INITIAL PROTOCOL SUBMISSION FORM

SECTION I: GENERAL INFORMATION

1. Study Title: ______________________________________________________________

2. Today’s Date: ____________________________________________________________

3. Proposed start date of data collection: ________________________________

4. Do you expect data collection to continue longer than one calendar year? □ Yes □ No

5. Nature of Study (please check one):

   □ Faculty Research

   □ Dissertation

   □ Master’s Thesis/Project

   □ Undergraduate Course/Project (please specify course) ________

   □ Graduate Course/Project (please specify course) ____________

6. Investigator Information (If there are multiple student investigators, please add extra rows to the table to include this information. Other co-investigators can be listed under #8.

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
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<tbody>
<tr>
<td>Institutional Affiliation:</td>
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<tr>
<td>Department:</td>
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<tr>
<td>PI Mailing Address:</td>
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<tr>
<td>Email:</td>
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<tr>
<td>Phone:</td>
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<tr>
<td>CCSU ID# (if student):</td>
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7. Faculty Advisor Information *(If you are a student, please complete the following information about your faculty advisor. Faculty advisors are to review and forward submissions, as well as any subsequent revisions, to HSC on their advisee's behalf.)*

<table>
<thead>
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<th>Faculty Advisor:</th>
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<tbody>
<tr>
<td>Department:</td>
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<tr>
<td>FA Mailing Address:</td>
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<td>Email:</td>
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<td>Phone:</td>
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</table>

8. Co-Investigator(s) name(s) and department(s): *(if applicable).* Please attach either NIH or CITI certificates for all investigators.

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SECTION II: RESEARCH OVERVIEW

1. Please provide a 250 – 500 word summary of your research project. Be sure to include your hypothesis and/or research question, the goals of the proposed study, and the overall study design. Please describe the sequence and timing of all study procedures, especially those that involve human participants and/or data obtained from human participants.

2. Does your study involve analysis of existing samples or records? □ Yes □ No
   If yes, whether or not these samples or records are publically available, please explain how you are authorized to use these records and how you will protect the identities of the people who are described in these records. If the records are publicly available, please include this information in your explanation.

3. Describe the data collection materials you intend to use for this study. Be sure to include what these materials intend to measure.

   Please attach as an appendix a copy of all measures, survey instruments, interview guides/questions, and questionnaires you plan to use for your study.

   *If you think your study may be exempt, please answer the following question. Otherwise, you may leave this question blank.

4. Do you think your study meets a federal exemption category? □ Yes □ No.
   If YES, please specify which exemption category _______ (the list of exemption categories can be found at www.ccsu.edu/hsc). Please note that your answer to this question will facilitate our review but it does not guarantee that the protocol will be deemed exempt.
SECTION III: SPONSORS, AFFILIATES, AND COLLABORATORS

1. Is this research funded (through a grant award or other method)? □ Yes □ No

If yes, please name funding source:

2. Do you plan to obtain data from or recruit within CCSU such as through the CCSU Registrar, Office of Institutional Research and Assessment, Banner, and/or any other CCSU office, program, club, or course? □ Yes □ No

If yes, please name the collaborating organization and your official contact:

3. Do you plan to obtain data from or recruit through an agency, school, organization, or institution other than CCSU, including websites managed by private and non-profit organizations? □ Yes □ No

If yes, please answer the following questions and be sure to include a gatekeeper letter from your collaborating agency as a part of your HSC proposal. Please see www.ccsu.edu/hsc for sample gatekeeper letters.

3a. Please name the agency, organization, or institution with which you plan to collaborate:

3b. Please list the name and title of your official contact:

3c. Are any of the researchers affiliated with or employed by this collaborating agency, organization, or institution? If so, what is the position held by the researcher[s]? And, if yes, please explain the work relationship between the researchers and the potential participants, and how any potential conflicts of interest will be addressed in your study.

