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|  | EASTERN CONNECTICUT STATE UNIVERSITY  Office of the Vice President for Academic Affairs  Gelsi-Young Hall, Willimantic, CT 06226  Ph: 860-465-5245 | CUHSR use only:  Full Board  Expedited  Protocol # Click or tap here to enter text. |

COMMITTEE ON THE USE OF HUMAN SUBJECTS IN RESEARCH

OHRP IRB00005900 Eastern Connecticut State U IRB #1 Federalwide Assurance FWA00011898

**IRB-1 Protocol Application for the Involvement of Human Subjects in Research**

Read these important notes before completing your application:

1. There may be periodic updates to this application, so please be sure to use the current version.
2. Only complete applications with all the required information and documentation (consent forms, CITI certificates, etc.) will be reviewed.
3. Do not alter this application/convert it to another format (PDF, etc.). Altered applications will not be reviewed.
   1. Tap in the boxes to check/uncheck your selections.
   2. Use the “Click or tap here to enter text” to enter all information. The boxes will adjust to accommodate however much space you need. Do not bold the text you enter in the text boxes.
4. The CUHSR includes faculty (science and non-science), administrative faculty, and a non-ECSU affiliated community member. As such, your application must be clear to someone outside of your discipline.
5. Expedited review feedback from the CUHSR typically takes 2-3 weeks and feedback from full board reviews typically take 4-5 weeks. If revisions are required, the approval process will take longer.
   1. Revisions: make all the changes before submitting. The committee has reviewed past applications 4-6 subsequent times due to researchers not addressing all the comments from the initial CUHSR review.

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| **Section 1: General Information** | |
| **Study Information**  **Nature of study (check only one):**  Faculty Research  Staff Research  Undergraduate Student Research  Graduate Student Research  Other (specify): Click or tap here to enter text.  **Study title:** Click or tap here to enter text.  **Study Objective (2-3 sentence summary of study):**  Click or tap here to enter text.  **Principal Investigator (PI) Information**  *Note: only complete one of the boxes below for Faculty/Staff Research or Student Research.* | |
| **Faculty / Staff Research**  **Name of PI:** Click or tap here to enter text.  **Department:** Click or tap here to enter text.  **Email:** Click or tap here to enter text.  **Phone:** Click or tap here to enter text. | **Student Research**  ***(Only for student-initiated research; students working on faculty/staff-initiated research should be listed as Research Personnel below).***  **Name of PI:** Click or tap here to enter text.  **Department:** Click or tap here to enter text.  **Email:** Click or tap here to enter text.  **Phone:** Click or tap here to enter text.  **Name of Student Research Mentor:** Click or tap here to enter text.  **Department:** Click or tap here to enter text.  **Email:** Click or tap here to enter text.  **Phone:** Click or tap here to enter text. |
| **Research Personnel**  *(e.g., may enroll participants, conduct consent process, collect data/identifiable information from participants, intervene/interact by performing invasive procedures, have access to information that links participants' names or other identifiers with their data, or act as authoritative representatives for the investigators):* | |
| **ECSU Research Personnel**  **Name:** Click or tap here to enter text.  **Role:** Click or tap here to enter text.  Student  Faculty / Staff  **Name:** Click or tap here to enter text.  **Role:** Click or tap here to enter text.  Student  Faculty / Staff  **Name:** Click or tap here to enter text.  **Role:** Click or tap here to enter text.  Student  Faculty / Staff  **Name:** Click or tap here to enter text.  **Role:** Click or tap here to enter text.  Student  Faculty / Staff  **Name:** Click or tap here to enter text.  **Role:** Click or tap here to enter text.  Student  Faculty / Staff | **Non-ECSU Research Personnel**  **Name:** Click or tap here to enter text.  **Affiliated Institution**: Click or tap here to enter text.  **Role:** Click or tap here to enter text.  Student  **Name:** Click or tap here to enter text.  **Affiliated Institution**: Click or tap here to enter text.  **Role:** Click or tap here to enter text.  Student  **Name:** Click or tap here to enter text.  **Affiliated Institution**: Click or tap here to enter text.  **Role:** Click or tap here to enter text.  Student    **Name:** Click or tap here to enter text.  **Affiliated Institution**: Click or tap here to enter text.  **Role:** Click or tap here to enter text.  Student |
| **Collaborating Institutions**  **Are you collaborating with another research institution on this project?**  Yes  No  *Note: if yes, you will need to obtain IRB approval from every collaborating institution that has an IRB before you can initiate research there.*  **Are any collaborating institution IRB approval letter(s) attached**?  Yes  No | |
| **Study Location(s)**  ECSU Campus (i.e., in-person collection on campus, online collection from only ECSU-affiliated individuals)  Off Campus **(specify):** Click or tap here to enter text.  If the study is to take place in a controlled facility (school, nursing home, etc.) you must provide written documentation that the facility has given its permission for the study to take place there. Please name each facility.  **Name:** Click or tap here to enter text.  **Is documentation of permission attached?**  Yes  No  **Name:** Click or tap here to enter text.  **Is documentation of permission attached?**  Yes  No  **Name:** Click or tap here to enter text.  **Is documentation of permission attached?**  Yes  No  **Research Conducted in a Foreign Country**  **Will any research involving human subjects take place outside of the United States?**  Yes  No  **If yes, please list the international locations**: Click or tap here to enter text.  NOTE: You will need to obtain IRB or local community approval in the country where the research is taking place. For federally funded research, a foreign institution sponsoring an IRB must have a Federalwide Assurance (FWA) for International Institutions on file with the U.S. Office of Human Research Protections (OHRP); alternatively, in the absence of an international FWA, the OHRP may certify a foreign country’s guidelines for research on human subjects. Please refer to the OHRP website for additional information (<http://www.hhs.gov/ohrp/international>).  **Describe the foreign IRB or local community approval for the proposed research**:  Click or tap here to enter text.  **Are any foreign IRB or local community approval letter(s) attached?**  Yes  No  **Is OHRP documentation of approval of foreign guidelines for research on human subjects attached?**  Yes  No | |

