



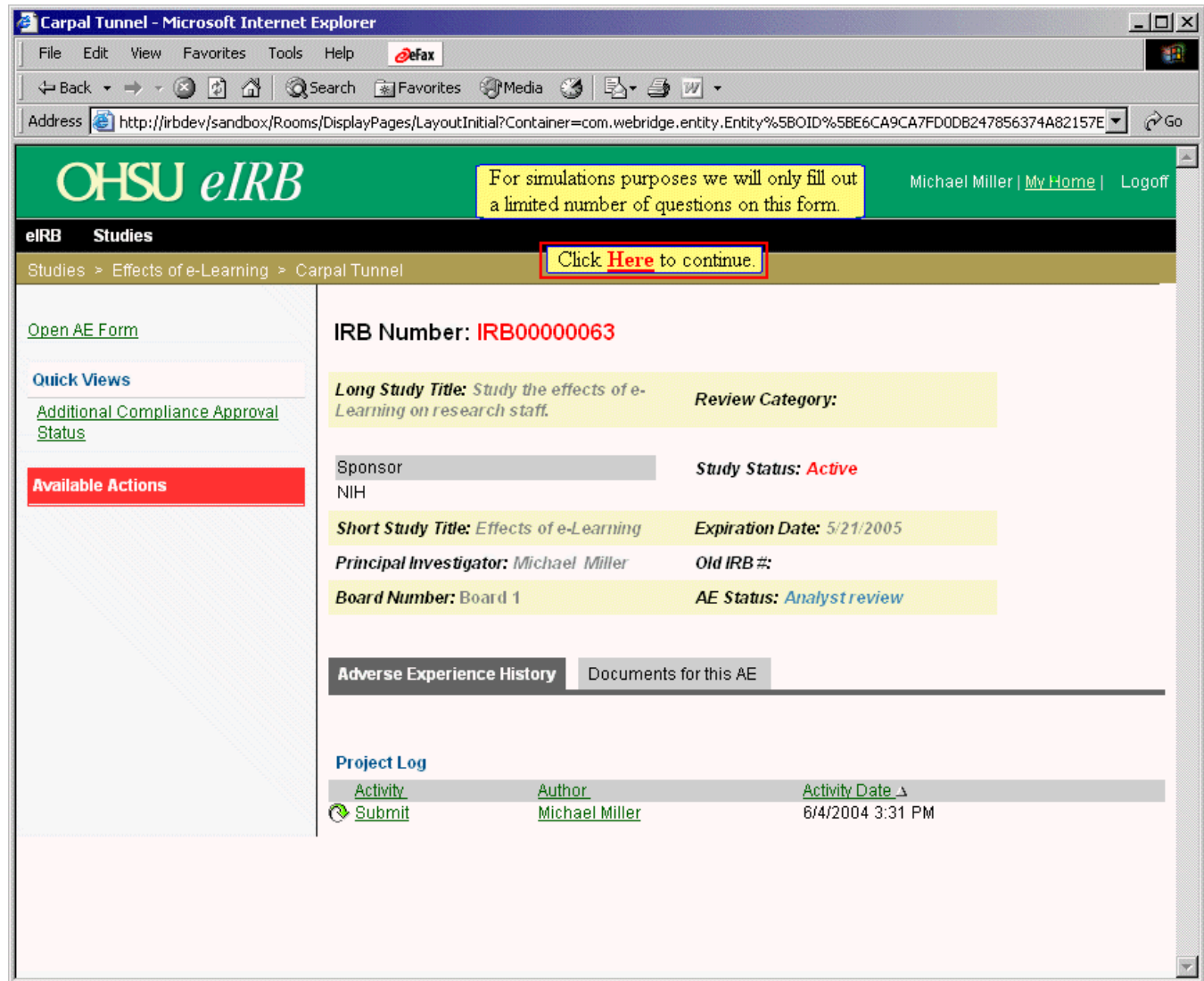
## **eIRB Create Protocol Violation**

July 19, 2004



## Carpal Tunnel - Microsoft Internet Explorer

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



The screenshot shows the OHSU eIRB web application interface. At the top, there is a green header with the OHSU eIRB logo on the left and a navigation area on the right containing the text "Michael Miller | [My Home](#) | [Logout](#)". A yellow box in the header contains the text: "For simulations purposes we will only fill out a limited number of questions on this form." Below the header, a navigation bar shows "eIRB Studies" and a breadcrumb trail: "Studies > Effects of e-Learning > Carpal Tunnel". A red box highlights a button labeled "Click Here to continue." The main content area is divided into a left sidebar and a main panel. The sidebar includes links for "Open AE Form", "Quick Views" (with sub-links for "Additional Compliance Approval Status"), and a red "Available Actions" button. The main panel displays study information: "IRB Number: IRB00000063", "Long Study Title: Study the effects of e-Learning on research staff.", "Review Category:", "Sponsor: NIH", "Study Status: Active", "Short Study Title: Effects of e-Learning", "Expiration Date: 5/21/2005", "Principal Investigator: Michael Miller", "Old IRB #:", "Board Number: Board 1", and "AE Status: Analyst review". Below this is a section for "Adverse Experience History" with a sub-link "Documents for this AE". At the bottom, there is a "Project Log" table with columns for Activity, Author, and Activity Date.

Activity	Author	Activity Date
<a href="#">Submit</a>	<a href="#">Michael Miller</a>	6/4/2004 3:31 PM

### Notes:

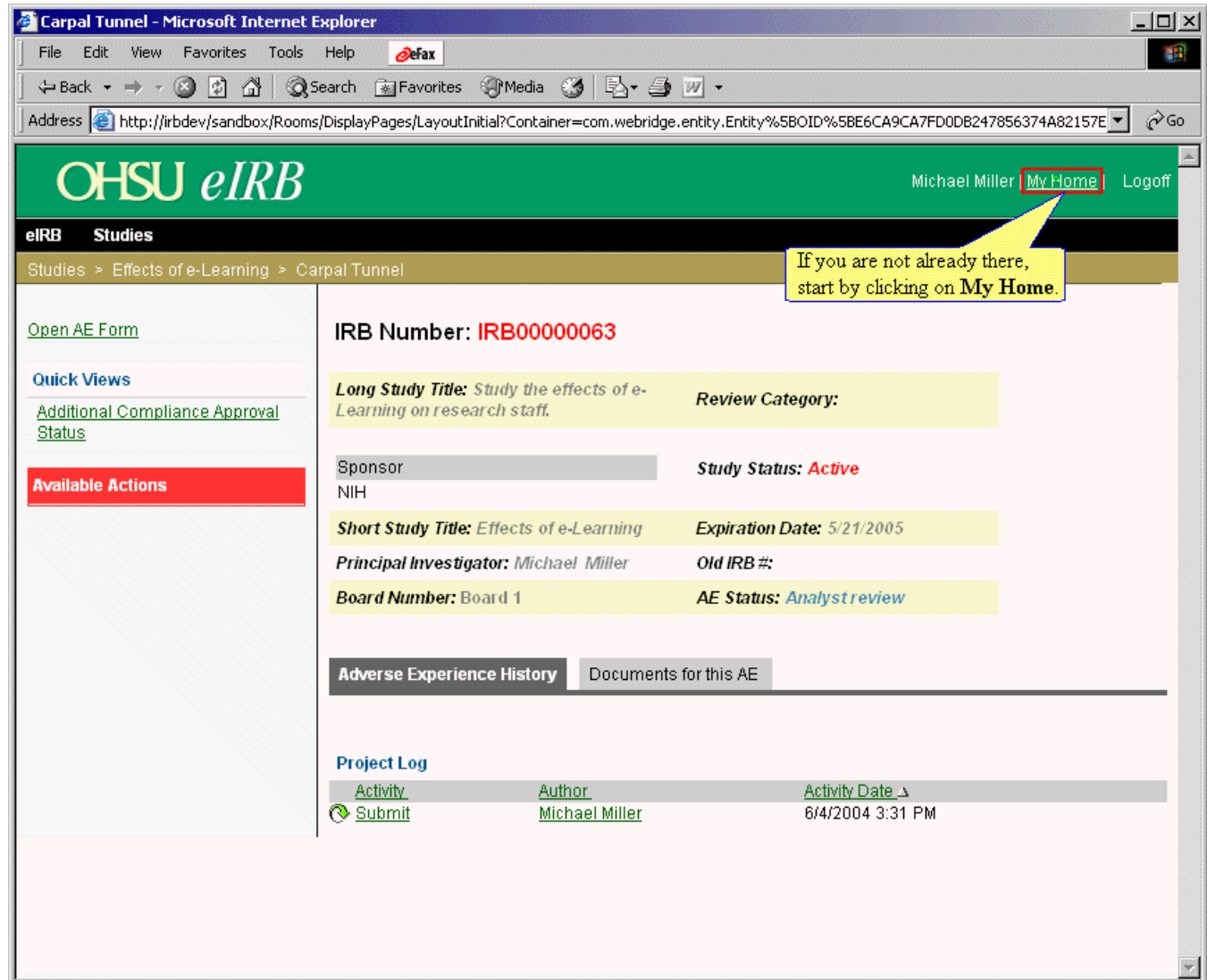
For simulations purposes we will only fill out a limited number of questions on this form.

[Click Here to continue.](#)



## Carpal Tunnel - Microsoft Internet Explorer

Step 2 - Click on [My Home](#)



The screenshot shows the OHSU eIRB web application in Microsoft Internet Explorer. The browser title is "Carpal Tunnel - Microsoft Internet Explorer". The address bar shows the URL: <http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge.entity.Entity%5B...>

The page header includes the OHSU eIRB logo and the user name "Michael Miller". A "My Home" link is highlighted with a red box, and a yellow callout bubble points to it with the text: "If you are not already there, start by clicking on My Home."

The main content area displays the following information:

- IRB Number:** IRB00000063
- Long Study Title:** Study the effects of e-Learning on research staff.
- Review Category:** (blank)
- Sponsor:** NIH
- Study Status:** Active
- Short Study Title:** Effects of e-Learning
- Expiration Date:** 5/21/2005
- Principal Investigator:** Michael Miller
- Old IRB #:** (blank)
- Board Number:** Board 1
- AE Status:** Analyst review

Below the study information, there are tabs for "Adverse Experience History" and "Documents for this AE".

The "Project Log" section shows the following activity:

Activity	Author	Activity Date
Submit	Michael Miller	6/4/2004 3:31 PM

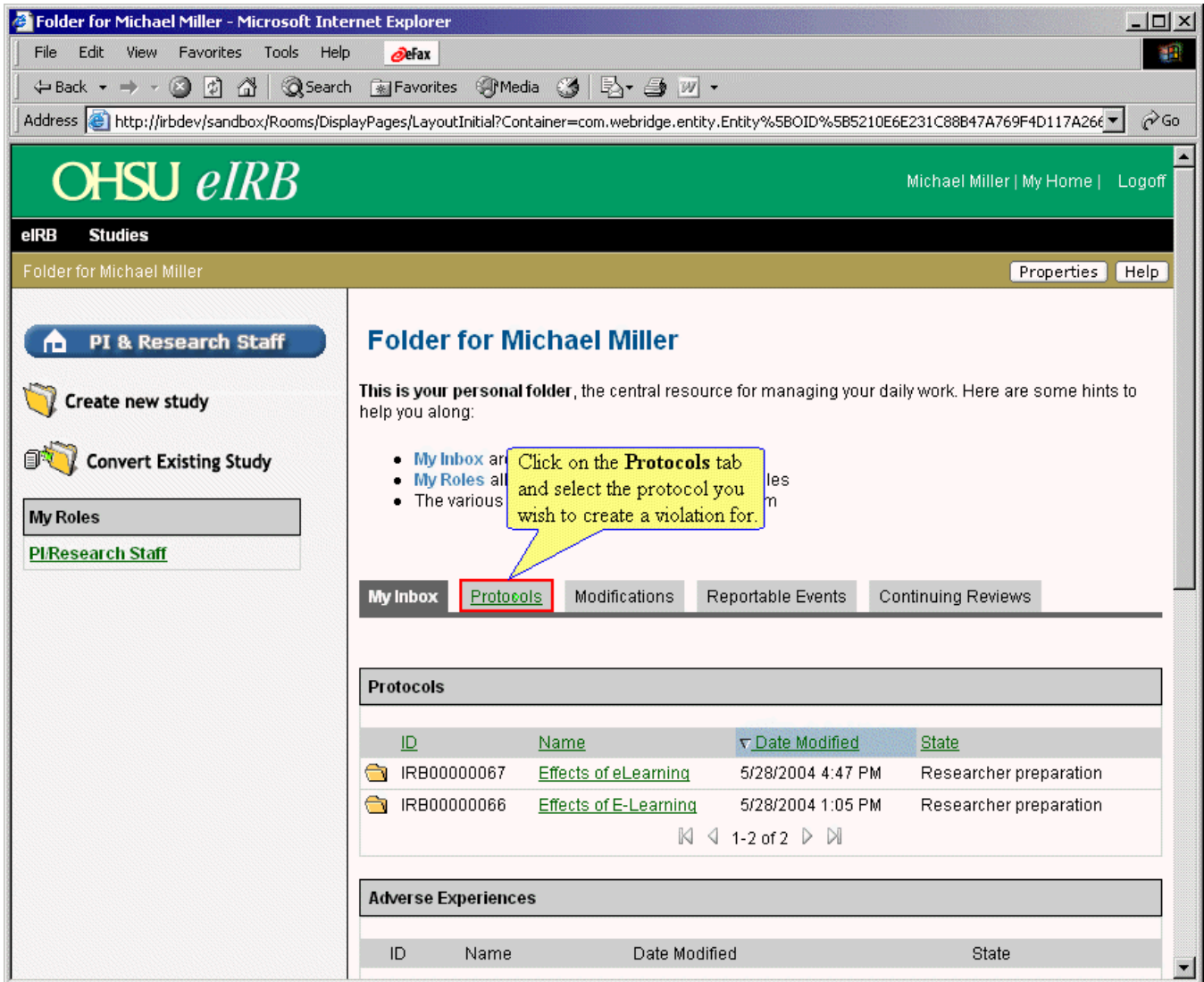
### Notes:

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



**Folder for Michael Miller - Microsoft Internet Explorer**

Step 3 - Click on [Protocols](#)



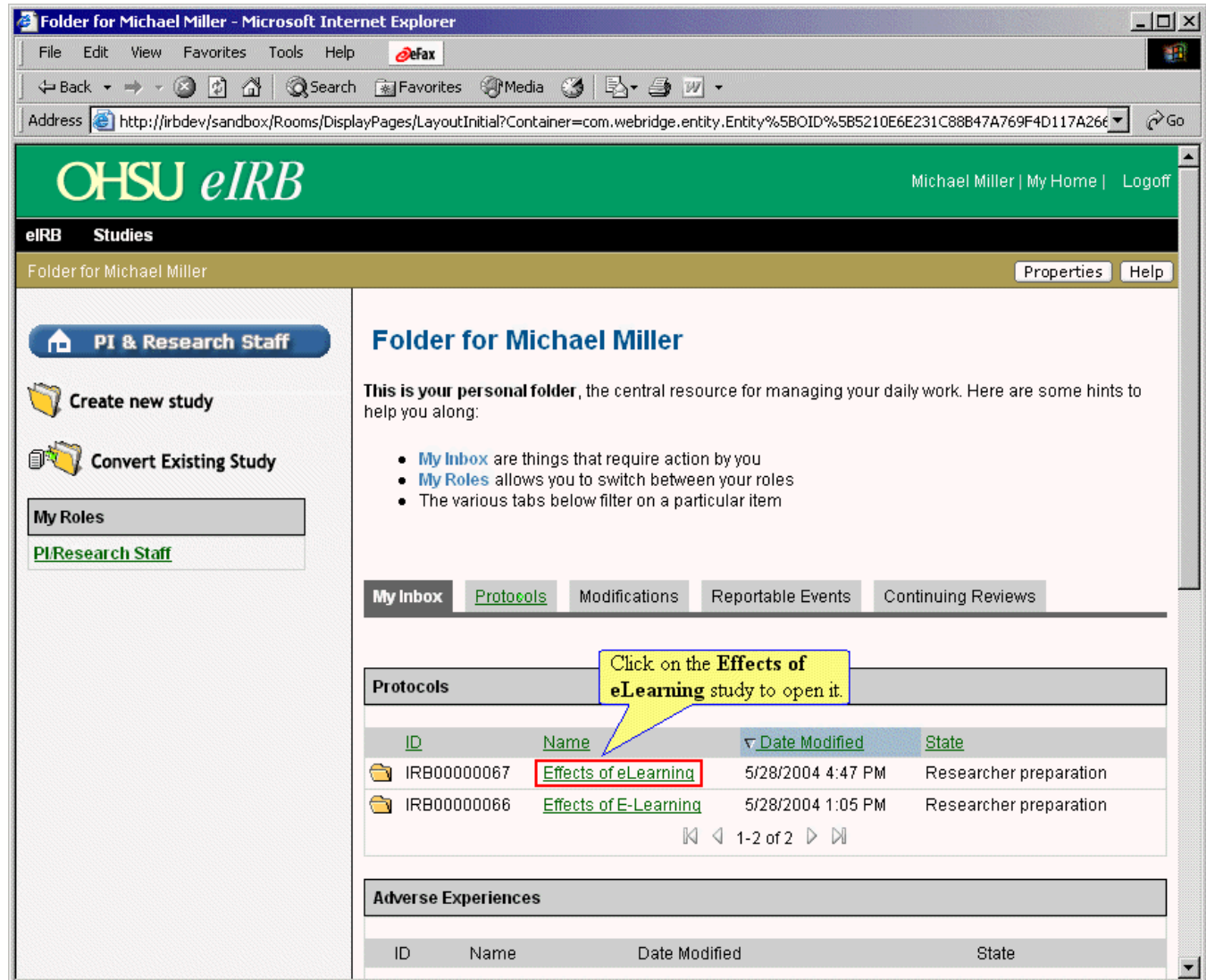
**Notes:**

Click on the Protocols tab and select the protocol you wish to create a violation for.



