

How to View and Respond to Reviewer Notes

ePIRATE Training



ePIRATE uses a reviewer note system in which questions, comments, concerns and requested changes can be communicated to study teams. This tutorial will show you how to find, read and respond to reviewer notes logged within the system.

While this tutorial uses reviewer notes logged during a Departmental Review of a new study, the process is the same for all submission types (new studies, amendments, continuing reviews, etc.) and for all types of reviews (Department, Ancillary, IRB).

When changes are requested, a notification will be emailed to the study team. The link in the email can be clicked to bring you to the specific workspace or you can login to the system and access the item from your inbox.

[Dashboard](#)[Home](#)[IRB
Studies](#)[Committees](#)[Meetings](#)[Contact](#)[Components](#) [Properties](#) [Pe](#)[ePIRATE Training](#)[Institutional Review
Board](#)[Common Rule
Changes - Effective
01.21.19](#)[General Information](#)[Related Links](#)[Contact Us](#)[Application Version
Information](#)[Find out more about...](#)[ePIRATE Training](#)

If you are accessing the item by logging into the system rather than using the link in the email, click on "Dashboard" once you are in the ePIRATE system.

Welcome to ePIRATE, the electronic Portal for Institutional Research at East Carolina University.

This site enables East Carolina University to manage all aspects of Institutional Review Board (IRB) compliance processes.

Click on **Dashboard** in the upper left hand corner of this screen to create a study, create and edit your **Profile**, and perform other actions on existing research studies.

*****UPGRADE NOTIFICATION: ePIRATE was upgraded on Wednesday, March 17, 2021.** The biggest change that existing users will notice is with the *look* of the IRB application smartform. The "Jump To" menu has moved to the left side of the screen and several other navigation tools on the application pages have been moved. Please review the following 5 minute tutorial explaining this newest upgrade: [ePIRATE Upgrade](#)

*****9.11.2020:** Existing research studies that are changing their method of paying

IRB Submissions

Page for UMCIRB UMCIRB

My Roles

IRB Submissions

- Dept/Div Approvers
- Faculty Advisor/Supervisor Approvers
- New Registered User

Create

New Study

Please note:

Click on the item name to access the workspace.

Make sure you are in the IRB Submissions role

Your Inbox will show any items that require your attention. The "Test Study" below is in a state of "Clarification Required". This means that the submission has been returned to you for changes by the Departmental Reviewer.




starting point for all interactions with this site. Note the following:

- may require immediate action by you to speed your submission through the review process.
- Monitor the progress of your submissions using the Inbox and IRB tabs.
- Use the Profile tab below to view and edit your profile. This information will enter the database.
- Quick Links in the lower left corner provide access to the submission process modules and the application.

Inbox IRB Studies

Displays all items which require action by the study team. Click on links for more information.

Filter by ? Name ▼ 🔍 + Add Filter ✕ Clear All

Name	Date Modified	Type	Owner	State	Last State Change
 Test Study	6/16/2021 8:30 PM	Study		Clarification Required (Department Review)	6/16/2021 8:10 PM
 Missed study visit	6/16/2021 7:34 PM	Reportable Event	Gilbird, Neil	Pre Submission	5/24/2021 5:51 PM
 New Template Study To Start Working On	6/16/2021 7:29 PM	Study		Pre Submission	5/24/2021 5:48 PM

Quick Links

Consent Form Templates, COI

Navigation bar with tabs: Dashboard, Home, IRB Studies, Issues. Sub-tabs: Amendments, Continuing Reviews, Final Report, Reportable Events.

Help

Clarification Required (Department Review)

Edit Study

Printer Version

View Differences

Study: Test Study (UMCIRB 18-001624)

Description: test
Principal Investigator: [blank]
Study Coordinator: [blank]
Study Type: [blank] (There are no items to display)
Review Type: Exempt

Click on "Edit Study"

My Activities

- Submit Changes
- Withdraw
- Log Public Comment
- Edit Email List
- Send Email to Study Team
- Request Participant Agreement
- Agree to Participate

History | Attachments | Pre Review Status | Reviewer Notes | ...

