eIRB - Create a Study

July 15, 2004
Step 1 - Click on

**Create new study**

From "My Home", click on Create a new Study.

**Notes:**
From "My Home", click on Create a new Study.
Step 2 - For simulation purposes we will only fill out a limited number of questions.

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

Click Here to continue.
Step 3 - Type "Effects of eLearning" in edit box

Notes:
Click in the Short Study Title and type Effects of eLearning.
Step 4 - New Study is selected by default.

Use this form to initiate a new Initial Review Questionnaire, convert an existing study, request a waiver of oversight, or submit a study with use of future human subjects

Enter a short study title for your study. You will use this title to identify your study in the system. If the NIH requires a short study title for your study, use the same short study title here.

* Short Study Title: Effects of eLearning
  Note: Short study title is limited to 54 characters

* Are you submitting a new study, converting an existing study, requesting a waiver of oversight, or submitting a study with use of human subjects in the future?

Please select one of the following:

- New Study
- Converting an Existing Study
- Request a Waiver of Oversight
- Future Human Subjects

Add Personnel to this Study

* Principal Investigator: [None] Select...

Notes:
The New Study option will already be selected by default.

Click Here to continue.
Step 5 - Click on

Use this form to initiate a new Initial Review Questionnaire, convert an existing study, request a waiver of oversight, or submit a study with use of future human subjects

Enter a short study title for your study. You will use this title to identify your study in the system. If the NIH requires a short study title for your study, use the same short study title here.

*Short Study Title:* Effects of eLearning

*Note:* Short study title is limited to 54 characters

*Are you submitting a new study, converting an existing study, requesting a waiver of oversight, or submitting a study with use of human subjects in the future?*

- [ ] New Study
- [ ] Converting an Existing Study
- [ ] Request a Waiver of Oversight
- [ ] Future Human Subjects

**Add Personnel to this Study**

*Principal Investigator:* [None] Select...

**Notes:**

Scroll down to display more of the current page.
Step 6 - Click on **Select...**

**Add Personnel to this Study**

**Principal Investigator:** [None] **Select...**

Sub-Investigators (all collaborators must be selected):

- Add
- First Name
- **Required**

**Research Staff:**

- Add
- First Name
- Last Name
- **Required**

**Notes:**
Click on the Select button to associate a Principal Investigator to this study.
Step 7 - Click on Select...

**Personnel Selection**

*Use this page to add or edit members of the study team.* If the person you are adding is not an OHSU employee (e.g. a collaborator from another university), they will first need to be added into the system (more information).

Select Person: [None] Select...

**Responsibilities**

What responsibilities will the person have?

- [ ] Determine eligibility
- [ ] Consent and/or enroll subjects
- [ ] Primary study contact
- [ ] Financial contact
- [ ] Shipping biological specimens
- [ ] Carrying out study visits or activities with subjects

**Conflict of Interest**

For all investigators and any other study staff consenting subjects. "Yes" indicates that you have a significant financial interest in the sponsoring agency or manufacturer/producer of investigational product under study. To view the conflict of interest policy, please visit http://www.ohsu.edu/policies/chart/15710-01-01-01.html

Do you have a potential conflict of interest?  
- [ ] Yes  
- [ ] No   

The following questions pertain only to Principal Investigators.

---

**Notes:**

From the Personnel Selection screen, click on Select.
Select Persons - Microsoft Internet Explorer

Step 8 - Type "mi" in edit box

Notes:
Type mi in the Last Name field.
Select Persons - Microsoft Internet Explorer

Step 9 - Click on Find Now

Notes:
Click on Find Now.
Select Persons - Microsoft Internet Explorer

Step 10 - Click on Miller, Michael C (Oregon Health and Sciences University).

Notes:
Click on Miller, Michael C (Oregon Health and Sciences University).
Select Persons - Microsoft Internet Explorer

Step 11 - Click on **OK**

Notes:
Click on OK.
Step 12 - Click on 

**Personnel Selection**

Use this page to add or edit members of the study team. If the person you are adding is not an OHSU employee (e.g., a collaborator from another university) they will first need to be added into the system (more information).

Select Person: Michael Miller | Select | Reset

**Responsibilities**

What responsibilities will this person have on the study?