## Folder for Michael Miller - Microsoft Internet Explorer

Step 4 - Click on [Effects of eLearning](#)



The screenshot shows the OHSU eIRB web application interface. The browser window title is "Folder for Michael Miller - Microsoft Internet Explorer". The address bar contains the URL: <http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge.entity.Entity%5B...>

The page header includes the OHSU eIRB logo and the user name "Michael Miller | My Home | Logoff". Below the header, the page is titled "Folder for Michael Miller" and includes "Properties" and "Help" buttons.

The main content area is divided into a left sidebar and a main panel. The sidebar contains a "PI & Research Staff" button, "Create new study" and "Convert Existing Study" options, and a "My Roles" section with a link to "PI/Research Staff".

The main panel is titled "Folder for Michael Miller" and contains a message: "This is your personal folder, the central resource for managing your daily work. Here are some hints to help you along:"

- **My Inbox** are things that require action by you
- **My Roles** allows you to switch between your roles
- The various tabs below filter on a particular item

Below the message are several tabs: "My Inbox", "Protocols", "Modifications", "Reportable Events", and "Continuing Reviews". The "Protocols" tab is selected.

The "Protocols" section displays a table of protocols. A yellow callout box points to the "Effects of eLearning" entry, with the text: "Click on the **Effects of eLearning** study to open it." The "Effects of eLearning" entry is highlighted with a red box.

ID	Name	Date Modified	State
IRB00000067	<a href="#">Effects of eLearning</a>	5/28/2004 4:47 PM	Researcher preparation
IRB00000066	<a href="#">Effects of E-Learning</a>	5/28/2004 1:05 PM	Researcher preparation

Below the table are navigation controls: "1-2 of 2".

The "Adverse Experiences" section is also visible, with a table header showing "ID", "Name", "Date Modified", and "State".

### Notes:

Click on the Effects of eLearning study to open it.



**Effects of e-Learning - Microsoft Internet Explorer**

Step 5 - Click on 

The screenshot shows the OHSU eIRB web application interface. At the top, there is a green header with the OHSU eIRB logo and the user name 'Michael Miller | My Home | Logoff'. Below the header, the page title is 'eIRB Studies' and the breadcrumb is 'Studies > Effects of e-Learning'.

On the left side, there is a sidebar with several buttons: 'Open IRQ', 'Quick Views' (with sub-links for 'Additional Compliance Approval Status'), 'Available Actions' (with sub-links for 'Add or Edit Documents' and 'Update Edit or Read Rights'), 'New Modification', 'New Adverse Event', 'New Protocol Violation' (highlighted with a red box), 'New Continuing Review', and 'Terminate This Study'. A yellow callout bubble points to the 'New Protocol Violation' button with the text: 'Click on the New Protocol Violation button to begin creating a new one.'

The main content area displays details for an IRB study:

- IRB Number:** IRB00000063
- Progress Indicators:** Pre-submission (red), IRB Screening (orange), IRB Review (grey), Approved (green)
- Long Study Title:** Study the effects of e-Learning on research staff. **Review Category:**
- Sponsor:** NIH **Study Status:** Active
- Short Study Title:** Effects of e-Learning **Expiration Date:** 5/21/2005
- PI:** Michael Miller **Old IRB #:**
- Board Number:** Board 1

Below the study details, there are tabs for 'Initial Review History', 'Study Documents', 'Modifications', 'Reportable Events', and 'Continuing Reviews'. At the bottom, there is a 'Project Log' table:

Activity	Author	Activity Date
IRQ edited	System Administrator	5/24/2004 9:29 AM
Update Edit or Read Rights	Michael Wright	5/24/2004 9:26 AM
Update Edit or Read Rights	Michael Wright	5/24/2004 8:25 AM

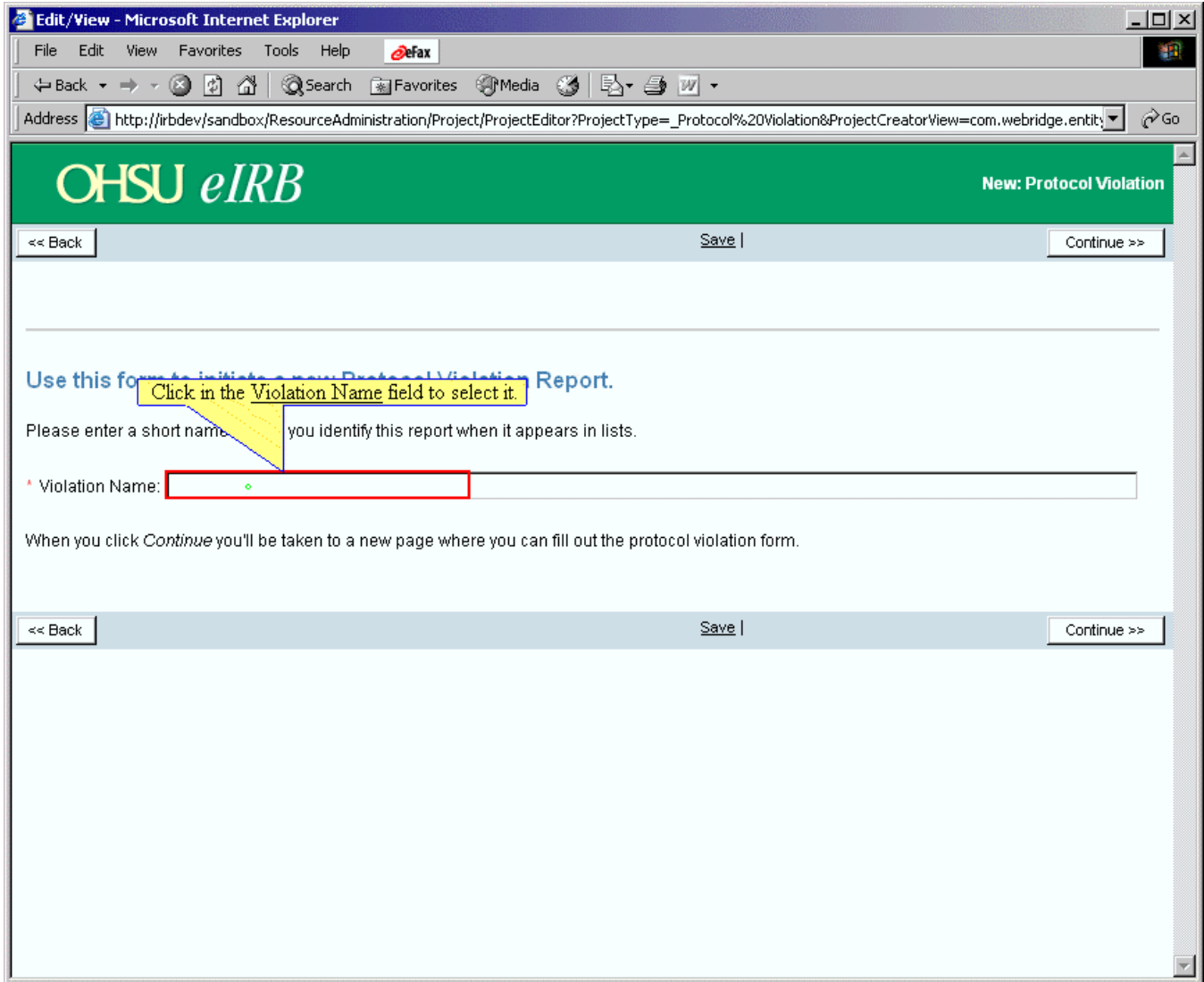
**Notes:**

Click on the New Protocol Violation button to begin creating a new one.



**Edit/View - Microsoft Internet Explorer**

Step 6 - Click on

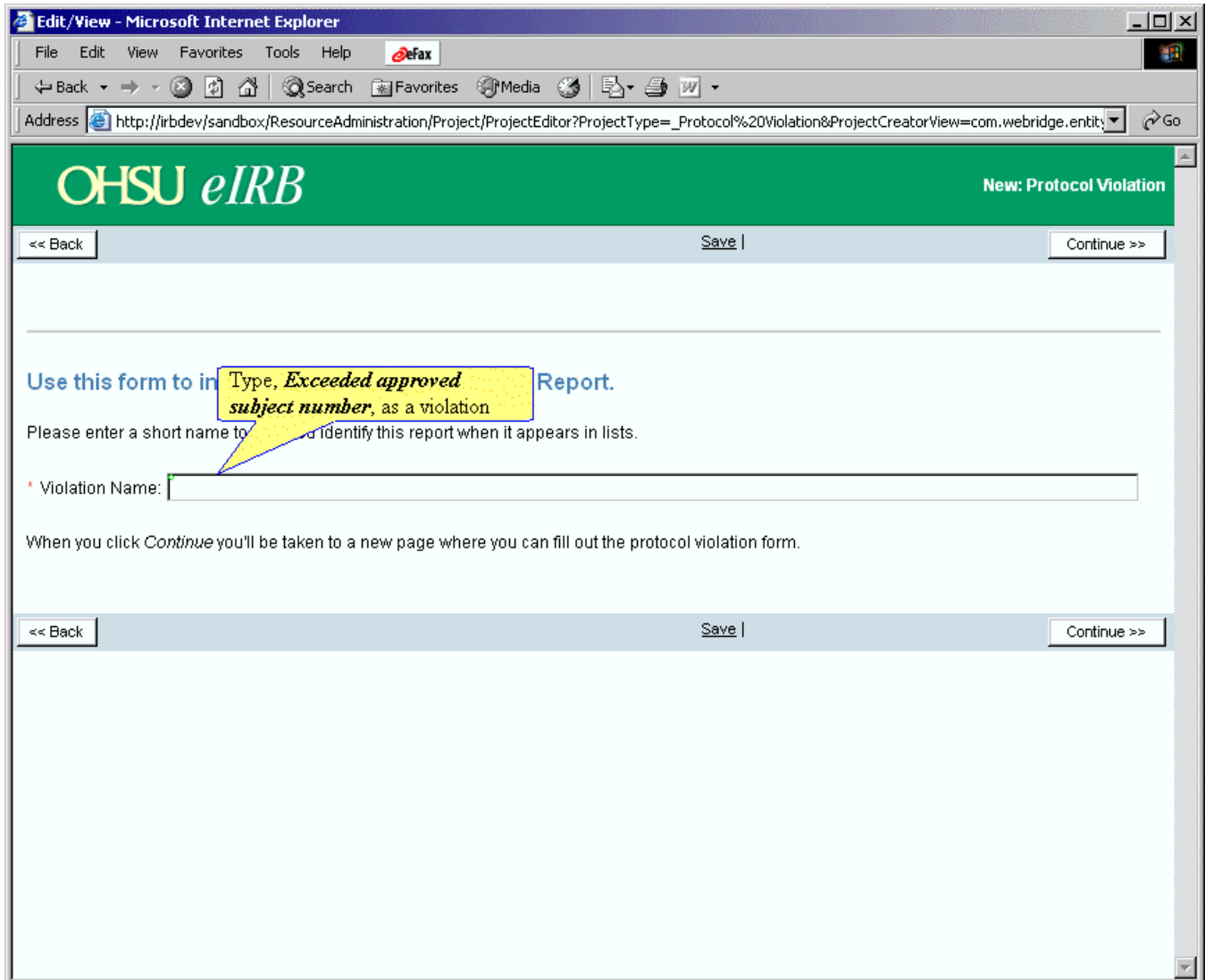


**Notes:**

Click in the Violation Name field to select it.

**Edit/View - Microsoft Internet Explorer**

Step 7 - Type "Exceeded approved subject number" in edit box



Use this form to in Type, *Exceeded approved subject number*, as a violation Report.

Please enter a short name to identify this report when it appears in lists.

\* Violation Name:

When you click *Continue* you'll be taken to a new page where you can fill out the protocol violation form.

**Notes:**

Type, Exceeded approved subject number, as a violation name.

**OHSU eIRB****Edit/View - Microsoft Internet Explorer**

Step 8 - Click on

**Edit/View - Microsoft Internet Explorer**

File Edit View Favorites Tools Help **efax**

Back Forward Stop Home Search Favorites Media Print W

Address [http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?ProjectType=\\_Protocol%20Violation&ProjectCreatorView=com.webridge.entit](http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?ProjectType=_Protocol%20Violation&ProjectCreatorView=com.webridge.entit) Go

**OHSU eIRB** **New: Protocol Violation**

<< Back [Save](#) |

**Use this form to initiate a new Protocol Violation Report.**

Please enter a short name to help you identify this report when it appears in lists.

\* Violation Name:

When you click *Continue* you'll be taken to a new page where you can fill out the protocol violation form.

After verifying your choices, click on the **Continue** button to move to the next screen.

<< Back [Save](#) |

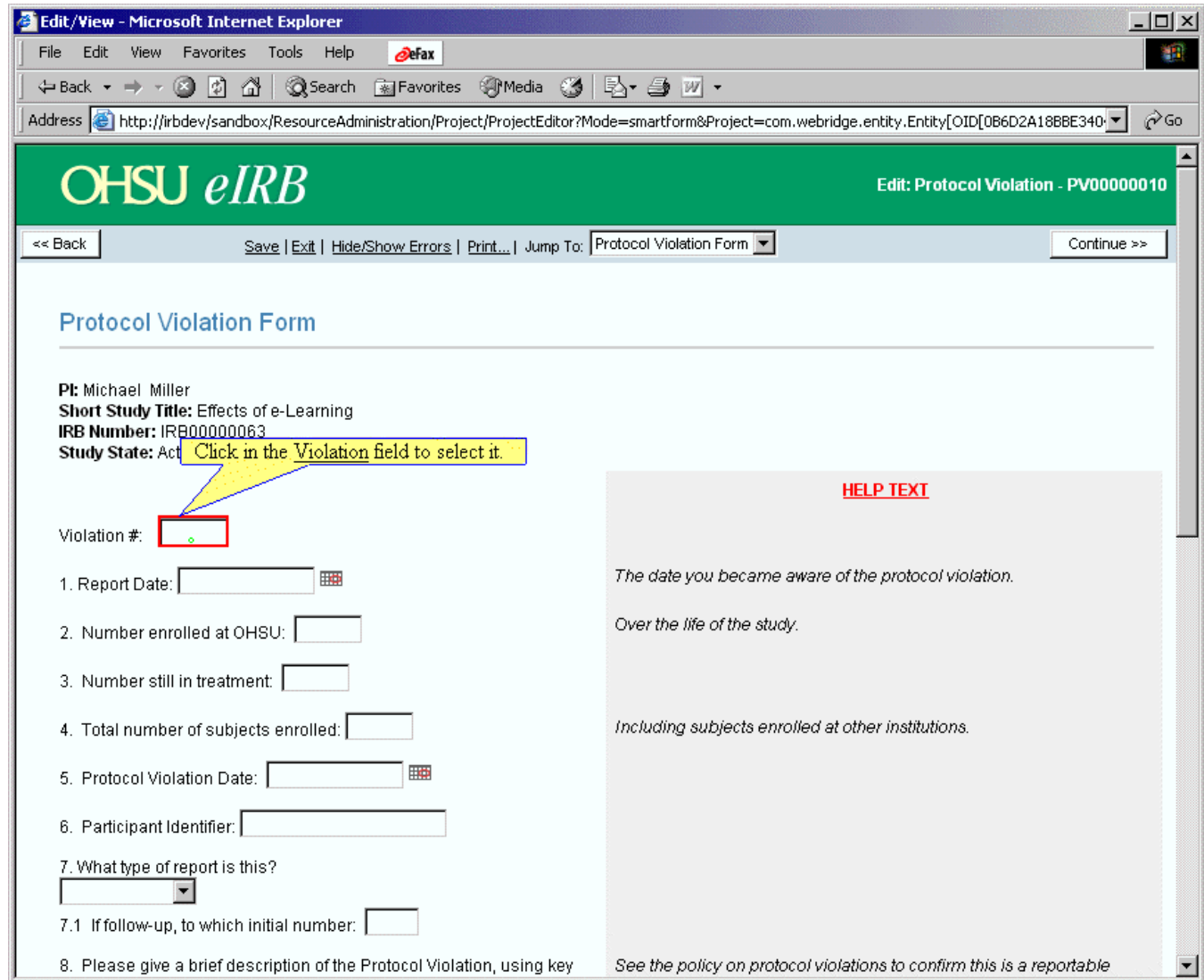
**Notes:**

After verifying your choices, click on the Continue button to move to the next screen.



## Edit/View - Microsoft Internet Explorer

Step 9 - Click on



<< Back      Save | Exit | Hide/Show Errors | Print... | Jump To: Protocol Violation Form      Continue >>

### Protocol Violation Form

**PI:** Michael Miller  
**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB000000063  
**Study State:** Act Click in the Violation field to select it.