3d. Does the agency, organization, or institution with which you are collaborating have an IRB? □ Yes □ No

If yes, and you have already received external IRB approval, please attach a copy of this approval to your HSC Form. If yes, and you have not received external IRB approval, please note if/when you expect to receive this approval:

SECTION IV: HUMAN PARTICIPANTS
1. Please describe your sample, including the expected number of human participants, and the anticipated demographics of your sample (e.g. gender, ethnicity, age range, income, education level, and language spoken):


2. Please describe your recruitment procedure, including who will recruit participants, when and where recruitment will take place, and how potential participants will be identified.


Please attach as an appendix to this HSC form copies of all recruitment materials including oral scripts, email notices, web postings, flyers, etc. that you plan to use to advertise your study. If you are recruiting at off-campus sites, written permission from the collaborating institution may be required. Flyers posted at CCSU must display your HSC approval code (which will be given to you upon HSC approval).

2a. Do you plan to recruit participants online? □ Yes □ No

If yes, please list the sites from which you plan to recruit participants and please indicate if these sites are public forums or not public forums. Please note that some websites require webmaster approval of all posted survey links. Be sure to note the specific posting requirements for each site.


3. Do you plan to recruit CCSU students through a class that you or one of your faculty collaborators instruct? □ Yes □ No

If yes, please explain why this population is necessary to the study and indicate what precautions will be taken to minimize potential undue influence or coercion:


If no, what specifically is the PI’s relationship to the participants? For example, is the PI a supervisor, peer, teacher, or has no relationship to the participants? If there is a supervisory relationship, please explain why this population is necessary to the study and indicate what precautions will be taken to minimize potential undue influence or coercion:


4. Please check all categories that apply in the table below regarding participants from special populations who you anticipate may be selected for participation in your study:

| Minors                             | Developmentally/Psychologically/Physically Impaired |
5. Please check all potential risks and inconveniences your human participants may experience as a result of their participation in your research.

<table>
<thead>
<tr>
<th>Minimal Risks</th>
<th>Psychological or physical trauma or pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deception</td>
<td>Embarrassment, disappointment, other disagreeable emotion</td>
</tr>
<tr>
<td>Stress or emotional arousal</td>
<td>Alteration of self-concept (e.g. via knowledge of test scores)</td>
</tr>
<tr>
<td>Loss of privacy</td>
<td>Personal material (interviews, opinions, test scores)</td>
</tr>
<tr>
<td>Threat to employability</td>
<td>Loss of legal rights</td>
</tr>
<tr>
<td>Other (explain):</td>
<td></td>
</tr>
</tbody>
</table>

5a. Explain all potential risks checked above and indicate what steps will be taken to minimize these risks (such as procedures to minimize changes in self-concept, having M.D. or other appropriately trained individual in attendance, post-deception debriefing, etc.):

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6. Can the information you plan to collect be linked to participants directly or indirectly by potentially identifying content? □ Yes □ No

If yes, please detail what steps you will take to minimize any possible risks to participant confidentiality or anonymity, and what steps you will take to maintain and/or destroy information/data after study completion:

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7. Please describe the anticipated benefits of your study to individual participants and to society. If your individual participants may directly or indirectly benefit from your study, please state so here.

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8. Will any compensation or incentive be offered to participants to engage in this study? □ Yes □ No

If so, please describe:

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8a. If course credit is being offered, you MUST offer an alternative way for students to earn credit that does not require research participation. Please describe this alternative:

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SECTION V: INFORMED CONSENT

As the designated investigator, you are responsible for taking reasonable steps to ensure that the participants in this study are fully informed about and understand the study. Please keep in mind the
population included in your study, and consider developmental level and/or abilities to comprehend the information you provide to enable participants to make an informed decision to consent.

1. Capacity to consent: Do you anticipate enrolling any non-English speakers, minors or participants with decisional impairment*?
   □ Yes □ No

*Decisional impairment refers to a limitation or incapacity that is not part of normal growth and development such as a cognitive or emotional disorder.

2. Parent/Guardian Permission and Assent: (If enrolling children and proposed activities fall outside of normal classroom practice, state how parents/guardians will provide permission, whether the child’s assent will be obtained, and if assent will be written or oral. Provide a copy of the script to be used if oral assent will be obtained. Studies that involve only normal classroom activity do not need to obtain parent/guardian permission nor students’ assent, however, you may wish to send an information letter to parents/guardians about your proposed study.)

