Bloorview RESEARCH INSTITUTE

Holland Bloorview Kids Rehabilitation Hospital

eREB Applicant Manual

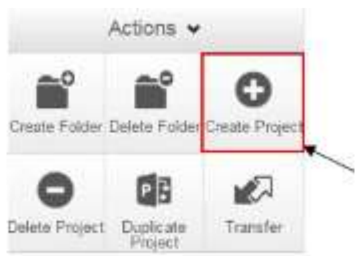
(version 2.0.1, Oct 2020)

Access eREB Platform

1. Launch **Internet Explorer or Google Chrome** and Log In to eREB using the following link: ereb.hollandbloorview.ca. The link can be accessed on or off site.
2. If this is your first time using the eREB platform, you will need to create a new account. To register, click the "**New User**" button. New User **Users are required to utilize their Holland Bloorview email address.**
3. Once registered, the eREB System Administrator will validate your request. Once your account is validated, you will receive a confirmation email from the eREB System Administrator.

Create Project and Begin Initial Application

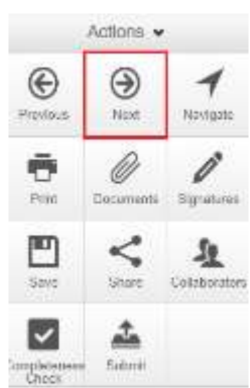
1. Under the Actions menu, select **Create Project** dialog box.



2. Enter the Project Title and click **Create**. This will be used to differentiate studies in the "**Projects**" menu in your Work Area. You will have an opportunity in the application to include your Full Study Tile. Once a project is approved by the REB, the Project Title can only be changed through an amendment.

3. Once the Project has been created, you will be taken directly to the Initial Application and you can start answering questions and uploading documents. Please note the Initial Application is a smart form and sections will appear depending on your answers.

4. Once you arrive to the end of a page, press "Next" to continue to the next section of the application. Selecting any icon on the Actions menu will save your application.

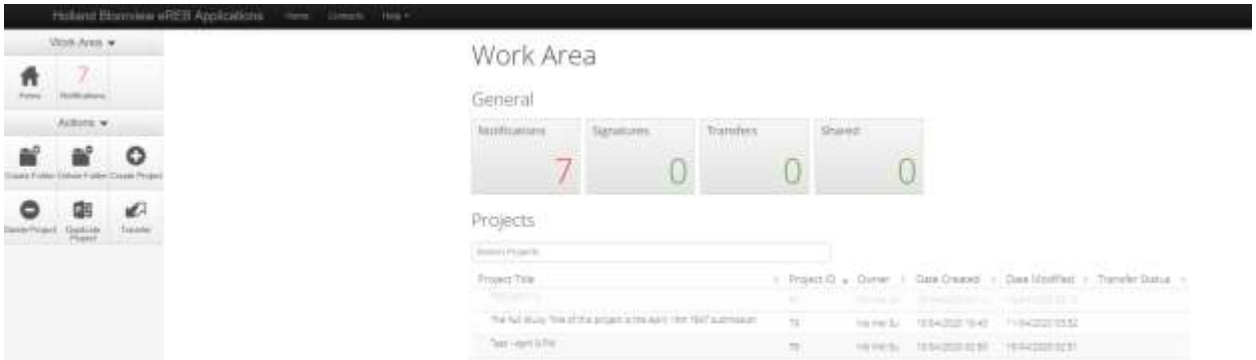


NOTE: The application form is a smart form. Only questions that are triggered by your previous responses will appear. All questions that appear in the form are mandatory questions. The only exception is if the question says 'if applicable'.

Access Project and Submission Home Page

Home Page

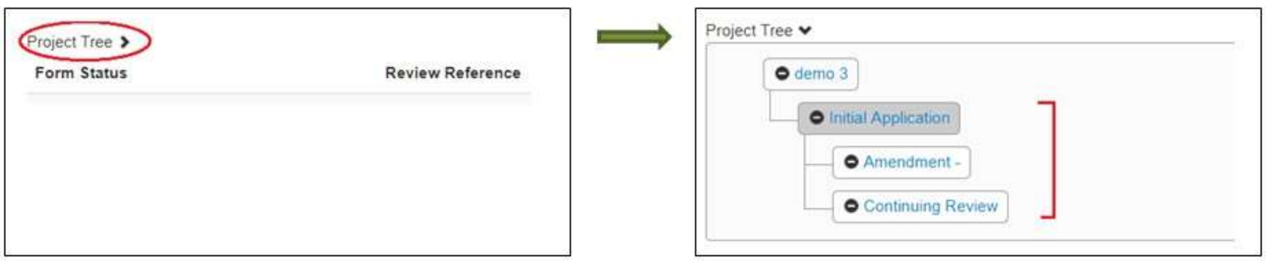
1. **Access a Project:** Projects are listed under the **home page**. (If you are not at the homepage, click **Home** ).