Violation #:

1. Report Date:

2. Number enrolled at OHSU:

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?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key

**HELP TEXT**

*The date you became aware of the protocol violation.*

*Over the life of the study.*

*Including subjects enrolled at other institutions.*

*See the policy on protocol violations to confirm this is a reportable*

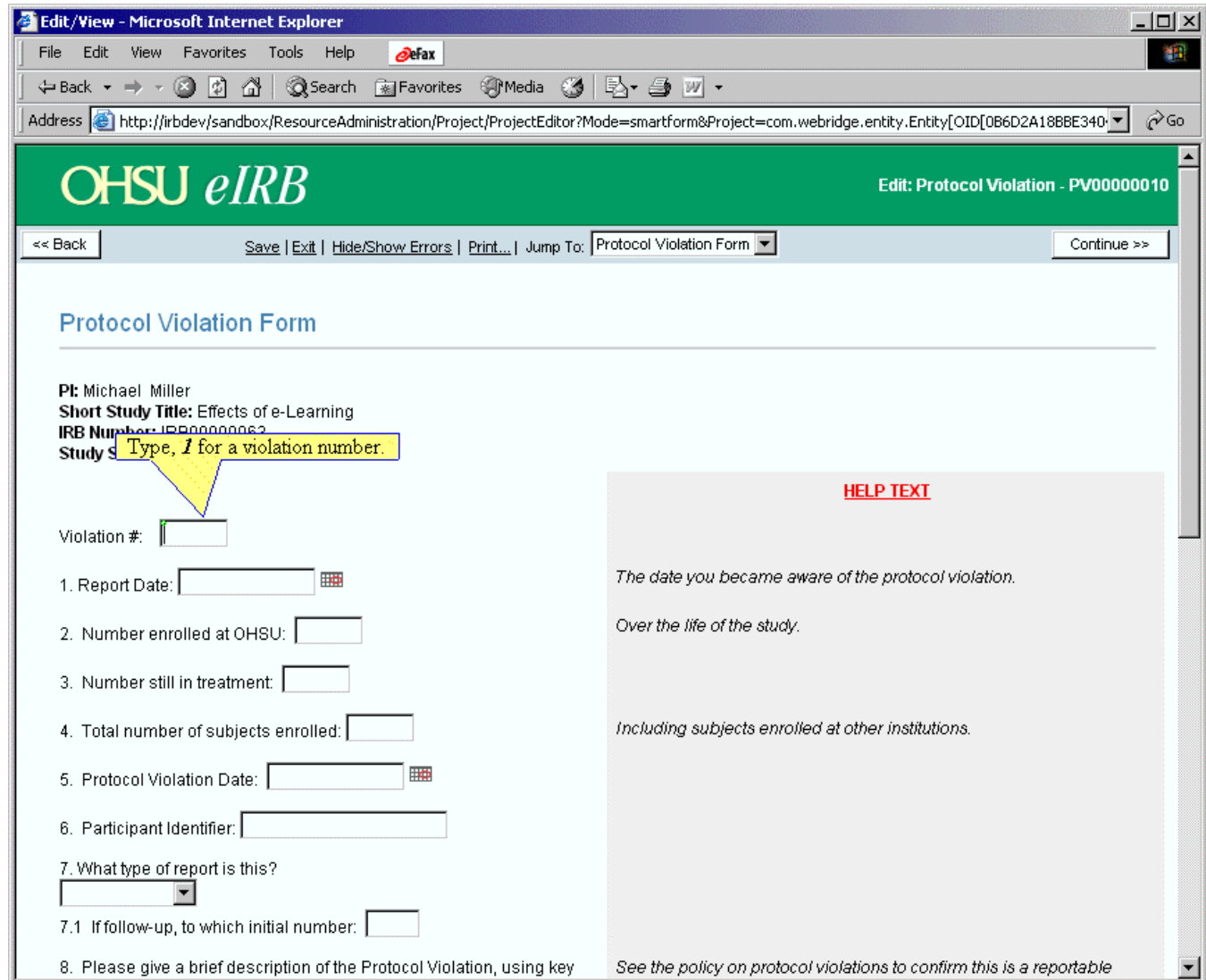
### Notes:

Click in the Violation field to select it.



## Edit/View - Microsoft Internet Explorer

### Step 10 - Type key 1




**OHSU eIRB** Edit: Protocol Violation - PV00000010

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Protocol Violation Form Continue >>

### Protocol Violation Form

PI: Michael Miller  
Short Study Title: Effects of e-Learning  
IRB Number: IRB00000003  
Study ID:  Type, 1 for a violation number.


Violation #:

1. Report Date:  

2. Number enrolled at OHSU:

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?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key

**HELP TEXT**

*The date you became aware of the protocol violation.*

*Over the life of the study.*

*Including subjects enrolled at other institutions.*

*See the policy on protocol violations to confirm this is a reportable*

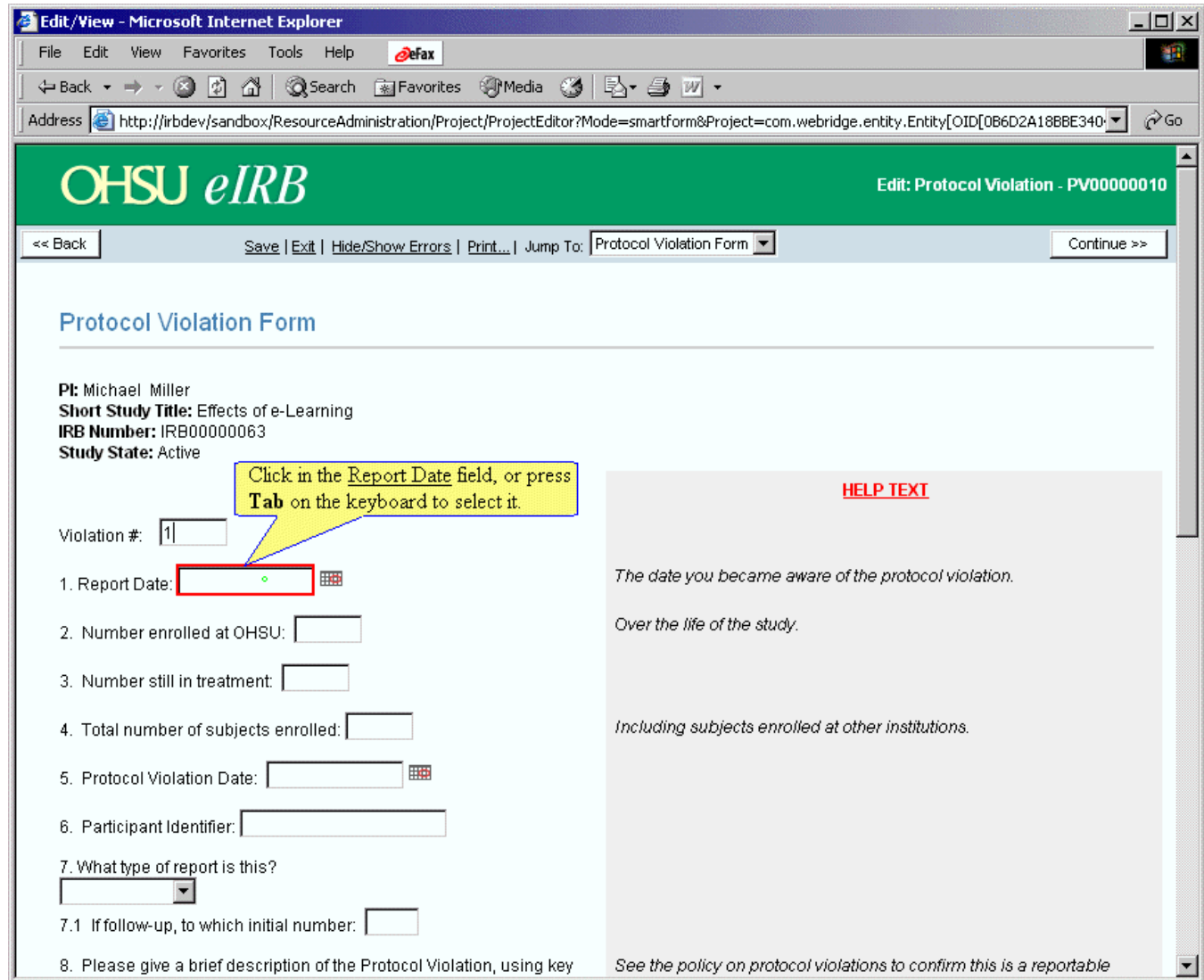
### Notes:

Type, 1 for a violation number.



## Edit/View - Microsoft Internet Explorer


Step 11 - Click on



**Protocol Violation Form**

PI: Michael Miller  
**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB000000063  
**Study State:** Active


Violation #:

1. Report Date:  

2. Number enrolled at OHSU:

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?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key

**HELP TEXT**

*The date you became aware of the protocol violation.*

*Over the life of the study.*

*Including subjects enrolled at other institutions.*

*See the policy on protocol violations to confirm this is a reportable*

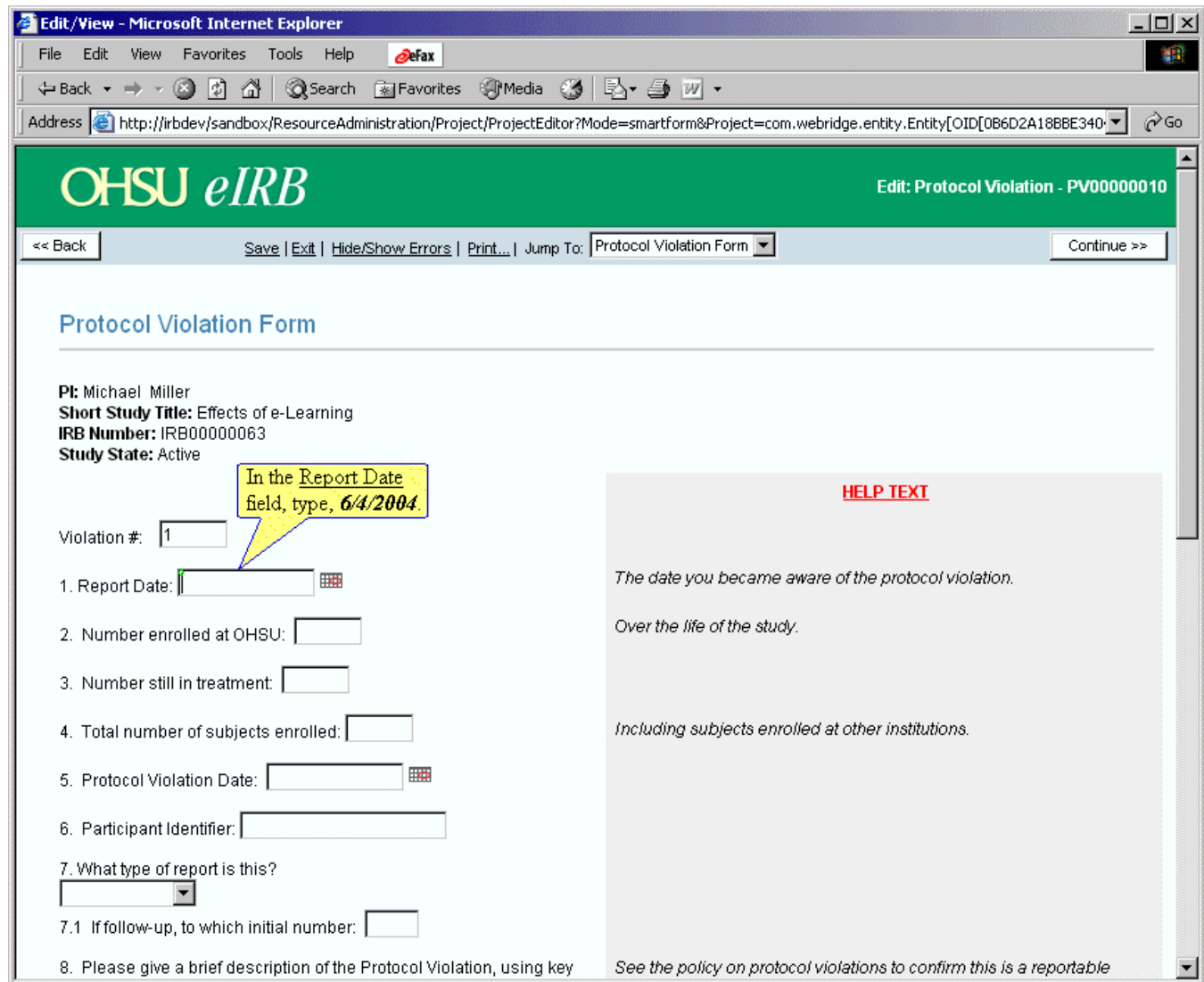
### Notes:

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



## Edit/View - Microsoft Internet Explorer

Step 12 - Type "6/4/2004" in edit box



Edit/View - Microsoft Internet Explorer  
 File Edit View Favorites Tools Help eFax  
 Back Forward Stop Home Search Favorites Media Print W  
 Address http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webbridge.entity.Entity[OID[0B6D2A18BBE340] Go

**OHSU eIRB** Edit: Protocol Violation - PV00000010  
 << Back Save | Exit | Hide/Show Errors | Print... | Jump To: Protocol Violation Form Continue >>

### Protocol Violation Form

**PI:** Michael Miller  
**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB00000063  
**Study State:** Active

Violation #:

1. Report Date:

2. Number enrolled at OHSU:

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?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key

**HELP TEXT**  
*The date you became aware of the protocol violation.*  
*Over the life of the study.*  
*Including subjects enrolled at other institutions.*  
*See the policy on protocol violations to confirm this is a reportable*

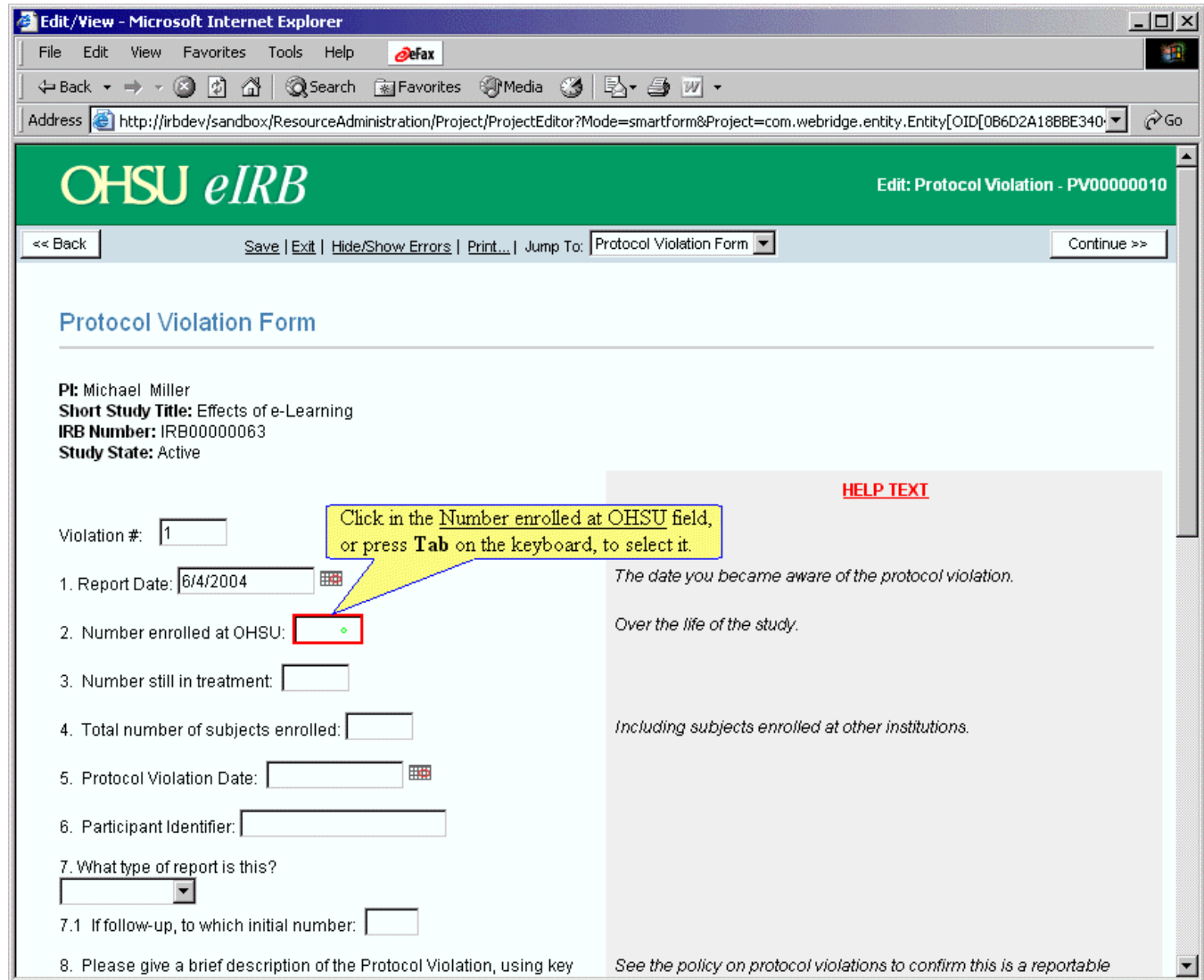
### Notes:

In the Report Date field, type, 6/4/2004.



