

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

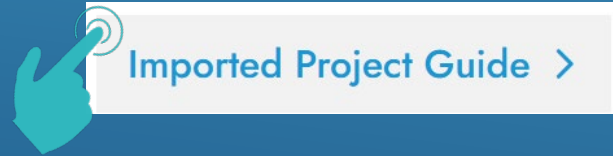
- ▶ Imported projects exist in Harmony with a “to be Validated” status until opened and validated by the Principal Investigator. Once the Imported Project validation is complete, with signature, the status of the project will become “Validated” .
- ▶ When first opening an Imported Project, it is very 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Warning: There is a newer version of this form.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

The screenshot shows a "Update Project" dialog box. At the top is a title bar with the text "Update Project" and a close button (X). Below the title bar is a light blue box containing a "Note": "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". Below the note is a section titled "Update Description" with a text area containing "Made reportable events form available.". At the bottom right of the dialog are two buttons: a blue "Update" button and a grey "Close" button. A hand cursor icon is pointing at the "Update" button.

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 and click on Overview on the right side of the screen to expand the window to view the form status

The screenshot displays the 'Imported Project' interface. At the top, there's a header with the title 'Imported Project' and a link to 'Go Back to Work Area'. Below this is a 'Project' section with a tab labeled 'Overview' on the right, which is highlighted by a hand icon. The main area is divided into a 'Project Tree' on the left, showing 'Imported Project' and a 'Get Started' button, and a right-hand section with a 'Get Started' heading and a list of questions. The questions are categorized into 'General/Routing', 'Consultation', 'Existing/Imported Projects', and 'Instructions and Signatures'. The 'General/Routing' category includes 'General', 'Routing', and 'Confirm'. The 'Consultation' category includes 'RITHIM Consultation'. The 'Existing/Imported Projects' category includes 'Project Summary', 'Approved Project Documents', 'Ethics & PHRPC Approvals', and 'Health System Approval(s)'. The 'Instructions and Signatures' category includes 'Instructions' and 'Signature(s)'. At the bottom, there's a navigation bar with tabs for 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Site', and 'History'. A 'Show Inactive Sections' checkbox is also visible.

Imported Project
← Go Back to Work Area

Project

Project Tree

Imported Project
Get Started

Create Sub Form Project Roles View as PDF Request Withdrawal

Navigation Documents Signatures Collaborators Submissions Site History

Get Started
Show Inactive Sections

Section

General/Routing
Consultation
Existing/Imported Projects
Instructions and Signatures

Questions

General Routing Confirm
RITHIM Consultation
Project Summary Approved Project Documents Ethics & PHRPC Approvals Health System Approval(s)
Instructions Signature(s)

CREATE SUB FORM

- ▶ The imported project should now show as Validated
- ▶ Click on Create Subform

The screenshot displays the 'Imported Project' interface. At the top, there's a header with the title 'Imported Project' and a link to 'Go Back to Work Area'. Below this, a 'Project Tree' shows a hierarchy with 'Imported Project' and a sub-item 'Get Started'. A teal hand icon points to the 'Create Sub Form' button, which is located among other action buttons like 'Project', 'Roles', 'View as PDF', and 'Request Withdrawal'. Below the buttons is a navigation bar with tabs: 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Site', and 'History'. The main content area is titled 'Get Started' and contains a 'Section' list (General/Routing, Consultation, Existing/Imported Projects, Instructions and Signatures) and a 'Questions' list (General, Routing, Confirm, RITHIM Consultation, Project Summary, Approved Project Documents, Ethics & PHRPC Approvals, Health System Approval(s), Instructions, Signature(s)). A checkbox 'Show Inactive Sections' is also present. On the right, an 'Overview' sidebar lists project details: Project Title (Imported Project), Project Id (5867), Form Title (Get Started), Status (Validated), Review Reference (5867 - 12558), Last Modified (26/Jun/2026), and Action Required (No). The 'Get Started' link in the 'Form Title' row is highlighted with a pink box. A blue arrow points from the text 'Click on Create Subform' to the 'Create Sub Form' button.

Imported Project
← Go Back to Work Area

Project

Project Tree

- Imported Project
 - Get Started

Navigation | Documents | Signatures | Collaborators | Submissions | Site | History

Create Sub Form | Project | Roles | View as PDF | Request Withdrawal

Get Started ☒ Show Inactive Sections

Section

- General/Routing
- Consultation
- Existing/Imported Projects
- Instructions and Signatures

Questions

- General | Routing | Confirm
- RITHIM Consultation
- Project Summary | Approved Project Documents | Ethics & PHRPC Approvals | Health System Approval(s)
- Instructions | Signature(s)

Overview

BASIC INFO

Project Title	Imported Project
Project Id	5867
Form Title	Get Started
Status	Validated
Review Reference	5867 - 12558
Last Modified	26/Jun/2026
Action Required	No

