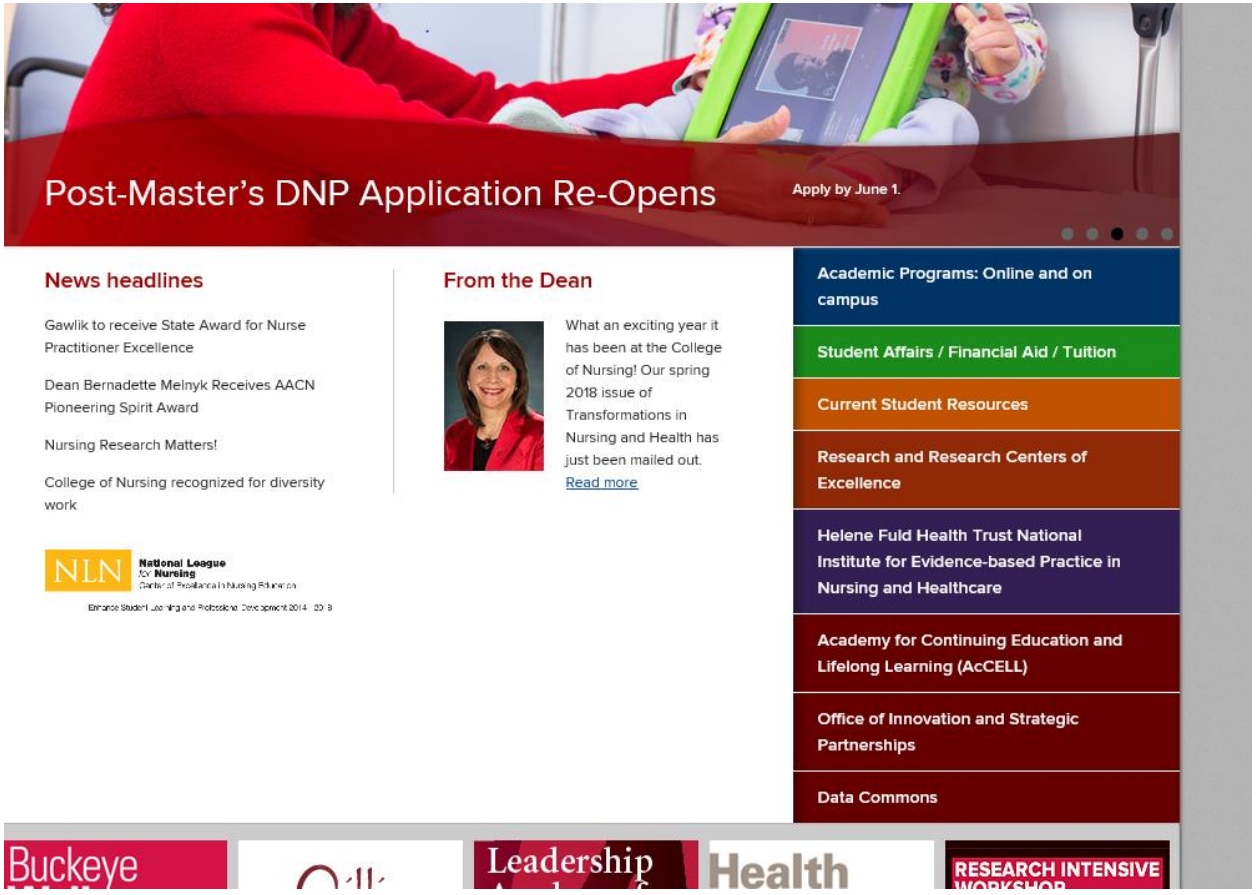
Human Subjects Research versus Quality Improvement

