



# **eIRB Submit Modification**

June 30, 2004



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

Step 1 - Click on

**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

**Adverse Experiences**

ID	Name	Date Modified	State
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**Notes:**

Start by scrolling down, if necessary, to view any listed modifications.



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

Step 2 - Click on [Recruitment Advertisement](#)

The screenshot shows a web browser window titled "Folder for Michael Miller - Microsoft Internet Explorer". The address bar contains a URL starting with "http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?". The main content area displays four sections: "Adverse Experiences", "Protocol Violations", "Modifications", and "Continuing Reviews". Each section has a table header and a message "There are no items to display" except for the "Modifications" section, which contains two rows of data. A yellow callout box with a blue arrow points to the "Recruitment Advertisement" link in the first row of the "Modifications" table.

ID	Name	Date Modified	State	IRB Number	Short Study Title
MR00000023	<a href="#">Recruitment Advertisement</a>	6/4/2004 3:09 PM	Researcher preparation	IRB00000063	Effects of e-Learning
MR00000022	<a href="#">Change consent form</a>	5/21/2004 3:28 PM	Researcher preparation	IRB00000063	Effects of e-Learning

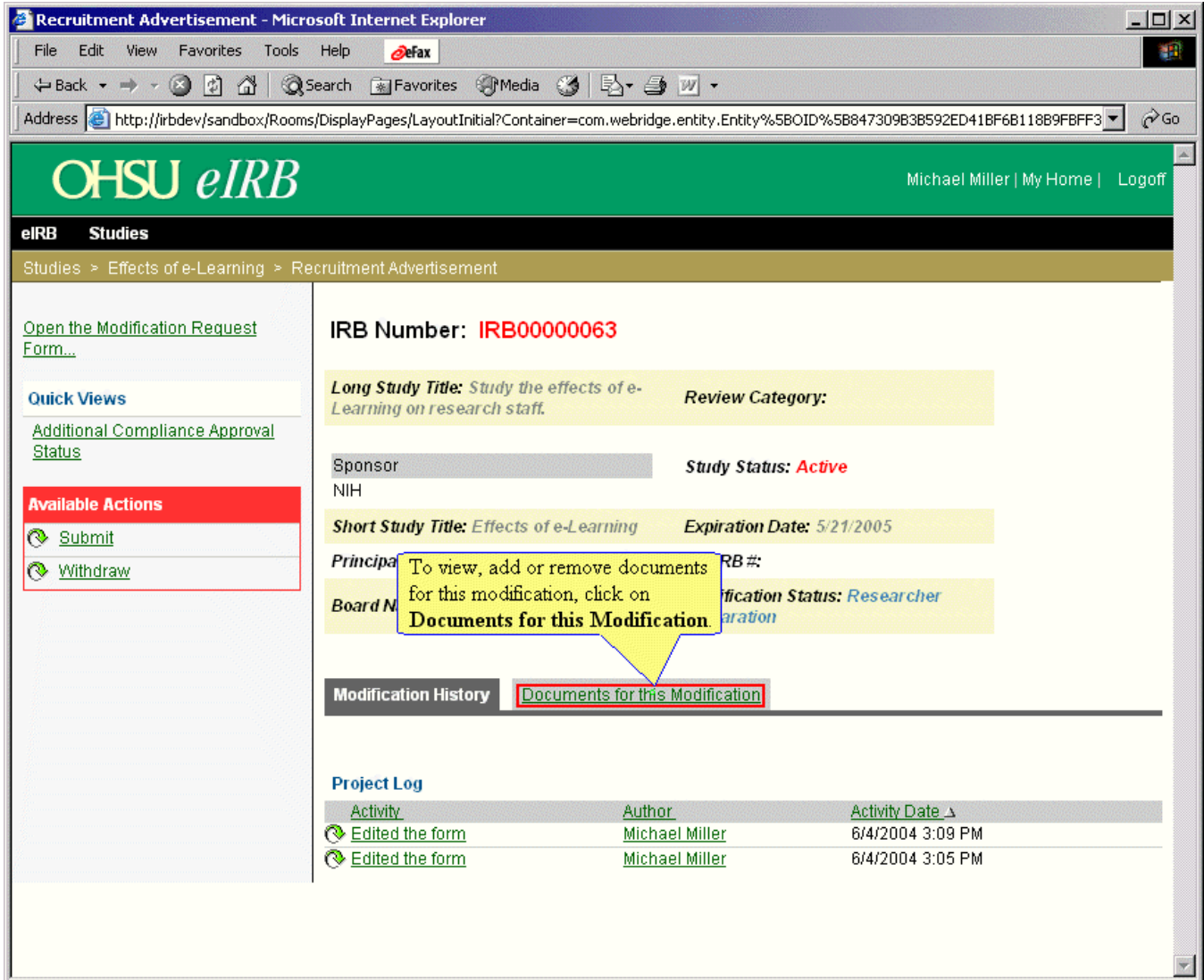
**Notes:**

Click on the modification you wish to submit.



**Recruitment Advertisement - Microsoft Internet Explorer**

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



**Notes:**

To view, add or remove documents for this modification, click on Documents for this Modification.



**Recruitment Advertisement - Microsoft Internet Explorer**

Step 4 - Click on [Open the Modification Request Form...](#)

**Open the Modification Request Form...**

**IRB Number: IRB00000063**

**Long Study Title: Study the effects of e-** **Review Category:**

**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**

**Study Status: Active**

**Sponsor: NIH**

**Available Actions:**

- Submit
- Withdraw

**Modification History** | **Documents for this Modification**

Modification Related Documents:

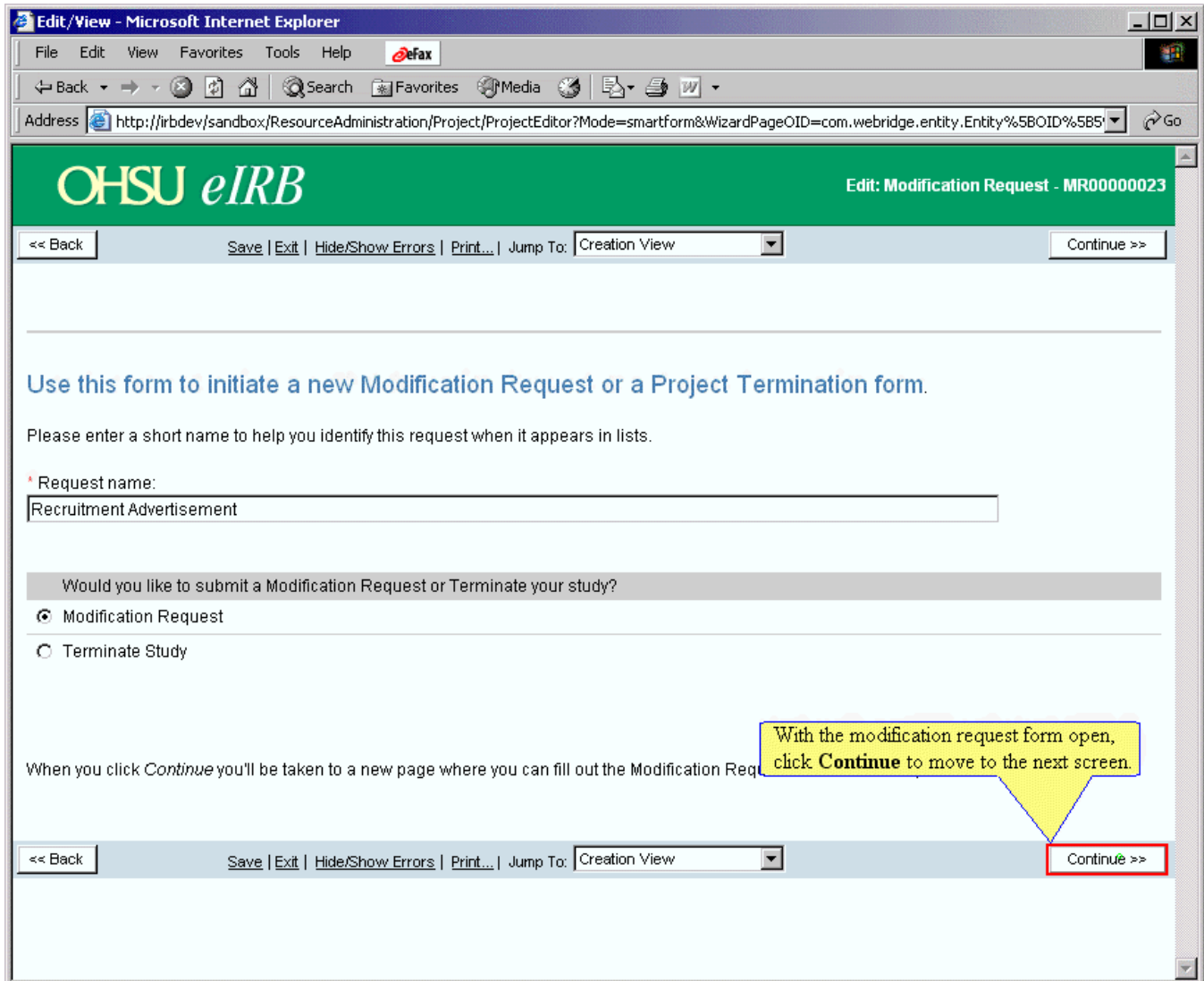

Title	Date Created	Date Modified	Version
There are no items to display.			

**Upload Documents Page**

[Upload Forms](#)

**Notes:**

To make modifications, click, Open the Modification Request Form...

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

**OHSU eIRB** Edit: Modification Request - MR00000023

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Creation View 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:  
Recruitment Advertisement

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.

With the modification request form open, click **Continue** to move to the next screen.

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Creation View Continue >>

**Notes:**

With the modification request form open, click Continue to move to the next screen.



**Edit/View - Microsoft Internet Explorer**

Step 6 - 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): . 3. Does this change affect subject participation? [dropdown menu]. A '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.' A yellow callout box points to the bottom right of the page with the text: 'Review the options on this page and scroll down to view more of the form.'"/>