Activity	Author	Activity Date
Administration Moved to clarification required dept for tutorial	Gilbird, Neil	6/16/2021 8:30 PM
Item Withdrawn	Gilbird, Neil	6/16/2021 8:10 PM
Tutorial only		
Submitted Changes	Gilbird, Neil	6/16/2021 8:10 PM
1 Changes Logged.		
Changes Requested by Department Reviewer	UMCIRB, UMCIRB	6/16/2021 8:06 PM
2 Reviewer Notes Logged. Additional changes are required.		
Submitted Changes	Gilbird, Neil	6/16/2021 6:58 PM

Editing: UMCIRB 18-001624

Study Identification Information

This is the first step in your Human Research Application. You will automatically be guided to the appropriate page views needed to complete your submission. If a question is not applicable to your study, you may state this as your response. Please read the help text located on the right side of the page throughout this application.

- 1 - Study Personnel & Funding
 - 1 Study Identification 2
 - 1.1 Study Staff Roles and Responsibilities
 - 1.2 IRB Researcher
 - 1.4 Conflict of Interest
 - 1.43 Sponsored Programs & Conflict of Interest
 - 1.5 Study Locations
 - 1.51 Multi-Site Coordination

* Study Name (Short):
Test Study

Study Name (Long):
test

* Summary of Research in Lay Terms 1
test

4.0 * Principal Investigator:
Neil Gilbird

Any speech bubble that is gold, indicates a reviewer note. General notes can be logged for the entire screen view or for specific questions within that screen view. General notes appear at the top of the page, while comments tied to specific questions appear next to that question. For instance, in this case a general note has been logged about the credentials of the Principal Investigator while a specific comment has been logged for the response to question 3.0.

Any screen view where comments have been logged will have a speech bubble like the one above in this side bar. You can click these speech bubbles to take you directly to the page where comments have been logged. The number in the bubble above indicates the total number of reviewer notes logged in that screen view.

Reviewer Notes for 1 Study Identification

Close



UMCIRB UMCIRB

Department Change Request

I'm not sure the Principal Investigator is qualified to conduct this research. Please provide additional information on his credentials and relevant research experience.

posted 19 minutes ago

Reply Resolve this thread

Print Icons Help



To respond to the reviewer note, click the "Reply" button.

Clicking on a gold speech bubble will open a window such as the one on the left. This contains the reviewer notes associated with that speech bubble. There may be more than one comment that appears because there are both a general note for the page and one for question 3.0, you will need to click both in order to see all reviewer notes on the page.

- Validate Compare
- 1 - Study Personnel & Funding
 - 1 Study Identification 2
 - 1.1 Study Staff Roles and Responsibilities
 - 1.2 IRB Researcher Training Records
 - 1.3 Funding Sources
 - 1.31 Industry Sponsor Information
 - 1.32 Federal Government Sponsored Studies
 - 1.33 Non-Profit Sponsored Studies
 - 1.34 State or Local Government
 - 1.35 Other University or College
 - 1.36 Internally Funded (ECU)
 - 1.4 Conflict of Interest
 - 1.43 Sponsored Programs & Conflict of Interest
 - 1.5 Study Locations
 - 1.51 Multi-Site Coordination

4.0 * Principal Investigator:

Neil Gilbird ...

Exit

Save

Continue

Reviewer Notes for 1 Study Identification

Close



UMCIRB UMCIRB

Department Change Request

I'm not sure the Principal Investigator is qualified to conduct this research. Please provide additional information on his credentials and relevant research experience.

posted 19 minutes ago

Resolve this thread

Additional information on the PI's credentials have been included in the protocol document

Attach Files

OK

Cancel

Drop files in the text area to upload

The textbox can be used to include any comments you would like to make. Once you have responded to the request, click "OK"

Any requested changes can be made in the smart form at this time as well, using the side bar on the left to navigate to screen views and the buttons on the right to save and exit the form once the changes have been made.

- 1 - Study Personnel & Funding
 - 1 Study Identification 2
 - 1.1 Study Staff Roles and Responsibilities
 - 1.2 IRB Researcher Training Records
 - 1.3 Funding Sources
 - 1.31 Industry Sponsor Information
 - 1.32 Federal Government Sponsored Studies
 - 1.33 Non-Profit Sponsored Studies
 - 1.34 State or Local Government
 - 1.35 Other University or College
 - 1.36 Internally Funded (ECU)
 - 1.4 Conflict of Interest
 - 1.43 Sponsored Programs & Conflict of Interest
 - 1.5 Study Locations
 - 1.51 Multi-Site Coordination

Print Icons Help

guided to the applicable to your study, you may state this as throughout this application.

