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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:  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-2 Exempt 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. Exempt review feedback from the CUHSR typically takes 2-3 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.

The following are some examples that must use the IRB-1 Protocol Application instead of this IRB-2 Protocol Application.

1. Research with children or other vulnerable populations (see IRB-1 for examples).
2. Research using drugs/devices, collection of biological samples, or conducting genetic testing.
3. Research on sensitive or personal topics which may cause stress to participants.
4. Research with more than minimal risk. Minimal risk is defined as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45 CFR 46.102(i))
5. Research where the PI is an undergraduate student.
6. Research in a foreign country.
7. Research with identifiable sensitive information.
8. Research using deception.
9. Research with extreme physical exertion.
10. Other research that does not meet the criteria for one of the six exempt categories.

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| **Section 1: General Information** | |
| **Study Information**  **Nature of study (check only one):**  Faculty Research  Staff 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**  **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. | |
| **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 (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 | |

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| **Section 2: Categories of Exemption** |
| **Exempt Category 1**  This category is for research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Note: If this research includes a request to access or obtain personally identifiable information from an ECSU student’s education record (GPA, SAT score, class assignments), prior written consent is required per FERPA regulations.  **Does this study meet the above criteria?**  Yes  No  **Exempt Category 2**  This category is for research that involves only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).*[Surveys, interviews, educational tests, and observation of public behavior where the investigator does not participate in the activity being observed.]*  **Does this study meet the above criteria?**  Yes  No  **If yes, choose how the data will be collected below.**  1. Data will be collected anonymously (it will never be connected to any personal identifiers of the participant). [*No identifiers can be directly connected to the data through coding or use of pseudonyms*. *Audio or video recordings are not considered anonymous.]*  Yes  No  2. Data collected will include participant identifiers, but any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.  Yes  No  If yes, data **may not** be sensitive in nature, for example, illegal activities, medical conditions, or negative attitudes/experiences in the workplace. Is there any sensitive data?  Yes (you need to complete the IRB-1)  No  3. Data collected will include participant identifiers and disclosure may place participants at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation if disclosed. Yes (you need to complete the IRB-1)  No  **Exempt Category 3**  This category is for research that involves a benign behavioral intervention. The intervention must be brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the intervention is not offensive or embarrassing.  *Behavioral intervention defines research procedures that are employed in the study of psychological states and processes, cognition, ideas and attitudes, or behavior, and do not include physical (bodily) tasks or physical manipulations (range of motion activities, physical exercise, etc.) unless these are minor activities that are incident to the behavioral intervention and do not increase risk. They do not involve the introduction or administration of instruments, substances or energy onto or into the body and may not include exposure to extremes of heat, cold, noise or light.*  *What is brief in duration under this category? Intervention lasts a few minutes to a few hours. While it does not have to occur in a single session, the entire time for the intervention should occur on a single day and not exceed a few hours in its entirety. Brief in duration applies to the intervention and not the data collection.*  Examples include asking participants to play an online game, solve puzzles under various noise conditions, or deciding how to allocate a nominal amount of received cash between themselves and someone else.  **Does this study involve a benign behavioral intervention?**  Yes  No  **If yes, provide a description of the intervention:**  Click or tap here to enter text.  **If yes, answer the sections below.**  ***Exemption Criteria***  1. What is the maximum amount of time the intervention could take for any single participant?  Click or tap here to enter text.  2. Is the intervention harmless?  Yes  No (you need to complete the IRB-1)  3. Is the intervention painless?  Yes  No (you need to complete the IRB-1)  4. Is the intervention physically invasive?  Yes (you need to complete the IRB-1)  No  5. Is the intervention likely to have a significant adverse lasting impact on the participants?  Yes (you need to complete the IRB-1)  No  6. Do you have any reason to think the participants will find the intervention offensive or embarrassing?  Yes (you need to complete the IRB-1)  No  ***Is the intervention limited to procedures involving one of the following?***  1. Communication or interpersonal contact with the participants.  Yes  No  2. The performance of a cognitive, intellectual, educational, or behavioral task.  Yes  No  3. Manipulation of participants’ physical, sensory, social, or emotional environment.  Yes  No  ***Please choose the means of collecting data.***  1. Verbal (oral) or written responses by the participants.  Yes  No  2. Data entry by the participants.  Yes  No  3. Observation of the participants, including audiovisual recording.  Yes  No  ***NOTE: data collection by a device (blood pressure monitoring, activity trackers, eye trackers, etc.) are not allowed in Exempt Category 3.***  ***Please select how the data will be collected.***  1. Data will be collected anonymously (it will never be connected to any personal identifiers of the participant). [*No identifiers can be directly connected to the data through coding or use of pseudonyms*. *Audio or video recordings are not considered anonymous.]*  Yes  No  2. Data collected will include participant identifiers, but any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.  Yes  No  If yes, data **may not** be sensitive in nature, for example, illegal activities, medical conditions, or negative attitudes/experiences in the workplace. Is there any sensitive data?  Yes (you need to complete the IRB-1)  No  3. Data collected will include participant identifiers and disclosure may place participants at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation if disclosed. Yes (you need to complete the IRB-1)  No  **Exempt Category 4**  This category is for research that involves secondary research of identifiable private information/biospecimens.  **Does this study involve secondary research of identifiable private information/biospecimens?**  Yes  No  **If yes, describe the nature of the data/biospecimens**. Click or tap here to enter text.  **If yes, complete the items below.**  1. Are the data publicly available?  Yes  No  2. Is the information/biospecimens recorded in an identifiable manner where the identity of participants can be readily ascertained directly or through a code?  Yes  No  **If Yes**:  Will participants be re-contacted?  Yes  No  Will participants be re-identified?  Yes  No  3. Does this research involve secondary use of identifiable private information regulated under HIPAA as “healthcare operations,” “research,” or “public health”? Note that HIPAA does not apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information obtained from biospecimens).  Yes  No  4. Does this study involve secondary research conducted by or on behalf of a federal department or agency, using data collected or generated by the government for nonresearch purposes, and the information is subject to federal privacy standards and other requirements specified in the exemption?  Yes  No  5. Describe how you obtained the data and attach a copy of any approval letter(s) for use of the data. If the external institution or agency from which the dataset(s) will be acquired requires a Confidentiality/Data Use Agreement or Memorandum of Understanding, attach one copy of each.  Click or tap here to enter text.  **Exempt Category 5**  This category is for research/demonstration projects conducted or supported by a Federal department or agency (or agency head), which is designed to study, evaluate, improve, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.  **Does this study meet the criteria above?**  Yes  No  **If yes, provide a detailed description:** Click or tap here to enter text.  **Exempt Category 6**  This category is for research on taste and food quality evaluation and consumer acceptance studies.  **Does this study meet the description above?**  Yes  No  **If yes, complete the following:**  The food consumed must fall into one of these two categories: 1) wholesome foods without additives, or 2) food that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.  **Does the food in this study fall into one of the two categories listed above?**  Yes  No (you need to complete the IRB-1) |

