

Departmental Review and Approval

ePIRATE Training



The UMCIRB expects Department approvers to provide a robust and complete review of any human research study submission coming from their department. The electronic application should be reviewed in its entirety as well as all uploaded documents.

The purpose of the Departmental Review and Approval in ePIRATE is to ensure the following:

1. The project is consistent with the mission, goals and objectives of the Department/Division/School;
2. The investigator and study staff have the appropriate expertise to conduct the research as described in the submission;
3. The science of the project is sound; and
4. The Dept/Div/School has the resources required to support the project.

As the Department Reviewer you will receive a notification from UMCIRB@ecu.edu, generated by ePIRATE, informing you that a study has been submitted and requires your review and approval. This notification will go to your regular email account. There will be a link in the notification you receive which will allow you to log into ePIRATE to review the study. When you log in from this link you will be taken directly to the workspace of the study which requires your review and approval. If you are accessing the study via the link provided in this notification, begin with slide 5 of this tutorial.



[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

Dept/Div Approvers

Page for UMCIRB UMCIRB

My Roles

IRB Submissions

Dept/Div Approvers

Faculty Advisor/Supervisor Approvers

New Registered User

Departments I Approve For

UMCIRB Office

1 itemspage 1 10 / page

Make sure you are in the Dept/Div approvers role

Your Inbox will show any items that require your attention. The "Test Study" below is in a state of "Department Review". This means that the submission is awaiting your review.

Follow the following guidelines to process your Studies:

- Review all submissions in your inbox that are in a state of **Changes** that the study team has requested.
- Find studies you have reviewed.

My Inbox Studies Reports Profile

ID	Name	Date Created	Date Modified	State	PI
UMCIRB 18-001624	Test Study	7/23/2018 1:21 PM	6/16/2021 6:08 PM	Department Review	Gilbird
UMCIRB 14-001022	Neil study	5/29/2014 8:35 AM	7/6/2020 12:32 PM	Pre Submission	UMCIRB
UMCIRB 18-000600	Copy of Neil's Template	3/2/2018 2:09 PM	3/2/2018 2:09 PM	Pre Submission	UMCIRB
UMCIRB 17-002837	Whole Group Instruction verses Small Group Instruction	11/29/2017 9:37 PM	11/29/2017 9:37 PM	Pre Submission	UMCIRB
UMCIRB 17-002835	Whole Group Instruction verses Small Group Instruction	11/29/2017 7:58 PM	11/29/2017 9:33 PM	Pre Submission	UMCIRB
UMCIRB 15-001136	How to Upload Documents in ePIRATE	6/22/2015 10:40 AM	9/8/2017 4:16 PM	Pre Submission	UMCIRB

Click on the item name to access the workspace.

Department Review

View Study

Printer Version

View Differences

Study: Test S

Description:
Principal Investigator: Coordinator:
Study Type: There are no items to display Review Type: Exempt

The "View Study" button will allow you to see the screen views of the study one at a time.

The "Printer Version" button will open all the screen views in one page that you can scroll through

My Activities

- Dept Issue Departmental Approval
- Dept Changes Requested by Department Reviewer
- Log Public Comment

(Submitted)

Activity	Author	Activity Date
Submitted Changes	Gilbird, Neil	6/16/2021 6:08 PM
0 Changes Logged. Changes made		
Changes Requested by Department Reviewer	Gilbird, Neil	6/16/2021 6:07 PM
0 Reviewer Notes Logged. Changes Requested		
Administration	Gilbird, Neil	6/16/2021 6:06 PM
Moved to UMCIRB Office		
Administration	Gilbird, Neil	6/16/2021 6:01 PM
Moved to departmental review for tutorial		
Participant Agreement Recorded	Test, ECU	2/25/2019 11:13 AM

If you click the "View Study" button you will be able to navigate the form using the side bar on the left or by scrolling the page using the scroll bar on the right-hand side.



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.

As you review the submission, you may have questions, comments or concerns for the study team. Clicking the speech bubbles will allow you to log comments in each screen view. A bubble at the top of the page is for general comments while bubbles next to questions will be specific for that question.