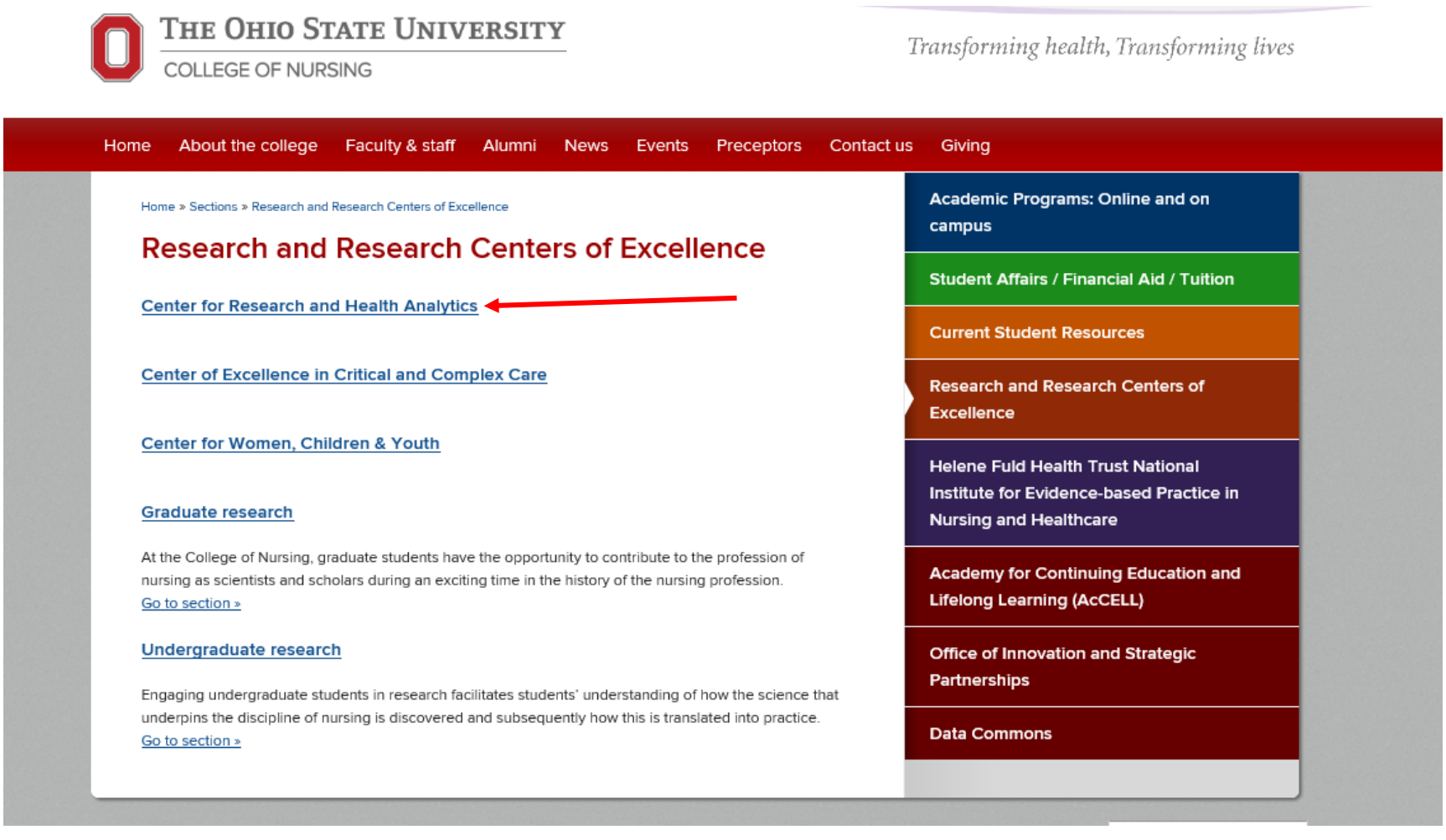
The federal definition of research is, "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted 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.eduClick on the Research and Research Centers of Excellence



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



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

Please note: This form requires Adobe reader

Center for Research and Health Analytics

Center Mission

The mission of the Center for Research and Health Analytics is to provide centralized grant and research services for faculty.
The Center provides resources to streamline grant submissions, IRB applications, grant management, and research projects. The Center is home to two wet laboratories available for faculty internal and external the College of Nursing.

Center Structure

The Center is led by Mary Beth Happ the Associate Dean of Research and Innovation. Dr. Happ, an active researcher, focuses on critical care gerontology, patient care and communication during mechanical ventilation, and end-of-life-care and treatment decision making in the ICU.

