Bloorview RESEARCH INSTITUTE

Holland Bloorview Kids Rehabilitation Hospital

eREB Applicant Manual

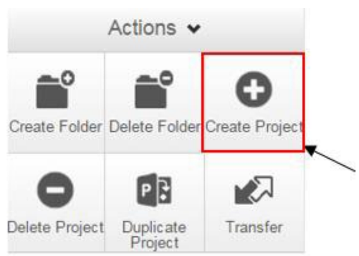
(for eREB version 3.0, Dec 2023)

Access eREB Platform

1. Launch **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

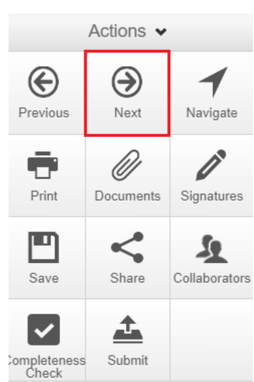
1. Under the Actions menu, select **Create Project** dialog box.



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 at 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.

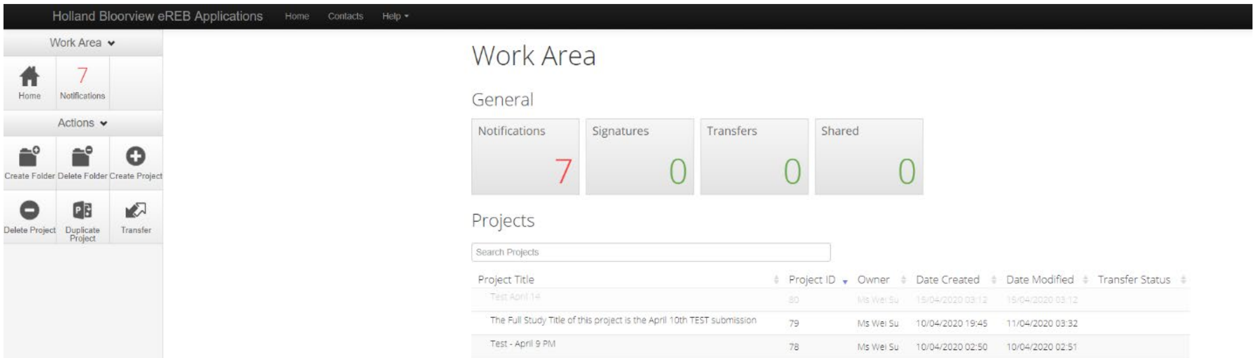


NOTE: The application form is a smart form. Only questions that are triggered by your previous responses will appear. All questions that appear in the form are mandatory questions. The only exception is if the question says 'if applicable'.

Access Project and Submission Home Page

Home Page

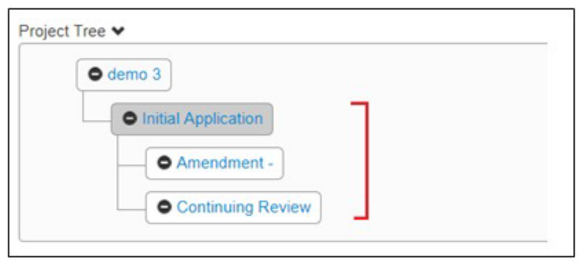
1. **Access a Project:** Projects are listed under the **home page**. (If you are not at the homepage, click **Home** ).



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*

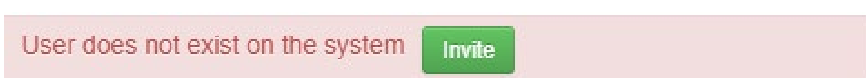


Give Others Access to a Project

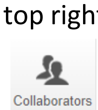
1. Select **Home Page** and click on the project of interest.

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.



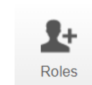
4. For additional collaborators click the **plus** button  at the top right of the pop-up window.