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| **Section 2: Funding** |
| It is the responsibility of the PI to notify the CUHSR via an IRB-6 Change of Protocol form if the funding source changes in any way.  **Anticipated funding source (check any that apply):**  Unfunded or Investigator Out-of-Pocket  Departmental Funds  CSU Faculty Research Award  ECSU Faculty Development Award  ECSU Foundation Award  Private Foundation Grant or Contract  State of Connecticut Grant or Contract  Federal Grant or Contract  Other **(specify):** Click or tap here to enter text.  **For Externally Funded Studies**  If you have applied for, or received, any external (non-ECSU/CSU) funding (e.g., federal, state, private) to support this research, include one COMPLETE copy of each grant application or contract with this application.  **Is the grant application or contract attached?**  Yes  No  N/A  For each external funding source please complete the following.  *NOTE: If the PI on the grant/contract is not the PI on this CUHSR protocol, submit an e-mail with this application in which the PI who is receiving the grant acknowledges use of this protocol under the grant****.***  **Funding Source:** Click or tap here to enter text.  **PI of Grant/Contract:** Click or tap here to enter text.  **Grant/Contract Title:** Click or tap here to enter text.  **FRS Account Number:** Click or tap here to enter text.  **OSP Proposal Number:** Click or tap here to enter text.  **Grant/Contract Status:**  Pending  Approved  **Funding Source:** Click or tap here to enter text.  **PI of Grant/Contract:** Click or tap here to enter text.  **Grant/Contract Title:** Click or tap here to enter text.  **FRS Account Number:** Click or tap here to enter text.  **OSP Proposal Number:** Click or tap here to enter text.  **Grant/Contract Status:**  Pending  Approved |

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| **Section 3: Human Participants** |
| **Participant Population(s)**  **Describe the participant population(s) including gender, race, ethnicity, and age range.**  ***Note: Participants under the age of 18 years are considered legal minors under Connecticut statutes and parental consent to participate must be obtained.***  Click or tap here to enter text.  *Note: targeting student-athletes (i.e., members of an intercollegiate sport team) because of their student-athlete status and providing material compensation for their participation could violate NCAA regulations. Questions about compensating student-athletes who are targeted for a study should be directed to the Eastern Director of Athletics.*  **Anticipated Total Enrollment**  **List the anticipated total enrollment. If you are enrolling more than one population, list the anticipated enrollment for each:**  Click or tap here to enter text.  **Recruitment**  **Describe how participants will be identified and recruited. Also attach copies of all advertisements or recruitment materials for CUHSR review (this includes descriptive statements for studies posted online):**  Click or tap here to enter text.  **Are advertisement/recruitment materials attached?**  Yes  No  **Special Populations**  Identify any special participant population(s) that you will be specifically targeting for the study.  **Check all that apply:**  Minors (under age 18)  Prisoners  Pregnant Women/Neonates  Females of Childbearing Potential  Decisionally Impaired Individuals  ECSU students  ECSU Employees  Employees of Research Sponsor  Economically Disadvantaged Individuals  Low Literacy/Educationally Disadvantaged Individuals  Members of the Armed Forces  Non-English Speaking Individuals  Individuals Living with AIDS/HIV  Other **(specify):** Click or tap here to enter text.  Recruitment of ECSU Students or Employees by a Faculty or Staff PI:  **Are you recruiting students who are in a class you teach or for which you have responsibility?**  Yes  No  **Are you recruiting employees who report to you?**  Yes  No  **If yes, explain why this population is necessary to study:**  Click or tap here to enter text.  Recruitment of your friends and family members poses issues of power dynamics, real and perceived coercion, and voluntariness. This must be justified by addressing the scientific rational and participant protection rationale for inclusion.  Examples of scientific rational for inclusion are when your friends and family:   1. are few of the people who speak a certain language 2. are few of the people who have experienced a specific environment, culture, or phenomenon   **Are you recruiting friends and/or family members?**  Yes  No  **If yes, provide the scientific rational and participant protection rational for inclusion**:  Click or tap here to enter text. |

