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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-4 Protocol Application for the Involvement of Human Subjects in Student Research Projects within a Course**

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 template, IRB members course 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. 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.

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| **Section 1: General Information** | |
| **Course Information**  **Course Number and Sections:** Click or tap here to enter text.  **Title of Course:** Click or tap here to enter text.  **Semester (check all that apply) and add the year in the text box:**  Fall Click or tap here to enter text.  Spring Click or tap here to enter text.  Summer Click or tap here to enter text.  **Course Description (2-3 sentence summary):** Click or tap here to enter text.  **Course Instructor(s) Information** | |
| If multiple sections will be taught, all instructors covered by this Protocol Application should be listed. Each instructor must submit documentation of completion of the CITI IRB Members course within the past three years. | |
| *Course Instructor 1*  **Name:** Click or tap here to enter text.  **Highest Degree**: 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.  *Course Instructor 3*  **Name:** Click or tap here to enter text.  **Highest Degree**: 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. | *Course Instructor 2*  **Name:** Click or tap here to enter text.  **Highest Degree**: 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.  *Course Instructor 4*  **Name:** Click or tap here to enter text.  **Highest Degree**: 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 Location(s)**  **Where will the data collection take place?**  ECSU Campus (i.e., in-person collection on campus, online collection from only ECSU-affiliated individuals)  Off Campus  **If off campus, please specify the location(s):**  Click or tap here to enter text. | |

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| **Section 2: Research Not Covered by an IRB-4 Application** |
| In the following cases, the student investigator(s) must submit an IRB-1 Protocol Application for Expedited or Full CUHSR review:  1. If a research project is to take place in a controlled facility (school, daycare center, nursing home, etc.).  2. If a research project will enroll members of a vulnerable population as subjects. Vulnerable populations include: children (under age 18), prisoners, pregnant women, handicapped or mentally disabled persons, economically or educationally disadvantaged persons.  3. A study involving genetic analysis of a biological specimen obtained from an identified living human subject. Note: Nucleic acid sequences obtained from a public genetic data base and/or specimens obtained from a tissue repository that are not linked to an identifiable person can be included under an IRB-4 Protocol Application.  **I/we certify that any research projects that meet the above criteria will be submitted as IRB-1 Protocol Applications.** |

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| **Section 3: Human Participants** |
| **Participant Population(s)**  **Describe the participant population(s) including gender, race, ethnicity, and age range:**  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.*  **Recruitment**  **Describe how participants will be identified and recruited:**  Click or tap here to enter text. |

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| **Section 4: Description of Course/Research Plan** |
| **Introduction**  **Provide the course research objectives:**  Click or tap here to enter text.  **Provide the estimated number of students conducting projects for the semester(s) covered by this application:**  Click or tap here to enter text.  **Provide a list of representative examples (e.g., titles) of past student projects from this course:**  Click or tap here to enter text.  **Design, Procedures, Materials, and Methods**  **Describe how students will collect data and report results:**  Click or tap here to enter text.  **Describe the training in the protection of human research subjects that students will receive from the course instructor:**  Click or tap here to enter text.  **Check which CITI course(s) students will complete:**  Social & Behavioral Research  Biomedical Research  **Describe who will evaluate the projects for compliance with university policies for protection of human research subjects. The Review Sheet for Student Research Projects Covered by an IRB-4 Protocol Form is available on the CUHSR website or from the CUHSR Chair (Dr. Melanie Evans Keyes;** [**CUHSR@easternct.edu**](mailto:CUHSR@easternct.edu)**). This must be completed for each project covered by this Protocol Application and saved for one calendar year following the end of the current semester. These copies must be submitted to the CUHSR if requested.**  Click or tap here to enter text.  **Inclusion/Exclusion Criteria**  **List major inclusion and exclusion criteria. Any proposed exclusion based on gender, age, or race must include justification for the exclusion.**  Click or tap here to enter text.  **Risks and Inconveniences**  **Describe the potential risks and steps taken to minimize risks. Also describe any anticipated inconveniences the participants may experience (time, etc.):**  Click or tap here to enter text. |
| **Benefits**  **Describe anticipated benefits to the individual participants (if any). 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.  **Economic Considerations**  **In most cases there will be no cost to or compensation for participants. Describe any costs to the participants or amount and method of compensation that will be given to them. Experimental or extra course credit for participation should be considered an economic consideration and included in this section.**   Click or tap here to enter text.  **Confidentiality**  **Describe procedures for protecting confidentiality of data collected and stored. Describe who will have access to the data, where the data will be kept and for how long.** Click or tap here to enter text. |

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| **Section 5: Informed Consent** |
| As the Course Instructor, you are responsible for taking reasonable steps to assure that the participants the students enroll in their studies are fully informed about and understand the study.  **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:**  Click or tap here to enter text.  **Documentation of Consent**  Provide a copy of the consent form or information sheet that students will use. This can be in the form of a template that has areas that students complete for their individual projects (name, contact information, details of their study, etc.). There are sample forms on the CUHSR website.  **Did you attach a copy of the consent form/information sheet?**  Yes  No  **Waiver of Signed Consent**  The CUHSR may waive or alter the elements of consent in some minimal risk studies. If students will be collecting anonymous data without signed consent (participants give oral consent only after reading an information sheet, participants check a box to participate online without providing an electronic signature, etc.) the following information must be completed.  **Why is the study considered to be minimal risk?**  Click or tap here to enter text.  **Does a breach of confidentiality 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 6: Course Instructor Responsibilities and Certification** |
| I/we hereby certify that:  1. I/we must complete the **Review Sheet for Student Research Projects Covered by an IRB-4 Protocol** for each project covered by this Protocol Application and save them for one calendar year following the end of the current semester. These copies must be submitted to the CUHSR if requested.  Yes  No  2. I/we must keep for a period of one calendar year following the end of the current semester an archived copy of the final research report for each student project covered by this IRB-4 Protocol Application. These copies must be submitted to the CUHSR if requested.  Yes  No  3. I/we have completed the required CITI IRB Members course and will train my/our students in the basics of the protection of human research subjects as it relates to the projects in the course.  Yes  No  **Are certificates attached in the email submission for all course instructors?**  Yes  No  4. I/we will review the student research in this course and, to the best of my/our ability and knowledge, apply the standards for the protection of human research subjects to the projects covered by this IRB-4 Protocol Application.  Yes  No  **Name(s) of course instructor(s):** Click or tap here to enter text.  **Date:** Click or tap here to enter text. |