## Edit/View - Microsoft Internet Explorer

Step 13 - Click on





<< Back      Save | Exit | Hide/Show Errors | Print... | Jump To: Protocol Violation Form      Continue >>

### Protocol Violation Form

**PI:** Michael Miller  
**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB000000063  
**Study State:** Active


Violation #:

1. Report Date:   *The date you became aware of the protocol violation.*

2. Number enrolled at OHSU:   *Over the life of the study.*

3. Number still in treatment:

4. Total number of subjects enrolled:  *Including subjects enrolled at other institutions.*

5. Protocol Violation Date:  

6. Participant Identifier:

7. What type of report is this?

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**

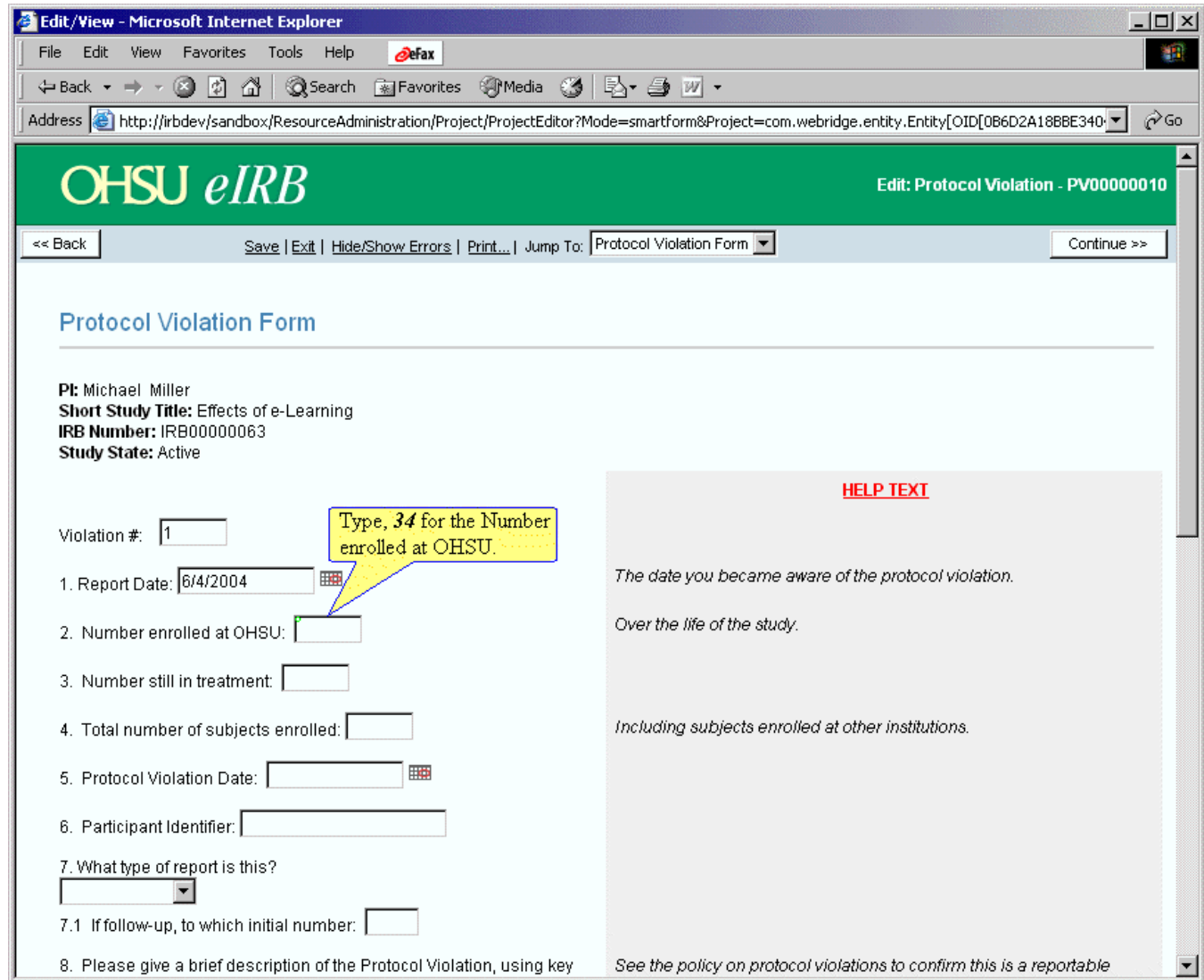
### Notes:

Click in the Number enrolled at OHSU field, or press Tab on the keyboard, to select it.



## Edit/View - Microsoft Internet Explorer

Step 14 - Type "34" in edit box



**OHSU eIRB** Edit: Protocol Violation - PV00000010

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Protocol Violation Form Continue >>

### Protocol Violation Form

**PI:** Michael Miller  
**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB000000063  
**Study State:** Active

Violation #:

1. Report Date:

2. Number enrolled at OHSU:

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?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key

**HELP TEXT**

*The date you became aware of the protocol violation.  
Over the life of the study.  
Including subjects enrolled at other institutions.  
See the policy on protocol violations to confirm this is a reportable*

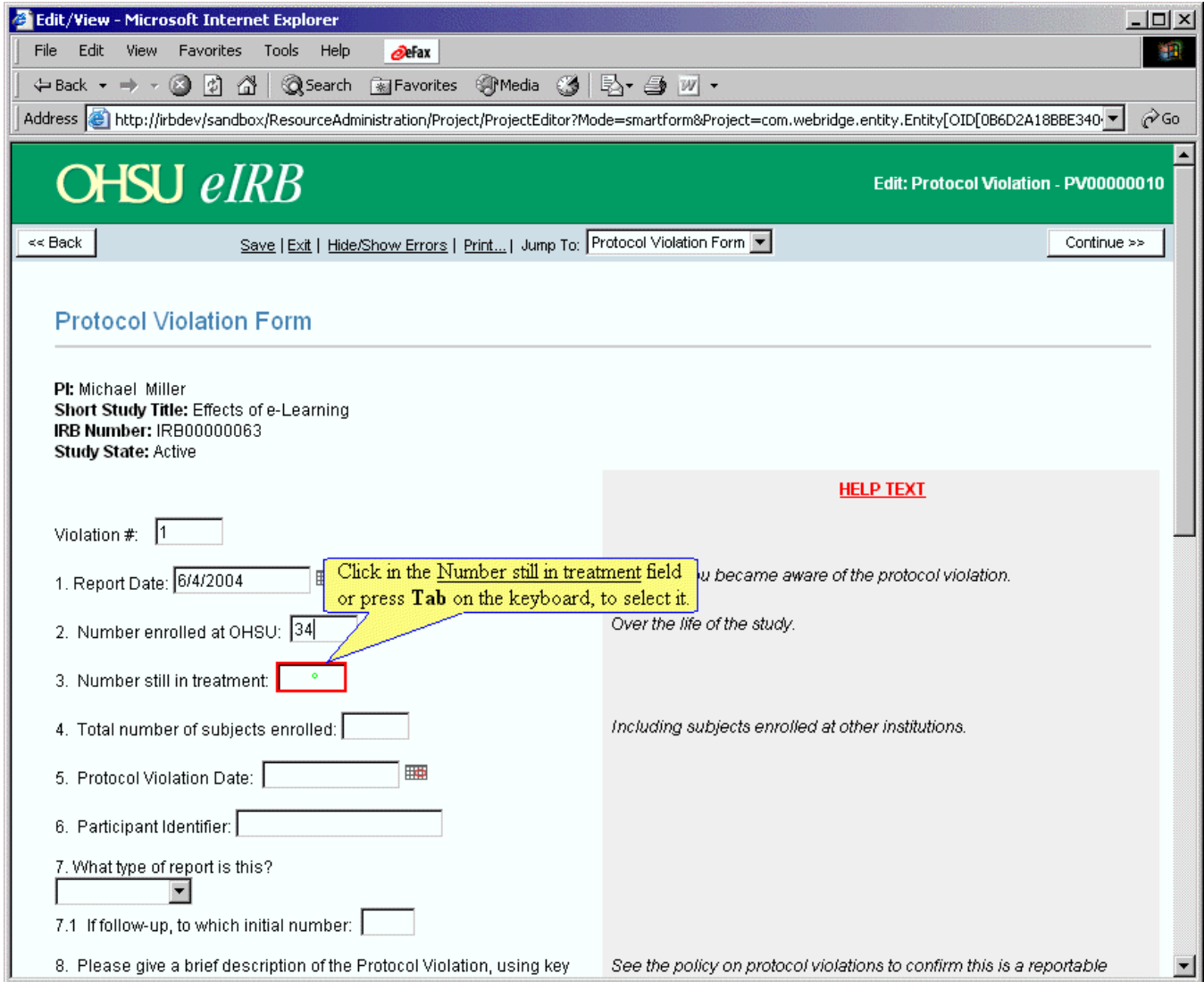
### Notes:

Type, 34 for the Number enrolled at OHSU.



### Edit/View - Microsoft Internet Explorer

Step 15 - Click on

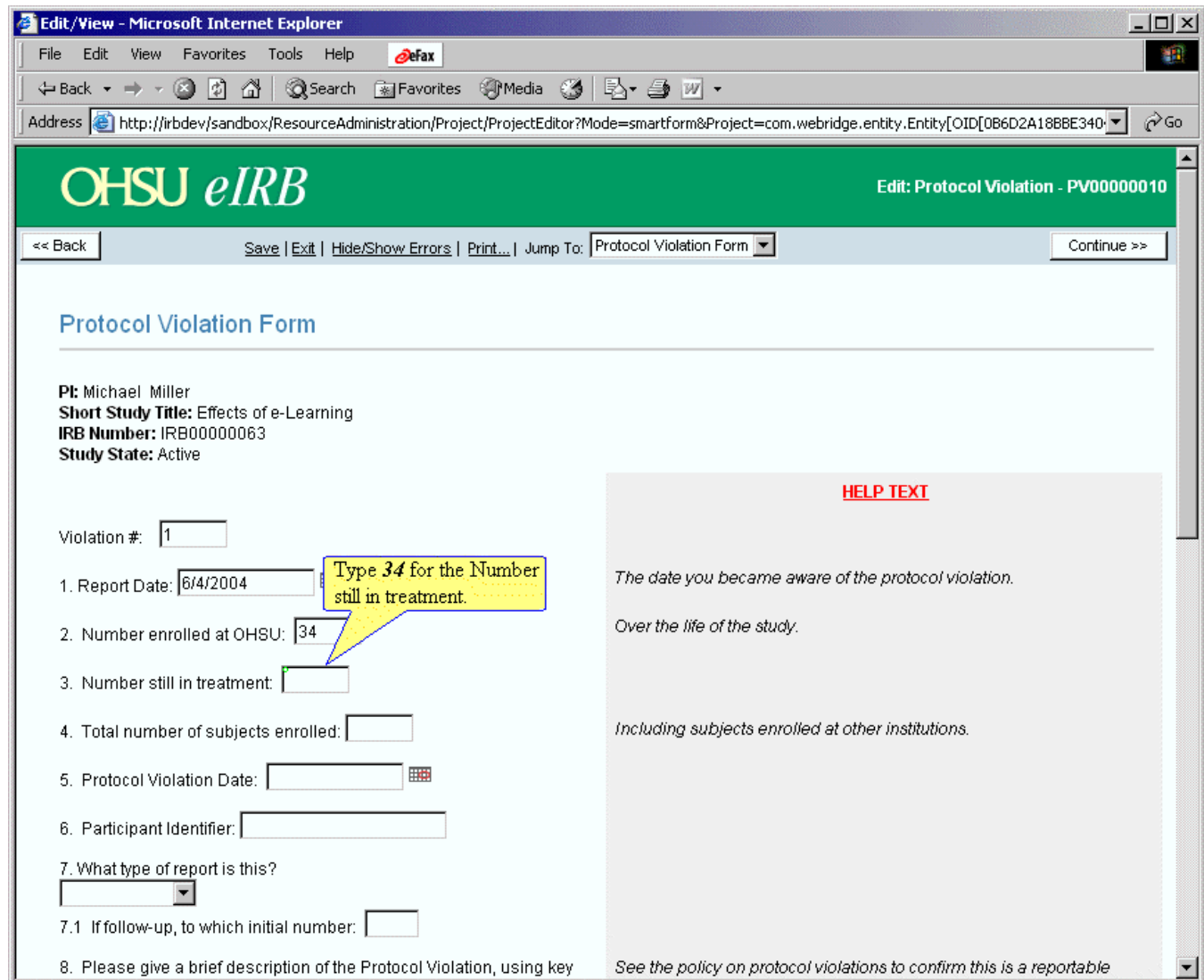


#### Notes:

Click in the Number still in treatment field or press Tab on the keyboard, to select it.

**Edit/View - Microsoft Internet Explorer**

Step 16 - Type "34" in edit box



**OHSU eIRB** Edit: Protocol Violation - PV00000010

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Protocol Violation Form Continue >>

### Protocol Violation Form

**PI:** Michael Miller  
**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB000000063  
**Study State:** Active

Violation #:

1. Report Date:  **Type 34 for the Number still in treatment.**

2. Number enrolled at OHSU:

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?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key

**HELP TEXT**

*The date you became aware of the protocol violation.*

*Over the life of the study.*

*Including subjects enrolled at other institutions.*

*See the policy on protocol violations to confirm this is a reportable*

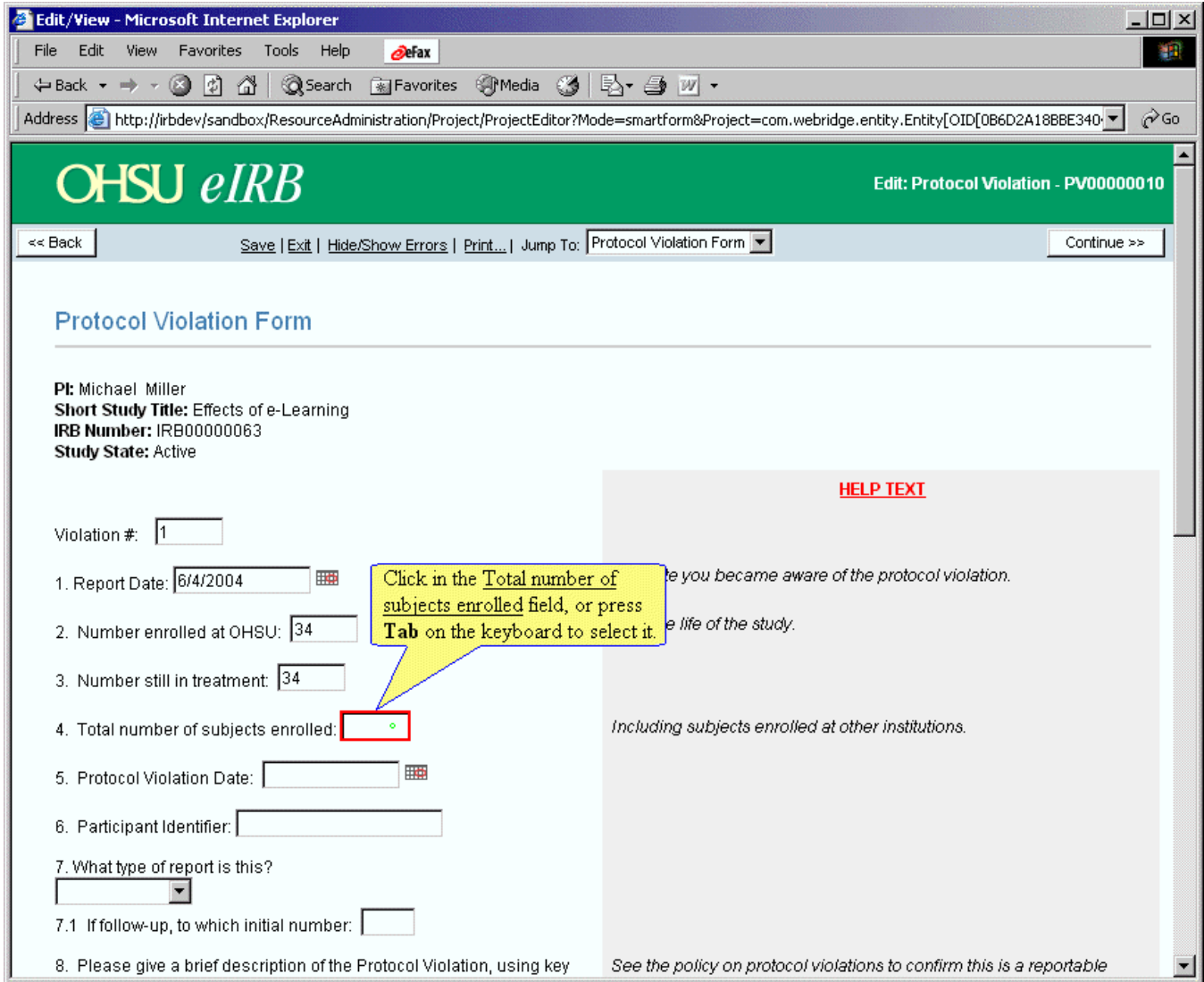
**Notes:**

Type 34 for the Number still in treatment.