CREATE SUB FORM

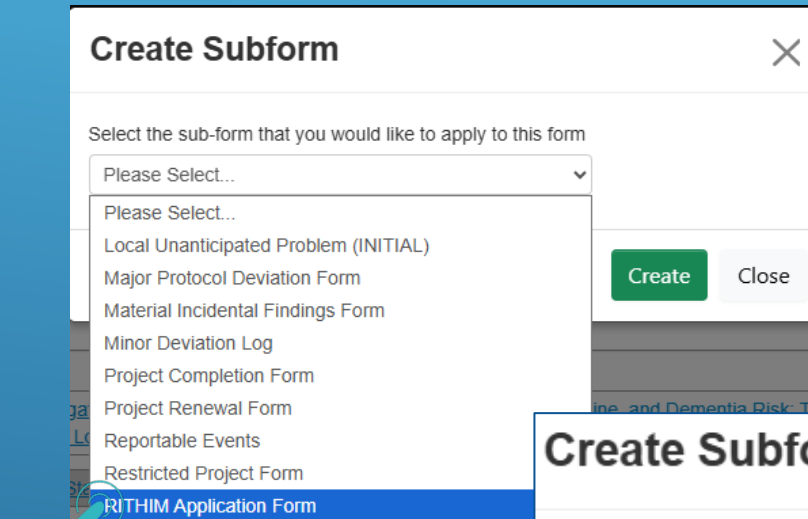
RITHIM HARMONY

9

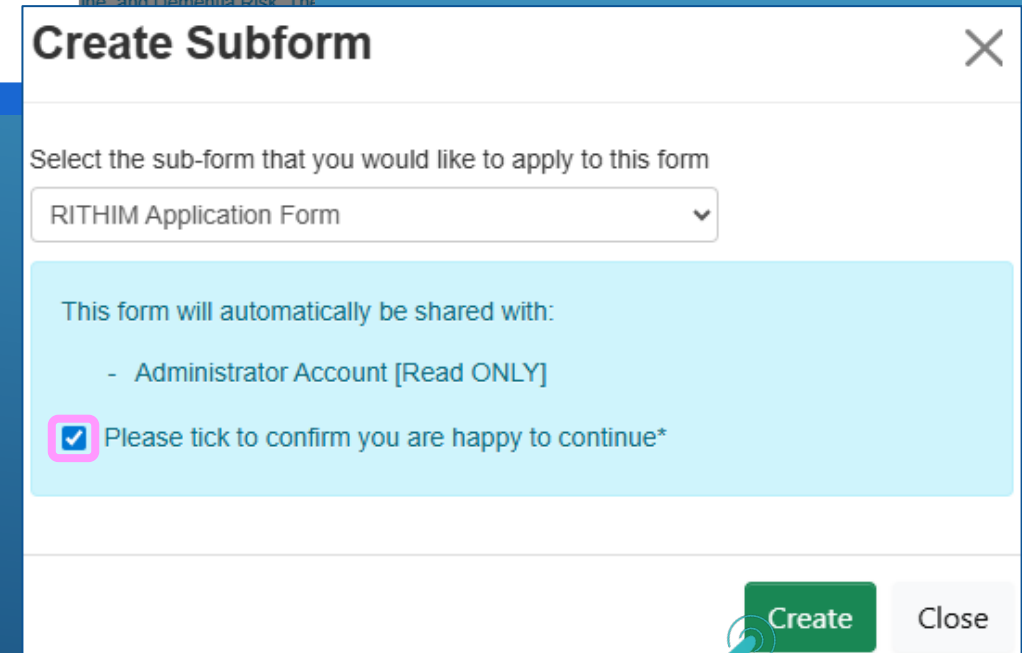
July 2026

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

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



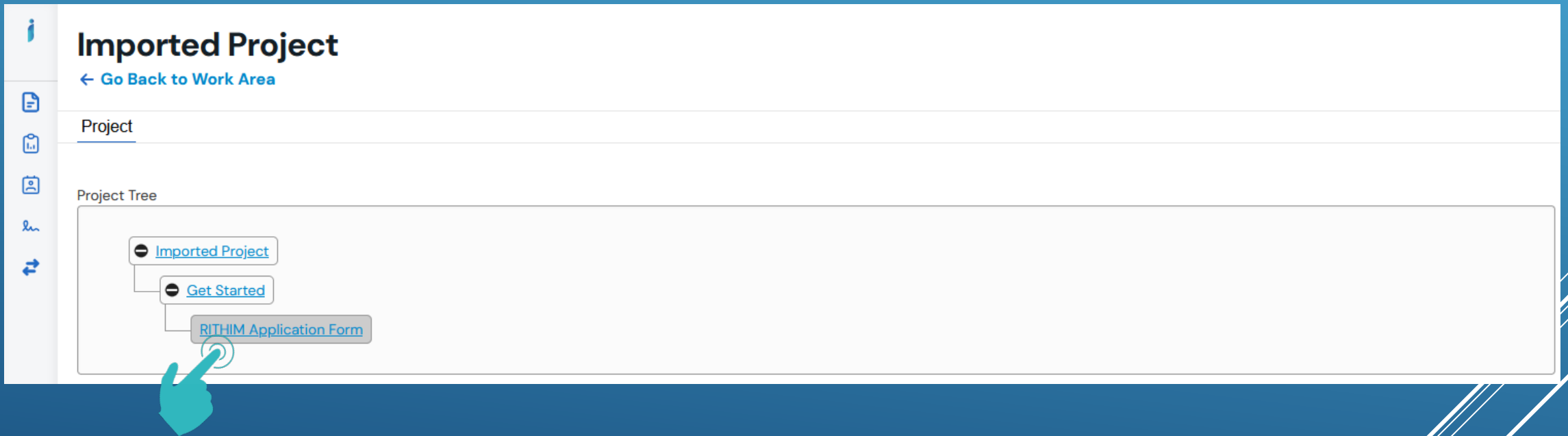
The screenshot shows the 'Create Subform' dialog box. The title bar says 'Create Subform' with a close button (X). Below the title bar, it says 'Select the sub-form that you would like to apply to this form'. A dropdown menu is open, showing a list of sub-forms: 'Please Select...', 'Local Unanticipated 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' is highlighted in blue. To the right of the dropdown menu are two buttons: 'Create' (green) and 'Close' (grey).



