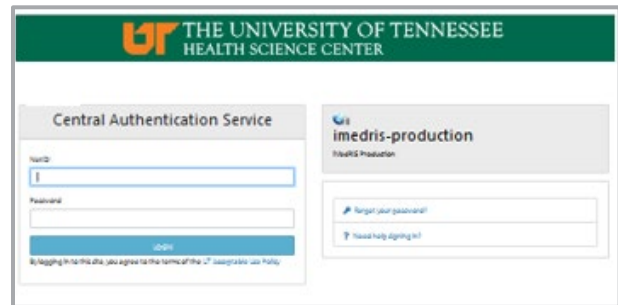


Follow the steps below to attach additional study documents (recruitment materials, grant materials, etc.) to your IRB submission.

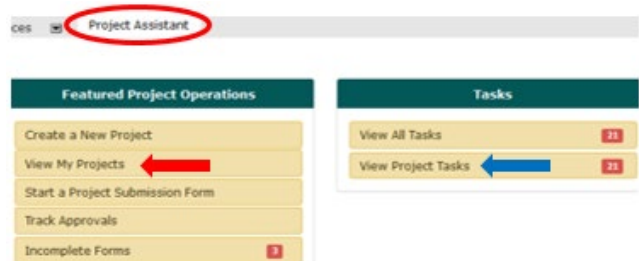
Find and Open the Study

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




2. **Project Assistant** screen (tab circled in red)

- Click **View Project Tasks** (blue arrow) to see your pending **Study Tasks** if responding to a request from the IRB, or
- Click **View My Projects** (red arrow) to see all the studies on which you are listed as study personnel.



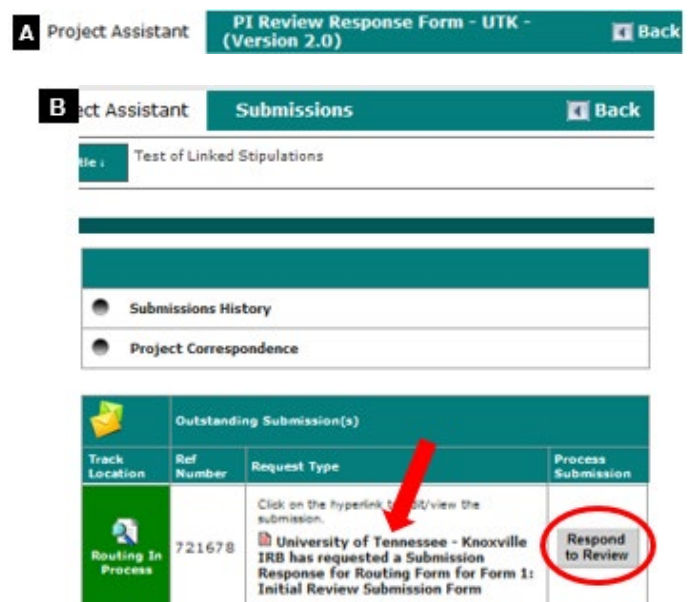
3. **Locate your study.**

Click the  (red arrow) under the **Click to Open** column.

Click to open	Project States	Review Board	RB Number	RB Expiration	Project Title	Principal Investigator
	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 either **Respond to Review** (circled in red) or **University of Tennessee - Knoxville IRB has requested a Submission Response for Routing Form for Form 1: Initial Review Submission Form** (red arrow) under the **Request Type** column.

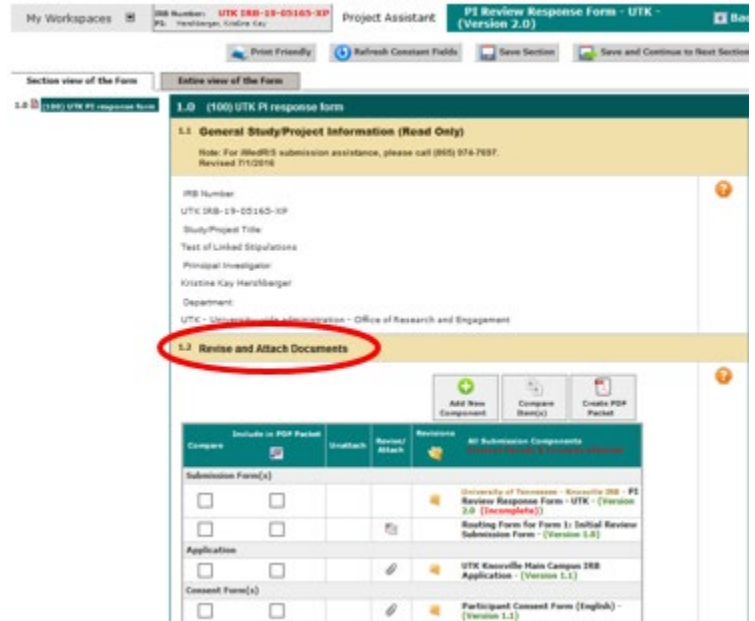


Attach Other Study Documents

5. PI Review Response (or Correction) Form

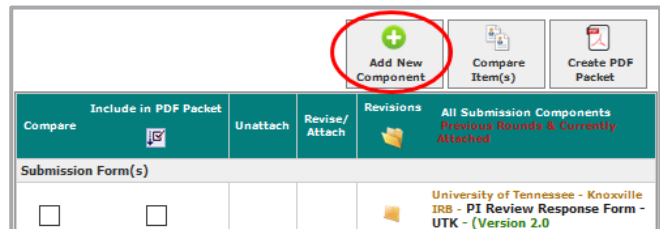
- Scroll down to section **1.2 Revise and Attach Documents** (circled in red).
- Find the form or document that needs the correct version attached.

