



eIRB Create Adverse Experience

June 30, 2004

OHSU eIRB

Effects of e-Learning - Microsoft Internet Explorer

Step 1 - Click on



Effects of e-Learning - 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.webbridge.entity.Entity%5B...> Go

OHSU eIRB Michael Miller | My Home | Logoff

eIRB Studies

Studies > Effects of e-Learning

Open IRQ

Quick Views

[Additional Compliance Approval Status](#)

Available Actions

[Add or Edit Documents](#)

[Update Edit or Read Rights](#)

[New Modification](#)

New Adverse Experience

[New Protocol Violation](#)

[New Continuing Review](#)

[Terminate This Study](#)

IRB Number: **IRB00000063**

Pre-submission IRB Screening IRB Review Approved

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

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*

Initial Review History Study Documents Modifications Reportable Events Continuing Reviews

Project Log

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

Click on the New Adverse Experience button to begin the process.

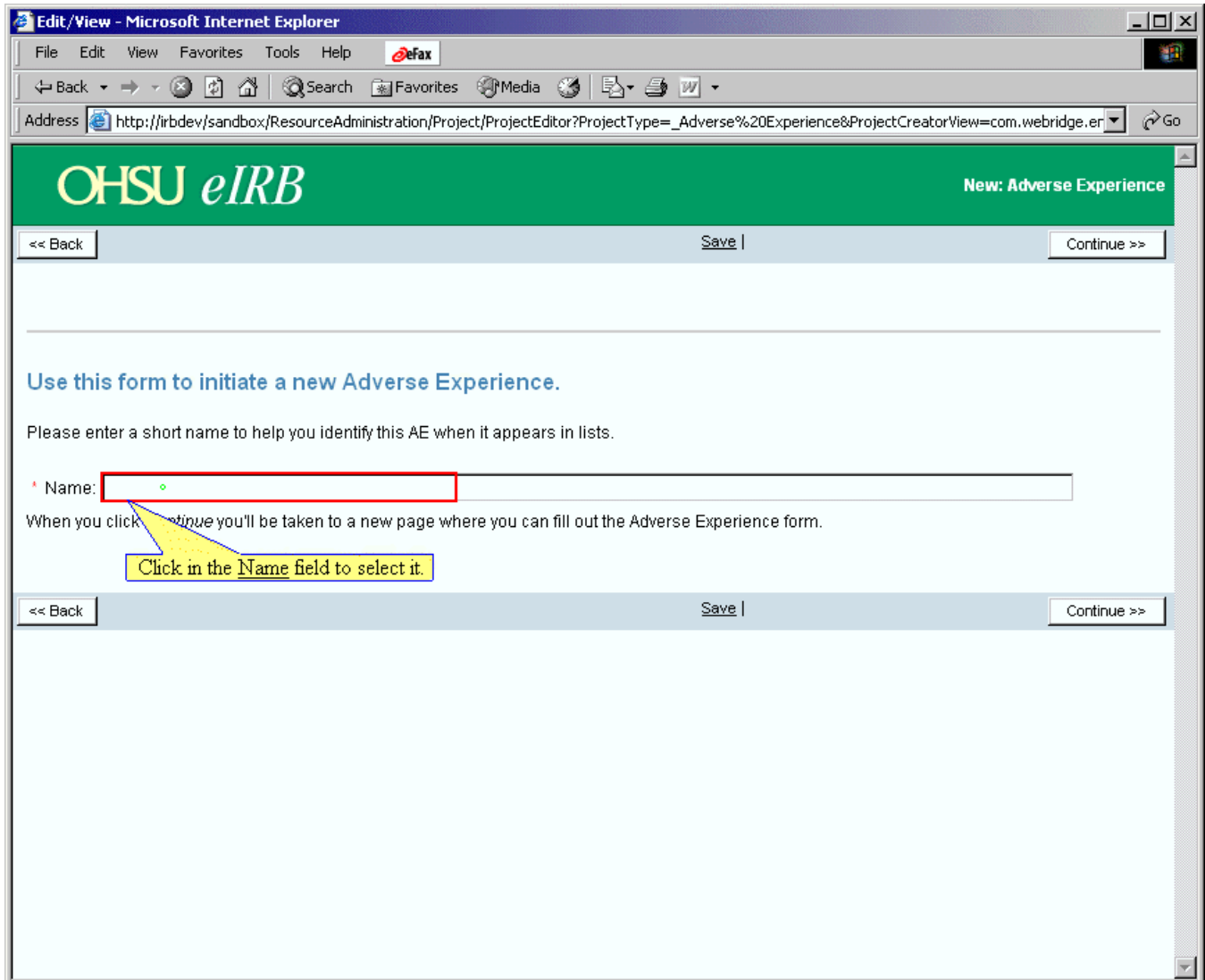
Notes:

Click on the New Adverse Experience button to begin the process.



Edit/View - Microsoft Internet Explorer

Step 2 - Click on



Use this form to initiate a new Adverse Experience.

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

* Name:

When you click [Continue](#) you'll be taken to a new page where you can fill out the Adverse Experience form.

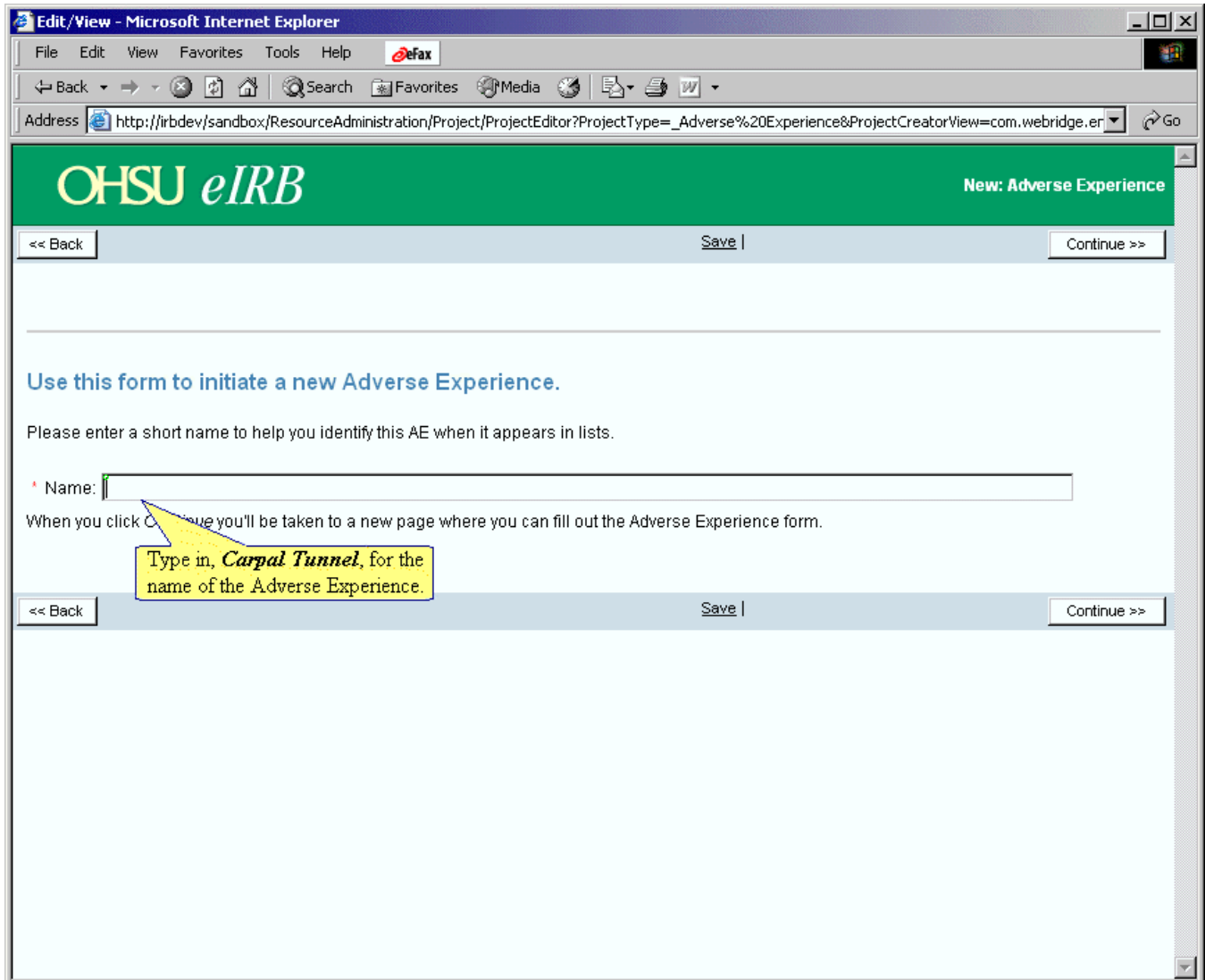
Click in the Name field to select it.

Notes:

Click in the Name field to select it.

**Edit/View - Microsoft Internet Explorer**

Step 3 - Type "Carpal Tunnel" in edit box



Use this form to initiate a new Adverse Experience.

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

Name:

When you click Continue you'll be taken to a new page where you can fill out the Adverse Experience form.

Type in, *Carpal Tunnel*, for the name of the Adverse Experience.

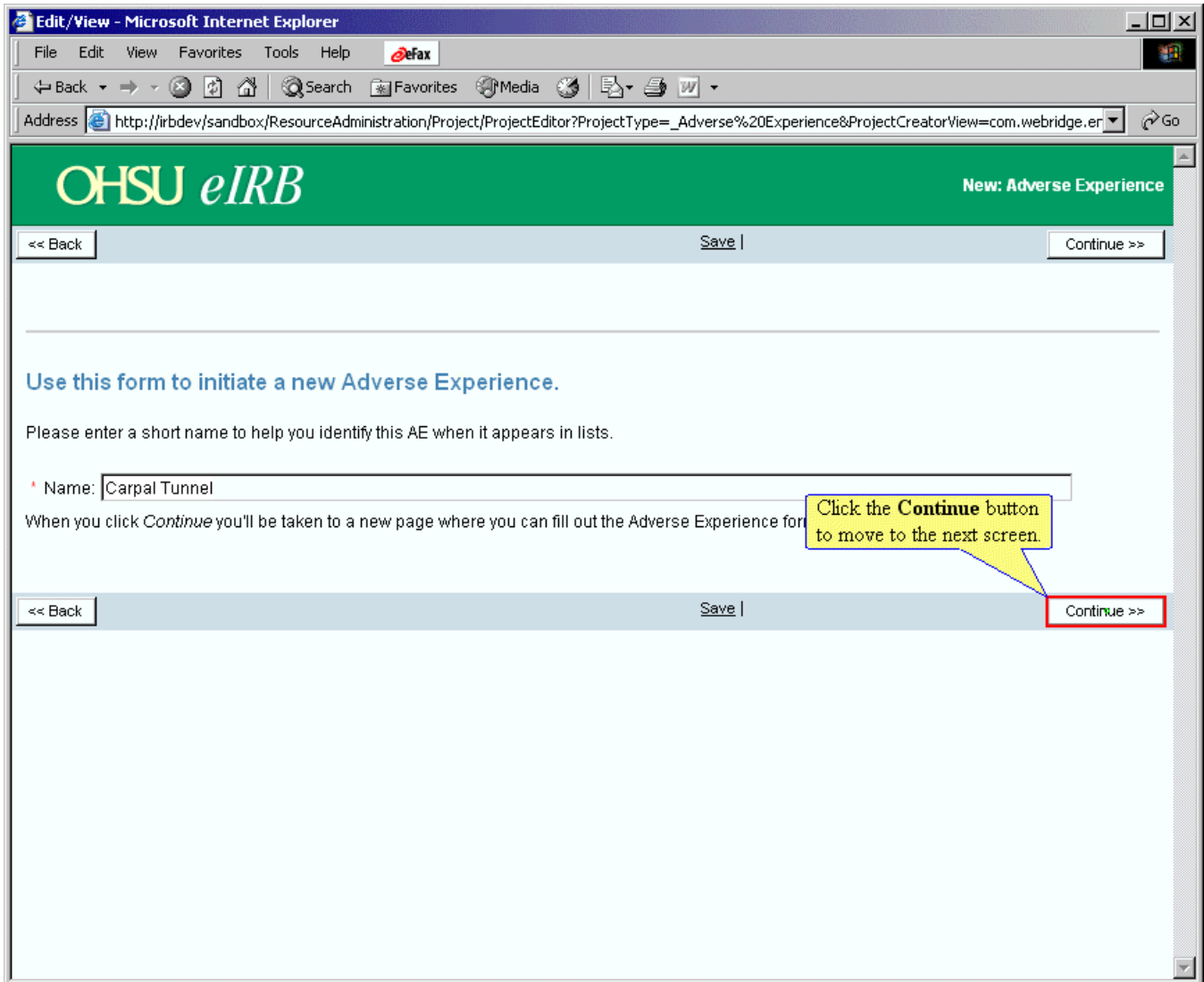
Notes:

Type in, Carpal Tunnel, for the name of the Adverse Experience.



