



Navigating the Not Approved Protocol Resubmission Process

21 Steps [View most recent version](#) 

Created by	Creation Date	Last Updated
Crystal Lijadu	July 21, 2023	July 21, 2023

STEP 1

Navigate to the All Studies section

	006585	IRB	IRISID-2023-1638	IRB Reliance Agreement Form
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3 result(s) found...

All Studies

Recently Used

Study Status

All

Draft

3 result(s) found...

Click to open Study Dashboard	Study Status	Review Board	RB Number	RB Expiration
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STEP 2

Locate the Not Approved study you are resubmitting.

All

























Draft

3 result(s) found...

Click to open Study Dashboard	Study Status	Review Board	RB Number	RB Expiration
	Not Approved	IRB	IRISID-2023-1638	
	Approved With No Further Continuing Review	IRB	21D.1016	01/01/2900
	Approved	IRB	22G.462	05/31/2024

STEP 3

Click on Forms.

Actions									
Training Study									
									
Applications	Documents	Forms	Hide	Exempt	Copy	Delete	Correct		
Primary Care Motivational Interviewing Nutrition Education Program for Weight Loss									
									
Applications	Documents	Forms	Hide	Exempt	Copy	Delete	Correct		
Delivered Motivational Interviewing Nutrition Education Program and Melatonin for...									
									
Applications	Documents	Forms	Hide	Exempt	Copy	Delete	Correct		

STEP 4

Locate the Resubmission of a Not Approved Protocol form.

The screenshot shows a form selection interface. On the left, there is a sidebar with a 'Study Status' filter. The main area displays a list of forms. The 'Resubmission of a Not Approved Protocol' form is highlighted with a purple box. Below the list, there is a 'Cancel' button and a calendar for July 2023.

Study Status	Form Name	Form ID	Form Type
Draft	Annual Check-in Form for Exempt and No Further Continuing Review Studies		
	Continuing Review or Final Report (formerly OHR-9)		
	External IRB - Annual Update and Closure		
Not Approved	IRB Reliance Agreement Follow-up Form		
Not Approved	Request for Acknowledgement/Receipt		
Not Approved	Resubmission of a Not Approved Protocol		

July 2023

26 Mon 27 Tue 28 Wed 29 Thu 30 Fri

STEP 5

Click to start a new form.

The screenshot shows a form selection interface. On the left, there is a list of forms. The 'Add a new Form' button is highlighted with a yellow box. Below the list, there is a 'Cancel' button.


Form Name	Form ID	Form Type
Annual Check-in Form for Exempt and No Further Continuing Review Studies		
Continuing Review or Final Report (formerly OHR-9)		
External IRB - Annual Update and Closure		
IRB Reliance Agreement Follow-up Form		
Request for Acknowledgement/Receipt		
Resubmission of a Not Approved Protocol		

Add a new Form

Cancel

STEP 6

Review the Instructions.



Account: Steven Muller
Department: TJU - Orthopaedic Surgery
Path: Home

Calendar ? Help My Profile

IRB Number: **IRISID-2023-1638**
PI: Ujadu, Crystal

Study

Resubmission of a Not Approved Protocol - (Version 1.0)

Print Friendly Save Section Save and Continue

Entire view of the Form

1.0 Instructions and Attachments

1.1 Instructions

When re-submitting based on a **NOT APPROVED** protocol, please be sure to adhere to the following instructions:

- Revise Responses to stipulations directly in the Master Application
- Include a typed cover letter that presents an itemized response to the Board's concerns. Please incorporate the stipulations listed above in your response letter. The PI must respond to the concerns listed above and sign the response.
- Include a clean (final) and tracked changes copy of all revised documents.


Please be sure to proofread all documents carefully after changes have been made. Following these guidelines will ensure efficient processing of your re-submission.

1.2 Confirmation

Please confirm your protocol was reviewed by a convened IRB and was determined to be Not Approved.

☐ Yes ☐ No

1.3 Revise the Master Application

 Click here to attach the application.

No Application has been associated with this submission.