- [ ] Determine eligibility
- [ ] Consent and/or enroll subjects
- [ ] Primary study contact
- [ ] Financial contact
- [ ] Shipping biological specimens
- [ ] Carrying out study visits or activities with subjects

**Conflict of Interest**

For all investigators and any other study staff consenting subjects, “Yes” indicates that you have a significant financial interest in the sponsoring agency or manufacturer/licensee of investigational product under study. To view the conflict of interest policy, please visit: [http://zone.ohsu.edu/policy/pdchatp_10/10-01-025.htm](http://zone.ohsu.edu/policy/pdchatp_10/10-01-025.htm)

Do you have a potential conflict of interest?  

- [ ] Yes  
- [ ] No

The following questions pertain only to Principal Investigators.

**Notes:**

Scroll down to display more of the current page.
Step 13 - Click on ☑ Yes

Rights

In this section you need to declare what rights this individual has on the study (only this study, this does not affect their rights on any other study).

- **Edit rights**: Allows the person to edit forms (e.g., IRB, ORQ, Modification), upload and delete documents associated with the study, read all information associated with this study. Principal Investigators must have edit rights in order to submit forms.
- **Read rights**: Allows a person to read all information associated with the study including uploaded documents. They may not, however, edit anything related to this study.
- **No rights**: It is possible in certain situations that a person is not allowed to read, or edit anything associated with the study. For example, if the person is a reviewer, they would not allow them access to information that would potentially unblind them.

Will this person be allowed edit rights for this study? ☑ Yes ☐ No

Will this person be allowed read rights on this study? ☑ Yes ☐ No

Non-OHSU Personnel

Is this person not affiliated with OHSU? ☐

The following questions only pertain to those individuals who are not employees of OHSU.

What type of agreement is in place?:

Notes:

Click Yes for Will this person be allowed edit rights for this study?
Step 14 - Click on

Rights

In this section, you need to declare what rights this individual has on the study (only this study, this does not affect their rights on any other study).

- **Edit rights** - Allows the person to edit forms (e.g., IRO, COP, Modification), upload and delete documents associated with the study, and read all information associated with the study. **Principal Investigators must have edit rights in order to submit forms.**
- **Read rights** - Allows a person to read all information associated with the study including uploaded documents. They may not, however, edit anything related to this study.
- **No rights** - It is possible in certain situations that a person is a member of the study team, but is not allowed to read or edit anything associated with the study. For example, if certain staff are blinded, you may not allow them access to information that would potentially unblind them.

Will this person be allowed edit rights for this study? ☑ Yes

Will this person be allowed read rights on this study? ☑ Yes

Non-OHSU Personnel

Is this person not affiliated with OHSU? ☑

The following questions only pertain to those individuals who are not employees of OHSU.

What type of agreement is in place?:

Notes:

Click Yes for Will this person be allowed read rights on this study?
Step 15 - Click on

Is the Principal Investigator a licensed physician or dentist with clinical privileges at OHSU OR a nurse practitioner or physicians assistant at OHSU providing procedures within the scope of licensure?  ☐ Yes  ☐ No

Is the Principal Investigator qualified to conduct research at OHSU?  
☐ Yes  ☐ No
For clarification, see the Investigator eligibility requirements.

Rights

In this section you need to declare what rights this individual has on the study (only this study, this does not affect their rights on any other study).

- **Edit rights** - Allows the person to edit forms (e.g. IRO, CRO, Modification), upload and delete documents associated with the study, read all information associated with this study. **Principal Investigators must have edit rights in order to submit forms.**
- **Read rights** - Allows a person to read all information associated with the study including uploaded documents. They may not, however, edit anything related to this study.
- **No rights** - It is possible in certain situations that a person is a member of the study team, but is not allowed to read, or edit anything associated with the study. For example, if certain staff are blinded you may not allow them access to information that would potentially unblind them.

Will this person be allowed edit rights for this study?  ☐ Yes  ☐ No

Will this person be allowed read rights on this study?  ☐ Yes  ☐ No

Non-OHSU Personnel

Is this person not affiliated with OHSU?  ☐

The following questions only pertain to those individuals who are not employees of OHSU.