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| **Section 3: Human Participants** |
| **Participant Population(s)**  **Describe the participant population(s) including gender, ethnicity, and age range.**  Click or tap here to enter text.  **Recruitment**  **Describe how participants will be identified and recruited. Also submit 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  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.  Recruitment of non-English speaking individuals will require you to translate the consent form once the English version has been approved.  **Are you recruiting non-English speaking individuals?**  Yes  No |

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| **Section 4: 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.* 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 5: 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, and location of all study procedures, and length of time each procedure takes to complete. Describe what the participants will be asked to do. Provide copies of surveys/instruments/interview questions.**  Click or tap here to enter text.  **Are copies of surveys/instruments/interview questions attached**?  Yes  No  **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.). Only minimal risk research is permitted for IRB-2 Exempt review.**  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 participant may not benefit directly, state so here. Do not include compensation or course credit in this section.**  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.  **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 nor it is intended to be presented in this order):**   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, etc.)** 3. **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** 4. **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.** 5. **Specific confidentiality information pertaining to any data that is collected in a less secure manner such as use of WiFi 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 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  **Study Dates**  Exempt review feedback from the CUHSR typically takes 2-3 weeks. If revisions are required, the approval process will take longer. Approvals are good for one year. To collect data after one year, an 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 6: 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. See the CUHSR webpage 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, etc.).**  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.  **Documentation of Consent**  Copies of all consent forms must be submitted with this application in the same format that they will be given to participants.  **Are copies of consent form(s) 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 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 7: Protocol Certification** |
| 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. |