

# RITHIM HARMONY IMPORTED PROJECT AMENDMENTS



- ▶ Amendments to Imported Projects require completion of the RITHIM Application Form, to enable all features of Harmony to support the amended project going forward.
- ▶ The Imported Project must be previously validated (see Slide 4-5).
- ▶ **The Harmony Application must be filled out to reflect the desired amended state (i.e., the form should include all changes proposed with the amendment).**
- ▶ The details from the Imported Project will be used during review for any necessary historical (pre-amendment) perspective.
- ▶ **All questions presented in the Harmony Application for amendment to Imported Projects are mandatory and mirror the requirements of a regular Harmony Application.**
- ▶ Once complete, the amended Imported Project can leverage all the functionality of Harmony for future changes and reporting.

## CONTEXT

# IMPORTED PROJECTS – UPDATING FORMS

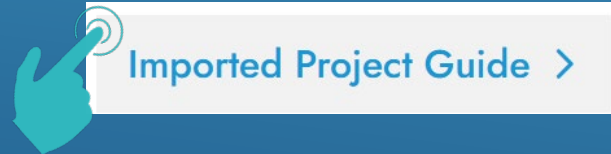
- ▶ Imported projects exist in Harmony with a “to be Validated” status until opened and validated by the Principal Investigator. Once the Imported Project validation is complete, with signature, the status of the project will become “Validated” .
- ▶ When first opening an Imported Project, it is very important to update the form to the latest version, if required. Users may see the banner below at the top of their project and should click on **Update**.

**Warning:** There is a newer version of this form. **Update**



## IMPORTED PROJECTS

- ▶ After clicking Update, a pop-up window will appear to confirm the update.
- ▶ Users should read the Note and then click the **Update** button with this understanding.
- ▶ Users should then follow the guidance on the RITHIM website



to complete Validation, and return here for the remaining guidance on Imported Projects Amendments

A screenshot of a "Update Project" pop-up window. The window has a title bar with "Update Project" and a close button (X). Inside, there is a light blue box with a "Note" stating: "This will update all the forms within this project. Any electronic signatures on unsubmitted forms will be invalidated – NOTE updating does not invalidate signatures on submitted forms". Below this is a section titled "Update Description" with a text area containing "Made reportable events form available.". At the bottom right, there are two buttons: a blue "Update" button and a grey "Close" button. A hand cursor icon is pointing at the "Update" button.

Update Project

**Note:** This will update all the forms within this project.  
Any electronic signatures on unsubmitted forms will be invalidated – NOTE updating does not invalidate signatures on submitted forms

**Update Description**

Made reportable events form available.

Update Close

# IMPORTED PROJECTS

# IMPORTED PROJECT AMENDMENTS

- ▶ With the Forms update complete and the Imported Project validation complete, you are ready to proceed with an amendment to the Imported Project.
- ▶ Just before the signature page during the validation, you would have observed this message:

#### Amendments

Amendments to the project will require completion and submission of the RITHIM Application Form. On the Application Type page, please indicate 'Amendment to a previously approved application'. The RITHIM Application Form should be completed to reflect the desired AMENDED STATE of the project.

- ▶ Instructions to guide this activity follow.

## IMPORTED PROJECT AMENDMENTS

- ▶ Navigate to the Imported Project, which should show as Validated.
- ▶ Click on “Create Sub Form.”

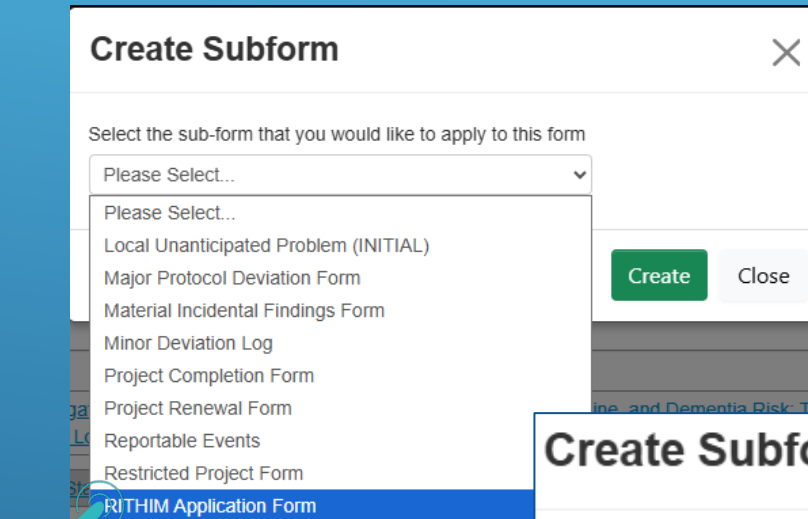
The screenshot shows a web application interface. On the left is a sidebar with three buttons: 'Project' (with a tree icon), 'Create Sub Form' (with a plus icon and a red hand cursor pointing to it), and 'Roles' (with a person icon). Below these is a 'View as PDF' button (with a printer icon). The main area has a header 'Imported Project Title' with the number '2432' on the right. Below the header is a 'Project Tree' section containing a link: 'Investigating the Relationship Between Multimorbidity, Cognitive Decline, and Dementia Risk: The Modifying Role of Physical Activity and Fitness in the Canadian Longitudinal Study on Aging'. Below the link is a 'Get Started' button. At the bottom is a table with four columns: 'Action Required on Form', 'Status', 'Review Reference', and 'Date Modified'. The table has one row with the values: 'No', 'Validated', '2432 - 3698', and '25/Nov/2025 15:59'. A red arrow points from the 'Create Sub Form' button to the 'Validated' status in the table.