What type of agreement is in place?:

[Option]

Notes:

Scroll down to display the bottom of the page.
Notes:
Click on OK.
Step 17 - Click on 

Notes:
Scroll down to display the bottom of the page.
Step 18 - Click on **Add**

Notes: Click on Add to associate additional people to this study.
Step 19 - Click on `Select...`
Step 20 - Type "wr" in edit box

Notes:
Type wr in the Last Name field.
Select Persons - Microsoft Internet Explorer

Step 21 - Click on \[Find Now\]

Notes:
Click on Find Now.
Select Persons - Microsoft Internet Explorer

Step 22 - Click on Wright, Michael R (Research Collaborations).

Notes:
Click on Wright, Michael R (Research Collaborations).
Step 23 - Click on OK

Notes:
Click on OK.
Step 24 - Click on

Do you have a potential conflict of interest?  ○ Yes  ○ No

The following questions pertain only to Principal Investigators.

Do you want to receive the full set of notifications?  ○ Yes  ○ No

Note: The limited set includes those that are absolutely required by the IRB (e.g., approval memos). There are a number of notifications that are meant as tickers, or reminders that some action is required by you. Additionally, some notifications go out as a means of updating you on the status of items in question (i.e., initial review, AE, continuing review).

Is the Principal Investigator a licensed physician or dentist with clinical privileges at OHSU OR a nurse practitioner or physician assistant at OHSU providing procedures within the scope of license?  ○ Yes  ○ No

Is the Principal Investigator qualified to conduct research at OHSU?  ○ Yes  ○ No

For clarification, see the Investigator Eligibility Requirements.

Rights

In this section you need to declare what rights this individual has on the study (only this study, this does not affect their rights on any other study).

- **Edit rights** - Allows the person to edit forms (e.g., IRG, CRG, Modification), upload and delete documents associated with the study, read all information associated with this study. **Principal Investigators must have edit rights in order to submit forms.**
- **Read rights** - Allows a person to read all information associated with the study including uploaded documents. They may not, however, edit anything related to this study.
- **No rights** - It is possible in certain situations that a person is a member of the study team, but is not allowed to read, or edit anything associated with the study. For example, if certain staff are blinded you may not allow them access to information that would potentially unblind them.

Will this person be allowed edit rights for this study?  ○ Yes  ○ No

Will this person be allowed read rights on this study?  ○ Yes  ○ No

Notes:

Scroll down to display more of the page.
Step 25 - Click on **No**

Click on **No** for Will this person be allowed edit rights for this study?

**Notes:**
Click on **No** for Will this person be allowed edit rights for this study?
Step 26 - Click on Yes for read rights

Rights

In this section you need to declare what rights this individual has on the study (only this study, this does not affect their rights on any other study).

- **Edit rights**: Allows the person to edit forms (e.g., IRG, CRQ, Modification), upload and delete documents associated with the study, read all information associated with this study. **Principal Investigators must have edit rights in order to submit forms.**
- **Read rights**: Allows a person to read all information associated with the study including uploaded documents. They may not, however, edit anything related to this study.
- **No rights**: It is possible in certain situations that a person is a member of the study team, but is not allowed to read or edit anything associated with the study. For example, if certain staff are blinded you may not allow them access to information.

Click on Yes for **Will this person be allowed read rights on this study?**

Will this person be allowed read rights on this study?  [ ] Yes  [ ] No

Non-OHSU Personnel

Is this person not affiliated with OHSU?  [x]

The following questions only pertain to those individuals who are not employees of OHSU.

What type of agreement is in place?

[ ] Received

Notes:

Click on Yes for **Will this person be allowed read rights on this study?**
Step 27 - Click on 

- **Edit rights** - Allows the person to edit forms (e.g. IRC, COR, Modification), upload and delete documents associated with the study, read all information associated with this study. Principal Investigators must have edit rights in order to submit forms.
- **Read rights** - Allows a person to read all information associated with the study including uploaded documents. They may not, however, edit anything related to this study.
- **No rights** - It is possible in certain situations that a person is a member of the study team, but is not allowed to read, or edit anything associated with the study. For example, if certain staff are blinded you may not allow them access to information that would potentially unblind them.

Will this person be allowed edit rights for this study?  ○ Yes  ○ No
Will this person be allowed read rights on this study?  ○ Yes  ○ No

**Non-OHSU Personnel**

Is this person not affiliated with OHSU?  ○

The following questions only pertain to those individuals who are not employees of OHSU.

