How to Create and Submit a Reportable Event

ePIRATE Training

This tutorial shows you how to create and submit a reportable event in ePIRATE.

Reportable events include protocol deviations, unanticipated problems and data safety monitoring board (DSMB) reports.

Because they are the most common of the three, this tutorial is primarily focused on protocol deviations. However, the same general steps would be used for unanticipated problems and DSMB reports as well. You would simply complete different screen views in the smart form.

Unanticipated problems are significant events and are generally rare. Please see the UMCIRB SOP on this topic for more information

East Carolina University

Hell

» | Dashboard | Home | IRB Studies | Committees | Meetings | Contac

Components | Properties | Pe

Click on IRB Studies

- 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

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

East Carolina University

Hello, UMCIRB UMCIRB

Dashboard | Home | IRB Studies | Issues

Amendments | Continuing Reviews | Final Report | Reportable Events

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

Other Submission Types

- Amendments
- Continuing Reviews
- Final Report
- Reportable Events

IRB S

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 | 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

East Carolina University

Hello, UMCIRB 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 reportable event 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 | Enter text to search for | + Add Filter | × 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

ECU
University & Medical Center Institutional Review Board
600 Moye Boulevard | Brody School of Medicine 4N-70 | Mail Stop 682 | Greenville, NC 27834
252-744-2914 | 252-744-2284 (fax) | Contact Us

East Carolina University

Hello, UMCIRB UMCIRB

Dashboard | Home | IRB Studies | Issues

Amendments | Continuing Reviews | Final Report | Reportable Events

Help

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

Click “New Reportable Event”

New Amendment

New Continuing Review

Final Report

Activi	ion	Activity Date
Project		5/24/2021 5:48 PM

View Project Snapshot

History | Amendments | Continuing Reviews | Final Report | ...

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

East Carolina University

Hello, UMCIRB UMCIRB

» | Dashboard | Home | IRB Studies | Issues

Amendments | Continuing Reviews | Final Report | Reportable Events

Help

Current State

Pre Submission

Edit Reportable Event

Printer Version

View Differences

Reportable Event:Missed study visit Adv00003040 / UMCIRB 21-001255

Principal Investigator: UMCIRB UMCIRB **Study Coordinator:**

Submis

Click “Edit Reportable Event”

History | Reviewer Notes | Change Log

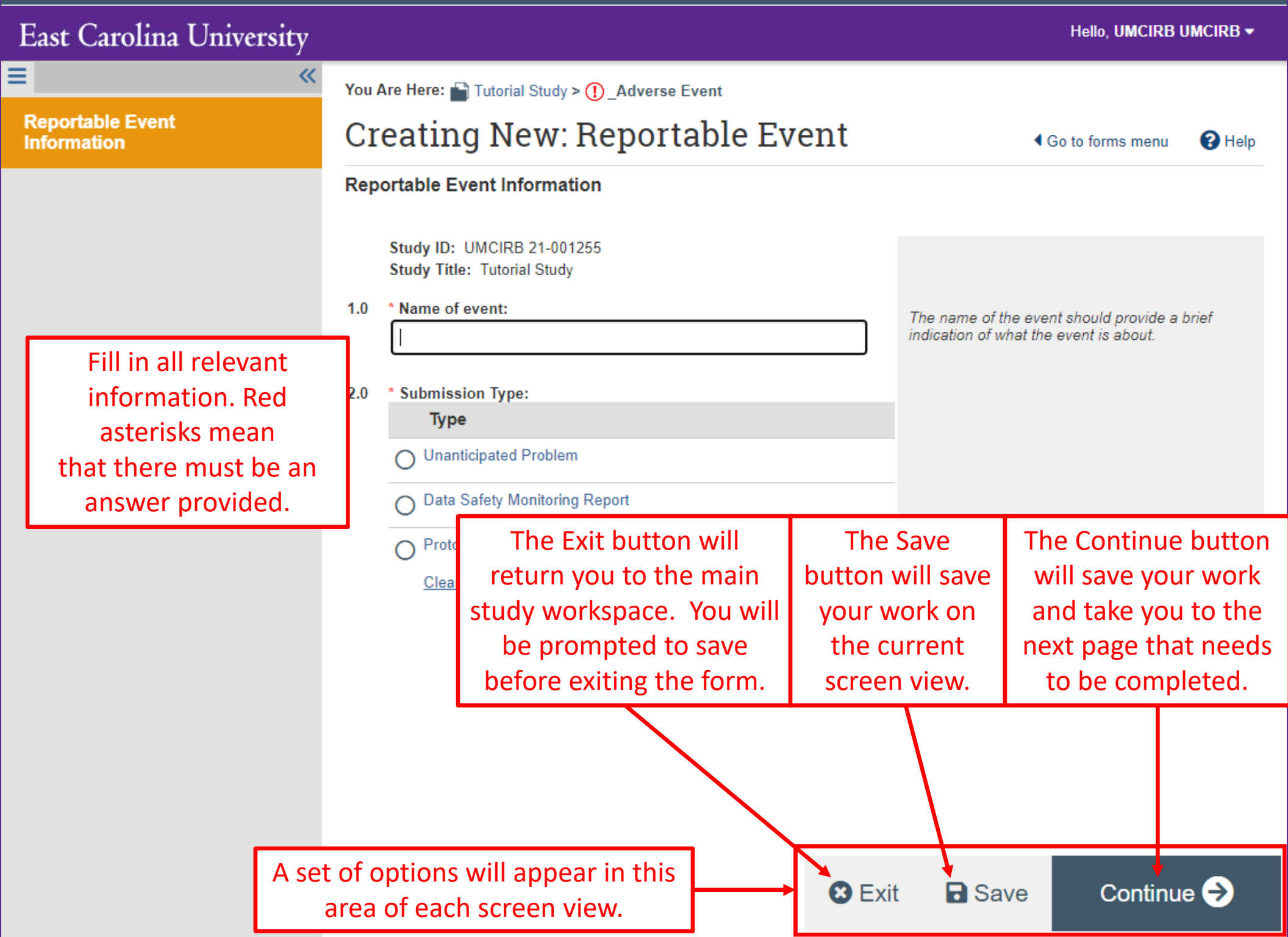
	Activity	Author	Activity Date
	Created Reportable Event	UMCIRB, UMCIRB	5/24/2021 5:51 PM