Edit/View - Microsoft Internet Explorer

Step 4 - Click on



Notes:

Click the Continue button to move to the next screen.

OHSU eIRB**Edit/View - Microsoft Internet Explorer**Step 5 - Click on

The screenshot shows a Microsoft Internet Explorer browser window displaying the OHSU eIRB website. The browser's address bar shows the URL: [http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webbridge.entity.Entity\[OID\[87BDF77CD975F2\]](http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webbridge.entity.Entity[OID[87BDF77CD975F2]). The page title is "Edit: Adverse Experience - AE00000009".

The main content area is titled "Adverse Experience Form". It displays the following information:

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

The form contains several input fields and a help text area:

1. Experience Number: (This field is highlighted with a red box and a yellow callout box pointing to it with the text "Click in the Experience Number field to select it.")
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:

On the right side, there is a grey box labeled "HELP TEXT" containing the following text:

Over the life of this study.

Enrolled at all sites.

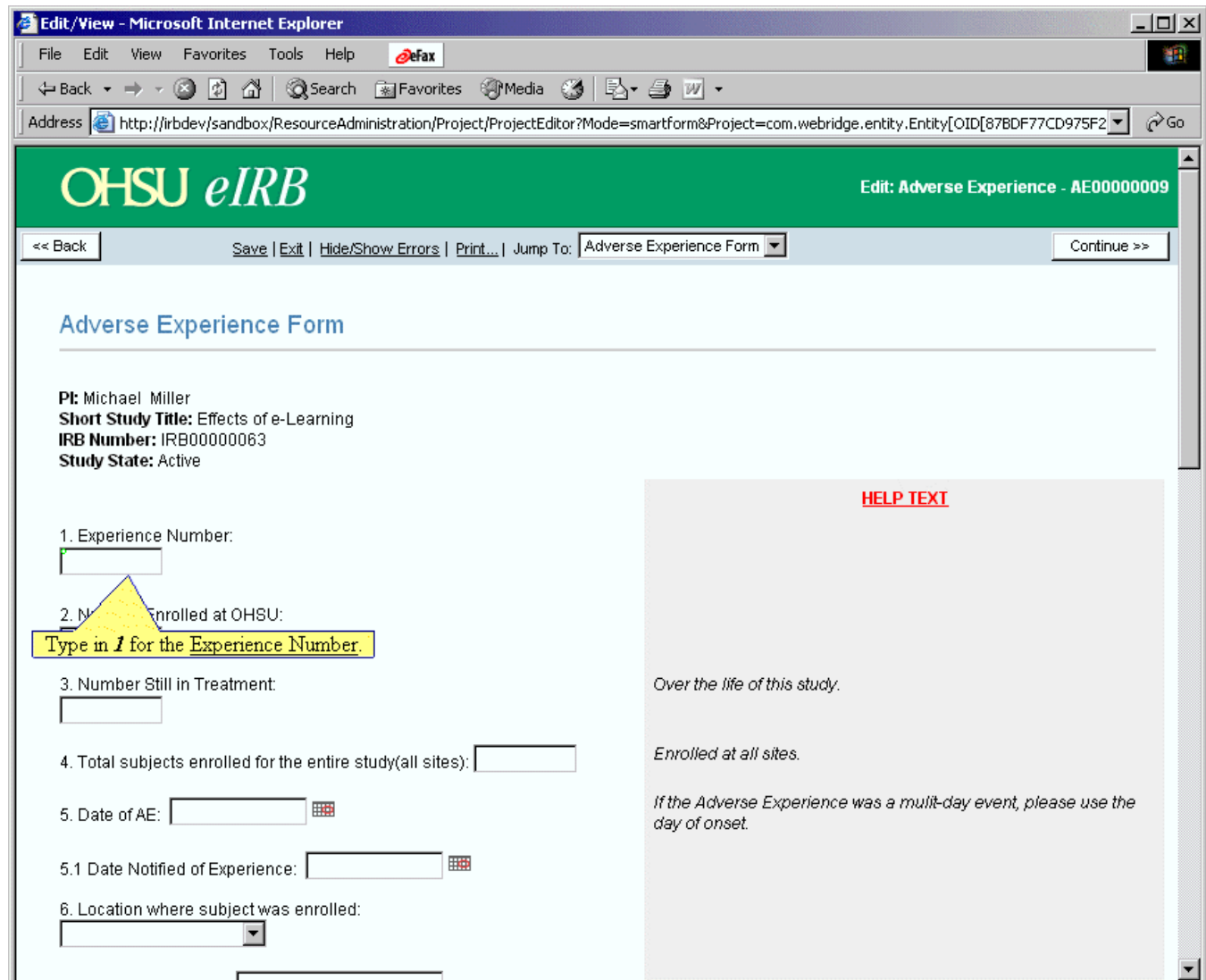
If the Adverse Experience was a multi-day event, please use the day of onset.

Notes:

Click in the Experience Number field to select it.

**Edit/View - Microsoft Internet Explorer**

Step 6 - Type key 1



The screenshot shows a Microsoft Internet Explorer browser window displaying the OHSU eIRB website. The browser's address bar shows the URL: `http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webbridge.entity.Entity[OID[87BDF77CD975F2]`. The page title is "Edit: Adverse Experience - AE0000009".

The main content area of the page is titled "Adverse Experience Form". It contains the following information:

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

The form includes several input fields and a help text area:

1. Experience Number:
2. Number enrolled at OHSU:
Type in 1 for the Experience Number.
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:

The help text area on the right contains the following text:

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.

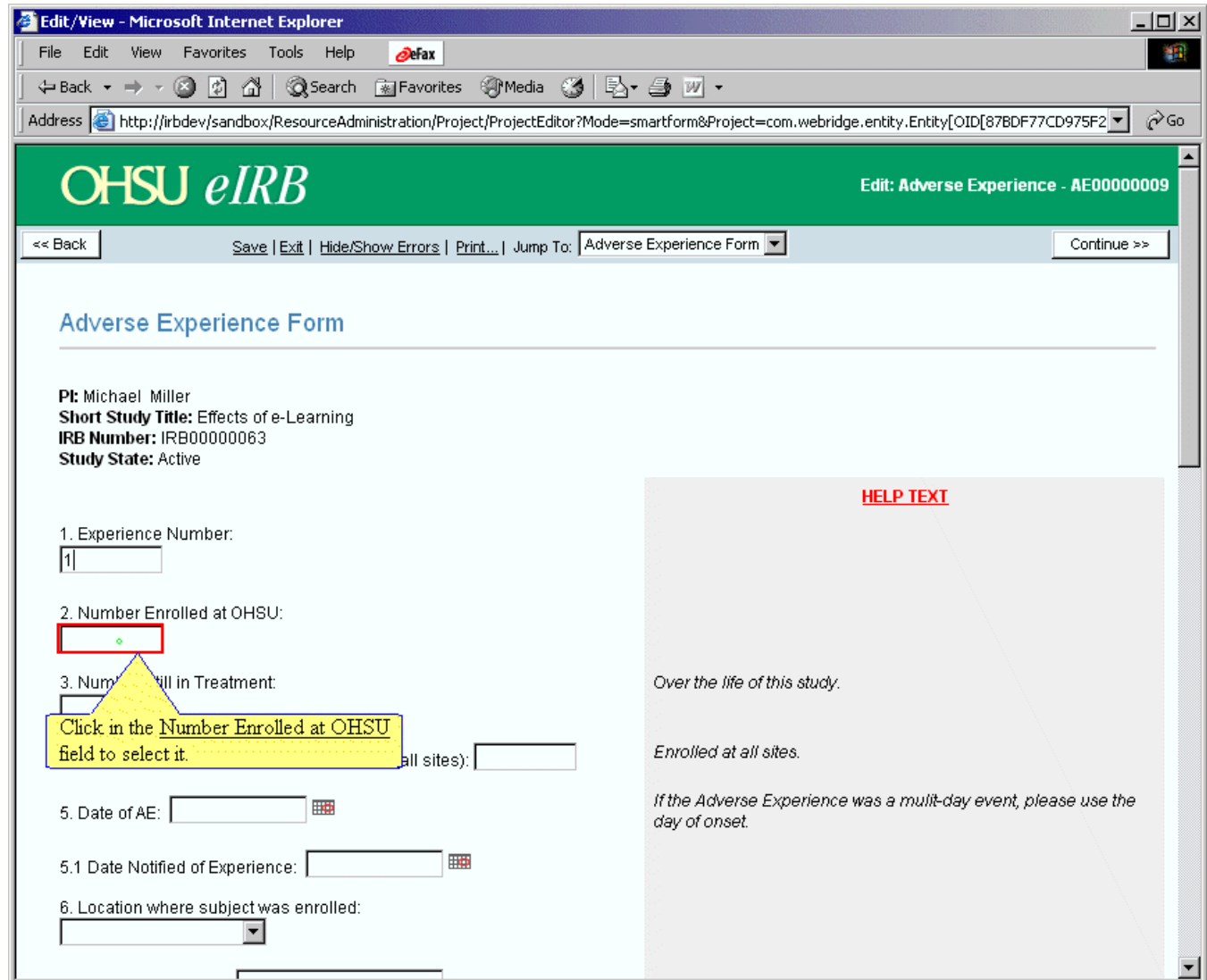
Notes:

Type in 1 for the Experience Number.



Edit/View - Microsoft Internet Explorer

Step 7 - Click on



The screenshot shows a Microsoft Internet Explorer browser window displaying the OHSU eIRB website. The browser's address bar shows the URL: `http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webbridge.entity.Entity[OID[87BDF77CD975F2]`. The page title is "Edit: Adverse Experience - AE0000009".

The main content area of the page is titled "Adverse Experience Form". It displays the following information:

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

The form contains several input fields and a help text area:

- Experience Number:
- Number Enrolled at OHSU: (This field is highlighted with a red box and a yellow callout box that says "Click in the Number Enrolled at OHSU field to select it.")
- Number still in Treatment:
- Date of AE:
- 5.1 Date Notified of Experience:
- Location where subject was enrolled:

On the right side of the form, there is a grey box labeled "HELP TEXT" containing the following instructions:

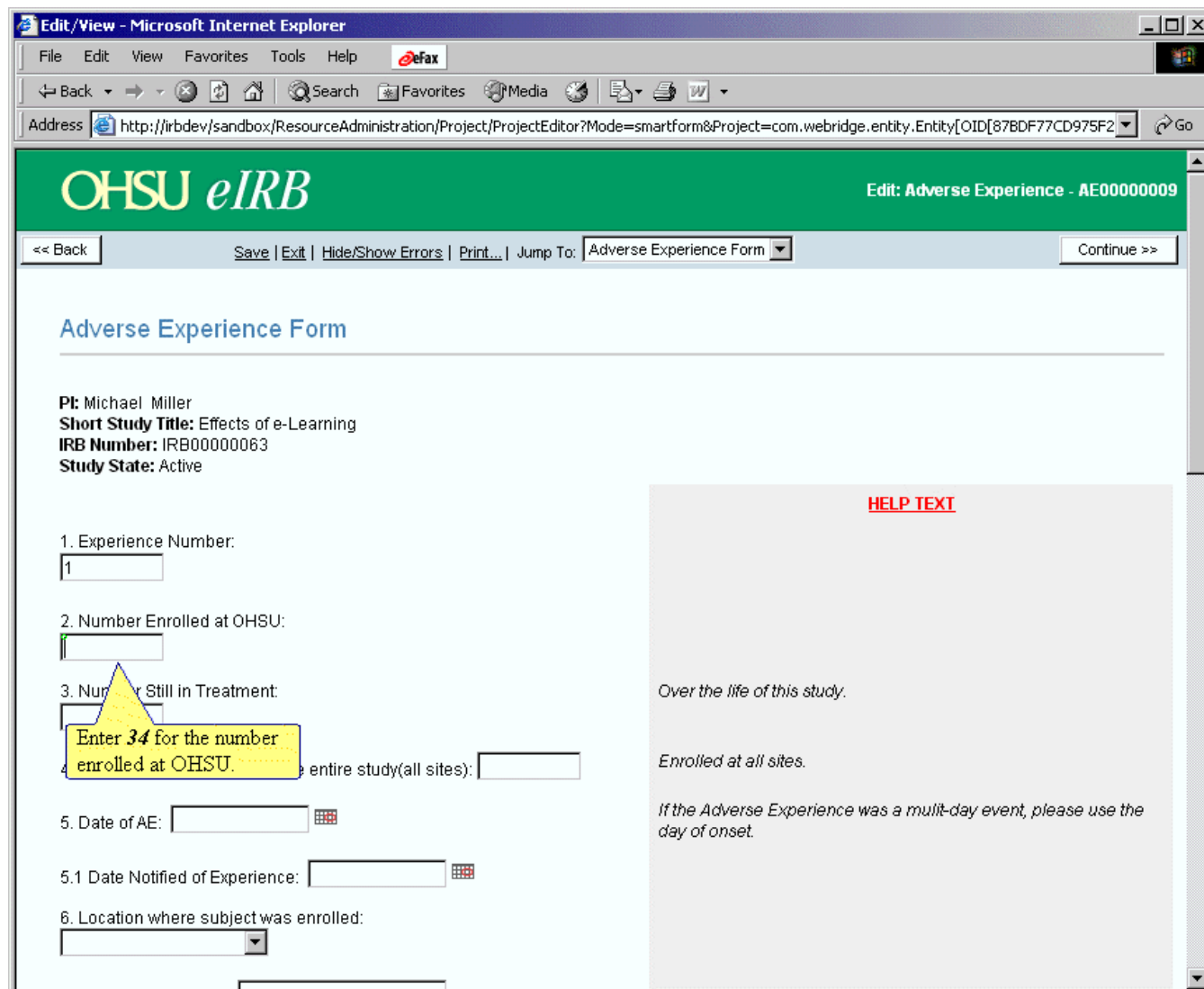
- Over the life of this study.*
- Enrolled at all sites.*
- If the Adverse Experience was a multi-day event, please use the day of onset.*

Notes:

Click in the Number Enrolled at OHSU field to select it.