- **What type of agreement is in place?**
  -

  - **If other agreement please explain**
    -

  - Is there a conflict of interest in research policy in compliance with PHS regulation 42 C.F.R. Subpart F in place at the person's institution? If not, a current OHSU Conflict of Interest in Research disclosure for Outside Investigator. Download this form at [http://www.ohsu.edu/research/irbforms.shtml](http://www.ohsu.edu/research/irbforms.shtml)

  - Has responsible conduct of research training been completed at the person's institution?  ○

**Notes:**

Scroll down to display the bottom of the page.
Step 28 - Click on OK

Notes:
Click on OK.
Step 29 - Click on

Enter a short study title for your study. If you are editing an existing study in the system, the title requires a short study title for your study, use the same short study title here.

* Short Study Title: Effects of eLearning
  
  Note: Short study title is limited to 54 characters

* Are you submitting a new study, converting an existing study, requesting a waiver of oversight, or submitting a study with use of human subjects in the future?

   Please select one of the following:
   - New Study
   - Converting an Existing Study
   - Request a Waiver of Oversight
   - Future Human Subjects

**Add Personnel to this Study**

* Principal Investigator: Michael Miller  [Select...]

Sub-Investigators (all collaborators must be included):

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<th>Add</th>
<th>Delete</th>
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<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Primary Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Edit]</td>
<td>Michael</td>
<td>Wright</td>
</tr>
</tbody>
</table>

Research Staff:

<table>
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<tr>
<th>Add</th>
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<th>First Name</th>
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<th>Primary Contact</th>
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<td></td>
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</table>

There are no items to display.

* = Required

Notes:

Scroll down to display the bottom of the page.
Step 30 - Click on Continue >>

* Are you submitting a new study, converting an existing study, requesting a waiver of oversight, or submitting a study with use of human subjects in the future?

Please select one of the following:

- New Study
- Converting an Existing Study
- Request a Waiver of Oversight
- Future Human Subjects

Add Personnel to this Study

* Principal Investigator: Michael Miller

Sub-Investigators (all collaborators must be included):

<table>
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<th>Add</th>
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<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Primary Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michael</td>
<td>Wright</td>
<td>no</td>
</tr>
</tbody>
</table>

Research Staff:

<table>
<thead>
<tr>
<th>Add</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

There are no items to display.

* = Required

Click on Continue.

Notes:
Click on Continue.
Step 31 - Type "Study the effects of eLearning on research staff" in edit box

Notes:
Click in the 1.1 Protocol Title text field and type, Study the effects of elearning on research staff.
Step 32 - Click on

**Initial Review Questionnaire Instructions**

This questionnaire is based on Federal requirements for the protection of human participants and Oregon Health & Science University (OHSU) policies. All research involving humans (including human organs, tissues, fluids or potentially confidential information), regardless of the funding source, must be reviewed by the Institutional Review Board.

Various words throughout this form will be highlighted as a link. These words are defined in the [eIRB Glossary](#), and can be viewed simply by clicking the link.

**Study Information**

* 1.1. Protocol Title:
   
   Study the effects of eLearning on research staff

1.2. Funding Source(s):

List all of the funding sources for this study.

**Notes:**

Scroll down to display more of the page.
This questionnaire is based on Federal requirements for the protection of human participants and Oregon Health & Science University (OHSU) policies. All research involving humans (including human organs, tissues, fluids or potentially confidential information), regardless of the funding source, must be reviewed by the Institutional Review Board.

Various words throughout this form will be highlighted as a link. These words are defined in the eIRB Glossary, and can be viewed simply by clicking the link.

**Study Information**

*1.1. Protocol Title:*

Study the effects of eLearning on research staff

*1.2. Funding Source(s):*

Add

Click on Add to display the **Funding Source** dialog screen.

List all of the funding sources for this study.

Check this box if this study is unfunded: 

**Notes:**
Click on Add to display the Funding Source dialog screen.
Step 34 - Type "NIH" in edit box

Notes:
Click on the Funding Source text field and type NIH.
Step 35 - Select list box item

From the Funding Agency Type menu, select NIH.

