

iMedRIS Quick Guide Responding to Provisos in iMedRIS

iMedRIS version: 11.01

Last Revised: 07.10.2020

Follow the steps below to respond to provisos and to attach and revise the application and study documents as requested by your reviewer.

Step-by-Step Instructions

1. Log into iMedRIS using your NetID



2. Select **View All Tasks**



3. Click on the **Notepad** next to the study you wish to respond to and the study will open.

The screenshot shows the 'Project Assistant' interface. At the top, there are tabs for 'Study Tasks' (Outstanding, Completed) and a search bar. Below this is a table with columns: Task Type, Received, Project Status, Project Title, Principal Investigator, Review Board, IRB Number, and All Expiration. The first row is highlighted in yellow and has a red circle around the 'Notepad' icon in the 'Task Type' column. The second row is highlighted in red and has a status of 'Demanded/Administratively Closed'.

Task Type	Received	Project Status	Project Title	Principal Investigator	Review Board	IRB Number	All Expiration
Research Response	06/09/2019 09:51:27 AM EDT	Open	TEST STUDY No. 2	Earl, Jennifer	University of Tennessee - Knoxville IRB		
Substance Response	02/03/2018 01:12:11 PM EDT	Demanded/Administratively Closed	TEST STUDY	Earl, Jennifer	University of Tennessee - Knoxville IRB LTR 18-0589-FR		03/30/2020

4. Scroll to section 1.3 of the **PI Review Response Form** and read the provisos.

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:

The screenshot shows a 'Proviso 1 out of 3' section. It includes a 'Description' field with the text: 'Please revise section (925) Study/ Project Synopsis to include a thorough discussion of the project including the purpose, methods, recruitment, data collection, and analysis.' Below this is a 'Stipulation Type: (Proviso must be addressed)' field. At the bottom, there is a question 'Do you accept this Proviso?' with radio buttons for 'N/A', 'Yes', and 'No'. A red arrow points to the 'Proviso 1 out of 3:' header.

5. If your proviso requires you to revise the application, follow the next couple steps. If your proviso only asks you to revise or attach documents skip to step 8.
- To revise the application, scroll back up to section 1.2 Revise and Attach Documents. **Click on the Revise/Attach icon** in the table to the left of the application hyperlink

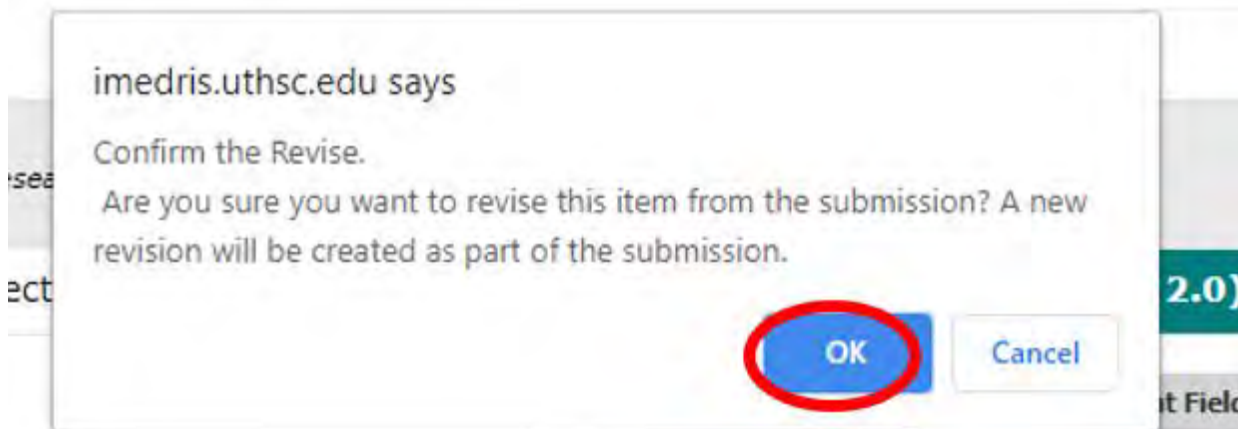
1.2 Revise and Attach Documents

The screenshot shows the '1.2 Revise and Attach Documents' section of the iMedRIS interface. At the top right, there are three buttons: 'Add New Component', 'Compare Item(s)', and 'Create PDF Packet'. Below these is a table with columns: 'Compare', 'Include in PDF Packet', 'Unattach', 'Revise/Attach', 'Revisions', and 'All Submission Components'. The table lists several items:

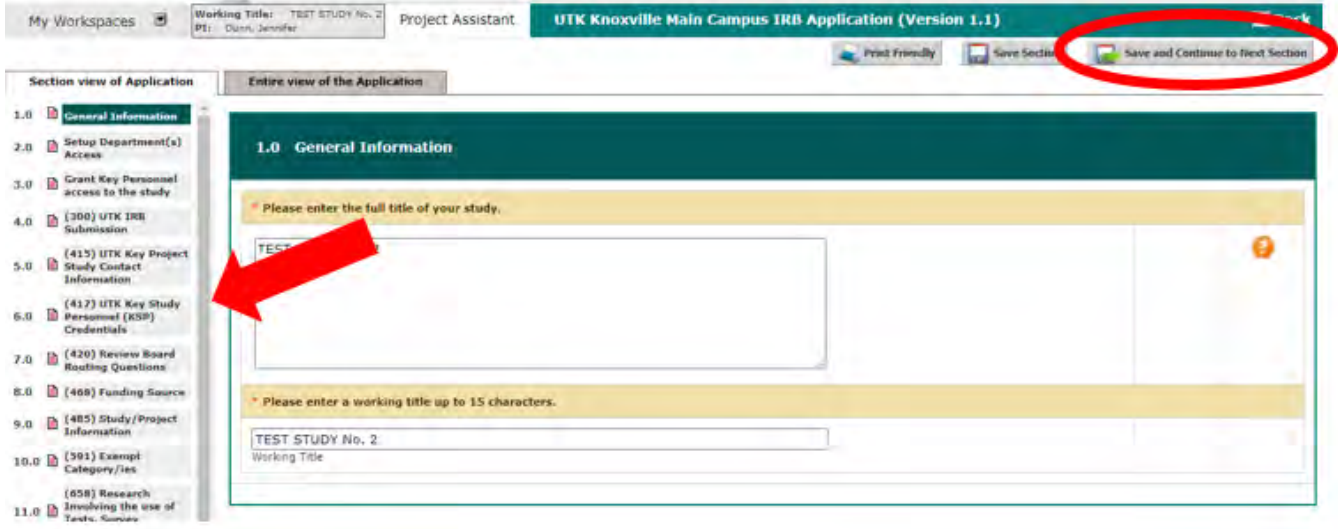
Compare	Include in PDF Packet	Unattach	Revise/Attach	Revisions	All Submission Components
<input type="checkbox"/>	<input type="checkbox"/>				University of Tennessee - Knoxville IRB - PI Review Response Form - UTK - (Version 2.0 (Incomplete))
<input type="checkbox"/>	<input type="checkbox"/>				Attachment 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 1.0)
Document(s)					
Category : Funding Proposal					
<input type="checkbox"/>	<input type="checkbox"/>				Grant Application - (Version 1.0)

A red arrow points to the 'Revise/Attach' icon in the row for 'UTK Knoxville Main Campus IRB Application - (Version 1.0)'.