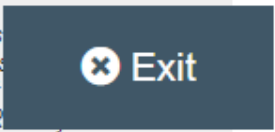
- 1 - Study Personnel & Funding
 - 1 Study Identification
 - 1.1 Study Staff Roles and Responsibilities
 - 1.2 IRB Researcher Training Records
 - 1.3 Funding Sources
 - 1.31 Industry Sponsor Information
 - 1.32 Federal Government Sponsored Studies
 - 1.33 Non-Profit Sponsored Studies
 - 1.34 State or 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 Center

- 1.0 * Study Name (Short):
Test Study
- 2.0 Study Name (Long):
test
- 3.0 * Summary of Research in Lay Terms:
test
- 4.0 * Principal Investigator:
Neil Gilbird
- 5.0 Faculty Investigator (Serving as the responsible individual in the oversight of the research study when the PI is a student, resident, fellow or visiting faculty.)
Faculty Investigator IRB Certification Renewal Deadline:
- 6.0 Study Coordinator or Contact Individual:
- 7.0 Contact Individual(s) (if different from Study Coordinator or Principal Investigator):

Last Name	First Name	Organization Profile	IRB Certification Renewal Deadline

People added here will be able to edit the study.

Clicking the "Add" button allows individuals that are already registered in ePIRATE. This function will not be available for individuals that have not registered in ePIRATE.



You Are Here: Test Study

Reading: UMCIRB 18-001624

Go to forms menu Print Icons Help

1 - Study Personnel & Funding

1 Study Identification

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 Center

Study Identification Information

This is the first step in your Human Research... appropriate page views needed to complete... as your response. Please read the help text.

1.0 * Study Name (Short):
Test Study

Clicking the bubbles at the top of pages will open comment windows like this.

4.0 * Principal Investigator:
Neil Gilbird

5.0 Faculty Investigator (Serving as the responsible individual in the oversight of the research study when the PI is a student, resident, fellow or visiting faculty.)

Faculty Investigator IRB Certification Renewal Deadline:

6.0 Study Coordinator or Contact Individual:

7.0 Contact Individual(s) (if different from Study Coordinator or Principal Investigator):

Last Name	First Name	Organization Profile	IRB Certification Renewal Deadline

Reviewer Notes for 1 Study Identification

Close

Add New Reviewer Notes

Department Draft 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|

Response Required Attach Files OK

Drop files in the text area to upload

People added here will be able to edit the study.

Clicking the "Add" button allows individuals that are already registered in ePIRATE. This function will not allow individuals that have not registered in ePIRATE.

Exit

Compare

1 - Study Personnel & Funding

1 Study Identification

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

You Are Here: Test Study

Reading: UMCIRB 18-001

Print Icons Help

Study Identification Information

This is the first step in your Human Research Application. Please read the help text located on the appropriate page views needed to complete your submission as your response.

- 1.0 * Study Name (Short):
Test Study
- 2.0 Study Name (Long):
test
- 3.0 * Summary of Research in Lay Terms:
test

And clicking the bubbles for specific questions will open comment windows like this. For both click "OK" once you have logged your comment to save it.

Change History

Reviewer Notes

Add New Reviewer Notes

Department Draft Change Request

This is not sufficient as a summary of the research

Response Required Attach Files OK

Drop files in the text area to upload

Close

Exit

- 6 Risks & Benefits Assessment
- 6.1 Potential Benefits and Alternatives
- 7 - Informed Consent & Recruitment**
 - 7 Informed Consent Determination
 - 7.01 Exempt Informed Consent Determination
 - 7.02 Exempt Consent Forms & Process of Consent**
 - 7.1 Consent Forms & Process of Consent
 - 7.11 Non-English Speaking Participants
 - 7.2 Waiver of Written or Signed Consent
 - 7.3 Waiver or Alteration of Consent
 - 7.3.5 Waiver or Alteration of Consent Jan 2019
- 8 - Data Privacy & Confidentiality**
 - 8 Data Privacy & Confidentiality
 - 8.01 Exempt Data Privacy & Confidentiality

Documents that have been uploaded by the study team will appear in the form like this. You can click the link to save or view the documents throughout.

