



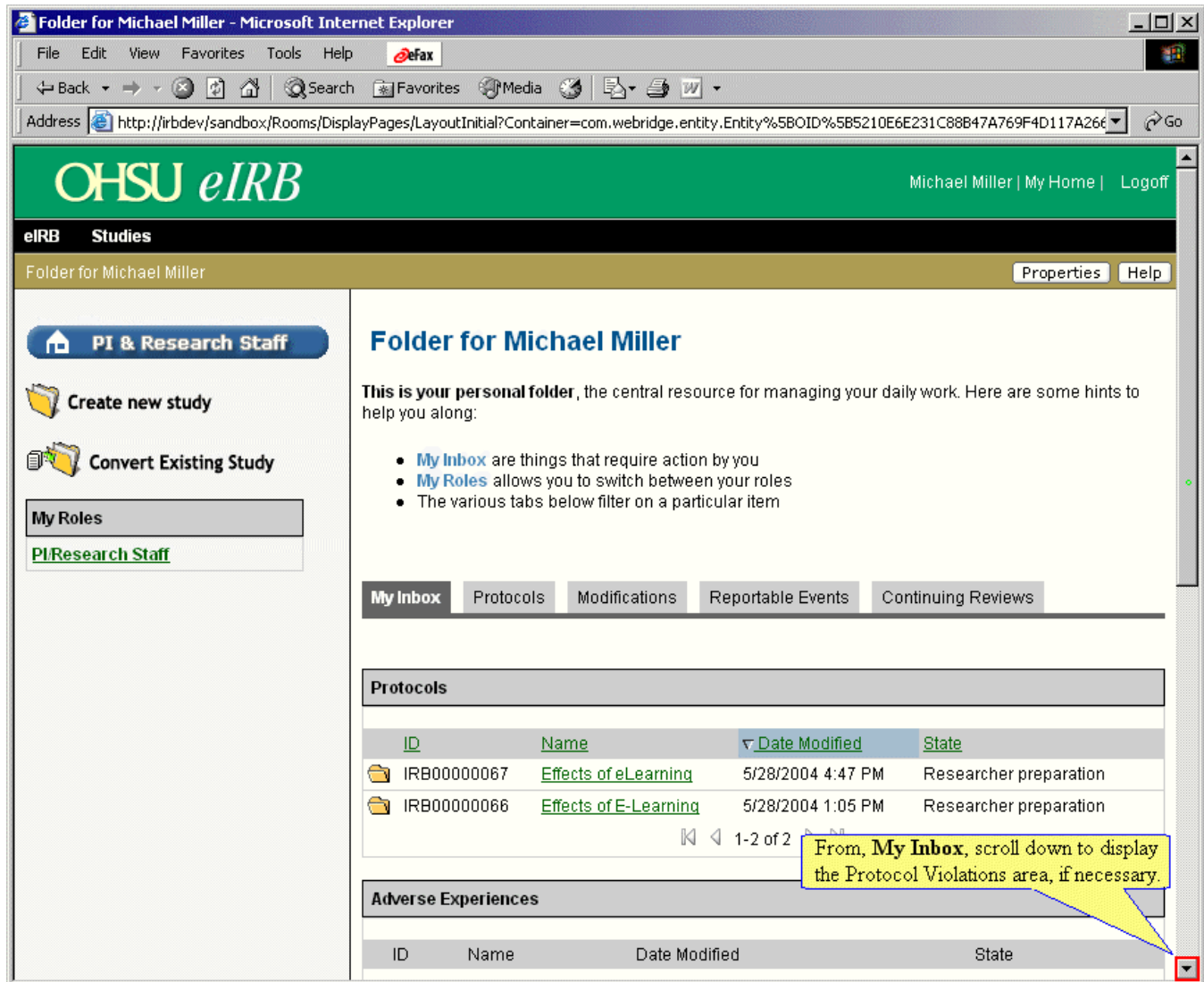
eIRB Submit Protocol Violation

June 30, 2004



Folder for Michael Miller - Microsoft Internet Explorer

Step 1 - Click on 



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

The application interface includes a green header with 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 left sidebar contains navigation options: "PI & Research Staff", "Create new study", "Convert Existing Study", and "My Roles" (with "PIResearch Staff" selected).

The main content area is titled "Folder for Michael Miller" and contains the following text:

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

The "Protocols" section displays a table with the following data:

ID	Name	Date Modified	State
IRB00000067	Effects of eLearning	5/28/2004 4:47 PM	Researcher preparation
IRB00000066	Effects of E-Learning	5/28/2004 1:05 PM	Researcher preparation

Below the Protocols table is the "Adverse Experiences" section, which has a table with columns for ID, Name, Date Modified, and State. A yellow callout box points to a dropdown arrow in the bottom right corner of the Adverse Experiences table, containing the text: "From, My Inbox, scroll down to display the Protocol Violations area, if necessary."

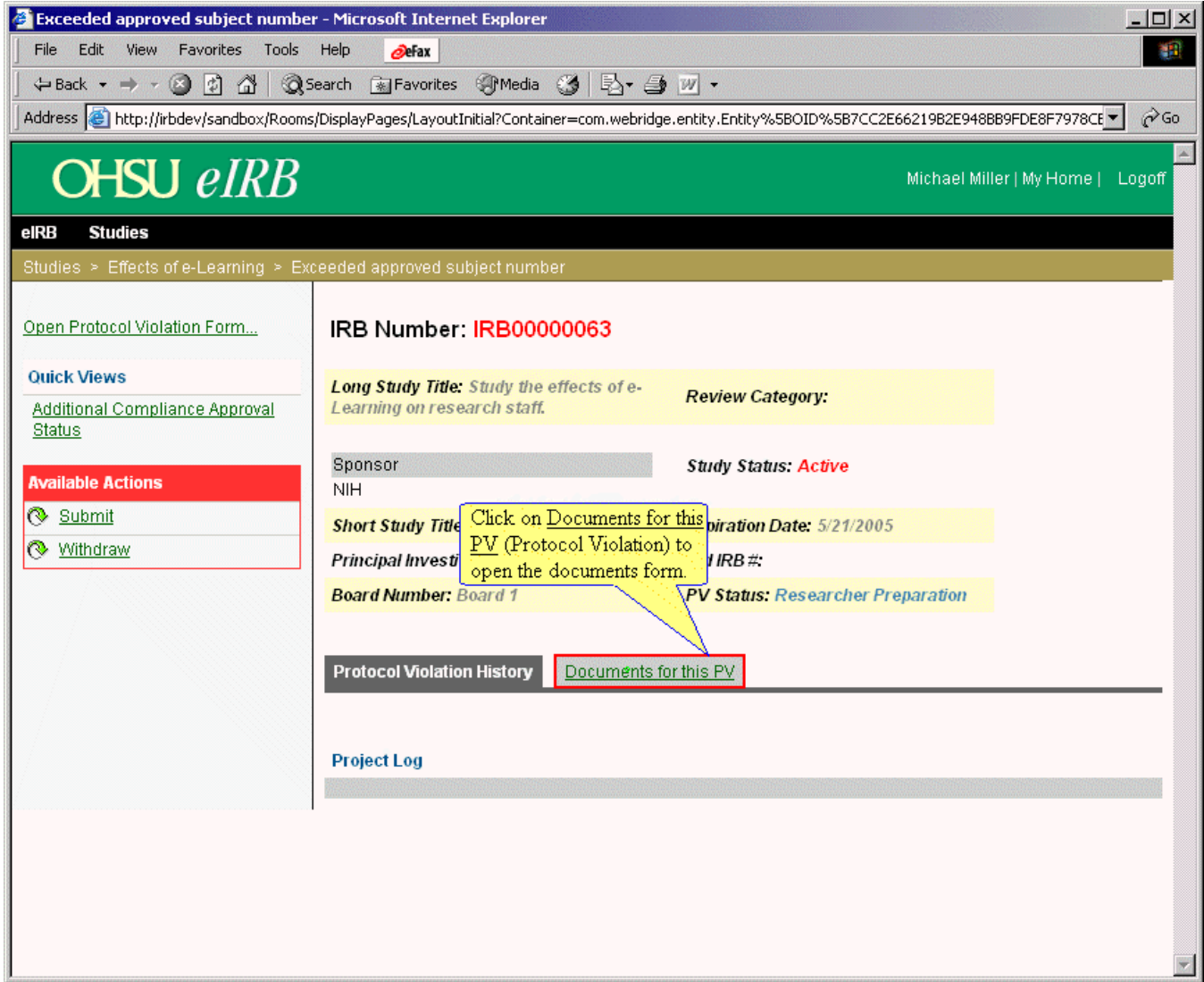
Notes:

From, My Inbox, scroll down to display the Protocol Violations area, if necessary.