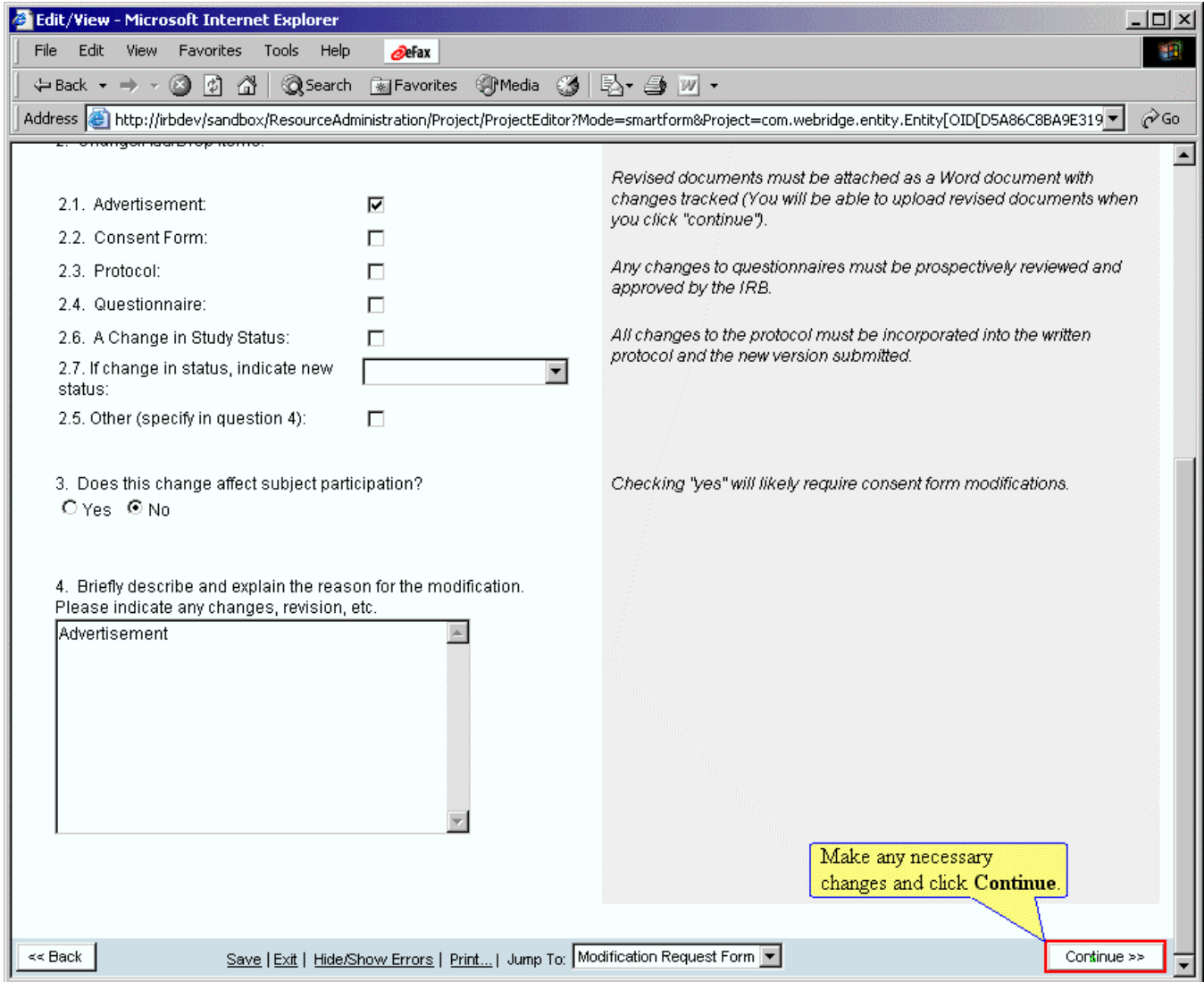
**Notes:**

Review the options on this page and scroll down to view more of the form.



### Edit/View - Microsoft Internet Explorer

Step 7 - Click on 



**Notes:**

Make any necessary changes and click Continue.



**Edit/View - Microsoft Internet Explorer**

Step 8 - Click on

**OHSU eIRB** Edit: Modification Request - MR00000023

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Upload docs view 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 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"/>

From here you would manage any associated documents. Scroll down when ready.

**Notes:**

From here you would manage any associated documents. Scroll down when ready.



### Edit/View - Microsoft Internet Explorer

Step 9 - Click on

The screenshot shows a Microsoft Internet Explorer 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\[D5A86C8BA9E319\]](http://irbdev/sandbox/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity[OID[D5A86C8BA9E319]). The main content area is a form with a checklist of documents, each with three checkboxes. The items in the checklist are:

- Child Assent
- Media Informed Consent
- HIPAA Research Authorization
- HIPAA Authorization for Existing PHI
- HIPAA Waiver of Authorization
- HIPAA Data Use Agreement
- HIPAA Business Associate Agreement
- Other HIPAA Form(s):
- An Investigator's brochure/Package Inserts/Safety Sheets for Food Supplements, Herbs, etc.
- Advertisements/Recruitment letters (Call UNP at 494-8231 for assistance with wording)
- Survey instrument(s)/Data collection form(s)
- Collaborative Agreement(s)
- CLIA Certifications (non-OHSU labs)
- Other:

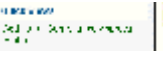
Below the checklist is an "Upload Documents:" section with an "Add" button and a "Title" field. Below that, it says "There are no items to display." To the right of this section is a text box: "Use this area to upload the documents you indicated in the checklist above." A yellow callout box points to the "Finish" button in the bottom right corner with the text: "When you are done making any document modifications, click **Finish**." The "Finish" button is highlighted in red. At the bottom of the page, there are navigation buttons: "<< Back", "Save | Exit | Hide/Show Errors | Print...", and "Jump To: Upload docs view".