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| **Section 4: Research Involving Drugs/Devices, Biological Samples, Genetic Testing, and/or Radiation** |
| **Drugs/Devices**  Does the study involve the use of any of the following?  **An FDA approved drug or medical device**  Yes  No  **An investigative/unapproved drug or medical device**  Yes  No  **A non-medical device**  Yes  No  **A proprietary product**  Yes  No  **A biological agent**  Yes  No  If yes, please complete the Drug/Device Supplemental Form (IRB-1A) and submit it with your application.  **Is a Drug/Device Supplemental Form attached?**  Yes  No  N/A  **Biological Samples**  **Does the study involve the use of biological samples (either banked or prospectively obtained**)**?**  Yes  No  If yes, you will need to obtain approval from the Environmental Health and Safety Coordinator (EHSC) before the study can be initiated. Please submit a copy of the approval letter if approval has already been granted from the EHSC.  **Is an EHSC approval letter attached?**  Yes  No  N/A  **Genetic Testing**  **Does the study involve the genetic testing of biological samples?**  Yes  No  If yes, please complete the Genetic Testing Supplemental Form (IRB-1B) and submit it with your application.  **Is a Genetic Testing Supplemental Form attached?**  Yes  No  N/A  **Radiation or Radioisotopes**  The use of radiation or radioisotopes is not permitted on campus. You will need to gain IRB approval from the institution where you are collecting data. |
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| **Section 5: PI and Research Personnel Qualifications** |
| **Briefly describe the professional and/or academic qualifications of the PI to conduct the proposed research (e.g., academic title and affiliation, degrees earned, prior research or research training in this field, relevant licensure). A student PI should list relevant coursework and/or other training or work experience.**  Click or tap here to enter text.  Documentation of training in the relevant ethical principles, federal regulations, and institutional policies pertaining to the protection of human research subjects. You must provide documentation within the last 3 years. Please check at least one of the following trainings and the expiration date of your certificate.  CITI Online Course: Social & Behavioral Research **Expiration date:** Click or tap here to enter text.  CITI Online Course: Biomedical Research **Expiration date:** Click or tap here to enter text. |
| You must attach certification of completed training course(s) for *all research personnel.* Undergraduate student PIs must submit certification for their faculty mentors as well. Please send the certificate(s) as attachment(s) with your application. Non-ECSU research personnel can complete the training through our CITI subscription. They do not need an Eastern email address to create their account.  **Are certificates attached for all research personnel?**  Yes  No |