Health Analytics Home

Grants Management

Tips for submitting a new grant

Research Laboratory

Stress Science

Compliance - IRB Requirements

Resources

GRA request form

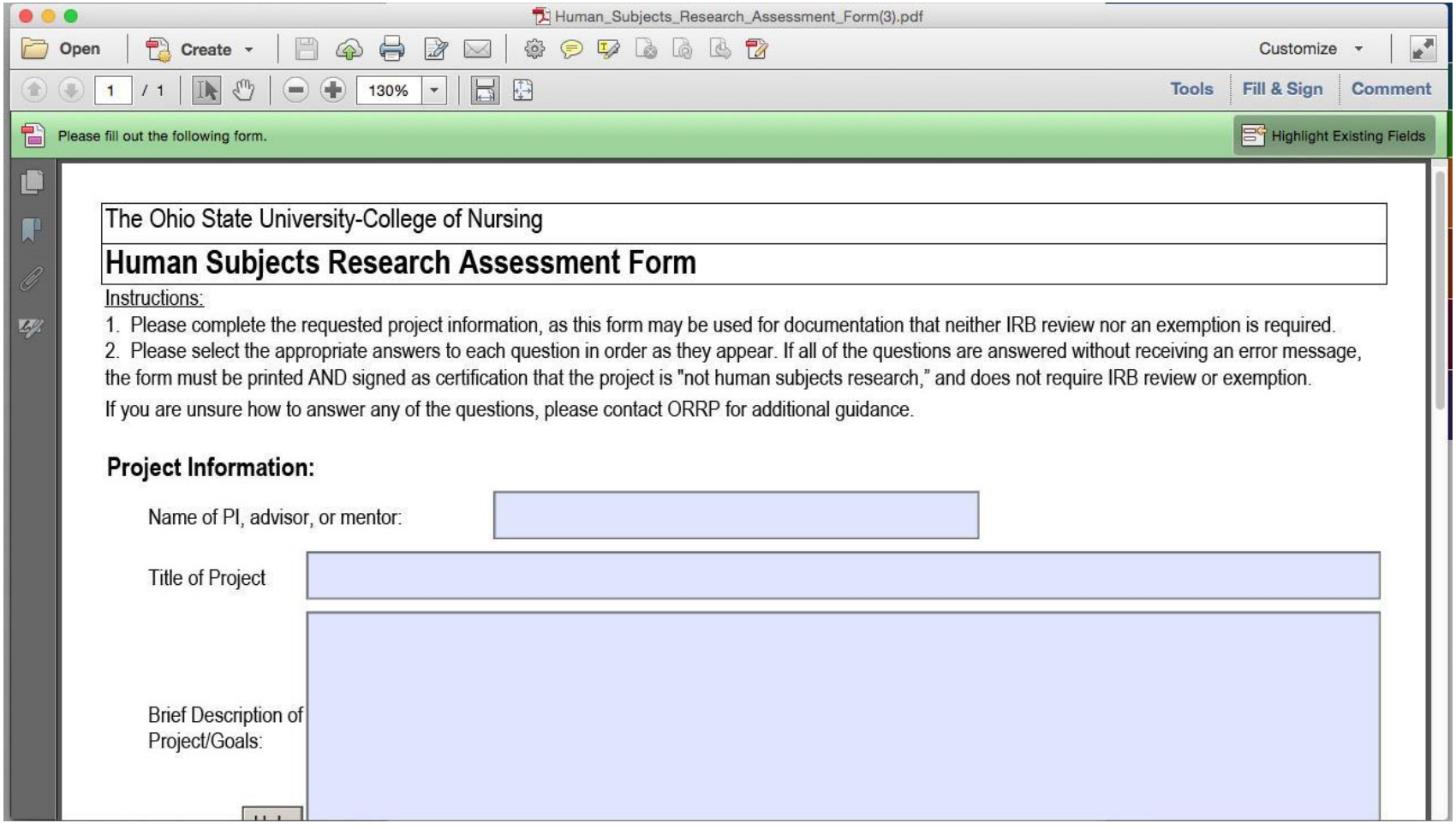
