

Human Subjects Research versus Quality Improvement

The federal definition of research is, “...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes” (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>). This is an important distinction to make because it determines whether IRB review and oversight of a project is needed. IRB review and oversight of activities involving human subjects is limited to those activities that meet the definition of Human Subjects Research.

Differentiating Human Subjects Research from other types of activities such as Quality Improvement projects involves multiple considerations. The OSU Office of Responsible Research Practices (ORRP) often receives requests that the IRB make a formal determination that a project falls outside of the federal definition of research. For example, a written IRB determination that the project does not require IRB review is requested in anticipation of such documentation being required for academic assignments (e.g., Master’s thesis, doctoral dissertation), as well as scholarly activities such as journal publications, conference presentations, seeking funding, and other similar activities.

Access the “Human Subjects Research Assessment Form” via the OSU CON website at <https://nursing.osu.edu> Click on the Research and Research Centers of Excellence

Post-Master's DNP Application Re-Opens Apply by June 1

News headlines

- Gawlik to receive State Award for Nurse Practitioner Excellence
- Dean Bernadette Melnyk Receives AACN Pioneering Spirit Award
- Nursing Research Matters!
- College of Nursing recognized for diversity work

From the Dean

What an exciting year it has been at the College of Nursing! Our spring 2018 issue of Transformations in Nursing and Health has just been mailed out. [Read more](#)

Academic Programs: Online and on campus

Student Affairs / Financial Aid / Tuition

Current Student Resources

Research and Research Centers of Excellence

Helene Fuld Health Trust National Institute for Evidence-based Practice in Nursing and Healthcare

Academy for Continuing Education and Lifelong Learning (AcCELL)

Office of Innovation and Strategic Partnerships

Data Commons

Buckeye **Leadership** **Health** **RESEARCH INTENSIVE WORKSHOP**

Next, **click** the Center for Research and Health Analytics



Home » Sections » Research and Research Centers of Excellence

Research and Research Centers of Excellence

[Center for Research and Health Analytics](#) ←

[Center of Excellence in Critical and Complex Care](#)

[Center for Women, Children & Youth](#)

[Graduate research](#)

At the College of Nursing, graduate students have the opportunity to contribute to the profession of nursing as scientists and scholars during an exciting time in the history of the nursing profession.

[Go to section »](#)

[Undergraduate research](#)

Engaging undergraduate students in research facilitates students' understanding of how the science that underpins the discipline of nursing is discovered and subsequently how this is translated into practice.

[Go to section »](#)

Academic Programs: Online and on campus

Student Affairs / Financial Aid / Tuition

Current Student Resources

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Data Commons

Next, **Right click** on the Human Subjects Research Form.

NOTE: Please Use Internet Explorer browser for direct access this form. If using Mozilla Firefox, there is an additional step to accessing the form.

The form will appear (as below) (For Internet Explorer users)

The screenshot shows a PDF viewer window titled "Human_Subjects_Research_Assessment_Form(3).pdf". The viewer interface includes a top toolbar with "Open", "Create", and various utility icons, and a right-side toolbar with "Tools", "Fill & Sign", and "Comment". A green status bar at the top of the document area contains the text "Please fill out the following form." and a "Highlight Existing Fields" button. The document content is as follows:

The Ohio State University-College of Nursing

Human Subjects Research Assessment Form

Instructions:

1. Please complete the requested project information, as this form may be used for documentation that neither IRB review nor an exemption is required.
2. Please select the appropriate answers to each question in order as they appear. If all of the questions are answered without receiving an error message, the form must be printed AND signed as certification that the project is "not human subjects research," and does not require IRB review or exemption.

If you are unsure how to answer any of the questions, please contact ORRP for additional guidance.

Project Information:

Name of PI, advisor, or mentor:

Title of Project

Brief Description of Project/Goals:

If using Mozilla Firefox, when you click on the form, you will get the message below:

A screenshot of a Mozilla Firefox browser window. The address bar shows a partially visible URL ending in 't supported.'. The browser's toolbar includes zoom controls (minus and plus signs) and a dropdown menu set to 'Automatic Zoom'. On the right side of the toolbar, there are icons for full screen and printing, and a button labeled 'Open With Diffe...'. The main content area of the browser displays a white page with the following text:

Please wait...

If this message is not eventually replaced by the proper contents of the document, your PDF viewer may not be able to display this type of document.

You can upgrade to the latest version of Adobe Reader for Windows®, Mac, or Linux® by visiting <http://www.adobe.com/products/acrobat/readstep2.html>.

For more assistance with Adobe Reader visit <http://www.adobe.com/support/products/acrreader.html>.

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Click on **Open with Different Viewer** and select the “Open with Adobe Acrobat” option and this will open the Form.

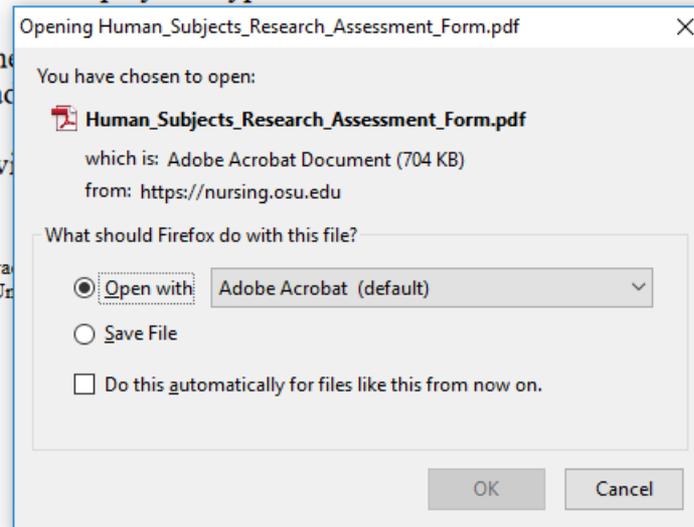
Please wait...

