



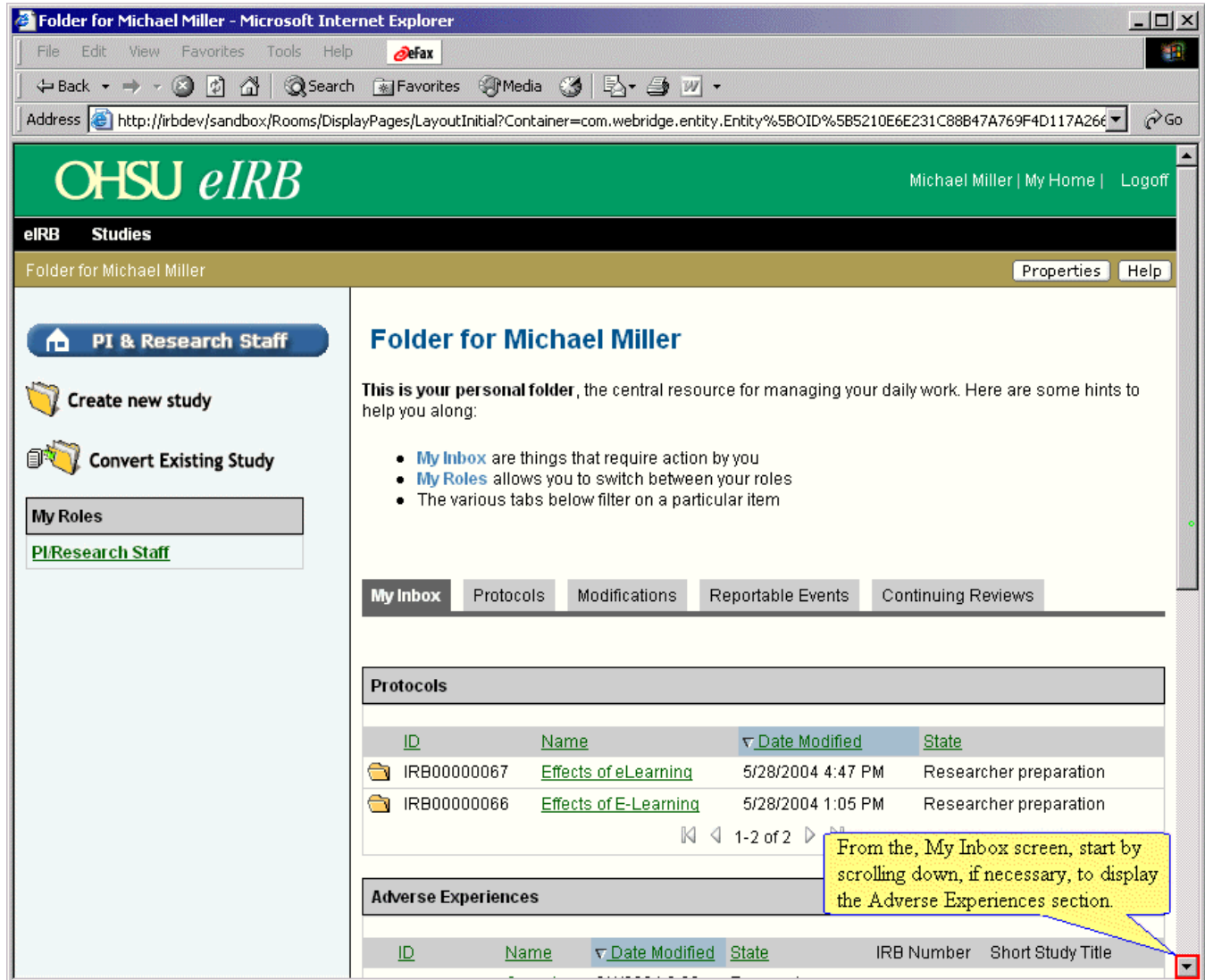
eIRB Submit Adverse Experience

June 30, 2004



Folder for Michael Miller - Microsoft Internet Explorer

Step 1 - Click on 



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

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

The main content area is divided into a left sidebar and a main panel. The sidebar contains navigation options: "PI & Research Staff", "Create new study", "Convert Existing Study", and "My Roles" (with "PIResearch Staff" selected). The main panel displays the "Folder for Michael Miller" title and 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 hints, there are tabs for "My Inbox", "Protocols", "Modifications", "Reportable Events", and "Continuing Reviews". The "My Inbox" tab is selected, showing a table of "Protocols":

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, there is a section for "Adverse Experiences" with a table header including "ID", "Name", "Date Modified", "State", "IRB Number", and "Short Study Title". A yellow callout box points to a dropdown arrow in the bottom right corner of the page, containing the text: "From the, My Inbox screen, start by scrolling down, if necessary, to display the Adverse Experiences section."

Notes:

From the, My Inbox screen, start by scrolling down, if necessary, to display the Adverse Experiences section.