**Edit/View - Microsoft Internet Explorer**

Step 17 - Click on

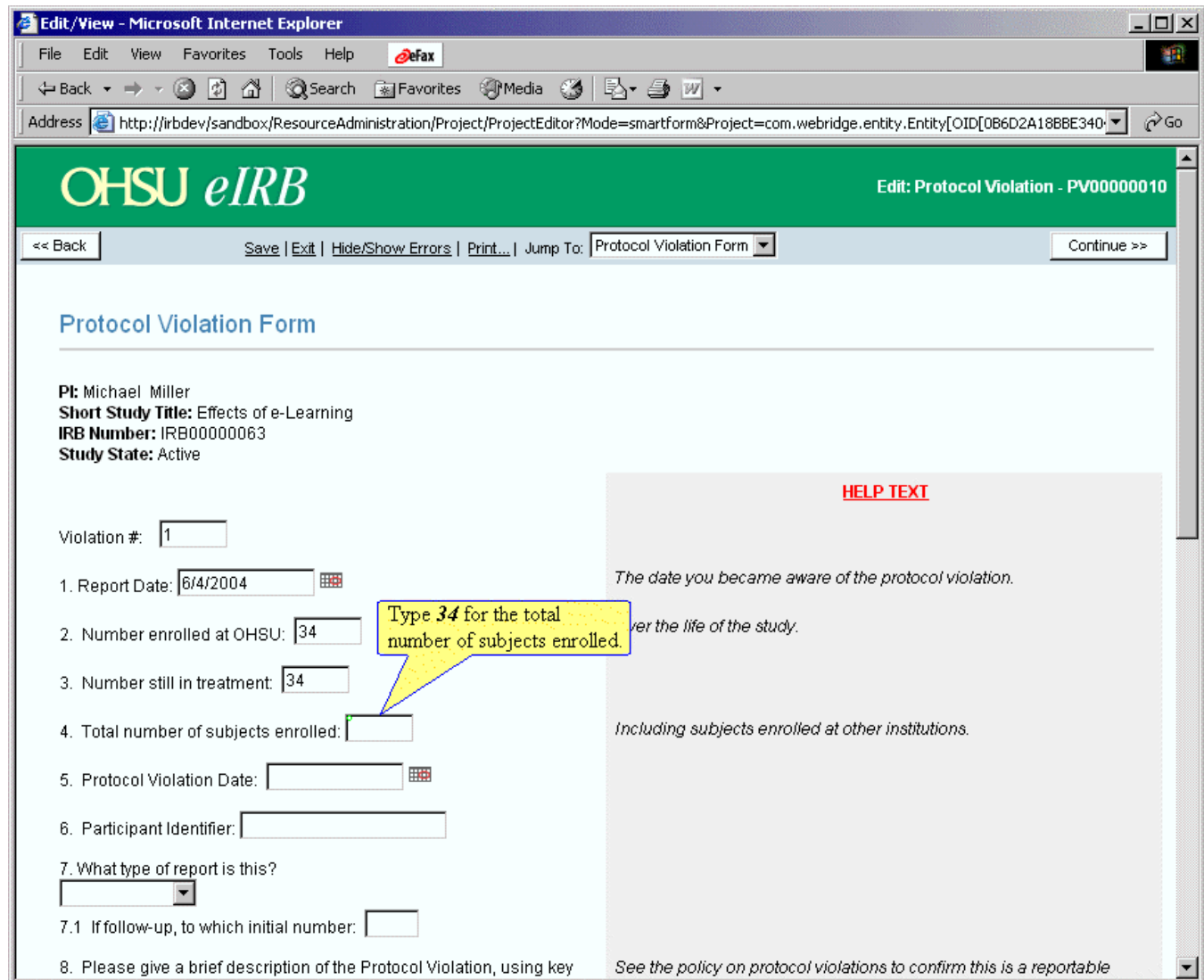


**Notes:**

Click in the Total number of subjects enrolled field, or press Tab on the keyboard to select it.

**Edit/View - Microsoft Internet Explorer**

Step 18 - Type "34" in edit box



**OHSU eIRB** Edit: Protocol Violation - PV00000010

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Protocol Violation Form Continue >>

### Protocol Violation Form

**PI:** Michael Miller  
**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB000000063  
**Study State:** Active

Violation #:

1. Report Date:

2. Number enrolled at OHSU:

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?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key

**HELP TEXT**

The date you became aware of the protocol violation.

over the life of the study.

Including subjects enrolled at other institutions.

See the policy on protocol violations to confirm this is a reportable

**Notes:**

Type 34 for the total number of subjects enrolled.




### Edit/View - Microsoft Internet Explorer

Step 19 - Click on 

**Protocol Violation Form**

PI: Michael Miller  
Short Study Title: Effects of e-Learning  
IRB Number: IRB000000063  
Study State: Active


Violation #:

1. Report Date:  

2. Number enrolled at OHSU:

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?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key

**HELP TEXT**

*The date you became aware of the protocol violation.*

*Over the life of the study.*

*Including subjects enrolled at other institutions.*

*See the policy on protocol violations to confirm this is a reportable*

**Notes:**

To enter a protocol violation date, click on the select date button.



**http://irbdev/sandbox/components/ERMComponents/LocalizedCalendar?date=&attr=\_Protocol Violation - Microsoft Internet Explorer**

Step 20 - Click on 

The screenshot shows a Microsoft Internet Explorer window displaying a web application. A calendar modal is open, showing the month of June 2004. A yellow callout box with a red arrow points to the 'June' dropdown menu in the calendar header, with the text 'Click on the month drop-down menu.' The background page is titled 'Edit: Protocol Violation - PV00000010' and contains a form for reporting a protocol violation. The form includes fields for PI (Michael Miller), Short Study Title (Effects of e-Learning), IRB Number (IRB00000063), and Study State (Active). It also has a 'Violation #' field with the value '1' and a list of 8 numbered items for reporting the violation. A 'HELP TEXT' box on the right provides instructions: 'The date you became aware of the protocol violation. Over the life of the study. Including subjects enrolled at other institutions. See the policy on protocol violations to confirm this is a reportable'.

**Notes:**

Click on the month drop-down menu.



Step 21 - Select list box item **May**

The screenshot shows a Microsoft Internet Explorer browser window displaying a web application. A calendar selection dialog is open, showing the month of June 2004. The month is currently set to June, but the 'May' option is selected in the dropdown menu. A yellow callout box with the text 'Select May' points to the 'May' option. The background web page is titled 'Edit: Protocol Violation - PV00000010' and contains a form with the following fields:

- PI: Michael Miller
- Short Study Title: Effects of e-Learning
- IRB Number: IRB00000063
- Study State: Active
- Violation #:
- 1. Report Date:
- 2. Number enrolled at OHSU:
- 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?
- 7.1 If follow-up, to which initial number:
- 8. Please give a brief description of the Protocol Violation, using key

On the right side of the form, there is a section titled 'HELP TEXT' with the following text:

*The date you became aware of the protocol violation.*

*Over the life of the study.*

*Including subjects enrolled at other institutions.*

*See the policy on protocol violations to confirm this is a reportable*

**Notes:**  
Select May.



**http://irbdev/sandbox/components/ERMComponents/LocalizedCalendar?date=&attr=\_Protocol Violation - Microsoft Internet Explorer**

Step 22 - Click on

The screenshot shows a Microsoft Internet Explorer window with a calendar pop-up over a web form. The calendar is for May 2004, and the 19th is highlighted with a red box and a yellow callout that says "Select the 19th." The web form is titled "Edit: Protocol Violation - PV00000010" and contains the following information:

**PI:** Michael Miller  
**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB000000063  
**Study State:** Active

Violation #:

1. Report Date:

2. Number enrolled at OHSU:

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?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key

**HELP TEXT**

*The date you became aware of the protocol violation.*

*Over the life of the study.*

*Including subjects enrolled at other institutions.*

*See the policy on protocol violations to confirm this is a reportable*

**Notes:**  
 Select the 19th.



http://irbdev/sandbox/components/ERMComponents/LocalizedCalendar?date=&attr=\_Protocol Violation - Microsoft Internet Explorer

Step 23 - Click on

The screenshot shows a Microsoft Internet Explorer window displaying a web form titled "Edit: Protocol Violation - PV00000010". A calendar dialog box is open, showing the month of May 2004. The date 19 is highlighted in yellow. Below the calendar, there are "OK" and "Cancel" buttons. A yellow callout box points to the "OK" button with the text "Click OK to confirm your selection." The background form contains the following information:

**PI:** Michael Miller  
**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB00000063  
**Study State:** Active

Violation #:

1. Report Date:

2. Number enrolled at OHSU:

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?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key

**HELP TEXT**

*The date you became aware of the protocol violation.*

*Over the life of the study.*

*Including subjects enrolled at other institutions.*

*See the policy on protocol violations to confirm this is a reportable*

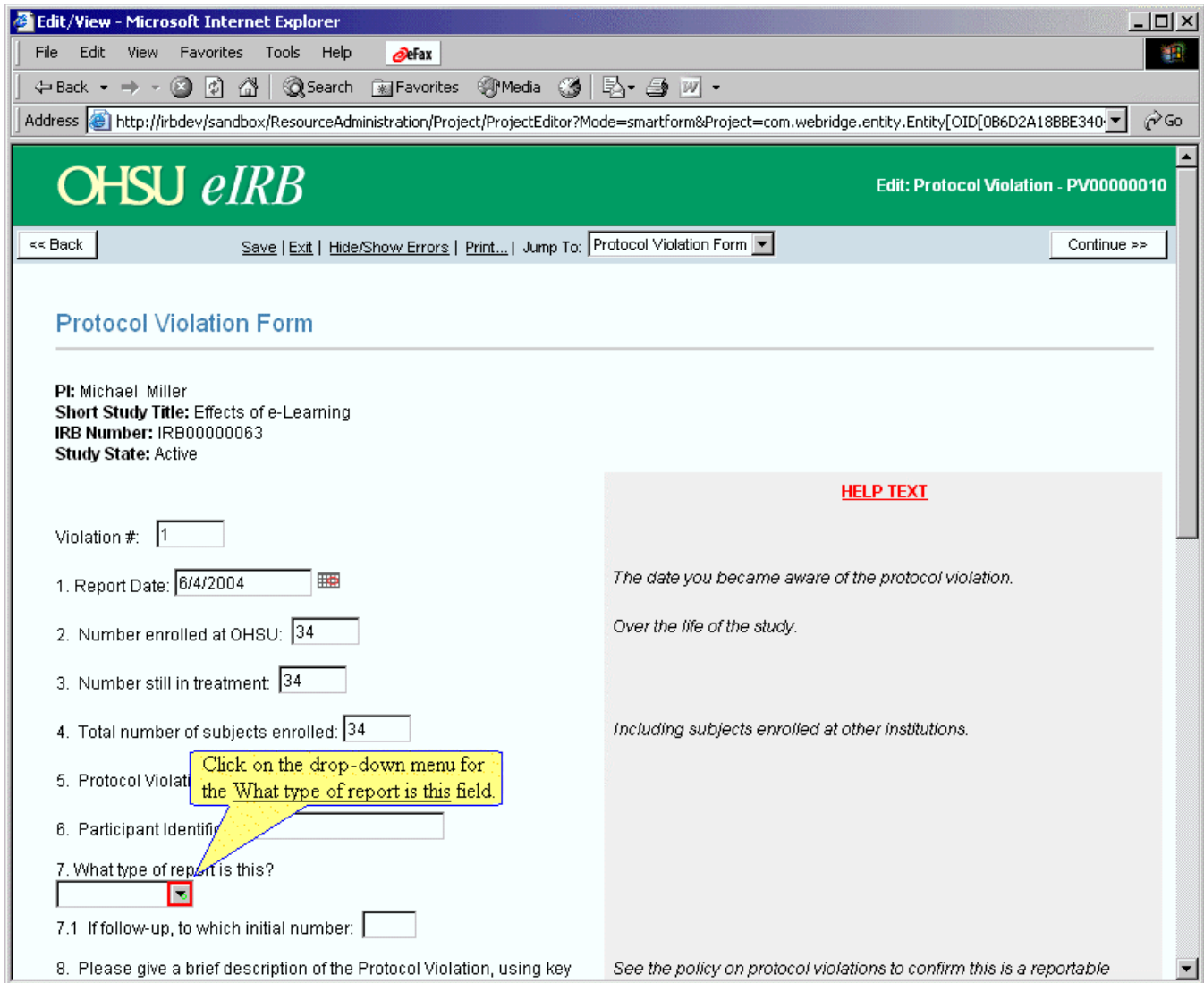
**Notes:**

Click OK to confirm your selection.



## Edit/View - Microsoft Internet Explorer

Step 24 - Click on 



Protocol Violation Form

PI: Michael Miller  
**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB00000063  
**Study State:** Active

Violation #:

1. Report Date:

2. Number enrolled at OHSU:

3. Number still in treatment:

4. Total number of subjects enrolled:

5. Protocol Violation:

6. Participant Identification:

7. What type of report is this?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key words:

**HELP TEXT**

*The date you became aware of the protocol violation.*

*Over the life of the study.*

*Including subjects enrolled at other institutions.*

*See the policy on protocol violations to confirm this is a reportable*

### Notes:

Click on the drop-down menu for the What type of report is this field.



Step 25 - Select list box item **Initial**

**Protocol Violation Form**

**PI:** Michael Miller  
**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB00000063  
**Study State:** Active

Violation #:

1. Report Date:

2. Number enrolled at OHSU:

3. Number still in treatment:

4. Total number of subjects enrolled:

5. Protocol Violation Date:

6. Participant Identifier:

7. What type of violation is this?  
  
 which initial number:   
 Initial  
 Follow-Up

**HELP TEXT**

*The date you became aware of the protocol violation.*

*Over the life of the study.*

*Including subjects enrolled at other institutions.*

*See the policy on protocol violations to confirm this is a reportable*

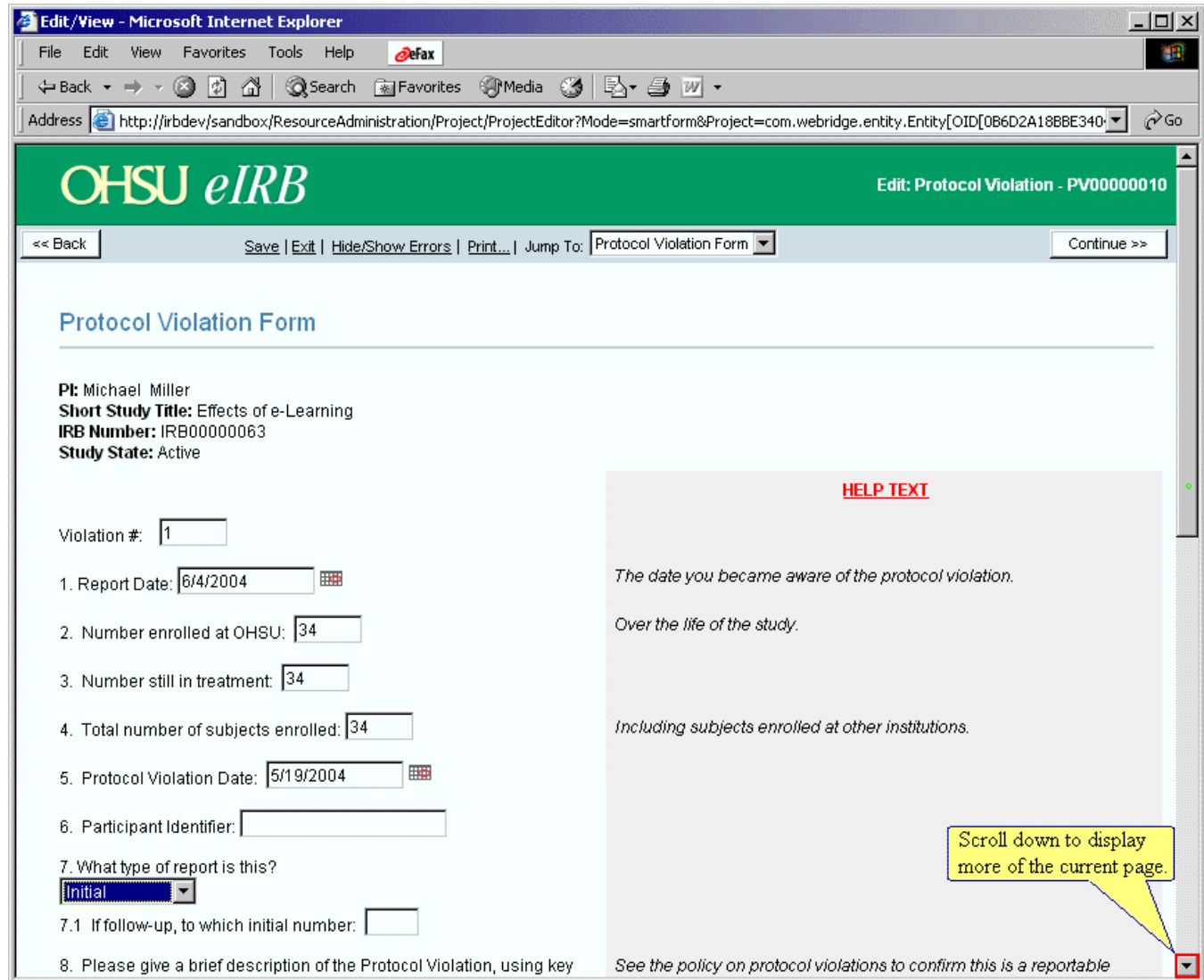
**Notes:**



Select Initial as the report type.