5. Once shared, the collaborators can be seen in **Collaborators**. 

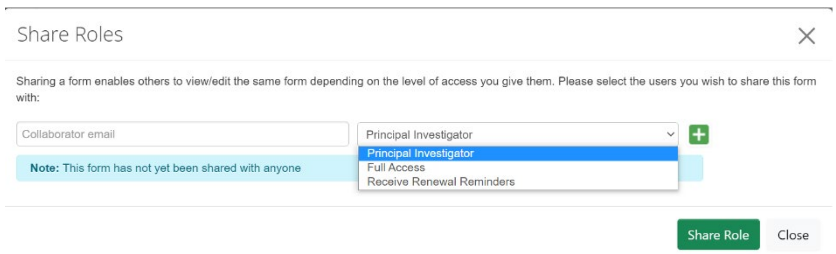
Applicant Roles

1. Forms can be shared with collaborators to grant them full permission to the application (ie. to read, write, share, submit, etc). **Applicant Roles should be used for PIs and research team members** who require full access to the application. New to version 2.3 is the “Receive Renewal Reminders” role. Please ensure everyone who should receive Continuing Review reminders be assigned this role.

2. To grant a research team member full access or to receive notification, select **Roles** in the application toolbar. Selecting **Roles** instead of **Share** gives the added individuals permissions on all forms within an application.



3. Enter the individual’s email into the “Collaborator’s email” field in the pop-up window and select either the “Principal Investigator” “Full Access” or “Receive Renewal Reminders” role from the drop-down menu. Then select “Share Role” to share the application.



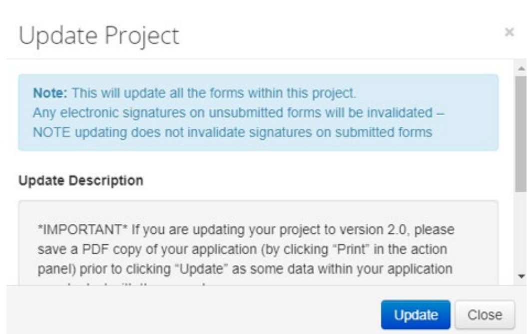
NOTE: The PI **MUST** be added as a collaborator and given the role of “Principal Investigator”. This will soon be the only way PIs are identified internally and only PIs identified in through Applicant Roles will receive notification emails.

Updating Forms to Version 3.0

1. When in a pre-existing form, if a newer version of that form is available, an “**Update**” option will appear above the Project Tree. If creating a new form, it will automatically update to the newest version.

2. Before updating the forms, save a PDF copy of the application by clicking “View as PDF” in the Action toolbar.

3. Once saved, select the “**Update**” option and then select the “**Update**” button in the pop-up window. Any new or modified questions added to the revised application forms will need to be completed.



Upload Documents

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

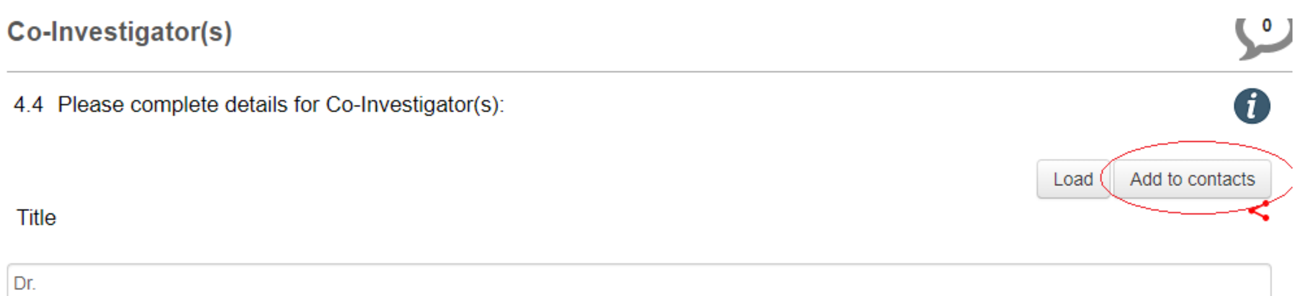
2. Click **Upload Document**
3. Click **Browse** to upload documents.
4. Enter both the Version date and Version ID (if applicable) and click **Upload.**