Folder for Michael Miller - Microsoft Internet Explorer

Step 2 - Click on [Carpal Tunnel](#)

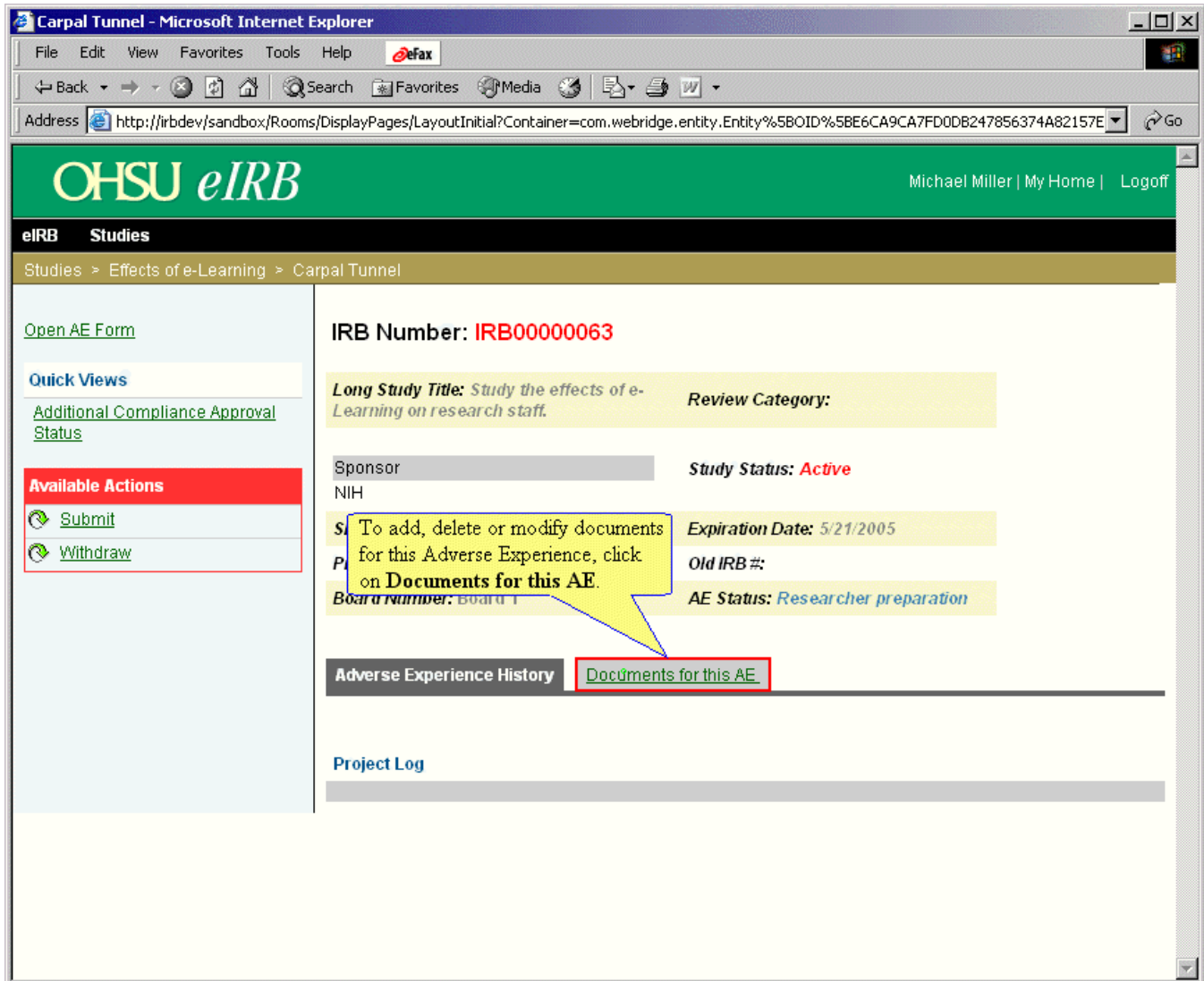
Notes:

Click on the name of the Adverse Experience you wish to open and submit.



Carpal Tunnel - Microsoft Internet Explorer

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



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

The page header features the OHSU eIRB logo on the left and the user name "Michael Miller | My Home | Logoff" on the right. Below the header, the navigation menu shows "eIRB" and "Studies". The breadcrumb trail indicates the current location: "Studies > Effects of e-Learning > Carpal Tunnel".

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
- Expiration Date:** 5/21/2005
- Old IRB #:** (blank)
- AE Status:** Researcher preparation

A callout box points to the "Documents for this AE" link in the "Adverse Experience History" section, stating: "To add, delete or modify documents for this Adverse Experience, click on Documents for this AE." The "Documents for this AE" link is highlighted with a red box.

The left sidebar contains the following sections:

- Open AE Form**
- Quick Views**
 - [Additional Compliance Approval Status](#)
- Available Actions**
 - [Submit](#)
 - [Withdraw](#)

Below the sidebar, there is a "Project Log" section which is currently empty.