Editor Request Form

Human Subjects Research Form

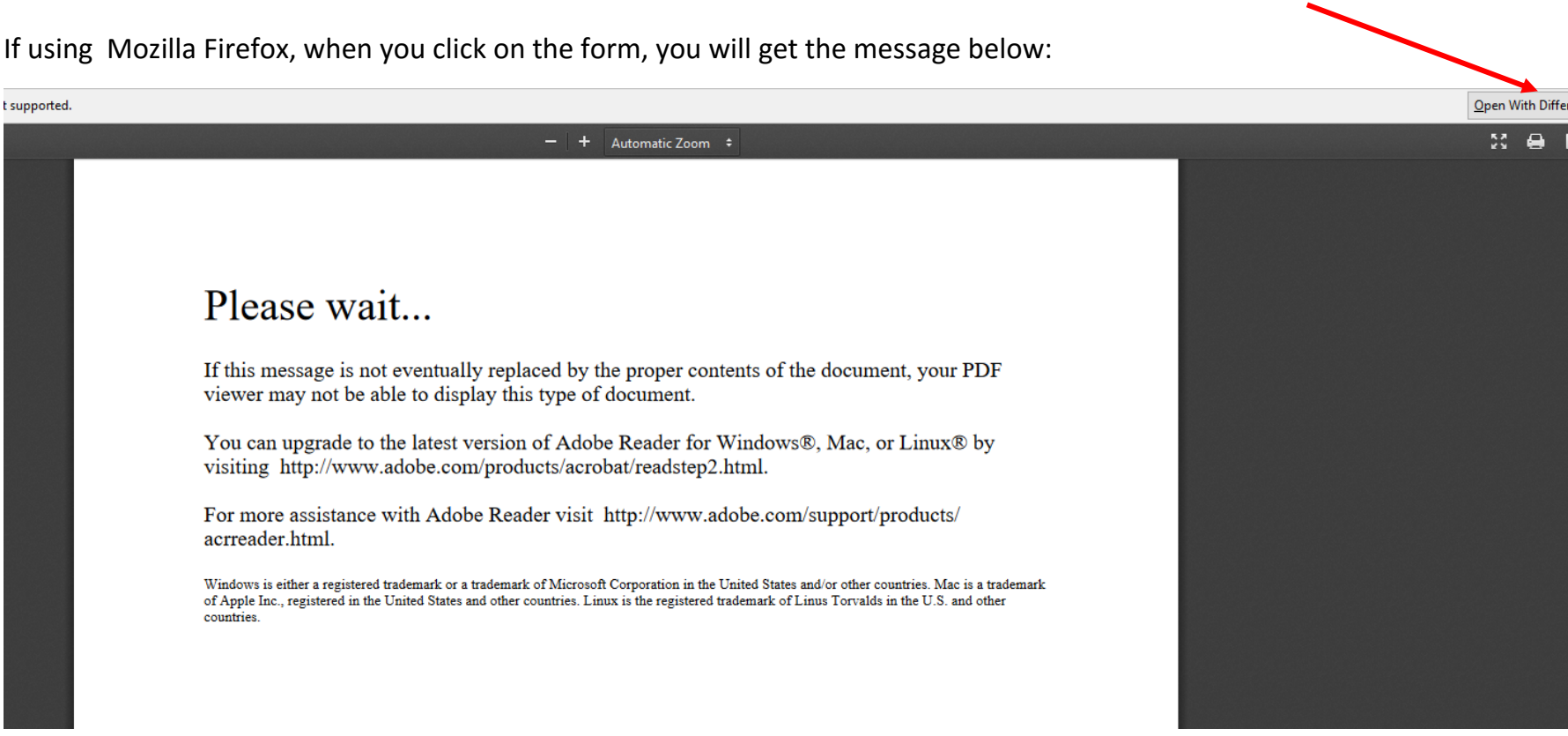
The forms above require Adobe Reader which is a free resource available for download.

