INITIAL PROTOCOL SUBMISSION FORM

SUBMISSION INSTRUCTIONS – The Initial Protocol Submission Form (IPSF) is a fill-in form. There may be periodic updates to this form, so please be sure to use the current version.

Each item on the IPSF has a text field (Click or tap here to enter text), a check box (☐) or a date menu (Click or tap to enter a date) to enter information about the proposed research. Text fields will expand as information is entered. Click on the check box to place a mark (“x”) where necessary.

To initiate the IRB review process, submit the completed IPSF and required supplemental materials to irb@ccsu.edu as a single Word or PDF email attachment. The IRB cannot accept multiple attachments.

Please provide all information requested. If an item is not applicable, enter N/A. If information is not available, enter “Info not available” with an explanation. If there is relevant information about the research that is not requested on the IPSF, please enter the information in Section VIII, Additional Information.

Principal Investigators (PIs) are to submit the completed IPSF and supplemental materials to the IRB. PIs who are serving as faculty advisors are to review their students’ forms for completeness and verify all relevant supplemental materials have been included. The PI should forward the IPSF to the IRB on behalf of the student(s) under their supervision. Submissions sent to the IRB by student researchers will be returned to the student’s faculty advisor.

SECTION I – General Information

1. PROTOCOL TITLE: Click or tap here to enter text.

2. RESEARCH TEAM: A researcher is any person who is directly involved with the development and implementation of the research, and/or has access to the raw data. This designation may include faculty, staff, or student researchers who are involved in developing methodology, recruitment or testing of participants or in managing datasets or data analysis. Researchers need to be listed in the table below and must provide CITI certification.

   Principal Investigator (PI) is the designation for faculty/staff members who are conducting research and/or are serving as faculty advisors.

   Lead Investigator (LI) is the designation for student researchers who are conducting their own research under the direction of a faculty advisor.

   Other Researcher is the designation for an individual who is part of the research team and will have direct involvement with research subjects or data about the research subjects, but is not a PI, Co-PI, LI, or Co-LI.

   Large research teams may need to add additional rows to the tables below.

<table>
<thead>
<tr>
<th>NAME</th>
<th>CCSU ID</th>
<th>INSTITUTION/DEPARTMENT</th>
<th>PHONE/EMAIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator / Faculty Advisor</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Co-Principal Investigator</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Lead Investigator</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Co-Lead Investigator</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>----------------------</td>
<td>----------------------------------</td>
<td>----------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Other Researcher</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Other Researcher</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
</tr>
</tbody>
</table>

3. **HUMAN SUBJECTS PROTECTION EDUCATION:** Enter requested information in the appropriate space.

<table>
<thead>
<tr>
<th>NAME</th>
<th>ETHICS EDUCATION (e.g. CITI)</th>
<th>DATE COMPLETED</th>
<th>CITI CERTIFICATE INCLUDED W/APPLICATION?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator / Faculty Advisor</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Co-Principal Investigator</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Lead Investigator</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Co-Lead Investigator</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Other Researcher</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Other Researcher</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
<td>Click or tap here to enter text.</td>
</tr>
</tbody>
</table>

4. **RESEARCH PURPOSE:** Check the appropriate box in the column to the left of the research purpose options. If the option checked is undergraduate, graduate, or other, briefly describe the course, project and department in the space to the right.

- Faculty Research
- Undergraduate Course/Project
- Click or tap here to enter text.
- Dissertation
- Graduate Course/Project
- Click or tap here to enter text.
- Master’s Thesis/Project
- Other
- Click or tap here to enter text.

5. **FUNDING SOURCES:** Check the appropriate box in the column to the left of the funding options. If research has funding, enter funding source information in the space to the right.

- Research not funded
- Click or tap here to enter text.
- Funded by federal agency or department
- Click or tap here to enter text.
- Funded by Connecticut state agency or department
- Click or tap here to enter text.
- Funded by CCSU center, department, school or other
- Click or tap here to enter text.
- Funded by private organization
- Click or tap here to enter text.
- Funded by other entity
- Click or tap here to enter text.

**SECTION II – Research Overview**

Please provide the information requested. If an item is not applicable or information is not available, enter N/A.
1. Proposed start date of research activities: Click or tap to enter a date.

2. In 250 to 500 words please provide a brief summary of the proposed research, including study hypothesis or research question, objectives, and rationale. Also cite relevant published research and articles to support the hypothesis or research question for the proposed research.

SECTION III – External Collaborations

3. Describe any arrangements with an external agency, school, organization, or institution with whom you intend to collaborate for this research project, including any plans to recruit subjects or to obtain data from an agency, school, organization, or institution other than CCSU.

   Attach a gatekeeper letter that fully describes the proposed collaboration. If the gatekeeper letter is not available, indicate the status for procuring the letter.

