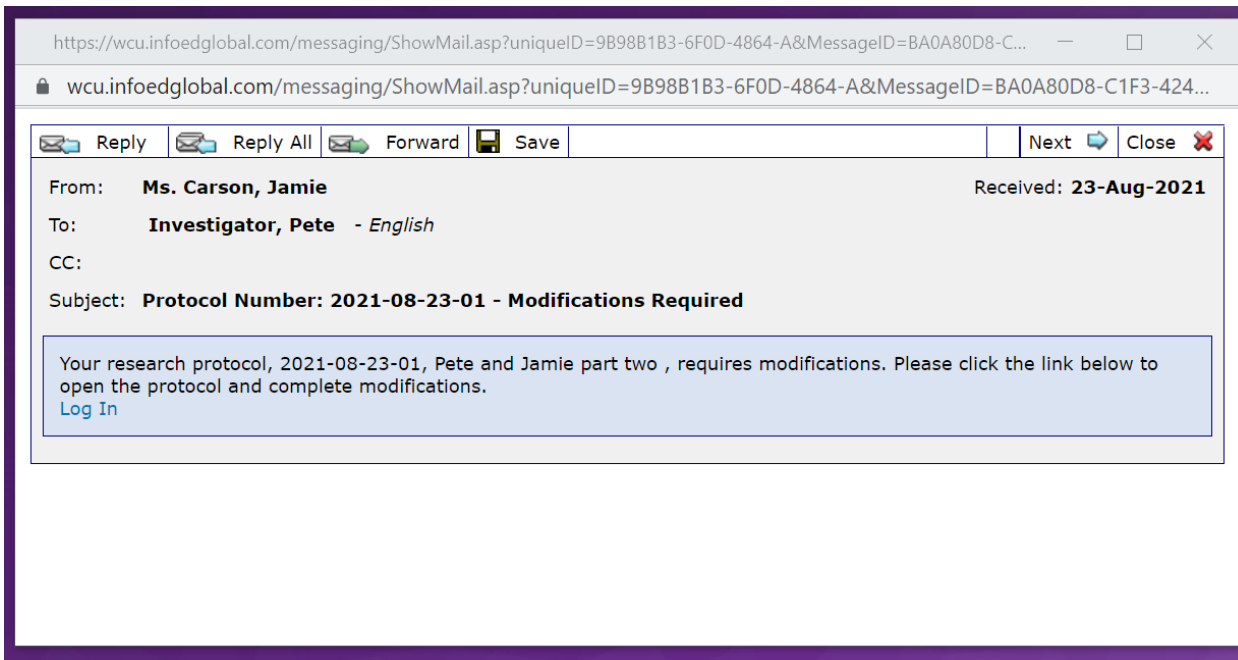


How to respond when modifications to your project are required

You will receive an email from the IRB Administrator (Jamie Carson) informing you that modifications are required. Click the link to login.



You will be taken to your application.

https://wcu.infoedglobal.com/ComplianceNet/SharedSystems/EForms/Form.aspx?ObjectFormId=13CDD321-6A34-48BD-A047-CF7469F6E893&recordid=986324603&systeme...
wcu.infoedglobal.com/ComplianceNet/SharedSystems/EForms/Form.aspx?ObjectFormId=13CDD321-6A34-48BD-A047-CF7469F6E893&recordid=986324603&systeme...

Western Carolina University Graduate School and Research View PDF Lock Form

ASSIGNMENT

Your research protocol, 2021-08-23-01, Pete and Jamie part two, requires modifications. Please click the link below to open the protocol and complete modifications.

The yellow and red exclamation points mean that your attention is required in those sections. The yellow one means additional or clarifying information is needed.

To begin making corrections or responding to a question, you must unlock the form. Click the blue box next to Lock Form. This will unlock the Form, and you will be able to make corrections.

Comments:

Next Step/Decision: Compliance Office
Assign to: Automatic as per configurations.

I am done

The red one means the reviewer has asked a question and is requiring an answer.






ADMINISTRATION

Required Human Subjects Training : Prior to submitting your application to the IRB, please make sure all personnel listed on the application have completed human subjects training. WCU's human subjects training can be accessed at www.citiprogram.org. Detailed instructions for registering, affiliating with WCU, and selecting the correct course can be found on the [IRB Website](#).