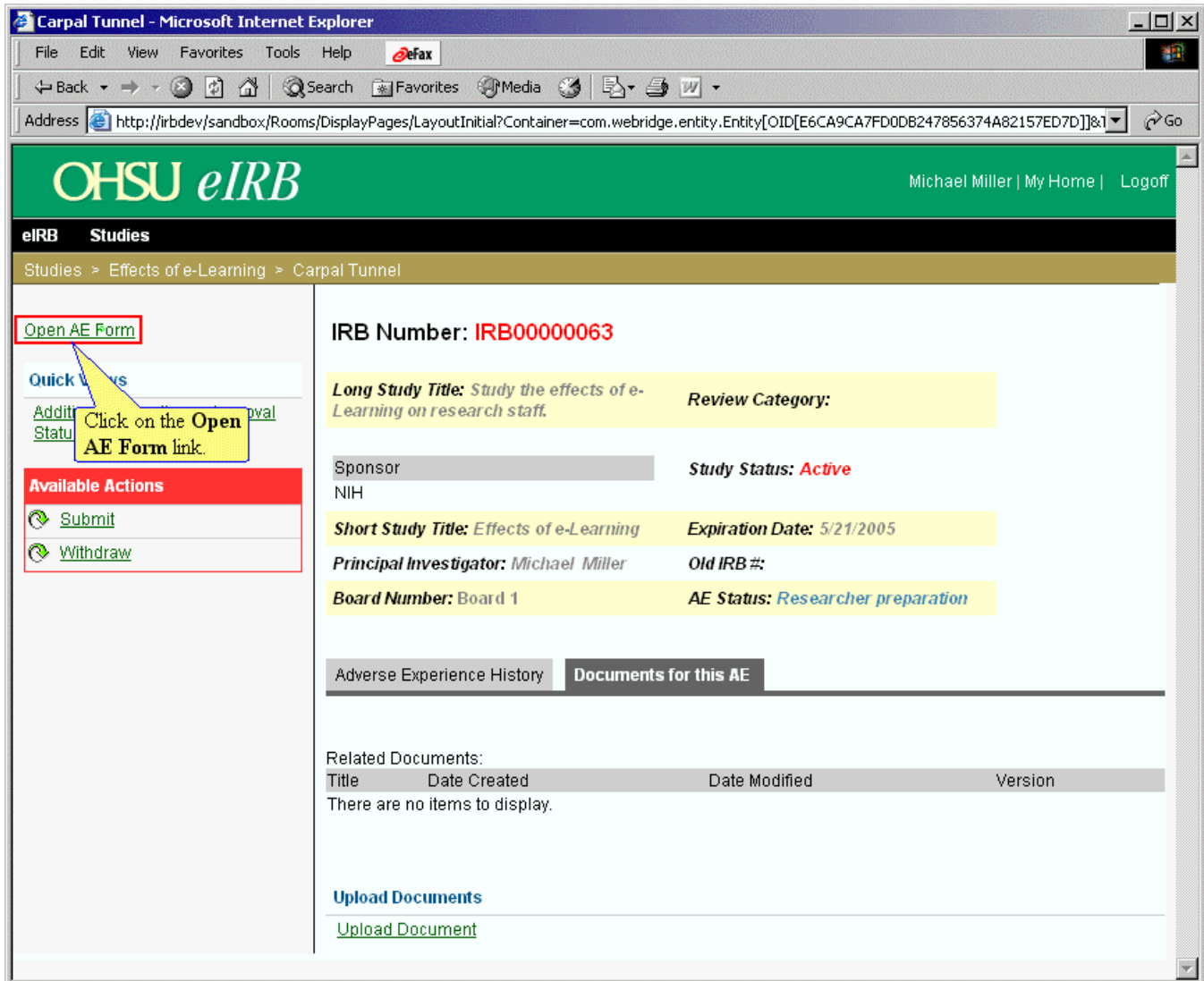
Notes:

To add, delete or modify documents for this Adverse Experience, click on Documents for this AE.



Carpal Tunnel - Microsoft Internet Explorer

Step 4 - Click on [Open AE Form](#)



Open AE Form

Quick Links
[Addition](#) [Approval](#)
[Status](#) [Open AE Form](#)

Click on the **Open AE Form** link.

Available Actions

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

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 **AE Status:** Researcher preparation

Adverse Experience History | **Documents for this AE**

Related Documents:

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

Upload Documents

[Upload Document](#)

