

# How to Create and Submit a Continuing Review

ePIRATE Training



This tutorial shows you how to create and submit a continuing review in ePIRATE.

Continuing reviews include information about the status of the study, including updates on enrollment and progression of research subjects (or their data in secondary analyses).

Continuing review is not required for all studies following an update to the common rule (implemented January 2019). Studies that display an expiration date on the main study workspace require continuing review and the ePIRATE system will send reminder emails periodically leading up to the expiration date.

The process for extending the expected end date (applies to most studies approved after the previously mentioned rule change) is completed via amendment.

Studies granted an exempt certification do not expire.



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## 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

If the study has expired it will be found in the "Expired" tab which you may need to click the three buttons below to find.

### Other Submission Types

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

## IRB Studies

Welcome to see the list of submissions related to you.   
 Filter by In Progress, Approved, Certified Exempt, Legacy Approved, Expired link

Click on "Approved"

In Progress

Approved

Certified Exempt

Legacy Approved

...

Filter by ?

ID

Enter text to search for



+ Add Filter

✕ Clear All

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 a continuing review 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 <sup>?</sup> ID <input type="text" value="Enter text to search for"/> <input type="button" value="Q"/> <input type="button" value="+ 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

New Reportable Event

New Amendment

New Continuing Review

Final Report

## 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

Activity	Description	Activity Date
Project Snapshot Generated		5/24/2021 5:48 PM
<a href="#">View Project Snapshot</a>		

History Final Report ...

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

Click "New Continuing Review"

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



### Current State

Pre Submission

Edit Continuing Review

Printer-Friendly Version

### My Activities

Submit Continuing Review

Withdraw

## Continuing Review:2022 Review for UMCIRB 21-001255

( CR00009264 / UMCIRB 21-001255 )

Principal Investigator: UMCIRB UMCIRB

Study Coordinator:

Study S

Click "Edit Continuing Review"

SAE since last continuing review?

Total enrolled for this site since last progress review:

Consent requires modification?

Significant new findings to disclose?

Any publications, presentations or reports related to this research?

History | Documents | Amendments | Reportable Events | ...

Activity	Author	Activity Date
Created Continuing Review	UMCIRB, UMCIRB	5/24/2021 5:50 PM

# Editing: CR00009264

## Study Status

Number of Participants

Reportable Event Details

Research Results

## Continuing Review

Study ID:UMCIRB 21-001255

Study Name:Tutorial Study

1.0 \* Study Status:

Name

- Enrolling Participants
- Enrollment Closed - Participants continue to receive study related treatment/interventions
- Enrollment Closed - Participants remain in follow-up with minimal risk procedures or interactions (including surveys/phone calls) or data collection only

2.0 \* H the the Yes

If yes, please describe:

Text input area for describing the response to question 2.0.

Fill in all relevant information. Red asterisks mean that there must be an answer provided.

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



# Editing: CR00009264

Study Status

**Number of Participants**

Reportable Event Details

Research Results

Final Page

## Numbers of Participant Activity

(if this is a record/chart review, this section should include the numbers of records/charts reviewed)

1.0 Total enrollment requested for local site:

\*

2.0 Total individuals who have signed the informed consent at this site:

\*

3.0 Total individuals who have signed informed consent for this site since last continuing review (if this is the first continuing review, this number will be the same as in question 2.0 above):

\*

4.0 Total who have completed all research related interventions or interactions required by study:

\*

5.0 Total continuing to receive research related interventions or interactions:

\*

6.0 Total in follow-up (e.g., not receiving research related intervention, but study team may still have contact with the participant for follow-up or access a participant's medical record to collect clinical data):

\*

7.0 Provide any comments/clarifications regarding the number of participants above:

8.0 \* Has the entire project or local site exceeded the proposed sample size?  Yes  No

Exit

Save

Continue

The numbers of subjects reported in the continuing review should be accurate at the time of submission and be consistent with any previous continuing reviews.

The UMCIRB needs to know how many subjects have been enrolled and where they are in the study. If the study is only utilizing secondary data, include the number of records accessed by the study team.

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



### Current State

Pre Submission

Edit Continuing Review

Printer-Friendly Version

### My Activities

Submit Continuing Review

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## Continuing Review:2022 Review for UMCIRB 21-001255

( CR00009264 / UMCIRB 21-001255 )

Principal Investigator: UMCIRB UMCIRB

Study Coordinator:

Study Status:

SAE since last continuing review?

Total enrolled for this site since last progress review:

Consent requires modification?

Significant new findings to disclose?

Any publications, presentations or reports related to this research?

Once you have completed the form click "Submit Continuing Review"

History Documents Amendments Reportable Events ...

Activity	Author	Activity Date
Created Continuing Review	UMCIRB, UMCIRB	5/24/2021 5:50 PM

**Submit Continuing Review**

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

Click "OK" to submit the continuing review for review

OK

Cancel