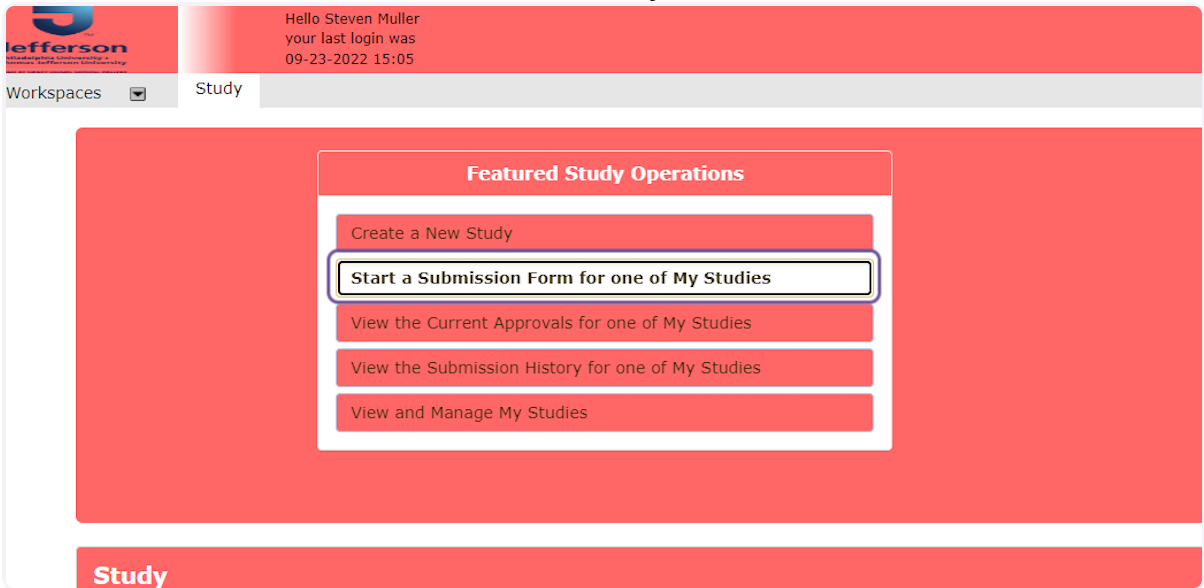
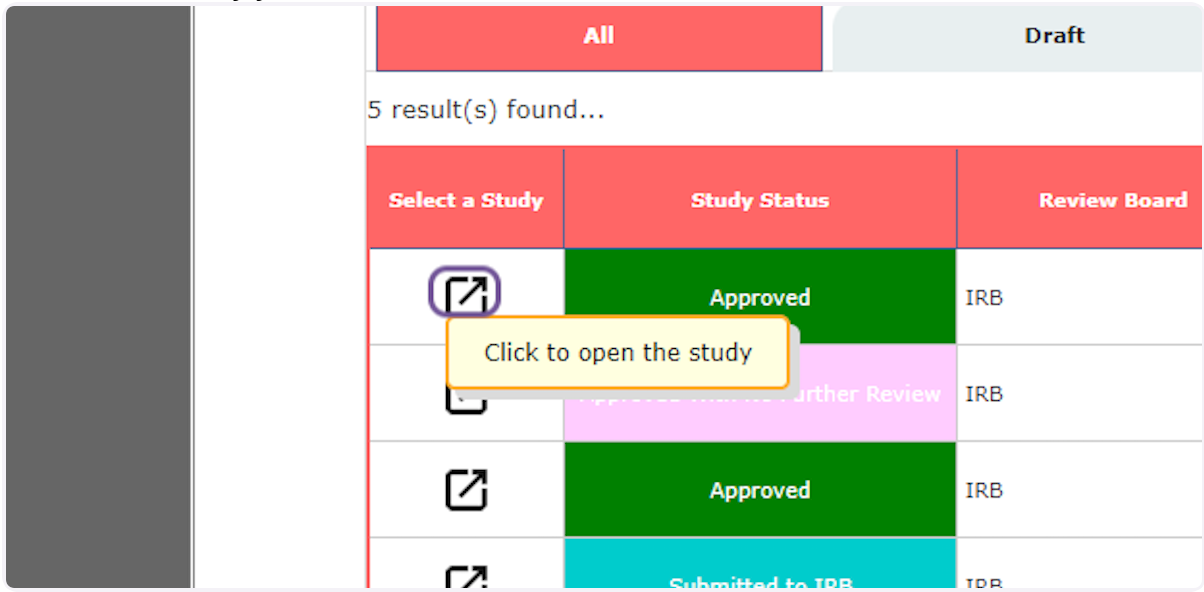


# Submitting an Amendment









- 1. Navigate to the iRIS homepage and Find Featured Study Operations.
- 2. Click on Start a Submission Form for one of My Studies



- 3. Select the study you wish to submit an amendment for.



