eIRB Create Protocol Violation

July 19, 2004
Step 1 - For sim purposes, you will only fill out a limited number of questions.

Notes:
For simulations purposes we will only fill out a limited number of questions on this form.

Click Here to continue.
Step 2 - Click on **My Home**

If you are not already there, start by clicking on **My Home**.

**Notes:**
If you are not already there, start by clicking on **My Home**.
Step 3 - Click on Protocols.

Notes:
Click on the Protocols tab and select the protocol you wish to create a violation for.
Step 4 - Click on **Effects of eLearning**

**Notes:**
Click on the Effects of eLearning study to open it.
Effects of e-Learning - Microsoft Internet Explorer

Step 5 - Click on [New Protocol Violation]

Notes:
Click on the New Protocol Violation button to begin creating a new one.
Step 6 - Click on

**Notes:**
Click in the Violation Name field to select it.
Step 7 - Type "Exceeded approved subject number" in edit box

Notes:
Type, Exceeded approved subject number, as a violation name.
Step 8 - Click on Continue >>

**Notes:**
After verifying your choices, click on the Continue button to move to the next screen.
Step 9 - Click on

Notes:
Click in the Violation field to select it.
Step 10 - Type key 1

Protocol Violation Form

Protocol Violation Form

Notes:
Type 1 for a violation number.
Step 11 - Click on

Click in the Report Date field, or press Tab on the keyboard to select it.

Notes:
Click in the Report Date field, or press Tab on the keyboard to select it.
Step 12 - Type "6/4/2004" in edit box

Notes:
In the Report Date field, type, 6/4/2004.
Step 13 - Click on

**Notes:**
Click in the Number enrolled at OHSU field, or press Tab on the keyboard, to select it.
Step 14 - Type "34" in edit box

Notes:
Type, 34 for the Number enrolled at OHSU.
Step 15 - Click on

**Notes:**
Click in the Number still in treatment field or press Tab on the keyboard, to select it.
Step 16 - Type "34" in edit box

Protocol Violation Form

PT: Michael Miller
Short Study Title: Effects of e-Learning
IRB Number: IRB00000363
Study Status: Active

Violation #: 1

1. Report Date: 04/02/2004
2. Number enrolled at OHSU: 24
3. Number still in treatment: [ ]
4. Total number of subjects enrolled: [ ]
5. Protocol Violation Date: [ ]
6. Participant Identifier: [ ]
7. What type of report is this?
   Select: [ ]
   Type 34 for the number still in treatment.
7.1 If follow-up, to which initial number: [ ]
8. Please give a brief description of the Protocol Violation, using key
   See the policy on protocol violations to confirm this is a reportable

HELP TEXT

The date you become aware of the protocol violation.
Over the life of the study:
Including subjects enrolled at other institutions.

Notes:
Type 34 for the Number still in treatment.
Step 17 - Click on

Notes:
Click in the Total number of subjects enrolled field, or press Tab on the keyboard to select it.
Step 18 - Type "34" in edit box

Notes:
Type 34 for the total number of subjects enrolled.
Step 19 - Click on 

Notes:
To enter a protocol violation date, click on the select date button.
Step 20 - Click on 

![Click on the month drop-down menu.](image)

**Notes:**
Click on the month drop-down menu.
Step 21 - Select list box item May.

Notes:
Select May.
Step 22 - Click on 19

**Notices: Select the 19th.**
Step 23 - Click on **OK**

**Notes:**
Click OK to confirm your selection.
Step 24 - Click on:

Notes:
Click on the drop-down menu for the What type of report is this field.
Step 25 - Select list box item "Initial"

Notes:
Select Initial as the report type.
Step 26 - Click on

Notes:
Scroll down to display more of the current page.
Step 27 - Click on

Notes:
Click in the protocol violation description field to select it.
Step 28 - Type "Enrolled more subjects than approved" in edit box

Notes:
Type, Enrolled more subjects than approved, as the brief protocol violation description.
Step 29 - Click on No.

Notes:
Click No, for the Resulted in AE question.
Step 30 - Click on ☐ No

Notes:
Click, No, for the Resulted in intervention for the subject question.
Step 31 - Click on **No**

### Notes:
Click, No, for the Affected Study Results question.
Step 32 - Click on

Notes:
Click in the Number of similar protocol violations field to select it.
Step 33 - Type key 0

Notes:
Type, 0 for the number of similar protocol violations.
Step 34 - Click on

Notes:
Scroll down to display more of the current page.
Step 35 - Click in the text box for question 14 to select it.

Notes:
Click in the prevention plan description field to select it.
Step 36 - Type "Request increase for number of approved subjects" in edit box

Notes:
Type, Request increase for number of approved subjects for the prevention plan description.
Notes:
After verifying your choices, click on the Continue button to move to the next screen.
Step 38 - Use this page to submit associated documents. Click Finish when done.

**Notes:**
This page allows you to submit electronic documents with your Protocol Violation and to indicate any documents you will be mailing in hard copy.

Click Here to continue.
Step 39 - Click on [Finish]

**Notes:**
Click on the Finish button to complete this form.
Step 40 - End of simulation