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.



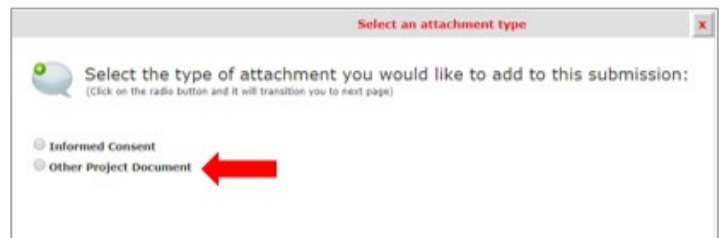
6. Revise and Attach Documents section

If the requested document is not listed in the table, click the **Add New Component** button (circled in red).



7. Select an Attachment Type pop-up window

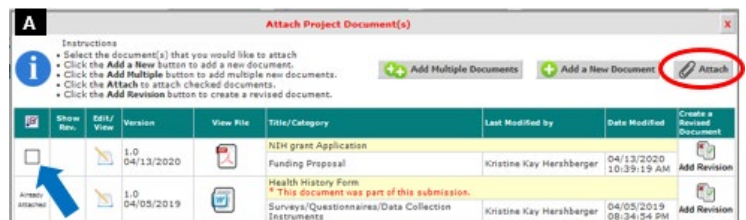
Click **Other Project Document** (red arrow) if you are attaching anything other than an Informed Consent.



8. Attach Project Document(s) window – Document uploaded but not attached.

If the document was previously uploaded, but was not part of the submission package, it may be listed here (**picture A**). If so:

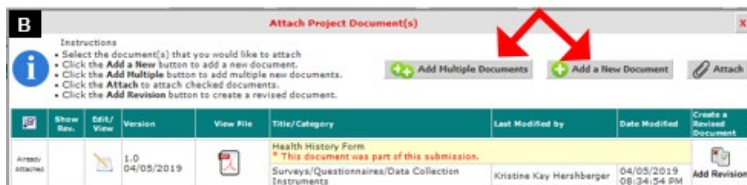
- Click the **check box** under the first column (blue arrow).
- Click **Attach** (circled in red).
- You will be returned to the **Review Response** form.



TIP: Do Not upload consent forms to Other Project Documents **unless** as a consent audit for a Continuing Review Request.

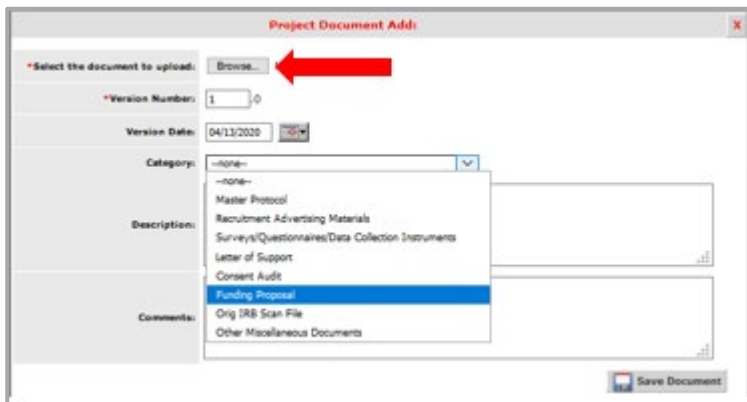
9. **Attach Project Document(s)** window – Upload Document. To upload other study documents (not consent forms):

- click **Add a New Document (picture B)** to add a single document (red arrow on right), or
- if adding more than one document, click **Add Multiple Documents** (red arrow on left).



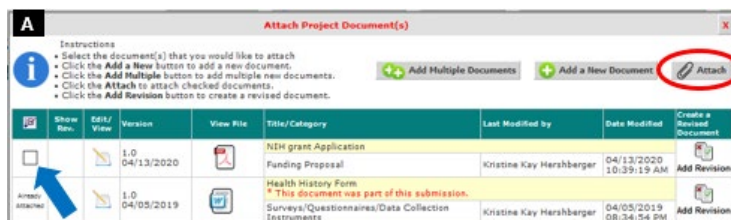
10. **Project Document Add** window/screen – Upload Document.

- Click **Browse/Upload** (red arrow) to upload the desired document.
- **Category** – Select Funding Proposal for grant documents, etc.
- **Version Number** – 1.0 for new documents.
- **Version Date** – Click calendar icon for the date.
- Add optional additional information in the Description and Comment text boxes.
- Click **Save Document**.