## Edit/View - Microsoft Internet Explorer

Step 26 - Click on 



Edit/View - Microsoft Internet Explorer  
 File Edit View Favorites Tools Help   
 Back Forward Stop Home Search Favorites Media Print W  
 Address  http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity[OID[0B6D2A18BBE340] Go

**OHSU eIRB** Edit: Protocol Violation - PV00000010

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Protocol Violation Form Continue >>

### Protocol Violation Form

**PI:** Michael Miller  
**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB00000063  
**Study State:** Active

Violation #:

1. Report Date:

2. Number enrolled at OHSU:

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?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key

**HELP TEXT**

*The date you became aware of the protocol violation.*

*Over the life of the study.*

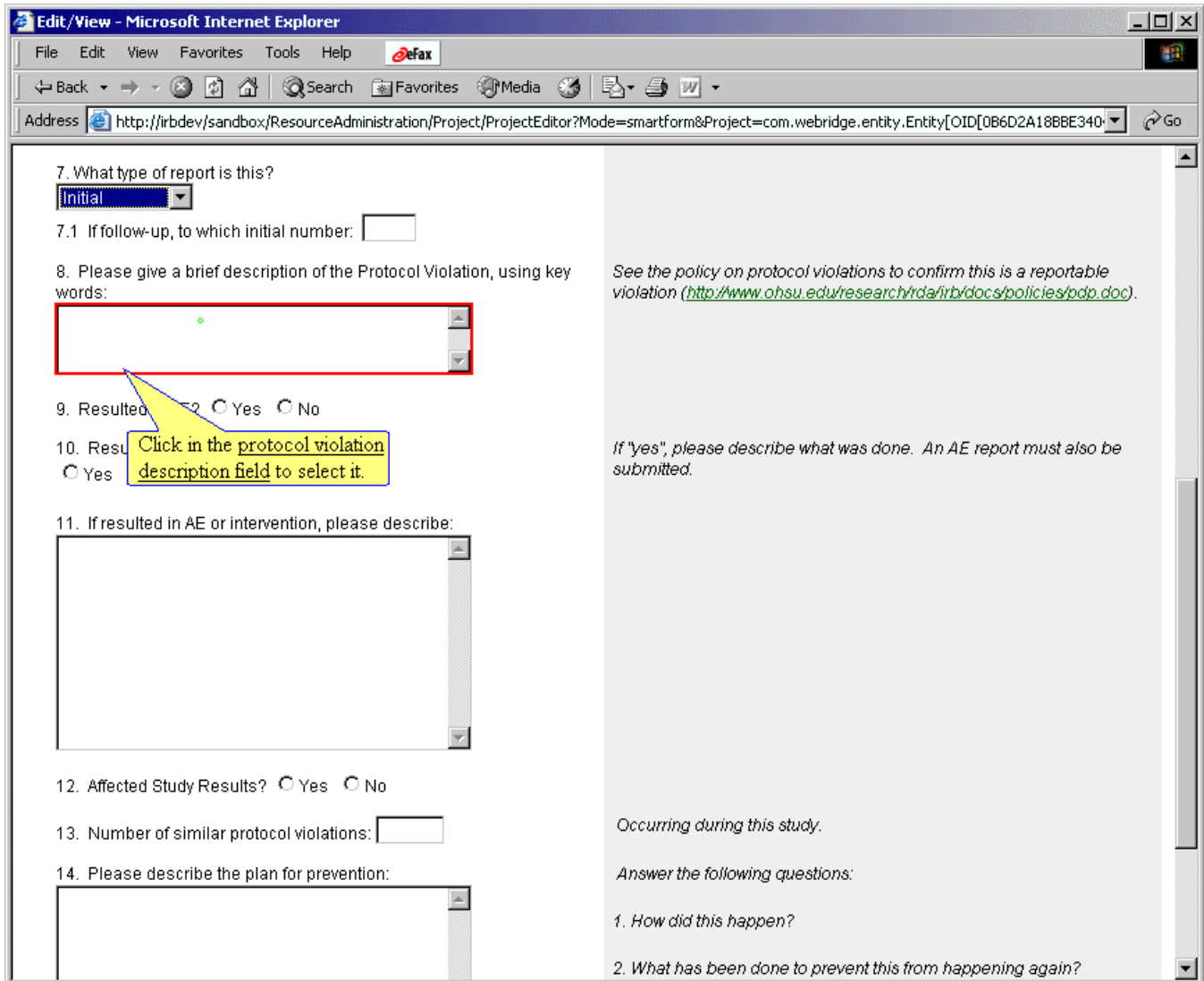

*Including subjects enrolled at other institutions.*

*See the policy on protocol violations to confirm this is a reportable*

Scroll down to display more of the current page.

### Notes:

Scroll down to display more of the current page.

**Edit/View - Microsoft Internet Explorer**Step 27 - Click on 

7. What type of report is this?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key words:

9. Resulted in AE?  Yes  No

10. Resulted in intervention?  Yes  No  
**Click in the protocol violation description field to select it.**

11. If resulted in AE or intervention, please describe:

12. Affected Study Results?  Yes  No

13. Number of similar protocol violations:

14. Please describe the plan for prevention:

*See the policy on protocol violations to confirm this is a reportable violation (<http://www.ohsu.edu/research/irb/docs/policies/pdp.doc>).*

*If "yes", please describe what was done. An AE report must also be submitted.*

*Occurring during this study.*

*Answer the following questions:*

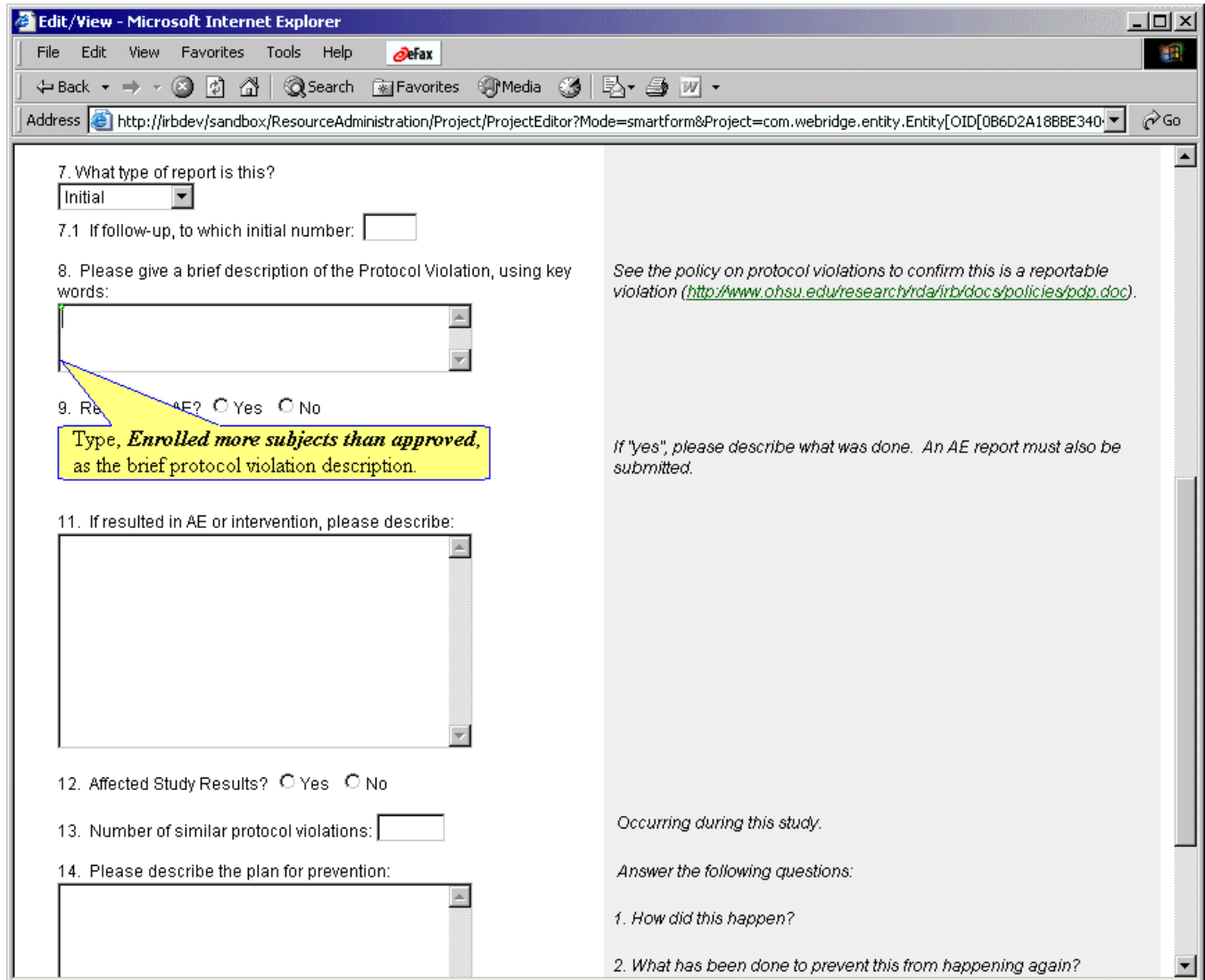
- 1. How did this happen?*
- 2. What has been done to prevent this from happening again?*

**Notes:**

Click in the protocol violation description field to select it.

## Edit/View - Microsoft Internet Explorer

Step 28 - Type "Enrolled more subjects than approved" in edit box



7. What type of report is this?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key words:

9. Resulted in AE?  Yes  No

Type, **Enrolled more subjects than approved**, as the brief protocol violation description.

11. If resulted in AE or intervention, please describe:

12. Affected Study Results?  Yes  No

13. Number of similar protocol violations:

14. Please describe the plan for prevention:

See the policy on protocol violations to confirm this is a reportable violation (<http://www.ohsu.edu/research/vrda/irb/docs/policies/pdp.doc>).

If "yes", please describe what was done. An AE report must also be submitted.

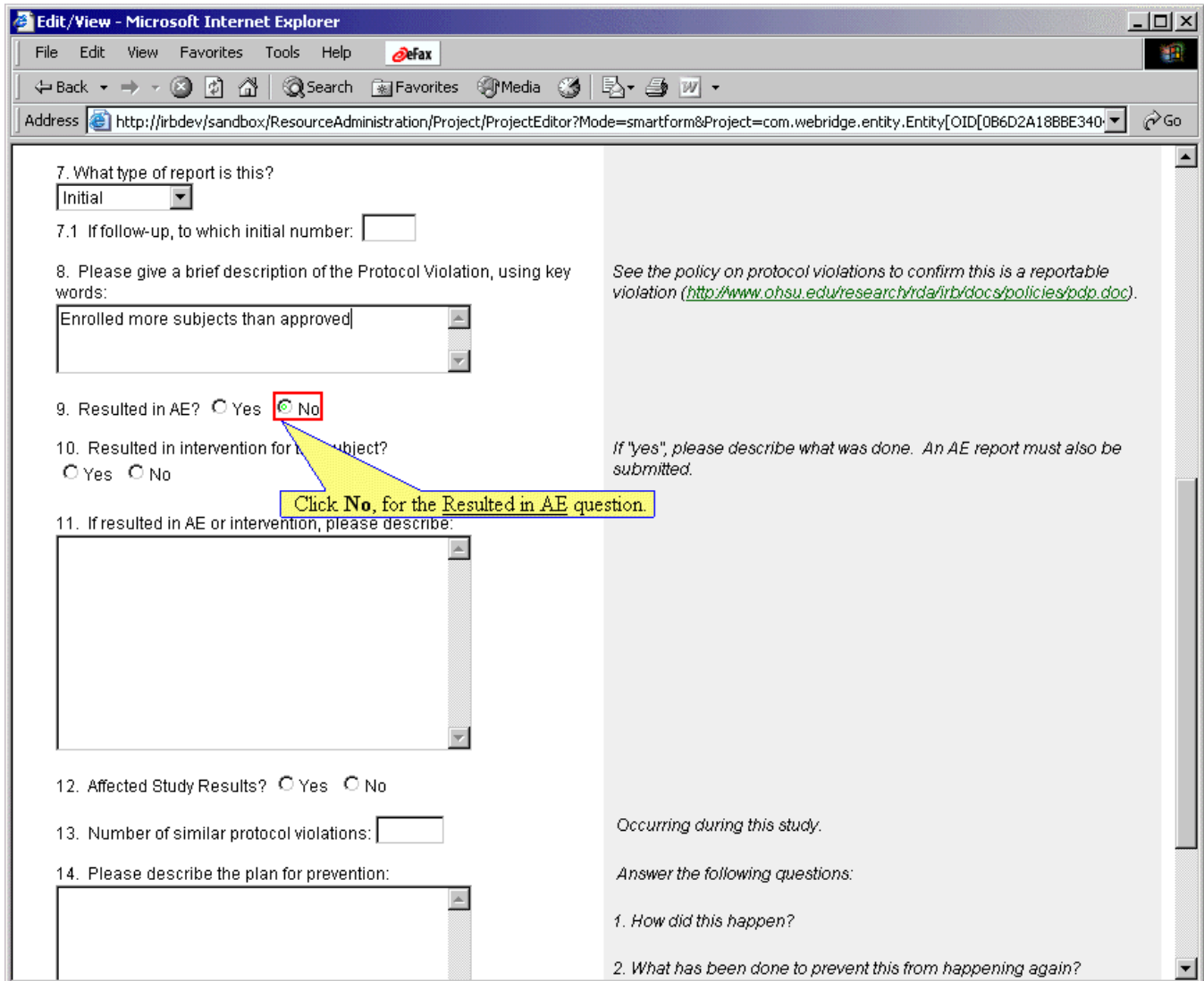
Occurring during this study.

Answer the following questions:

- How did this happen?
- What has been done to prevent this from happening again?

### Notes:

Type, Enrolled more subjects than approved, as the brief protocol violation description.

**Edit/View - Microsoft Internet Explorer**Step 29 - Click on  No

7. What type of report is this?  
Initial

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key words:  
Enrolled more subjects than approved

9. Resulted in AE?  Yes  No

10. Resulted in intervention for this subject?  
 Yes  No

11. If resulted in AE or intervention, please describe:

12. Affected Study Results?  Yes  No

13. Number of similar protocol violations:

14. Please describe the plan for prevention:

See the policy on protocol violations to confirm this is a reportable violation (<http://www.ohsu.edu/research/rda/irb/docs/policies/pdp.doc>).

If "yes", please describe what was done. An AE report must also be submitted.

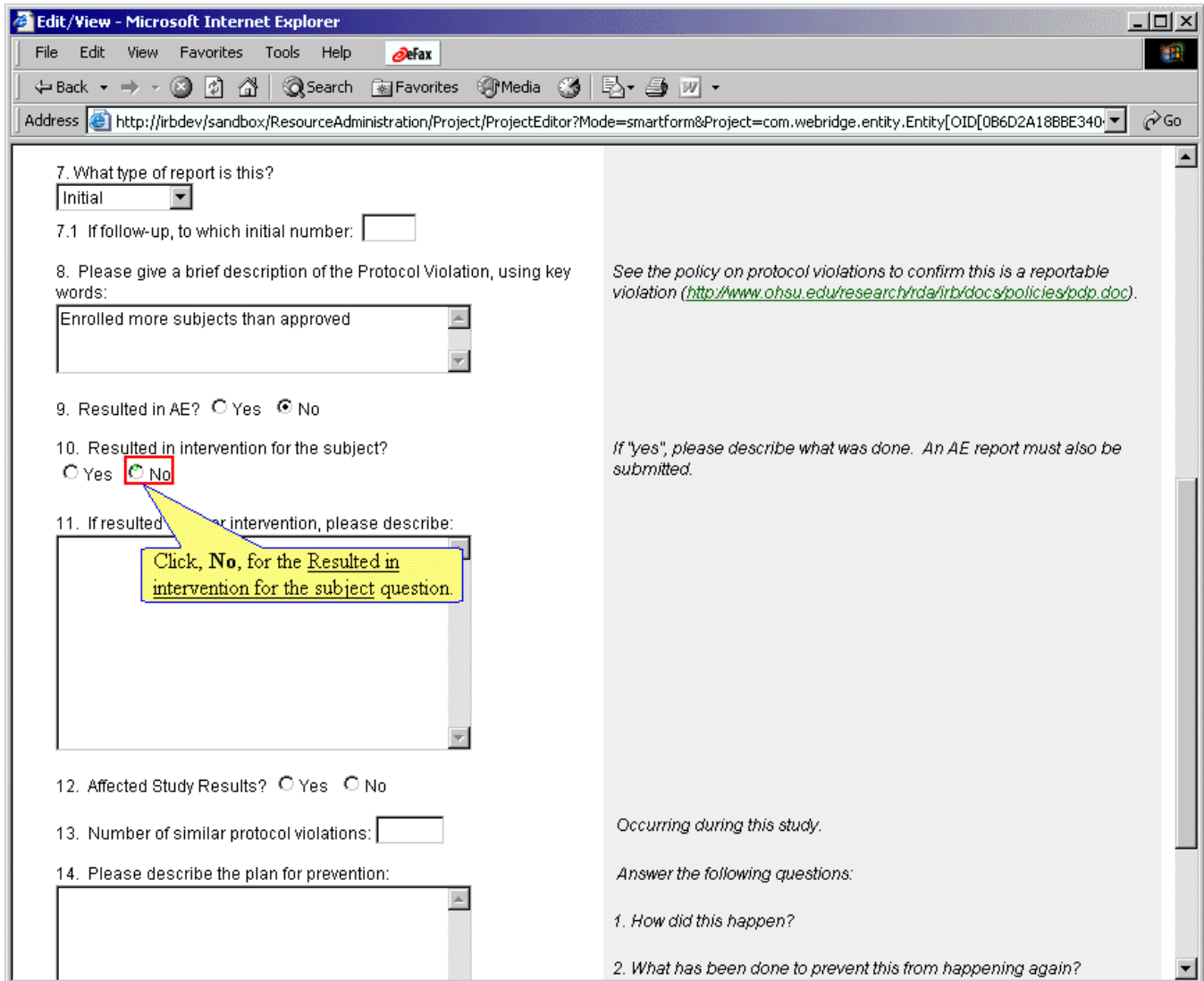
Occurring during this study.

Answer the following questions:

1. How did this happen?
2. What has been done to prevent this from happening again?

**Notes:**

Click No, for the Resulted in AE question.