Exceeded approved subject number - Microsoft Internet Explorer

Step 3 - Click on [Documents for this PV](#)



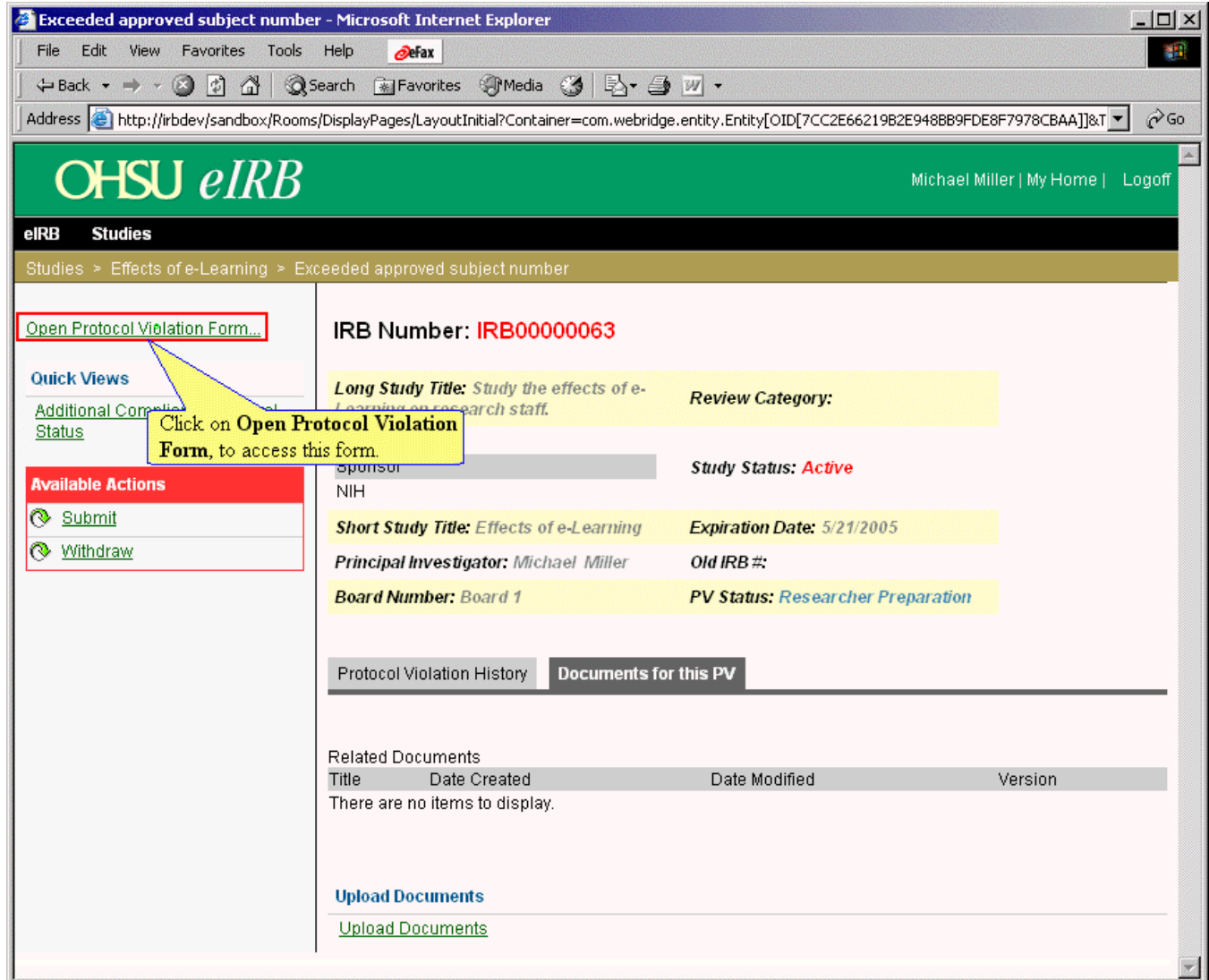
Notes:

Click on Documents for this PV (Protocol Violation) to open the documents form.




Exceeded approved subject number - Microsoft Internet Explorer

Step 4 - Click on [Open Protocol Violation Form...](#)



Exceeded approved subject number - Microsoft Internet Explorer

File Edit View Favorites Tools Help 

Back Forward Stop Home Search Favorites Media Print

Address [http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity\[OID\[7CC2E66219B2E948BB9FDE8F7978CBAA\]\]&T](http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity[OID[7CC2E66219B2E948BB9FDE8F7978CBAA]]&T) Go

OHSU eIRB Michael Miller | My Home | Logoff

eIRB Studies

Studies > Effects of e-Learning > Exceeded approved subject number

[Open Protocol Violation Form...](#)

IRB Number: **IRB0000063**

Long Study Title: Study the effects of e-Learning on research staff. **Review Category:**

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

Study Status: Active

Sponsor: NIH

Available Actions

- [Submit](#)
- [Withdraw](#)

Protocol Violation History **Documents for this PV**

Related Documents

Title	Date Created	Date Modified	Version
There are no items to display.			

Upload Documents

[Upload Documents](#)

Click on **Open Protocol Violation Form**, to access this form.

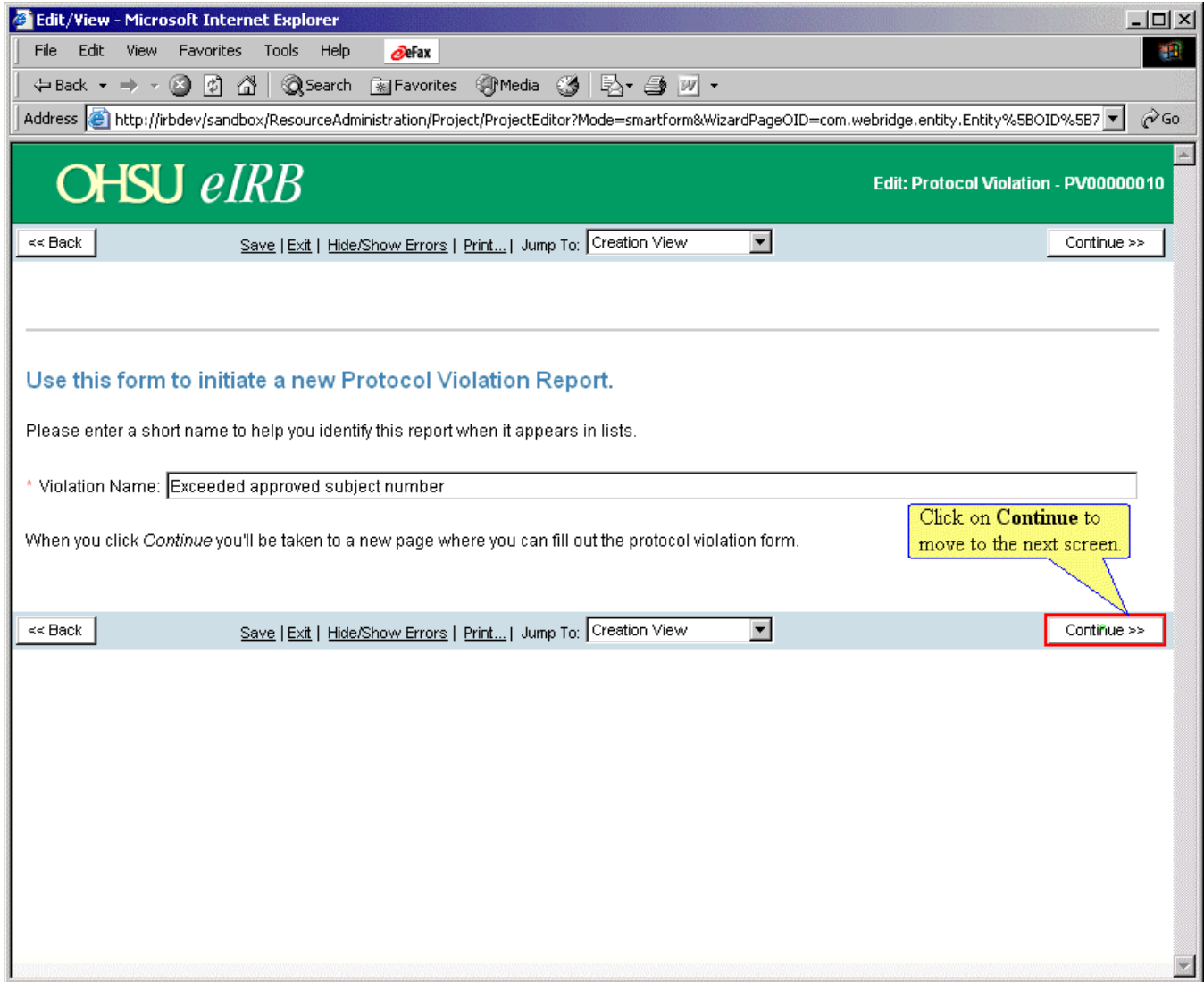
Notes:

Click on Open Protocol Violation Form, to access this form.



Edit/View - Microsoft Internet Explorer

Step 5 - Click on



Notes:

Click on Continue to move to the next screen.



