Attach a Revised IRB Application to Your Submission

Step 1: Log in to iMedRIS. Once on your home page, click on the Submission Response icon (red arrow), then click the Open icon (blue arrow) to open the PI Response Form.

Below are your incomplete University of Tennessee - Knoxville IRB tasks:

Submission Response

1 task(s) found...

Open	Principal Investigator	IRB Number	Study Alias	Study Status	Submission Form Name	Submission Date	Review Process
	Testing Submission & Provisos						
	Ms. Kristine Hershberger	UTK IRB-16-02784	Response Steps	Pending – Corrections	Routing Form for Form 1: Initial Review Submission Form	07/31/2016	Expedited

Step 2: On the PI Response Form, scroll down to section 1.3 **Issues Requiring a Response**. If item 1, circled below, contains a recommendation, provide a response in the text box. If no recommendation is entered, type **N/A** in the text box and then scroll down to item 2.

1.3 Issues Requiring a Response

1. Recommendations pertaining to general issues raised during the pre-review process:

No recommendation entered.

* State whether all recommendations were addressed, and if not, give the reason why all recommendations were not addressed. If any recommendations require a direct response to the IRB (i.e., did not require a change to the application, consent form, or other document), indicate your response below (or type n/a if no recommendations were listed):

N/A

1

Step 3: Indicate that you accept this Proviso by clicking **Yes**, and in the text box explain how it will be addressed. In the last text box under item 2, indicate if all the Provisos were addressed.

2. Provisos pertaining to general issues raised during the IRB meeting or during an administrative review:

⚠ **Proviso 1 out of 1:**

Description:

The revised IRB application (Version 1.1) was not attached to your recent response to the IRB's request for changes. Please attach the revised IRB application (Version 1.1) to the submission. We have sent the document, PI Response Form Instructions, to you via email. These instructions are also posted in the iMedRIS Help menu under the UT Knoxville iMedRIS Instructions section. Please contact us if you need assistance.

Stipulation Type: (Proviso must be addressed)

Do you accept this Proviso?	○ N/A ● Yes ○ No
Provide an explanation on how you addressed this Proviso:	See the attached new version of the IRB Application.

* State whether all provisos were addressed, and if not, give the reason why all provisos were not addressed. If any provisos require a direct response to the IRB (i.e., did not require a change to the application, consent form, or other document), indicate your response below (or type n/a if no provisos were listed):

All provisos were addressed.

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Step 4: If any changes were made to the IRB Application or supporting materials in addition to those requested in the Provisos, identify them in the item 3 text box. If no additional changes were made, type **N/A**.

3. Any additional changes made to the submission:

* List **each** additional change that was made to any of the documents associated with this submission that was <u>not</u> requested in the recommendations/provisos listed above.

N/A

Step 5: Scroll up to section 1.2 **Revise and Attach Documents**. Click on the **Revise Submission** button.

1.2 **Revise and Attach Documents**

Revise Submission   Create PDF Packet

Include in PDF Packet	Remove	Revisions	All Submission Components Previous Rounds & Currently Attached
Submission Form(s)			
☐			PI Review Response Form - UTK - (Version 1.0) (Parent of the submission package) - Submitted in round(s) Currently attached
☐			Routing Form for Form 1: Initial Review Submission Form - (Version 2.0) - Submitted in round(s) Currently attached,1
Application			
☐			UTK Knoxville Main Campus IRB Application - (Version 1.0) - Submitted in round(s) Currently attached,1
Consent Form(s)			
Category : Consent Statement/Elements			
☐	❌		Consent Form (English) - (Version 1.0) - Submitted in round(s) Currently attached,1

A window will appear asking you to confirm. Click **OK**.

Confirm the adding a revision.
Are you sure you want to create a revision?

OK   Cancel
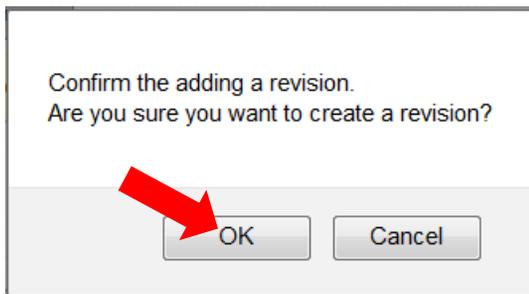
If a window appears titled **New Form Version has been published** asking if you want to convert, click the X to close it.

