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

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<th>ID</th>
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Find the study you wish to create a reportable event for and click the name to access the main study workspace.
Click "New Reportable Event"
Reportable Event: Missed study visit

**Principal Investigator:** UMCIRB

**Study Coordinator:**

### Current State

- **Pre Submission**

- **Edit Reportable Event**

- **Submit**

### My Activities

- **Submit Reportable Event**

- **Withdraw Reportable Event**

### Reportable Event Details

<table>
<thead>
<tr>
<th>Activity</th>
<th>Author</th>
<th>Activity Date</th>
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<td>5/24/2021 5:51 PM</td>
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**Click “Edit Reportable Event”**
Fill in all relevant information. Red asterisks mean that there must be an answer provided.

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

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.
Editing: Adv00003040

Reportable Event Information

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

1.0 Name of event:
   Missed study visit

2.0 Submission Type:
   - Unanticipated Problem
   - Data Safety Monitoring Report
   - Protocol Deviation/Violation

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

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

5.0 Has the sponsor been notified?

- Yes
- No

6.0 Has the appropriate regulatory agency been notified?

- Yes
- No

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

+ Add

Exit ✗ Save ▶ Continue →
Once you have completed the form, click "Submit Reportable Event"
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 UMCIRE 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