If your study will include tribal members from the Eastern Band of the Cherokee Indians (EBCI) or will occur on Cherokee lands (e.g. the Qualla Boundary or Snowbird community) approval may also be required by the FRCI

Unlock the form and navigate to the first section that requires your attention. You may scroll down the page to find the section, or you may click the appropriate section in the purple menu on the left.

Once you have navigated to the section that requires your attention, you will see which question(s) needs additional information. Click on the yellow exclamation point.

ASSIGNMENT	PROJECT SUMMARY
ADMINISTRATION	Protocol Number: 2021-08-23-01 Submission Number: 2021-08-23-01-01
RESEARCH PERSONNEL	
UNAFFILIATED PERSONNEL	
PROJECT SUMMARY 	1. Project Title: Pete and Jamie part two Principal Investigator: Investigator, Pete 
CONFLICT OF INTEREST/DUAL RELATIONSHIPS 	Submission Type: IRB Request for Initial Review of Research Protocol Type: IRB
STUDY PROCEDURES	2. Funding Source, if applicable. For internal grants and/or awards please select, Western Carolina University. 
RISK AND BENEFITS SECTION	3. Project Description: provide a concise (3-5 sentences) summary of the purpose and rationale of the activity using lay language.  This is a test project
PROTECTION OF PARTICIPANT PRIVACY AND CONFIDENTIALITY	4. Does data collection involve the use of a survey? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
EXTERNAL SITES	5. Does your research only involve using an existing data set where no recruitment is necessary? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
FOR RESEARCH INVOLVING QUALTRICS SURVEYS	a. Is the data publicly available? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
CERTIFICATION	b. Is the data set de-identified? De-identified means all personally identifiable information has been removed. <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
ALL PAGES	
MANAGEMENT RECORD	

Clicking on the yellow exclamation point opens a box that shows what clarification or additional information is needed. You are able to reply to, comment on, or forward the request. You may also hover over the yellow exclamation point by the question to view the request.

https://wcu.infoedglobal.com/ComplianceNet/SharedSystems/EForms/Form.aspx?ObjectFormId=13CDD321-6A34-48BD-A047-CF7469F6E893&recordid=986324603&system...

wcu.infoedglobal.com/ComplianceNet/SharedSystems/EForms/Form.aspx?ObjectFormId=13CDD321-6A34-48BD-A047-CF7469F6E893&recordid=986324603&system...

Comment Filter By: [] [] Clear Sort By: [] Ascending Clear X Save Lock Form

Expand All Comment Points Collapse All Comment Points

3. Project Description: provide a concise (3-5 sentences) summary of the purpose and rationale of the activity using lay language. Comment

From: Carson, Jamie To: Coordinator - PI

Please provide more information here.

23-Aug-2021 02:43 PM Reply Forward

You may reply to or forward the request.

In this case, the Admin is requesting the PI to include more information in the Project Description section.

A comment and a reply are very similar. When you reply, you may request a response. A comment does not allow you to request a response.

FOR RESEARCH INVOLVING QUALTRICS SURVEYS
CERTIFICATION
ALL PAGES
MANAGEMENT RECORD

5. Does your research only involve using an existing data set where no recruitment is necessary?
 Yes No

a. Is the data publicly available?
 Yes No

b. Is the data set de-identified? De-identified means all personally identifiable information has been removed.
 Yes No

Click 'Reply' if you would like to respond to the request. Type your message.

https://wcu.infoedglobal.com/ComplianceNet/SharedSystems/EForms/Form.aspx?ObjectFormId=13CDD321-6A34-48BD-A047-CF7469F6E893&recordid=986324603&system...

wcu.infoedglobal.com/ComplianceNet/SharedSystems/EForms/Form.aspx?ObjectFormId=13CDD321-6A34-48BD-A047-CF7469F6E893&recordid=986324603&system...

Comment Filter By: [] [] Clear Sort By: [] Ascending Clear X

Expand All Comment Points Collapse All Comment Points

3. Project Description: provide a concise (3-5 sentences) summary of the purpose and rationale of the activity using lay language. Comment

From: Carson, Jamie To: Coordinator - PI

Please provide more information here.