**Edit/View - Microsoft Internet Explorer**

Step 8 - Type "34" in edit box



The screenshot shows a Microsoft Internet Explorer browser window displaying the OHSU eIRB website. The browser's address bar shows the URL: `http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webbridge.entity.Entity[OID[87BDF77CD975F2]`. The page title is "Edit: Adverse Experience - AE0000009".

The main content area is titled "Adverse Experience Form". It displays the following information:

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

The form contains several input fields:

1. Experience Number:
2. Number Enrolled at OHSU:
3. Number Still in Treatment:
4. Number enrolled at OHSU for entire study(all sites):
5. Date of AE:
- 5.1 Date Notified of Experience:
6. Location where subject was enrolled:

A yellow callout box points to the input field for "Number Enrolled at OHSU" (field 2) with the text: "Enter 34 for the number enrolled at OHSU."

On the right side of the form, there is a grey box labeled "HELP TEXT" containing the following instructions:

- 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.*

Notes:

Enter 34 for the number enrolled at OHSU.

OHSU eIRB**Edit/View - Microsoft Internet Explorer**Step 9 - Click on

The screenshot shows a Microsoft Internet Explorer browser window displaying the OHSU eIRB website. The browser's address bar shows the URL: [http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity\[OID\[87BDF77CD975F2\]](http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity[OID[87BDF77CD975F2]). The page title is "Edit: Adverse Experience - AE00000009".

The main content area is titled "Adverse Experience Form". It displays the following information:

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

The form contains several input fields:

1. Experience Number:
2. Number Enrolled at OHSU:
3. Number Still in Treatment: (This field is highlighted with a red box and a yellow callout box that says "Click in the Number Still in Treatment field to select it.")
4. Total subjects enrolled for the entire study(all sites):
- 5.1 Date Notified of Experience:
6. Location where subject was enrolled:

On the right side of the form, there is a section titled "HELP TEXT" with the following 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.

Notes:

Click in the Number Still in Treatment field to select it.

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

Step 10 - Type "34" in edit box

The screenshot shows a Microsoft Internet Explorer browser window displaying the OHSU eIRB website. The browser's address bar shows the URL: `http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webbridge.entity.Entity[OID[87BDF77CD975F2]`. The page title is "Edit: Adverse Experience - AE00000009".

The main content area is titled "Adverse Experience Form". It displays the following information:

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

The form contains several input fields:

- 1. Experience Number:
- 2. Number Enrolled at OHSU:
- 3. Number Still in Treatment:
- 4. Number of people enrolled at all sites:
- 5. Date of AE:
- 5.1 Date Notified of Experience:
- 6. Location where subject was enrolled:

A yellow callout box points to the "Number Still in Treatment" field with the text: "Type in 34 for the number of people still in treatment." A red "HELP TEXT" box on the right side of the form contains the following text:

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.

Notes:

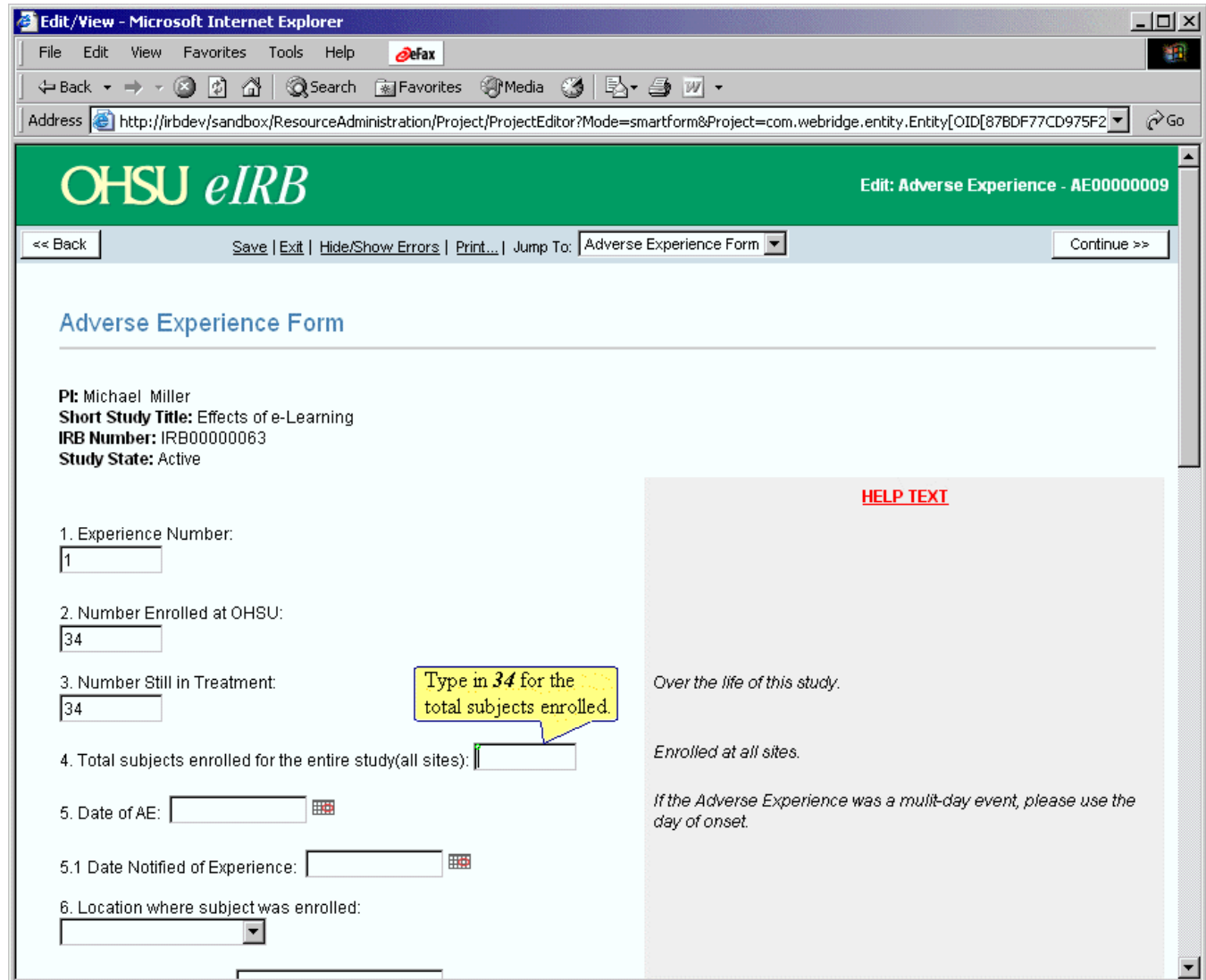
Type in 34 for the number of people still in treatment.

OHSU eIRB**Edit/View - Microsoft Internet Explorer**Step 11 - Click on **Notes:**

Click in the Total subjects enrolled field to select it.

**Edit/View - Microsoft Internet Explorer**

Step 12 - Type "34" in edit box



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: IRB00000063
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.

Type in 34 for the total subjects enrolled.

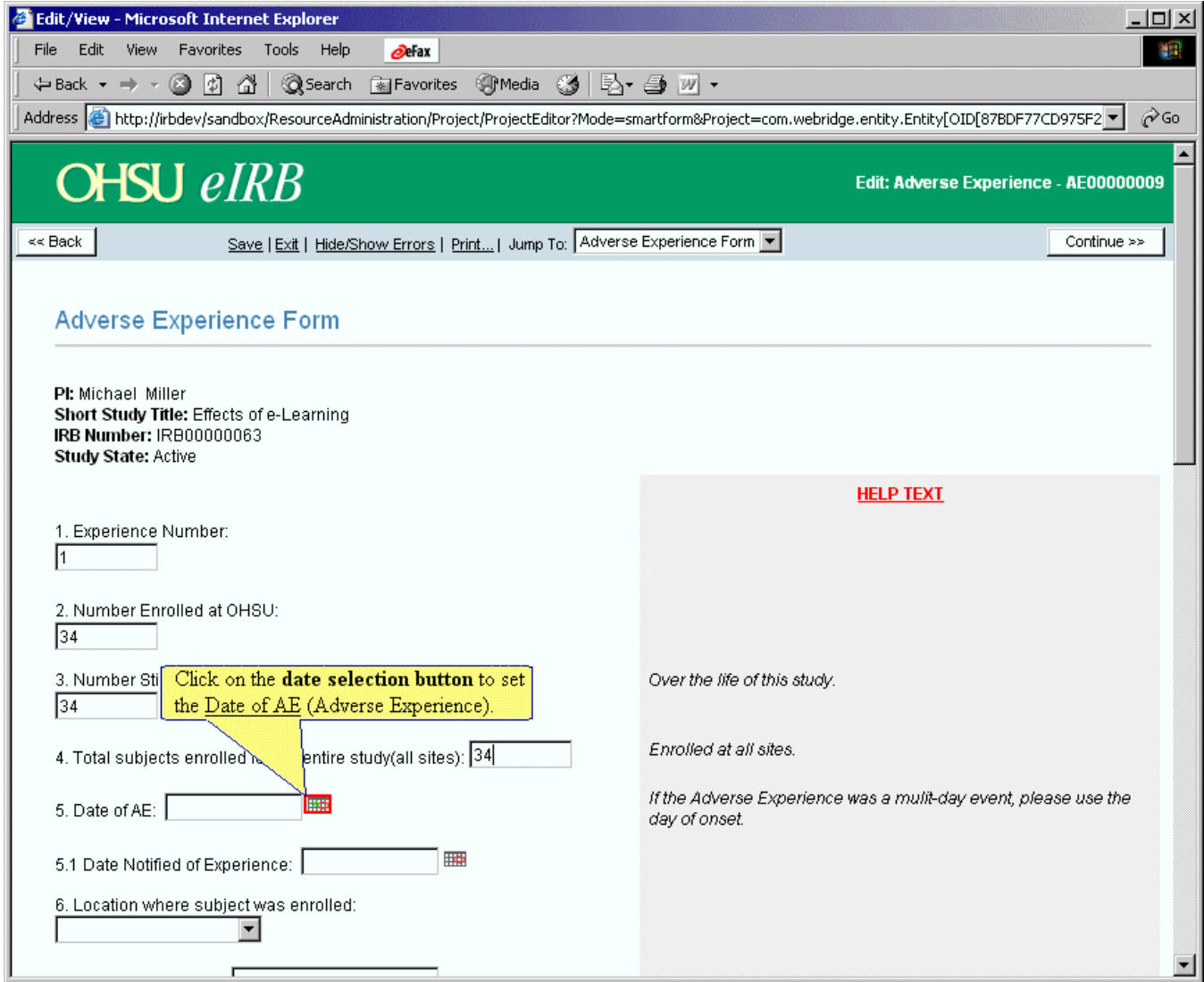
Notes:

Type in 34 for the total subjects enrolled.



Edit/View - Microsoft Internet Explorer

Step 13 - Click on 



Notes:

Click on the date selection button to set the Date of AE (Adverse Experience).



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

Step 14 - Click on

The screenshot shows a Microsoft Internet Explorer window displaying a web form for editing an adverse experience. A calendar pop-up is open, showing the month of June 2004. The date June 2nd is highlighted with a red box, and a yellow callout bubble points to it with the text "Select the button for June second." The background form includes the following fields:

- 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:

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

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.

Notes:

Select the button for June second.