11. After returning to the **Attach Project Document(s)** window:

- **Confirm** the correct documents are uploaded.
- Click the check box in the first column if the document is not already attached (blue arrow, **picture A**)
- Click **Attach** (circled in red).



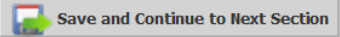
12. On the **PI Review Response Form**

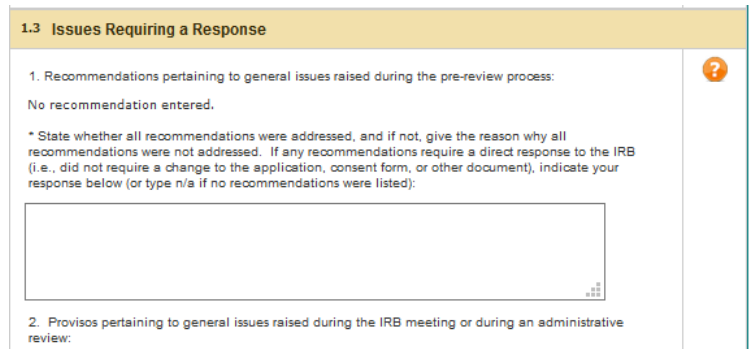
The documents are attached (circled in red).

TIP: Other Project Documents are organized by category. Categories are shown in yellow (red arrow).

Compare	Include in PDF Packet	Unattach	Revise/ Attach	Revisions	All Submission Components <i>Previous Records & Currently Attached</i>
Submission Form(s)					
<input type="checkbox"/>	<input type="checkbox"/>				University of Tennessee - Knoxville IRB - PI Review Response Form - UTK - (Version 2.0)
<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 : Funding Proposal					
<input type="checkbox"/>	<input type="checkbox"/>				NIH grant Application - (Version 1.0)

13. Issues Requiring a Response section

- Scroll down to section **1.3 Issues Requiring a Response**.
- Respond to each item by entering information in the text box and, if applicable, by selecting **Yes**, **No** or **N/A** for each proviso.
- 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.

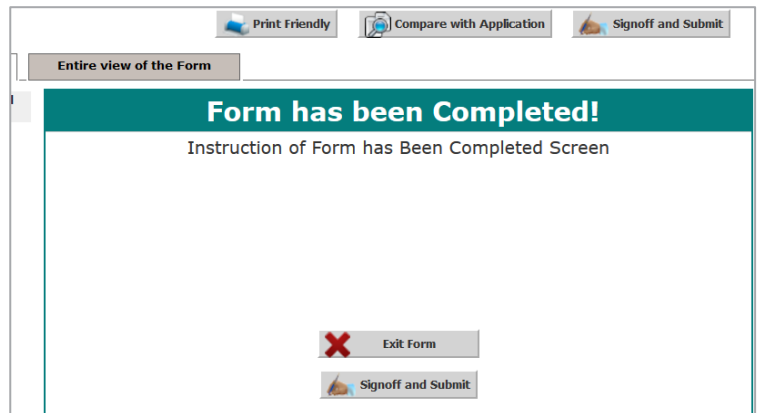
* State whether all recommendations were addressed, and if not, give the reason why all recommendations were not addressed. If any recommendations require a direct response to the IRB (i.e., did not require a change to the application, consent form, or other document), indicate your response below (or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

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

14. 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

15. Setup Signoff Submission Routing

- Click **No** (red arrow)
- Click **Save and Continue** (circled in red).



My Workspaces Project Assistant Setup Signoff Submission Routing Back

Save and Continue

Does this submission require additional routing for approval?

YES - Click YES to select additional personnel for routing.

NO - Click NO to bypass selecting additional personnel for routing.

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.

Project Title: iMedRIS Form Development for Production
Submission Reference Number: 718471

Include in PDF Packet

Include in PDF Packet	Submission Component Name - Version
<input type="checkbox"/>	Pre-Review Correction Form - University of Tennessee - Knoxville IRB - (Version 1.0)
<input type="checkbox"/>	Routing Form for Form 1: Initial Review Submission Form - (Version 1.0)
Application	
<input type="checkbox"/>	UTK Knoxville Main Campus IRB Application - (Version 1.1)
Document(s)	
<input type="checkbox"/>	Miscellaneous Corrections to IRB Application - 11.29.2018 - (Version 1.0)
Category : --none--	
<input type="checkbox"/>	Pop-up Windows - Consent Document Add - Project Document Add - (Version 1.2)
<input type="checkbox"/>	468 Funding - (Version 1.2)
<input type="checkbox"/>	1600 Recruitment - (Version 1.2)
<input type="checkbox"/>	2000 Risks and Benefits - (Version 1.2)
<input type="checkbox"/>	2800 Privacy and Confidentiality - (Version 1.2)

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

Approve Deny

Document History

Date	Summary of Changes
04.15.2020	Original Document Approved.