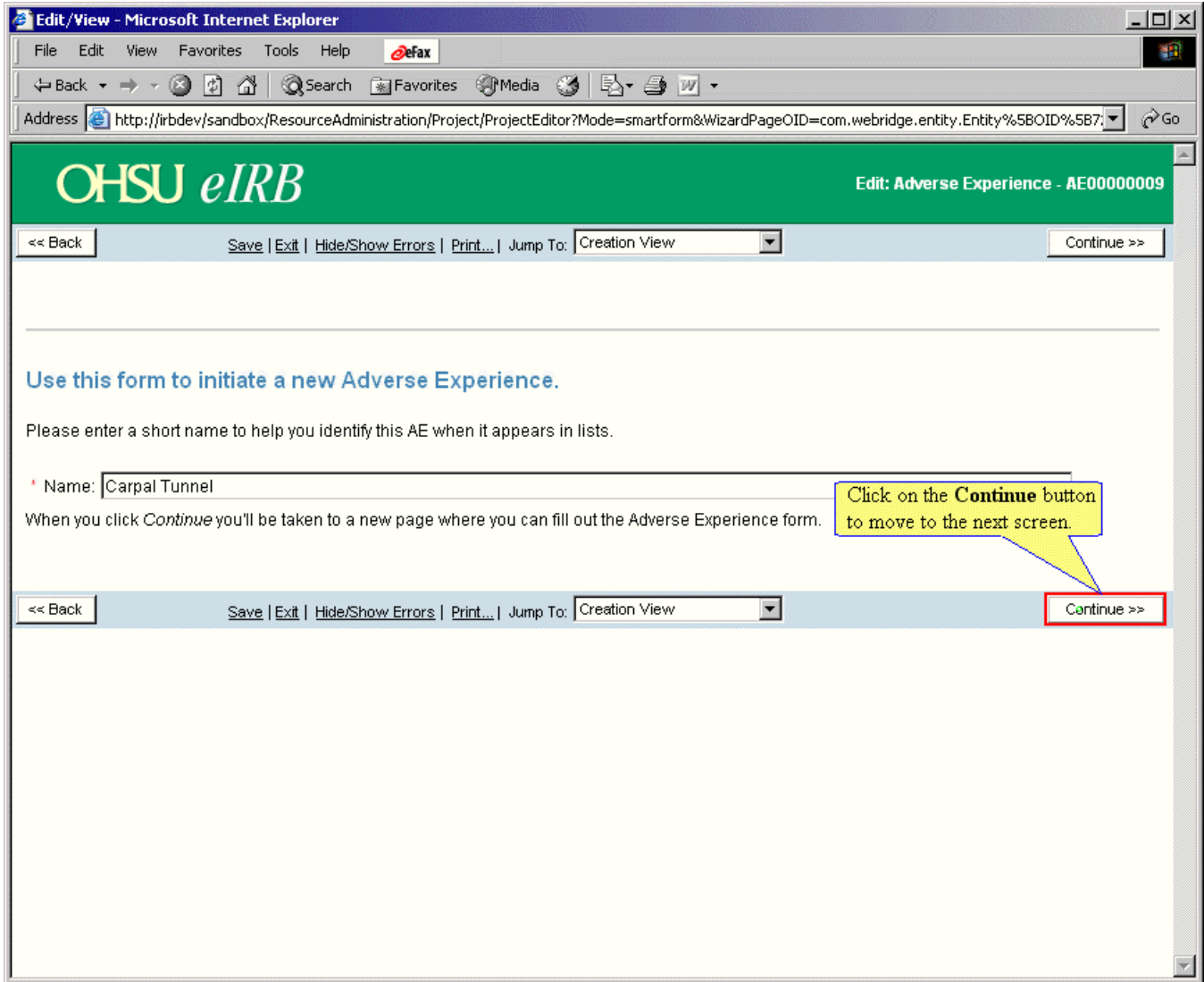
Notes:

Click on the Open AE Form link.



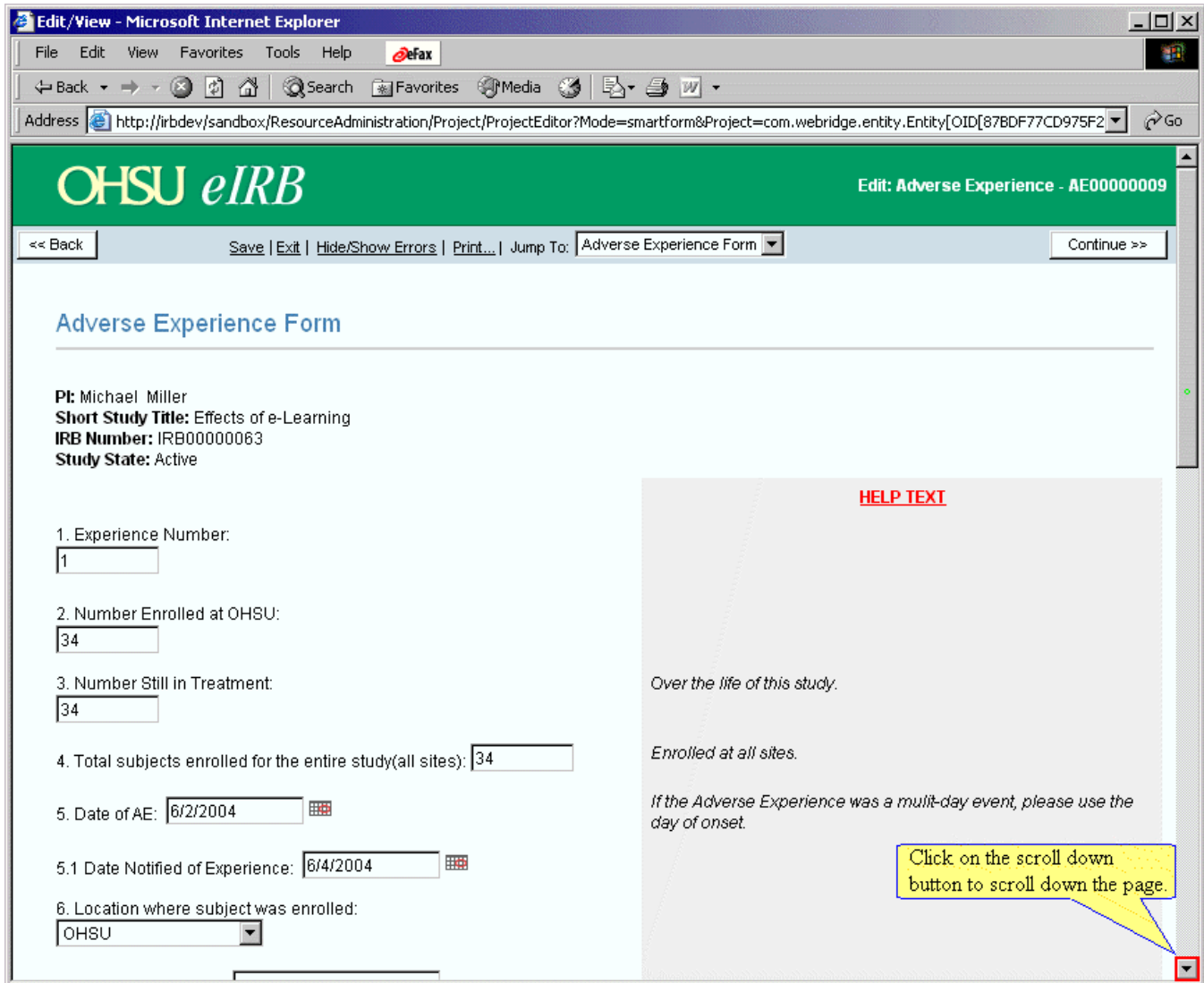
Edit/View - Microsoft Internet Explorer

Step 5 - Click on



Notes:

Click on the Continue button to move to the next screen.