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

Step 15 - Click on

The screenshot shows a Microsoft Internet Explorer window displaying a web form titled "Edit: Adverse Experience - AE00000009". A calendar pop-up is overlaid on the form, showing the month of June 2004. The date June 2nd is highlighted in the calendar. Below the calendar, there are "OK" and "Cancel" buttons. A yellow callout box with a blue arrow points to the "OK" button, containing the text "Click OK to confirm your choice." The background form includes a header with the OHSU logo and the title "Edit: Adverse Experience - AE00000009". Below the header, there is a "Continue >>" button. The main content area of the form contains the following information:

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:

On the right side of the form, there is a grey box labeled "HELP TEXT" containing the following 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.

Notes:

Click OK to confirm your choice.

OHSU eIRB**Edit/View - Microsoft Internet Explorer**Step 16 - Click on

The screenshot shows a Microsoft Internet Explorer browser window displaying the OHSU eIRB website. The browser's address bar shows the URL: `http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity[OID[87BDF77CD975F2]`. The page title is "Edit: Adverse Experience - AE0000009".

The main content area is titled "Adverse Experience Form". It displays the following information:

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

The form contains several input fields:

1. Experience Number:
2. Number Enrolled at OHSU:
3. Number Still in Treatment:
4. Total subjects enrolled for the entire study:
5. Date of AE:
- 5.1 Date Notified of Experience:
6. Location where subject was enrolled:

A yellow callout box points to the "5.1 Date Notified of Experience" field with the text: "Click in the Date Notified of Experience field to select it." A red box highlights the "5.1 Date Notified of Experience" field.

On the right side of the form, there is a grey box labeled "HELP TEXT" containing the following 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.

Notes:

Click in the Date Notified of Experience field to select it.

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

Step 17 - Type "6/4/2004" in edit box

OHSU eIRB Edit: Adverse Experience - AE0000009

<< 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: IRB00000063
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.

Type 6/4/2004 in the date field.

Notes:

Type 6/4/2004 in the date field.

OHSU eIRB**Edit/View - Microsoft Internet Explorer**Step 18 - 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.

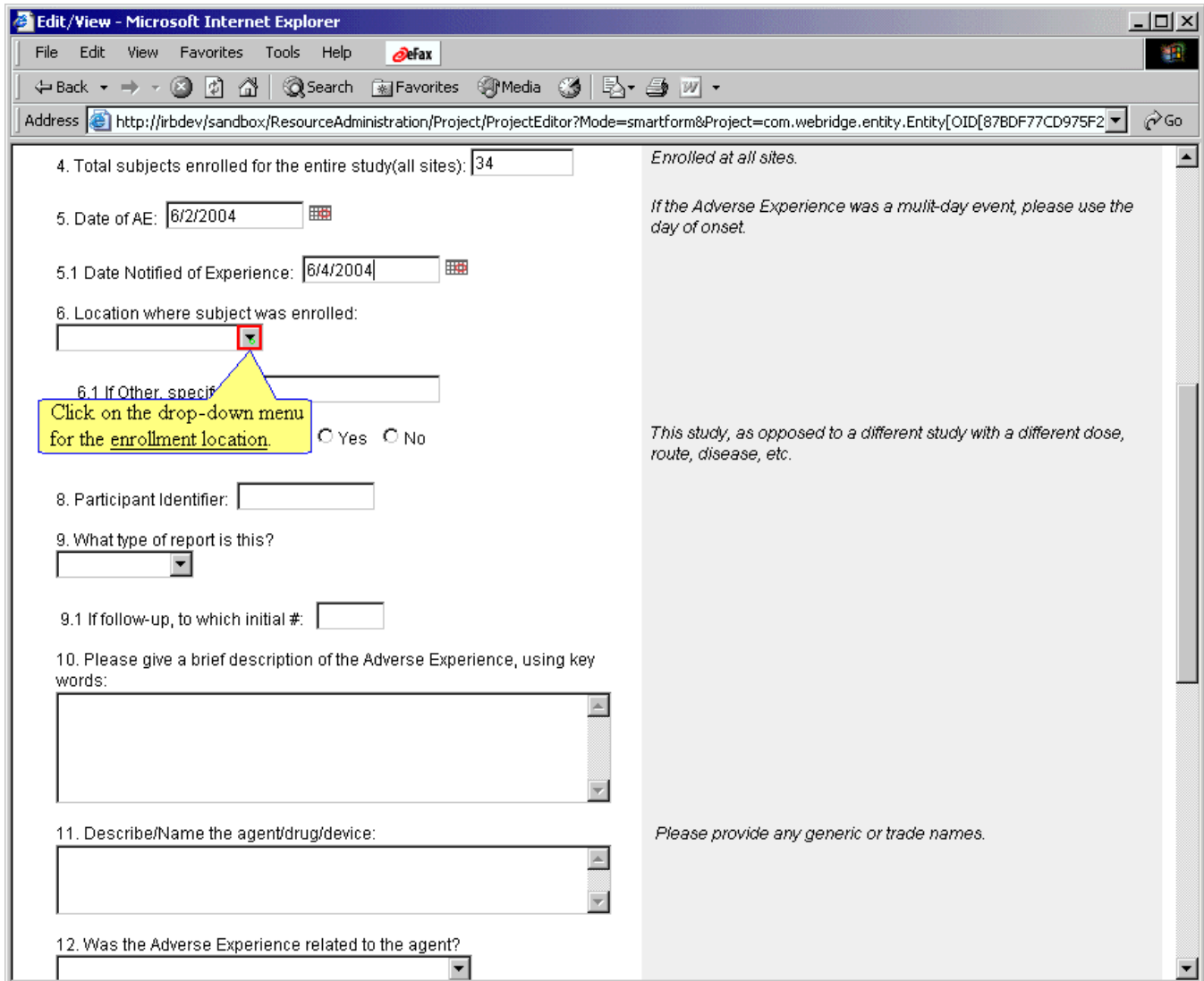
Enrolled at all sites.

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

Scroll down to display more of the page.

Notes:

Scroll down to display more of the page.

Edit/View - Microsoft Internet ExplorerStep 19 - Click on 

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:

6.1 If Other, specify:
 Yes No

8. Participant Identifier:

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the agent?

Enrolled at all sites.

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

This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

Notes:

Click on the drop-down menu for the enrollment location.



Step 20 - Select list box item **OHSU**

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:

7. Was subject on this study? Yes No

8. *Select OHSU for the enrollment location.*

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the agent?

Enrolled at all sites.

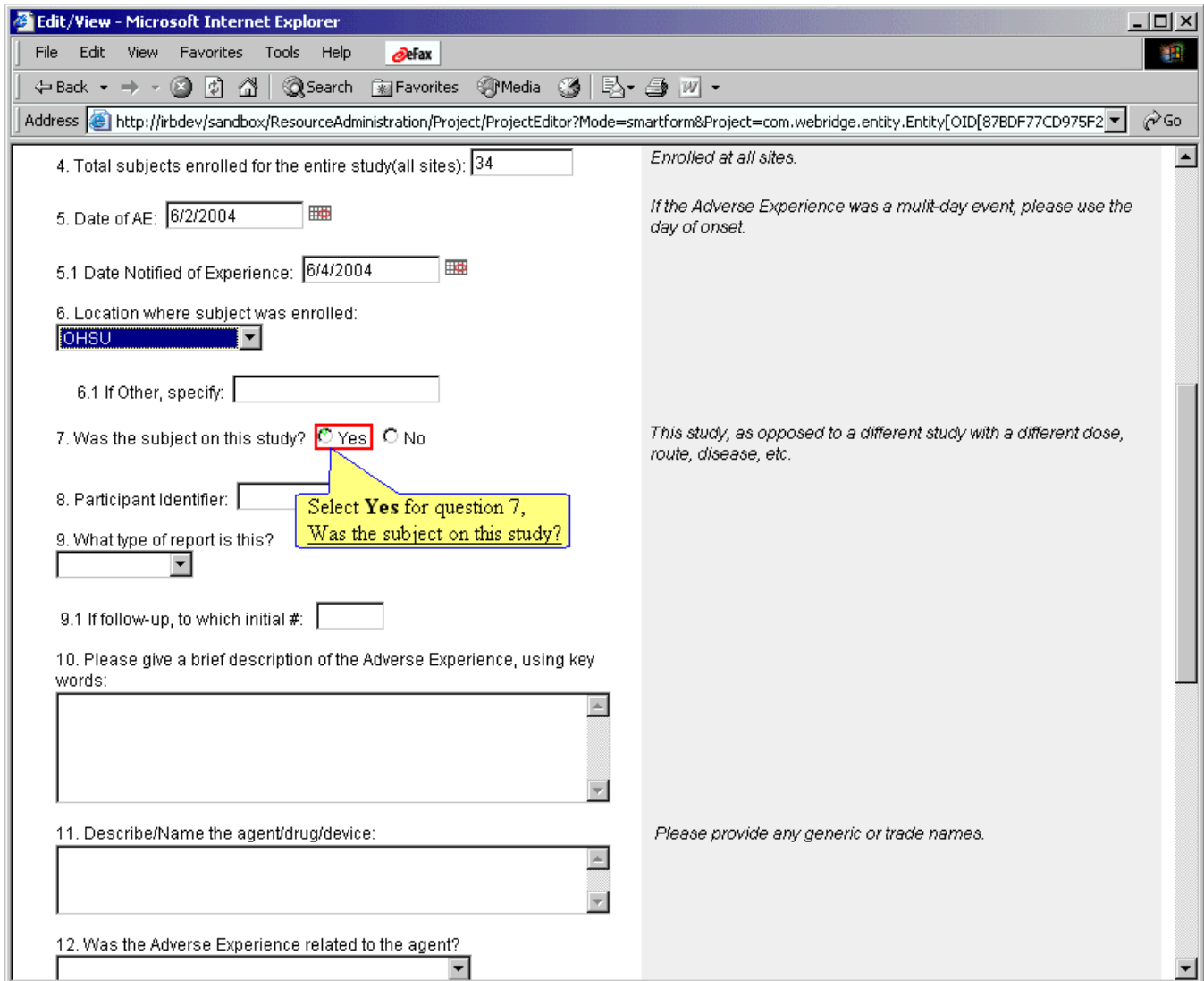
If the Adverse Experience was a multi-day event, please use the day of onset.

This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

Notes:

Select OHSU for the enrollment location.

Edit/View - Microsoft Internet ExplorerStep 21 - Click on Yes

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:

6.1 If Other, specify:

7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the agent?

Enrolled at all sites.

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

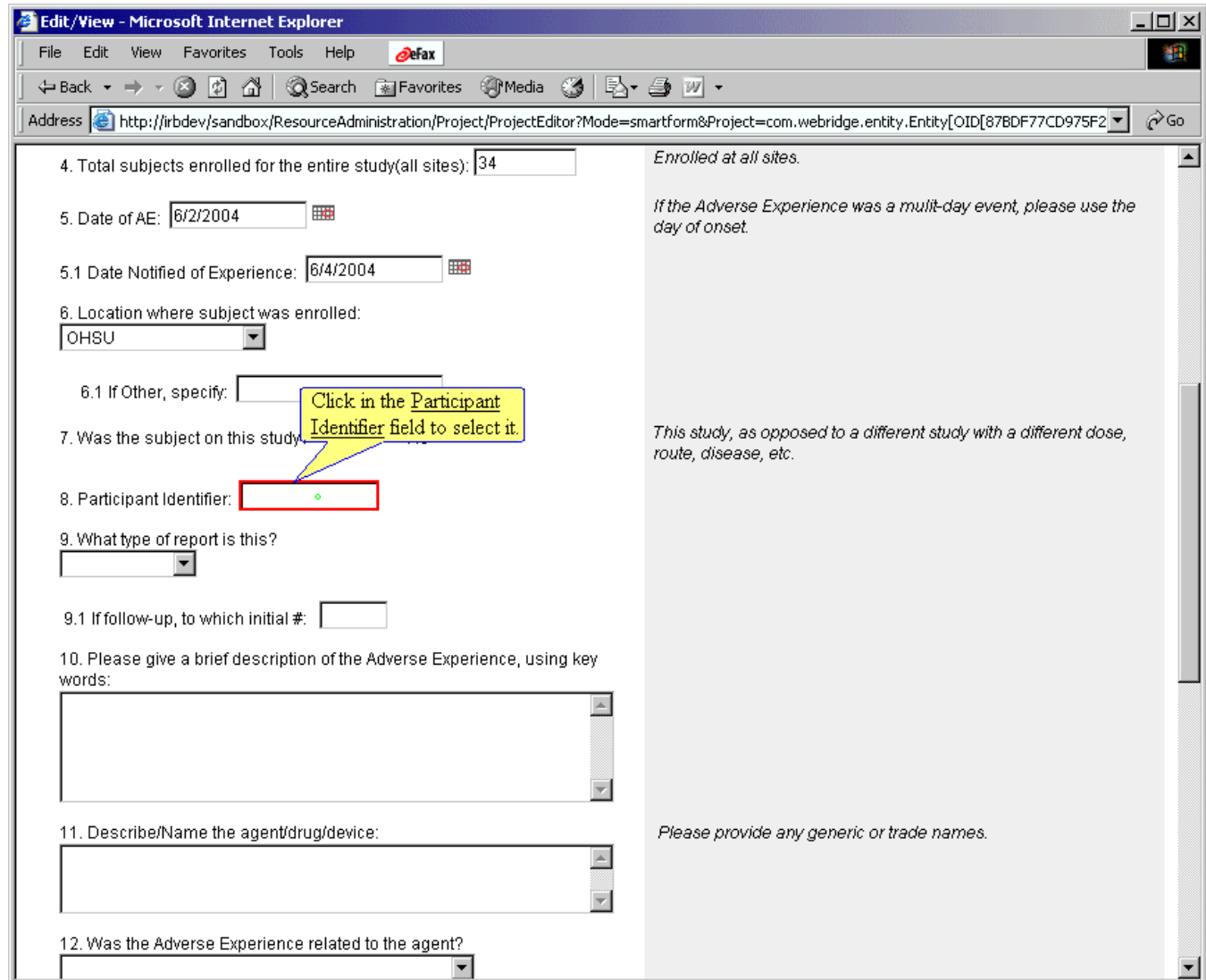
This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

Select Yes for question 7, Was the subject on this study?