   Include the contact details for your contact(s) at the collaborating agency, school, organization, or institution, and list all individuals from the collaborating organization who will be involved in your project. You must identify which of the below categories best describe any collaborators listed in this section:

   **External Collaborator Type 1:** Any person not associated with CCSU who is directly involved in the research OR who is indirectly involved in the research with access to raw data or datasets being shared among other researchers. This type of external collaborator needs to be listed as an “Other Researcher” in Section I #2 and needs to document knowledge of ethical principles relevant to their role in the research. Documentation may be done by a) supplying a CITI certification or b) providing other appropriate documentation (e.g., for collaborators providing raw data or datasets, documentation verifying how the data is accessed/handled/protected in line with Federal ethical guidelines). Documentation could include supporting letters from supervisors, organizational/agency policies or procedures, or other appropriate documents.

   **External Collaborator Type 2:** Any person not associated with CCSU who is indirectly involved in the research by providing resources that contribute to the research such as supplying access to instruments, materials, or space, and/or writing or editing drafts. This person will not have access to the raw data or datasets. This type of external collaborator does not need to supply a CITI certification and is not considered a researcher for the purposes of this form.

   **Gatekeeper:** The role of a gatekeeper is to permit access to the population. A gatekeeper should not be directly involved in the research nor actively involved in recruitment, testing, or data analysis. A gatekeeper does not need to supply a CITI certification. Sometimes a gatekeeper may also contribute to the project in similar ways to a Type II External Collaborator. A gatekeeper should not be listed as a researcher on the project. Occasionally a gatekeeper may be someone at CCSU who is granting access to a restricted population rather than a collaborator from an external agency. These types of “internal collaborators” should also be included in this section.

   If your project does not involve any external collaborators, enter N/A for this item and for item #4.

4. If the collaborating external agency, school, organization, or institution has an IRB, describe the status of the collaborator’s IRB approval for this proposed research. If the collaborator does not have an IRB, please state this. If the collaborator’s IRB has already approved this research, please email irb@ccsu.edu with a copy of the collaborator’s IRB approval letter and your responses on this form for Sections I, II, and III before proceeding any further in completing this form.
SECTION IV – Human Subjects

5. Describe the expected demographics for the proposed research sample.
   Click or tap here to enter text.

   The categories below indicate populations that are considered vulnerable to coercion or undue influence. Check each category that is applicable to this proposed research. Please explain why any categories you select are necessary for the completion of this research project. If none, enter N/A. Click or tap here to enter text.

   ☐ Children
   ☐ Individuals with impaired decision-making capacity
   ☐ Economically or educationally disadvantaged persons
   ☐ Prisoners
   ☐ Probationers or parolees
   ☐ Veterans

6. Describe any relationship that members of the research team might have with the prospective subjects.
   Click or tap here to enter text.

7. Do you plan to recruit students through a class that you or another one of the investigators instruct?
   ☐ Yes (Answer #7a)  ☐ No (Go to #8)

   7a. Please explain why this population is necessary to the study and indicate what precautions will be taken to minimize potential undue influence or coercion.
   Click or tap here to enter text.

8. Describe the proposed recruitment procedures in detail and attach recruitment materials.
   Click or tap here to enter text.

9. Describe criteria for subject inclusion and screening procedures of prospective subjects. If any inclusion/exclusion criteria are based on gender or ethnicity/race, explain rationale.
   Click or tap here to enter text.

10. Describe the minimum number of eligible subjects needed for the proposed research and/or the anticipated number that will participate.
    Click or tap here to enter text.

11. Describe any compensation of subjects or indicate if there is no compensation. SONA credits are considered compensation. If subjects are compensated, provide a detailed explanation of how compensation would be affected should a subject not complete a task or withdraw from the research activity.
    Click or tap here to enter text.

12. Describe the research procedures. Procedures could include interviews, self-administered surveys or questionnaires, focus groups, psychometric or educational testing, or follow-up for longitudinal studies. Procedures could also include web-based data collection, analyzing data obtained from institutional records or secondary data sources both publicly available or with limited access. Attach a copy of all materials that will be used for collecting data.
    Click or tap here to enter text.
13. Describe who will administer the proposed research procedures, where and when procedures will take place, and the frequency and duration of visits /sessions.

Click or tap here to enter text.

14. If applicable, describe any audio or video recording that will occur and the purpose. If not applicable, enter N/A.

Click or tap here to enter text.

15. If applicable, describe if any deception or incomplete disclosure of informed consent will take place and explain the rationale. If not applicable, enter N/A.

Click or tap here to enter text.

16. Describe all potential risks and discomforts associated with participation whether physical, psychological, economic or social (e.g., pain, stress, invasion of privacy, embarrassment, breach of confidentiality), including minimal or everyday risks. Most studies incur some type of risk to participants. If you believe there are no risks at all for your participants, please explain why you believe this to be the case.

