



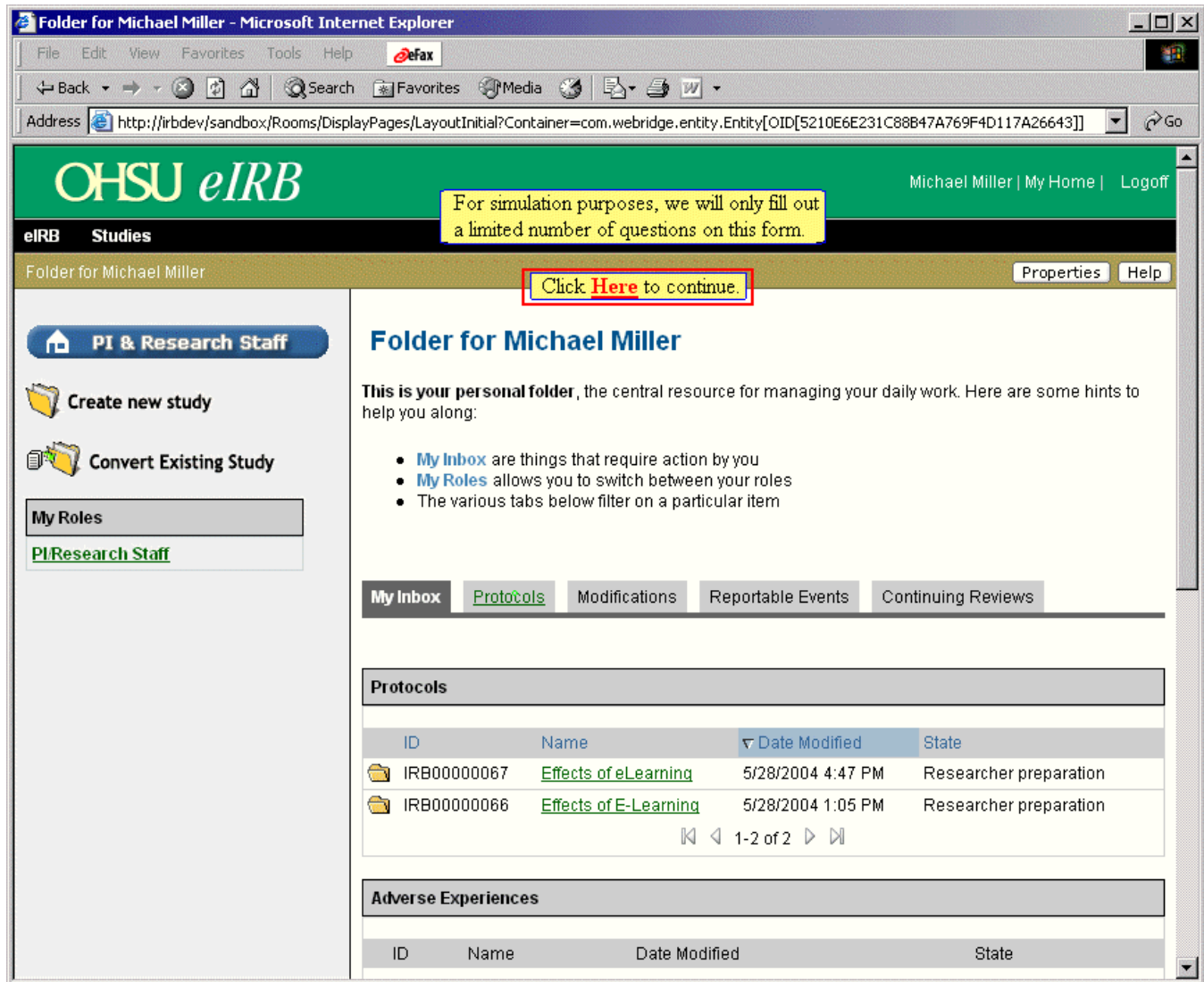
eIRB Create Modification

July 16, 2004



Folder for Michael Miller - Microsoft Internet Explorer

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



Folder for Michael Miller - Microsoft Internet Explorer

File Edit View Favorites Tools Help eFax

Back Forward Stop Home Search Favorites Media Print W

Address http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge.entity.Entity[OID[5210E6E231C88B47A769F4D117A26643]] Go

OHSU eIRB Michael Miller | My Home | Logoff

eIRB Studies

Folder for Michael Miller Properties Help

Click [Here](#) to continue.

Folder for Michael Miller

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

My Inbox **Protocols** Modifications Reportable Events Continuing Reviews

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

1-2 of 2

Adverse Experiences

ID	Name	Date Modified	State
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Notes:

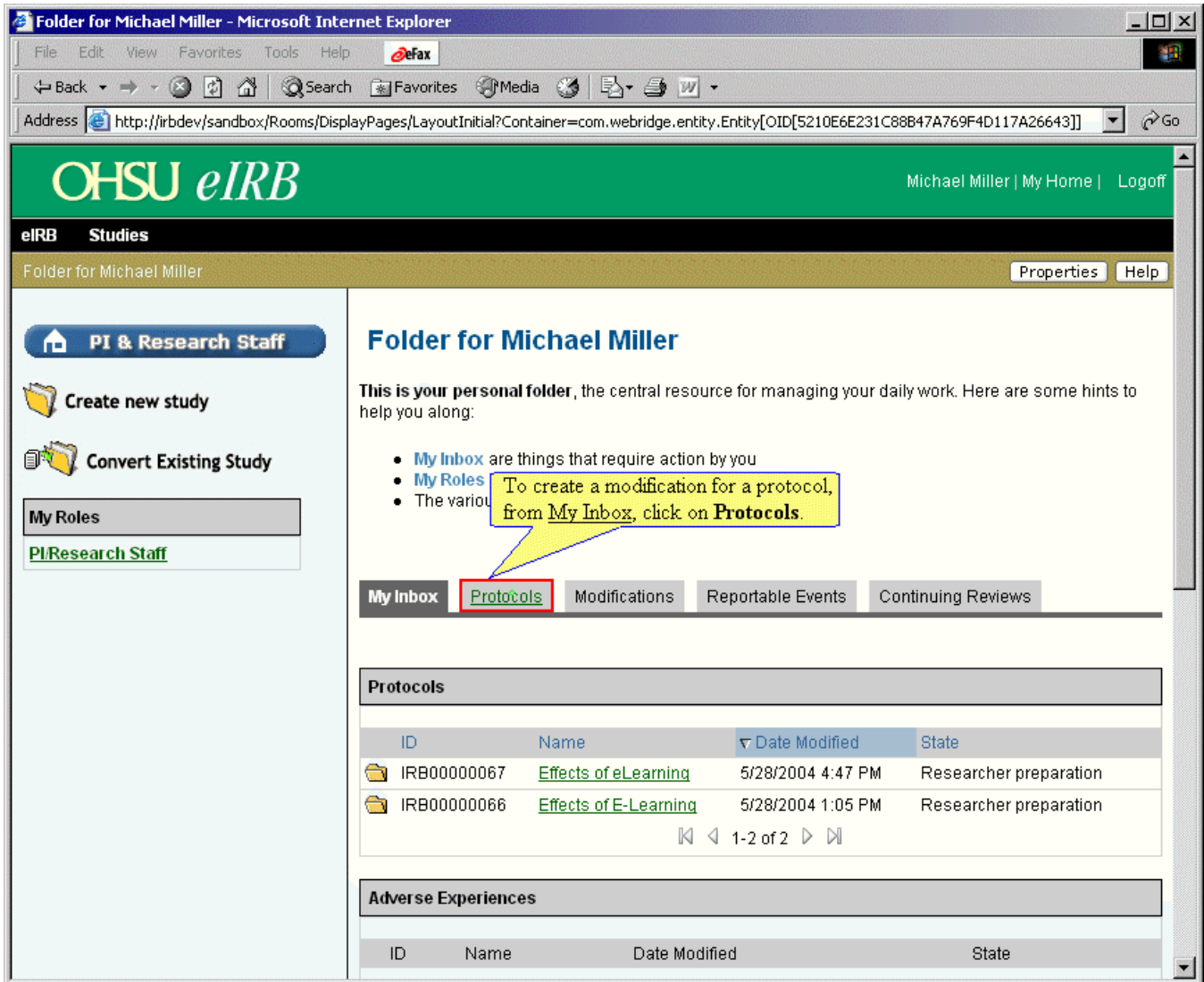
For simulation purposes, we will only fill out a limited number of questions on this form.