- 4. Start a New Submission.

	Version List	Start a new Submission	Edit Incomplete Submissions
			
			
Review Studies			
			

Add a new Form

Principal Investigator

tion Education Program for ...

5. Section 1.0 will be prepopulated, as it was pulled from the Master Application.

Department: TJU - Office of Human Research  
 Path: Home

Calendar
 Help
 My Profile
 Log out

Number: IRISID-2022-0728  
 Lujadu, Crystal

Study
 Amendment to Research Protocol - (Version 1.0)

Back

Print Friendly
 Refresh Constant Fields
 Save Section
 Save and Continue to Next Section

Entire view of the form

1.0

Amendment to Research Protocol

1.1 Instructions:

Use this form to report changes to this study. If you wish to add or remove a Jefferson Principal Investigator, Co-Investigator, or Key Personnel, use the Personnel Change form. If you are adding or removing non-Jefferson personnel, use this form.

1.2 Name of person completing this form:

Steven Muller

1.3 Protocol Information:

IRB #:  
 IRISID-2022-0728  
 Study Title:  
 NCI-CIRB-2-FOR-CL-6-6-2022  
 PI:  
 Crystal Lujadu  
 Department:  
 TJU - Office of Human Research  
 Funding Sponsor:

6. Click on Save and Continue to Next Section

Calendar
 Help
 My Profile
 Log out

Back

Print Friendly
 Refresh Constant Fields
 Save Section
 Save and Continue to Next Section

Adding or removing non-Jefferson personnel, use this form.

**7. Indicate if an Continuing Review or Final Report is being submitted simultaneously.**

Account: Steven Muller Department: TJU - Office of Human Research Path: Home	Calendar             Help             My Profile
spaces  IRISID-2022-0728 PI: Ujadsu Crystal	Study

Amendment to Research Protocol - (Version 1.0)

[Print Friendly](#)   
 [Refresh Constant Fields](#)   
 [Save Section](#)   
 [Save and Continue](#)

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[View of the Form](#)  
[Edit of the Form](#)

**IRB**  
 Office Of Human Research  
 Amendment to Research Protocol (OHR-12)

**2.0**

**2.1** Is OHR-9 (continuing review) being submitted simultaneously with this amendment?

☐ Yes    ☒ No

**2.2** This amendment contains:

- ☐ Revision to consent form only
- ☐ Revisions to Master Application and/or Separate Protocol
- ☐ Revisions to Master Application/Protocol and Consent Form
- ☐ Addition of Non-Jefferson site(s) and/or Investigators\*
- ☐ Other (e.g., advertising, supplementary materials, etc.)

**2.3 Financial Information:**

ORA ACCOUNT NUMBER (if applicable):

DEPARTMENT CHARGE CODE:

**2.4 Summarize key points of the amendment separating major and minor changes:**

Note: In general, all amendments to minimal risk research and minor changes in greater than minimal risk research can be reviewed as expedited. Examples of expedited amendments are: advertising, informational materials, grammar/syntax corrections to protocol and/or consent form.

- Examples of minor changes:** Formatting, consistency, grammar, spelling.
- Address the main changes affecting the subjects, the protocol, and the consent form(s) and provide rationale for the main changes (e.g., dose-limiting toxicities, suspension of enrollment for interim analysis, etc.).
- Include ANY change involving risk.

**8. Indicate the type of changes you are submitting.**

**2.2 This amendment contains:**

- ☐ Revision to consent form only
- ☐ Revisions to Master Application and/or Separate Protocol
- ☐ Revisions to Master Application/Protocol and Consent Form
- ☐ Addition of Non-Jefferson site(s) and/or Investigators\*
- ☐ Other (e.g., advertising, supplementary materials, etc.)