Action Required on Form	Status	Review Reference	Date Modified
No	Validated	2432 - 3698	25/Nov/2025 15:59

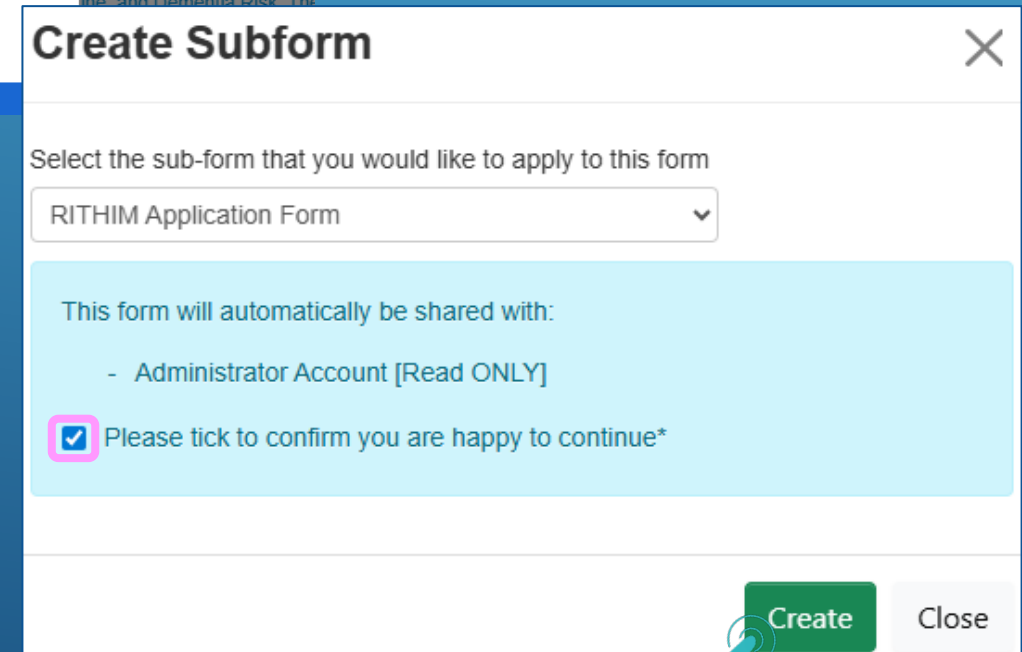
## CREATE SUB FORM

► Select RITHIM Application Form” from the Create Subform drop down

► Review the information, tick the Check Box, and click “Create” to proceed



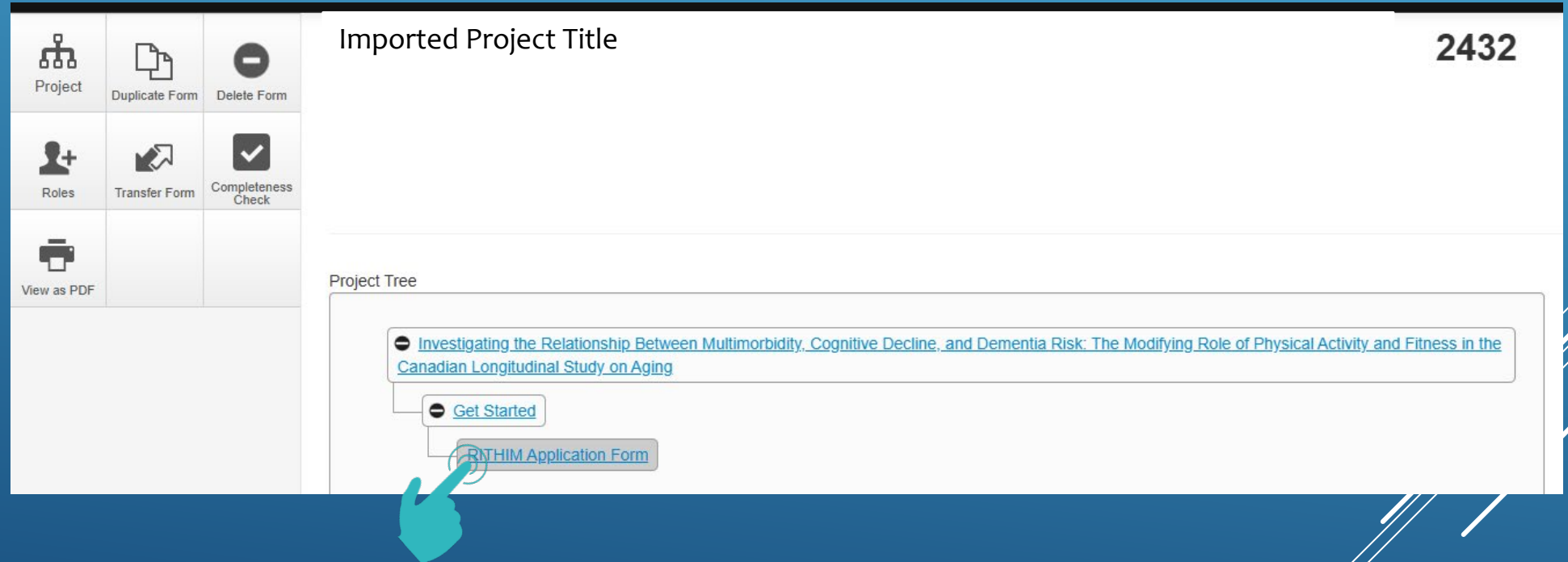
The screenshot shows the 'Create Subform' dialog box. The title bar says 'Create Subform' with a close button. Below the title bar, it says 'Select the sub-form that you would like to apply to this form'. There is a dropdown menu with 'Please Select...' as the placeholder. The dropdown is open, showing a list of options: 'Please Select...', 'Local Unanticipated Problem (INITIAL)', 'Major Protocol Deviation Form', 'Material Incidental Findings Form', 'Minor Deviation Log', 'Project Completion Form', 'Project Renewal Form', 'Reportable Events', 'Restricted Project Form', and 'RITHIM Application Form'. The 'RITHIM Application Form' option is highlighted in blue. To the right of the dropdown are 'Create' and 'Close' buttons.