Notes:
From the Funding Agency Type menu, select NIH.
Step 36 - Type "12345" in edit box

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>NIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding Agency Type</td>
<td>NIH</td>
</tr>
<tr>
<td>Funding Source # (if applicable)</td>
<td><strong>Click in the Funding Source # text field and type 12345.</strong></td>
</tr>
<tr>
<td>ID number assigned to project by funding source (i.e. grant number, industry sponsored protocol, etc.)</td>
<td></td>
</tr>
<tr>
<td>Grant Title (If applicable)</td>
<td></td>
</tr>
<tr>
<td>PPQ Number (if known)</td>
<td></td>
</tr>
</tbody>
</table>

* Required

Check this box if this study is unfunded: [ ]

Notes:
Click in the Funding Source # text field and type 12345.
Step 37 - Type "eLearning" in edit box

Notes:
Click in the Grant Title text field and type eLearning.
Step 38 - Click on **OK**.

**Notes:**
Click on OK.
Step 39 - Click on \( \text{scroll down} \) to scroll down

This questionnaire is based on Federal requirements for the protection of human participants and Oregon Health & Science University (OHSU) policies. All research involving humans (including human organs, tissues, fluids or potentially confidential information), regardless of the funding source, must be reviewed by the Institutional Review Board.

Various words throughout this form will be highlighted as a link. These words are defined in the eIRB Glossary, and can be viewed simply by clicking the link.

**Study Information**

1. **Protocol Title:**
   
   Study the effects of eLearning on research staff

2. **Funding Source(s):**

   ![Funding Sources Table]

   Check this box if this study is unfunded: ☐

**Notes:**

Scroll down to display the bottom of the page.
Step 40 - Click on Continue >>

involving humans (including human organs, tissues, fluids or potentially confidential information), regardless of the funding source, must be reviewed by the Institutional Review Board.

Various words throughout this form will be highlighted as a link. These words are defined in the eIRB Glossary, and can be viewed simply by clicking the link.

Study Information

* 1.1. Protocol Title:

Study the effects of eLearning on research staff

1.2. Funding Source(s):

Add  Delete

Funding Agency Type  Funding Source  Funding Source Number  Grant title
NIH  NIH  12345  eLearning

Check this box if this study is unfunded: ☐

List all of the funding sources for this study.

Click on Continue

Notes:
Click on Continue.
Project Questionnaire

2.2. Study Type (check all that apply):

2.2.1. Survey, questionnaire, interview or non-interventional study:

2.2.2. Retrospective chart review:

2.2.3. Secondary data analysis only

2.2.4. Pre-existing biological specimens:

2.2.5. Specimen collection only:

2.2.6. Other:

2.2.6.1. Specify: __________________________

Notes:

After completing the initial pages of the IRQ, you will be directed to a series of questions. For simulation purposes, you will only fill out a limited number of questions. Click in check box 2.2.3.
After completing the initial pages of the IRQ, you will be directed to a series of questions. For simulation purposes, you will only fill out a limited number of questions. Click in check box 2.2.3.
Step 42 - Click on

Notes:
Click on Continue.
Step 43 - Click on

Notes:
Scroll down to display more of the current page.
Step 44 - Click on ☑

### Collaboration with PVAMC:

2.6.14. Study utilizes GCRC resources:

2.7. Research data will be (check all that apply):
   - 2.7.1. Obtained from clinical chart review:
   - 2.7.2. Collected as part of previous research:
   - 2.7.3. Created (de novo):
   - 2.7.4. Created for research purposes only:
   - 2.7.5. Created during a diagnostic or therapeutic procedure:
   - 2.7.6. Created with the intent to store in a data repository (e.g., research database) for future research or analysis:
   - 2.7.7. Collected from an existing research data repository:
   - 2.7.8. Provided by the Center for Information Analysis and Decision Support (CIADS):

2.8. At the time the data is collected for this study (i.e., transcribed or recorded) it is:
   - 2.8.1. **Fully Identifiable**: ☑
   - 2.8.2. **Coded with a Unique Identifier**: ☑
   - 2.8.3. **Unlinked (anonymized)**:
   - 2.8.4. **Unidentified (anonymous)**:

2.9. Data will be later manipulated before analysis so that it is (check all that apply):
   - 2.9.1. **Fully Identifiable**:
   - 2.9.2. **Coded with a Unique Identifier**:
   - 2.9.3. **Unlinked (anonymized)**:
   - 2.9.4. **Unidentified (anonymous)**:

### Notes:

Click in check box 2.8.4.
Step 45 - Click on

---

Notes:
Scroll down to display more of the current page.
Step 46 - Click on □

Notes:
Click in check box 2.9.3.
Step 47 - Click on **No**

**Notes:**
Click No on 2.10.
Step 48 - Click on

Notes:
Scroll down to display the bottom of the page.
Step 49 - Click on **Save**

If you need to stop working during an IRQ, it is important to save your work. Click on **Save** to continue.