OHSU eIRB**Edit/View - Microsoft Internet Explorer**Step 6 - Click on 

OHSU eIRB Edit: Adverse Experience - AE00000009

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

Adverse Experience Form


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


1. Experience Number:

2. Number Enrolled at OHSU:

3. Number Still in Treatment:

4. Total subjects enrolled for the entire study(all sites):

5. Date of AE: 

5.1 Date Notified of Experience: 

6. Location where subject was enrolled:

HELP TEXT

Over the life of this study.

Enrolled at all sites.

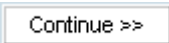
If the Adverse Experience was a multi-day event, please use the day of onset.

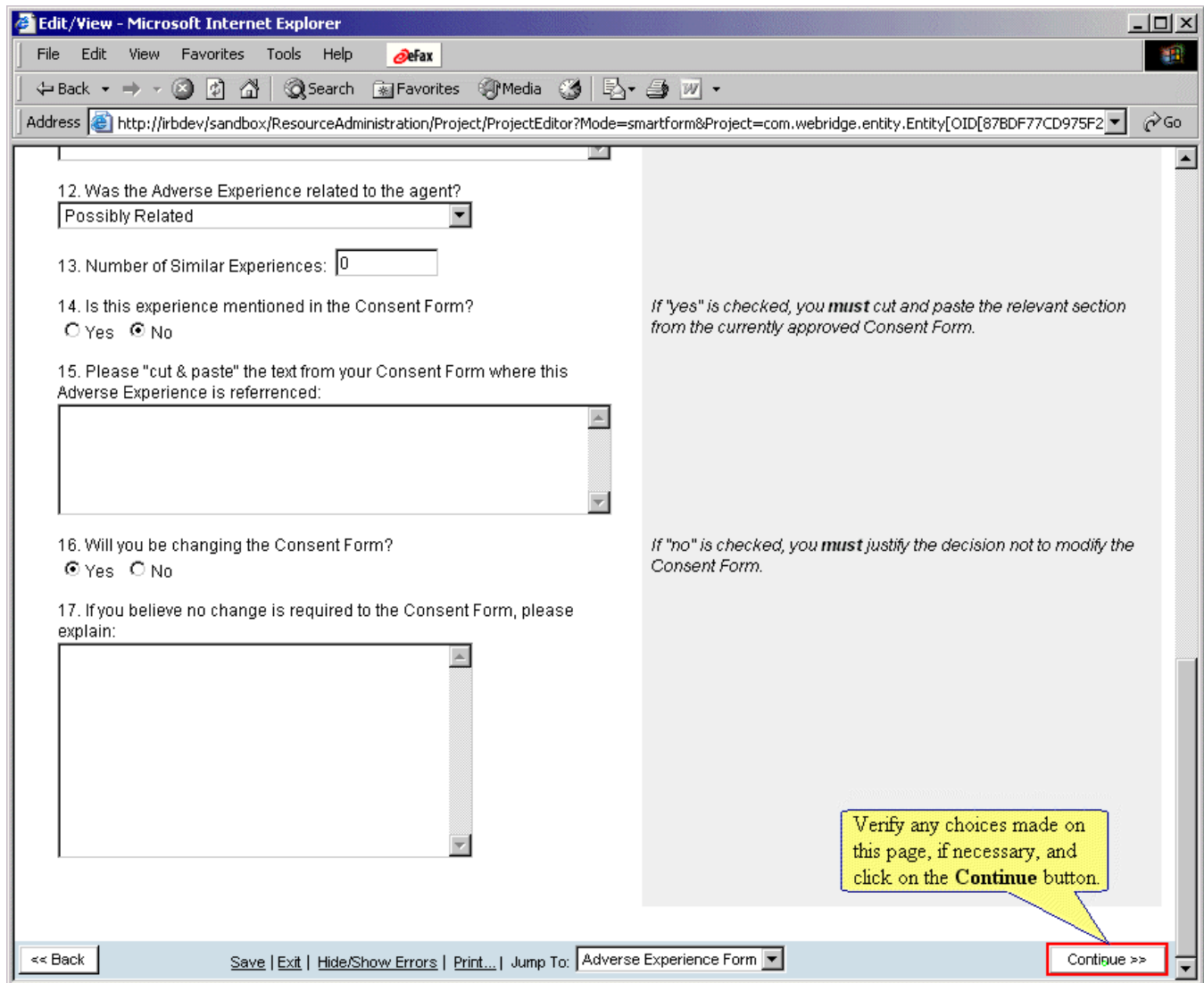
Click on the scroll down button to scroll down the page.

Notes:

Click on the scroll down button to scroll down the page.