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

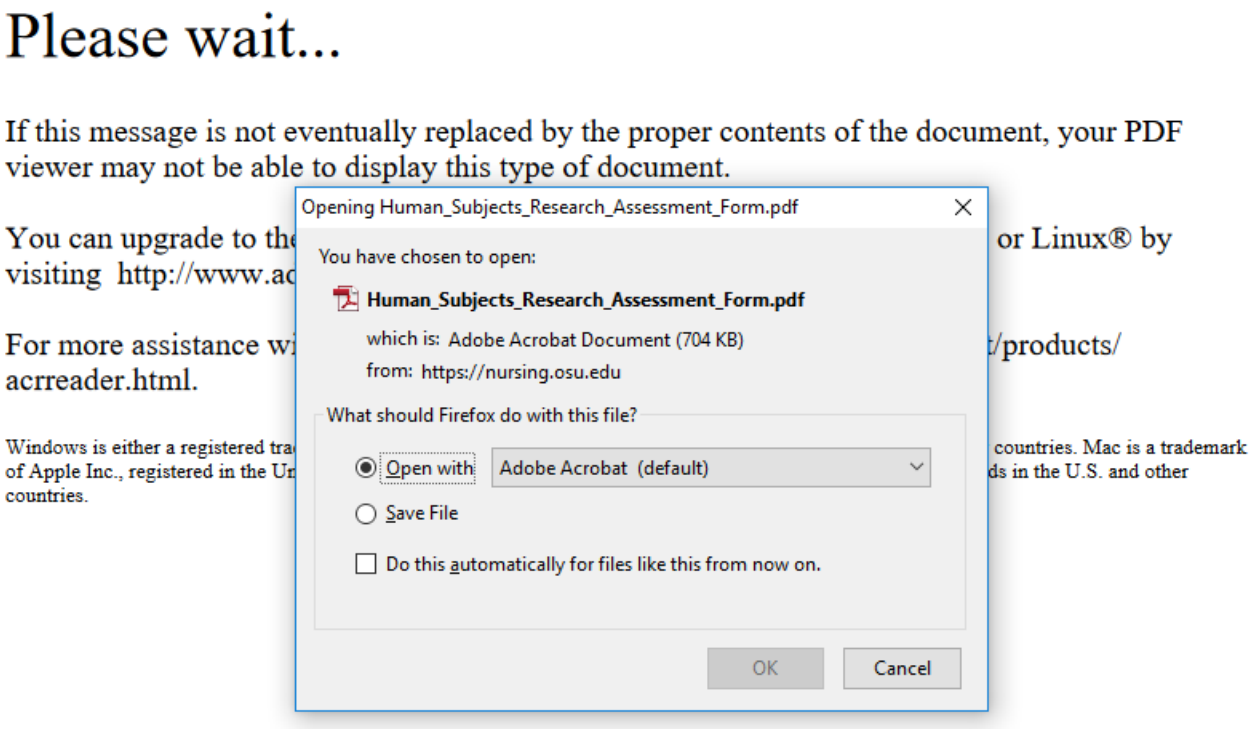
The form will appear (as below) (For Internet Explorer users)



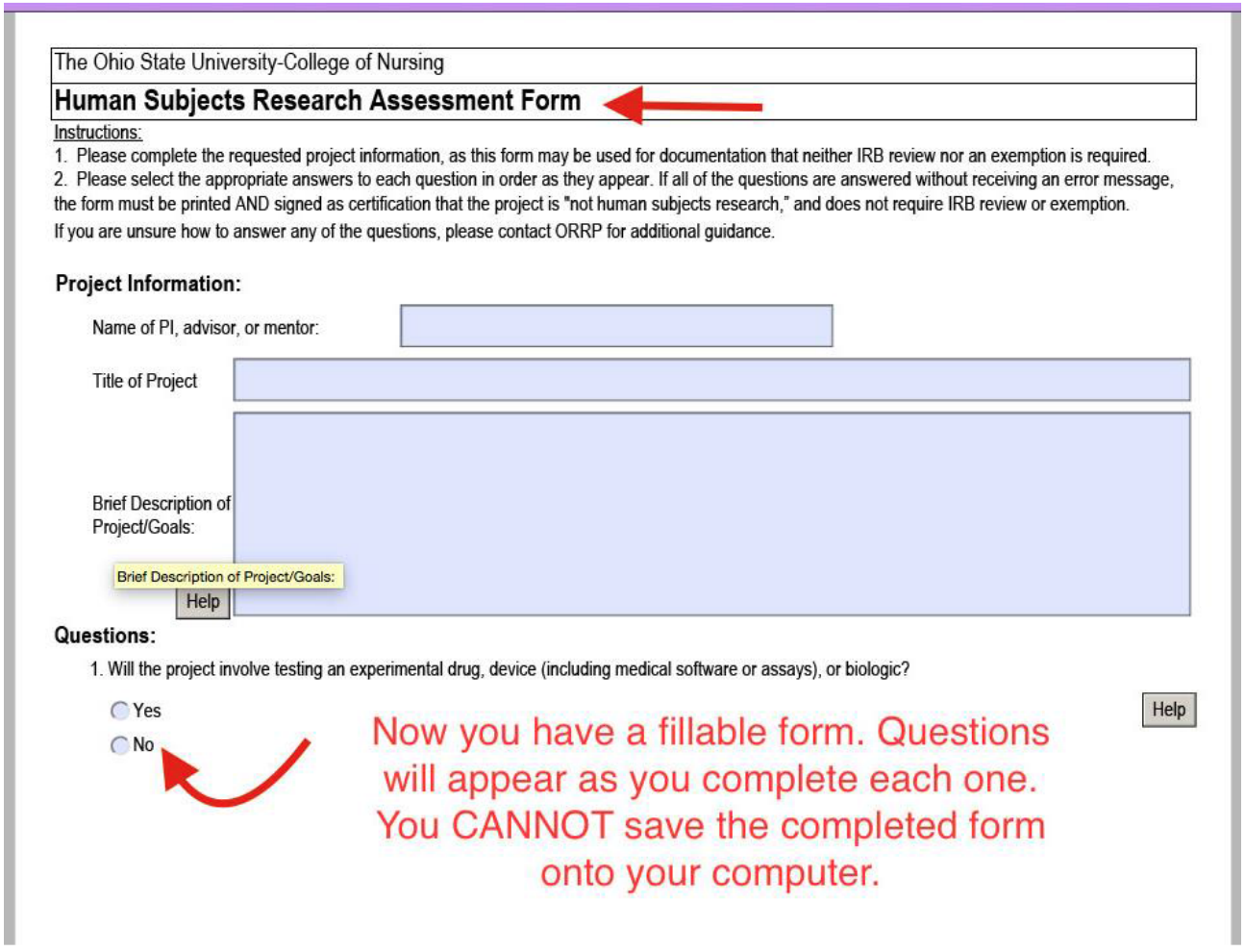
If using Mozilla Firefox, when you click on the form, you will get the message below:



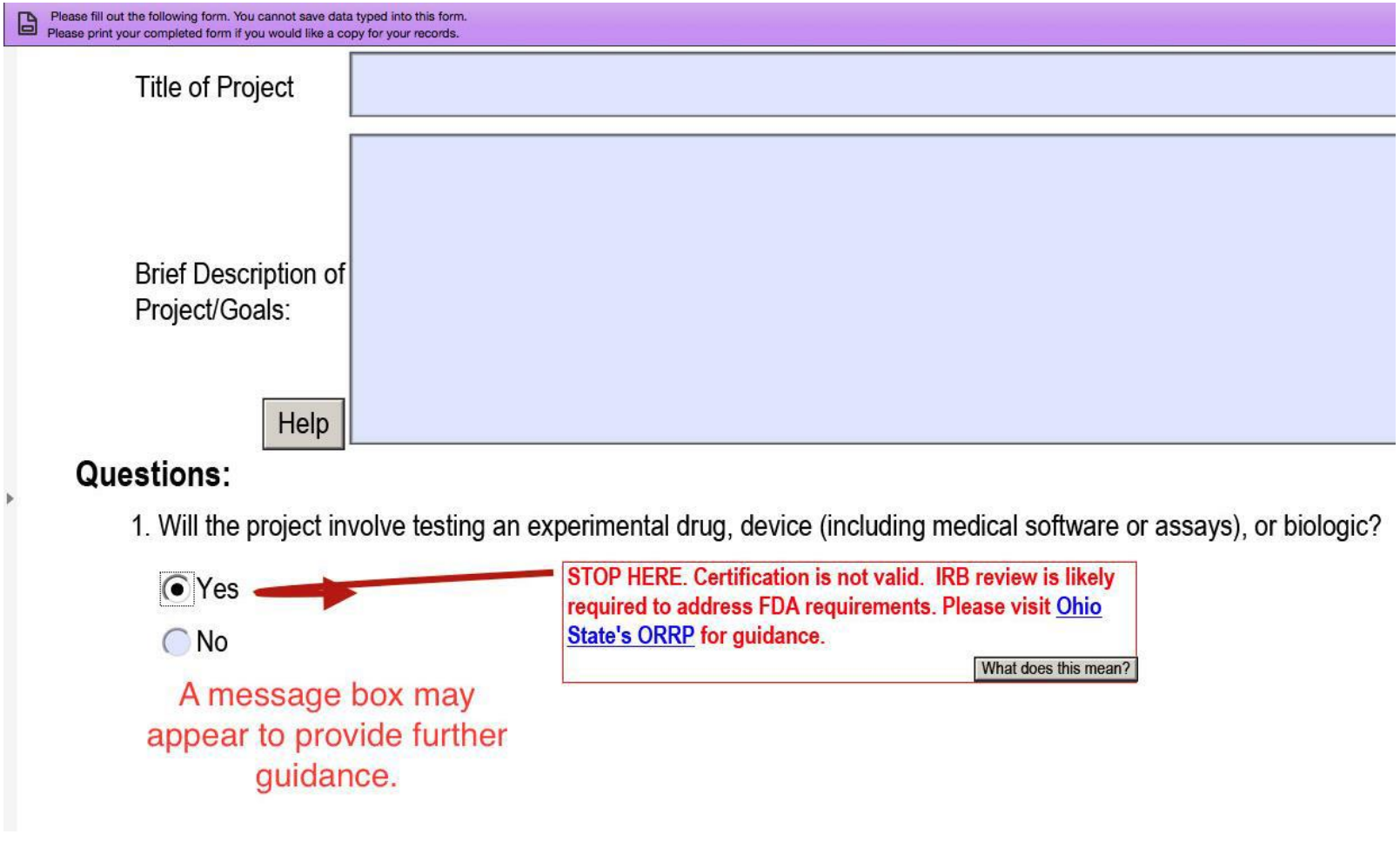
Click on **Open with Different Viewer** and select the “Open with Adobe Acrobat” option and this will open the Form.