- Research
- Consent Template: More Than Minimal Risk Research
- Consent Template: No More Than Minimal Risk Research
- Genetic Testing Consent Template
- Local Boilerplate Language for NCI-CIRB Approved Consents Only
- Local Boilerplate Language for NCI-CIRB Approved Youth Information Sheets (Assents)

* 1.2) Upload consent forms, assent forms, or information sheets here

Name	Modified	Version
 6 years.docx(0.02)	2/11/2019 4:06 PM	0.02

1.3) Upload Tracked Changes versions of consent forms, assent forms, or information sheets here:

Name	Modified	Version
There are no items to display		

2.0 * Describe how, when, and where the consent process will be initiated:
tesestestes

Once you have reviewed the entire submission and made any comments you would like to make, click the "Exit" button



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



Department Review

- View Study
- Printer Version
- View Differences

Study: Test Study (UMCIRB 18-001624)

Description: test
 Principal Investigator: Neil Gilbird Study Coordinator:
 Study Type: There are no items to display Review Type: Exempt

My Activities

- Issue Departmental Approval
- Changes Requested by Department Reviewer
- Log Public Comment

History Attachments Pre Review Status Reviewer Notes ...

Author	Activity Date
Gilbird, Neil	6/16/2021 6:08 PM
Gilbird, Neil	6/16/2021 6:07 PM
Gilbird, Neil	6/16/2021 6:06 PM
Gilbird, Neil	6/16/2021 6:01 PM
Test, ECU	2/25/2019 11:13 AM

0 Reviewer Notes Logged. Changes Requested

- Administration
- Moved to UMCIRB Office
- Administration
- Moved to departmental review for tutorial
- Participant Agreement Recorded

If you would like to request changes or clarifications from the study team, click the "Changes Requested by Department Reviewer" button



(Submitted)

Changes Requested by Department Reviewer:

When you submit this form, the Principal Investigator will be notified that changes or additional information is required to the protocol before you will approve it. Use the box below to add instructions or indicate the changes which you require.

Type below the changes or additional information you are requesting:

You have logged 2 Reviewer notes:

Page	Notes
1 Study Identification	This is not sufficient as a summary of the research
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.

* Comments:

Documents:

+ Add

Name	Version
------	---------

There are no items to display

Any additional comments you would like to send to the study team can be included in the Comments box above. Once you are ready to return it to the study team, click "OK".

OK

Cancel

After the study team has re-submitted the study for review, you will receive a notification from UMCIRB@ecu.edu, generated by ePIRATE, informing you that the study requires your review and approval. Accessing the study will use the same process as described earlier in this tutorial.

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 36 minutes ago Delete

Show 1 Reply

If the study team has provided a reply to your reviewer note, you can view it by clicking the "Show Reply" button

Clicking on a gold speech bubble will open a window such as the one on the left. This contains the reviewer notes you logged associated with that speech bubble.

- 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
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 - 1.5 Study Locations
 - 1.51 Multi-Site Coordination

Print Icons Help

4.0 * Principal Investigator:
UMCIRB UMCIRB ...

Exit Save Continue

1 - Study Personnel & Funding

1 Study Identification

- 1.1 Study Staff Roles and Responsibilities
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- 1.5 Study Locations
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Reviewer Notes for 1 Study Identification

Department Change Request

UMCIRB UMCIRB
 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 34 minutes ago [Delete](#)
[Hide Replies](#)

UMCIRB UMCIRB
 Additional information on the PI's credentials have been included in the protocol document.
 posted 13 minutes ago [Delete](#)

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

4.0 * Principal Investigator:
 UMCIRB UMCIRB [...](#)

[»](#)
[Dashboard](#)
[Home](#)
[IRB Studies](#)
[Issues](#)