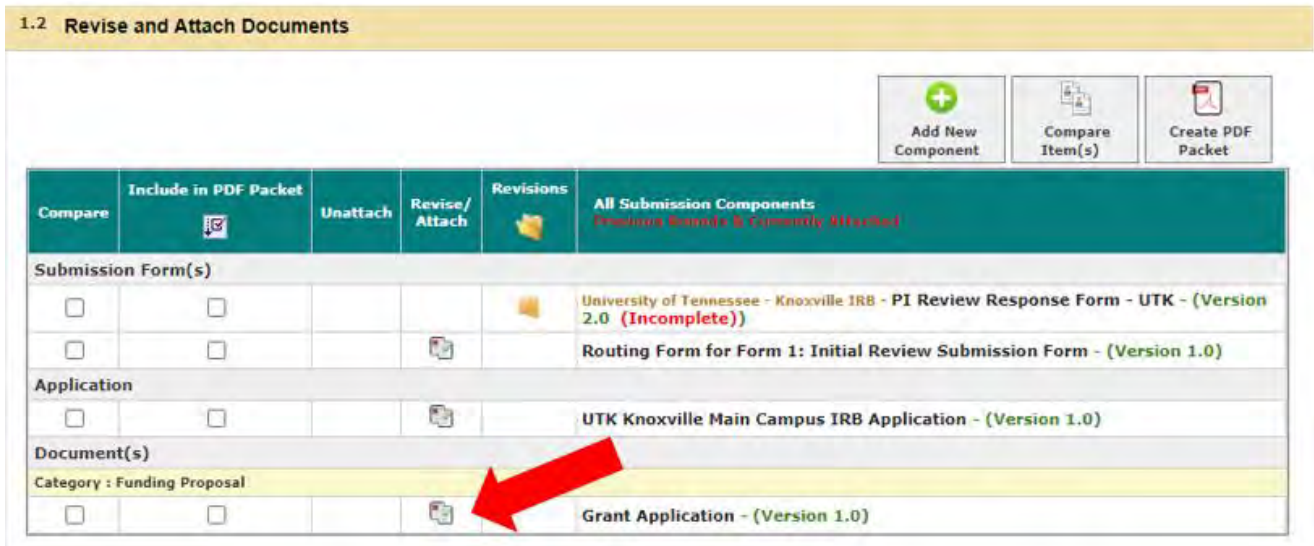
6. A window will appear, click **OK**



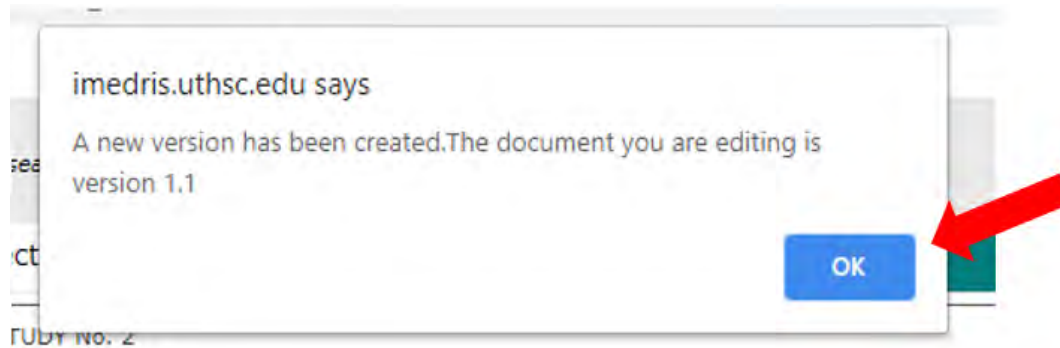
- To revise your application, **select the section** on the left that requires revising and edit it.
 - Once you've completed your revisions click **Save and Continue to Next Section** until you've revised every section required and reached the end of the application.



- Now you will be brought back to the PI Review Response Form
 - To revise a document, click on the icon to the left of the document in the table in Section 1.2.



9. Click **OK** when it asks you if you wish to create a new version of the document.



10. Click **Check-out Document** and the document will be downloaded to your computer for you to revise.

* Document Title:	Grant Application
*Version Number:	1 .1
Version Date:	02/12/2020
Category:	Funding Proposal
Description:	
Check-out the Document to your workstation for editing:	<input type="button" value="Check-out Document..."/>
Comments:	

11. Once you've revised the document, save it to your computer with the same name. Then click Complete Checkout.

ant **Download the Project Document** Back

INSTRUCTIONS

Step 1:
If your browser blocks pop-ups, then after a few moments a bar similar to the one shown below may appear in your browser.

To help protect your security, Internet Explorer blocked this site from downloading files to your computer. Click here for options...

Simply click on the bar and a small drop down list will appear. Click **Download File** from the list of options.

Download File...
What's the Risk?
More information

Step 2:
In a few moments, your browser will prompt you to either **Open** or **Save** the file (see example below).
Note: this is not the actual File Download box, it is only a picture. In order to Check - out the document and edit it, you will need to **Save** it to your workstation.

File Download

Do you want to open or save this file?

Open: [http://localhost:8080/.../.../...](#)
Type: Microsoft Word Document, 23,508
File: 16-200-45-114

Open Save Cancel

While files from the Internet can be useful, some files can potentially harm your computer. If you do not trust the source, do not open files from the Internet.