**Notes:**

When you are done making any document modifications, click Finish.



**Recruitment Advertisement - Microsoft Internet Explorer**

Step 10 - Click on 

The screenshot shows the OHSU eIRB web application interface. At the top, there is a green header with the OHSU eIRB logo and the user name 'Michael Miller | My Home | Logoff'. Below the header, the navigation path is 'Studies > Effects of e-Learning > Recruitment Advertisement'. The main content area displays study details:

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

On the left side, there is a sidebar with a link 'Open the Modification Request Form...' and an 'Available Actions' menu containing 'Submit' and 'Withdraw'. A red-bordered callout box points to the 'Available Actions' menu with the text: 'Once you have made changes, your available actions reflect your options. Click [Here](#) to continue.'

At the bottom, there is a 'Project Log' table:

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

**Notes:**

Once you have made changes, your available actions reflect your options. Click Here to continue.



**Recruitment Advertisement - Microsoft Internet Explorer**

Step 11 - Click on [Submit](#)

**Available Actions**

- [Submit](#)
- [View](#)

From Available Actions, click **Submit**.

**IRB Number:** IRB0000063

**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 #:**

**Modification Status:** Researcher preparation

**Modification History** Documents for this Modification

**Project Log**

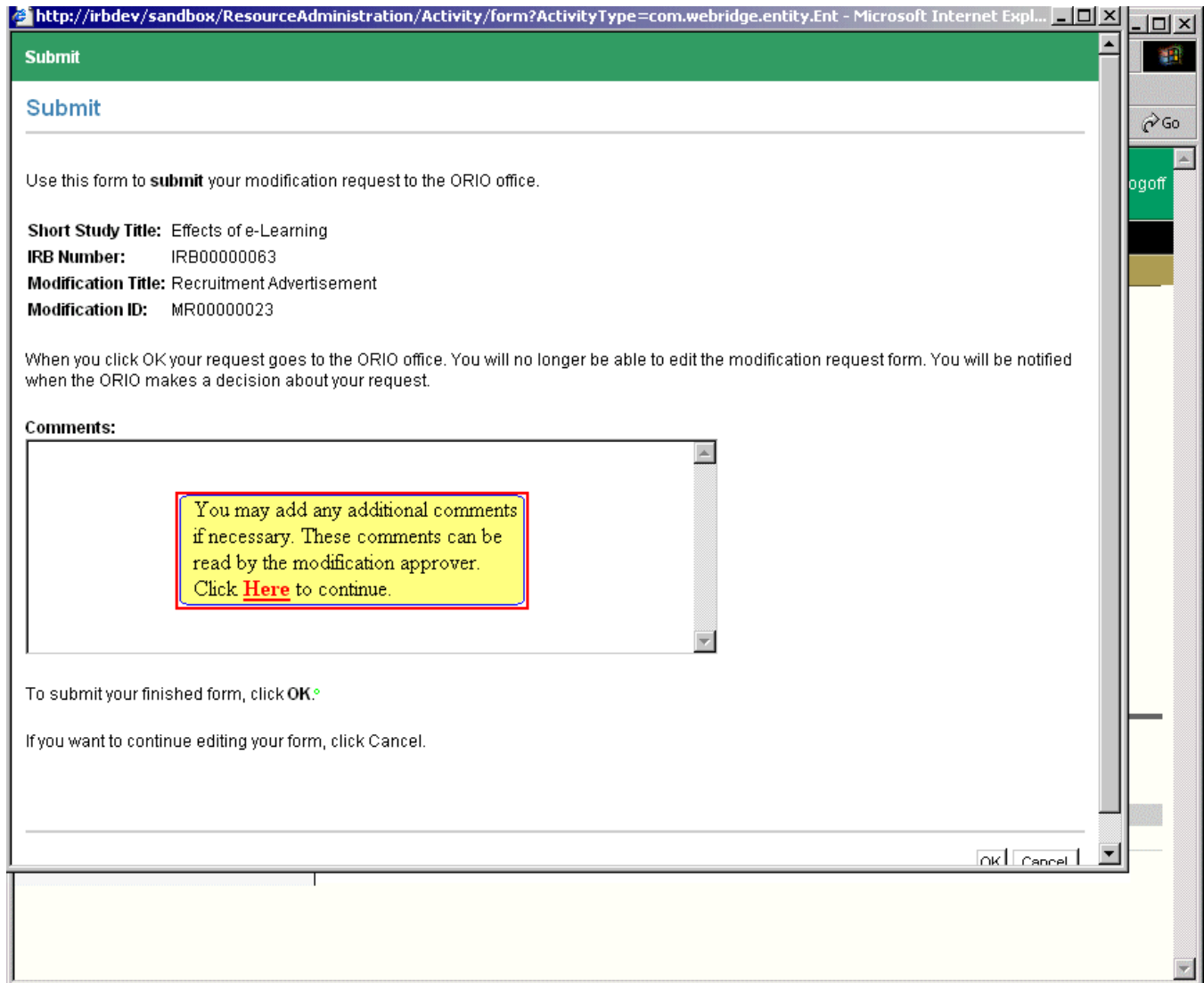
Activity	Author	Activity Date
Edited the form	Michael Miller	6/4/2004 3:09 PM
Edited the form	Michael Miller	6/4/2004 3:05 PM