2. **Access a Specific Form:**

   a. Click on the project row
   b. On the following page, click **Project Tree** at the top
   c. A drop down menu with all associated submissions will appear. Click on the submission. (**see below**)

*Click "**Project Tree**"* *Submissions appear*



- **NOTE:** If an application was started and not submitted prior to Aug 19th, 2020, you may complete and submit your application in v1.0 OR upgrade to v2.0 **until Sept 11th, 2020**. After Sept 11th, you must upgrade to v2.0.
- If upgrading, please click "Print" to download your application as some of your work may be lost in the upgrade. Click "Update" at the top of your application form to upgrade to v2.0.
- If you will be using MRI in your study, please upgrade to v2.0, as v1.0 does not have MRI review process.

Give Others Access to a Project

1. Select **Home Page** and click on the project of interest.
2. Under the Actions toolbar, click **Share**. 
3. Type in e-mail addresses of collaborators and select the levels of access. If the collaborator does not have an eREB account, you will be prompted to invite them to create an account. Once the collaborator has created an account, please **Share** the project with them again. If an external collaborator creates an account, please email the eREB system administrator to activate the individual.

4. For additional collaborators click the **plus** button  at the top right of the pop up window.
5. Once shared, the collaborators can be seen in **Collaborators**. 

TIP — The PI must be added as collaborator.

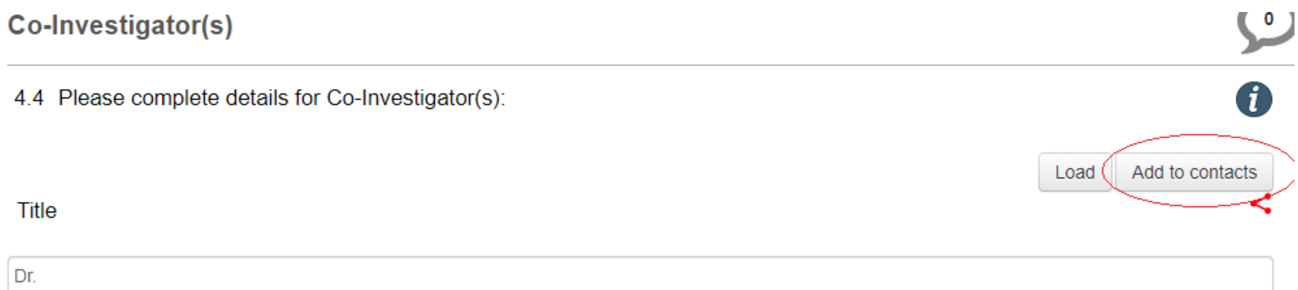
New version 2.0 Application Type and Legacy Studies

All existing paper based studies will be transitioned to the eREB to facilitate submission, review and tracking. Research teams have until Dec 31, 2020 to enter their legacy study data. The legacy pathway is a shortened application. Completing the questions will allow for legacy studies to complete post-approval forms via the eREB platform.

1. Follow steps in Create Application and Begin Application (pg 1)
2. In questions 1.1 "Pre-Submission Information", select "Legacy Submission"
3. Only questions required for the legacy submission will appear

Adding and Saving Study Contacts

1. In the application form, you can add and save contacts for future use. Once you fill in contact details, click "Add to contacts".



2. In future applications, select previously saved contacts by clicking "Load". Insert contact details by selecting contact and clicking "Insert".

Upload Documents

1. Within the submission application, you will be prompted to **Upload Documents** 

2. Click **Upload Document**
3. Click **Browse** to upload documents.
4. Enter both the Version date and Version ID (if applicable) and click **Upload.**

***TIP* -** Ensure the footer of the actual document includes the version date and number.
- Almost any file types can be uploaded (except exe files or excel files with macros).
- Files must be less than 150mb, if over, separate into multiple files or use a URL.

Please know that training certificates (e.g. TCPS2, RCR, and GCP) must be uploaded for the Principal Investigator (PI) for each new submission. At this time, training certificates should be uploaded for all co-principal investigators, co-investigators and study personnel if they are available. The PI is responsible for ensuring that all those involved in the study have appropriate training before the study starts.