Complete Checkout

Cancel

To do so, click **Save**. This will open up a window similar to the one shown below that allows you to choose where in your workstation you would like to save the document.

Once you've selected where you will save the document, click **Save**. After this, the Download Complete box will appear as shown below. From here you can choose to open the document to edit it, open the folder that contains the document, or Close the Download Complete box to edit the document later.

12. Now click Check-in Document.

*** Document Title:**

Version Number: .1

Version Date:

Category:

Description:

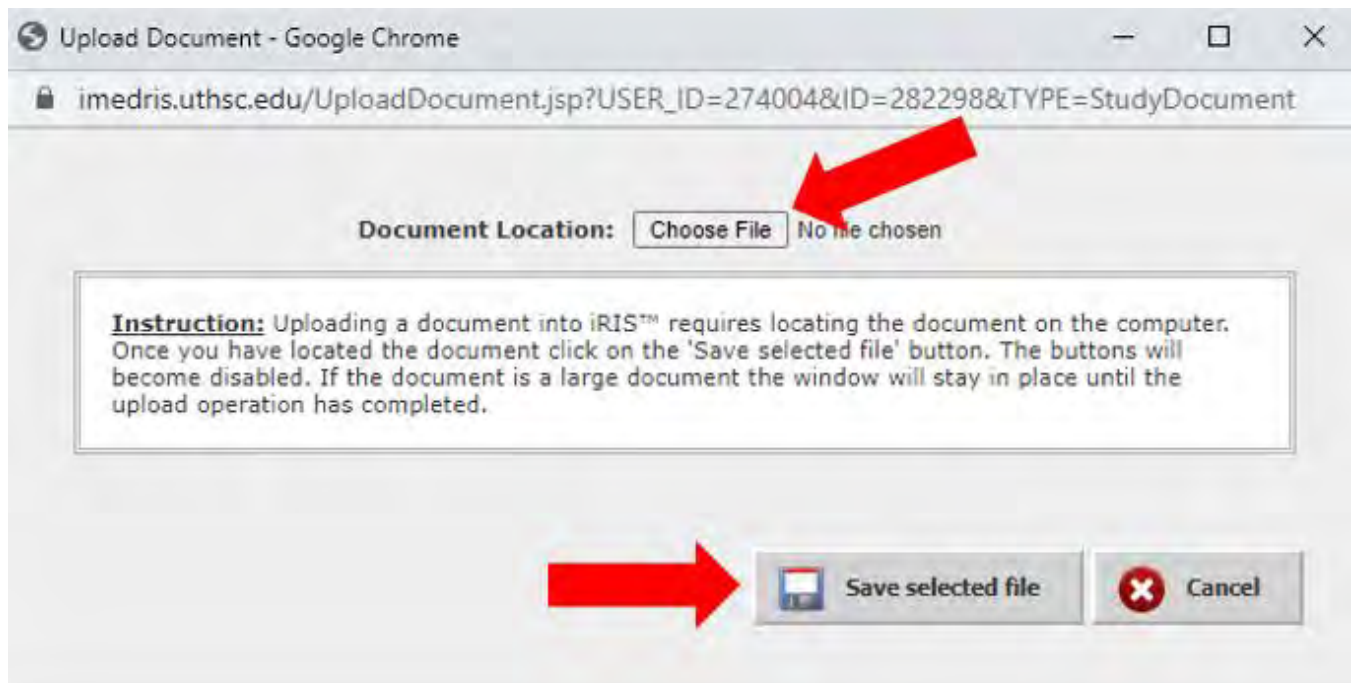
This document is currently checked out by: Jennifer Dunn at 06/29/2020

Check-in when you are done editing upload the document back into iRIS.