The study application must be included with the resubmission application. Attach the study application here. You will then click Create Revision and make changes as requested by the board. **You cannot proceed with the Resubmission application until the study application has been attached in this section.**

If you make changes to the protocol or Master Applications in addition to the changes requested by the board, you must identify those changes in your cover letter.

1.4 Attach Itemized Response and Other Relevant Documents

Please attach a typed cover letter that presents an itemized response to the Board's concerns. Please incorporate the stipulations listed above in your response letter. **The PI must respond to the concerns listed above and sign the response.**

In addition, other relevant documents may include the revised protocol and other study documents submitted with the initial application.

Please **do not** attach consent documents in this section. They should be included in the next section.

STEP 7

Confirm you are submitting the correct form.

1.1 Instructions

- Include a clean (final) and tracked changes copy


Please be sure to proofread all documents carefully aft

1.2 Confirmation

Please confirm your protocol was reviewed by a conver

☒ Yes ☐ No

1.3 Revise the Master Application

 Click here to attach the application.

No Application has been associated with this submissio

The study application must be included with the resubr
with the Resubmission application until the study

5 of 12

STEP 8

Click to attach the master application.

- Revise Responses to stipulations directly in the Master Application
- Include a typed cover letter that presents an itemized response to the Board's concerns. Please incorporate the stipulations above and sign the response.
- Include a clean (final) and tracked changes copy of all revised documents.


Please be sure to proofread all documents carefully after changes have been made. Following these guidelines will ensure efficient

1.2 Confirmation

Please confirm your protocol was reviewed by a convened IRB and was determined to be Not Approved.

☒ Yes ☐ No

1.3 Revise the Master Application

 **Click here to attach the application.**

No Application has been associated with this submission.

The study application must be included with the resubmission application. Attach the study application here. You will then click **Cr with the Resubmission application until the study application has been attached in this section.**

If you make changes to the protocol or Master Applications in addition to the changes requested by the board, you must identify t

1.4 Attach Itemized Response and Other Relevant Documents

Please attach a typed cover letter that presents an itemized response to the Board's concerns. Please incorporate the stipulations **listed above and sign the response.**

In addition, other relevant documents may include the revised protocol and other study documents submitted with the initial appli


Please **do not** attach consent documents in this section. They should be included in the next section.

STEP 9

Click Add Revision.