Click Here to continue.



Folder for Michael Miller - Microsoft Internet Explorer

Step 2 - Click on [Protocols](#)



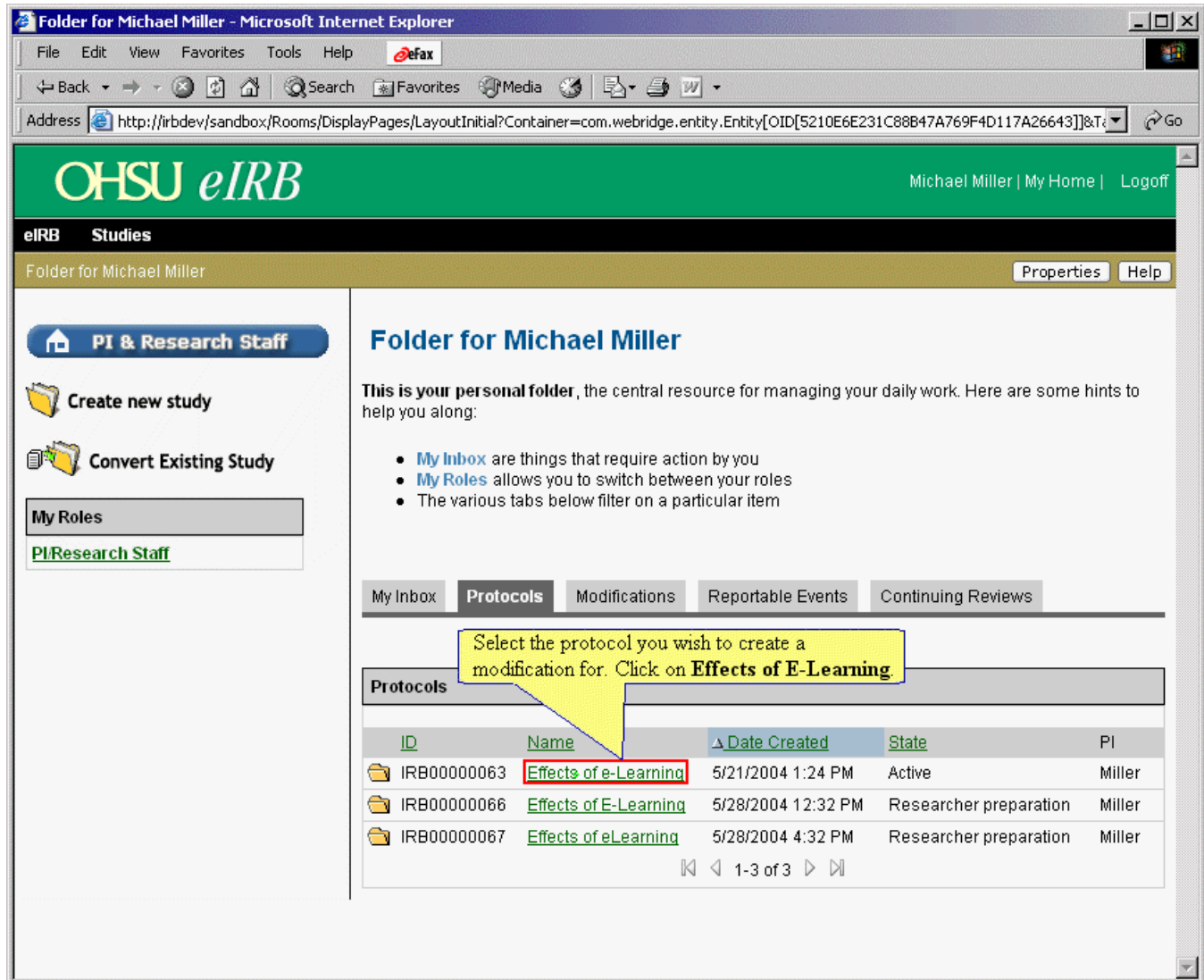
Notes:

To create a modification for a protocol, from My Inbox, click on Protocols.



Folder for Michael Miller - Microsoft Internet Explorer

Step 3 - Click on [Effects of e-Learning](#)



Folder for Michael Miller

PI & Research Staff

Create new study

Convert Existing Study

My Roles

PI/Research Staff

Folder for Michael Miller

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

My Inbox Protocols Modifications Reportable Events Continuing Reviews

Select the protocol you wish to create a modification for. Click on **Effects of E-Learning**

ID	Name	Δ Date Created	State	PI
IRB00000063	Effects of e-Learning	5/21/2004 1:24 PM	Active	Miller
IRB00000066	Effects of E-Learning	5/28/2004 12:32 PM	Researcher preparation	Miller
IRB00000067	Effects of eLearning	5/28/2004 4:32 PM	Researcher preparation	Miller

1-3 of 3

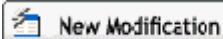
Notes:

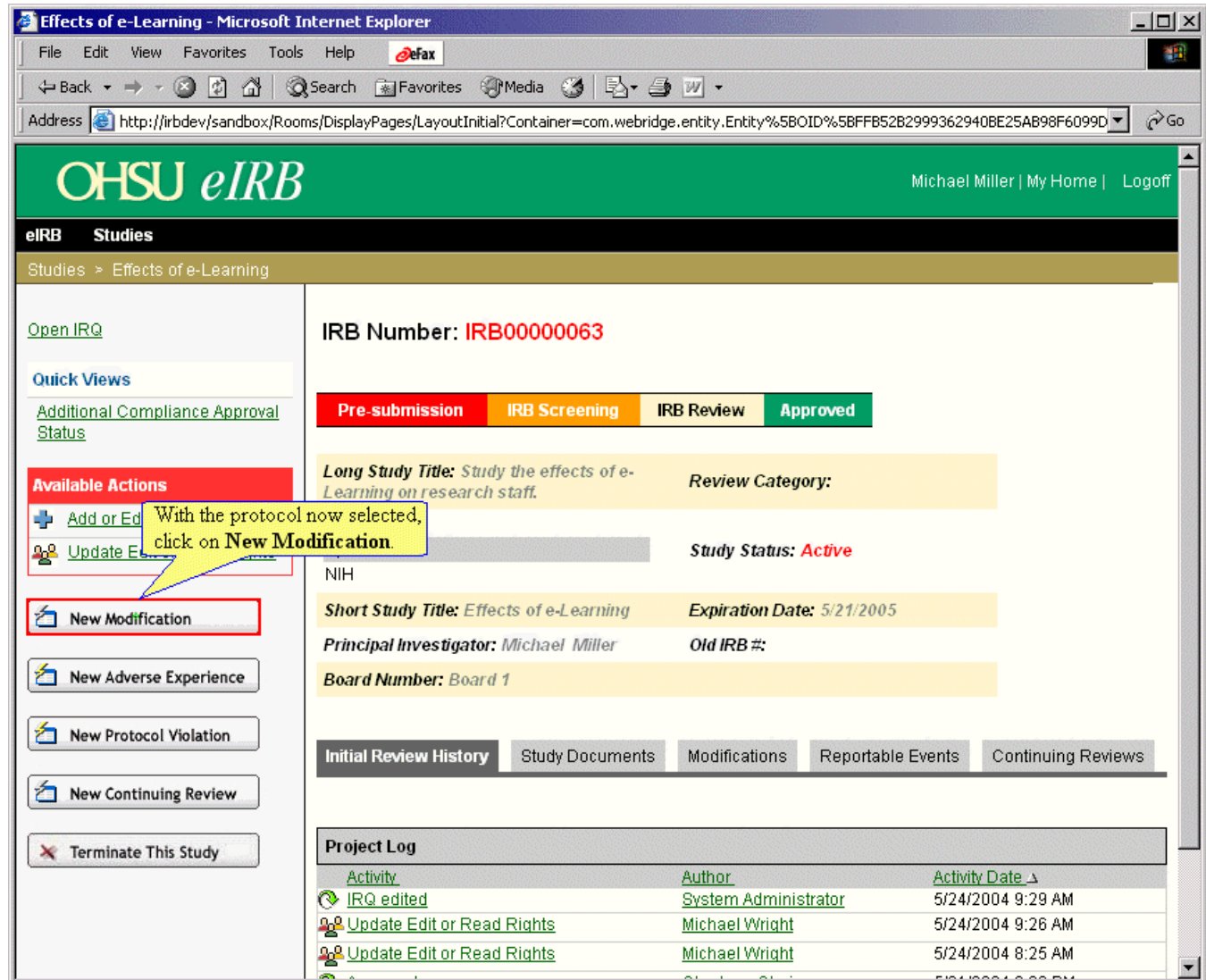
Select the protocol you wish to create a modification for. Click on Effects of E-Learning.

OHSU eIRB

Effects of e-Learning - Microsoft Internet Explorer

Step 4 - Click on

 **New Modification**



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

The page header displays "OHSU eIRB" and "Michael Miller | My Home | Logoff". The main navigation bar shows "eIRB Studies". The breadcrumb trail is "Studies > Effects of e-Learning".

On the left sidebar, under "Available Actions", the "New Modification" button is highlighted with a red box. A yellow callout bubble points to this button with the text: "With the protocol now selected, click on **New Modification**".

The main content area displays the details for IRB Number: **IRB00000063**. The status bar shows: **Pre-submission** (red), **IRB Screening** (orange), **IRB Review** (grey), and **Approved** (green).

Key information includes:

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

Navigation tabs include: **Initial Review History** (selected), Study Documents, Modifications, Reportable Events, and Continuing Reviews.

The **Project Log** table shows the following activities:

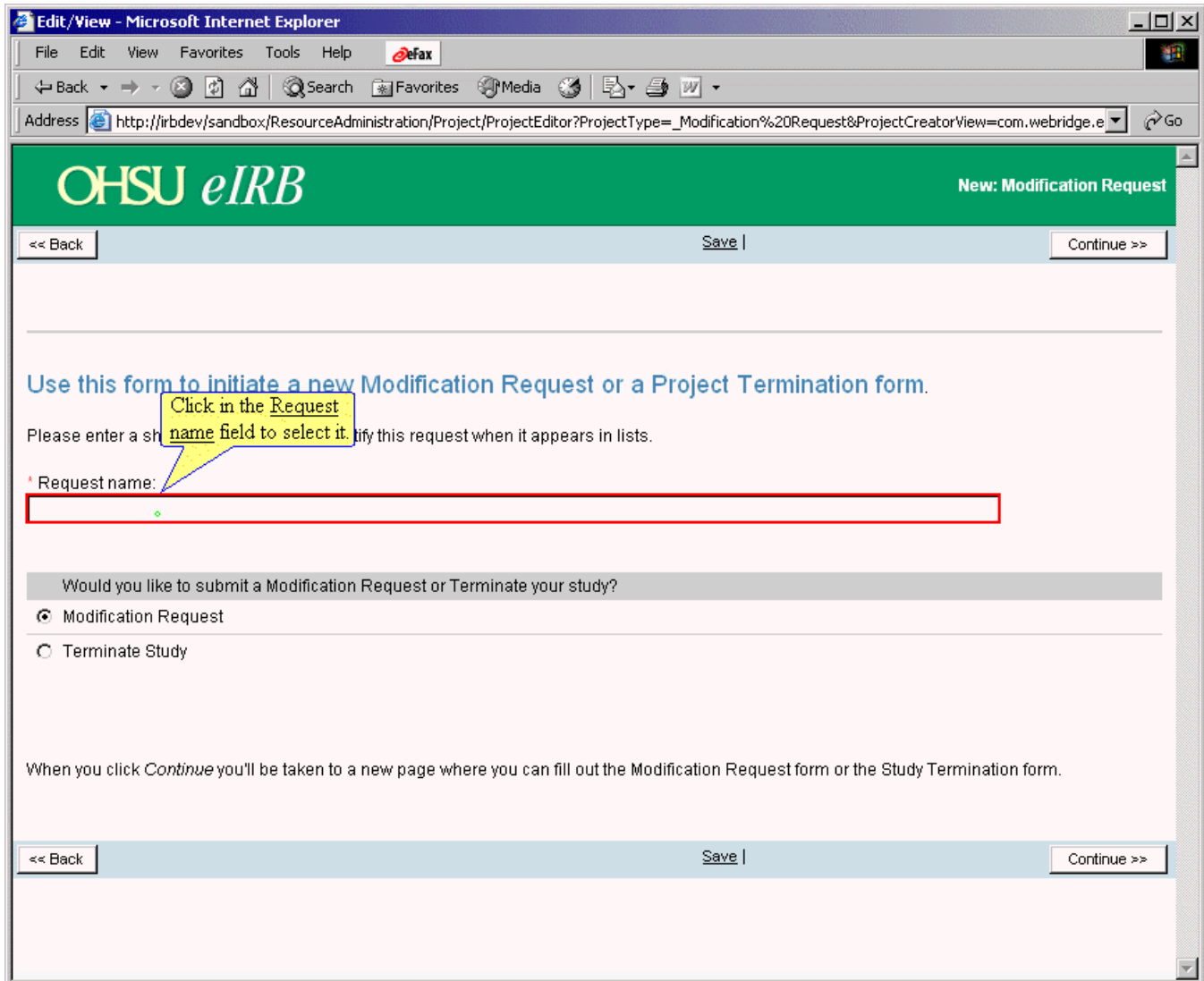
Activity	Author	Activity Date
IRQ edited	System Administrator	5/24/2004 9:29 AM
Update Edit or Read Rights	Michael Wright	5/24/2004 9:26 AM
Update Edit or Read Rights	Michael Wright	5/24/2004 8:25 AM