**Notes:**
If you need to stop working during an IRQ, it is important to save your work. Click on Save to continue.
Step 50 - Click on Exit.

2.6. Check all that apply:

2.6.1. Study involves cancer:

2.6.2. Subjects in the study will undergo a clinical procedure:

2.6.3. Biological specimens will be collected as part of this protocol:

2.6.4. The participant will be exposed to materials or procedures with potential radiation risks solely for the purpose of research:

2.6.5. An FDA approved drug will be used for an unapproved purpose:

2.6.6. A dietary supplement, herbal remedy, or other complementary or alternative remedy will be used:

2.6.7. An FDA approved device will be used for an unapproved purpose:

2.6.8. An investigational (unapproved) new drug will be used:

2.6.9. An investigational (unapproved) new device will be used:

2.6.10. Research data will be generated, collected, or analyzed at a non-OHSU Site:

HELP TEXT

Check 2.6.1 if the subjects are eligible simply because of their diagnosis with cancer. The study may be assessment in cancer patients. The protocol will reviewed by OHSU CI prior to IRB review.

*Specimens for research purposes, not clinical care, with or without an intent to store the specimen.

**For example, x-rays, radioisotopes, DEXA, etc. are not part of standard care.

***Genetic tests included tests to determine the existence or risk of disease, disorder, trait, or syndrome, including tests of nucleic acids (DNA, mitochondrial DNA), chromosomes, or protein.

For additional information please see:
http://www.ohsu.edu/research/nda/forms.shtml#:
http://www.ohsu.edu/research/nda/irb/genetic.shtml

Notes:
Click on Exit.
Step 51 - Click on OK button

Read the message and click on OK. You have already saved.
Read the message and click on OK. You have already saved.
Step 52 - Click on Open IRQ

To return to the IRQ, click on Open IRQ from your study workspace. The study workspace is accessible from the Protocol tab on your home page.

Notes:
To return to the IRQ, click on Open IRQ from your study workspace. The study workspace is accessible from the Protocol tab on your home page.
Use this form to initiate a new Initial Review (IR) or convert an existing study, request a waiver of oversight, or submit a study with use of future human subjects.

Enter a short study title for your study. You will use this title to identify your study in the system. If the NIH requires a short study title for your study, use the same short study title here.

**Short Study Title:** Effects of eLearning  
*Note:* Short study title is limited to 54 characters

Are you submitting a new study, converting an existing study, requesting a waiver of oversight, or submitting a study with use of human subjects in the future?

- New Study
- Converting an Existing Study
- Request a Waiver of Oversight
- Future Human Subjects

**Add Personnel to this Study**

**Principal Investigator:** Michael Miller

**Notes:**
Click on Continue to move through the IRQ.
**Initial Review Questionnaire Instructions**

This questionnaire is based on Federal requirements for the protection of human participants and Oregon Health & Science University (OHSU) policies. All research involving humans (including human organs, tissues, fluids or potentially confidential information), regardless of the funding source, must be reviewed by the Institutional Review Board.

Various words throughout this form will be highlighted as a link. These words are defined in the eIRB Glossary, and can be viewed simply by clicking the link.

**Study Information**

1.1. Protocol Title:

   Study the effects of eLearning on research staff

1.2. Funding Source(s):

   Add Delete

   Funding  Funding  Other

   List all of the funding sources for this study.

