

How to Create and Submit an Amendment

ePIRATE Training



This tutorial shows you how to create and submit an amendment in ePIRATE.

Amendments are necessary any time you want to make changes to a study that has already been approved by the UMCIRB.

[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](#)[Click on IRB Studies](#)[Find out more about...](#)[ePIRATE Training](#)

Home

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

» Dashboard

Home

IRB Studies

Issues

Amendments

Continuing Reviews

Final Report

Reportable Events

Other Submission Types

- ▶ Amendments
- ▶ Continuing Reviews
- ▶ Final Report
- ▶ Reportable Events

Click on "Approved" or "Certified Exempt" based on the level of review used for the initial study.

IRB Studies

Welcome to Click Commerce IRB. View all studies by **In Progress**, **Approved**, and **Archived** groupings. Use the 'My Home' link to see the list of **submissions** related to you.

In Progress

Approved

Certified Exempt

Legacy Approved

...

Filter by ? ID

ID	Name	Date Modified	Owner	State	Review Type	PI
MS1_UMCIRB 21-001255	Tutorial Study	5/25/2021 11:15 AM	Gilbird, Neil	Amendment Open	Expedited	UMCIRB
UMCIRB 18-001624	Test Study	3/4/2021 1:44 PM		Pre Submission	Exempt	UMCIRB
UMCIRB 14-001022	Neil study	7/6/2020 12:32 PM		Pre Submission	Exempt	UMCIRB
UMCIRB 18-000600	Copy of Neil's Template	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		Pre Submission		UMCIRB
UMCIRB 17-002835	Whole Group Instruction verses Small Group Instruction	11/29/2017 9:33 PM		Pre Submission	Expedited	UMCIRB
UMCIRB 15-001136	How to Upload Documents in ePIRATE	9/8/2017 4:16 PM		Pre Submission		UMCIRB

» Dashboard Home IRB Studies Issues

Amendments Continuing Reviews Final Report Reportable Events

Other Submission Types

- ▶ Amendments
- ▶ Continuing Reviews
- ▶ Final Report
- ▶ Reportable Events

Find the study you wish to create an amendment for and click the name to access the main study workspace

by In Progress, Approved, and Archived groupings. Use the 'My Home' link to

In Progress	Approved	Certified Exempt	Legacy Approved	...		
Filter by ? ID <input type="text"/> Enter text to search for <input type="button" value="Q"/> + Add Filter <input type="button" value="x Clear All"/>						
ID	Name	Date Modified	Owner	Review Type	ExpDate	PI
UMCIRB 21-001255	Tutorial Study	5/24/2021 5:51 PM	Gilbird, Neil	Expedited	5/23/2022	UMCIRB
1 items		page 1 of 1		25 / page		



Current State

Approved

View Study

Printer Version

View Differences

Study: Tutorial Study (UMCIRB 21-001255)

Description: This study has been created to show various functions within the ePIRATE system.

Principal Investigator: UMCIRB UMCIRB

Study Coordinator:

Expiration Date: 5/23/2022

Letter of Approval: [View](#)

Funding Sources:

Name	Type	Parent Organization
There are no items to display		

IRB Admin: Neil Gilbird

Snapshot

New Reportable Event

New Amendment

New Continuing Review

Final Report

Activity	Description	Activity Date
Project Snapshot Generated		5/24/2021 5:48 PM

Click "New Amendment"

Activity	Author	Activity Date
Revision Completed	UMCIRB, UMCIRB	6/16/2021 11:05 PM



Dashboard

Home

IRB
Studies

Issues

Amendments

Continuing Reviews

Final Report

Reportable Events

There are two separate workspaces you will need to access when submitting a new amendment.

Current State

Pre Submission

Edit Amendment

Print-Friendly Amendment

Edit Modified Study

Print-Friendly Study

View Changes

Amendment: Amendment 1 for IRB Study #UMCIRB 21-001

PI:

Amend

Date C

Coordinator:

Type: Amendment

Date Submitted: *Unsubmitted*

The "Amendment" workspace is where you summarize and propose the changes you would like to make.

Written Summary of Changes:

Updating the consent with minor changes.

List of

Change

Any changes to the study will need to be made in the "Modified Study" workspace.

My Activities

PI Submit Revision

SS Withdraw

SS Agree to Participate

PI Request Participant Agreement

Change Workspace Template

History

Reviewer Notes

Change Log

Activity	Author	Activity Date
Created Amendment	UMCIRB, UMCIRB	5/24/2021 5:49 PM

Validate

SF - Amendment Information

Cover Sheet

You Are Here: Tutorial Study > Amendment 1 for IRB Study #UMC...

Editing: Ame1_UMCIRB 21-001255

Go to forms menu Print Help

Amendment Request

- An amendment request includes two parts: the Amendment form and modifications to the Study form
- Only one amendment request is allowed at any given time, i.e: amendment 1 must be approved, denied or withdrawn before amendment 2 can be created.

1.0

* Type of change this amendment is making (check all that apply):

- Changes to Consent Form(s)
- Changes to Protocol Document(s)
- Changes to Advertisements
- Changes to Investigator Brochure

2.0

entity, payment is required at the time of submission.

[None] ...

3.0

Level of IRB review required by sponsor

Exempt

Fill in all relevant information. Red asterisks mean that there must be an answer provided. This applies to both the Amendment and Modified Study workspaces

The Exit button will return you to the main study workspace. You will be prompted to save before exiting the form.

The Save button will save your work on the current screen view.

The Continue button will save your work and take you to the next page that needs to be completed.

A set of options will appear in this area of each screen view.

Exit Save Continue

Other Changes

Final Page

The modified study workspace is a copy of the currently approved submission. All screen views will be pre-populated with the information approved at the point the amendment was created. This also includes copies of all approved documents.

Any changes being made to the study, must be reflected in the modified study workspace. For instance, if study team changes are being made, screen view 1 would need to reflect these changes and roles and responsibilities assigned for any new study team members.

Changing documents in ePIRATE is an important function and there is a separate tutorial for this process. This tutorial can be found on our “How Do I” website.



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



Current State

Pre Submission

Edit Amendment

Print-Friendly Amendment

Edit Modified Study

Print-Friendly Study

View Changes

Amendment:Amendment 1 for IRB Study #UMCIRB 21-001255

PI:	UMCIRB UMCIRB	Coordinator:	
Amendment #:	Ame1_UMCIRB 21-001255	Type:	Amendment
Date Created:	5/24/2021 5:49 PM	Date Submitted:	<i>Unsubmitted</i>

Written Summary of Changes:
Updating the consent with minor changes.

List of Changes:
Changes to Consent Form(s)

VIEW000187

My Activities

PI Submit Revision

SS Withdraw

SS Agree to Participate

PI Request Participant Agreement

Change Workspace Template

Once you have completed the Amendment workspace and updated the Modified Study workspace to reflect the proposed changes, click the "Submit Revision" button.

Activity Date

5/24/2021 5:49 PM

Submit Revision

Use this form to submit your **completed application amendment**. If you click **ok**, you are no longer able to modify the application. You will be notified about the review result by email. If you are not ready for submission, click **cancel**.

Click "OK" to submit the amendment for review

OK

Cancel