Edit/View - Microsoft Internet Explorer

Step 7 - Click on 



The screenshot shows a Microsoft Internet Explorer browser window titled "Edit/View - Microsoft Internet Explorer". The address bar contains the URL: `http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity[OID[87BDF77CD975F2]`. The main content area displays a form with the following questions and input fields:

- 12. Was the Adverse Experience related to the agent?
- 13. Number of Similar Experiences:
- 14. Is this experience mentioned in the Consent Form?
 Yes No
- 15. Please "cut & paste" the text from your Consent Form where this Adverse Experience is referenced:
- 16. Will you be changing the Consent Form?
 Yes No
- 17. If you believe no change is required to the Consent Form, please explain:

On the right side of the form, there are two instructional paragraphs:

- If "yes" is checked, you **must** cut and paste the relevant section from the currently approved Consent Form.*
- If "no" is checked, you **must** justify the decision not to modify the Consent Form.*

At the bottom of the form, there is a navigation bar with the following elements:

-
- Save | | | | Jump To:
-

A yellow callout box with a blue border points to the "Continue >>" button, containing the text: "Verify any choices made on this page, if necessary, and click on the **Continue** button."

Notes:

Verify any choices made on this page, if necessary, and click on the Continue button.



Edit/View - Microsoft Internet Explorer

Step 8 - Click on 

OHSU eIRB Edit: Adverse Experience - AE00000009

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Upload Document Finish

Use this form to manage your documents.

This checklist is intended to aid investigators in providing the documentation necessary to obtain Institutional Review Board (IRB) approval for research protocols involving human subjects. Please use the most recent version of the IRB forms, which can be found [here](#). For each item please check whether that document will be submitted electronically or via hard copy. If you are submitting document(s) please indicate how many.

*If you do not need to upload any documents, simply hit the "Finish" button.

	Electronic	Hard Copy	How Many?
Modified Consent Form (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Other (please specify the documents (e.g., handwritten documentation, sponsor report, etc.)): <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

Upload Documents:

Title

There are no items to display.

Use this area to upload the documents listed above.

If you need to upload documents, you can do that on this page. Click **Finish** to complete any changes.


<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Upload Document **Finish**

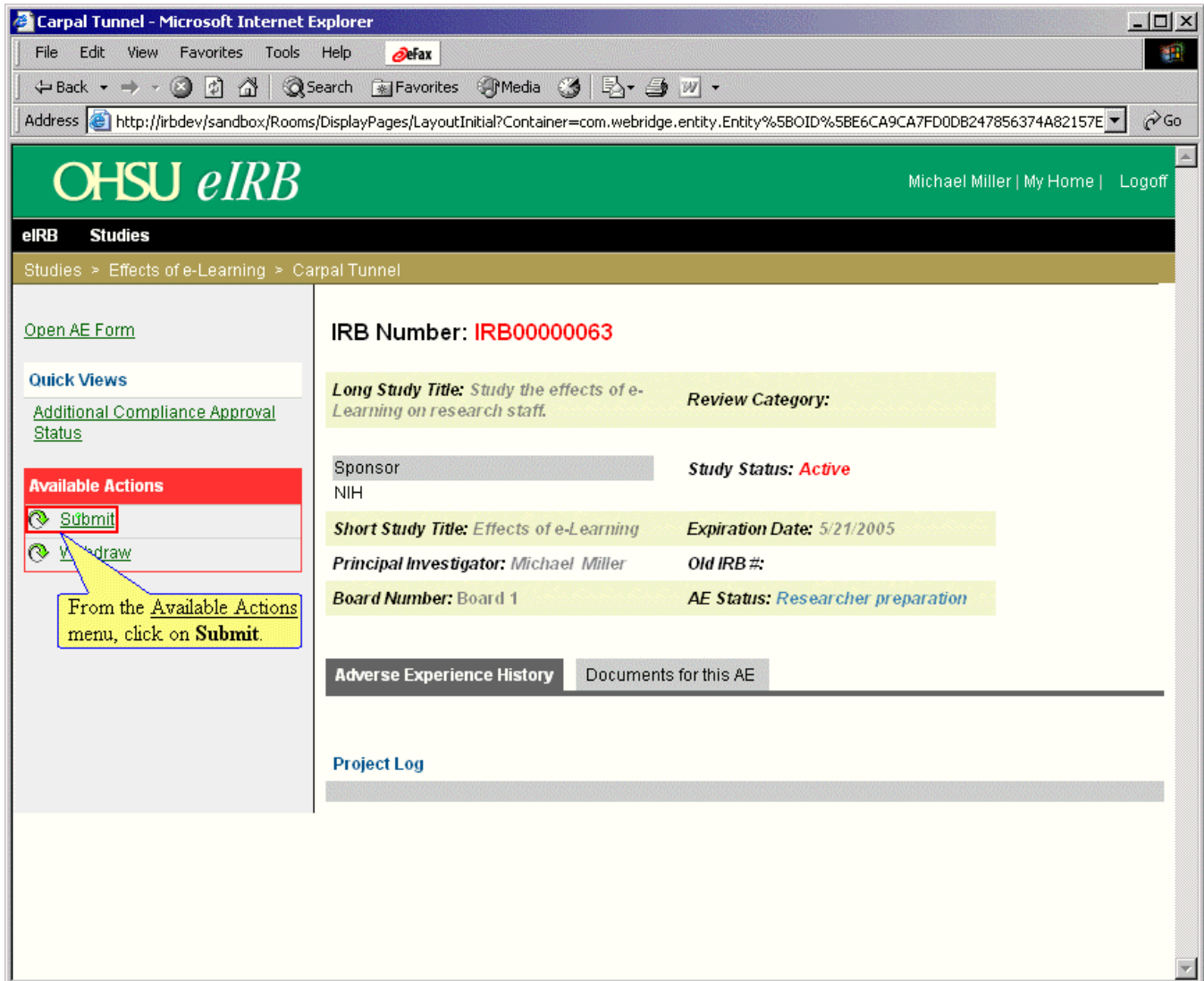
Notes:

If you need to upload documents, you can do that on this page. Click Finish to complete any changes.