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| **Section 6: Research Plan** |
| **Purpose**  **State the research goals for the study, including question(s) to be answered and hypothesis(es) to be tested:**  Click or tap here to enter text.  **Introduction**  **Summarize the background information that led to the plan for this project, with appropriate references to the published literature in this field:**  Click or tap here to enter text.  **Design, Procedures, Materials, and Methods**  **Describe the study design, including the sequence and timing of all study procedures. Provide copies of surveys/instruments/interview questions. If the research involves study of existing samples/records, describe how authorization to access samples/records will be obtained. If applicable, describe any recording procedures (e.g., audiotape, videotape, digital) and justification for use. If this study offers treatment for participants’ conditions, complete the Treatment Study Supplemental Form (IRB-1C) and submit it with your application for review.**  Click or tap here to enter text.  **Are copies of surveys/instruments/interview questions attached**?  Yes  No  **Justification of Sample Size**  **Describe how the proposed sample size is appropriate for achieving the anticipated results; include a power analysis if appropriate:**  Click or tap here to enter text.  **Inclusion/Exclusion Criteria**  **List major inclusion and exclusion criteria. Any proposed exclusion based on gender (e.g., women of childbearing potential), age, or race must include justification for the exclusion. Describe the conditions under which participants may be removed from the study (noncompliance with study rules, study termination, etc.).**  Click or tap here to enter text.  **Risks and Inconveniences**  **Describe the potential risks and steps taken to minimize risks. Types of risks to consider include: physical, psychological, social, legal, employment, and financial. Also describe any anticipated inconveniences the participants may experience (time, abstention from food, etc.).**  Click or tap here to enter text.  **Benefits**  **Describe anticipated benefits to the individual participants (if any). If individual results will be provided, describe and explain procedures to help participants understand the results. If individual participants may not benefit directly, state so here. Do not include compensation or course credit in this section.**  Click or tap here to enter text.  **Risk/Benefit Analysis**  **Provide your assessment of anticipated risks to participants balanced against anticipated benefits to the individual or to society:**  Click or tap here to enter text.  **Economic Considerations**  **Describe any costs to the participants or amount and method of compensation that will be given to them. Describe how you arrived at the amount and the plan of compensation; if it will be prorated, please provide the breakdown. Experimental or extra course credit for participation should be considered an economic consideration and included in this section. Indicate when participants will receive compensation. If data are collected through an anonymous survey, describe how participants will receive compensation while remaining anonymous.**  Click or tap here to enter text.  **Data Safety Monitoring**  This sub-section applies only to studies with more than minimal risk that are reviewed by the full board at a convened meeting OR as required by the IRB (e.g., with IRB-1A). Other applications should skip this sub-section. This sub-section should not describe procedures to protect confidentiality (see privacy and confidentiality sub-section below). Note: Under ECSU policy a student cannot be the sole person responsible for monitoring the data and safety of the protocol procedures.  The research plan should make adequate provisions for monitoring the data collected to ensure the safety of participants. Complete the following:  **Who will be responsible for analyzing individual events to determine whether the study should be modified to minimize risk?** Click or tap here to enter text.  **How and when will the data be monitored?** Click or tap here to enter text.  **Describe the “stopping rules” or parameters for when and how research will be revised, including the criteria for terminating the study, in response to interim data analysis:** Click or tap here to enter text.  **Give a clear description of the endpoints that are going to be evaluated and the decisions that are going to made if these endpoints are reached:** Click or tap here to enter text.  **Use of Deception**  **If deception is to be used in the study, the method and justification, and method of debriefing the participants, should be described. Check N/A if no deception will be used**.  N/A  Click or tap here to enter text.  **Privacy and Confidentiality**  **Describe how you will protect the privacy of participants. Include how you make sure others cannot overhear your conversations with participants and that participants will not be publicly identified or embarrassed.** Click or tap here to enter text.  **Describe how you will store research data (both paper records and electronic data) to maintain confidentiality (see sample consent form for suggestions). Points to consider in your description (this is not intended to be a comprehensive list):**   1. **Storage of paper data (where specifically stored, who has access and how limited, how long stored)** 2. **Storage of electronic data (stored on ECSU OneDrive, personal devices, or other; who has access and how limited, whether those devices are encrypted or password-protected, how long stored, etc.)** 3. **Storage of recordings (audiotape, videotape, digital, etc.)** 4. **Whether any portable devices will be utilized at any point of the study (laptops, USB drives, cameras, cell phones, etc.) and how data will be secured and managed** 5. **If identifiable data is retained, describe whether the data will be coded with links to identifiers stored separately or whether data will be stored with identifiers). Describe all locations.** 6. **Specific confidentiality information pertaining to any data that is collected in a less secure manner such as use of Wi-Fi connected devices, online sites or apps, or data emailed to/from another person.**   Click or tap here to enter text.  **Are you collecting data from Amazon MTurk?**  Yes  No  **If yes, have you included the required wording from the sample consent form provided by the CUHSR on your consent form?**  Yes  No  **If identifiable sensitive information (illegal drug use, criminal activity, etc.) will be collected, select whether a Certificate of Confidentiality will be obtained.**  Yes  No  N/A  **Study Dates**  Expedited review feedback from the CUHSR typically takes 2-3 weeks. Full board reviews typically take 4-5 weeks. If revisions are required, the approval process will take longer. Approvals are good for one year. To collect data after one year, an IRB-5 Application for Continuing Review must be submitted.    **Expected Starting Date (you may write upon approval if that is your plan):** Click or tap here to enter text.  **Expected Ending Date:** Click or tap here to enter text. |

