

### iMedRIS Quick Guide

## Attach a Revised Application

iMedRIS version: 11.01 Last Revised: 04.15.2020

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

<ol> <li>Log in to <u>iMedRIS</u> using your NetID and Password.</li> </ol>	HEALTH SCIENCE CENTER				
Passworu.	Central Authentication Service	Cut imedris-production heats resolution Proprior parameter ? heat top dying sit			
<b>2.</b> iMedRIS should open to your <b>Project</b> <b>Assistant</b> workspace (tab circled in red).	ces Project Assistant Featured Project Operations	Tasks			
Click <b>View Project Tasks</b> (red arrow).	Create a New Project View My Projects Start a Project Submission Form Track Approvals Incomplete Forms	View Project Tasks			
3. Project Tasks					
Locate your study.	Click to project open Status Review Board	RB Number RB Expiration Project Title Principal Investig			
<ul> <li>Click the <u>(red arrow</u>) under the Click to Open column.</li> </ul>		ΤΚ 88-18-04693-			
4. Submissions screen	A Project Assistant PI Review (Version 2.0	Response Form - UTK - 🛛 🖬 Ba			
<ul> <li>If the study opens to the PI Review Response (or Correction) Form (picture</li> </ul>	B ect Assistant Submis	isions 🗖 Back			

Test of Linked Stipulations

Submissions History

Project Correspondence

21678

Outstanding Submission(s)

Request Type

Click on the hyperlink to edit/view the

University of Tennessee - Knoxville IRB has requested a Submission Response for Routing Form for Form 1: Initial Review Submission Form

- A), skip to Step 5.
  If the study opens to the Submissions
  Grad the Outstanding
- 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).

## **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  $\mathscr{O}$  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.

UTR DEB-09-00105-XP Project Assistant Ny Workspaces Print Fr ( Rafresh Co Fields Save Section ion view of the form C1000 UTK PI re General Study Project Information (Read Only) Note: For illiedRtS submi Revised 71(2016 ion analatance, please call (865) 974 0 INS Number UTK 188-19-05165-XP Study Project Title Test of Linked Stipul siteal Investigator ine Kay He Revine and Attach 0 59 6 1 

#### 6. Revise and Attach Documents section

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

				Add I Compon	lew	Compare Item(s)	Create PDF Packet
Compare	Include in PDF Packet	Unattach	Revise/ Attach	Revisions	All S Prev Attac	ubmission Compo ious Rounds & Cu :hed	onents irrently
Submissi	on Form(s)						
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			<b>E</b>		Routing Form for Form 1: Initial Review Submission Form - (Version 1.0)		
Application	on						
			Ø	-	UTK Knoxville Main Campus IRB Application (Version 1.1)		
Consent I	Form(s)						
			Ø	-	Participant Consent Form (English) - (Version 1.1)		
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Category : S	urveys/Questionnaires/Da	ta Collection	Instrument	s			
						e Survey Conse ion 1.0)	ent Document -
			<b>*</b>		Healt 1.0)	h History Form	- (Version

# 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).

		Attaching Project Application	
	Select	the application that you would like to attach to the submission	on.
Select	Edit/ View	Form Name	Approved
0		UTK Knoxville Main Campus IRB Application (Version 1.2)	No
0	X	UTK Knoxville Main Campus IRB Application (Version 1.1)	No
0	M	UTK Knoxville Main Campus IRB Application (Version 1.0)	No

#### 8. After returning to the Response

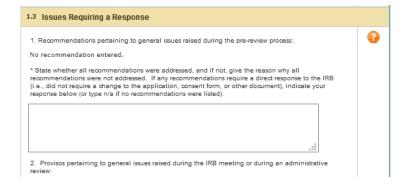
Submission (or Correction) form, confirm the correct version of the form/document is attached.

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

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Submissi	on Form(s)						
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Category : S	urveys/Questionnaires/Da	ta Collection	Instrument	s			
					Online Survey Consent Document - (Version 1.0)		
					Healt 1.0)	h History Form	- (Version

#### 9. Issues Requiring a Response section

- Scroll down to section 1.3 of the Response Submission form.
- Respond to the requested changes.
- Click Save and Continue to Next Section after responding to all the requested changes.



#### 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**.

Enti	Print Friendly Compare with Application ksignoff and Submit
1	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 individiuals to sign off.
- Click **Save and Continue** (circled in red).

My Workspaces	Project Assistant	Setup Signoff Submission Routing	27 Pack
			eve and Continue
oes this submission	require additional routin	ng for approval?	
0			
YES - Click YES to sel	lect additional personnel for rou	uting.	
NO - Click NO to bype	ass selecting additional personn	el for routing.	
1			

#### 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.

				Save Sign		
Project Title:	iMedRIS Fo	rm Development for Pro	duction			
bmission Reference	718471					
Humberr						
				Printable		
2				Version		
	Include	Submission Componen	Name - Maralan			
	PDF Packet	and an empower				
	Submission	Form(s)				
			Form - University of Tennessee - Kno	xville IRB -		
1		(Version 1.0)				
		Routing Form for Form 1: Initial Review Submission Form - (Version 1.0)				
	Applicatio	n				
Submission Form(s);		UTK Knoxville Main Campus IRB Application - (Version 1.1)				
	Document	(s)				
		Miscellaneous Corrections to IRB Application - 11.29.2018 - (Version 1.0)				
	Category :	-none				
		Pop-up Windows - Consent Document Add - Project Document Add - (Version 1.2)				
		468 Funding - (Version 1.2)				
		1600 Recruitment - (Version 1.2)				
		2000 Risks and Benefits - (Version 1.2)				
		2800 Privacy and Confi	dentiality - (Version 1.2)			
	-					

## **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.