Edit/View - Microsoft Internet Explorer

Step 6 - Click on

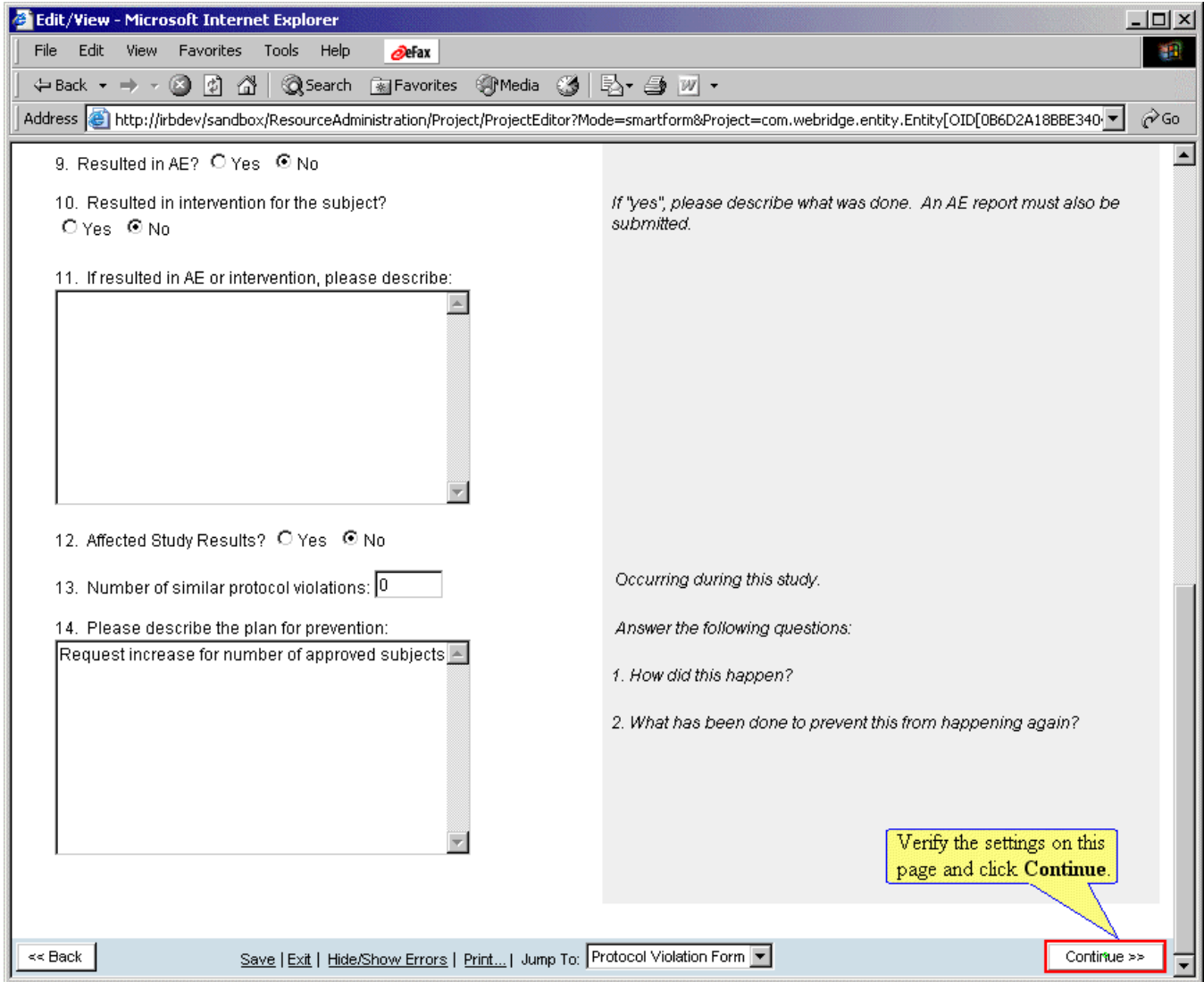
Notes:

Scroll down to display more of the current page.



Edit/View - Microsoft Internet Explorer

Step 7 - Click on 



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:

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?

Verify the settings on this page and click **Continue**.

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

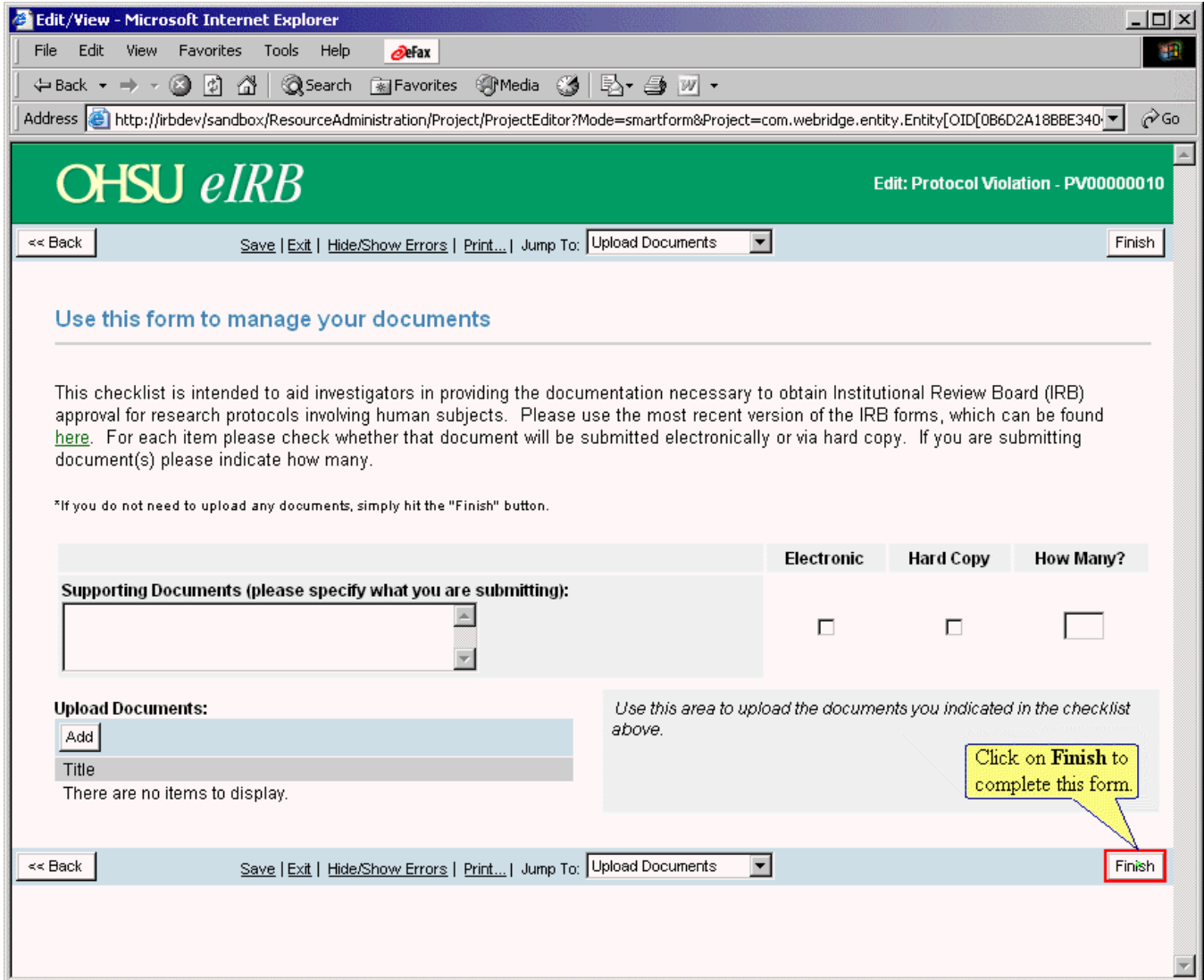
Notes:

Verify the settings on this page and click Continue.



Edit/View - Microsoft Internet Explorer

Step 8 - Click on 




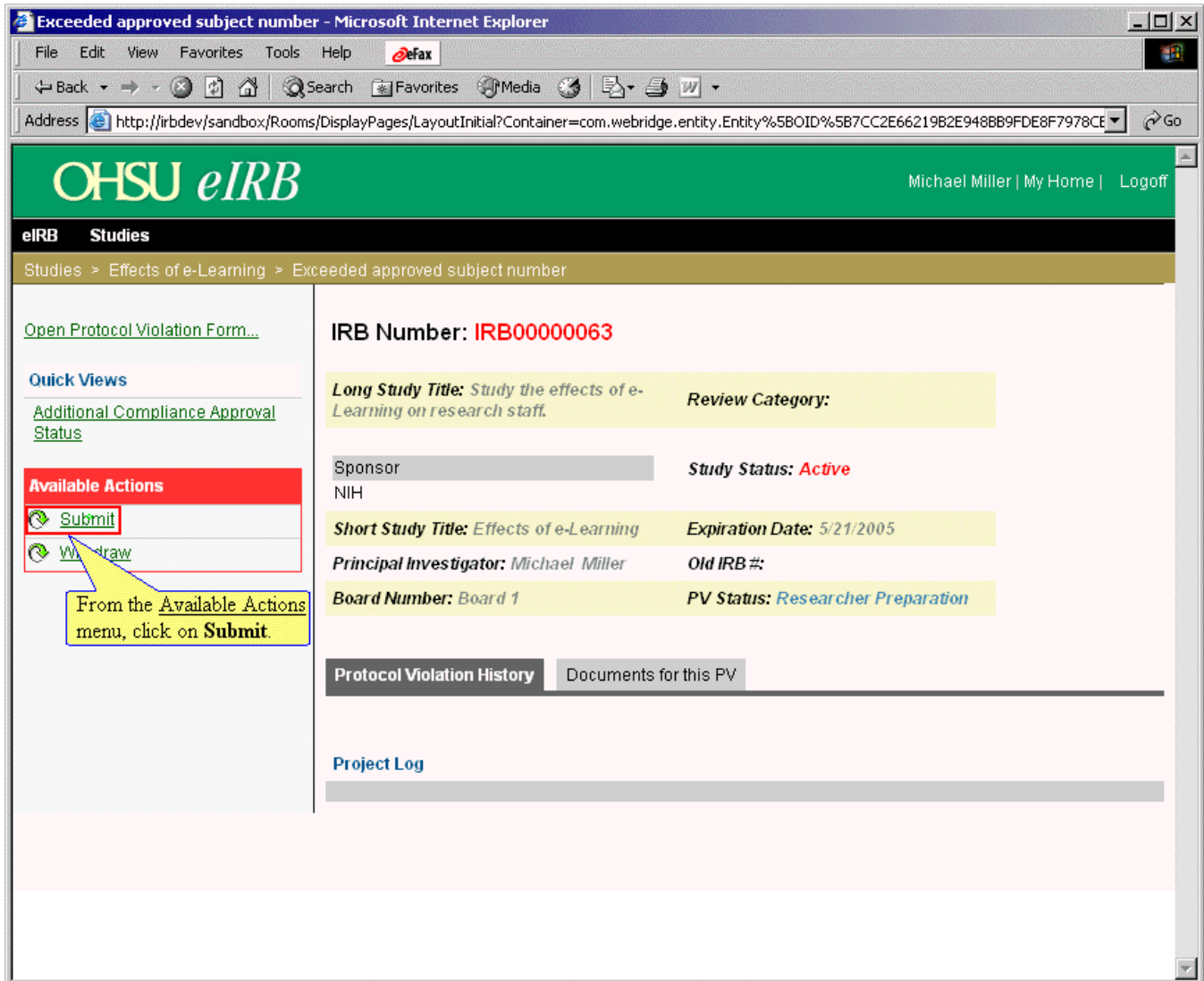
Notes:

Click on Finish to complete this form.



Exceeded approved subject number - Microsoft Internet Explorer

Step 9 - Click on  [Submit](#)



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

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 is a section titled "Available Actions" with a red background. It contains two buttons: "Submit" (highlighted with a red box) and "Withdraw" (with a mouse cursor over it). A yellow callout box points to the "Submit" button with the text: "From the Available Actions menu, click on Submit."

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

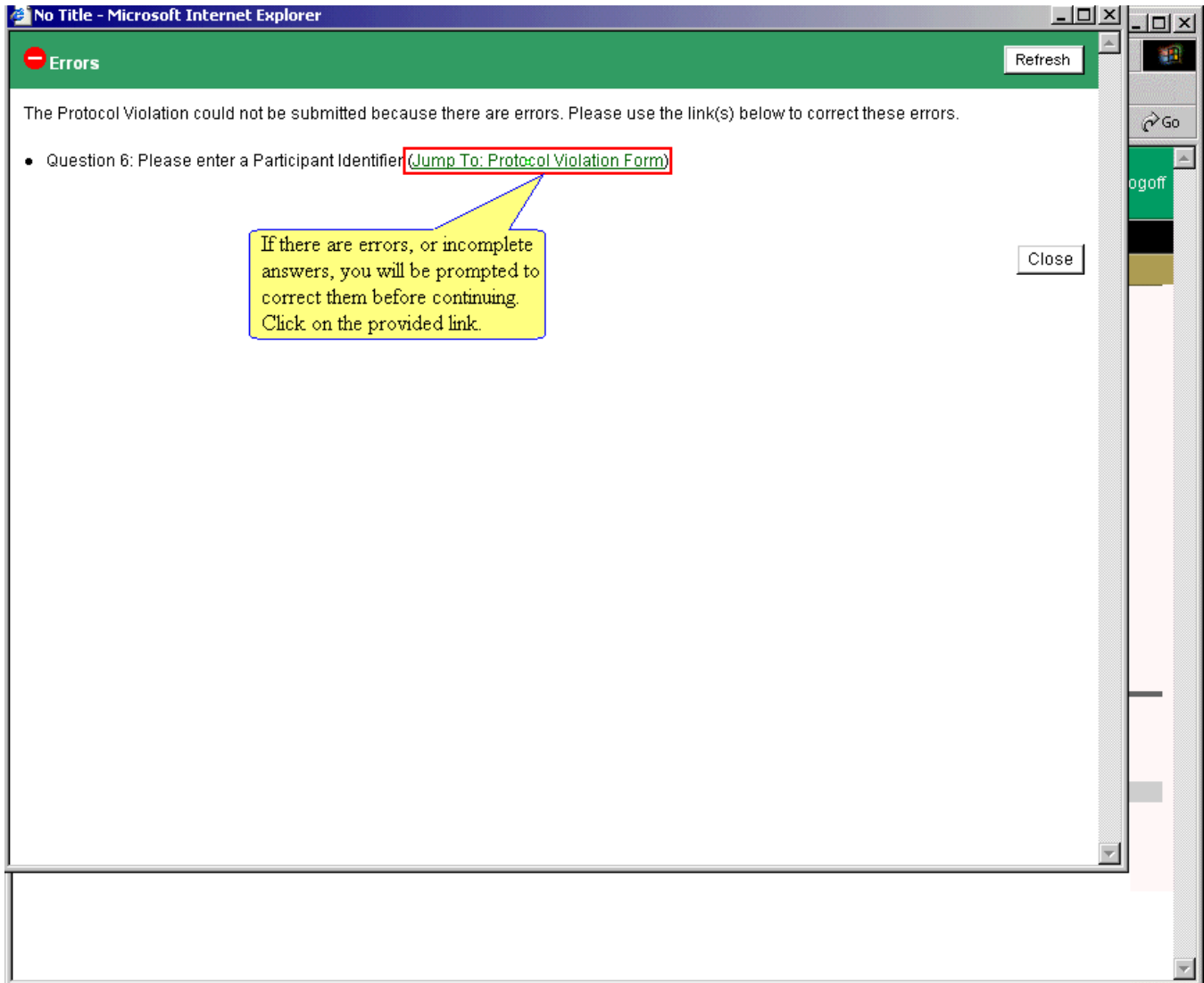
Below this information, there are tabs for "Protocol Violation History" and "Documents for this PV". A "Project Log" section is also visible at the bottom.

Notes:

From the Available Actions menu, click on Submit.

No Title - Microsoft Internet Explorer

Step 10 - Click on [\(Jump To: Protocol Violation Form\)](#)

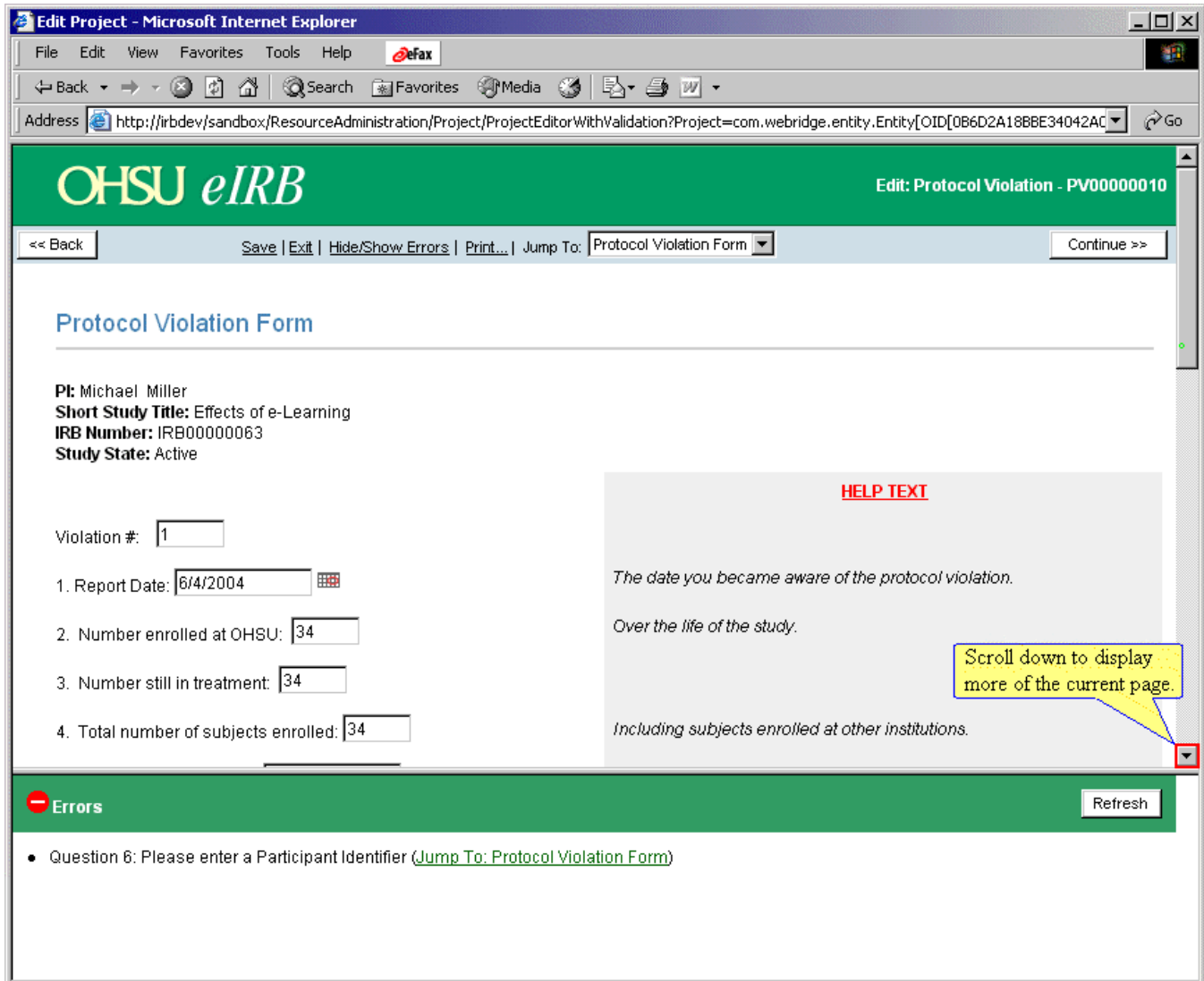
**Notes:**

If there are errors, or incomplete answers, you will be prompted to correct them before continuing. Click on the provided link.