Notes:

Select Yes for question 7, Was the subject on this study?

Edit/View - Microsoft Internet ExplorerStep 22 - Click on 

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

5. Date of AE: *If the Adverse Experience was a multi-day event, please use the day of onset.*

5.1 Date Notified of Experience:

6. Location where subject was enrolled:

6.1 If Other, specify:

7. Was the subject on this study?

8. Participant Identifier: *This study, as opposed to a different study with a different dose, route, disease, etc.*

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the agent?

Please provide any generic or trade names.

Notes:

Click in the Participant Identifier field to select it.



Edit/View - Microsoft Internet Explorer

Step 23 - Type "12345" in edit box

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:

6.1 If Other, specify:

7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the agent?

Enrolled at all sites.

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

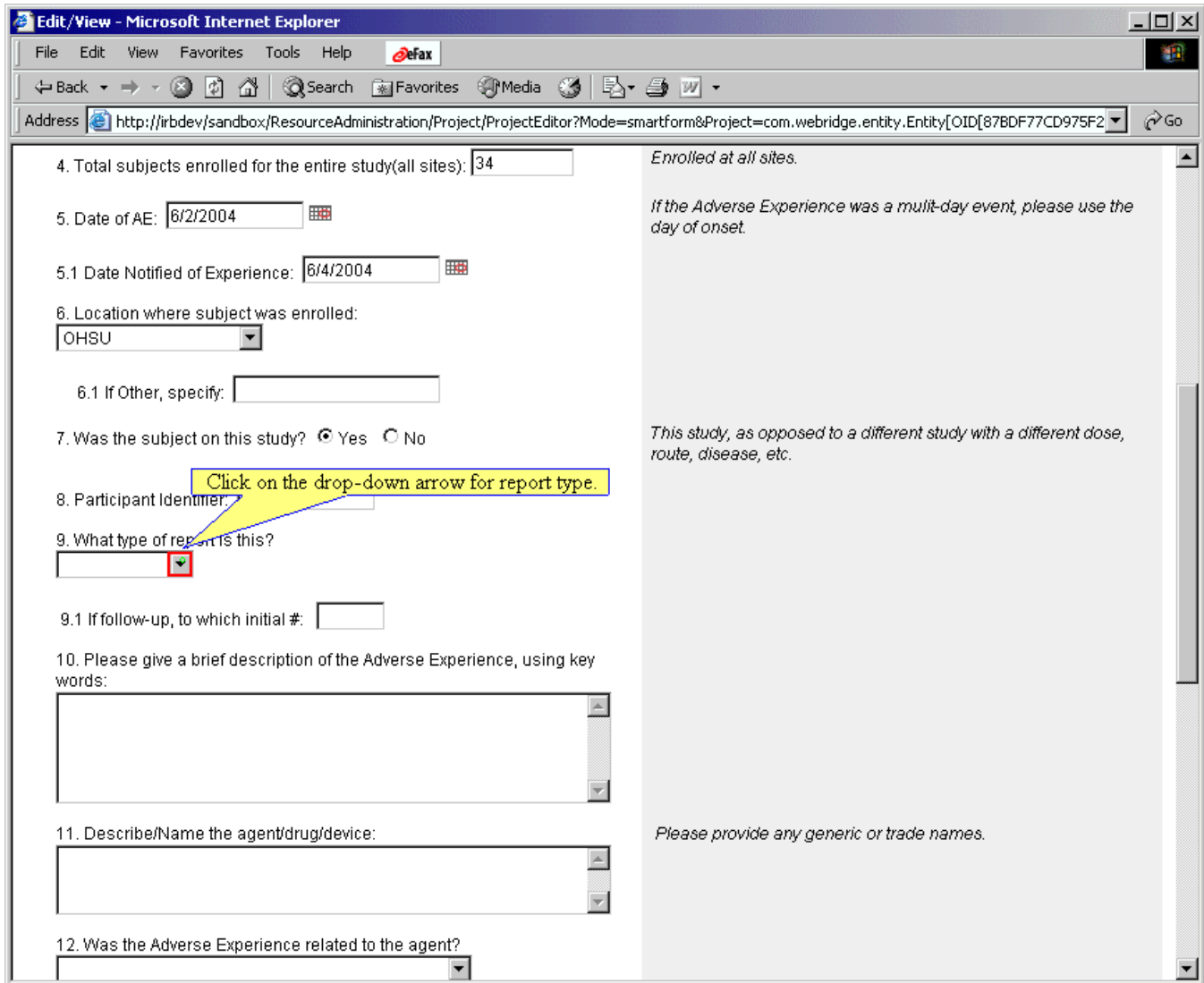
This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

Type, 12345, for the Participant Identifier.

Notes:

Type, 12345, for the Participant Identifier.

Edit/View - Microsoft Internet ExplorerStep 24 - Click on 

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:

6.1 If Other, specify:

7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the agent?

Enrolled at all sites.

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

This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

Click on the drop-down arrow for report type.

Notes:

Click on the drop-down arrow for report type.



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

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:

6.1 If Other, specify:

7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this?
 which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the agent?

Enrolled at all sites.

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

This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

Notes:

Select Initial, as the report type.



Edit/View - Microsoft Internet Explorer

Step 26 - Click on

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:

6.1 If Other, specify:

7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this?

9.1 If follow- **Click in the brief description field to select it.**

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the agent?

Enrolled at all sites.

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

This study, as opposed to a different study with a different dose, route, disease, etc.

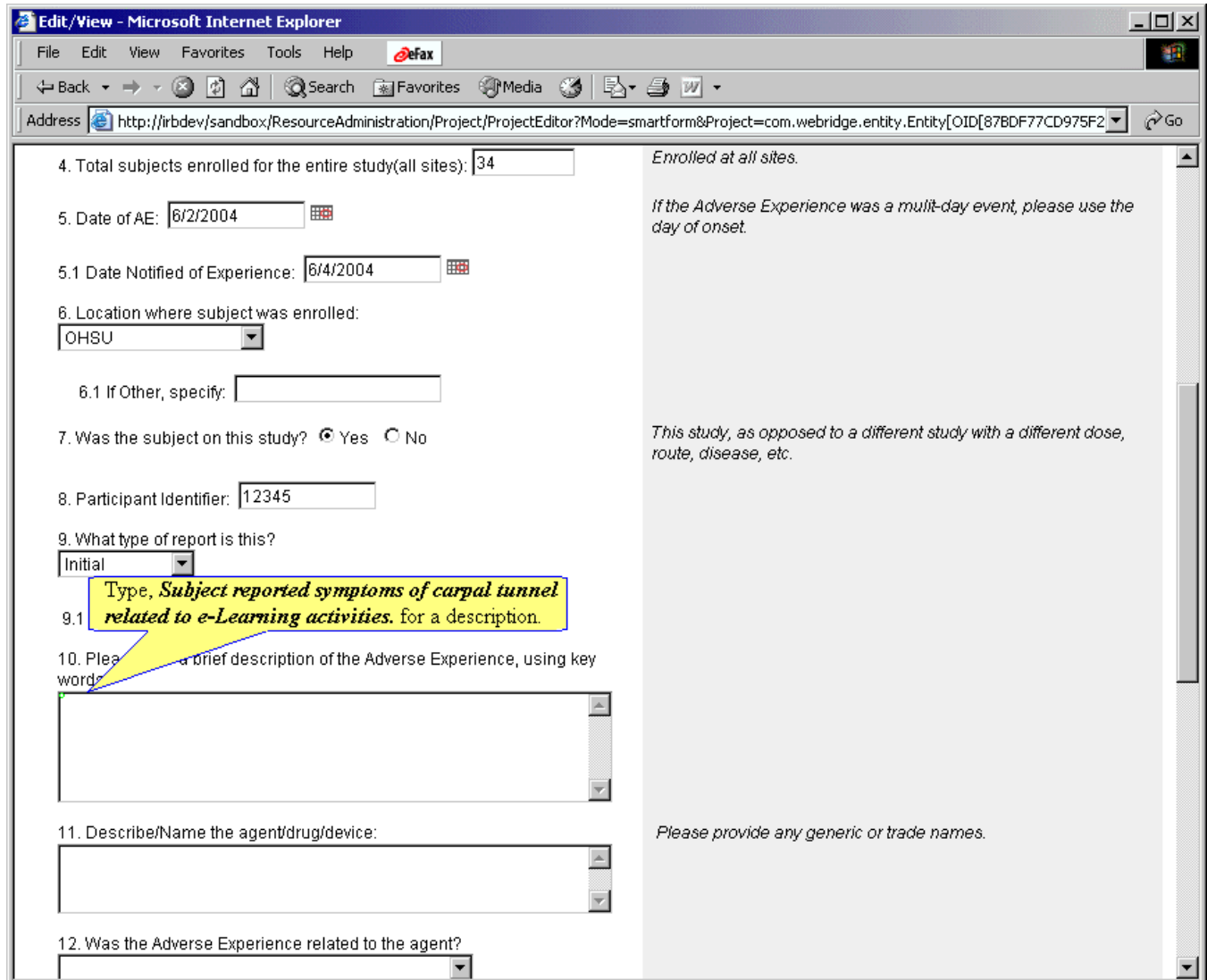
Please provide any generic or trade names.

Notes:

Click in the brief description field to select it.

Edit/View - Microsoft Internet Explorer

Step 27 - Type "Subject reported symptoms of carpal tunnel related to e-Learning activities." in edit box



4. Total subjects enrolled for the entire study(all sites): 34

5. Date of AE: 6/2/2004

5.1 Date Notified of Experience: 6/4/2004

6. Location where subject was enrolled:
OHSU

6.1 If Other, specify:

7. Was the subject on this study? Yes No

8. Participant Identifier: 12345

9. What type of report is this?
Initial

9.1 Type, Subject reported symptoms of carpal tunnel related to e-Learning activities. for a description.

10. Please provide a brief description of the Adverse Experience, using key words

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the agent?

Enrolled at all sites.

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

This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

Notes:

Type, Subject reported symptoms of carpal tunnel related to e-Learning activities. for a description.



Edit/View - Microsoft Internet Explorer

Step 28 - Click on

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:

6.1 If Other, specify:

7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the agent?

Enrolled at all sites.

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

This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

Click the scroll down arrow to display more of the current screen.

Notes:

Click the scroll down arrow to display more of the current screen.



Edit/View - Microsoft Internet Explorer

Step 29 - Click on

7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

Click in the agent, drug or device description field to select it.

