

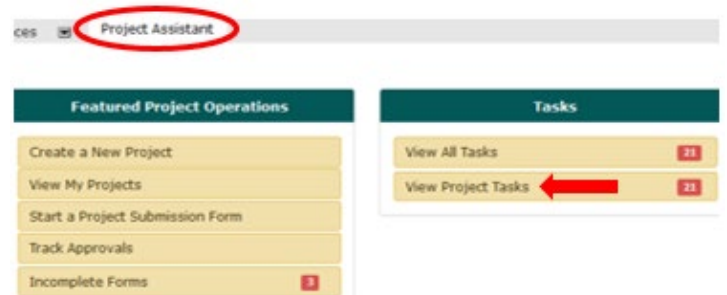
If you are informed that the revised study application or other revised documents (recruitment materials, informed consent documents, etc.) are not attached to your submission, please follow the steps in this guidance.

Find and Open the Study


1. Log in to [iMedRIS](#) using your **NetID** and **Password**.



2. iMedRIS should open to your **Project Assistant** workspace (tab circled in red).
Click **View Project Tasks** (red arrow).



3. **Project Tasks**


- Locate your study.
- Click the  (red arrow) under the **Click to Open** column.

Click to open	Project Status	Review Board	RB Number	RB Expiration	Project Title	Principal Investigator
 (red arrow)	Approved	University of Tennessee - Knoxville IRB	UTK IRB-18-04693-XM			

4. **Submissions** screen

- If the study opens to the **PI Review Response (or Correction) Form** (picture A), skip to **Step 5**.
- If the study opens to the **Submissions** screen (picture B), find the **Outstanding Submission(s)** section.
- In that section is an **IRB request for a Submission Response** (or Correction) (red arrow).
- Click **Respond to Review** (circled in red).




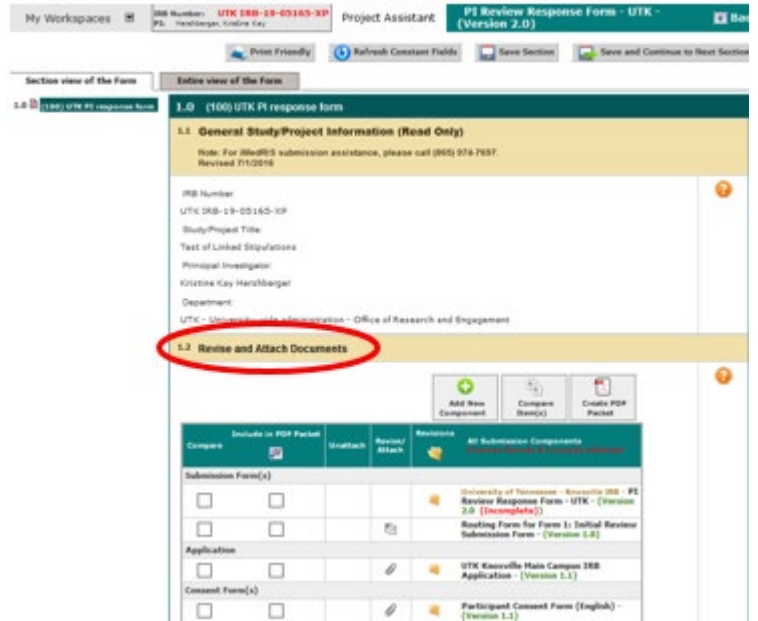
Track Location	Ref Number	Request Type	Process Submission
 (red arrow)	721678	Click on the hyperlink to edit/view the submission. University of Tennessee - Knoxville IRB has requested a Submission Response for Routing Forms for Form 1: Initial Review Submission Form	Respond to Review (circled in red)

Attach Revised Application


5. PI Review Response (or Correction) Form







- On the form, scroll down to section 1.2 **Revise and Attach Documents** (circled in red).
- Find the form or document that needs the correct version attached.

TIP: Find the  icon under the **Revise/Attach** column. The paperclip indicates there is a different version of that document available that is not attached to this submission.