Click Save Attachment

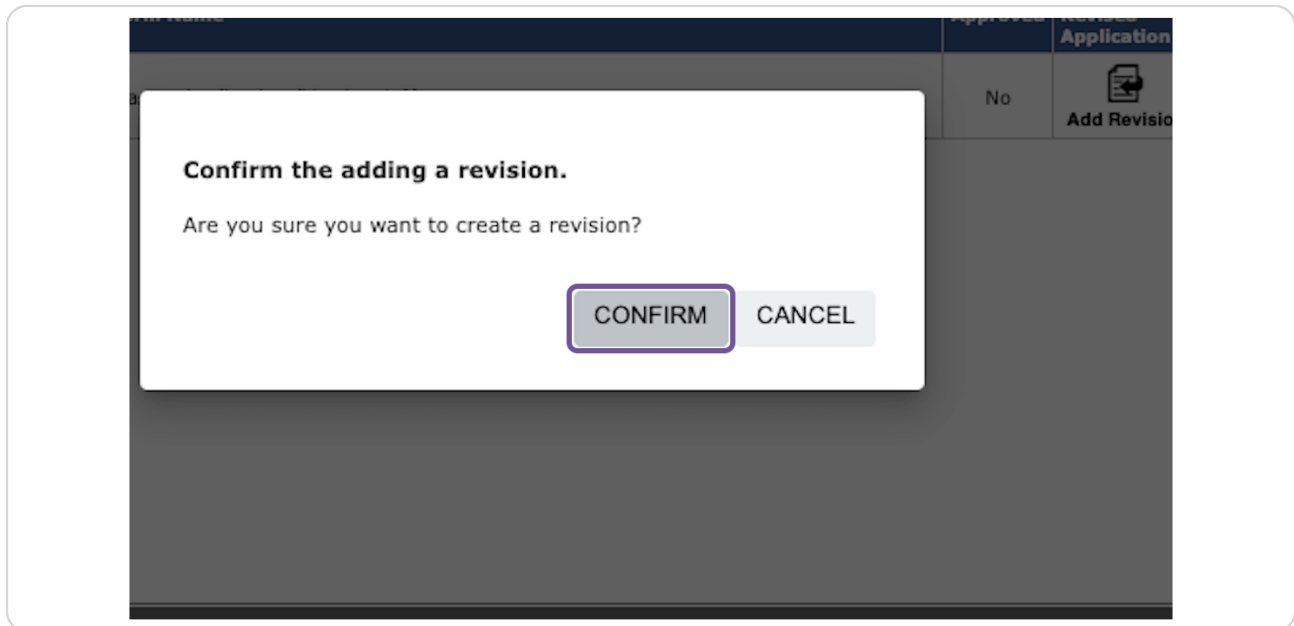
Save Attachment

	Approved	Create a Revised Application
	No	<div> Add Revision</div>

respond to the concerns listed

STEP 10

Click on confirm.



STEP 11

Make all necessary revisions.

Reminder: If you make revisions not requested by the board, please note them in your response letter.

A screenshot of the Jefferson IRB application form. The top header includes the Jefferson logo, department information (TJU - Orthopaedic Surgery), and the path "Home > form data". The main title is "Master Application (Version 1.1)". A sidebar on the left lists sections from 1.0 to 16.0, with "1.0 Study Title" selected and highlighted with a purple border. The main content area shows the "1.0 Study Title" section, which includes a prompt to enter the full protocol title of the study, a text input field containing "Copy of Office of Human Research Testing/Training Study", and a prompt to enter an abbreviated study title, with a text input field containing "OHR Test Study".

STEP 12

Click Save and Continue to Next Section.

The screenshot shows a user interface with a top navigation bar containing 'Calendar', 'Help', 'My Profile', and 'Log out' buttons. Below this is a dark blue bar with a 'Back' button. A row of three buttons is displayed: 'Print Friendly', 'Save Section', and 'Save and Continue to Next Section'. The 'Save and Continue to Next Section' button is highlighted with a purple border. Below the buttons is a large text area with a blue header and a light blue body. The text in the body reads: 'Documents, consent forms, and review the application.'

STEP 13

Click Add a New Document.

In this section, please upload the signed, itemized response and all documents for the study. Consents will be attached in the next section.

The screenshot shows a form with a blue header and a light blue body. The text in the body reads: 'with the Resubmission application until the study application has been attached in th'. Below this is a section titled '1.4 Attach Itemized Response and Other Relevant Documents'. The text in this section reads: 'Please attach a typed cover letter that presents an itemized response to the Board's concerns. listed above and sign the response. In addition, other relevant documents may include the revised protocol and other study docum Please **do not** attach consent documents in this section. They should be included in the next s'. Below the text is a row of two buttons: 'Add a New Document' and 'Add Multiple Documents'. The 'Add a New Document' button is highlighted with a purple border. Below the buttons is a table with the following columns: 'Detach', 'Version', 'Title', and 'Category'. The table is currently empty, and the text 'No Document(s) have been attached to this form.' is displayed below it. Below the table is a section titled '1.5 If applicable, attach revised consent form(s) below:'. Below this section is a button labeled 'Add a New Consent'. Below the button is another table with the following columns: 'Detach', 'Version', 'Title', and 'Category'.

STEP 14

Click Add a New Consent.

Please upload consent forms whether they have been revised for not.

1.4 Attach Itemized Response and Other Relevant Documents

Please attach a typed cover letter that presents an itemized response to the Board's concerns. **listed above and sign the response.**

In addition, other relevant documents may include the revised protocol and other study document.

Please **do not** attach consent documents in this section. They should be included in the next section.

Add a New Document

Add Multiple Documents

Detach	Version	Title	Category
No Document(s) have been attached to this form.			