11. Describe/Name the agent/drug/device:

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:

This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

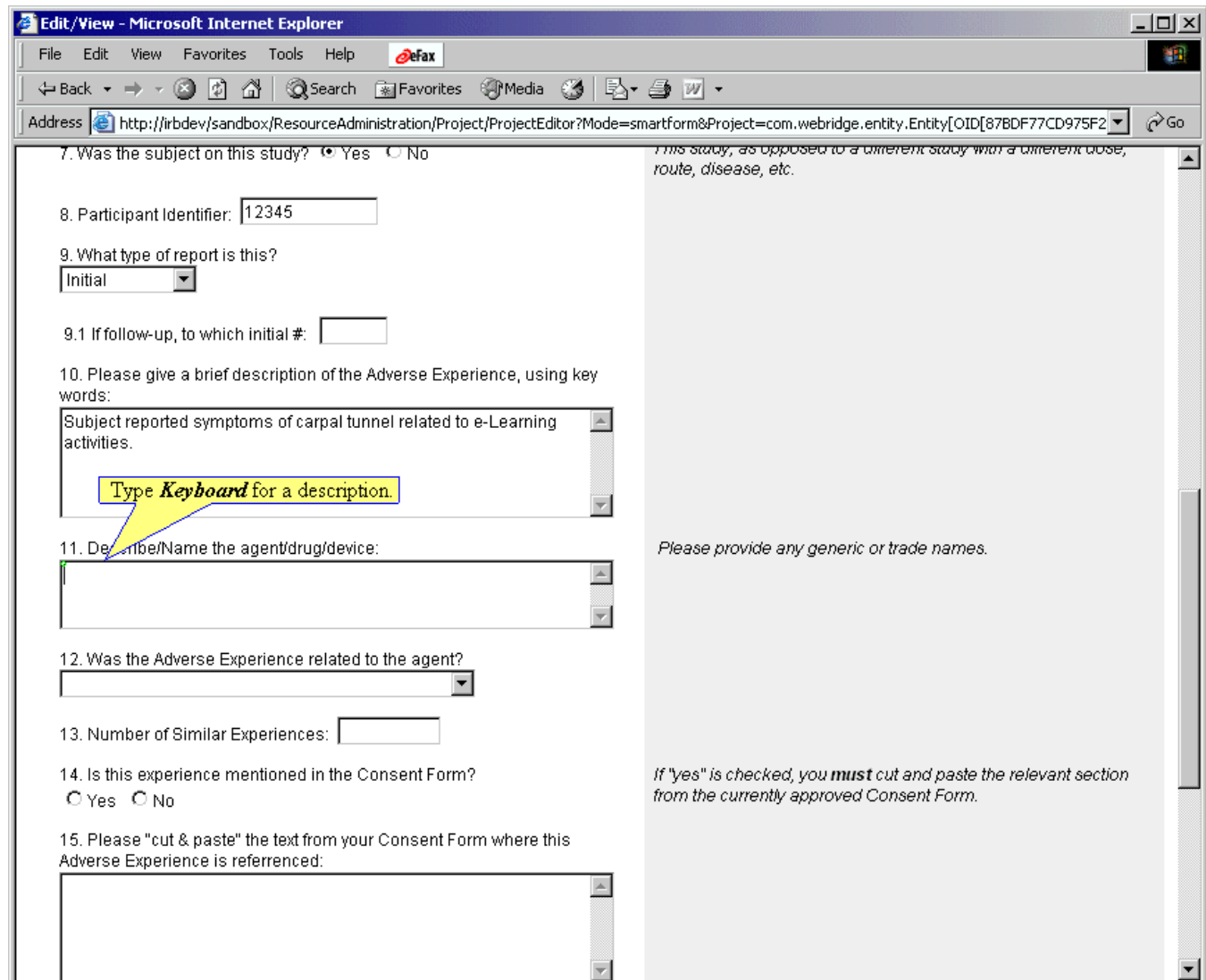
*If "yes" is checked, you **must** cut and paste the relevant section from the currently approved Consent Form.*

Notes:

Click in the agent, drug or device description field to select it.

Edit/View - Microsoft Internet Explorer

Step 30 - Type "Keyboard" in edit box



7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

Type *Keyboard* for a description.

11. Describe/Name the agent/drug/device:

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:

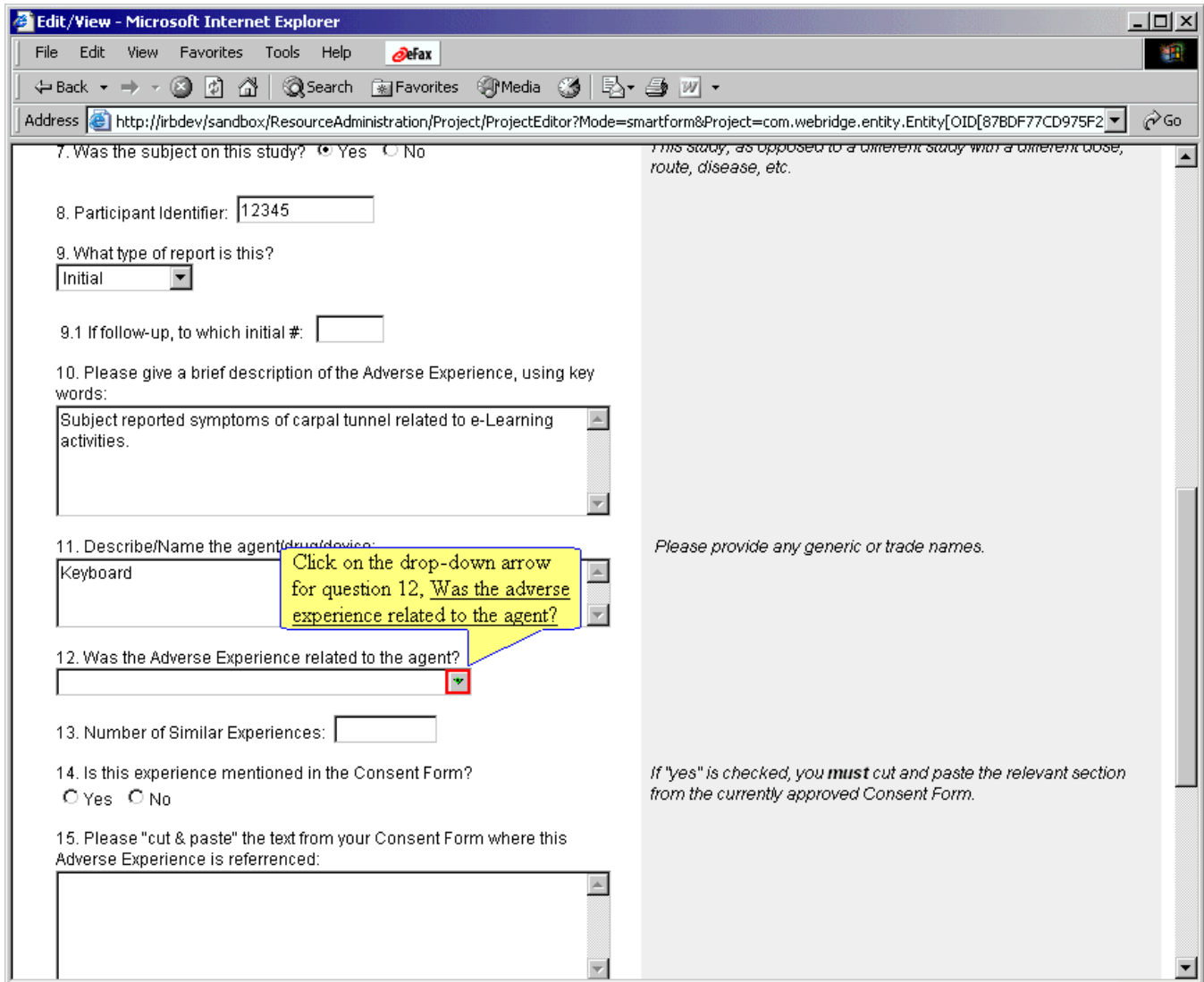
This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

*If "yes" is checked, you **must** cut and paste the relevant section from the currently approved Consent Form.*

Notes:

Type Keyboard for a description.

Edit/View - Microsoft Internet ExplorerStep 31 - Click on 

7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

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:

This study, as opposed to a different study with a different dose, route, disease, etc.

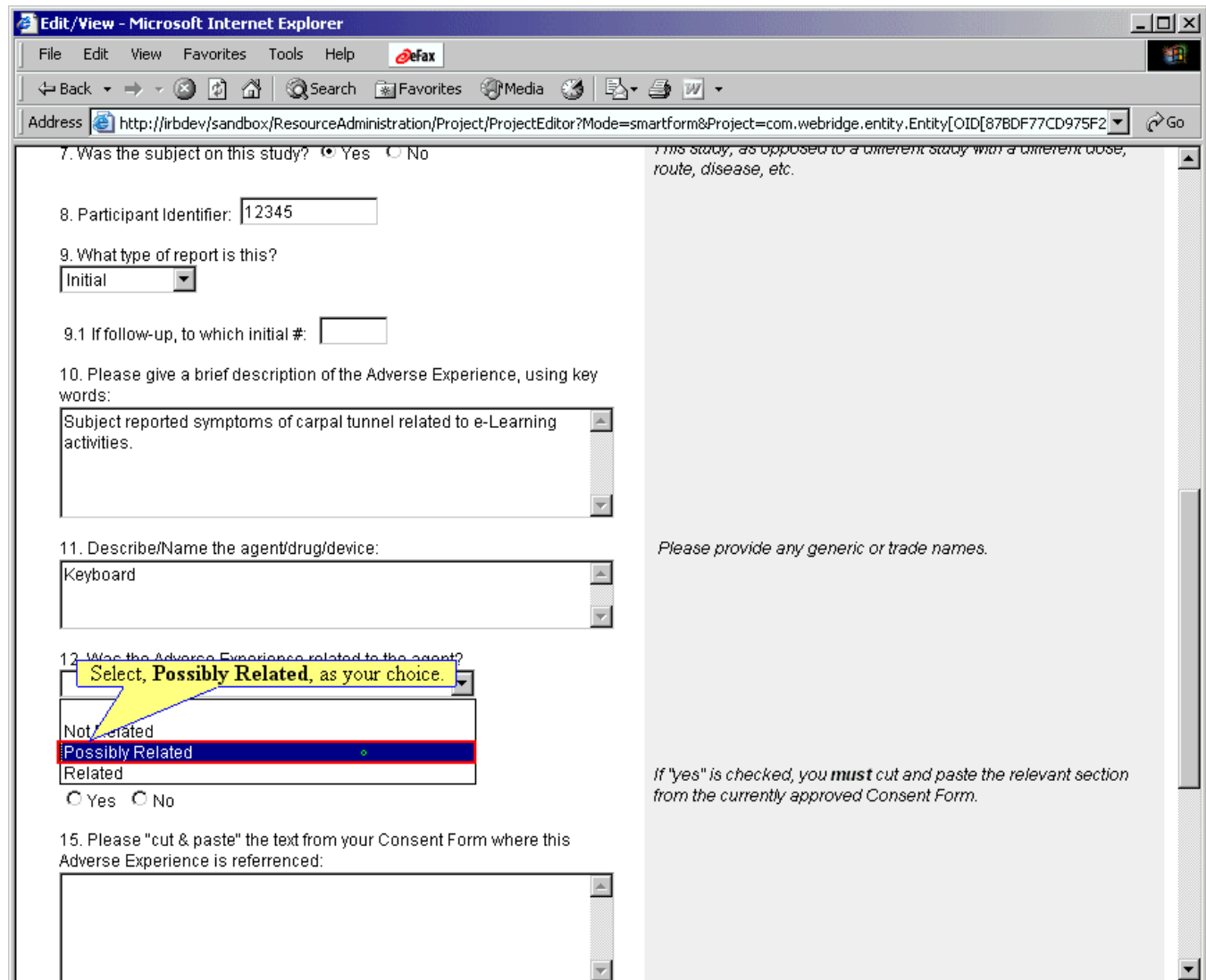
Please provide any generic or trade names.

*If "yes" is checked, you **must** cut and paste the relevant section from the currently approved Consent Form.*

Notes:

Click on the drop-down arrow for question 12, Was the adverse experience related to the agent?

Step 32 - Select list box item



7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the agent?
Select, Possibly Related, as your choice.