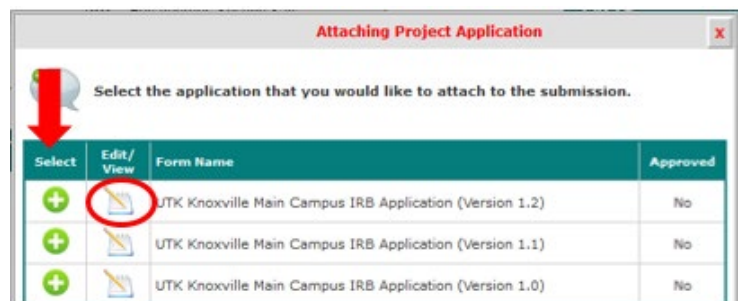
6. Revise and Attach Documents section

- Click the  (red arrow) for the form/document you want to attach.
- Version number of the form/document is circled in red.


Compare	Include in PDF Packet	Unattach	Revise/Attach	Revisions	All Submission Components Previous Rounds & Currently Attached
<input type="checkbox"/>	<input type="checkbox"/>				University of Tennessee - Knoxville IRB - PI Review Response Form - UTK - (Version 2.0 (Incomplete))
<input type="checkbox"/>	<input type="checkbox"/>				Routing Form for Form 1: Initial Review Submission Form - (Version 1.0)
<input type="checkbox"/>	<input type="checkbox"/>		 		UTK Knoxville Main Campus IRB Application (Version 1.1)
<input type="checkbox"/>	<input type="checkbox"/>				Participant Consent Form (English) - (Version 1.1)
Document(s)					
Category : Surveys/Questionnaires/Data Collection Instruments					
<input type="checkbox"/>	<input type="checkbox"/>				Online Survey Consent Document - (Version 1.0)
<input type="checkbox"/>	<input type="checkbox"/>				Health History Form - (Version 1.0)

7. Attaching Project Application pop-up window

- To select the correct version, find that version number, then click the  (red arrow).
- To view or edit the form/document, click the  (circled in red).

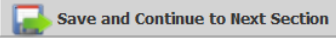


8. After returning to the Response Submission (or Correction) form, confirm the correct version of the form/document is attached.

If the document is attached, the  icon will appear in the Unattach column. The version number is circled in red.

Compare	Include in PDF Packet	Unattach	Revise/ Attach	Revisions	All Submission Components Previous Rounds & Currently Attached
Submission Form(s)					
<input type="checkbox"/>	<input type="checkbox"/>				University of Tennessee - Knoxville IRB - PI Review Response Form - UTK - (Version 2.0 (Incomplete))
<input type="checkbox"/>	<input type="checkbox"/>				Routing Form for Form 1: Initial Review Submission Form - (Version 1.0)
Application					
<input type="checkbox"/>	<input type="checkbox"/>				UTK Knoxville Main Campus IRB Application (Version 1.2)
Consent Form(s)					
<input type="checkbox"/>	<input type="checkbox"/>				Participant Consent Form (English) - (Version 1.1)
Document(s)					
Category : Surveys/Questionnaires/Data Collection Instruments					
<input type="checkbox"/>	<input type="checkbox"/>				Online Survey Consent Document - (Version 1.0)
<input type="checkbox"/>	<input type="checkbox"/>				Health History Form - (Version 1.0)

9. Issues Requiring a Response section

- Scroll down to section 1.3 of the Response Submission form.
- Respond to the requested changes.
- Click  after responding to all the requested changes.

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):

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

10. Form Completed screen

- Either the PI or another investigator (co/sub or co-PI) must click **Signoff and Submit**.
- Then users are routed to the **Setup Signoff Submission Routing** screen.

TIP: If study personnel other than an investigator completes the form, only the **Exit Form** button appears. The PI then must open the form and click **Signoff and Submit**.

Print Friendly
 Compare with Application
 Signoff and Submit

Entire view of the Form

Form has been Completed!

Instruction of Form has Been Completed Screen

Exit Form

Signoff and Submit

Required Routing and Submission Signoffs

22. Setup Signoff Submission Routing

- Click **No** (red arrow) unless the IRB asks for additional individuals to sign off.
- Click **Save and Continue** (circled in red).

26. Submission Routing Signoff

- **View a document** by clicking on it.
- If you want to **print documents** as a PDF
 - Check the box next to each document you want to print.
 - Click **Printable Version** PDF button (blue arrow).

If everything is in order:

- Click **Approve** (red arrow).
- Click **Save Signoff** (circled in red).

The packet is routed to the IRB after all required personnel have signed off.

Document History

Date	Summary of Changes
08.12.2019	Original Document Approved.
04.15.2020	Updated Title, added login information, updated some procedures, and reformatted some sections.