Notes:

With the protocol now selected, click on New Modification.

**Edit/View - Microsoft Internet Explorer**

Step 5 - Click in the Request Name field.



Use this form to initiate a new Modification Request or a Project Termination form.

Please enter a short name for this request when it appears in lists.

* Request name:

Would you like to submit a Modification Request or Terminate your study?

Modification Request

Terminate Study

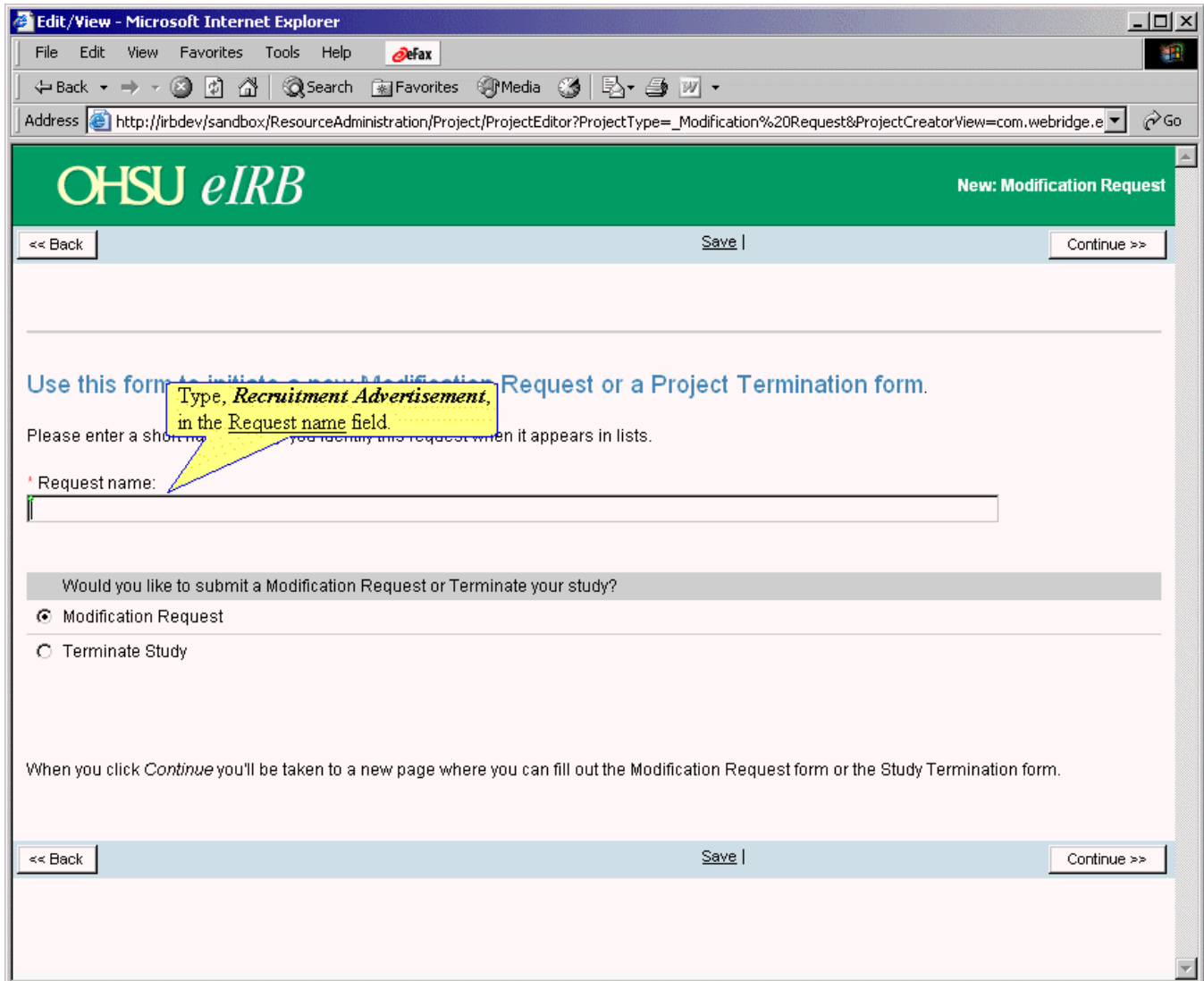
When you click *Continue* you'll be taken to a new page where you can fill out the Modification Request form or the Study Termination form.

Notes:

Click in the Request name field to select it.

**Edit/View - Microsoft Internet Explorer**

Step 6 - Type "Recruitment Advertisement" in edit box



Use this form to initiate a Modification Request or a Project Termination form.

Please enter a short name for your study and request when it appears in lists.

* Request name:

Would you like to submit a Modification Request or Terminate your study?

Modification Request

Terminate Study

When you click *Continue* you'll be taken to a new page where you can fill out the Modification Request form or the Study Termination form.

Notes:

Type, Recruitment Advertisement, in the Request name field.

OHSU eIRB**Edit/View - Microsoft Internet Explorer**Step 7 - Click on Modification Request

Use this form to initiate a new Modification Request or a Project Termination form.

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

* Request name:
Recruitment Advertisement

Would you like to submit a Modification Request or Terminate your study?

Modification Request

Terminate Study

Click on Modification Request.