The screenshot shows the 'Create Subform' dialog box with the 'RITHIM Application Form' selected in the dropdown menu. Below the dropdown menu, 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 two buttons: 'Create' (green) and 'Close' (grey). A hand icon is pointing at the 'Create' button.

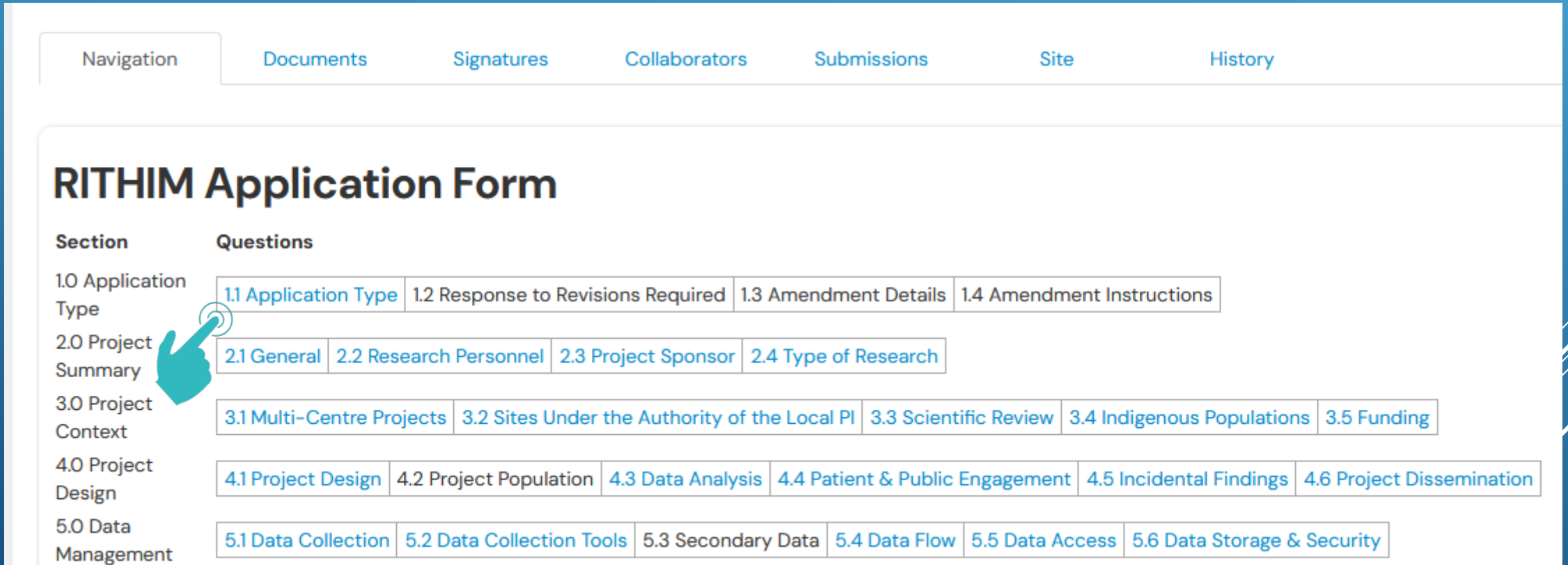
SELECT RITHIM APPLICATION FORM

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

SELECT APPLICATION TYPE

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

1.1 Application Type

What type of application is this?

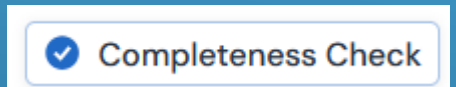
- ☐ Initial application
- ☒ Amendment to a previously approved application
- ☐ Corrections in response to Program Officer pre-review (initial application)
- ☐ Corrections in response to Program Officer pre-review (amendment)
- ☐ Response to Revisions Required Letter (initial application)
- ☐ Response to Revisions Required Letter (amendment)

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

1

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