Carpal Tunnel - Microsoft Internet Explorer

Step 9 - Click on  [Submit](#)



The screenshot displays the OHSU eIRB web application in Microsoft Internet Explorer. The browser window 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 content includes:

- Header:** OHSU eIRB logo and user information: Michael Miller | My Home | Logoff
- Navigation:** eIRB Studies, Studies > Effects of e-Learning > Carpal Tunnel
- Left Sidebar:**
 - Open AE Form
 - Quick Views
 - [Additional Compliance Approval Status](#)
 - Available Actions
 -  [Submit](#)
 -  [Withdraw](#)

A yellow callout box points to the "Submit" button in the Available Actions menu, containing the text: "From the Available Actions menu, click on **Submit**."

The main content area displays study details:

- 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 **AE Status:** Researcher preparation

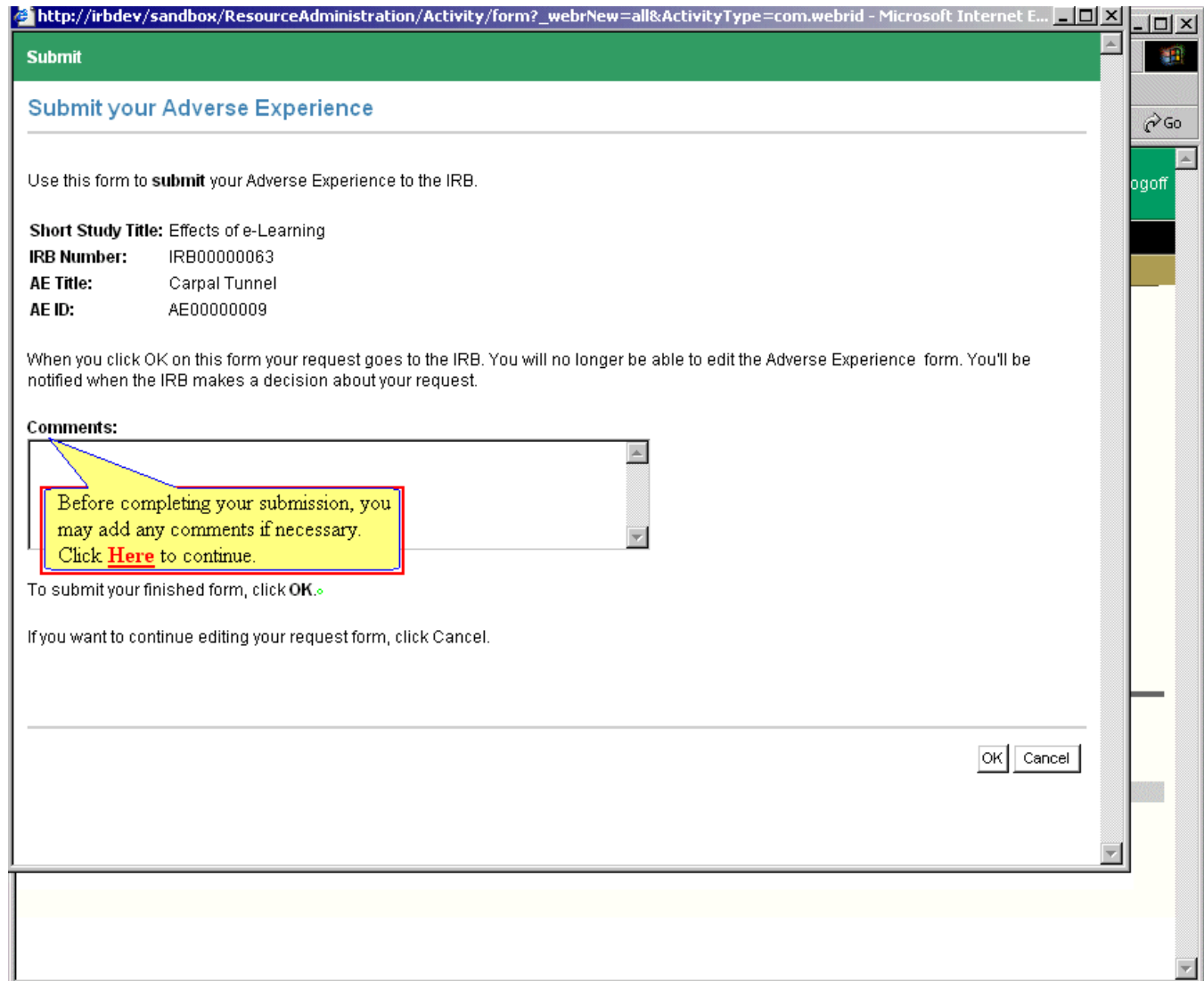
Below the study details are sections for Adverse Experience History (Documents for this AE) and Project Log.