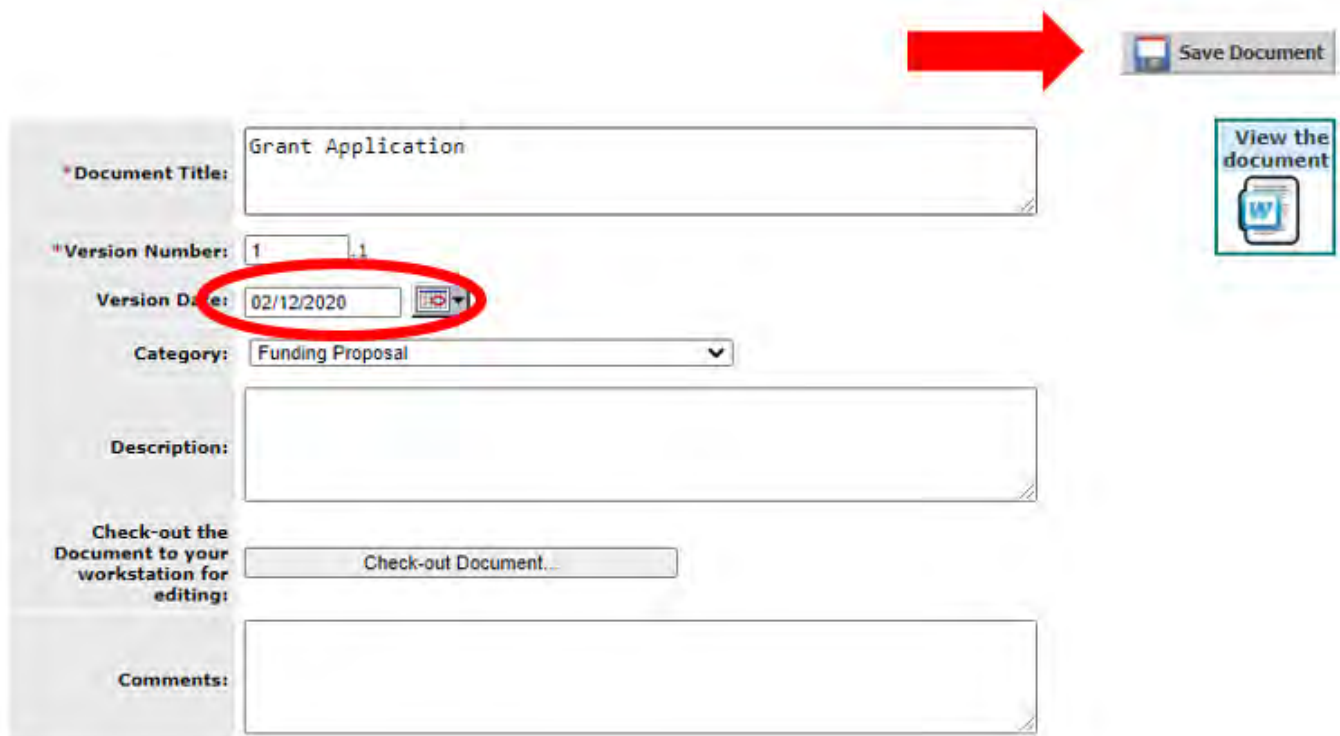
Revert to the document stored in iRIS.

Comments:

13. Click **Choose File** and upload the document you just edited. Then Click **Save selected file**.



14. Once the document has been uploaded change the version date to today's date and click **Save Document**.



15. If a proviso requests that you upload a new document follow this step. If not skip to step 20.

- Click **Add New Component**

1.2 Revise and Attach Documents

Compare	Include in PDF Packet	Unattach	Revise/ Attach	Revisions	All Submission Components <i>Previous Rounds & 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 (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 1.0)
Document(s)					
Category : Funding Proposal					
<input type="checkbox"/>	<input type="checkbox"/>				Grant Application - (Version 1.0)

16. Select which type of document you wish to upload

Select the type of attachment you would like to add to this submission:
(Click on the radio button and it will transition you to next page)

Informed Consent

Other Project Document

17. Click **Add a New Document** or **Add Multiple Documents**.

Attach Project Document(s)

Instructions

- Select the document(s) that you would like to attach
- Click the **Add a New** button to add a new document.
- Click the **Add Multiple** button to add multiple new documents.
- Click the **Attach** to attach checked documents.
- Click the **Add Revision** button to create a revised document.