***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.

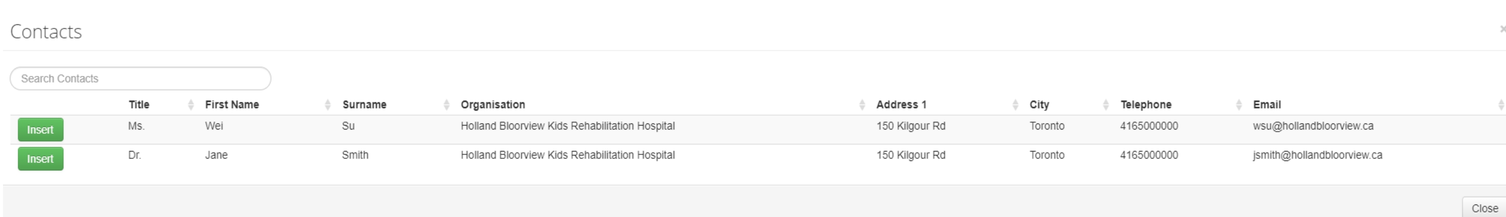
Please know that the TCPS-2 training certificate must be uploaded for the Principal Investigator (PI) and Co-Investigator (Co-I) for each new submission. The submitter should also attest that the Responsible Conduct of Research (RCR) and Good Clinical Practice (GCP) training has been completed and is still current for the individuals listed in the submission. The PI is responsible for ensuring that all those involved in the study, including all research study personnel, have appropriate training before the study starts.

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".


Contacts

Search Contacts

	Title	First Name	Surname	Organisation	Address 1	City	Telephone	Email
Insert	Ms.	Wei	Su	Holland Bloorview Kids Rehabilitation Hospital	150 Kilgour Rd	Toronto	4165000000	wsu@hollandbloorview.ca
Insert	Dr.	Jane	Smith	Holland Bloorview Kids Rehabilitation Hospital	150 Kilgour Rd	Toronto	4165000000	jsmith@hollandbloorview.ca

Close

PI/Delegate –Sign Submission Form/Request Signature

Scenario 1: If the PI created the project

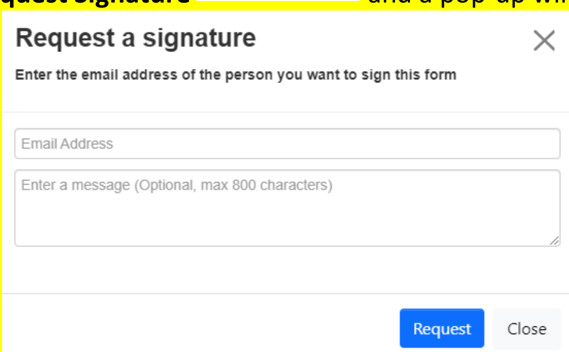
1. Within the form, click on **"Attestations and Signatures".**
2. Click **Sign** Sign.

Scenario 2: If the PI did NOT create the project

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 Signatures 3.
4. Locate the project and click **View Form.**
5. Click **Sign** 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**. Unlock

Scenario 3: If there is a change in PI (Amendment)

1. Within the form, click on **"Attestations and Signatures"**.
2. Click **Request Signature** Request Signature and a pop-up will appear.
   a.



3. Fill out the email of the individual, and click **Request**
4. Repeat this process for each signature needed
5. Once you've submitted signature requests, you can see the current signatures and signature requests by clicking **Sign** Signatures in the Actions menu on the left-hand side

NOTE: The Director must review and sign off on the application PRIOR to submission. You will NOT be able to submit your application without the Director Research Operation's signature. Please factor the institutional review process in your submission timeline. To expedite your request, please notify the Director that you have sent an application for signature.