If this message is not eventually replaced by the proper contents of the document, your PDF viewer may not be able to display this type of document.

You can upgrade to the latest version of the viewer by visiting <http://www.adobe.com/products/acrobat/readstep2.html>.

For more assistance with Acrobat, visit <http://www.adobe.com/products/acrobat/readstep2.html>.

Windows is either a registered trademark or trademark of Microsoft Corporation in the United States and other countries. Mac is a trademark of Apple Inc., registered in the United States and other countries.



or Linux® by

/products/

countries. Mac is a trademark
ds in the U.S. and other

This is a fillable form. As you complete a question, the next will appear

The Ohio State University-College of Nursing	
Human Subjects Research Assessment Form ←	
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Project Information:	
Name of PI, advisor, or mentor:	<input type="text"/>
Title of Project	<input type="text"/>
Brief Description of Project/Goals:	<input type="text"/>
	<input type="button" value="Help"/>
Questions:	
1. Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?	
<input type="radio"/> Yes	<input type="button" value="Help"/>
<input type="radio"/> No	

←

Now you have a fillable form. Questions will appear as you complete each one. You CANNOT save the completed form onto your computer.

As you are completing the determination form. A text box may appear as demonstrated above. This may indicate Certification is not valid. If you receive this notice, please consult with your advisor for further guidance.

Please fill out the following form. You cannot save data typed into this form.
Please print your completed form if you would like a copy for your records.

Title of Project

Brief Description of Project/Goals:

Help

Questions:

1. Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?

Yes

No

A message box may appear to provide further guidance.

STOP HERE. Certification is not valid. IRB review is likely required to address FDA requirements. Please visit [Ohio State's ORRP](#) for guidance.

What does this mean?

****Please note if you completed the form with ADOBE ACROBAT Complete capability. You may save and send completed via electronically to your advisor. Otherwise,.....The completed form needs to be printed. See next slide for details.**

Read this part CAREFULLY
and follow the directions



Help

Questions:

1. Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?

Yes
 No

2. Has the project received funding (e.g. federal, industry) to be conducted as a human subjects research study?

Yes
 No

3. In addition to any other purposes, is the project intended to develop or contribute to generalizable knowledge (e.g. testing a hypothesis) AND/OR has the project been designed in such a way that the findings will be generalizable (e.g. randomization of subjects; comparison of case vs. control)?

Yes
 No

4. Will the results of the project be published, presented or disseminated outside of the institution conducting it?

Yes
 No

5. Will the project occur exactly as proposed regardless of whether individuals conducting it may benefit professionally from it?

Yes
 No

6. Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program?

Yes
 No

If no message appears above indicating the certification is not valid, IRB Review is not required because, in accordance with federal regulations, the project does not constitute human subjects research as defined under 45 CFR 46.102(d). Print a copy of this form, have it signed by the PI, advisor, or mentor, and save with your files. This serves as record that IRB review is not required for this project.

What do my results mean? Signature Current Date 11/8/15 Print Form

A pop-up message will appear if your project is deemed to not fit the federal definition of research

4. Will the results of the project be published, presented or disseminated outside of the institution conducting it?

Yes

No

Help

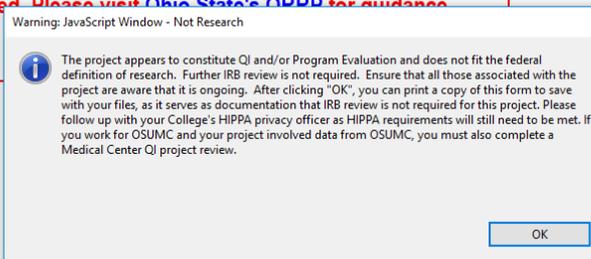
5. Will the project occur exactly as proposed regardless of whether individuals conducting it may benefit professionally from it?

Yes

No

Help

STOP HERE. Certification is not valid. IRB review is likely required. Please visit Ohio State's ORPP for guidance.



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Current Date

6/1/18

Print Form

Please print a copy of the completed form with the determination message, have it signed by your advisor .Once your advisor has approved save onto your E-portfolio under the tab “Project” for your records and verification. Also remember your “Project Proposal Form” signed by all committee members should also be up loaded onto your E-portfolio under the tab “Project”

Please fill out the following form. You cannot save data typed into this form. Please print your completed form if you would like a copy for your records.

Yes

No

5. Will the project occur exactly as proposed regardless of whether individuals conducting it may benefit professionally from it?

Yes

No

6. Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program?

Yes

No

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What do my results mean?

Signature

Current Date

11/8/15

Print Form

If further clarification is needed on whether your project qualifies as exempt from research status, a copy of the filled out form and the study proposal can be sent to ORRP ORRPDeterminations@osu.edu and they will promptly provide confirmation