**Edit/View - Microsoft Internet Explorer**Step 30 - Click on  No

7. What type of report is this?  
Initial

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key words:  
Enrolled more subjects than approved

9. Resulted in AE?  Yes  No

10. Resulted in intervention for the subject?  
 Yes  No

11. If resulted in intervention, please describe:

12. Affected Study Results?  Yes  No

13. Number of similar protocol violations:

14. Please describe the plan for prevention:

See the policy on protocol violations to confirm this is a reportable violation (<http://www.ohsu.edu/research/rda/irb/docs/policies/pdp.doc>).

If "yes", please describe what was done. An AE report must also be submitted.

Occurring during this study.

Answer the following questions:

1. How did this happen?
2. What has been done to prevent this from happening again?

**Click, No, for the Resulted in intervention for the subject question.**

**Notes:**

Click, No, for the Resulted in intervention for the subject question.



### Edit/View - Microsoft Internet Explorer

Step 31 - Click on  No

7. What type of report is this?

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key words:

9. Resulted in AE?  Yes  No

10. Resulted in intervention for the subject?  
 Yes  No

11. If resulted in AE or intervention, please describe:

12. Affected Study Results?  Yes  No

13. Number of similar protocol violations:

14. Please describe the plan for prevention:

*See the policy on protocol violations to confirm this is a reportable violation (<http://www.ohsu.edu/research/rda/irb/docs/policies/pdp.doc>).*

*If "yes", please describe what was done. An AE report must also be submitted.*

*Occurring during this study.*

*Answer the following questions:*

1. How did this happen?
2. What has been done to prevent this from happening again?

**Click, No, for the Affected Study Results question.**

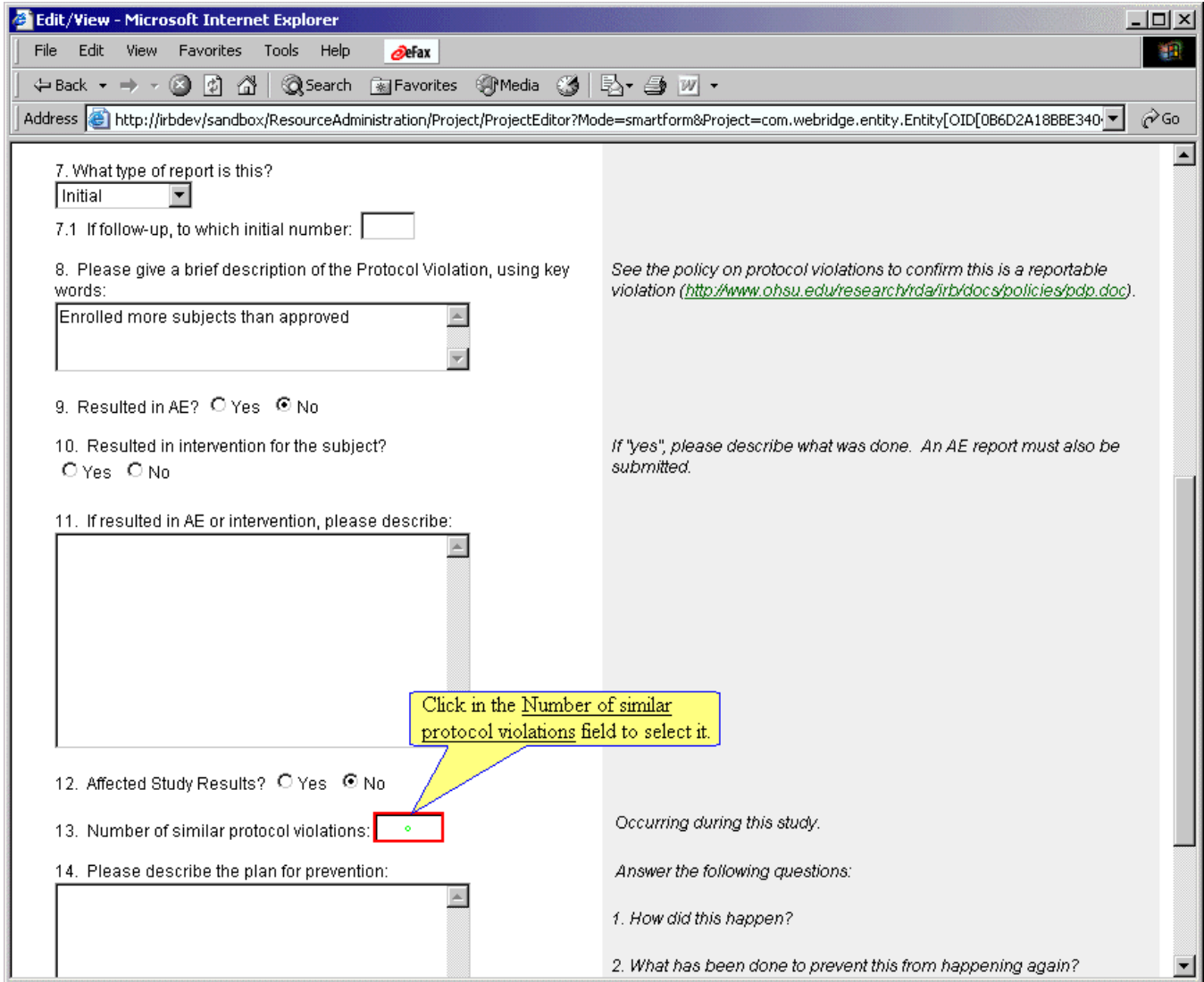
**Notes:**

Click, No, for the Affected Study Results question.



### Edit/View - Microsoft Internet Explorer

Step 32 - Click on

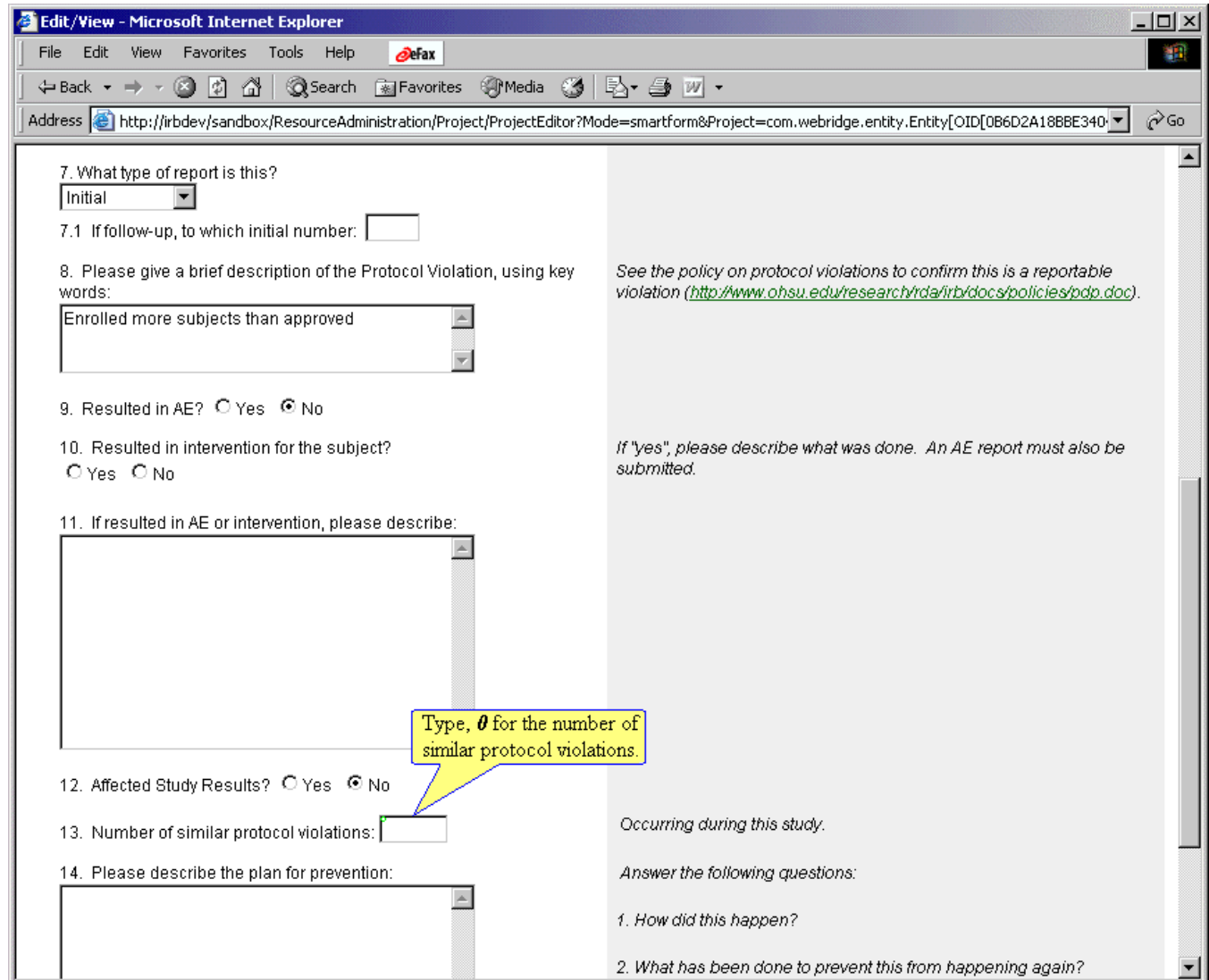


**Notes:**

Click in the Number of similar protocol violations field to select it.

**Edit/View - Microsoft Internet Explorer**

## Step 33 - Type key 0



7. What type of report is this?  
Initial

7.1 If follow-up, to which initial number:

8. Please give a brief description of the Protocol Violation, using key words:  
Enrolled more subjects than approved

9. Resulted in AE?  Yes  No

10. Resulted in intervention for the subject?  
 Yes  No

11. If resulted in AE or intervention, please describe:

12. Affected Study Results?  Yes  No

13. Number of similar protocol violations:

14. Please describe the plan for prevention:

See the policy on protocol violations to confirm this is a reportable violation (<http://www.ohsu.edu/research/irb/docs/policies/pdp.doc>).

If "yes", please describe what was done. An AE report must also be submitted.

Occurring during this study.

Answer the following questions:

1. How did this happen?
2. What has been done to prevent this from happening again?

Type, 0 for the number of similar protocol violations.

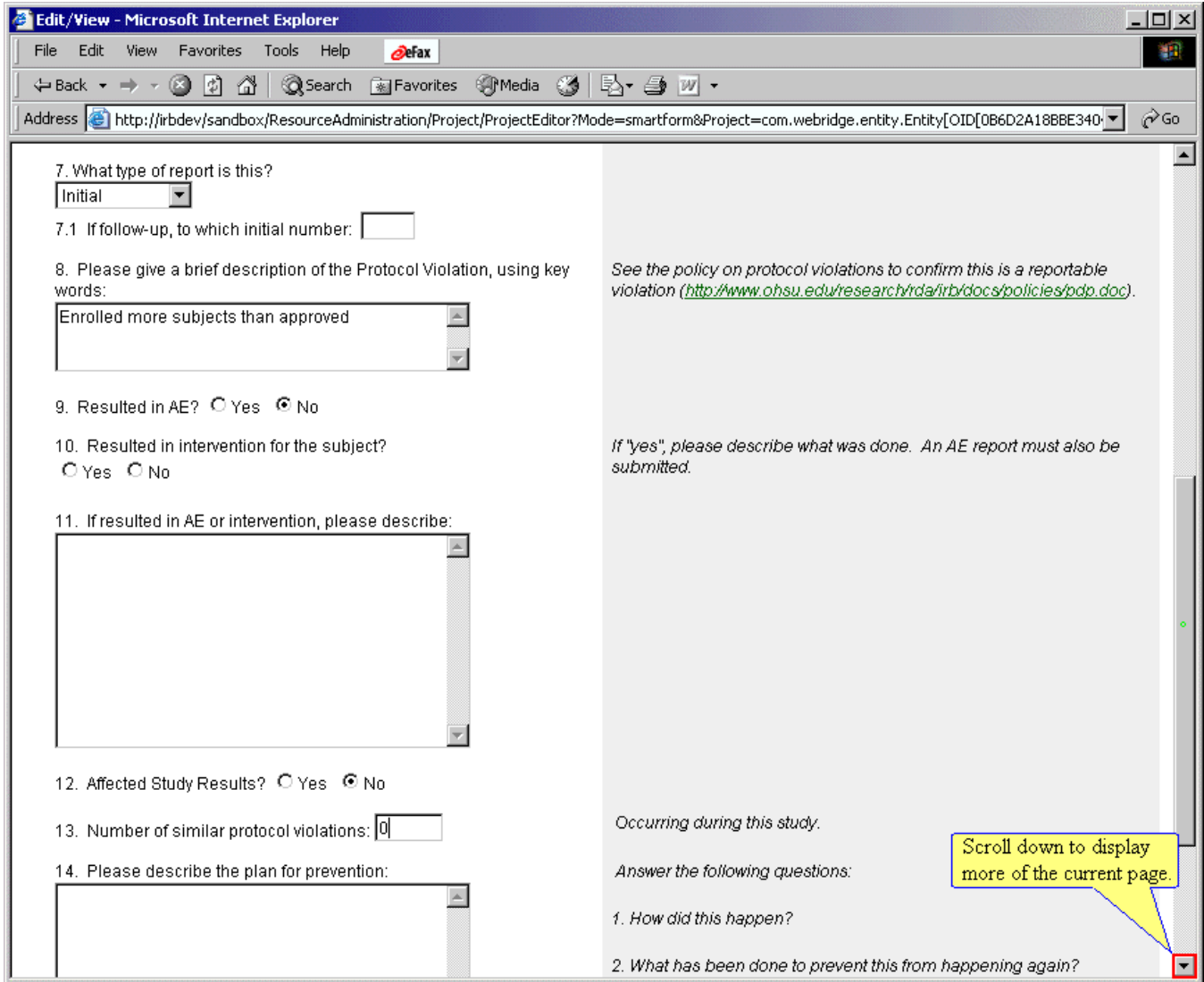
**Notes:**

Type, 0 for the number of similar protocol violations.



### Edit/View - Microsoft Internet Explorer

Step 34 - Click on 



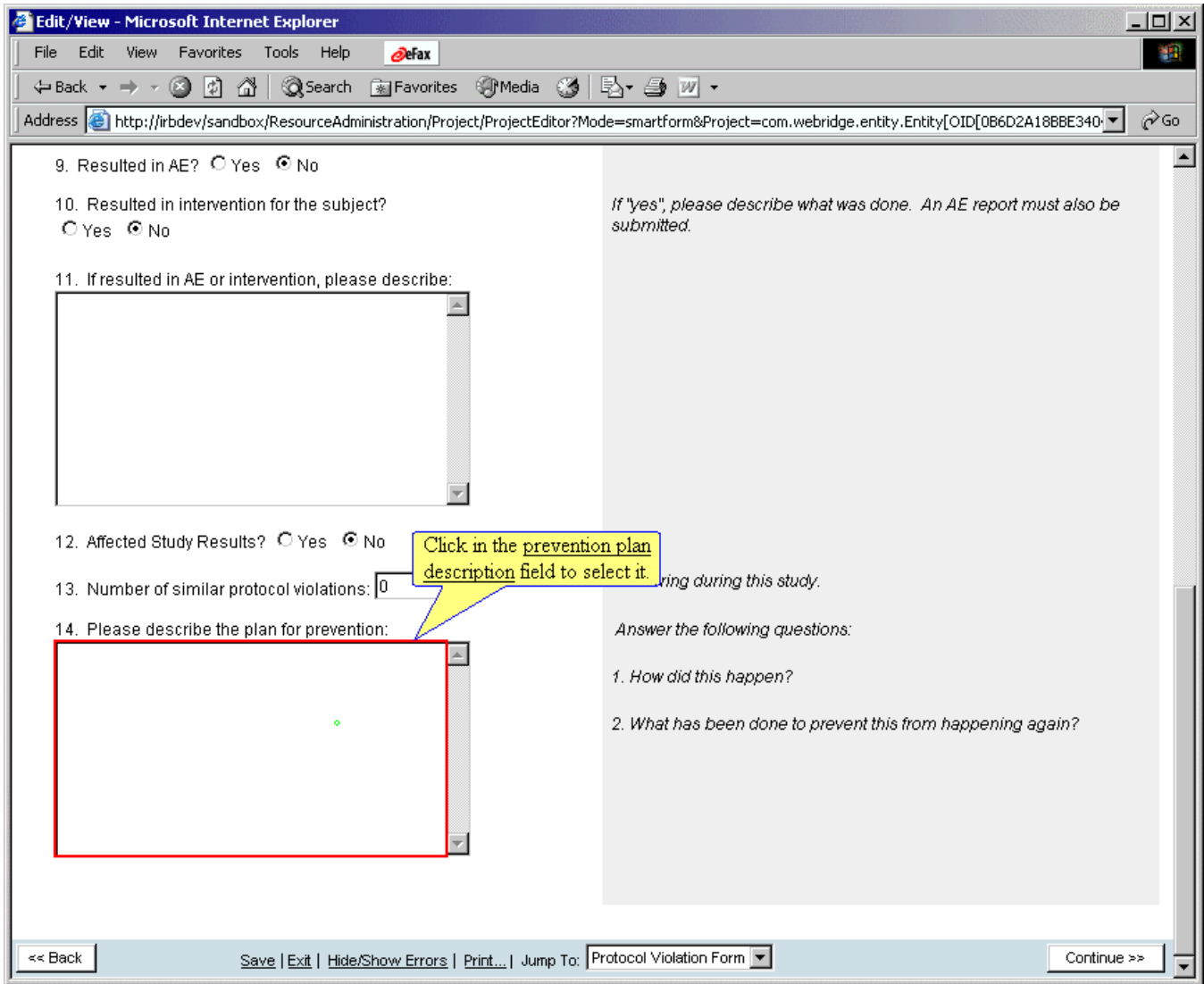
**Notes:**

Scroll down to display more of the current page.