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

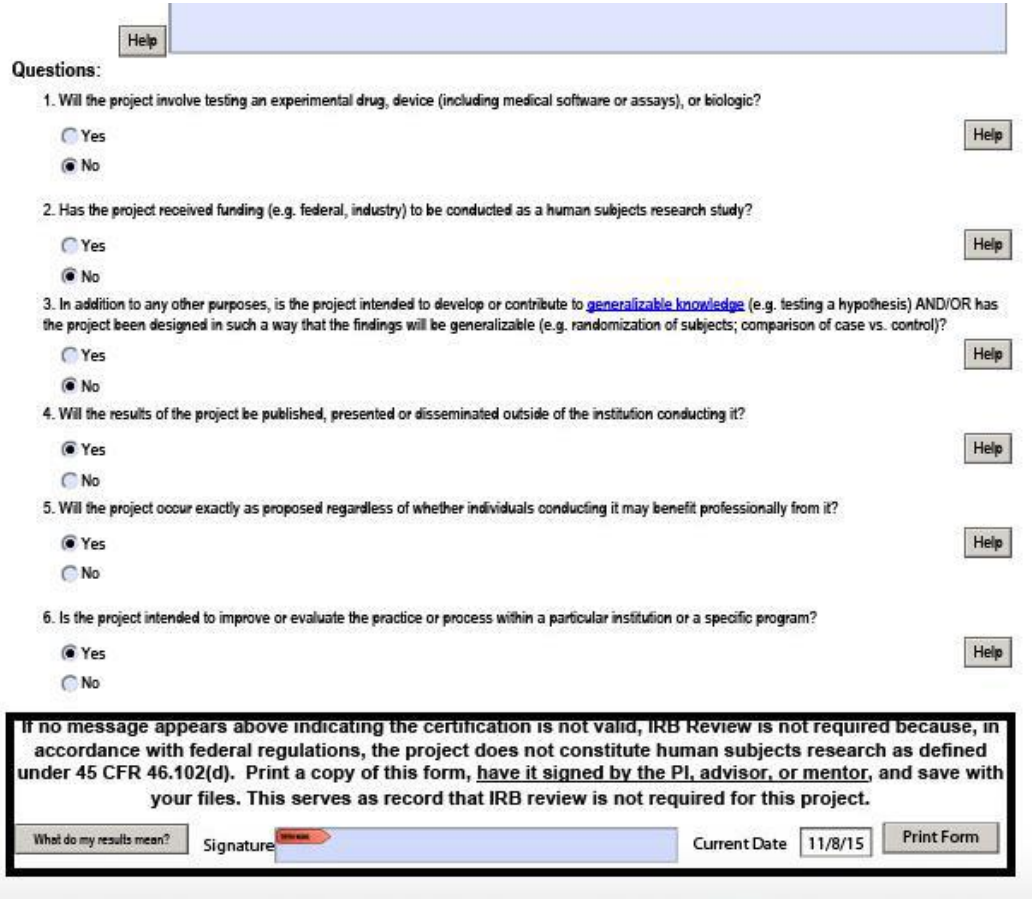


As you are completing the determination form. A text box may appear as demonstrated above. This may indicate Certification is not valid. If you receive this notice, please consult with your advisor for further guidance.



