initial Application
Principal Investigator: RAS Researcher   Print

| Summary | Research Personnel | Participants | Consent Process | Data | Deception | Risks/Benefits | Dissemination/Withdrawing | Indigenous Peoples | Attachments | Submit |

Summary -   Purpose of the Research -   Research -   General Questions

Follow-On Submissions

There are 5 different types of follow-on submissions. These submissions can occur once the initial submission has been approved.

1. Amendment
2. Personnel Change
3. Renewal Request
4. REB Event
5. Protocol Closure

Like the initial application the follow-on submissions employs the same 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.

Follow-on submissions can be submitted by anyone on the protocol that has **edit access** or **signature authority**.

Amendment / Personnel Change

There are two separate forms for amendment changes: **Amendment** and **Personnel Change** submissions.

The Amendment allows you to change/update the current protocol submission currently approved in the system. The Personnel Change allows you to change/update just the research personnel tab within the current protocol submission.

Note: Only one amendment or personnel change can be submitted at a time. If you are updating the current submission as well as the personnel section, you will submit just an amendment. If you only need to update the personnel section, then you will submit a personnel change.

Renewal Request

Protocols are approved for one year only. If your study will continue past one year, please submit a Renewal Request Form before the expiry date.

REB Event

Any adverse events that occur during the study must be reported using the REB Event Form (previously called the Adverse Event Form).

Protocol Closure

If communication with participants in regard to this study is complete, you may submit the Study Closure Form and close the study.

Note: Once the study is closed, you cannot reopen it. A new application, which will undergo review, will need to be submitted in order to continue the study.

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Migrated Protocols
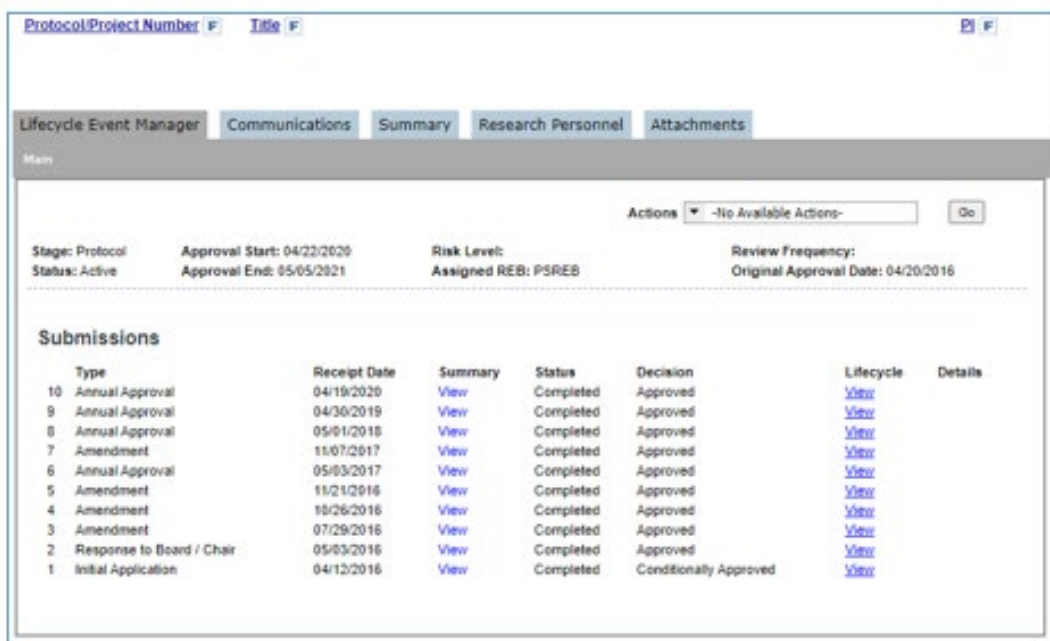
Migrated protocols include any current or historical protocols migrated from our current system to the new system.

How do I know if I am viewing a migrated protocol or not?
The migrated protocol will have an HS***** number and a protocol created in the system will have a HE***** number.

Important: The PI, Co-PI and Advisor/Supervisor will have **Signature Authority** on a protocol migrated into the system. All other roles, including the Co-I, will have **Read-Only Access** to the protocol. If you require any personnel (i.e. Study Coordinator) to have **Edit Access** to your protocol you must submit an **Amendment/Personnel Change** form to update their access.

Example of a Migrated Protocol:

View Migrated Protocol Attachments

All migrated protocol submission documents have been included and are downloadable in the system.

1. Go to the **Attachments** tab in the Lifecycle Event Manager
2. Under the **File Name/Uploaded Date** column, click on the submission pdf link to view/download the file

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Follow-On Submissions for Migrated Protocol

The follow-on submission process for a migrated protocol is the same as for a protocol created in the system with one exception, the Amendment and Personnel Change forms are combined into one.

When submitting this form there will be an option on the Amendment Summary to pick whether you want to submit an Amendment or Personnel change.

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Important: As the protocol was already previously approved with research personnel's CORE/PHIA certificates, these are not required to be uploaded to submit a follow-on submission. It is still important to get all CORE/PHIA certificates added to your profile to submit a new protocol in the system. See Certifications on how to upload your CORE and PHIA.