**Notes:**
Click on Continue.
Step 55 - Click on

| 2.7.7. Collected from an existing research data repository: |  
|----------------------------------------------------------|---|
| 2.7.8. Provided by the Center for Information Analysis and Decision Support (CIADS): |  
| 2.8. At the time the data is collected for this study (i.e., transcribed or recorded) it is: |  
| 2.8.1. **Fully Identifiable:** |  
| 2.8.2. **Coded with a Unique Identifier:** |  
| 2.8.3. **Unlinked (anonymized):** |  
| 2.8.4. **Unidentified (anonymous):** |  
| 2.9. Data will be later manipulated before analysis so that it is (check all that apply): |  
| 2.9.1. **Fully Identifiable:** |  
| 2.9.2. **Coded with a Unique Identifier:** |  
| 2.9.3. **Unlinked (anonymized):** |  
| 2.9.4. **Unidentified (anonymous):** |  
| 2.10. Will audio tapes (tape recordings or videos with sound) be made? |  
| ☐ Yes ☐ No |  
| 2.10.1. Will audio tapes be transcribed? |  
| ☐ Yes ☐ No |  
| 2.10.2. If tapes are transcribed, will the original recordings also be retained? |  
| ☐ Yes ☐ No |  
| 2.11. Will video tapes or photographs be made in which the subject could be recognized? |  
| ☐ Yes ☐ No |  

**Notes:**

Scroll down to display more of the current screen.
Step 56 - Click on  No

2.8.1.  Fully Identifiable: [ ]
2.8.2.  Coded with a Unique Identifier: [ ]
2.8.3.  Unlinked (anonymized): [ ]
2.8.4.  Unidentified (anonymous): [ ]

2.9. Data will be later manipulated before analysis so that it is (check all that apply):
2.9.1.  Fully Identifiable: [ ]
2.9.2.  Coded with a Unique Identifier: [ ]
2.9.3.  Unlinked (anonymized): [ ]
2.9.4.  Unidentified (anonymous): [ ]

2.10. Will audio tapes (tape recordings or videos with sound) be made?
   ○ Yes  ☐ No
2.10.1. Will audio tapes be transcribed?
   ○ Yes  [ ] No
2.10.2. If tapes are transcribed, will the original recordings also be retained?
   ○ Yes  ☐ No
2.11. Will video tapes or photographs be made in which the subject could be recognized?
   ○ Yes  ☐ No
   [Click No on 2.10.2.]

2.12. Will video or audio tapes, photographs, or transcriptions be labeled with:
2.12.1.  Full Identifiers: [ ]
2.12.2.  A Unique Code: [ ]
2.12.3.  An Unlinked Code (anonymized): [ ]
2.12.4.  No Identifier (anonymous): [ ]

Notes:
Click No on 2.10.2.
Step 57 - Click on No.

Notes:
Click No on 2.11.
Step 58 - Click on

Notes:
Scroll down to display more of the current screen.
Step 59 - Click on

Click the check box for 2.12.3.
Step 60 - Click on **No**

2.10. Will audio tapes (tape recordings or videos with sound) be made?
- Yes
- No

2.10.1. Will audio tapes be transcribed?
- Yes
- No

2.10.2. If tapes are transcribed, will the original recordings also be retained?
- Yes
- No

2.11. Will video tapes or photographs be made in which the subject could be recognized?
- Yes
- No

2.12. Will video or audio tapes, photographs, or transcriptions be labeled with:
- **Full Identifiers:**
- **A Unique Code:**
- **An Unlinked Code (anonymized):**
- **No Identifier (anonymous):**

2.13. Will audio, video, or photos in which the subject could be recognized be displayed publicly in classrooms or scientific meetings or published?
- Yes
- No

2.14. Identified information will be transmitted outside of OHSU:
- **Click on No for 2.13**

2.14.1. Describe how this information will be secured while in transit (e.g. encryption):

**Notes:**
Click on No for 2.13.
Step 61 - Click on

Notes:
Scroll down to display the bottom of the page.
Step 62 - Click on Continue >>

2.10.1. Will audio tapes be transcribed?
- Yes  ☐  No ☑

2.10.2. If tapes are transcribed, will the original recordings also be retained?
- Yes ☐  No ☑

2.11. Will video tapes or photographs be made in which the subject could be recognized?
- Yes ☐  No ☑

2.12. Will video or audio tapes, photographs, or transcriptions be labeled with:

2.12.1. Full Identifiers: ☐
2.12.2. A Unique Code: ☐
2.12.3. An Unlinked Code (anonymized): ☑
2.12.4. No Identifier (anonymous): ☐

2.13. Will audio, video, or photos in which the subject could be recognized be displayed publicly in classrooms or scientific meetings or published?
- Yes ☐  No ☑

2.14. Identified information will be transmitted outside of OHSU: ☐
2.14.1. Describe how this information will be secured while in transit (e.g. encryption):

Audio tapes of voices and video or photographs in which the subject is recognizable can never be considered anonymous, even if no label is given.