23-Aug-2021 02:43 PM Reply Forward

Press Post to send the message. Post To... Carson, Jamie ; Coordinator - PI **Make Comment Public** **Response Required**

Making a comment public means that whatever you type in the message box will be included in the IRB agenda under your project. Do not check this box.

Checking the box 'Response Required' is appropriate if you have a follow up question for the admin or reviewer.

Subject
3. Project Description: provide a concise (3-5 sentences) summary of the purpose and rationale of the activity using lay language.

Message

B *I* U abc x_2 x^2 Format

(inherited font) (inherited size) **A**

(inherited font) (inherited size) **A**

ALL PAGES



a. Is the data publicly available?




The screenshot shows a web application interface with a comment form and a popup window. The comment form has a 'To...' field circled in red. The popup window, titled 'Select Distribution Group(s)', has a URL of 'wcu.infoedglobal.com/popupselectlist.asp?DG=B3CE852E-D9CA-40CC-9,E8A0679C-92...'. It contains two radio button options: 'Coordinator - PI' (checked) and 'Coordinator - PI - Reviewers'. To the right of these options is red text: 'When you click To, another popup will appear. Select which recipients should be receiving your response. Select the appropriate group. Click Save and then Close.' Below this is another set of red text: 'Coordinator = IRB Administrator', 'PI = Principal Investigator', and 'Reviewers = IRB Member Reviewer'. The background shows a comment form with a subject line '3. Project Description: provide a concise (3-5 sentences) summary of the purpose and rationale of the activity using lay language.' and a 'Message' field with a rich text editor. At the bottom, there are checkboxes for 'a. Is the data publicly' and 'b. Is the data set de-identified? De-identified means all personally identifiable information has been removed.'



To make the requested revisions, make sure the project is unlocked. Type your updated answer directly into the question box.



ASSIGNMENT
ADMINISTRATION
RESEARCH PERSONNEL
UNAFFILIATED PERSONNEL
PROJECT SUMMARY 
CONFLICT OF INTEREST/DUAL RELATIONSHIPS 
STUDY PROCEDURES
RISK AND BENEFITS SECTION
PROTECTION OF PARTICIPANT PRIVACY AND CONFIDENTIALITY
EXTERNAL SITES
FOR RESEARCH INVOLVING QUALTRICS SURVEYS
CERTIFICATION
ALL PAGES
MANAGEMENT RECORD


PROJECT SUMMARY


 Protocol Number  Submission Number


 1. Project Title:  Principal Investigator Investigator, Pete 


 Submission Type IRB Request for Initial Review of Research  Protocol Type IRB


 2. Funding Source, if applicable. For internal grants and/or awards please select, Western Carolina University. 

 3. Project Description: provide a concise (3-5 sentences) summary of the purpose and rationale of the activity using lay language.

 4. Does data collection involve the use of a survey?
 Yes No

 5. Does your research **only** involve using an existing data set where no recruitment is necessary?
 Yes No

 a. Is the data publicly available?
 Yes No

 b. Is the data set de-identified? De-identified means all personally identifiable information has been removed.
 Yes No

Navigate to the section that requires your attention. In this case, it's a red exclamation point meaning that a question is being asked that you must answer. Scroll over the red exclamation point to view the question. You must click the red exclamation point to respond to the question.

- ASSIGNMENT
- ADMINISTRATION
- RESEARCH PERSONNEL
- UNAFFILIATED PERSONNEL
- PROJECT SUMMARY
- CONFLICT OF INTEREST/DUAL RELATIONSHIPS
- STUDY PROCEDURES
- RISK AND BENEFITS SECTION
- PROTECTION OF PARTICIPANT PRIVACY AND CONFIDENTIALITY
- EXTERNAL SITES
- FOR RESEARCH INVOLVING QUALTRICS SURVEYS
- CERTIFICATION
- ALL PAGES
- MANAGEMENT RECORD

CONFLICT OF INTEREST/DUAL RELATIONSHIPS

1. Are there any known or potential conflicts of interests (financial or other personal considerations that may compromise or potentially appear to compromise an investigator's objectivity, see University Policy 54) between the researchers and the participants or other entities related to this research?
 Yes No

2. Do any of the research team members have an authority relationship (ex. Instructor/student, supervisor/employee, physician/patient, or other) with the potential participants?
To: Coordinator - PI - Response Required For: What is your role at the school?