Yes No

15. Please "cut & paste" the text from your Consent Form where this Adverse Experience is referenced:

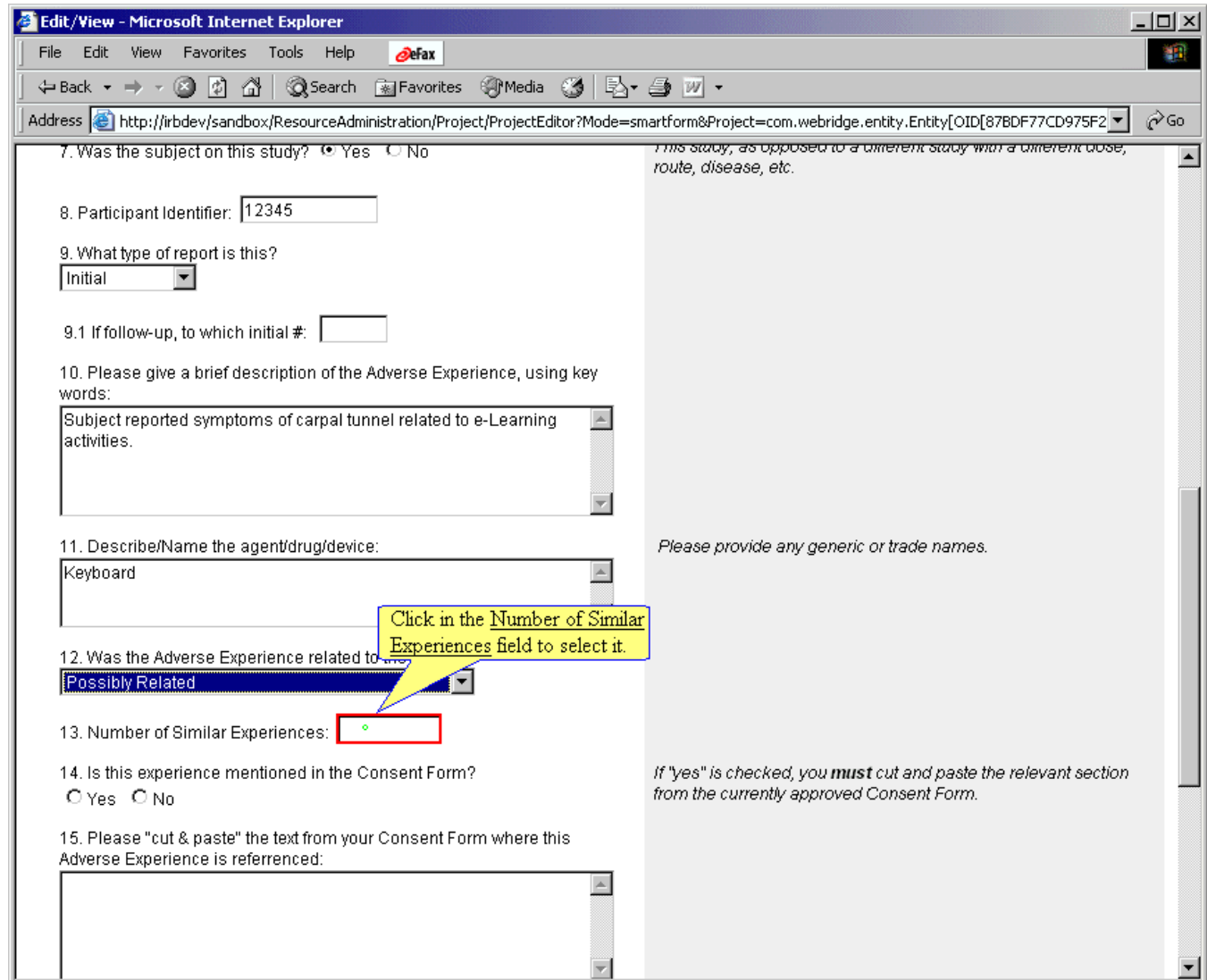
This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

*If "yes" is checked, you **must** cut and paste the relevant section from the currently approved Consent Form.*

Notes:

Select, Possibly Related, as your choice.

Edit/View - Microsoft Internet ExplorerStep 33 - Click on 

7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the study?

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:

This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

*If "yes" is checked, you **must** cut and paste the relevant section from the currently approved Consent Form.*

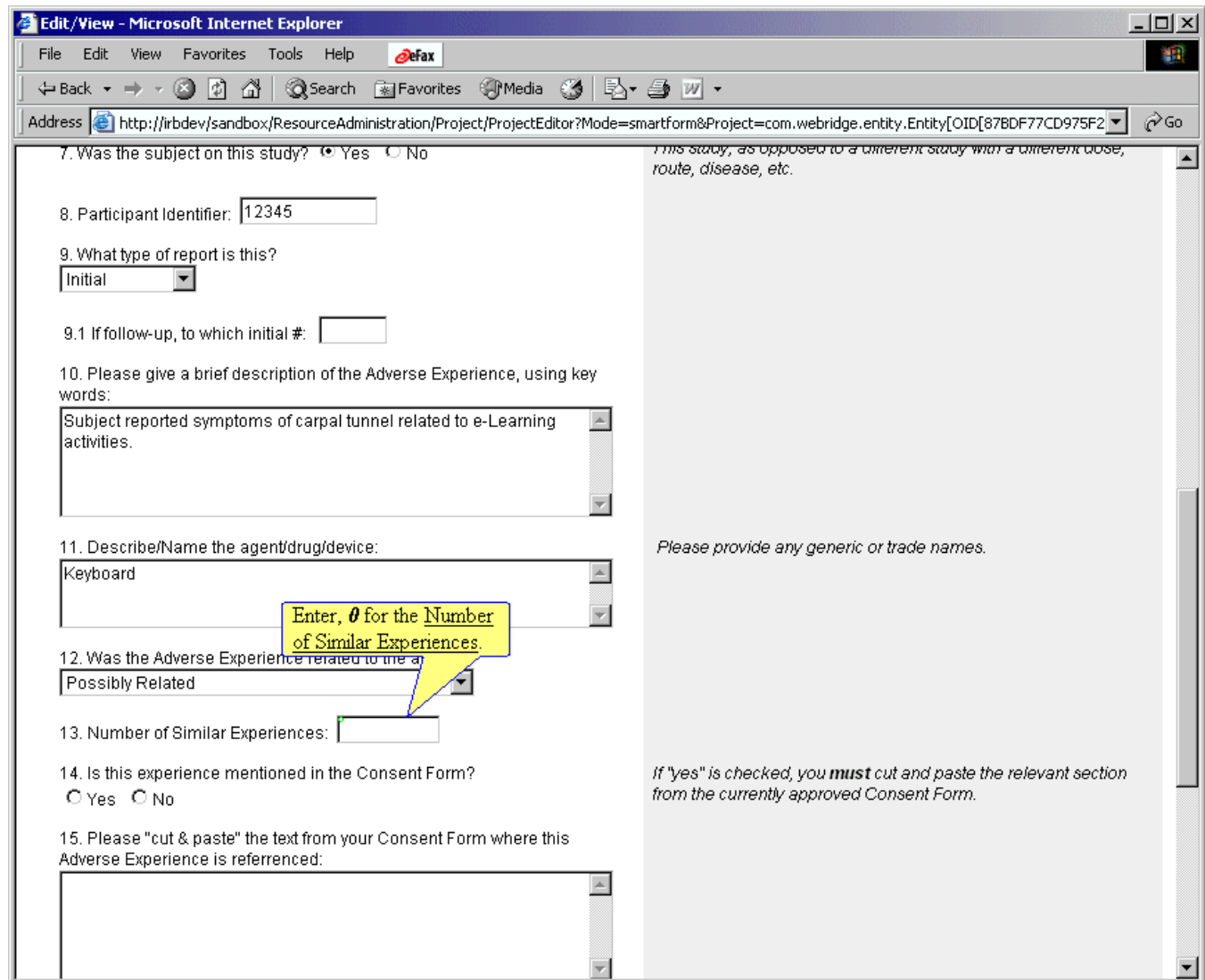
Click in the Number of Similar Experiences field to select it.

Notes:

Click in the Number of Similar Experiences field to select it.

Edit/View - Microsoft Internet Explorer

Step 34 - Type key 0



7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

12. Was the Adverse Experience related to the a

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:

This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

*If "yes" is checked, you **must** cut and paste the relevant section from the currently approved Consent Form.*

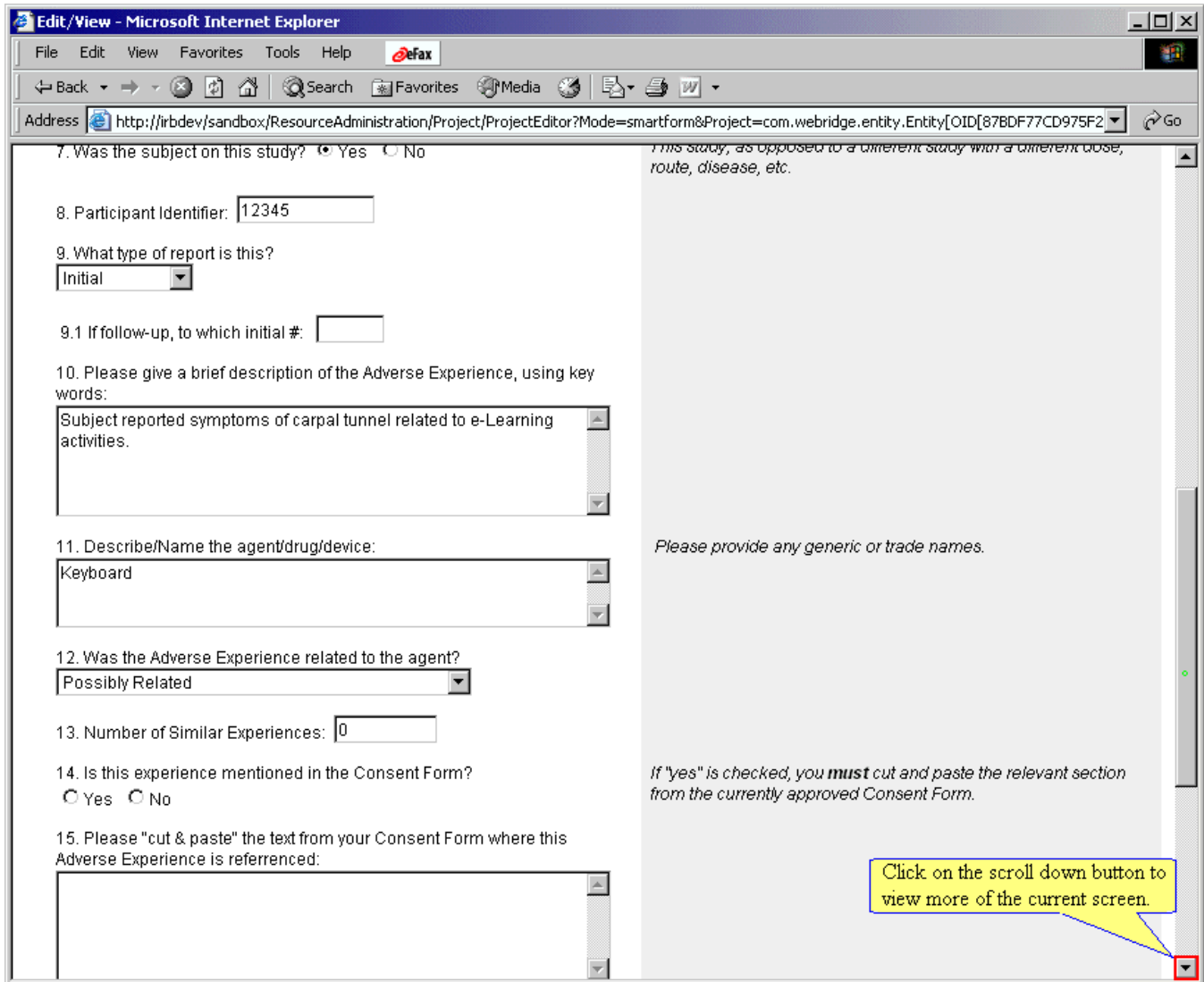
Enter, 0 for the Number of Similar Experiences.

Notes:

Enter, 0 for the Number of Similar Experiences.

Edit/View - Microsoft Internet Explorer

Step 35 - Click on 



7. Was the subject on this study? Yes No

8. Participant Identifier:

9. What type of report is this?

9.1 If follow-up, to which initial #:

10. Please give a brief description of the Adverse Experience, using key words:

11. Describe/Name the agent/drug/device:

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:

This study, as opposed to a different study with a different dose, route, disease, etc.

Please provide any generic or trade names.

*If "yes" is checked, you **must** cut and paste the relevant section from the currently approved Consent Form.*

Click on the scroll down button to view more of the current screen.

Notes:

Click on the scroll down button to view more of the current screen.



Edit/View - Microsoft Internet Explorer

Step 36 - Click on No

activities.

11. Describe/Name the agent/drug/device:
Keyboard

12. Was the Adverse Experience related to the agent?
Possibly Related

13. Number of Similar Experiences: 0

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:

Please provide any generic or trade names.

If "yes" is checked, you **must** cut and paste the relevant section from the currently approved Consent Form.