Edit Project - Microsoft Internet Explorer

Step 11 - Click on 



Edit Project - Microsoft Internet Explorer

File Edit View Favorites Tools Help defax

Back Forward Stop Home Search Favorites Media Print W

Address http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditorWithValidation?Project=com.webridge.entity.Entity[OID[0B6D2A18BBE34042AC] 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:

HELP TEXT

The date you became aware of the protocol violation.

Over the life of the study.

Including subjects enrolled at other institutions.

Scroll down to display more of the current page.

Errors Refresh

- Question 6: Please enter a Participant Identifier ([Jump To: Protocol Violation Form](#))

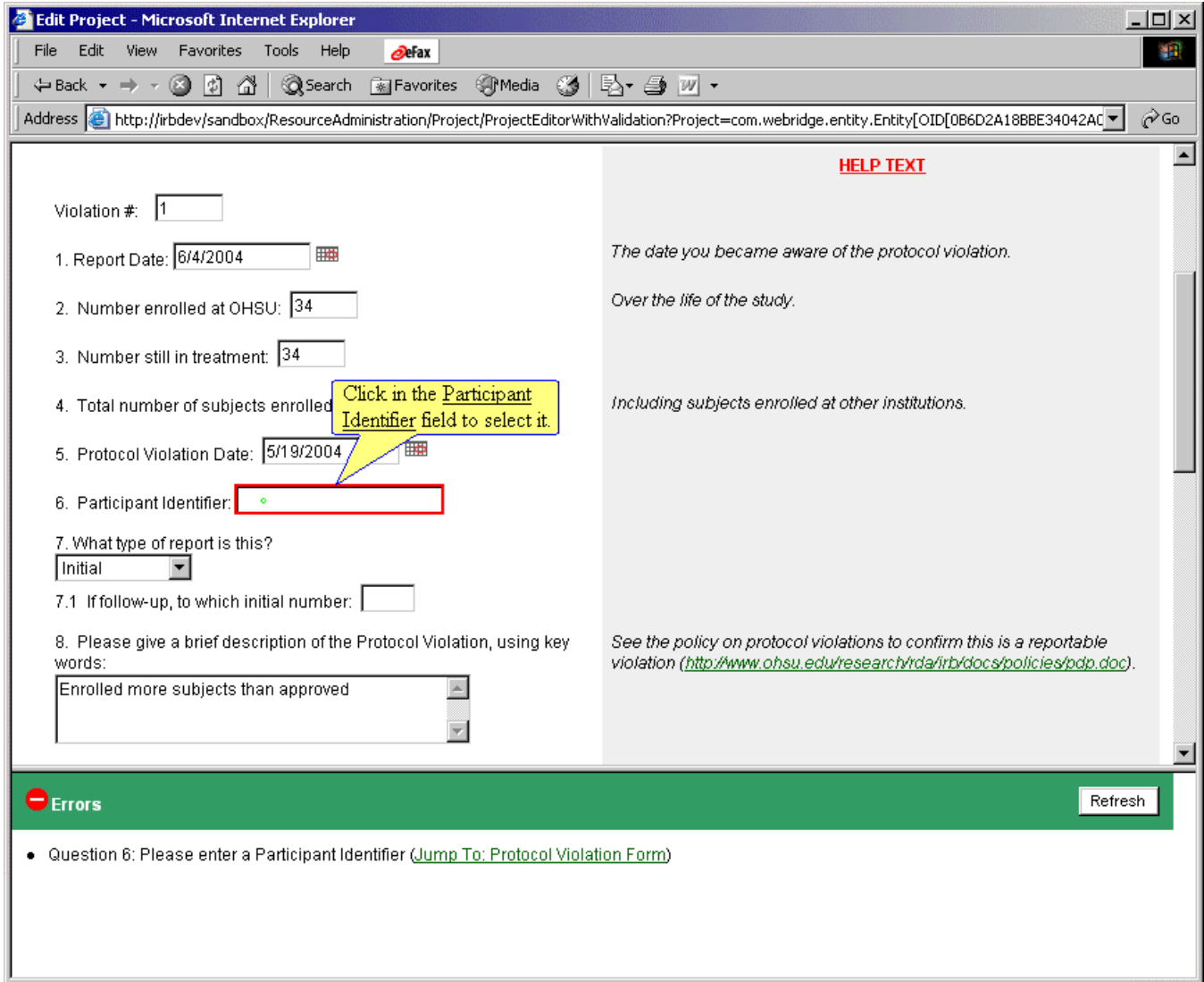
Notes:

Scroll down to display more of the current page.



Edit Project - Microsoft Internet Explorer

Step 12 - Click on



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 violation (<http://www.ohsu.edu/research/rda/irb/docs/policies/pdp.doc>).

Errors Refresh

- Question 6: Please enter a Participant Identifier ([Jump To: Protocol Violation Form](#))

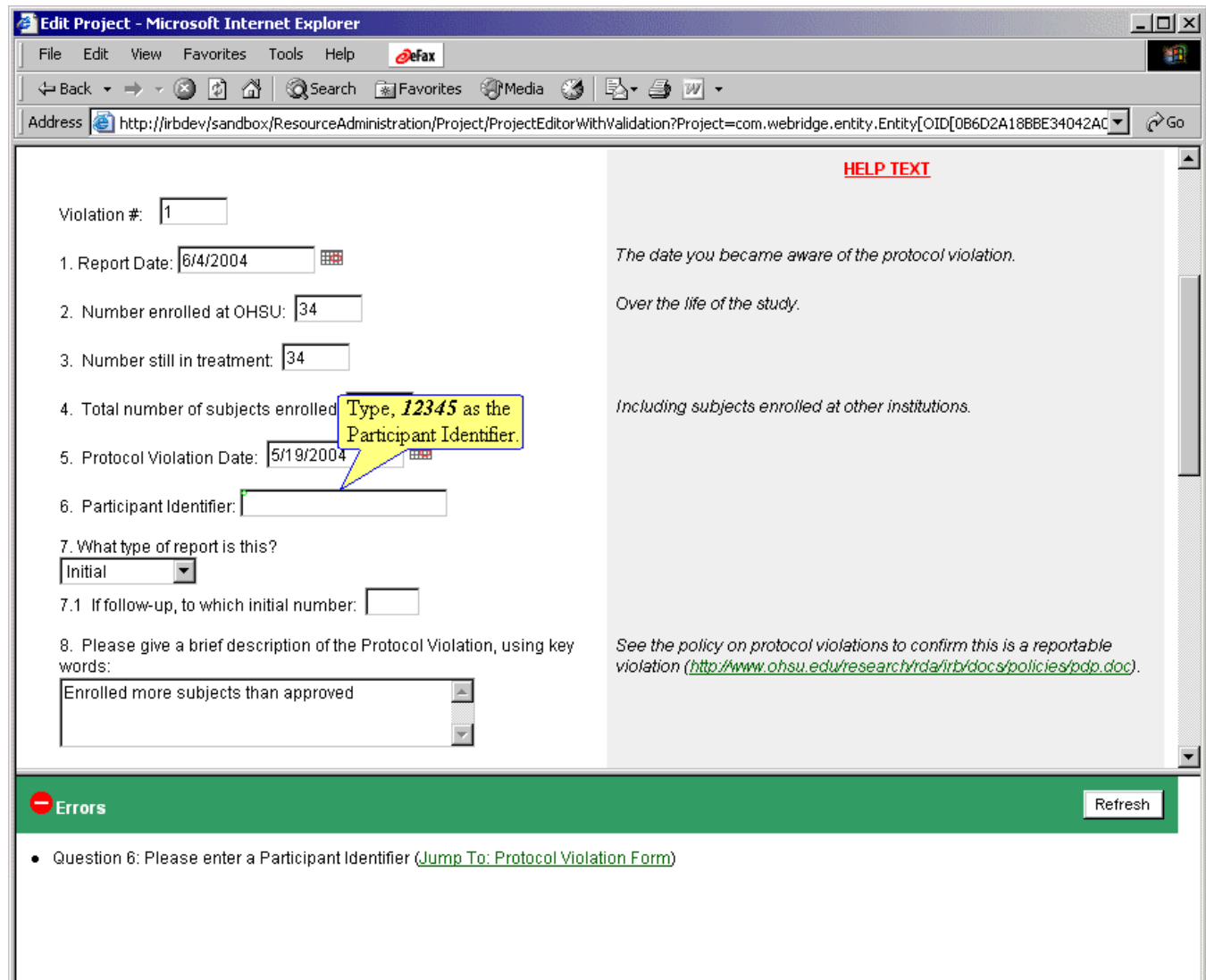
Notes:

Click in the Participant Identifier field to select it.