Please 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



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

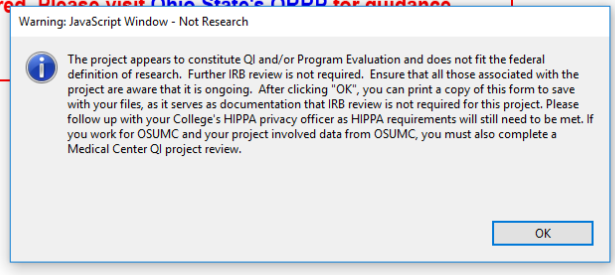
5. Will the project occur exactly as proposed regardless of whether individuals conducting it may benefit professionally from it?

Yes

No

Help

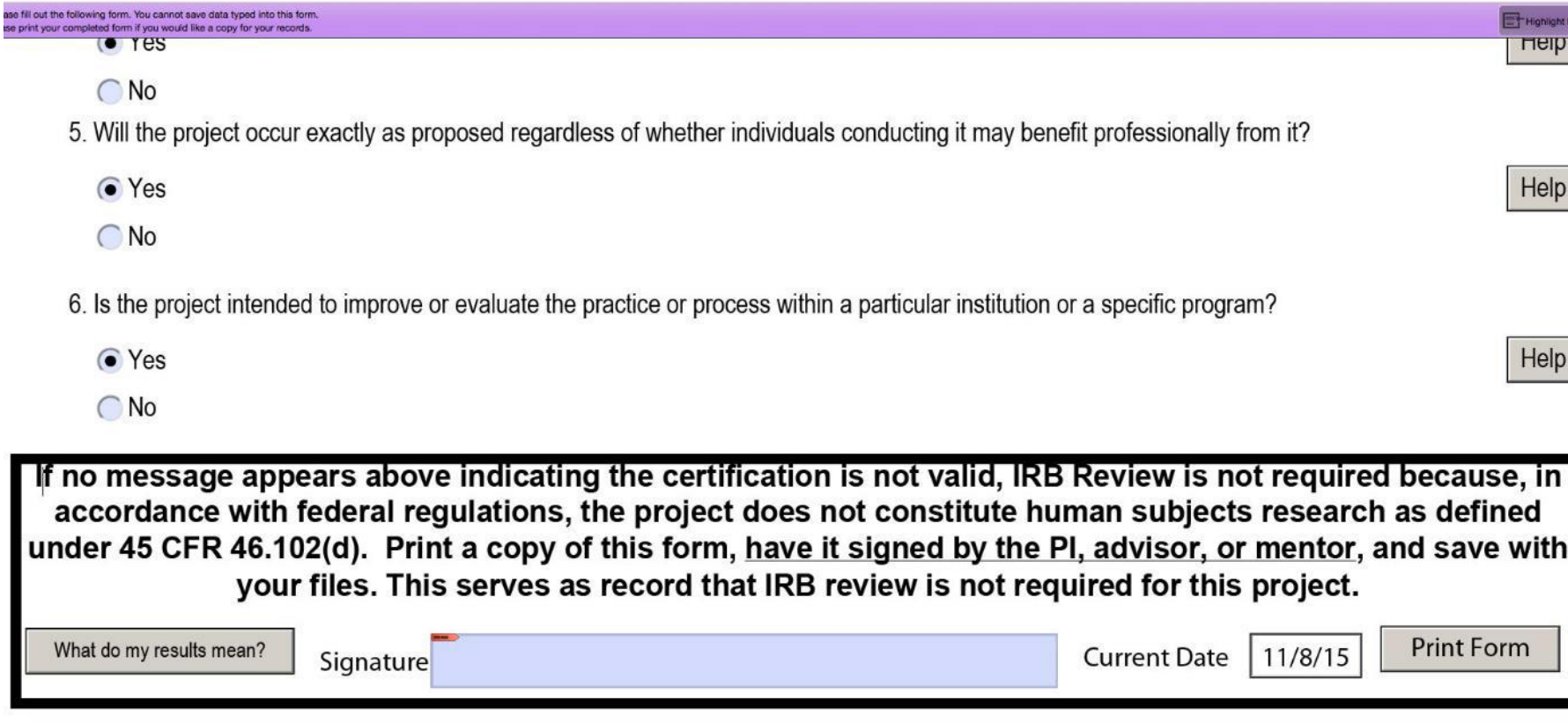
STOP HERE. Certification is not valid. IRB review is likely required. Please visit Ohio State's ORRP for guidance



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.

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”



If further clarification is needed on whether your project is 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