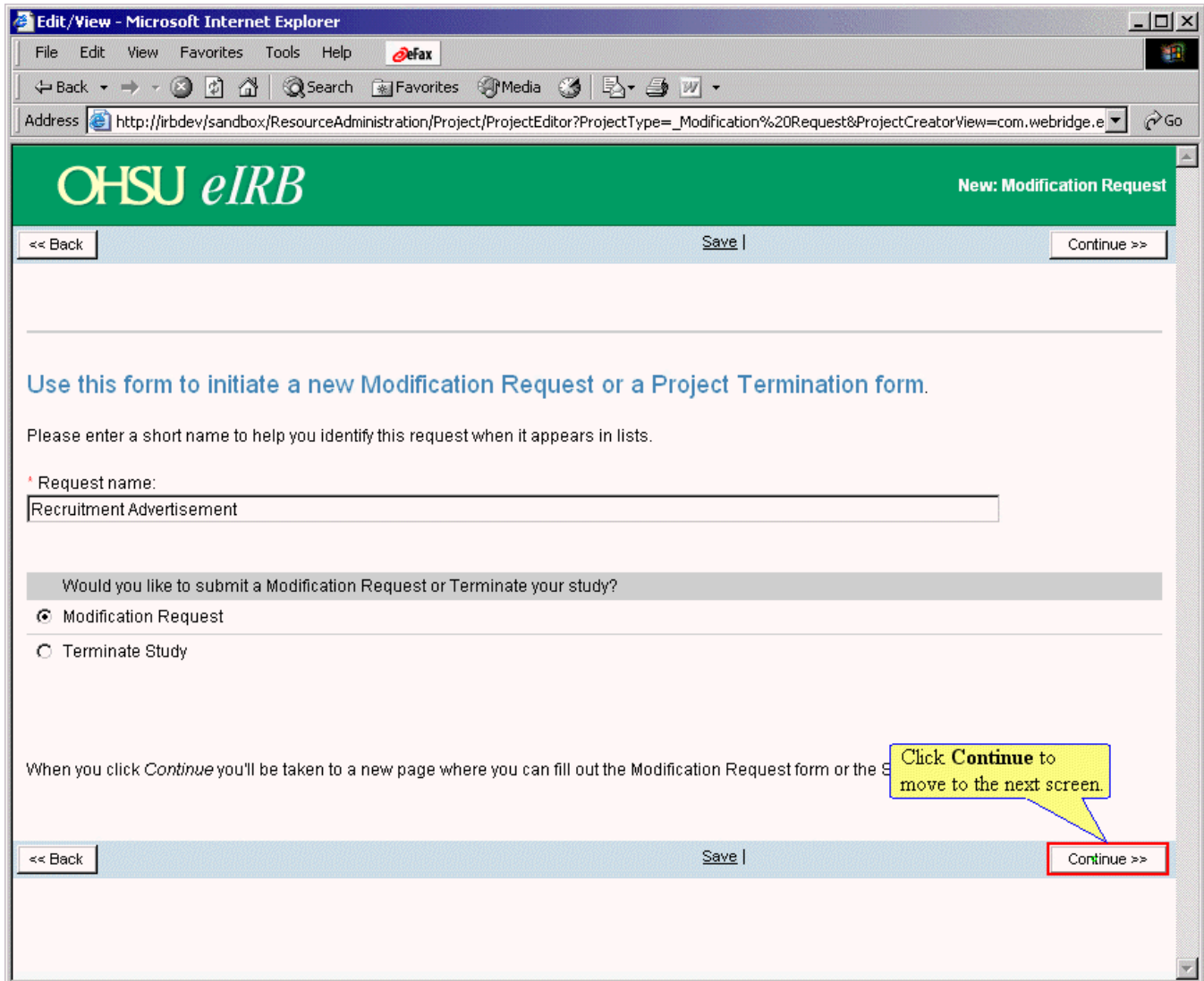
When you click *Continue* you'll be taken to a new page where you can fill out the Modification Request form or the Study Termination form.

Notes:

Click on Modification Request.

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

Step 8 - Click on



OHSU eIRB New: Modification Request

<< Back Save | Continue >>

Use this form to initiate a new Modification Request or a Project Termination form.

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

* Request name:

Would you like to submit a Modification Request or Terminate your study?

Modification Request
 Terminate Study

When you click *Continue* you'll be taken to a new page where you can fill out the Modification Request form or the S

<< Back Save | Continue >>

Click **Continue** to move to the next screen.

Notes:

Click Continue to move to the next screen.



Edit/View - Microsoft Internet Explorer

Step 9 - Click on

Modification Request Form

PI: Michael Miller
 Study Title: Effects of e-Learning
 Study Number: IRB00000063
 Study Status: Active

1. Current Subjects Enrolled:

2. Change/Add/Drop items:

2.1. Advertisement:

2.2. Consent Form:

2.3. Protocol:

2.4. Questionnaire:

2.6. A Change in Study Status:

2.7. If change in status, indicate new status:

2.5. Other (specify in question 4):

3. Does this change affect subject participation?

HELP TEXT

This means the number of subjects consented over the life of the study, or the number of subjects participating if consent was waived, or the number of files accessed for a retrospective chart review, or the number of biological specimens.

Revised documents must be attached as a Word document with changes tracked (You will be able to upload revised documents when you click "continue").

Any changes to questionnaires must be prospectively reviewed and approved by the IRB.

All changes to the protocol must be incorporated into the written protocol and the new version submitted.

Checking "yes" will likely require consent form modifications.

Notes:

Click in the Current Subjects Enrolled field to select it.

Edit/View - Microsoft Internet Explorer

Step 10 - Type "34" in edit box

OHSU eIRB Edit: Modification Request - MR00000023

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

Modification Request Form

PI: Michael Miller
Study Title: Effects of e-Learning
Study Number: IRB000000063
Study Status: Active

1. Current Subjects Enrolled:

2. Change/Add/Drop items:

2.1. Advertisement:

2.2. Consent Form:

2.3. Protocol:

2.4. Questionnaire:

2.6. A Change in Study Status:

2.7. If change in status, indicate new status:

2.5. Other (specify in question 4):

3. Does this change affect subject participation?

HELP TEXT

This means the number of subjects consented over the life of the study, or the number of subjects participating if consent was waived, or the number of files accessed for a retrospective chart review, or the number of biological specimens.

Revised documents must be attached as a Word document with changes tracked (You will be able to upload revised documents when you click "continue").

Any changes to questionnaires must be prospectively reviewed and approved by the IRB.

All changes to the protocol must be incorporated into the written protocol and the new version submitted.

Checking "yes" will likely require consent form modifications.

Notes:

Type, 34, for the current number of subjects enrolled.

