SUBMITTING AN IRB PROTOCOL IN KUALI

Institutional Review Board

JUNE 3, 2021
CENTRAL CONNECTICUT STATE UNIVERSITY
1615 Stanley Street, New Britain
Click on “Manage Protocols”

Your “Dashboard” will have a list on the left side. When you expand it, it should give the names of each icon. When in Dashboard, click on the clipboard check mark titled “Common Tasks”.

On this page you can find all protocols you have submitted or drafted and their status.

Click on “+ New Protocol” to create a new protocol. Then select “IRB”.

Enter the name of the **PRINCIPAL INVESTIGATOR** by searching for their email or name (STUDENTS: the PI must be your faculty advisor), what the **LEAD UNIT** will be (typically the department of the PI), and the **TITLE** of the protocol. The title and PI can be changed later on if necessary. If you have previously submitted to CCSU’s IRB and have an **ORIGINAL PROTOCOL NUMBER** for this study, add that. If not, leave it blank. Then click “Next”. 
Mark the category that describes your research type. If you know that your research is “Not Human Subjects Research Determination”, please click that. Otherwise, please click “Human Subjects Protocol – Full Board/Expedited Review/Exempt Determination”. If you are seeking an “External Reliance Request” please check that. Use “Converted from Word or PDF Protocol” if you are renewing or modifying a protocol that was approved prior to our implementation of Kuali. Then click “Next.”

Submission Type

- Human Subjects Protocol - Full Board/Expedited Review/Exempt Determination
- Not Human Subjects Research Determination
- CCSU Is Relying On Approval From Another Organization
- Converted from Word or PDF Protocol

Once you click “Next” located on the upper right, you will be taken to the protocol form. There will be 10 sections that must be completed to submit the protocol.

“CCSU Personnel”, “General Questionnaire”, and “Attachments” will already have checkmarks. The “General Questionnaire” will be completed as that information was completed on the previous page. “CCSU Personnel” and “Attachments” are not completed and you will need to add information to both of those sections prior to submission (STUDENTS: add yourself as a “Lead Investigator” and give yourself full access under “permissions” tab).

Put in all personnel information about everyone on the research study team into either “CCSU Personnel” if they are affiliated with CCSU, or under “External Organizations” if they are not affiliated with CCSU. Don’t forget to include all necessary CITI certifications. Use the pen tool to edit personnel information and add CITI certificates.

Be sure to complete each section. Once completed, each section should be marked with a green checkmark.

If you miss anything that is required, Kuali will alert you of what is missing when you try to submit.

If you are satisfied with your protocol and no further changes need to be made, click “Submit” on the right side. If you would like another researcher on the protocol to review or edit the protocol, do not submit, and give them permissions under the permissions tab at the top right (STUDENTS: be sure to alert your faculty advisor when you have completed your part in the protocol. DO NOT SUBMIT. Your faculty advisor must review and submit on your behalf. If you submit it will be returned without review).
sections that must be completed to submit the protocol:

1. General Information
   a. This will be completed already as the information is what you filled out on the first pages (PI, Lead Unit, and Title of Protocol). You can change this information if you need to.

2. CCSU Personnel
   a. In this area you will record all CCSU affiliated researchers on the protocol and their role using the “+ Add Line” button. Once you enter their names, their home units, and phone (optional), be sure to give them a researcher role with the access you’d like them to have in the protocol. Full access means they can view and make changes to the protocol before it is submitted, read-only means they can only view the protocol. Then update their CITI information (CITI completion date and CITI Certificate attachment). You will not be able to submit until all CITI attachments are uploaded for each researcher.

3. General Questionnaire
   a. This will be completed already as the information is what you previously filled out on the first pages (Human Subjects Protocol, Not Human Subjects Research, Exemption Reliance).

4. External Organizations*
   a. This section will only show if you have selected “yes” for the second question in the “General Questionnaire”. List any organization or person outside of CCSU that is involved in some capacity. The first area is for external organizations. List any organization outside of CCSU that is in any way involved with the research, and provide any necessary attachments (gatekeeper letters, summary of proposed arrangements, etc.). The second area is for external collaborators. For external collaborators, please be sure to provide their information and whether they are type 1 or 2.

5. Research Overview
   a. Describe what the main research purpose is (faculty research, master’s thesis, dissertation, etc.), when you are hoping to begin your research activities, and a summary about the proposed research. Additionally, you must agree that you will not begin any aspects of your research study until you have received IRB approval. Please pick an appropriate start date as well.

6. Funding Sources
   a. Information about any funding the study has or may potentially have. Keep in mind that if you click “Internal Grant Funding”, “Departmental Funding”, “External Grant Funding”, or “I plan to apply for funding” that you will have to enter that information (such as a funding source number, your proposed funding source, or the department that is funding your research).

7. Human Subjects
   a. Information about demographics, vulnerable populations, relationships between researchers and subjects, recruitment details and procedures, criteria for inclusion or exclusion, minimum number of participants and expected number of participants, compensation, research procedures, audio/visual recording, deception, risks and benefits, confidentiality and identifiable data.
   b. Describe what each researcher will be doing by clicking on “+ Add Line” and adding each researcher – what procedures will each researcher be tasked with, where and when will these take place, and how frequently.

8. Informed Consent Process
   a. Choose the description of your planned informed consent process, or explain why you would be requesting a waiver of documentation of informed consent.

9. Attachments
   a. This is where you put any attachments necessary that would aid in the understanding and review of your proposed research (informed consent, surveys, interview questions, etc.).

10. Investigator Certifications
    a. Certify that you are aware of conflicts of interest and have none to disclose. Certify that you are aware of CCSU’s policy of scientific misconduct and understand. Clarify if this is a student lead project and if so, the faculty advisor listed must read and answer the final question.

Finally, when you have completed the protocol submission form, click “submit” on the upper right side.