### 9. Enter an Major Changes.

<a href="#">Print Friendly</a> <a href="#">Refresh Constant Fields</a> <a href="#">Save Section</a> <a href="#">Save and Continue</a>	
<a href="#">View of the Form</a> <a href="#">Entire view of the Form</a>	
<input type="text"/>	
<p><b>Invent to Research or</b></p> <p><b>Rice Of Human</b></p> <p><b>ch Amendment to</b></p> <p><b>ch Protocol ...</b></p>	<h3>2.4 Summarize key points of the amendment separating major and minor changes:</h3> <p><i>Note: In general, all amendments to minimal risk research and minor changes in greater than minimal risk research can be reviewed as expedited. Examples of expedited amendments are: advertising, informational materials, grammar/syntax corrections to protocol and/or consent form.</i></p> <ul style="list-style-type: none"> <li>• <b>Examples of minor changes:</b> Formatting, consistency, grammar/spelling.</li> <li>• Address the main changes affecting the subjects, the protocol, and the consent form(s) and provide rationale for the main changes (e.g., dose-limiting toxicities, suspension of enrollment for interim analysis, etc.).</li> <li>• Include ANY change involving risk.</li> <li>• If available, attach amendment synopsis from the sponsor.</li> </ul> <p><b>Instructions:</b> Provide either detailed list of changes from sponsor as attached document, or provide detailed list of changes in text box below:</p> <p><b>Major changes:</b></p> <div style="border: 1px solid black; padding: 5px;"> <p>Font Family    12    [Icons]</p>            </div> <p><b>Minor changes:</b></p>

### 10. Enter Minor Changes.

Minor changes:

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✍️

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📎

🔄

⌂


Submitting recruitment flyers. |

**11. Answer the question in Section 2.5.**


2.5 Does the amendment include only minor changes according to the definition above and/or addition of external sites and external investigators?

☐ Yes ☐ No


## 12. Click on Save and Continue to Next Section




Calendar




Help



My Profile ▾



Log out



Back

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

**13. Click on Click here to attach the application.**

My Workspaces

IRB Number: **iRISID-2022-0728**

PI: Lijadu, Crystal

Study

Amendment to Research Protocol - (Version 1.0)

Section view of the Form

1.0 Amendment to Research Protocol

2.0 IRB Office Of Human Research Amendment to Research Protocol ...

3.0 Attach Application and Document Uploads

Entire view of the Form

3.0 Attach Application

3.1 Attach the application and make modifications

Click here to attach the application.

No Application has been associated with this submission.

The study application must be included with the amendment application. Attach the study application here. If you have not already created a **study application** until the **study application has been attached in this section.**

If modification to the study application is part of the amendment, you can make the modifications in the study application once it has been attached in the application itself. In this case, please be sure to clearly describe these modifications in section 2.0 of this amendment.


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

Add a New Consent

#### 14. Add a revision to the Master Application (if needed)

and then click Save Attachment

Save Attachment

	Approved	Create a Revised Application
	Yes	<div> Add Revision</div>

**15. Click Confirm.**

Select

Rev.

View

Form Name

Confirm the adding a revision.

Are you sure you want to create a revision?

CONFIRM

CANCEL

**16. You may be asked to Convert to New Form Version**

This may occur because updates were made to the master application from since the original was submitted.

New Sections and Questions may be present on this form so please click through each section to verify that the application is complete.

[Convert to New Form Version](#)

## 17. Make changes as necessary.

- 1.0 **Study Title**
- 2.0 Departments
- 3.0 Study Personnel
- 4.0 Determination Section
- 5.0 Selecting IRB of Record
- 6.0 General Information
- 7.0 Study Overview

### 1.0 Study Title

\* Please enter the full protocol title of your study:

Test Study That Needs Revisions to Things

\* Please enter an abbreviated study title:

Steve's Study

\* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

## 18. Click Save Attachment

**19. Upload Consent and Support Documents, as appropriate.**

## 20. Click on Save and Continue to Next Section

## 21. Click on Notify PI to Signoff

Note: If you are the PI, you will be routed to the signoff page. The form will not be submitted to the IRB until the PI has completed signoff.  
If you are ready to send for signoff, click Signoff and Submit. Clicking Exit Form will send this back to the start page.

*Notify PI to Signoff*

Create PDF Packet

Exit Form