Edit Project - Microsoft Internet Explorer

Step 13 - Type "12345" in edit box



HELP TEXT

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 words:

*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 violation (<http://www.ohsu.edu/research/rda/irb/docs/policies/pdp.doc>).*

Errors Refresh

- Question 6: Please enter a Participant Identifier ([Jump To: Protocol Violation Form](#))

Notes:

Type, 12345 as the Participant Identifier.



Edit Project - Microsoft Internet Explorer

Step 14 - Click on

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 violation (<http://www.ohsu.edu/research/yrda/irb>)

Errors Refresh

- Question 6: Please enter a Participant Identifier ([Jump To: Protocol Violation Form](#))

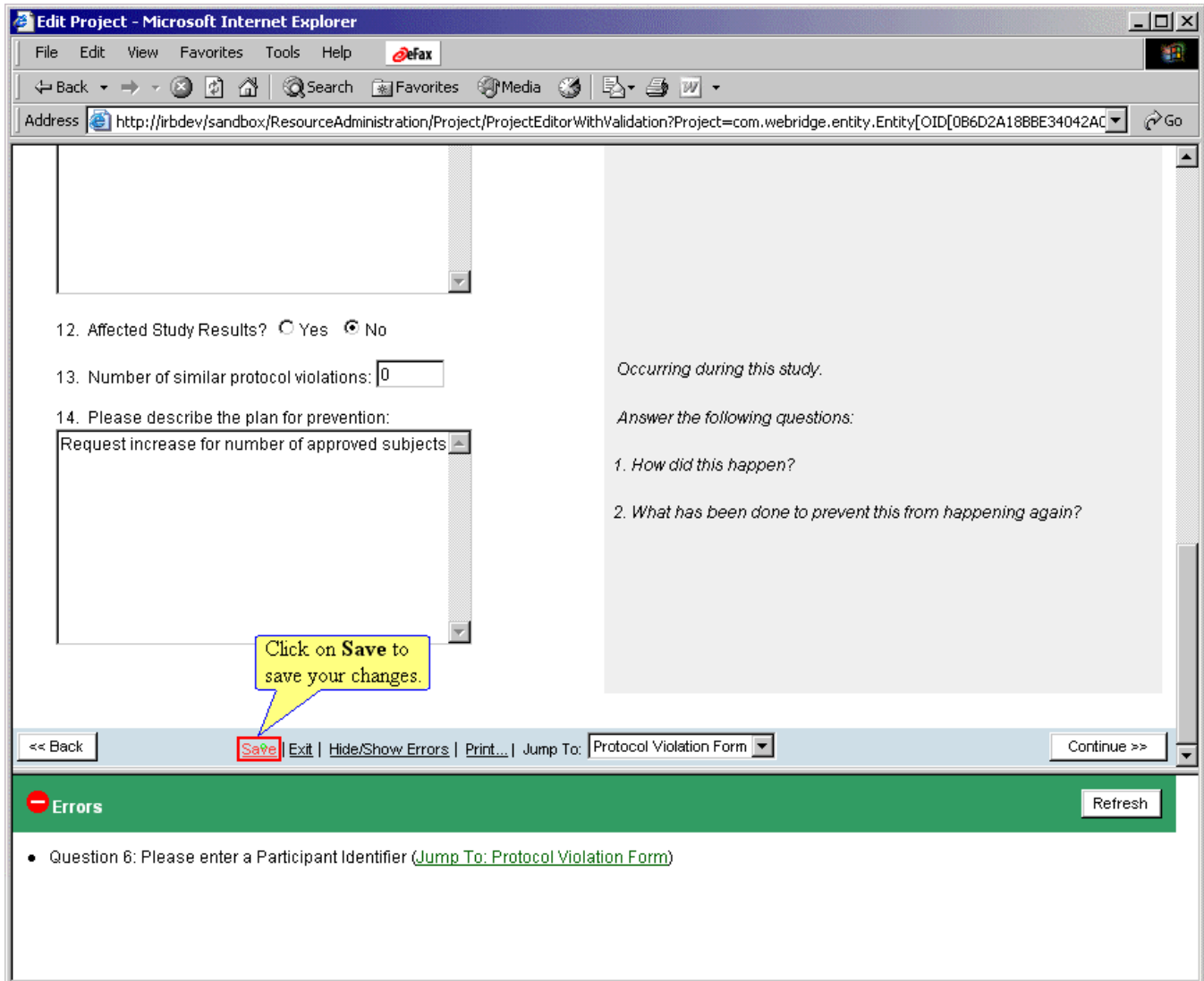
Notes:

Scroll down to display more of the current page.



Edit Project - Microsoft Internet Explorer

Step 15 - Click on **Save**



12. Affected Study Results? Yes No

13. Number of similar protocol violations:

14. Please describe the plan for prevention:

Occurring during this study.

Answer the following questions:

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

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

Errors Refresh

- Question 6: Please enter a Participant Identifier ([Jump To: Protocol Violation Form](#))

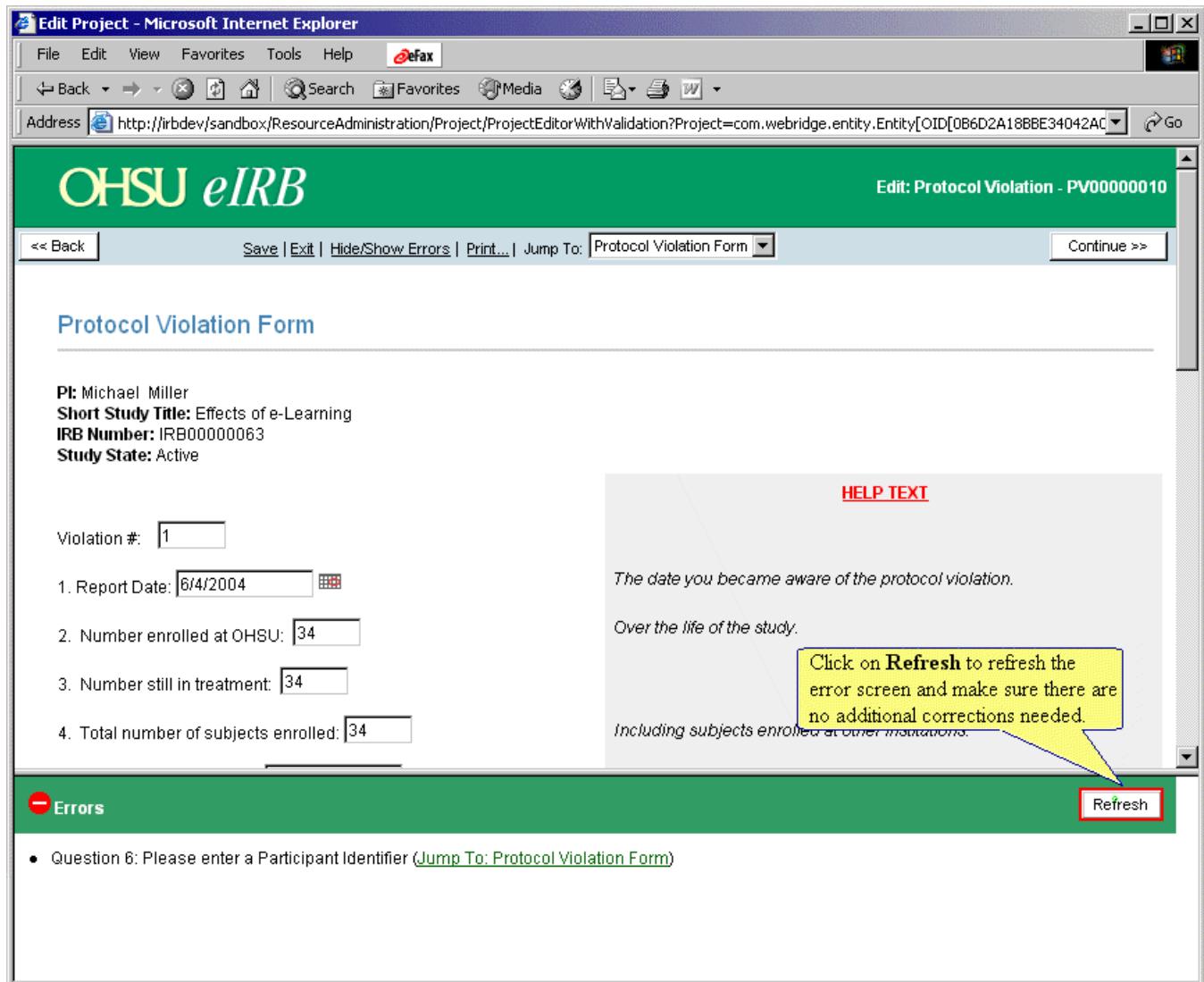
Notes:

Click on Save to save your changes.



Edit Project - Microsoft Internet Explorer

Step 16 - 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:

HELP TEXT

The date you became aware of the protocol violation.

Over the life of the study.

Including subjects enrolled at other institutions.

