SOUTHERN ILLINOIS UNIVERSITY
EDWARDSVILLE

Human Subjects Approval

In order to comply with federal regulations, projects that involve human subjects, animals, biohazards, or recombinant DNA must be cleared by the appropriate University leadership or committees before data collection begins. These include, for example, the systematic examination of educational practices, educational testing, surveys, interviews, observation, secondary analysis, and the examination of records, charts, or any data on human subjects. This approval must be obtained before the student can begin the research. While many of our DNP projects are quality improvement in nature and do not fall into the category of generalizable research, clearance to proceed with implementation must still be granted by the Institutional Review Board (IRB) office of SIUE.

All students who complete projects must complete the *Human Subjects Online Tutorial* course CITI training. Completion of the computer-based training program meets the certification requirements for a period of three years for all faculty, staff, and students at SIUE who engage in research using human subjects. When you have successfully completed the training course, you will be awarded a Certificate of Completion of Human Subjects Training. Please save this certificate in digital form. It is required for your IRB submission. SIUE's online instruction site for completing the training is: https://www.siue.edu/compliance/human-subjects/ . The site will then guide you through the procedure of signing on to the CITI training course and completing training. When in the course, choose the human subjects module. If you have questions, please contact the compliance office at researchcompliance@siue.edu or 618-650-3010.

Once your CITI training is complete and the ***Project Methods*** and ***Evaluation Process/Instruments*** submissions for phase 'b' are completed, you need to communicate with your project leader for permission to submit your IRB. The IRB submission is completed online and is accomplished through the Kuali electronic research software system. Prior to creating a proposal, please ask your Project Leader to email you a signed copy of the "Faculty Advisor's Signature Page". A blank copy of the Faculty Advisor's Signature Page can be located at SIUE's IRB website. You must have this document and your CITI certification in order to complete the submission process. If you do not have your CITI certificate, please refer to the section "Retrieving Your Human Subjects Training (CITI) Certificate", located at the end of this document. Once you are fully ready, please follow these basic guidelines for protocol submission:

1. Proceed to the following Kuali page, https://siue.kuali.co/res/ and use your SIUE e-ID and password to sign in. (Kuali's preferred browser is Google Chrome.)
2. On the left-hand side of the screen toward the bottom, click "Switch Apps" (Note: if the tool bar is not fully opened, click on the arrow button at the bottom to open the tool bar to see "Switch Apps") and then click on the "Protocols" icon.
3. On the top right side of the screen, click "+ New Protocol" and then click on "IRB."
4. Under **Principal Investigator**, begin typing your e-ID and click on your name when it appears. (IF doing a group project, use one name at this point. You will enter in the other names later.)
5. If you and your project leader agree that your project is a ***Quality Improvement*** type project and not generalizable research, chose "**Nursing QIP**" from the dropdown menu under the "**Lead Unit**" icon. If you believe that you project does not qualify as a quality improvement project, then please select "**Nursing, School of**."
6. Select "Yes" if you will be the Principal Investigator of this protocol.
7. Select "Yes" if your project is part of an SIUE course or degree requirement. Then select "Next" on the right-hand side of the page.