Notes:

From the Available Actions menu, click on Submit.

http://irbdev/sandbox/ResourceAdministration/Activity/form?_webrNew=all&ActivityType=com.webrid - Microsoft Internet Explorer

Step 10 - Click on



Submit

Submit your Adverse Experience

Use this form to **submit** your Adverse Experience to the IRB.

Short Study Title: Effects of e-Learning
IRB Number: IRB00000063
AE Title: Carpal Tunnel
AE ID: AE00000009

When you click OK on this form your request goes to the IRB. You will no longer be able to edit the Adverse Experience form. You'll be notified when the IRB makes a decision about your request.

Comments:

Before completing your submission, you may add any comments if necessary.
Click [Here](#) to continue.

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

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

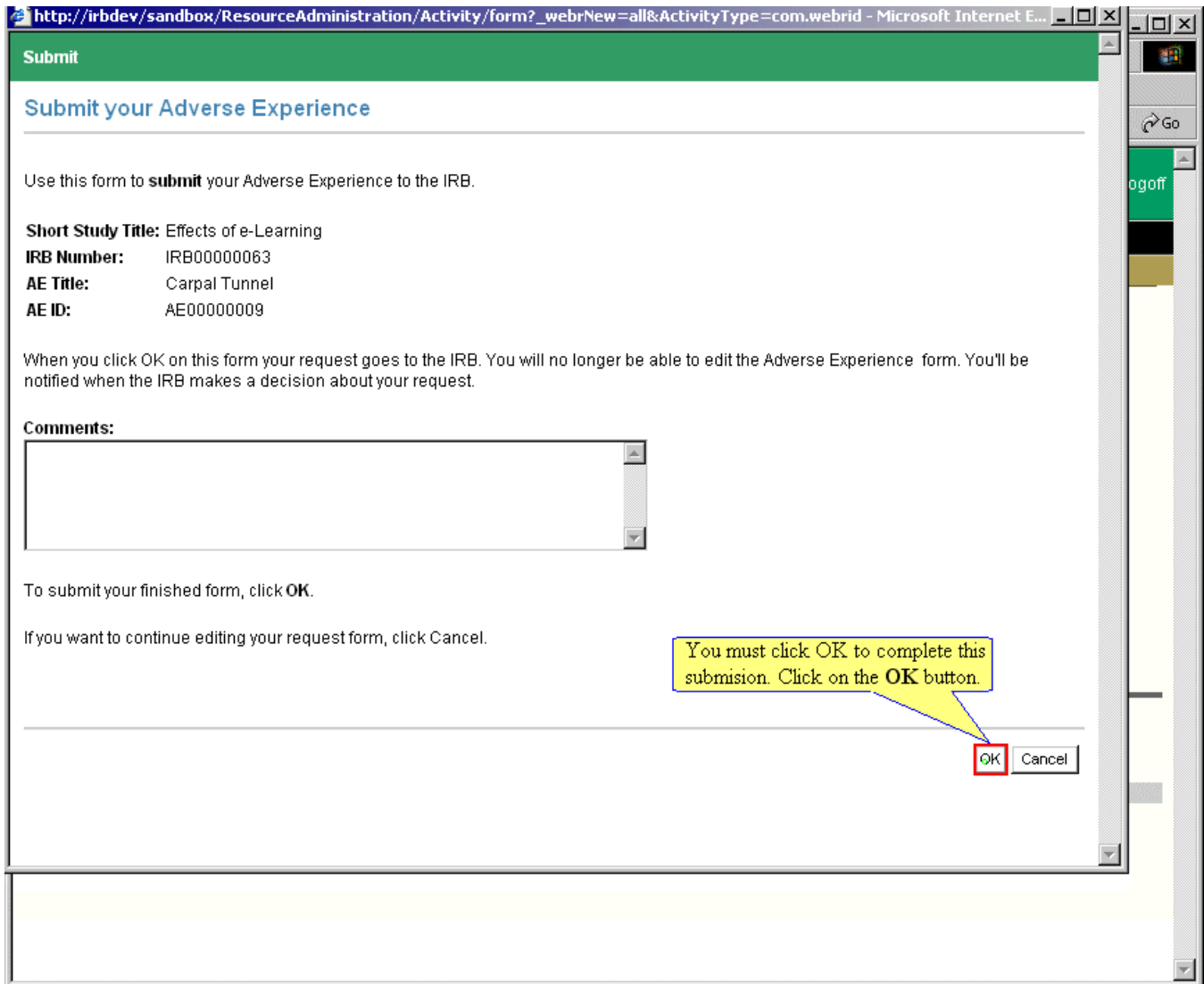
OK Cancel

Notes:

Before completing your submission, you may add any comments if necessary.
Click Here to continue.

http://irbdev/sandbox/ResourceAdministration/Activity/form?_webrNew=all&ActivityType=com.webrid - Microsoft Internet Explorer

Step 11 - Click on 



Submit

Submit your Adverse Experience

Use this form to **submit** your Adverse Experience to the IRB.

Short Study Title: Effects of e-Learning
IRB Number: IRB00000063
AE Title: Carpal Tunnel
AE ID: AE00000009

When you click OK on this form your request goes to the IRB. You will no longer be able to edit the Adverse Experience form. You'll be notified when the IRB makes a decision about your request.

Comments:

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

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

You must click OK to complete this submission. Click on the OK button.

Notes:

You must click OK to complete this submission. Click on the OK button.