Edit/View - Microsoft Internet ExplorerStep 11 - Click on ; 2.2. Consent Form: ; 2.3. Protocol: ; 2.4. Questionnaire: ; 2.6. A Change in Study Status: ; 2.7. If change in status, indicate new status: [dropdown menu]; 2.5. Other (specify in question 4): . Question 3: Does this change affect subject participation? [checkbox]. A yellow callout box points to the 'Advertisement' checkbox with the text 'Select the Advertisement check box.' A grey 'HELP TEXT' box on the right contains instructions: 'This means the number of subjects consented over the life of the study, or the number of subjects participating if consent was waived, or the number of files accessed for a retrospective chart review, or the number of biological specimens.'; 'Revised documents must be attached as a Word document with changes tracked (You will be able to upload revised documents when you click "continue").'; 'Any changes to questionnaires must be prospectively reviewed and approved by the IRB.'; 'All changes to the protocol must be incorporated into the written protocol and the new version submitted.'; 'Checking "yes" will likely require consent form modifications.'"/>**Notes:**

Select the Advertisement check box.



Edit/View - Microsoft Internet Explorer

Step 12 - Click on 

Modification Request Form

PI: Michael Miller
Study Title: Effects of e-Learning
Study Number: IRB00000063
Study Status: Active

1. Current Subjects Enrolled:

2. Change/Add/Drop items:

2.1. Advertisement:

2.2. Consent Form:

2.3. Protocol:

2.4. Questionnaire:

2.6. A Change in Study Status:

2.7. If change in status, indicate new status:

2.5. Other (specify in question 4):

3. Does this change affect subject participation?

HELP TEXT

This means the number of subjects consented over the life of the study, or the number of subjects participating if consent was waived, or the number of files accessed for a retrospective chart review, or the number of biological specimens.

Revised documents must be attached as a Word document with changes tracked (You will be able to upload revised documents when you click "continue").

Any changes to questionnaires must be prospectively reviewed and approved by the IRB.

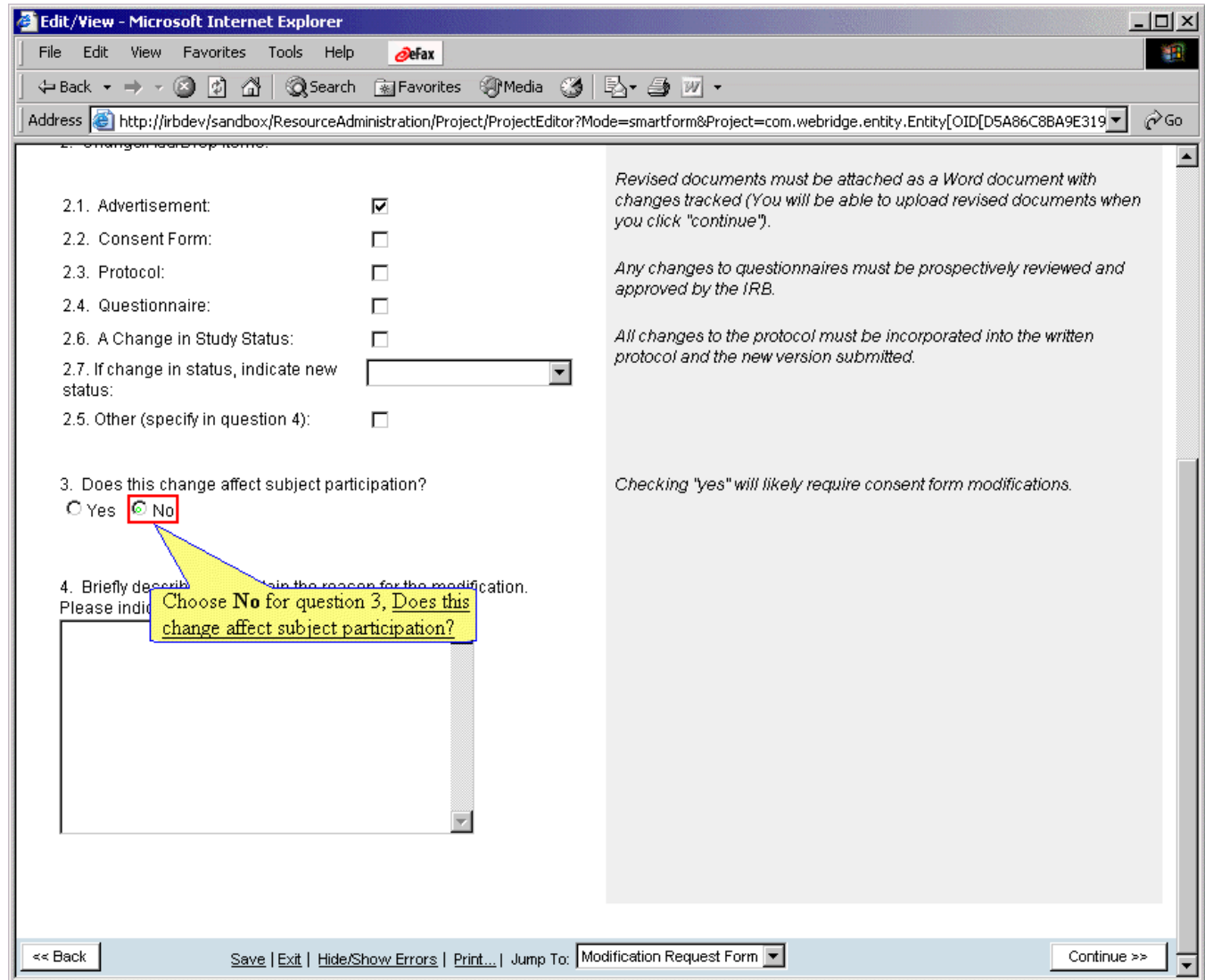
All changes to the protocol must be incorporated into the written protocol and the new version submitted.

Checking a "yes" will likely require consent form modifications.

Scroll down to view more of the page.

Notes:

Scroll down to view more of the page.

Edit/View - Microsoft Internet ExplorerStep 13 - Click on No

2.1. Advertisement:

2.2. Consent Form:

2.3. Protocol:

2.4. Questionnaire:

2.6. A Change in Study Status:

2.7. If change in status, indicate new status:

2.5. Other (specify in question 4):

3. Does this change affect subject participation?
 Yes No

4. Briefly describe the reason for the modification.
Please indicate:

Revised documents must be attached as a Word document with changes tracked (You will be able to upload revised documents when you click "continue").

Any changes to questionnaires must be prospectively reviewed and approved by the IRB.

All changes to the protocol must be incorporated into the written protocol and the new version submitted.

Checking "yes" will likely require consent form modifications.