[Amendments](#)
[Continuing Reviews](#)
[Final Report](#)
[Reportable Events](#)

Help

Department Review

View Study

Printer Version

View Differences

Study: Test Study (UMCIRB 18-001624)

Description: test

Principal Investigator: Neil Gilbird **Study Coordinator:**

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

My Activities

Issue Departmental Approval

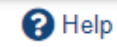
Changes Requested by Department Reviewer

Log Public Comment

(Submitted)

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> Submitted Changes</td> <td>Gilbird, Neil</td> <td>6/16/2021 6:08 PM</td> </tr> <tr> <td colspan="3">0 Changes Logged. Changes made</td> </tr> <tr> <td> Changes Requested by Department Reviewer</td> <td>Gilbird, Neil</td> <td>6/16/2021 6:07 PM</td> </tr> <tr> <td colspan="3">0 Reviewer Notes Logged. Changes Requested</td> </tr> <tr> <td> Administration</td> <td>Gilbird, Neil</td> <td>6/16/2021 6:06 PM</td> </tr> <tr> <td colspan="3">Moved to UMCIRB Office</td> </tr> <tr> <td> Administration</td> <td>Gilbird, Neil</td> <td>6/16/2021 6:01 PM</td> </tr> <tr> <td colspan="3">Moved to departmental review for tutorial</td> </tr> <tr> <td> Participant Agreement Recorded</td> <td>Test, ECU</td> <td>2/25/2019 11:13 AM</td> </tr> </tbody> </table>					Activity	Author	Activity Date	Submitted Changes	Gilbird, Neil	6/16/2021 6:08 PM	0 Changes Logged. Changes made			Changes Requested by Department Reviewer	Gilbird, Neil	6/16/2021 6:07 PM	0 Reviewer Notes Logged. Changes Requested			Administration	Gilbird, Neil	6/16/2021 6:06 PM	Moved to UMCIRB Office			Administration	Gilbird, Neil	6/16/2021 6:01 PM	Moved to departmental review for tutorial			Participant Agreement Recorded	Test, ECU	2/25/2019 11:13 AM
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Navigation menu with tabs: Dashboard, Home, IRB Studies, Issues. Sub-tabs: Amendments, Continuing Reviews, Final Report, Reportable Events.



Department Review

- View Study
- Printer Version
- View Differences

Study: Test Study (UMCIRB 18-001624)

Description: test
 Principal Investigator: Neil Gilbird Study Coordinator:
 Study Type: There are no items to display Review Type: Exempt

My Activities

- Issue Departmental Approval
- Changes Requested by Department Reviewer
- Log Public Comment

If you are satisfied that the study team has met the requirements for approval outlined in slide two of this tutorial (either when initially submitted or following submission of changes) click the "Issue Departmental Approval" button.

			Activity Date
			6/16/2021 6:08 PM
Dept	Changes Requested by Department Reviewer	Gilbird, Neil	6/16/2021 6:07 PM
0 Reviewer Notes Logged. Changes Requested			
!	Administration	Gilbird, Neil	6/16/2021 6:06 PM
Moved to UMCIRB Office			
!	Administration	Gilbird, Neil	6/16/2021 6:01 PM
Moved to departmental review for tutorial			
SS	Participant Agreement Recorded	Test, ECU	2/25/2019 11:13 AM

(Submitted)

Issue Departmental Approval:

1. The following is the list of Approval Departments. All the Approval Departments **must** approve this application before it can be forwarded on in the IRB Review process.

Department Name

UMCIRB Office

By clicking "Okay" below, I am certifying that

- There are adequate resources including space and support personnel available to the Principal Investigator to conduct this study in the proposed manner.
- The Principal Investigator has the appropriate expertise and/or knowledge to conduct the research as proposed; and
- The proposed research is scientifically sound, contributes to the scope and mission of the Department, and, therefore, to that of the University

* Department Approvals:

Departments I Approve For

UMCIRB Office

Make sure to check the box next to the Departments you approve for and click "OK"

Comments:

[Empty text area for comments]