**Notes:**

From Available Actions, click Submit.

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

Step 12 - Click on



Submit

Submit

Use this form to **submit** your modification request to the ORIO office.

**Short Study Title:** Effects of e-Learning  
**IRB Number:** IRB00000063  
**Modification Title:** Recruitment Advertisement  
**Modification ID:** MR00000023

When you click OK your request goes to the ORIO office. You will no longer be able to edit the modification request form. You will be notified when the ORIO makes a decision about your request.

**Comments:**

You may add any additional comments if necessary. These comments can be read by the modification approver. Click [Here](#) to continue.

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

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

OK Cancel

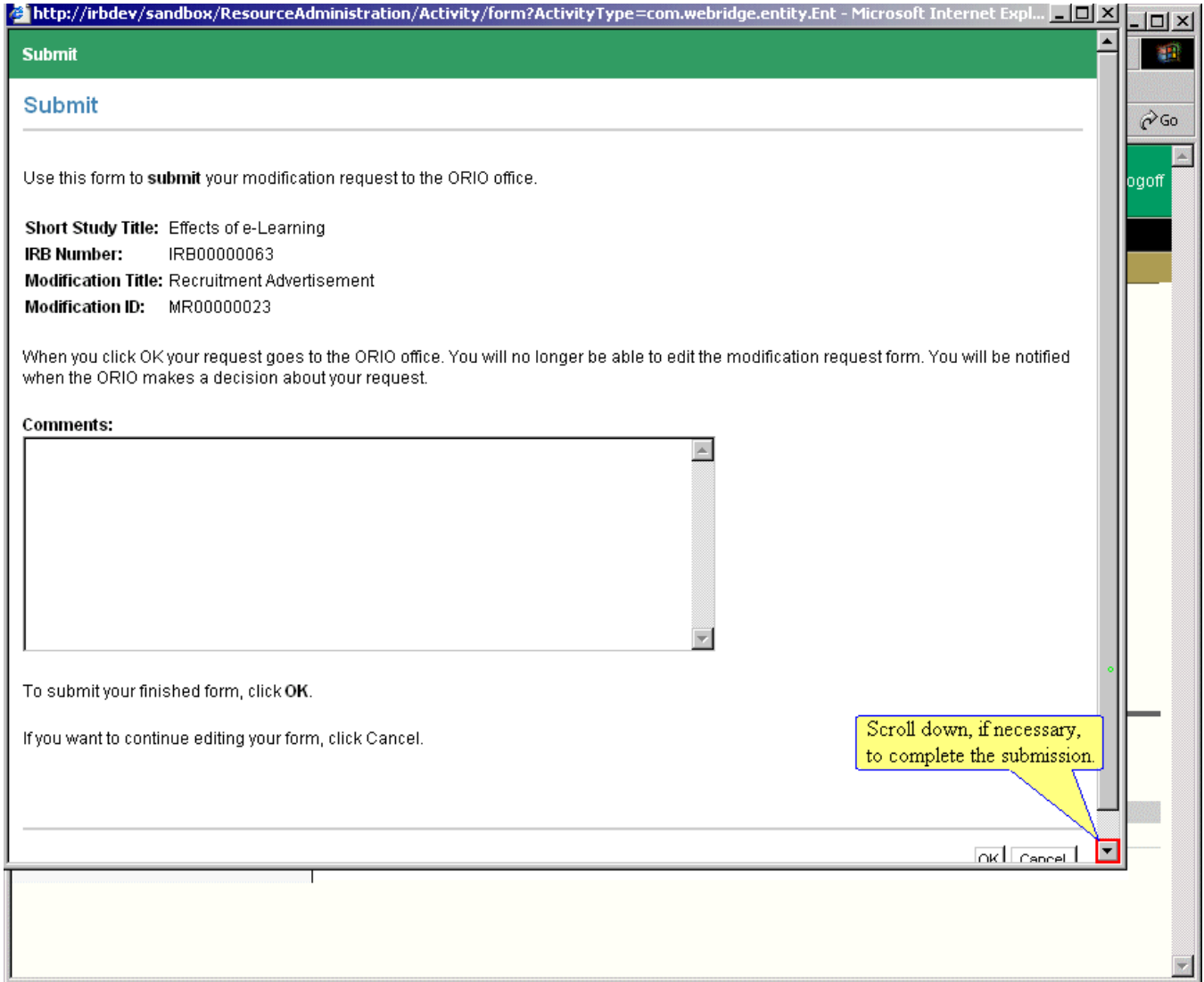
**Notes:**

You may add any additional comments if necessary. These comments can be read by the modification approver. Click [Here](#) to continue.