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 full access to the study forms. If the PI did not create the study in the system, the application must be shared with them and must be added as a collaborator before signing.

MRI Review Process and MRI Technologist Signature

If the 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. Amendment).

Step 1: MRI Technologist reviews application in progress

1. Please “Share” form with MRI technologist (see Give Others Access to a Project).
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.

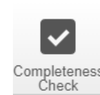
Step 2: MRI Technologist signature request

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 a signature is requested, the form will be locked.

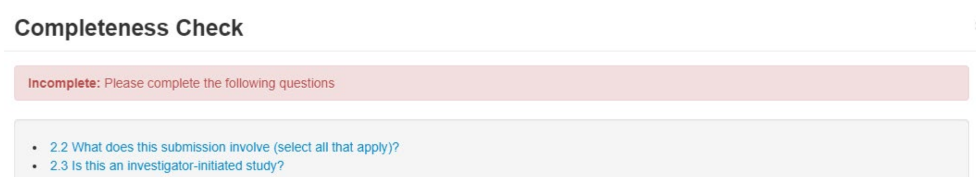
TIP— If changes to the MRI personnel are required, please fill out the form on REDCap, you can find it here. Going forward, all MRI personnel information will be submitted through REDCap.

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. 

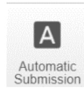
2. Any incomplete sections will be listed. Click on the incomplete section listed in blue to complete the outstanding question(s).



3. Once an application is complete, click “**Submit**”.

Automatic Submissions

1. Automatic submission is now enabled on each application form. To disable automatic submissions, select **Automatic Submission** on the Applications toolbar.



2. Enable/Disable automatic submissions and click "**Save**". If enabled, once a form is complete and signatures have been obtained, the form should automatically submit.

3. Once a form has been completed and signed, it will be automatically submitted. It may take a couple of seconds for the form to successfully go through. A message will appear once the form has successfully been submitted.

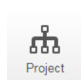
Submission Message

Thank you for submitting your form. It has been successfully received.

Home

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

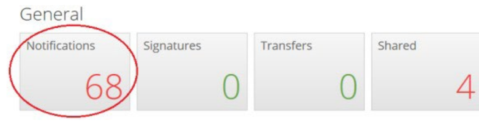
Search forms...

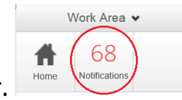
Form	Reference	Current Status	Date Modified
Initial application	Initial application - Exploring the eREB Initial Application	Application Submitted by Applicant	24/03/2020
Amendment	Amendment -	Not Submitted	24/03/2020

Action Required	Status	Review Reference	Date Modified
Yes	Not Submitted	N/A	28-Jan-2021 13:20

3. The submission status can also be found in the Action Required/Status bar above each application.

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.

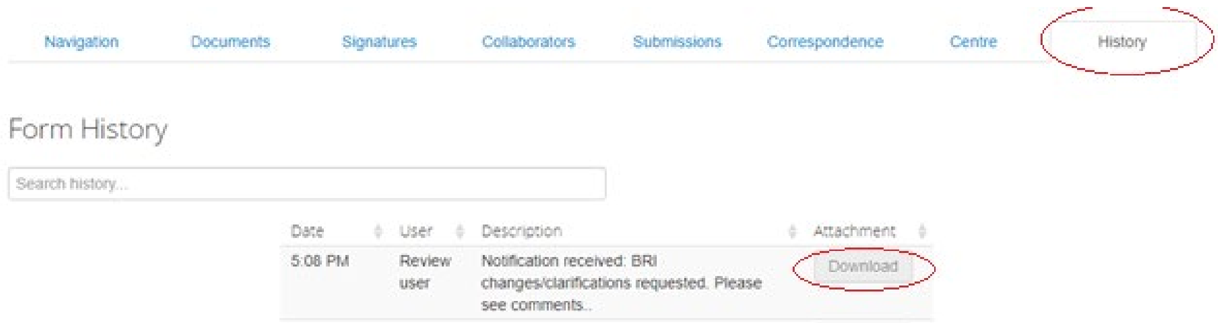
TIP— System notifications behave like emails. The number displays the number of *unread* notifications.