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| **Section 7: Informed Consent** |
| As PI, you are responsible for taking reasonable steps to assure that the participants in this study are fully informed about and understand the study. Even if you are not targeting participants from “Special Populations” as listed in Section 3, you may be recruiting from such populations. Please keep this in mind as you design the consent process and provide the information requested in this section. See the CUHSR website for information on forms (consent, assent, etc.) as well as templates.  **Consent Setting**  **Describe the consent process including who will obtain consent, where and when will it be obtained, and how much time participants will have to make a decision. State whether an assessment of consent materials will be conducted to assure that participants understand the information (may be warranted in studies with complicated study procedures, those that require extensive time commitments or those that expose participants to greater than minimal risk).**  Click or tap here to enter text.  **Capacity to Consent**  **Describe how the capacity to consent will be assessed for participants with language or reading barriers, limited decision-making capacity, or hearing difficulty. If a participant is incapable of providing consent, you will need to obtain consent from the participant’s legal guardian (please see the CUHSR website for additional information).**  Click or tap here to enter text.  **Parental Permission and Assent**  **If enrolling children (under age 18), state how a parent/guardian will provide consent and how the child’s assent will be obtained. Check N/A if no children will be enrolled**.  N/A  Click or tap here to enter text.  **Documentation of Consent/Assent**  **Specify the forms that will be used for each participant population in the box below (e.g., adult consent form, surrogate consent form, child assent form or oral assent script). Copies of all forms must be submitted with this application in the same format that they will be given to participants.**  Click or tap here to enter text.  **Are copies of all forms attached**?  Yes  No  **Waiver or Alteration of Consent**  The CUHSR may waive or alter the elements of consent in some minimal risk studies. You may apply for a waiver or alteration of consent below. You will only complete the one waiver section for what you are requesting.  ***Waiver of Consent***  A waiver of consent is when participants won’t give consent. Complete the following questions using specific information from the study if you are requesting a waiver:  **Why is the study considered to be minimal risk?**  Click or tap here to enter text.  **How will the waiver affect the participants’ rights and welfare?**  Click or tap here to enter text.  **Why would the research be impractical without the waiver?**  Click or tap here to enter text.  **How will the important information be returned to the participants, if appropriate?**  Click or tap here to enter text.  ***Alteration of Consent***  Examples of alteration of consent include but are not limited to 1) participants will give oral consent only after reading an information sheet, 2) participants check a box to participate online without providing an electronic signature. Complete the following questions using specific information from the study if you are requesting an alteration of consent:  **Why is the study considered to be minimal risk?**  Click or tap here to enter text.  **Does a breach of confidentiality when collecting names/signatures constitute the principal risk to participants?**  Click or tap here to enter text.  **Would the signed consent form be the only record linking the participant to the research?**  Click or tap here to enter text.  **Does the research include any activities that would require signed consent in a non-research setting?**  Click or tap here to enter text. |

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| **Section 8: Faculty/Staff/Graduate Student PI Protocols** |
| Complete this section if you are faculty, staff, or a graduate student. I hereby certify that:  **All study personnel have completed the required human subjects training:**  Yes  No  **All study personnel are knowledgeable about the study procedures:**  Yes  No  **This study has been designed, the best of my ability and knowledge, to protect human participants engaged in research in accordance with the standards set by Eastern Connecticut State University, the United States Department of Health and Human Services, the Food and Drug Administration, and any other sponsoring federal, state, or private agency:**  Yes  No  **PI Name:** Click or tap here to enter text.  **Date:** Click or tap here to enter text. |

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| **Section 9: Undergraduate Student PI Protocols** |
| Complete this section if you are an undergraduate student.  Submission Requirements:   1. This protocol application must be reviewed and approved by your Research Mentor before being submitted to the CUHSR for review. 2. You must get your Research Mentor’s written approval in an email. You will forward that email to [CUHSR@easternct.edu](mailto:CUHSR@easternct.edu) with the protocol application and other materials (consent form, CITI certificate, etc.) attached.   **I hereby certify that:**  **All study personnel and my faculty mentor have completed the required human subjects training:**  Yes  No  **This study has been designed, the best of my ability and knowledge, to protect human participants engaged in research in accordance with the standards set by Eastern Connecticut State University, the United States Department of Health and Human Services, the Food and Drug Administration, and any other sponsoring federal, state, or private agency:**  Yes  No  **Student PI Name:** Click or tap here to enter text.  **Research Mentor Name:** Click or tap here to enter text.  **Date:** Click or tap here to enter text.  Protocol applications that are not submitted with the above criteria will not be reviewed. |