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

Step 13 - Click on 

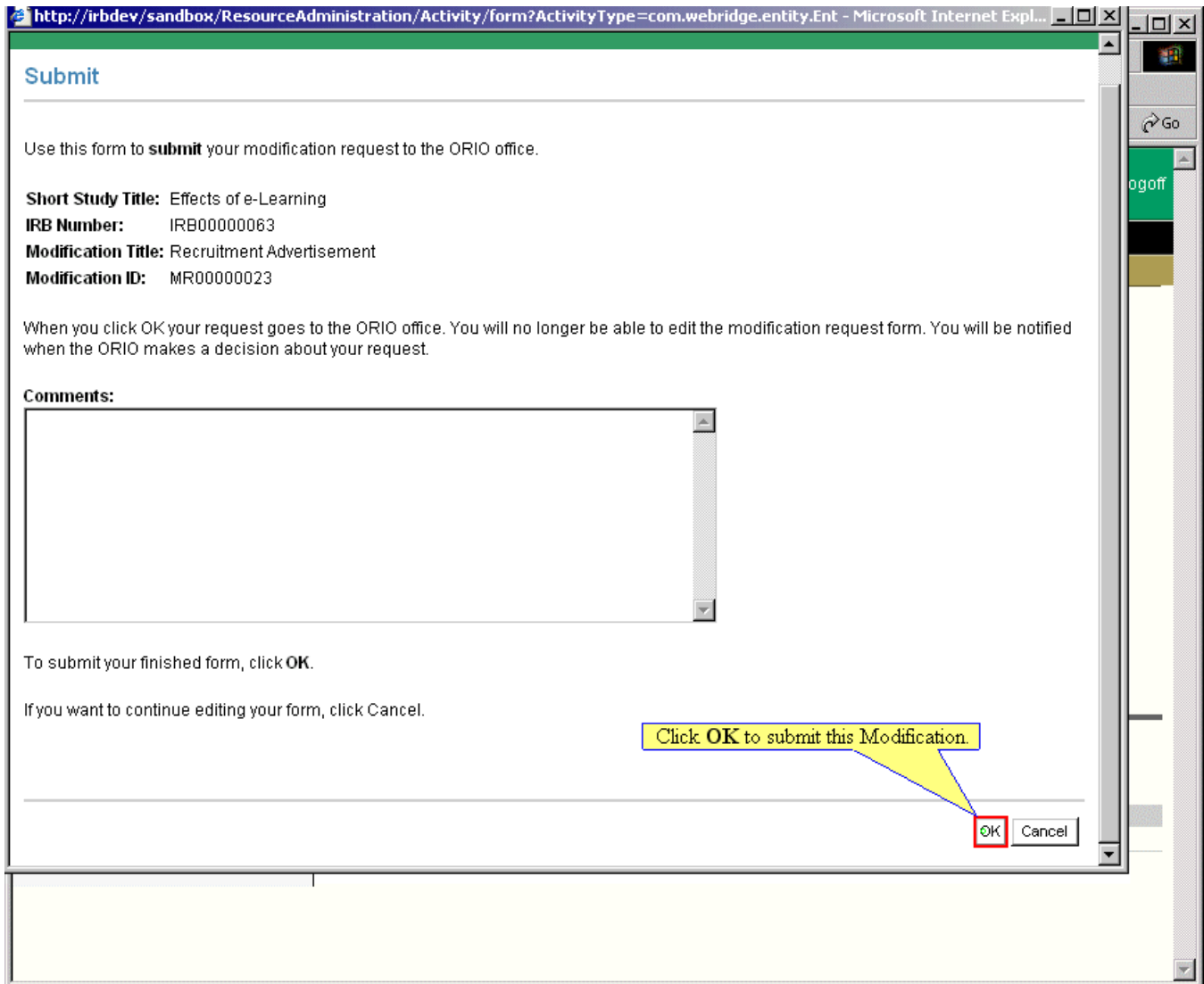


**Notes:**

Scroll down, if necessary, to complete the submission.

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

Step 14 - Click on 



**Notes:**

Click OK to submit this Modification.



**Recruitment Advertisement - Microsoft Internet Explorer**

Step 15 - Click on

**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:** Analyst review

**Modification:**

**Project Log**

Activity	Author	Activity Date
Submitted	Michael Miller	6/4/2004 3:16 PM
Edited the form	Michael Miller	6/4/2004 3:09 PM
Edited the form	Michael Miller	6/4/2004 3:05 PM

The project log for Modifications will reflect the newly submitted Modification. Click [Here](#) to continue, and complete this simulation.

**Notes:**

The project log for Modifications will reflect the newly submitted Modification. Click Here to continue, and complete this simulation.



Step 16 - End of simulation

Recruitment Advertisement - Microsoft Internet Explorer

Address: <http://irbdev/sandbox/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5B OID%5B847309B3B592ED41BF6B118B9FBFF3>

**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**

**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:** Analyst review

**Modification History** Documents for this Modification

**Project Log**

Activity	Author	Activity Date
Submitted	Michael Miller	6/4/2004 3:18 PM
Edited the form	Michael Miller	6/4/2004 3:09 PM
Edited the form	Michael Miller	6/4/2004 3:05 PM