Another window will appear like the one below. Click **OK**.

A new version has been created. The document you are editing is version 2.1

OK
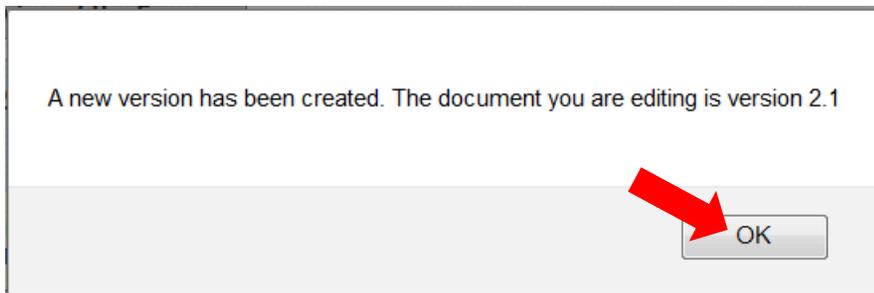
<u>Step 6:</u> A new version of the Routing Form will open. Scroll down to section 1.2. To access the newest version of the IRB Application, click on the **Click here to create a revision to the attached application** button.

1.2   * Please attach the study/project application form.

Click here to create a revision to the attached application.

Remove	Edit/ View	Version	Title
❌	📝	1.0	UTK Knoxville Main Campus IRB Application (Version 1.0) - Attached

The Attaching Project Application window will appear. Click on the **Show Rev** icon.

Click the **Select button** of the application version which contains the changes made in response to the IRB's Provisos. Then click the **Save Attachment** button.

The Routing Form should now reflect that the correct version of the IRB Application is attached.

1.2 * Please attach the study/project application form.

📎 Click here to create a revision to the attached application.

Remove	Show Rev.	Edit/ View	Version	Title
❌	📁	📝	1.2	UTK Knoxville Main Campus IRB Application (Version 1.2) - Attached
		📝	1.0	UTK Knoxville Main Campus IRB Application (Version 1.0)

If the IRB Application version is correct, at the top of the page click [💾 **Save Section**]

If no further changes are needed, click [❌ **Close Form**]

Step 7: The PI Response Form will reload.   Section 1.2 **Revise and Attach Documents** should reflect that the correct version of the IRB Application is attached.

1.2 Revise and Attach Documents

[Expand All] [Compare Item(s)] [Edit Submission] [Create PDF Packet]

Compare	Include in PDF Packet	Remove	Revisions	All Submission Components Previous Rounds & Currently Attached
Submission Form(s)				
☐	☐			**PI Review Response Form – UTK – (Version 1.0)** (Parent of the submission package) - Submitted in round(s) Currently attached
☐	☐		📁	**Routing Form for Form 1: Initial Review Submission Form – (Version 2.1)** - Submitted in round(s) Currently attached
Application				
☐	☐		📁	**UTK Knoxville Main Campus IRB Application – (Version 1.2)** - Submitted in round(s) Currently attached

If the correct version is attached, at the top of the screen click [Signoff and Submit]
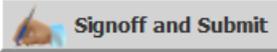
Step 8: After the Submission Routing Signoff Sheet loads, scroll to the bottom of the screen.

Click **Approve**, enter your NetID and password, then on the far right bottom of the screen click [Save Signoff]

Submission Routing Signoff Sheet

Project Title: Testing Submission & Provisos
Submission Reference Number: 577772

Include in PDF Packet	Submission Component Name - Version
Submission Form(s)	
☐	PI Review Response Form - UTK - **(Version 1.0)** (Parent of the submission package)
☐	Routing Form for Form 1: Initial Review Submission Form - **(Version 2.1)**
Application	
☐	UTK Knoxville Main Campus IRB Application - **(Version 1.2)**
Consent Form(s)	
Category : Consent Statement/Elements	
☐	Consent Form (English) - **(Version 1.0)**
Document(s)	
Category : Recruitment/Advertising Materials	
☐	Patient Recruitment letter-SuggestionsAccepted - **(Version 1.0)**

Submission Form(s):

Kristine Hershberger as Principal Investigator do you Approve or Deny this submission?

○ **Approve**   ○ **Deny**

This form requires your electronic signature. Please enter your User ID & Password:

User ID: _____

Password: _____

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