The short s name is lim 255 charac

Most other boxes do n any limits o of characte

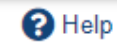
The lay sur should be r than 400 w should incl following: Background of Study Description Subjects/Pi Research Methods/Pi

Exit

Save

Continue

Navigation menu with tabs: Dashboard, Home, IRB Studies, Issues. Sub-tabs under IRB Studies: Amendments, Continuing Reviews, Final Report, Reportable Events.



Clarification Required (Department Review)

Edit Study

Printer Version

View Differences

Study: Test Study (UMCIRB 18-001624)

Description: test

Principal Investigator: UMCIRB UMCIRB Study Coordinator:

Study Type: There are no items to display Review Type: Exempt

My Activities

- Submit Changes
- Withdraw
- Log Public Comment
- Edit Email List
- Send Email to Study Team
- Request Participant Agreement
- Agree to Participate

History	Attachments	Pre Review Status	Reviewer Notes	...																					
<table border="1"> <thead> <tr> <th>Activity</th> <th>Author</th> <th>Activity Date</th> </tr> </thead> <tbody> <tr> <td>Administration Moved to clarification required dept for tutorial</td> <td></td> <td>6/16/2021 8:30 PM</td> </tr> <tr> <td>Item Withdrawn Tutorial only</td> <td></td> <td>6/16/2021 8:10 PM</td> </tr> <tr> <td>Submitted Changes 1 Changes Logged.</td> <td>Gilbird, Neil</td> <td>6/16/2021 8:10 PM</td> </tr> <tr> <td>Changes Requested by Department Reviewer</td> <td>UMCIRB, UMCIRB</td> <td>6/16/2021 8:06 PM</td> </tr> <tr> <td colspan="3">2 Reviewer Notes Logged. Additional changes are required.</td> </tr> <tr> <td>Submitted Changes</td> <td>Gilbird, Neil</td> <td>6/16/2021 6:58 PM</td> </tr> </tbody> </table>					Activity	Author	Activity Date	Administration Moved to clarification required dept for tutorial		6/16/2021 8:30 PM	Item Withdrawn Tutorial only		6/16/2021 8:10 PM	Submitted Changes 1 Changes Logged.	Gilbird, Neil	6/16/2021 8:10 PM	Changes Requested by Department Reviewer	UMCIRB, UMCIRB	6/16/2021 8:06 PM	2 Reviewer Notes Logged. Additional changes are required.			Submitted Changes	Gilbird, Neil	6/16/2021 6:58 PM
Activity	Author	Activity Date																							
Administration Moved to clarification required dept for tutorial		6/16/2021 8:30 PM																							
Item Withdrawn Tutorial only		6/16/2021 8:10 PM																							
Submitted Changes 1 Changes Logged.	Gilbird, Neil	6/16/2021 8:10 PM																							
Changes Requested by Department Reviewer	UMCIRB, UMCIRB	6/16/2021 8:06 PM																							
2 Reviewer Notes Logged. Additional changes are required.																									
Submitted Changes	Gilbird, Neil	6/16/2021 6:58 PM																							

You can also use the "Reviewer Notes" tab to see all comments in the smart form.

» Dashboard Home IRB Studies Issues

Amendments Continuing Reviews Final Report Reportable Events

Help

Clarification Required (Department Review)

Edit Study

Printer Version

View Differences

Study: Test Study (UMCIRB 18-001624)

Description: test

Principal Investigator: UMCIRB UMCIRB Study Coordinator:

Study Type: There are no items to display Review Type: Exempt

My Activities

Submit Changes

Withdraw

Log Public Comment

Edit Email List

Send Email to Study Team

Request Participant Agreement

Agree to Participate

History Attachments Pre Review Status Reviewer Notes ...

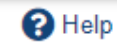
A list of all logged comments will appear here.

Print

Enter search terms to filter list

- 
UMCIRB UMCIRB created Department Change Request on June 16, 2021 for 1 Study Identification
 I'm not sure the Principal Investigator is qualified to conduct this research. Please provide additional information on his credentials and relevant research experience.
 Show 1 Reply
- 
UMCIRB UMCIRB created Department Change Request on June 16, 2021 for 1 Study Identification
Question: Summary of Research in Lay Terms:
 This is not sufficient as a summary of the research

Navigation menu with buttons: >>, Dashboard, Home, IRB Studies, Issues. Sub-menu: Amendments, Continuing Reviews, Final Report, Reportable Events.