Errors

- Question 6: Please enter a Participant Identifier ([Jump To: Protocol Violation Form](#))

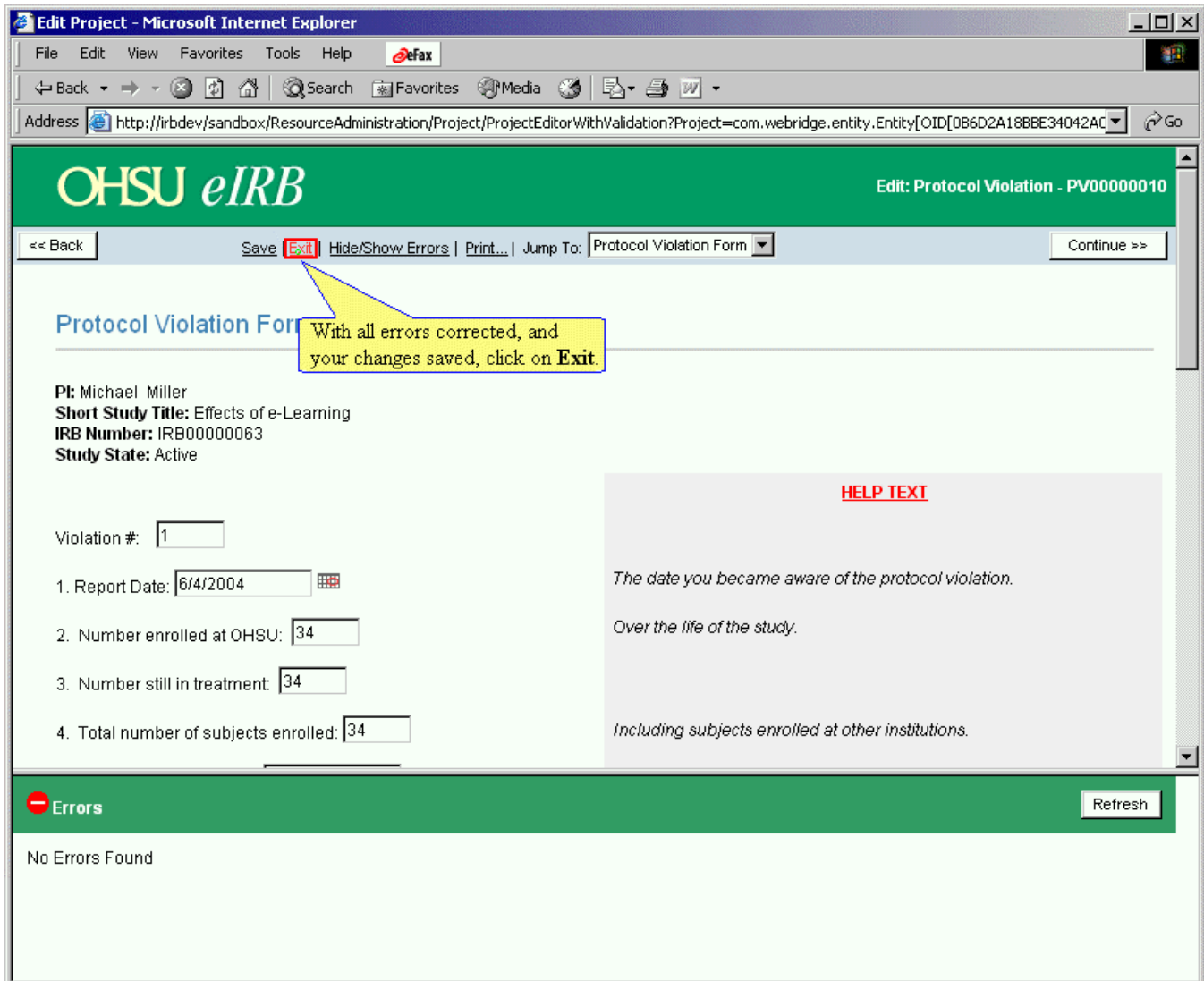
Notes:

Click on Refresh to refresh the error screen and make sure there are no additional corrections needed.



Edit Project - Microsoft Internet Explorer

Step 17 - Click on [Exit](#)



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:

HELP TEXT

The date you became aware of the protocol violation.

Over the life of the study.

Including subjects enrolled at other institutions.

Errors Refresh

No Errors Found

Notes:

With all errors corrected, and your changes saved, click on Exit.

OHSU eIRB**Microsoft Internet Explorer**

Step 18 - Click on OK button

OK

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/ProjectEditorWithValidation?Project=com.webridge.entity.Entity\[OID\[0B6D2A18BBE34042AC\]](http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditorWithValidation?Project=com.webridge.entity.Entity[OID[0B6D2A18BBE34042AC]) 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

Microsoft Internet Explorer

If you have not saved changes to the current form, they will be lost. Click Cancel to return to your form and click Save before exiting. Click OK to close the form without saving changes.

OK Cancel

Click OK on the save confirmation dialog box. If you had not saved, you would want to Cancel and click save.

Errors Refresh


No Errors Found

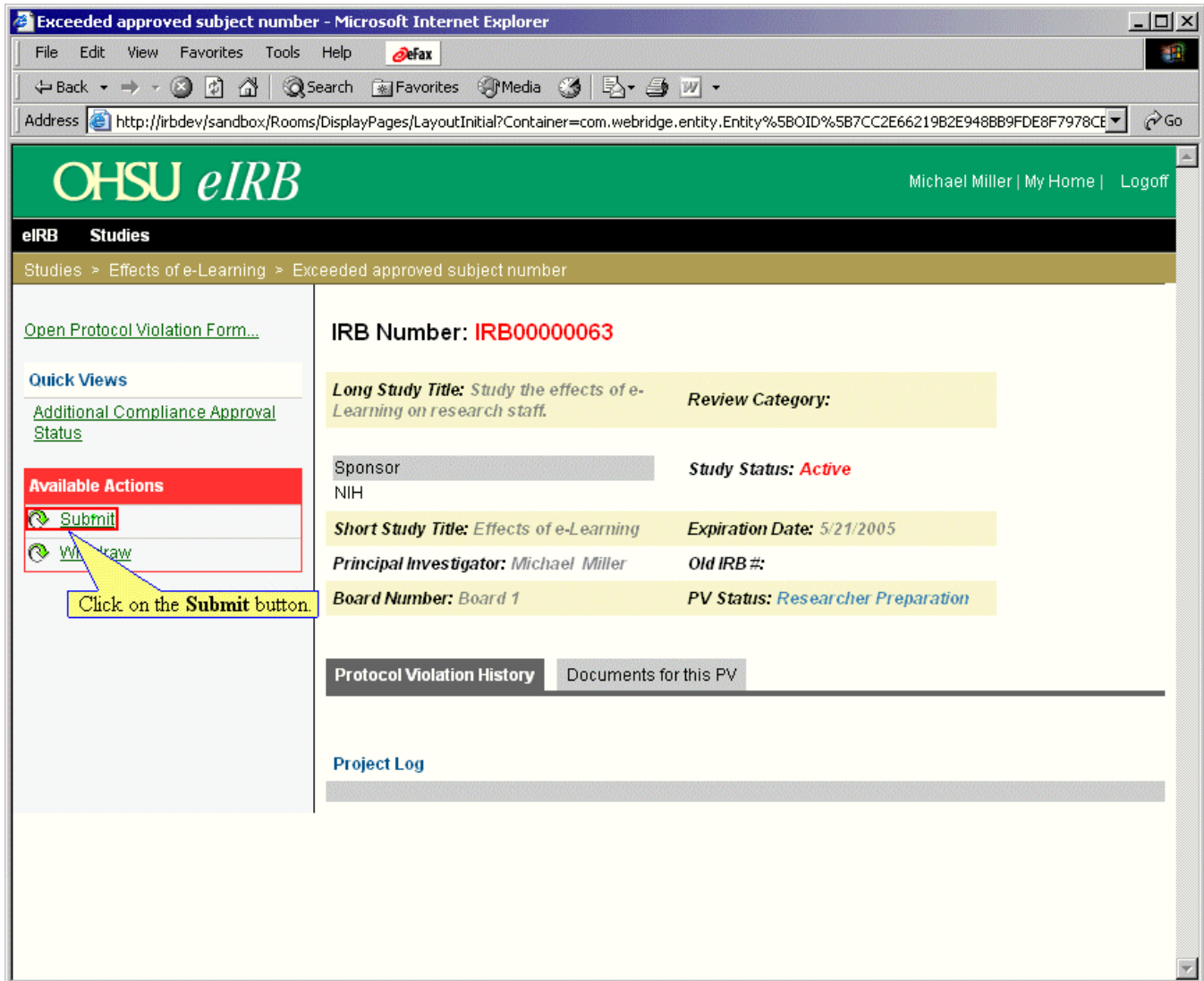
Notes:

Click OK on the save confirmation dialog box. If you had not saved, you would want to Cancel and click save.




Exceeded approved subject number - Microsoft Internet Explorer

Step 19 - Click on  [Submit](#)



Exceeded approved subject number - Microsoft Internet Explorer

File Edit View Favorites Tools Help 

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Address <http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5BBOID%5B7CC2E66219B2E948BB9FDE8F7978CE> Go

OHSU eIRB Michael Miller | My Home | Logout

eIRB Studies


Studies > Effects of e-Learning > Exceeded approved subject number


[Open Protocol Violation Form...](#)

Quick Views

[Additional Compliance Approval Status](#)

Available Actions

 **Submit**

 Withdraw

Click on the **Submit** button.