My Activities

Submit Reportable Event

Withdraw Reportable Event

ECU
University & Medical Center Institutional Review Board
600 Moye Boulevard | Brody School of Medicine 4N-70 | Mail Stop 682 | Greenville, NC 27834
252-744-2914 | 252-744-2284 (fax) | Contact Us


East Carolina University
Hello, UMCIRB UMCIRB
Reportable Event Information
You Are Here: Tutorial Study > _Adverse Event
Creating New: Reportable Event
Go to forms menu
Help
Reportable Event Information
Study ID: UMCIRB 21-001255
Study Title: Tutorial Study
1.0 * Name of event:
The name of the event should provide a brief indication of what the event is about.
2.0 * Submission Type:
Type
Unanticipated Problem
Data Safety Monitoring Report
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: Adv00003040

Reportable Event Information

Study ID: UMCIRB 21-001255
Study Title: Tutorial Study

1.0 * **Name of event:**

Missed study visit

The name of the event should provide a brief indication of what the event is about.

2.0 * **Submission Type:**

Type
○ Unanticipated Problem
○ Data Safety Monitoring Report
● Protocol Deviation/Violation

Clear

Reportable Event Information

Determining Reportable Unanticipated Problem

Not a Reportable Event

Unanticipated Problem

Data Safety Monitoring Report

Protocol Violation/Deviation

External Unanticipated Problem

Internal Unanticipated Problem

Medical Event Description

Psychological, Psychiatric or Behavioral Event Description

Breach of Confidentiality Event Description

Anticipated Event Exceeding Protocol

Editing: Adv00003040

Protocol Violation/Deviation

1.0

* Date of protocol violation/deviation: 6/1/2021

2.0 * Please describe as completely as possible the violation or deviation from the protocol:

A patient was having transportation issues and was unable to make their scheduled appointment on 6/1/2021. Visit was completed on 6/5/2021. Protocol requires visits be completed within a specific window and this was outside of the allowable window.

3.0 * Did the violation/deviation result in an unanticipated problem, increased risk or consequences to the subject?

○ Yes ● No Clear

4.0 If yes, indicate the steps that have been taken to address the issue.

5.0 Has the sponsor been notified? ● Yes ○ No Clear

6.0 Has the appropriate regulatory agency been notified? ○ Yes ● No Clear

7.0 If sponsored and the sponsor provided prospective permission for deviation, upload documentation from sponsor:

+ Add

Document | Description

See UMC Rule Defi and Rep Prot Dev

Exit | Save | Continue

East Carolina University

Hello, UMCIRB UMCIRB

Dashboard | Home | IRB Studies | Issues

Amendments | Continuing Reviews | Final Report | Reportable Events

Help

Current State

Pre Submission

Edit Reportable Event

Printer Version

View Differences

Reportable Event:Missed study visit Adv00003040 / UMCIRB 21-001255

Principal Investigator: UMCIRB UMCIRB **Study Coordinator:**

Submission Type: Protocol Deviation/Violation

History | Reviewer Notes | Change Log

My Activities

Submit Reportable Event

Withdraw Reportable Event

Activity	Author	Activity Date
		5/24/2021 5:51 PM

Once you have completed the form click “Submit Reportable Event”

University & Medical Center Institutional Review Board
600 Moye Boulevard | Brody School of Medicine 4N-70 | Mail Stop 682 | Greenville, NC 27834
252-744-2914 | 252-744-2284 (fax) | Contact Us

Submit Reportable Event

Reportable Event Submission

I certify that all information provided in this form represents an accurate description of the Reportable Event and meets the definitions set forth in the UMCIRB procedures for reporting an event.

Please note that once you click OK you will no longer be able to edit the Reportable Event form. After submission, you will receive an email notifying you of the current state of review or if changes/more information are required by you.

If you are ready to submit this Reportable Event, click **OK**. Otherwise, click **Cancel**.

Click “OK” to submit the reportable event for review