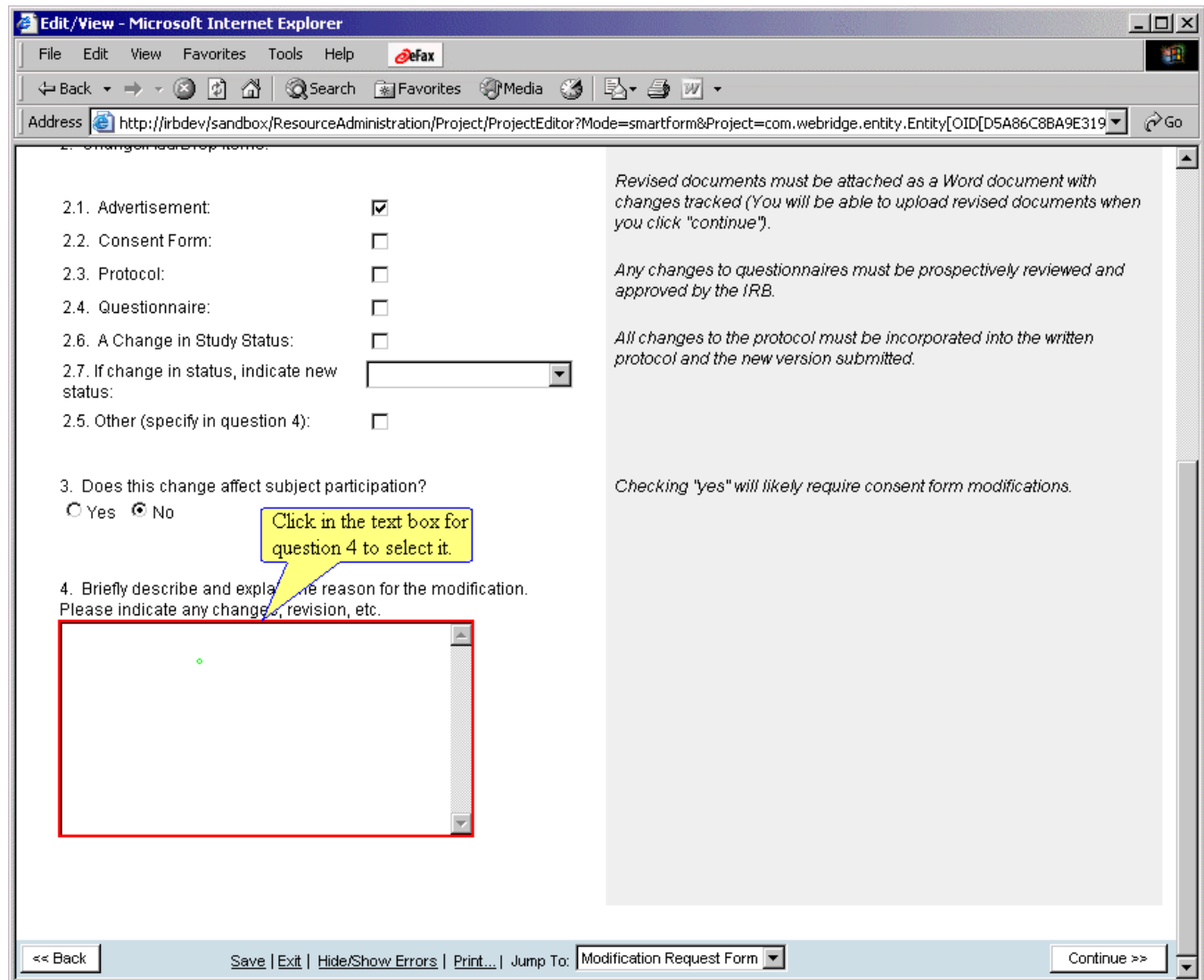
<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Modification Request Form Continue >>

Notes:

Choose No for question 3, Does this change affect subject participation?

Edit/View - Microsoft Internet Explorer

Step 14 - Click in the description field.



2.1. Advertisement:

2.2. Consent Form:

2.3. Protocol:

2.4. Questionnaire:

2.6. A Change in Study Status:

2.7. If change in status, indicate new status:

2.5. Other (specify in question 4):

3. Does this change affect subject participation?
 Yes No

4. Briefly describe and explain the reason for the modification. Please indicate any changes, revision, etc.

Revised documents must be attached as a Word document with changes tracked (You will be able to upload revised documents when you click "continue").

Any changes to questionnaires must be prospectively reviewed and approved by the IRB.

All changes to the protocol must be incorporated into the written protocol and the new version submitted.

Checking "yes" will likely require consent form modifications.

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

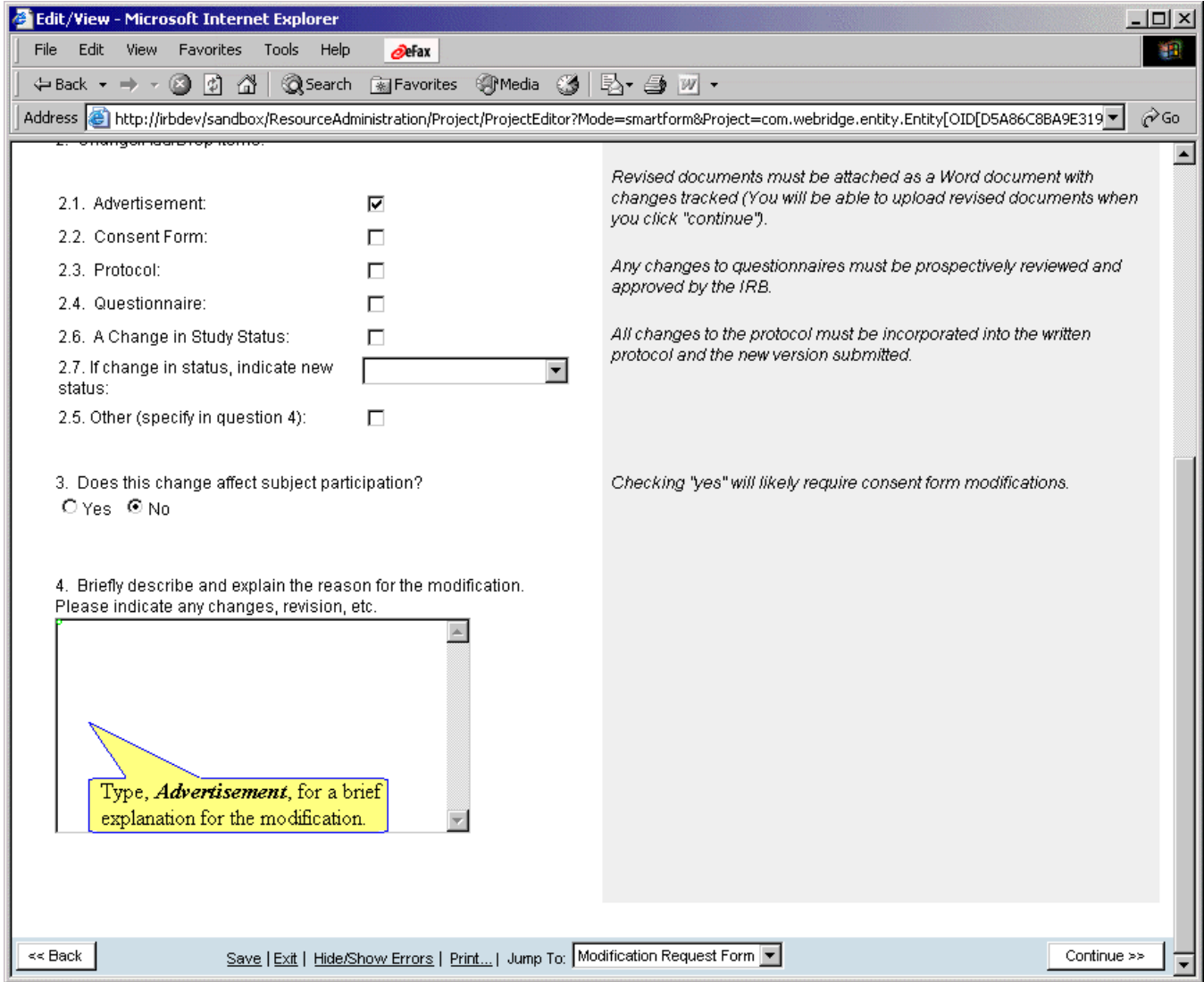
Notes:

Click in the text box for question 4 to select it.