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

Protocol Violation History Documents for this PV

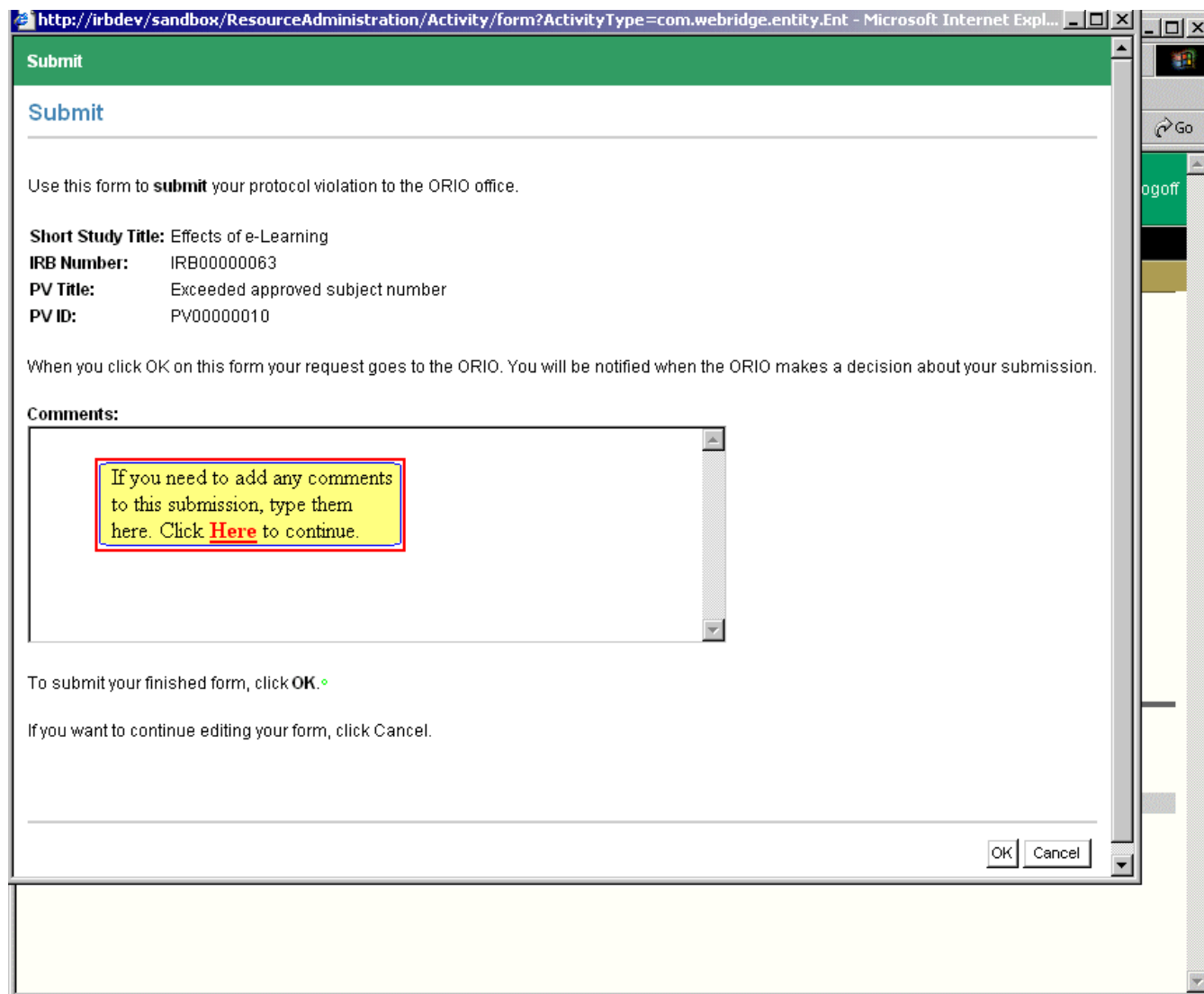
Project Log

Notes:

Click on the Submit button.

<http://irbdev/sandbox/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Ent> - Microsoft Internet Explorer

Step 20 - Click on



Submit

Submit

Use this form to **submit** your protocol violation to the ORIO office.

Short Study Title: Effects of e-Learning
IRB Number: IRB00000063
PV Title: Exceeded approved subject number
PV ID: PV00000010

When you click OK on this form your request goes to the ORIO. You will be notified when the ORIO makes a decision about your submission.

Comments:

If you need to add any comments to this submission, type them here. Click [Here](#) to continue.

To submit your finished form, click **OK**.

If you want to continue editing your form, click **Cancel**.

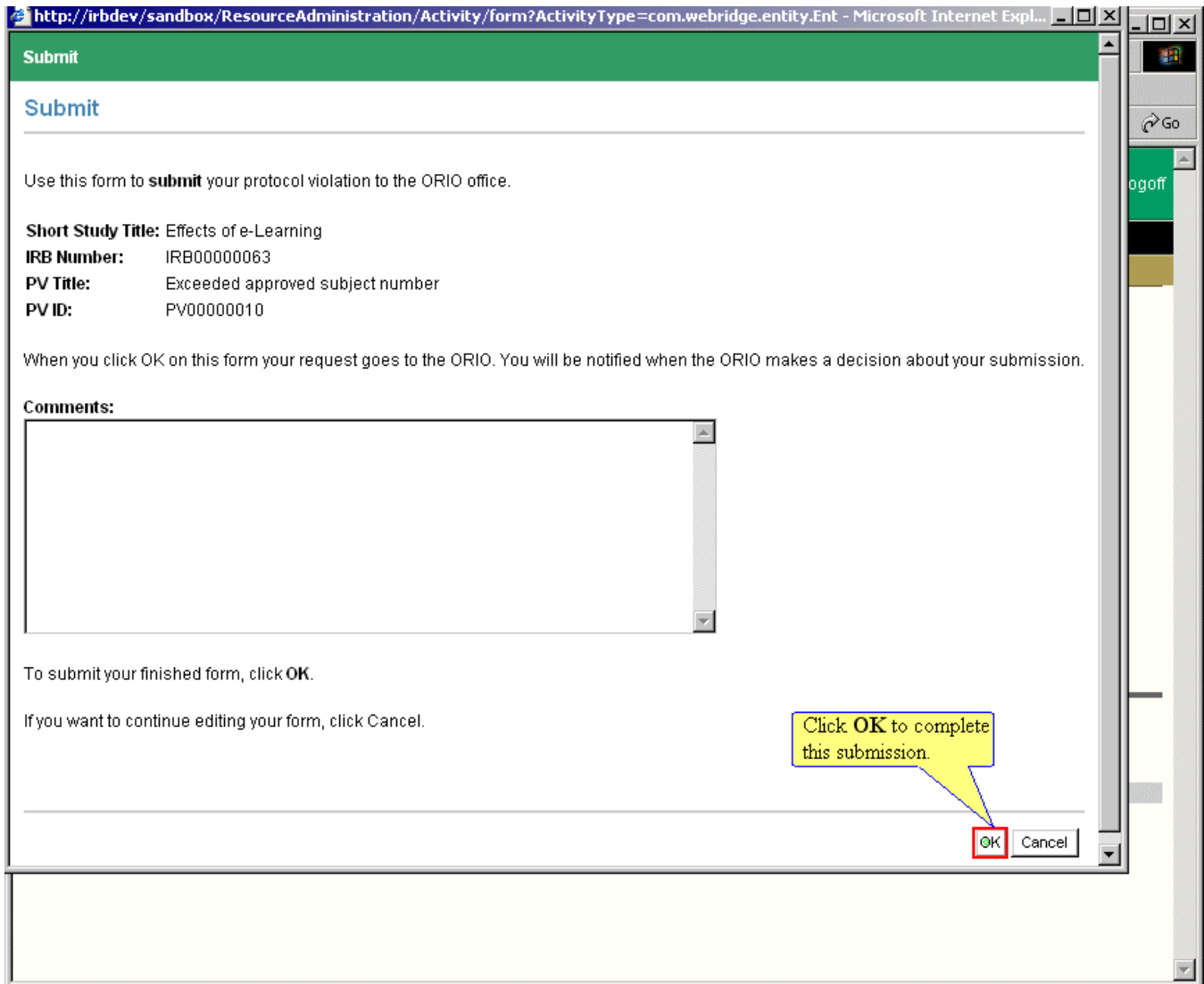
OK Cancel

Notes:

If you need to add any comments to this submission, type them here. Click Here to continue.

<http://irbdev/sandbox/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Ent> - Microsoft Internet Explorer

Step 21 - Click on 



Submit

Submit

Use this form to **submit** your protocol violation to the ORIO office.

Short Study Title: Effects of e-Learning
IRB Number: IRB00000063
PV Title: Exceeded approved subject number
PV ID: PV00000010

When you click OK on this form your request goes to the ORIO. You will be notified when the ORIO makes a decision about your submission.

Comments:

To submit your finished form, click **OK**.

If you want to continue editing your form, click **Cancel**.

Click **OK** to complete this submission.

Notes:

Click OK to complete this submission.



Step 22 - End of simulation

Exceeded approved subject number - Microsoft Internet Explorer

Address: <http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge.entity.Entity%5B OID%5B7CC2E66219B2E948BB9FDE8F7978CE>

OHSU eIRB Michael Miller | My Home | Logoff

eIRB Studies

Studies > Effects of e-Learning > Exceeded approved subject number

[Open Protocol Violation Form...](#)

Quick Views

[Additional Compliance Approval Status](#)

Available Actions

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:** Analyst Review

Protocol Violation History Documents for this PV

Project Log

Activity	Author	Activity Date
Submitted	Michael Miller	6/4/2004 3:48 PM