Scroll over the red exclamation point to view the question.

https://wcu.infoedglobal.com/ComplianceNet/SharedSystems/EFoms/Form.aspx?ObjectFormId=13CDD321-6A34-48BD-A047-CF7469F6E893&recordid=986324603&systeme...
wcu.infoedglobal.com/ComplianceNet/SharedSystems/EFoms/Form.aspx?ObjectFormId=13CDD321-6A34-48BD-A047-CF7469F6E893&recordid=986324603&systeme...

Comment

Filter By: [dropdown] [dropdown] Clear Sort By: [dropdown] Ascending [dropdown] Clear X

Expand All Comment Points Collapse All Comment Points

2. Do any of the research team members have an authority relationship (ex. Instructor/student, supervisor/employee, physician/patient, or other) with the potential participants? Comment

From: Carson, Jamie To: Coordinator - PI

What is your role at the school?

23-Aug-2021 02:44 PM Reply Forward

Clicking on the red exclamation point will open a popup that allows you to respond to the question.

FOR RESEARCH INVOLVING QUALTRICS SURVEYS
CERTIFICATION
ALL PAGES
MANAGEMENT RECORD

The same response template will populate. Respond and post accordingly. Close the popup.

https://wcu.infoedglobal.com/ComplianceNet/SharedSystems/EFoms/Form.aspx?ObjectFormId=13CDD321-6A34-48BD-A047-CF7469F6E893&recordid=986324603&systeme...
wcu.infoedglobal.com/ComplianceNet/SharedSystems/EFoms/Form.aspx?ObjectFormId=13CDD321-6A34-48BD-A047-CF7469F6E893&recordid=986324603&systeme...

Comment

Filter By: [dropdown] [dropdown] Clear Sort By: [dropdown] Ascending [dropdown] Clear X

Expand All Comment Points Collapse All Comment Points

2. Do any of the research team members have an authority relationship (ex. Instructor/student, supervisor/employee, physician/patient, or other) with the potential participants? Comment

From: Carson, Jamie To: Coordinator - PI

What is your role at the school?

23-Aug-2021 02:44 PM Reply Forward

Post **To...** Carson, Jamie ; Coordinator - PI **Make Comment Public** **Response Required**

Subject
2. Do any of the research team members have an authority relationship (ex. Instructor/student, supervisor/employee, physician/patient, or other) with the potential participants?

Message

B I U abc [bulleted list icon] [numbered list icon] [indent icon] [de-indent icon] x₂ x² [table icon] Format [dropdown]
(inherited font) (inherited size) A [color picker icon] [background color icon]

I am the Assistant Principal at the school.

When you are done with all clarifications and questions.

The screenshot shows a web browser window with the URL <https://wcu.infoedglobal.com/ComplianceNet/SharedSystems/EForms/Form.aspx?ObjectFormId=13CDD321-6A34-48BD-A047-CF7469F6E893&recordid=986324603&systeme...>. The page header includes the Western Carolina University logo and the text "Graduate School and Research". A red circle highlights the "ASSIGNMENT" tab in the left sidebar. A red circle highlights the "Lock Form" button in the top right corner, which has a checkmark. A red circle highlights the "I am done" button in the main content area. The main content area is titled "ASSIGNMENT" and contains the following text: "Your research protocol, 2021-08-23-01, Pete and Jamie part two, requires modifications. Please click the link below to open the protocol and complete modifications." Below this is a "Comments:" section with a text input field. Further down, it says "Next Step/Decision: Compliance Office" and "Assign to: Automatic as per configurations." The "I am done" button is a small grey button with the text "I am done".

(1.) Lock the form. You cannot resubmit unless the form is locked.

(2.) Navigate to the Assignment Tab

(3) Click "I am Done"

The window will close and your modifications will automatically be sent to the Research Compliance Office.

The window will close and the assignment will disappear from the Assignments tab. You are done with modifications.