3. Please classify your proposed consenting process: (Please attach as an appendix to the HSC form a copy of each consent form or script you plan to use.) For sample consent forms, please consult our website at www.ccsu.edu/hsc.

   □ Participants will be given a traditional consent form to read, sign and return to the researcher(s).

   □ Participants will be given an information sheet to read.

   □ Participants will be briefed orally by a research associate and given an information sheet.

   □ Participants will be briefed orally only.

   □ Participants will be given an online survey consent statement to read and acknowledge.

   □ None: The proposed interventions involve normal classroom activity.
SECTION VI: INVESTIGATOR CERTIFICATIONS

1. **Federally Required Ethics Education:** I certify that I have completed a generally accepted research ethics education program. *Please include a copy of your certificate of completion with your submission.*

   - [ ] I have completed the NIH Human Subjects Tutorial. Date of completion: ____________
   - [ ] I have met this requirement through other means. Date of completion: ____________

2. **Drug-Free Certification:** As a condition of approval of this research, I certify that I will not engage in unlawful manufacturing, distribution, dispensing, possession or use of a controlled substance in conducting any activity associated with this research. (45 CFR 620, subpart F, Appendix C)

   - [ ] Investigator check here to certify Add date and type initials here: ____________________

3. **Scientific Misconduct Statement:** I certify that I am aware that Central Connecticut State University does not tolerate scientific misconduct. The following PHS definition (NPRM) is accepted by the University: "Misconduct’ or ‘misconduct in science’ as used herein is defined as (1) plagiarism, deception or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research; or (2) material failure to comply with federal requirements that uniquely relate to the conduct of research."

   - [ ] Investigator check here to certify Add date and type initials here: ____________________

4. **Veracity Statement:** I certify that everything I have reported on this form is accurate and true to the best of my knowledge. I understand that deception on this form may result in the rejection of my application and/or the revocation of HSC approval for this project.

   - [ ] Investigator check here to certify Add date and type initials here: ____________________

   - [ ] For all student research, the *faculty advisor* must check here to certify: I certify that everything reported on this form is accurate and true to the best of my knowledge. I understand that deception on this form may result in the rejection of this application and/or the revocation of HSC approval for this project.

   The *faculty advisor* must add the date and type his or her initials here: ____________________
SECTION VII – SUBMISSION INSTRUCTIONS AND CHECKLIST

Please facilitate the HSC review process by submitting this form together with all supplemental materials as a SINGLE Word or .pdf document. For clarity, please use pagination and page titles atop each separate document to make clear the separate components of the addenda (e.g., written recruitment communication, questionnaires, surveys, interview questions/guides, consent document(s) and/or verbal text, gatekeeper and/or external IRB letter).

Faculty investigators and advisors are to forward submissions to HSC@ccsu.edu.

FACULTY ADVISORS PLEASE NOTE: The HSC requires faculty advisors to forward student submissions directly to the HSC to ensure student submissions are complete and free of typographical errors. Direct submission by the advisor provides confirmation of proposal review and support, which is required to begin the HSC review process. Submissions received by students will be returned for re-routing through their advisor.

SUBMISSION CHECKLIST:

☐ I have completed all relevant sections of the entire HSC New Protocol Submission Form.

☐ I have attached all required gatekeeper letters and/or external IRB information and documentation for all planned external collaborations. (If no external collaborations are planned, please leave this box blank.)

☐ I have attached as an appendix a copy of all measures, survey instruments, interview guides/questions, and questionnaires I plan to use for my study.

☐ I have attached copies of all recruitment materials including oral scripts, email notices, web postings, flyers, etc. that I plan to use to advertise my study.

☐ I have attached a copy of each consent form and/or oral script I plan to use to obtain informed consent from participants.

☐ I have attached NIH ethics certificates (or other ethics training completion certifications) for the primary investigator and each additional researcher involved in this study.