	Show Rev.	Edit/ View	Version	View File	Title/Category	Last Modified by	Date Modified	Create a Revised Document
Already Added			1.1 02/12/2020		Grant Application	Jennifer Dunn	06/29/2020 10:22:58 AM	Add Revision
					Funding Proposal			

18. Fill in the boxes and upload your document by clicking **Upload**.

- Once you've completed the boxes click **Save Document**

The screenshot shows a form for uploading a document. The fields are: Document Title (Recruitment Email), Version Number (1.0), Version Date (06/29/2020), Category (Recruitment Advertising Materials), and Description (empty). Below the description is an 'Upload' button. To the right of the form is a 'Save Document' button. Red arrows point from the 'Save Document' button to the right and from the 'Upload' button to the left.

19. You will then be brought back to the previous screen. If the document is not listed as Already Attached, put a Checkmark next to the items you wish to attach and then click **Attach**.

The screenshot shows the 'Attach Project Document(s)' dialog box. It includes instructions, buttons for 'Add Multiple Documents', 'Add a New Document', and 'Attach', and a table of documents. A red arrow points to the 'Attach' button, and a red circle highlights a checkmark in the 'Already Added' column of the table.

IRIS	Show Rev.	Edit/View	Version	View File	Title/Category	Last Modified by	Date Modified	Create a Revised Document
Already Added			1:1 02/12/2020		Grant Application			
					Funding Proposal	Jennifer Dunn	06/29/2020 10:22:58 AM	Add Revision
<input checked="" type="checkbox"/>			1:0 06/29/2020		Recruitment Email			
					Recruitment Advertising Materials	Jennifer Dunn	06/29/2020 10:34:38 AM	Add Revision

20. Once you have addressed all of the provisos, you need to respond to each one in the PI Review Response Form.

- Select either N/A, Yes, or NO depending on your response to the proviso.
- Then write a response in the text box explaining the revisions you did or did not complete.
- Complete this for each proviso

Proviso 1 out of 3:


Description:
Please revise section (925) Study/ Projec Synopsis to include a thorough discussion of the project including the purpose, methods, recruitment, data collection, and analysis.

Stipulation Type: (Proviso must be addressed)

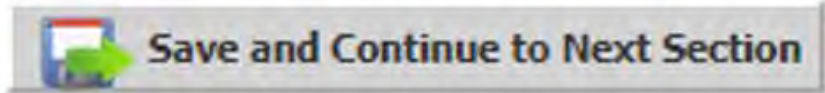
Do you accept this Proviso? N/A Yes No

Provide an explanation on how you addressed this Proviso:

Complete|



21. Answer the final two text boxes and then click **Save and Continue to Next Section**



* 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):

complete

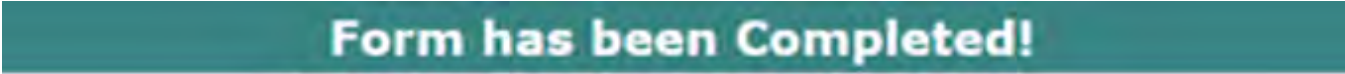
3. Any additional changes made to the submission:

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

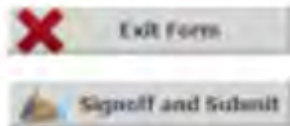
N/A

1.4 INSTRUCTIONS FOR USING THIS FORM:
This form allows you to respond to issues identified by the IRB analysts and Board members.
For UTK iMedRIS application assistance, please call (865) 974-7697.

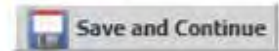
22. Click Signoff and Submit



Instruction of Form has Been Completed Screen



23. Click **NO**, unless someone on your project has specifically requested they sign off on all revisions.
Click **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.

- Make sure all of the correct versions of the documents are listed in the table. Then, click **Approve** and **Save Signoff**

My Workspaces | Project Assistant | **Submission Routing Signoff** | Back | Save Signoff

Project Title:
Submission Reference Number:

Submission Form(s):

Include in PDF Packet	Submission Component Name - Version
Submission Form(s)	
	UTK Request to Resume In-Person Research Activity during COVID-19 - (Version 2.0)
Document(s)	
Category : COVID-19 Documents	
	COVID-19 Research Participants Screening Questions - (Version 1.0)
	COVID-19 Information for Research Participants Online - (Version 1.0)
	COVID-19 Information for Research Participants Hard Copy - (Version 1.0)
	Request for Continuation of in-person Research - (Version 1.0)

Colleen P Gilrane as Principal Investigator
do you Approve or Deny this submission?

Approve Deny

Save Signoff