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

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.

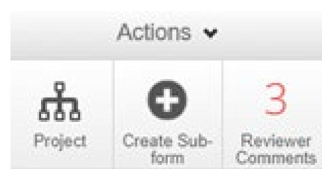


3. Click the **Navigation** tab to return to the submission. If changes are requested by the **Research Ethics Board**, in the Pre-Submission Information section of the submission, change response for “Is this a resubmission in response to a request from the Research Ethics Board to make changes to your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

4. Include the tracked changes copy and a clean revised version of any documents the REB has requested revision on in the “Resubmission Information” section. For example, the tracked changes version of the revised protocol for a new study should be uploaded in the “Resubmission Information” section.

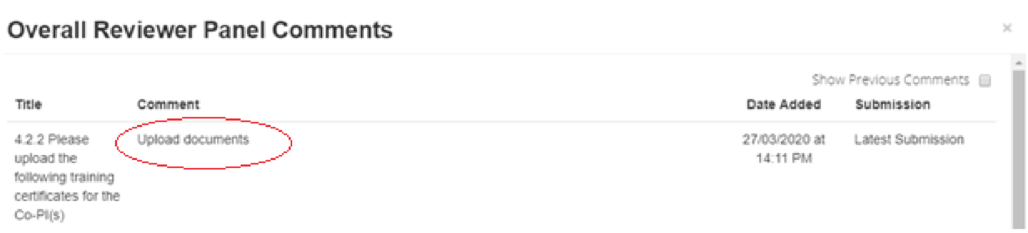
Remove the old version and include the revised copy of any documents the REB has requested revision on in the location of the original document. For example, a clean copy of the revised protocol should be uploaded in the “Protocol” section.

TIP - Please make this change **ONLY** in response to comments from the REB (not comments from BRI).



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

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

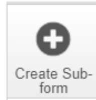


7. Once complete, under the Actions toolbar, click **Submit.**

Create a Sub-Form (Reportable Event, Continuing Review, Amendment, 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.

CTO Studies

If you currently have an **active study** that has been approved by Clinical Trials Ontario (CTO) and has not been submitted via Holland Bloorview's eREB system; OR if you plan to submit a **new study** to CTO, please complete an abridged form within the eREB for institutional acknowledgement.

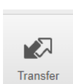
1. To do so, please start a new initial application
2. Select "Yes" to "Do you intend to/have you already submitted via CTO" in question 1.3.
3. Once the CTO study is closed, please notify the institution.

Leaving a Form

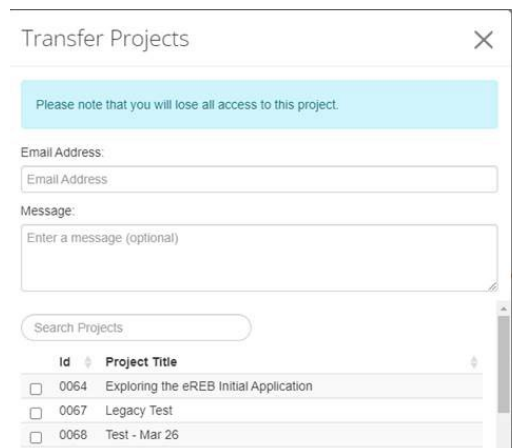
When the owner of a form leaves, they MUST transfer their eREB application to the PI.

1. Go to the eREB applicant work area

2. Select "Transfer"



3. Select which projects to transfer, enter the PIs email, and enter an optional message



Contact Information

TIP — If there any questions about the submission, contact the Research Ethics Office before 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)