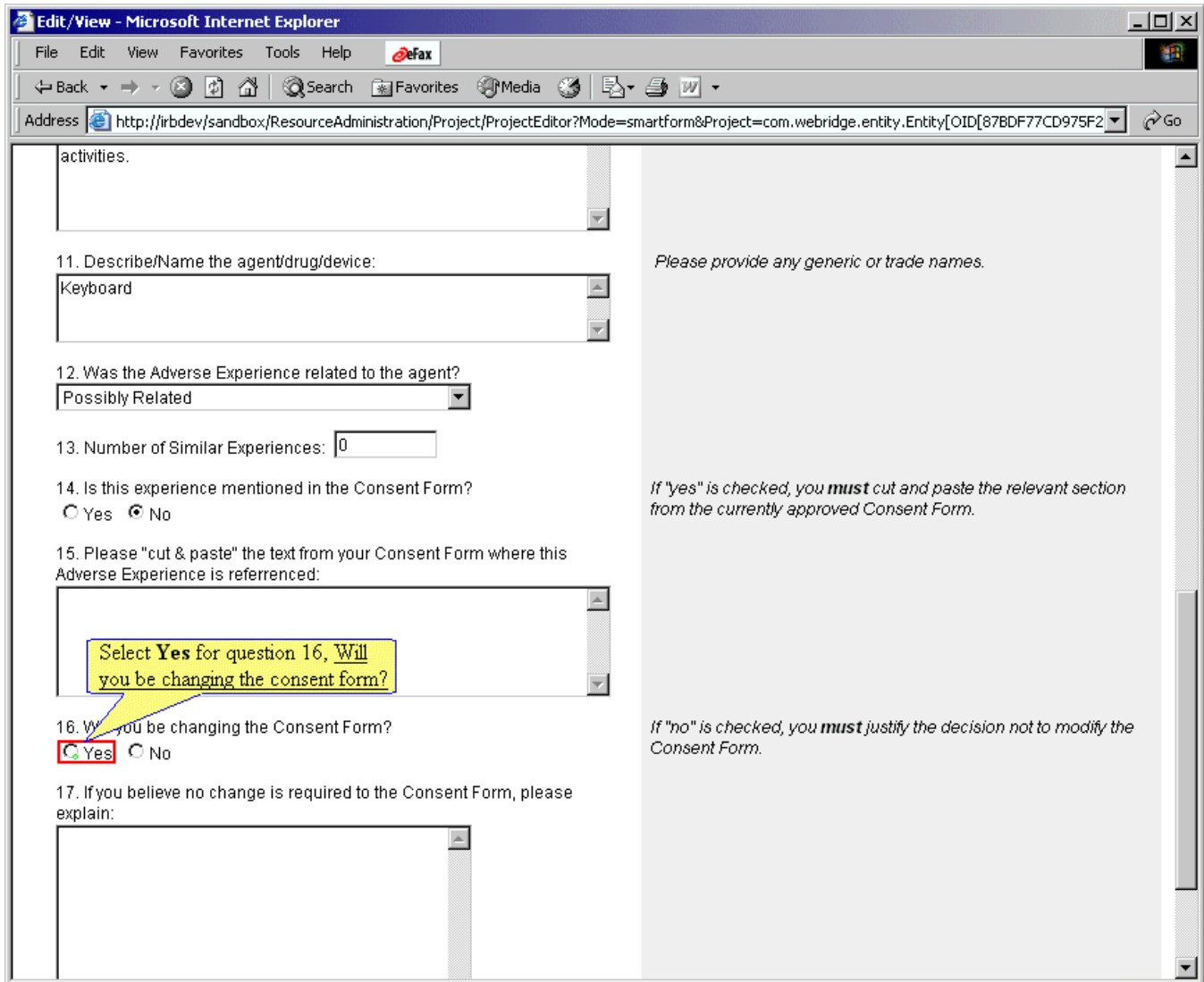
If "no" is checked, you **must** justify the decision not to modify the Consent Form.

Notes:

Select No for question 14, Is this experience mentioned in the consent form?

Edit/View - Microsoft Internet Explorer

Step 37 - Click on Yes



activities.

11. Describe/Name the agent/drug/device:
Keyboard

12. Was the Adverse Experience related to the agent?
Possibly Related

13. Number of Similar Experiences: 0

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:

Select **Yes** for question 16, **Will you be changing the consent form?**

16. Will you be changing the Consent Form?
 Yes No

17. If you believe no change is required to the Consent Form, please explain:

Please provide any generic or trade names.

If "yes" is checked, you **must** cut and paste the relevant section from the currently approved Consent Form.

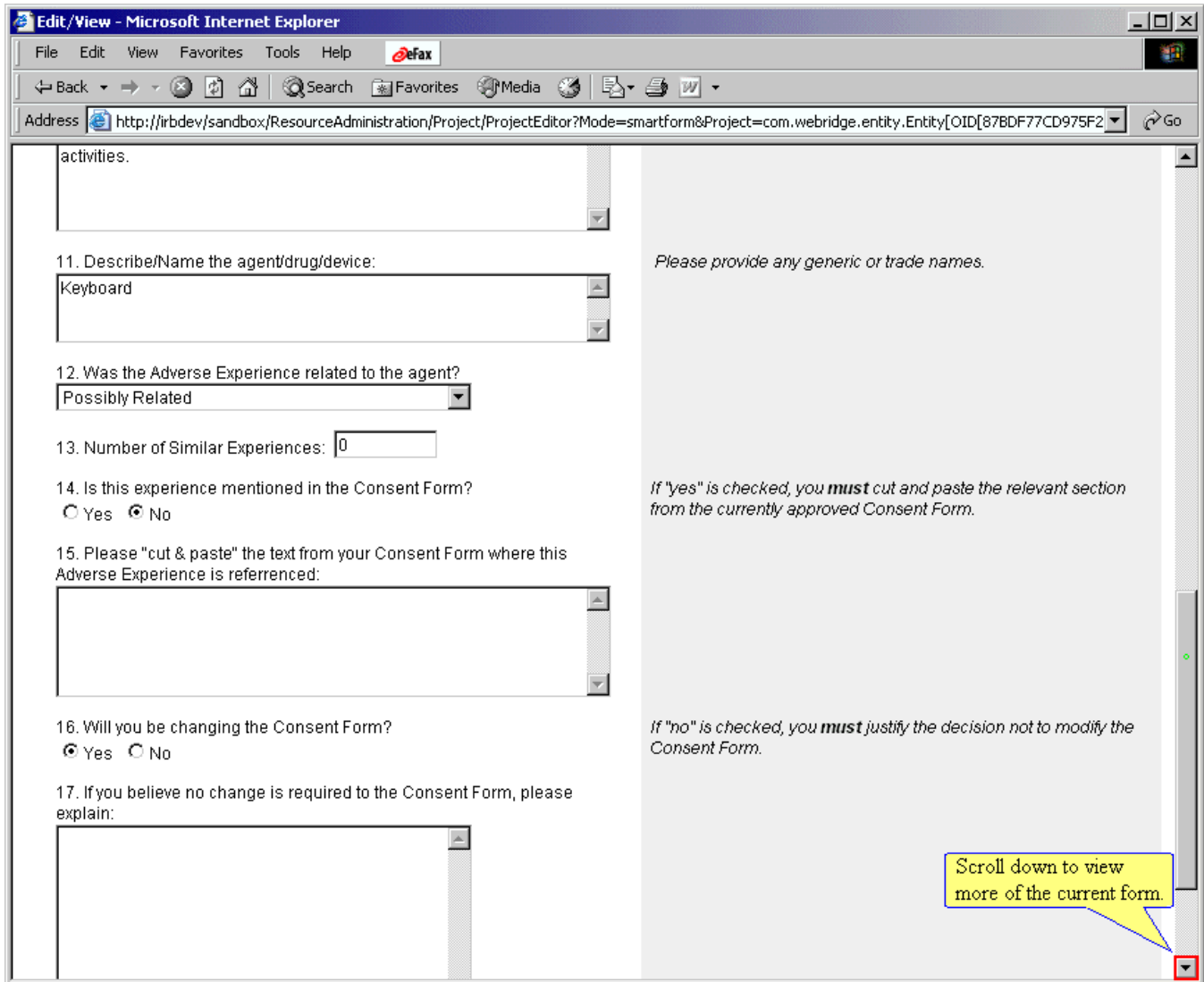
If "no" is checked, you **must** justify the decision not to modify the Consent Form.

Notes:

Select Yes for question 16, Will you be changing the consent form?

Edit/View - Microsoft Internet Explorer

Step 38 - Click on 



activities.

11. Describe/Name the agent/drug/device:
Keyboard

12. Was the Adverse Experience related to the agent?
Possibly Related

13. Number of Similar Experiences: 0

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:

Please provide any generic or trade names.

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.

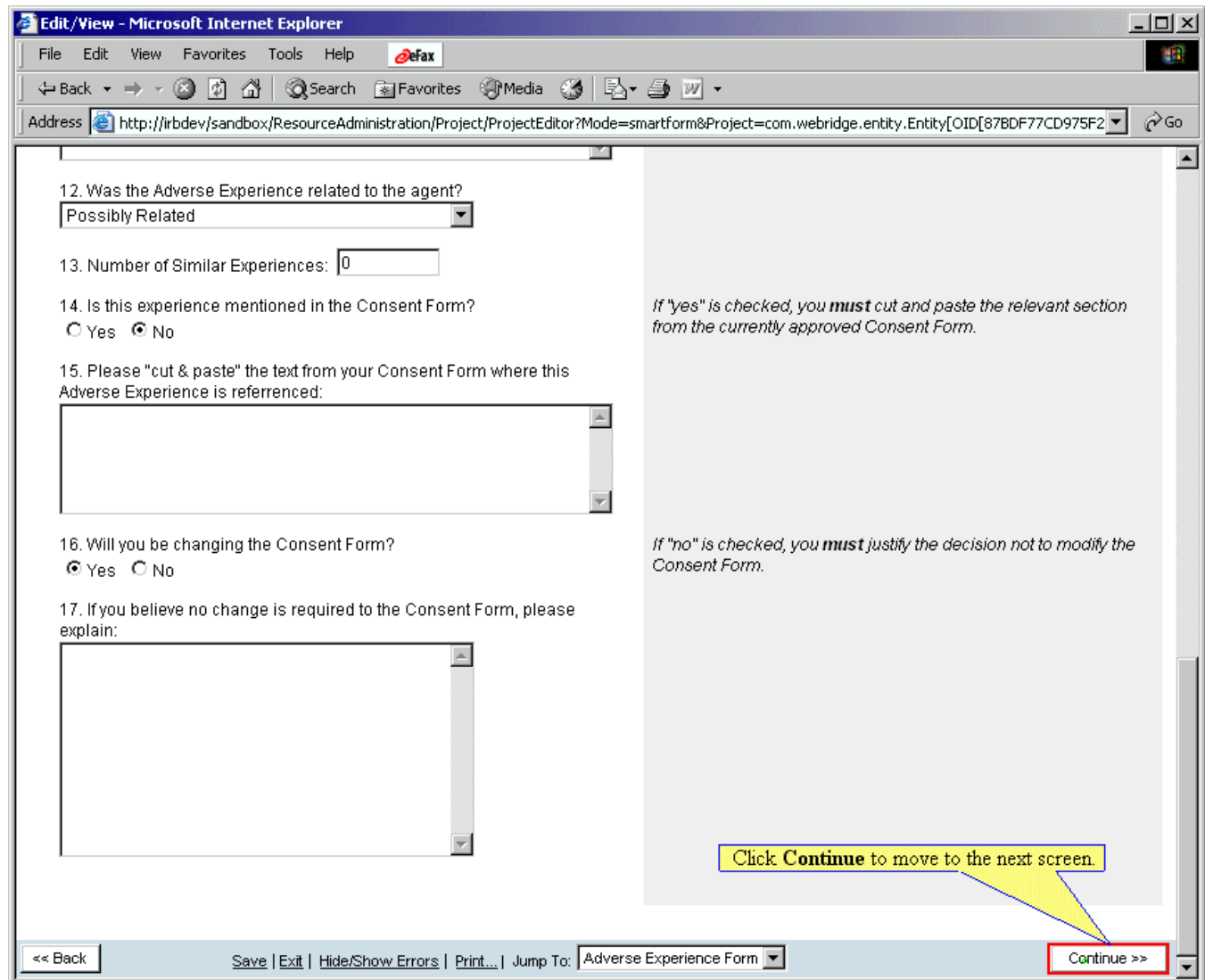
Scroll down to view more of the current form.

Notes:

Scroll down to view more of the current form.

Edit/View - Microsoft Internet Explorer

Step 39 - Click on 



The screenshot shows a Microsoft Internet Explorer browser window titled "Edit/View - Microsoft Internet Explorer". The address bar displays the URL: [http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity\[OID\[87BDF77CD975F2\]](http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity[OID[87BDF77CD975F2]). The main content area contains 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 yellow callout box with the text: "Click **Continue** to move to the next screen." The "Continue >>" button at the bottom right of the form is highlighted with a red border.

The browser's status bar at the bottom shows: "<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: Adverse Experience Form | Continue >>".

Notes:

Click Continue to move to the next screen.



Edit/View - Microsoft Internet Explorer

Step 40 - Click on "Upload Documents"

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 [Back](#) button.

From this screen you could add any additional documents if necessary. Click [Here](#) to continue.

	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="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

Upload Documents:

Add

Title

There are no items to display.

Use this area to upload the documents you indicated in the checklist above.

Notes:

From this screen you could add any additional documents if necessary. Click Here to continue.



Edit/View - Microsoft Internet Explorer

Step 41 - Click on 

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="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

Upload Documents:

Add

Title

There are no items to display.

Use this area to upload the documents you indicated in the checklist above.

Click on the **Finish** button to complete the Adverse Experience entry.

Notes:

Click on the Finish button to complete the Adverse Experience entry.



Step 42 - End of simulation

Carpal Tunnel - Microsoft Internet Explorer

File Edit View Favorites Tools Help eFax

Address: http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity[OID[E6CA9CA7FD0DB247856374A82157ED7D]]

OHSU eIRB Michael Miller | My Home | Logoff

eIRB Studies

Studies > Effects of e-Learning > Carpal Tunnel

[Open AE Form](#)

Quick Views

[Additional Compliance Approval Status](#)

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

Project Log