8. The next page will ask you to indicate the type of review you are requesting from the IRB. If your project is a QIP, in the drop-down box, please select "Not Human Subjects Research Determination." If your project is generalizable research, in the drop-down box, please select either "Exempt Category Determination" or "Full Board/Expedited IRB Review."
    a. An example of a Quality Improvement Project is a student wanting to improve the safety standards at their hospital. They will implement a pre-educational survey, followed by an educational seminar, and concluded with a post-educational survey. The purpose of the QIP is not to contribute to generalizable knowledge, but to improve the safety standards at one hospital, with one specific population.
    b. An example of an exempt project would be the project described above, but instead intending to contribute to generalizable knowledge and analyze the findings to be applied to other areas, such as schools.
    c. Please note, if you or your faculty advisor have any questions about the review category, please contact the compliance office **before** submitting your protocol.
9. Once you've selected your review from the drop-down box, please select "Next" on the right-hand side of the protocol.
10. Insert your project title under the "Study Title" icon. (You may not be referring to your project as a "study," but keep in mind, this 1st page is used for all IRB submissions.)
11. In the SIUE Personnel section, please fill out every column. This section may be partially completed with answers given earlier.
    a. In the "**People**" section, click on the pencil icon next to your name. Page down to the bottom of the "**Edit**" box and upload your **Human Subjects Training (CITI) certificate**. When the document is uploaded, click on the "Done" icon located in the bottom right hand corner of the dropdown box.
    b. Also in the "**People**" section, click on the "**Add Line**" icon and add your project leader to this proposal. Once you find their name, most data points will self-populate. There are only three additional items that must be selected for adding information; 1) under *Home Unit* select "**Nursing QIP**"**,** 2) under *Researcher Role*, choose "**Faculty Advisor**" and under 3) *Permissions*, grant them "**Full Access**." Once all three of these are filled in click "**Done**". You are not required to upload a Human Subjects (CITI) Certificate for your faculty project leader. If you are doing a group project, add the other members of your group following the same instructions, except label them as **Co-Investigators** under the *Researcher Role* and upload the required Human subjects (CITI) certificate for each additional student group member.
    - Please note, sometimes the green checkmark will not appear next to the SIUE Personnel section, even if all the information is filled in. You may still submit a protocol without that green check mark.
12. Select either "Yes" or "No" if you will be working with any external researchers on this project.
13. If your project is a QIP, you should have "Not Human Subjects Research Determination" selected in the Review Category Question section. If your project is generalizable research, either "Exempt Category Determination" or "Full Board/Expedited IRB Review" should be selected here.
14. Select either "Yes" or "No" if your project has external funding or external (non-SIUE) support.
15. In the NHSR Determination, in the first question, select "Yes" if your project will involve the use of human subjects
16. In second question, select "No" that you are NOT conducting research. If you select "Yes" for this question, your project does not qualify as a QIP.
17. Please write a brief narrative describing the basic methodology and evaluation process of your project. The response here should be at least a few sentences long.
18. When asked why you believe this is not research, mark **Quality Improvement Project**.

19. Proceed by answering yes to nursing QI and answer all 9 questions that appear. (**NOTE: The answers to all these questions should be true, if your project is quality improvement. If not, you will be directed back to the more extensive IRB process.**)
20. You will be asked to upload your "External Stakeholder Agreement" (this document was emailed to you when the stakeholder submitted it). At the request, please upload the "Faculty Advisor's Signature Page" (This must be signed by your leader and is found as #11 in the DNP Guidelines). Both these documents should remind you that your team must be informed regarding your final processes.
21. Please answer the Conflict of Interest section questions and certify that your statements are accurate.
22. Click on the "**Submit**" icon located in the upper right-hand corner of the page. Once submitted, contact your Team leader and ask them to review the proposal. You should hear from the IRB within 48 hours of completion. The email received will constitute the proof of clearance.
23. If your project is not a quality improvement project, please read and follow the instructions for IRB submission as appropriate to your proposal (Exempt or Full Board/Expedited). Please consult your Team Leader regarding which submission is appropriate. These types of proposals will require a much more extensive submission and review process. It will take additional time, even months, so plan accordingly.

Retrieving Your Human Subjects Training (Citi) Certificate

- Go to citiprogram.org
- Click on Log in, then click on Log in through Institution
- Find and click on Southern Illinois University Edwardsville
- Log in as prompted using your e-ID and password
- Click on "Records" in the top information bar
- Click on View-Print-Share next to your most recent Human subjects course
- Find and download your certificate

It is important to remember that SIUE's Graduate School's clearance for your project does not imply clearance at the clinical site. You must follow the IRB protocols at your project facility to assure you are properly cleared to complete your project. If your project was deemed as not requiring IRB approval by the graduate school, do not indicate to the clinical site that the project had IRB approval. Be clear to them that the project was judged a quality improvement non-research type project not requiring an IRB. Please keep the email received from IRB as proof.