PI/Delegate –Sign Submission Form/Request Signature

<u>**Scenario 1:** If the PI created the project</u>

1. Within the form, click on **"Attestations and Signatures".**
2. Click **Sign** Sign.

<u>**Scenario 2:** If the PI did NOT create the project</u>

1. Project Owner: Within the form, click on **"Attestations and Signatures".**
2. Select **Request Signature** Request Signature**.** An email will be sent to the PI.
3. PI: Click the **Signatures** tile .
4. Locate the project, and click **View Form.**
5. Click **Sign**  found in the Actions menu on the left-hand side.
6. Click **Accept**. You will be asked to provide your login details to confirm. 
7. Once a form is signed, it will be locked. If you need to unlock the form to make changes, click **Unlock**.

TIP*— The study coordinator ("Delegate") may sign the form on the PI's behalf only if it is a resubmitted Initial Form or a Post Approval Form. However Reportable Event forms must always be signed by the PI.

TIP*— The PI must always have access to the study. If the PI did not create the study in the system, the application must be shared with them.

NEW in Version 2.0 MRI Review Process and MRI Technologist Signature

If MRI is required for your study, please enter details in the MRI section. Prior to submitting your application, the Senior MRI Technologist must be consulted to review and sign. Please factor MRI Review Process in your timeline for your Initial Application and Post-Approval forms (e.g. Change in Personnel, Amendment).

<u>**Step 1**: MRI Technologist reviews application in progress</u>

1. Please "Share" form with MRI technologist (see Give Others Access to a Project pg 2.)
2. Please Email MRI technologist to notify that MRI section is ready for review.
3. The MRI technologist will review and add comments if applicable.
4. Please make changes if required. Once all sections of the application are finalized, move to Step 2.

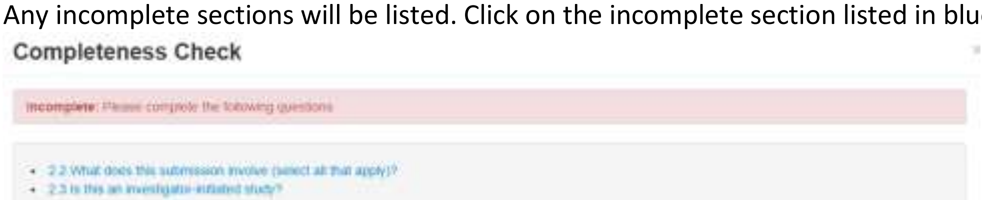
<u>**Step 2**: MRI Technologist signature request</u>

5. Within the form, click on **"Attestations and Signatures".**
6. Select **Request Signature** Request Signature**.** An automatic email will be sent to the MRI Technologist. Once signature is requested, the form will be locked.

Submit a Form

TIP— An application can be submitted only after all sections are complete and all signatures are obtained.

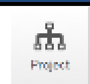
1. Check if all sections are complete: Click **Completeness Check** on the Actions toolbar. 
2. Any incomplete sections will be listed. Click on the incomplete section listed in blue to complete the outstanding question(s).



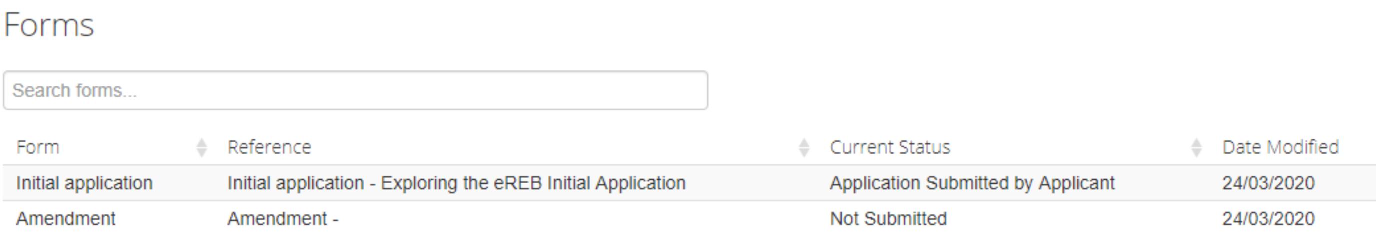
3. Once an application is complete, click "**Submit**".

Check Project and Submission Status

1. Under the Actions toolbar, click **Project.**



2. In the **Forms** tab, the "**Current Status**" column displays the current status of the submission form.



Forms

Search forms...