1.5 If applicable, attach revised consent form(s) below:


Add a New Consent


Detach	Version	Title	Category
No Consent(s) have been attached to this form.			


STEP 15

Click Save and Continue to Next Section

 Calendar

 Help

 My Profile ▾

 Log out

Back

Friendly

Save Section

Save and Continue to Next Section

Signoff and Submit

se letter. The PI must respond to the concerns listed

Click on Signoff and Submit

Exit Form

Setup Routing for the PI.

n. For studies that include
purpose of Einstein COI review

STEP 18

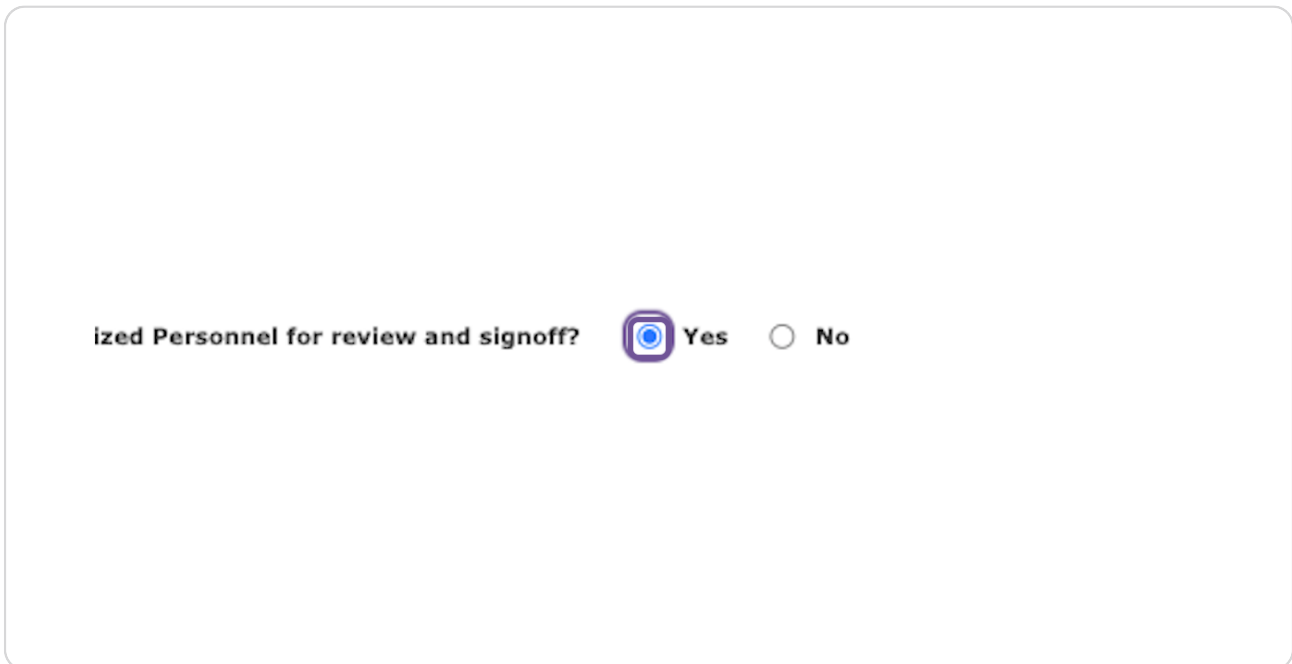
Click on Save – Signoff Routing List



A screenshot of a software interface. At the top, there is a dark gray header bar. Below it, a large white area contains two buttons. The button on the left is blue with white text that reads "Cancel - Finalize later". The button on the right is white with a red border and red text that reads "Save - Signoff Routing List". Below these buttons is a large dark gray rectangular area.

STEP 19

Click Yes.



A screenshot of a software interface. It shows a question: "ized Personnel for review and signoff?". Below the question are two radio button options. The "Yes" option is selected, indicated by a red circle around the radio button. The "No" option is unselected, indicated by a gray circle around the radio button.

STEP 20

Click on Save - Start Signoff Routing



STEP 21

Click OK.