Notes:
Click on Continue.
Step 63 - Click to continue.

Use this form to manage your study 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 an item please fill in the 'How Many?' column.

<table>
<thead>
<tr>
<th>Electronic</th>
<th>Hard Copy</th>
<th>How Many?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2 page protocol summary written in lay language</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete and final study protocol</td>
<td></td>
<td></td>
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<tr>
<td>Complete grant (if an NIH grant is funding this study)</td>
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</tr>
<tr>
<td>Data Safety Monitoring Plan for NIH-Sponsored studies or GCRC studies</td>
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<tr>
<td>Adult Informed Consent Form</td>
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<td>Genetic Informed Consent Form</td>
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<tr>
<td>Child Assent</td>
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</tbody>
</table>

Notes:
This page allows you to submit electronic documents with your IRQ and to indicate any documents you will be mailing in as hard copies.

Click Here to continue.
Use this form to manage your study documents.

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

**Notes:**
Click the check box for Electronic.
Step 65 - Type key 1

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

Click on the How Many? text field and type 1.
Step 66 - Click on

---

**Use this form to manage your study documents.**

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

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<td>✔️</td>
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<tr>
<td>Child Assent</td>
<td>☐</td>
<td>☐</td>
<td>✔️</td>
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**Notes:**

Click the check box for **Electronic**.
Use this form to manage your study documents.

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

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</tbody>
</table>

Notes:
Click on the How Many? text field and type 1.
Step 68 - Click on

Notes:
Scroll down to display the bottom of the page.
Step 69 - Click on **Add**

The text box allows for the upload of study documents. To do so, click **Add** to continue.

### Collaborative Agreement(s)
- CLIA Certifications (non-OHSU labs)
- Clinical Study Billing Schedule
- Use of Ionizing Radiation in Humans Form
- Humanitarian Device Exemption Application (if held by PI)
- IND (if held by PI)
- IDE (if held by PI)
- FDA 2891 (if 510k exempt device or diagnostic)
- FDA SE (if 510k was submitted for a device)
- Inter-institutional Agreement
- Fee Agreement (for GCRC industry-sponsored studies only)
- Industry Budget (for GCRC industry-sponsored studies only)

### Study Documents:

<table>
<thead>
<tr>
<th>Add</th>
<th>Title</th>
<th>Date Created</th>
<th>Date Modified</th>
<th>Version</th>
</tr>
</thead>
</table>

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

Notes:
You can upload electronic documents to the IRQ. Click Add to continue.
Security Warning

Step 70 - Click on Yes button.

Notes:
You may get a Security Warning dialog box. Click on Yes to accept this I.E. add on.
Step 71 - Type "Protocol" in edit box

**Notes:**
Click in the Title text field and type, **Protocol**.
Step 72 - Click on **Browse**.
Click on Browse.
Choose file

Step 73 - Click on e-Learning Protocols.doc

Notes:
Select the e-Learning Protocols.doc document.
Choose file

Step 74 - Click on Open button

Notes:
Click on Open.
Step 75 - Click on OK

Click on OK.
Step 76 - Click on **Hide/Show Errors**

You may turn on the Hide/Show Errors functionality at any time during the IRQ. Click on **Hide/Show Errors**.

**Notes:**
You may turn on the Hide/Show Errors functionality at any time during the IRQ. Click on **Hide/Show Errors**.
Step 77 - Click to continue

Notes:
If you had missed any necessary fields to complete this study, they would be listed here as Errors. Links back to the missing fields would provide you quick access to correct them.

Click Here to continue
Step 78 - Click to continue

Notes:
Click on Save after correcting any errors, then click on Refresh.

Click Here to continue
Step 79 - Click on Finish.

Use this form to manage your study documents.

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</table>

Notes:
Click on Finish.
Step 80 - End of simulation

IRB Number: IRB00000067

Long Study Title: Study the effects of eLearning on research staff

Review Category:

Sponsor: NIH

Study Status: Researcher preparation

Short Study Title: Effects of eLearning

Expiration Date:

Principal Investigator: Michael Miller

Old IRB #:

Board Number:

Initial Review History

Study Documents

Project Log