Form	Reference	Current Status	Date Modified
Initial application	Initial application - Exploring the eREB Initial Application	Application Submitted by Applicant	24/03/2020
Amendment	Amendment -	Not Submitted	24/03/2020

Check System Notifications

1. On the home page, click on the **Notifications** tile at the top.

2. If you are not at the home page, click on **Notifications** on the left-hand side bar.

TIP— System notifications are generated and emails are sent out when there is an update to the study.

TIP— System notifications behave like emails. The number displays the number of *unread* notifications.

Some notifications have letters attached (which can also be found within the actual project). You can choose to delete notifications.

Create a Post-Approval Form (Reportable Events, Continuing Review, Amendment, Change in Personnel, Study Closure)

1. Go to the Initial Application form (see page 2)

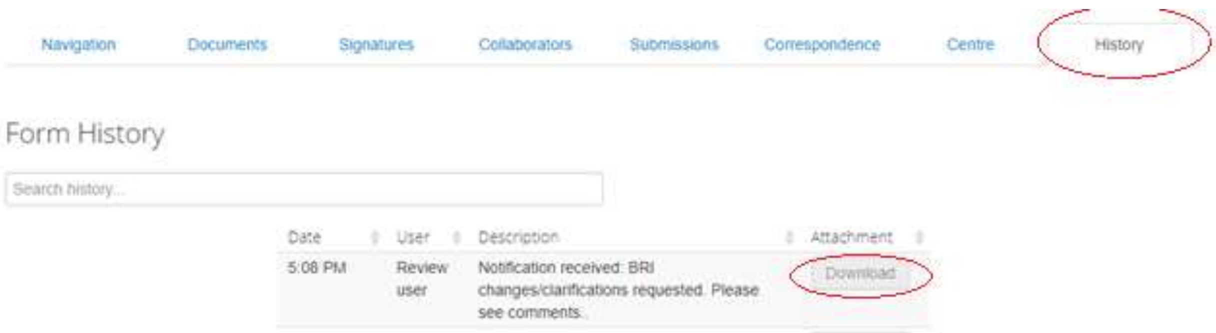
2. Click **Create Sub-Form** under the Actions toolbar

NOTE: While completing a form you may encounter a locked question or a question that already contains an answer, this is because the question is shared with the Initial Application which is locked.

Respond to Issues

1. Access the submission and click the **History** tab on the right hand side.

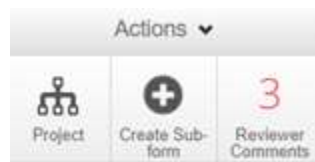
2. Click **Download** on the applicable notification to access any attachments from the Institutional Reviewer/REB.



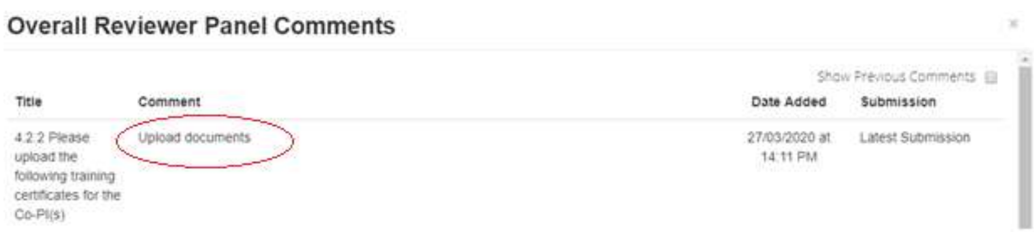
3. Click the **Navigation** tab to return to the submission. *IMPORTANT* If changes are requested by the **Research Ethics Board**, in the Pre-Submission Information section of the submission, change response for “Is this a resubmission in response to a request from the Research Ethics Board to make changes to your application” to “**Yes**”. Clicking “Yes” will open up the “Resubmission” section of the application forms which will allow you to upload revised documents.

   TIP Please make this change **ONLY** in response to comments from the REB (not comments from BRI).
   - Please include the tracked changes revised version of your documents in the “Resubmission “Section
   - Please include clean revised version of your document in the place you uploaded the original document

4. Under the Actions bar, click on the **Reviewer Comments** tile.



5. Clicking on the comment will bring you to the question that needs to be addressed. Please review comments and make any necessary changes in application form. Upload response letter and revised documents (if any).



6. Once complete, under the Actions toolbar, click **Submit.**

Contact Information

TIP— If there any questions about the submission, contact the Research Ethics Office <u>before</u> submitting to eREB.

1. For any questions related to the REB process or submission forms — Contact the **Research Ethics Office.**
2. For questions related to eREB accounts — Contact [ereb@hollandbloorview.ca.](mailto:ereb@hollandbloorview.ca)