Click or tap here to enter text.

17. Describe measures that will be implemented to minimize risks and discomforts to subjects. Risk mitigation can include practices such as informing subjects of University resources, providing thorough consent processes, etc.

Click or tap here to enter text.

18. Describe any potential benefits to the individual subjects, group of subjects, and/or society. If there is no direct benefit to subjects, this should be stated. NOTE: Compensation/payment for participation is not considered a benefit.

Click or tap here to enter text.

19. Describe what identifiable data will be obtained from the subjects. NOTE: Audio, photo, and video recordings are generally considered identifiable unless distinguishing features are masked.

Click or tap here to enter text.

20. Describe how confidentiality of subject information will be maintained and how long research data will be kept. Maintaining confidentiality of subject information can be managed by limiting access to research records, securing records on password protected computer, saving data in encrypted files, storing information in a locked cabinet, etc.

Click or tap here to enter text.

SECTION V – Informed Consent Process

21. Check the space next to the informed consent process option for this proposed research and attach a copy of the consent form, script, or statement for the option. If not applicable, enter N/A

Click or tap here to enter text.

☐ 1. Subjects will be given an online survey consent statement to read and acknowledge.

☐ 2. Subjects will be given an information sheet to read.

☐ 3. Subjects will be briefed orally by the researcher and given an information sheet.

☐ 4. Subjects will only be briefed orally.

☐ 5. Subjects will be given a standard, hard copy consent form to read, sign, and return to researcher(s).

☐ 6. Subjects will be given a short form consent with a witness to the oral presentation.
22. Describe the process for obtaining parental/guardian permission and assent from a child for research involving children. Attach copy of parental/guardian permission form and child assent form. If not applicable, enter N/A.

23. NOTE: Skip this section if you have checked off any of the informed consent processes in #21.
If you would like to request a waiver for documentation of informed consent because you believe your study qualifies for a consent waiver based on the limited scenarios outlined in the federal regulations found at 45 CFR 46.116, please describe under which condition outlined in the regulations you would like to request a waiver. In the space below you must clearly articulate a justification based on the regulations found at 45 CFR 46.116 if you are requesting to waive consent. If you feel you need to request a waiver of consent and you are unsure how to interpret the federal regulations, please contact the IRB for assistance. Please note that waiving consent is not justified for the majority of studies. Waivers may only be considered if the research cannot be practicably carried out without the requested waiver and/or the collection of information during the consenting process poses a larger risk to participants than do the proposed research measures.

SECTION VI – Investigator Certifications

1. Potential Conflicts of Interest: Potential conflicts of interest exist when there is a divergence between an individual’s private interests and his or her professional obligations to CCSU such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise.

Each investigator will disclose all significant financial interests: (I) that would reasonably appear to be affected by the research, educational, or service activities or proposed for funding, by an external sponsor; or (II) in entities whose financial interests would reasonably appear to be affected by such activities.

I certify that I am aware of this policy and have no conflicts to disclose.

Date and LI initials: Click or tap here to enter text. Date and PI initials: Click or tap here to enter text.

2. Scientific Misconduct Statement: CCSU does not tolerate scientific misconduct as defined by the Public Health Service (PHS): “Misconduct in science is defined as (1) plagiarism, deception or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting or reporting research; or (2) material failure to comply with federal requirements that uniquely relate to the conduct of research.” I certify that I am aware of CCSU’s policy on scientific misconduct, and that everything I have reported on this form is accurate and true to the best of my knowledge. I also understand that deception on this form may result in the rejection of my application and/or the revocation of IRB approval for this project.

Date and LI initials: Click or tap here to enter text. Date and PI initials: Click or tap here to enter text.

3. Faculty Advisor Responsibilities: If applicable, the PI as a faculty advisor must certify that he or she has reviewed the student’s proposed research application and assures that the application is complete and the information contained accurate, confirms the integrity of the student’s proposed research design, and that rights and welfare of the research subjects are protected at all times.

Date and LI initials: Click or tap here to enter text. Date and PI initials: Click or tap here to enter text.

SECTION VII – IPSF Checklist of submission materials.

Check each appropriate box before sending submission materials.

☐ The relevant sections of the IPSF are complete.
☐ Attached is a copy of each informed consent document, parent permission form, and assent or oral consent script if applicable.

☐ Attached are all required gatekeeper letters and/or documentation for any planned external collaborations.

☐ Attached are copies of all measures, survey instruments, interview guides/questions, and questionnaires, etc.

☐ Attached are copies of all recruitment materials including oral scripts, email notices, web postings, flyers, etc.

☐ Attached is a copy of an ethics tutorial completion certificate for each member of the research team (e.g., CITI).

Date and LI initials: Click or tap here to enter text.  
Date and PI initials: Click or tap here to enter text.

SECTION VIII – Additional Information
  Click or tap here to enter text.