Clarification Required (Department Review)

- Edit Study
- Printer Version
- View Differences

Study: Test Study (UMCIRB 18-001624)

Description: test

Principal Investigator: UMCIRB UMCIRB Study Coordinator:

Study Type: There are no items to display Review Type: Exempt

My Activities

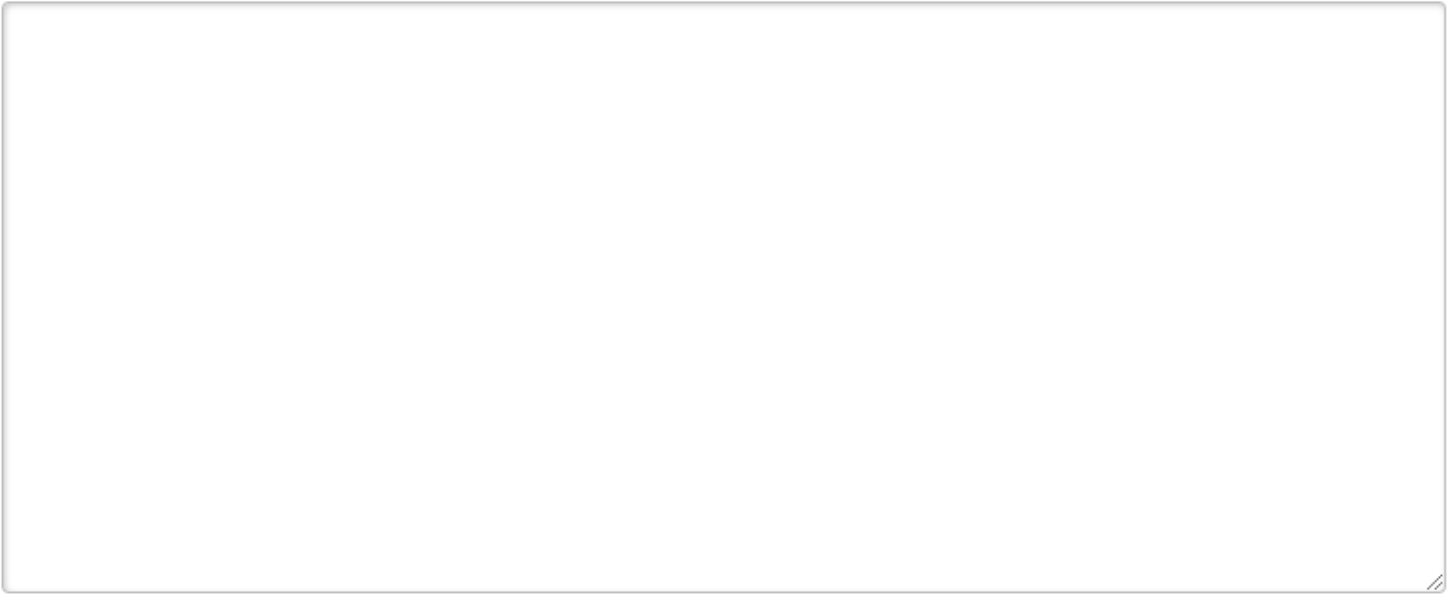
- Submit Changes**
- Withdraw
- Log Public Comment
- Edit Email List
- Send Email to Study Team
- Request Participant Agreement
- Agree to Participate

Once you have made all requested changes and responded to any questions, click the "Submit Changes" button


History	Reviewer Notes	...
	Author	Activity Date
Moved to clarification required dept for tutorial	Gilbird, Neil	6/16/2021 8:30 PM
Item Withdrawn	Gilbird, Neil	6/16/2021 8:10 PM
Tutorial only		
Submitted Changes	Gilbird, Neil	6/16/2021 8:10 PM
1 Changes Logged.		
Changes Requested by Department Reviewer	UMCIRB, UMCIRB	6/16/2021 8:06 PM
2 Reviewer Notes Logged. Additional changes are required.		
Submitted Changes	Gilbird, Neil	6/16/2021 6:58 PM

Submit Changes:

In addition to your response to requested changes, please provide any other summary information requested by the reviewer:



The textbox can be used for any communication you would like to include with your submission of changes.



Once you are ready to re-submit the item for review of changes click "OK"