The screenshot shows the 'Create Subform' dialog box with 'RITHIM Application Form' selected in the dropdown menu. Below the dropdown, there is a light blue box containing the text 'This form will automatically be shared with:' followed by a list: '- Administrator Account [Read ONLY]'. Below this list is a checkbox that is checked, with the text 'Please tick to confirm you are happy to continue\*'. At the bottom right of the dialog box are 'Create' and 'Close' buttons. A hand icon is pointing at the 'Create' button.

# SELECT RITHIM APPLICATION FORM

- ▶ Select the newly created RITHIM Application Form (sub form)



# SELECT RITHIM APPLICATION

- Scroll down to the RITHIM Application Form detail and select “1.1 Application Type”

Section	Questions
1.0 Application Type	<a href="#">1.1 Application Type</a>   <a href="#">1.2 Response to Revisions Required</a>   <a href="#">1.3 Amendment Details</a>   <a href="#">1.4 Amendment Instructions</a>
2.0 Project Summary	<a href="#">2.1 General</a>   <a href="#">2.2 Research Personnel</a>   <a href="#">2.3 Project Sponsor</a>   <a href="#">2.4 Type of Research</a>
3.0 Project Context	<a href="#">3.1 Multi-Centre Projects</a>   <a href="#">3.2 Sites Under the Authority of the Local PI</a>   <a href="#">3.3 Scientific Review</a>   <a href="#">3.4 Indigenous Populations</a>   <a href="#">3.5 Funding</a>
4.0 Project Design	<a href="#">4.1 Project Design</a>   <a href="#">4.2 Project Population</a>   <a href="#">4.3 Data Analysis</a>   <a href="#">4.4 Patient &amp; Public Engagement</a>   <a href="#">4.5 Incidental Findings</a>   <a href="#">4.6 Project Dissemination</a>
5.0 Data Management	<a href="#">5.1 Data Collection</a>   <a href="#">5.2 Data Collection Tools</a>   <a href="#">5.3 Secondary Data</a>   <a href="#">5.4 Data Flow</a>   <a href="#">5.5 Data Access</a>   <a href="#">5.6 Data Storage &amp; Security</a>

# SELECT RITHIM APPLICATION

- ▶ Select “Amendment to a previously approved application.”
- ▶ Set the Amendment Number to 1 (one)
- ▶ Click Next Page

**RITHIM Application Form**

Imported Project Title

### 1.1 Application Type

What type of application is this?

- ☐ Initial application
- ☒ Amendment to a previously approved application
- ☐ Corrections in response to completeness check (initial or amendment)
- ☐ Response to Revisions Required Letter (initial or amendment)

Please assign an amendment number (start with 1 for the first amendment and increase incrementally for each subsequent amendment)

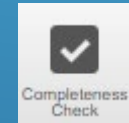
1

Reminder: For amendment number 2 and onward, please review and update all applicable responses in the Amendment Details section.

Previous page Next page

## SELECT RITHIM APPLICATION

- ▶ The Imported Project is now correctly established to complete the amendment.
- ▶ Answer all questions and navigate through the form as you would with a regular Harmony Application.
- ▶ After all questions have been completed (use Completeness Check to verify), the amendment can be reviewed and signed for submission and review.



## COMPLETE THE FORM AND SUBMIT