### Edit/View - Microsoft Internet Explorer

Step 35 - Click in the text box for question 14 to select it.



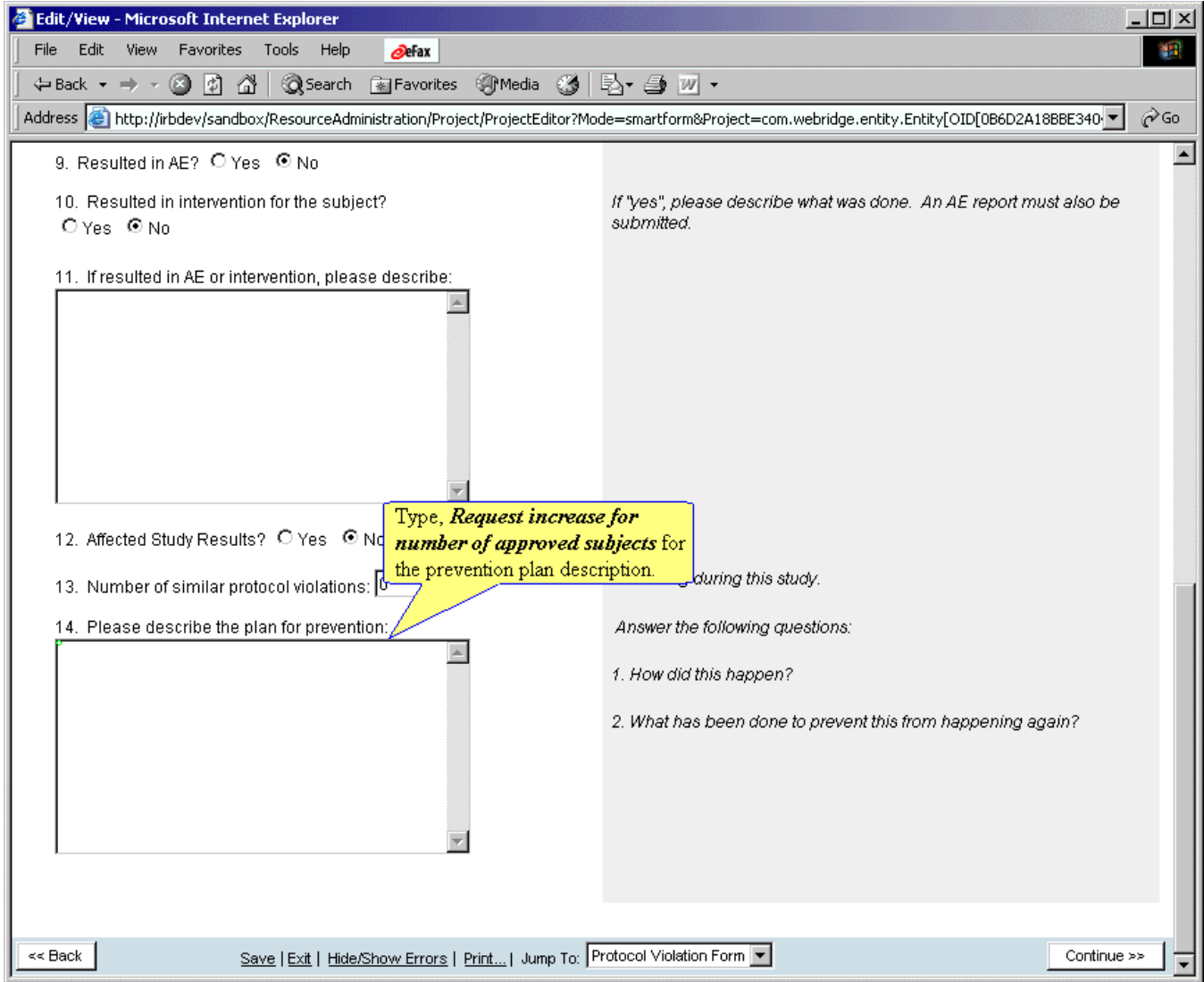
**Notes:**

Click in the prevention plan description field to select it.



### Edit/View - Microsoft Internet Explorer

Step 36 - Type "Request increase for number of approved subjects" in edit box



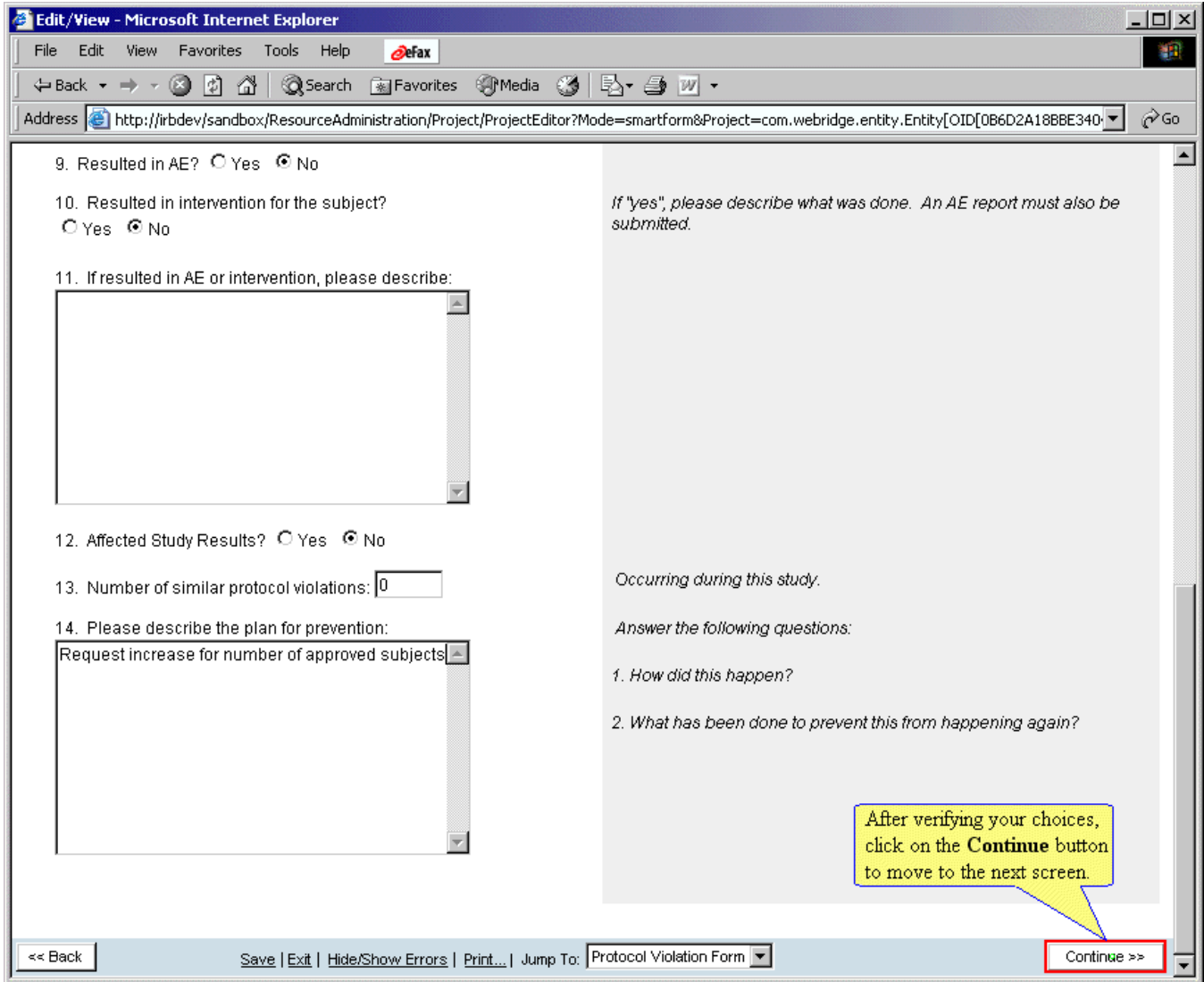
**Notes:**

Type, Request increase for number of approved subjects for the prevention plan description.



### Edit/View - Microsoft Internet Explorer

Step 37 - Click on



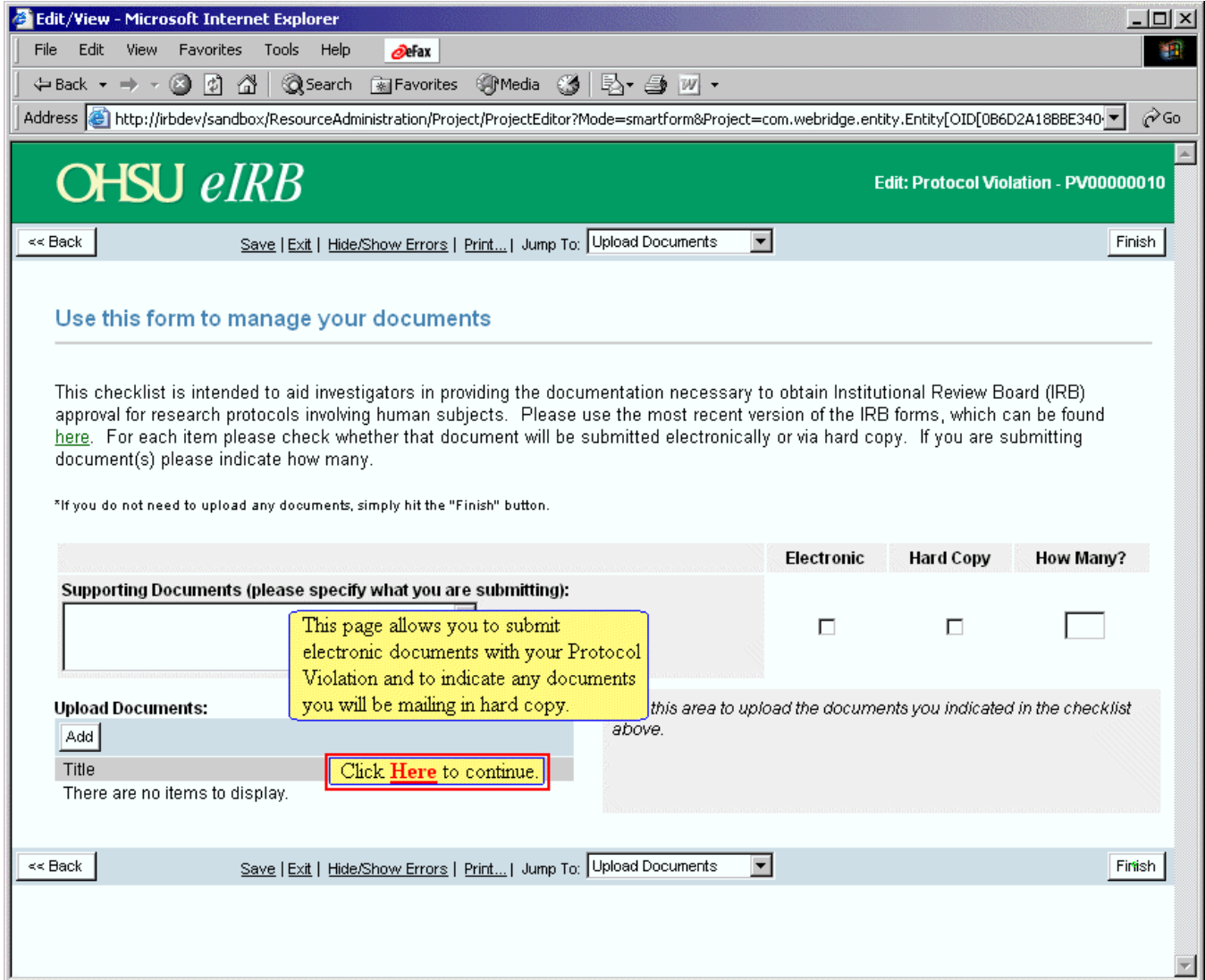
**Notes:**

After verifying your choices, click on the Continue button to move to the next screen.



**Edit/View - Microsoft Internet Explorer**

Step 38 - Use this page to submit associated documents. Click Finish when done.



**Notes:**

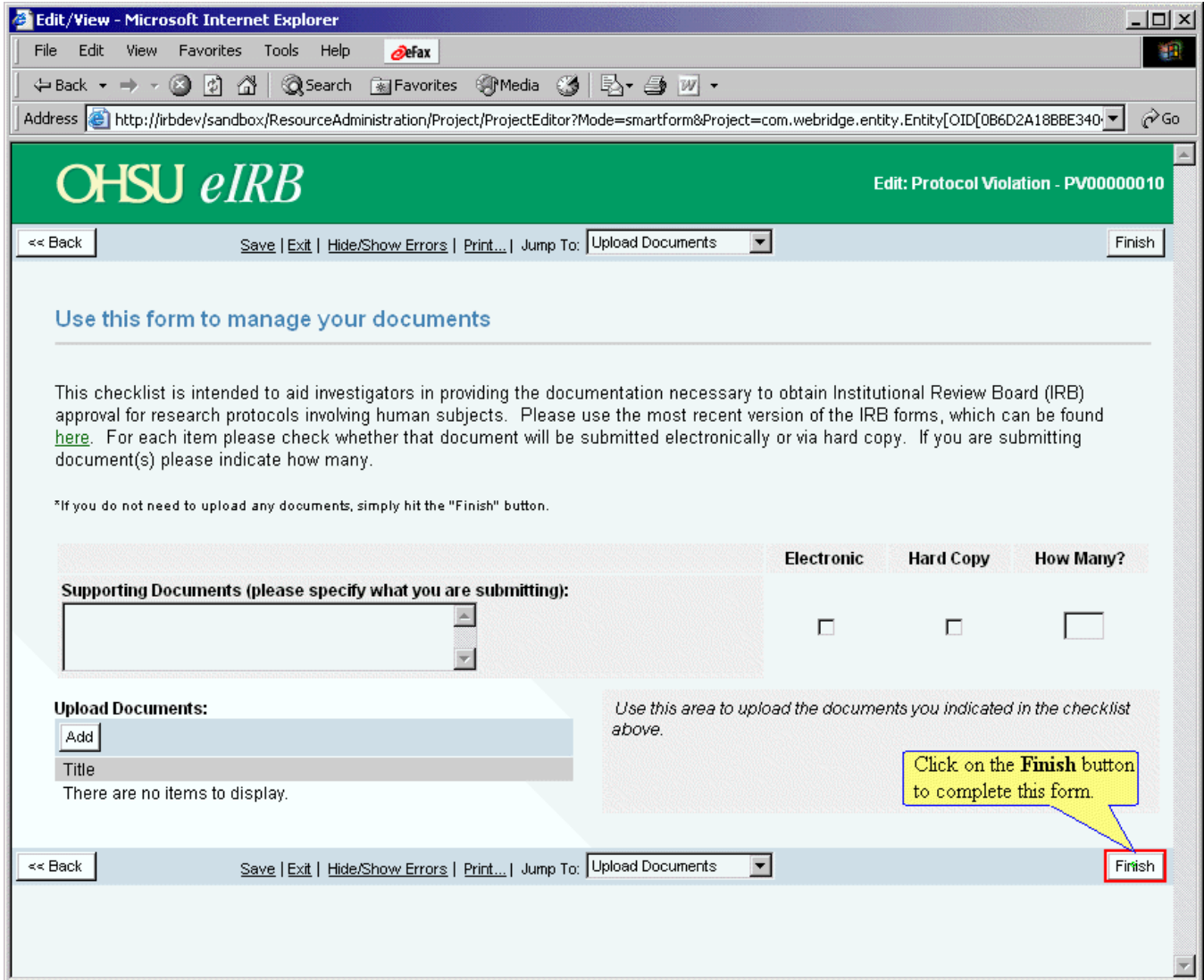
This page allows you to submit electronic documents with your Protocol Violation and to indicate any documents you will be mailing in hard copy.

Click Here to continue.



**Edit/View - Microsoft Internet Explorer**

Step 39 - Click on 



**Notes:**

Click on the Finish button to complete this form.



### Step 40 - End of simulation

The screenshot shows a Microsoft Internet Explorer browser window with the title "Exceeded approved subject number". The address bar contains the URL: [http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge.entity.Entity\[OID\[7CC2E66219B2E948BB9FDE8F7978CBAA\]\]](http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge.entity.Entity[OID[7CC2E66219B2E948BB9FDE8F7978CBAA]]). The page header features the OHSU eIRB logo and the user name "Michael Miller | My Home | Logoff".

The main content area is titled "eIRB Studies" and shows a breadcrumb trail: "Studies > Effects of e-Learning > Exceeded approved subject number".

On the left sidebar, there are several links: "Open Protocol Violation Form...", "Quick Views", "Additional Compliance Approval Status", and "Available Actions" (containing "Submit" and "Withdraw" buttons).

The main content area displays the following information:

- IRB Number:** IRB00000063
- Long Study Title:** Study the effects of e-Learning on research staff. **Review Category:**
- Sponsor:** NIH **Study Status:** Active
- Short Study Title:** Effects of e-Learning **Expiration Date:** 5/21/2005
- Principal Investigator:** Michael Miller **Old IRB #:**
- Board Number:** Board 1 **PV Status:** Researcher Preparation

Below this information, there are tabs for "Protocol Violation History" and "Documents for this PV". A "Project Log" section is also visible at the bottom of the main content area.