Edit/View - Microsoft Internet Explorer

Step 15 - Type "Advertisement" in edit box



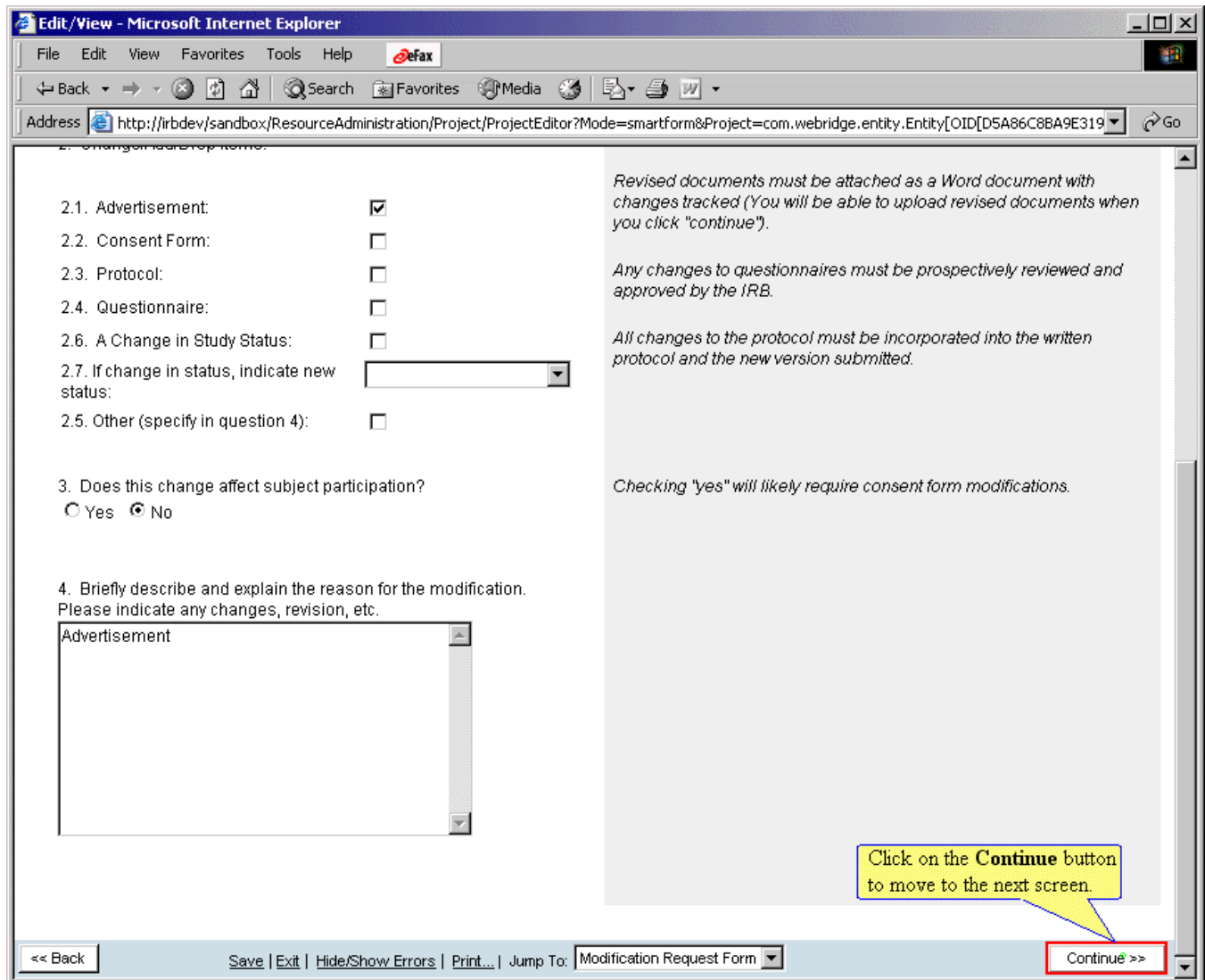
Notes:

Type, Advertisement, for a brief explanation for the modification.



Edit/View - Microsoft Internet Explorer

Step 16 - Click on



Address [http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity\[OID\[D5A86C8BA9E319\]](http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity[OID[D5A86C8BA9E319])

2.1. Advertisement:

2.2. Consent Form:

2.3. Protocol:

2.4. Questionnaire:

2.6. A Change in Study Status:

2.7. If change in status, indicate new status:

2.5. Other (specify in question 4):

3. Does this change affect subject participation?
 Yes No

4. Briefly describe and explain the reason for the modification.
 Please indicate any changes, revision, etc.

Advertisement

Revised documents must be attached as a Word document with changes tracked (You will be able to upload revised documents when you click "continue").

Any changes to questionnaires must be prospectively reviewed and approved by the IRB.

All changes to the protocol must be incorporated into the written protocol and the new version submitted.

Checking "yes" will likely require consent form modifications.

Notes:

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



Edit/View - Microsoft Internet Explorer

Step 17 - 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 Protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Copy of grant (if NIH grant as new funding source)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Data Safety Monitoring Plan for NIH-Sponsored studies or GCRC studies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Adult Informed Consent Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Genetic Informed Consent Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Child Assent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Media Informed Consent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
HIPAA Research Authorization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
HIPAA Authorization for Existing PHI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

Notes:

Click on the Finish button to complete this Modification.



Step 18 - End of simulation

Recruitment Advertisement - Microsoft Internet Explorer

Address: http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity[OID[847309B3B592ED41BF6B118B9F8FF312]]

OHSU eIRB Michael Miller | My Home | Logoff

eIRB Studies

Studies > Effects of e-Learning > Recruitment Advertisement

[Open the Modification Request 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 **Modification Status:** Researcher preparation

Modification History Documents for this Modification

Project Log

Activity	Author	Activity Date
Edited the form	Michael Miller	6/4/2004 3:09 PM
Edited the form	Michael Miller	6/4/2004 3:05 PM