**IRB-4 Submission Instructions**

**Background Information**

1. Eastern Connecticut State University adheres to U.S. federal regulations covering research on human subjects as described in the Code of Regulations, Title 45, Part 46 Protection of Human Subjects (45 CFR 46, or "The Common Rule"):

   https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

   Additional information about federal policies covering research on human subjects can be found at the Office of Human Research Protections (OHRP), Dept of Health and Human Services, website: https://www.hhs.gov/ohrp/

2. Eastern's Committee on the Use of Human Subjects in Research (CUHSR) is registered as an Institutional Review Board (IRB) with the OHRP. Our registration number and name are as follows:
   IORG Number: IORG0004941
   IRB Number: IRB00005900
   IRB Name: Eastern Connecticut State U IRB#1.
   Federalwide Assurance Number: FWA00011898
   Eastern Connecticut State University Human Protections Administrator: Dr. William Salka, Provost and Vice President for Academic Affairs

3. Instructors teaching research methods courses or any other courses where students will be conducting research with human subjects may submit an IRB-4 Protocol Application for Student Research Projects within a Course in lieu of having students submit IRB-1 Protocol Applications. This form may downloaded from the CUHSR website.

4. This procedure was developed in response to faculty requests for an approval process that would allow for their students conducting research within a course to be able to present their research at conferences.

**Submitting an IRB-4 Protocol Application**

1. On the Protocol Application, you will tap in the boxes to check/uncheck your selections and use the "Click or tap here to enter text" to enter all other information. The boxes will adjust to accommodate however much space you need. Do not bold the text you enter in the text boxes.

   NOTE: Please do not reformat the Protocol Application (this includes converting it to PDF, etc.), or delete any sections that are not applicable to your research; any form that has been reformatted, or has sections missing, will be returned without review.

2. This form can be completed for multiple instructors teaching the same course in a

given semester.

3. As noted on the IRB-4 Protocol Application, all instructors listed on the form must provide documented evidence of having completed the CITI course IRB Members within the past three years. Students in the course will need to complete one of the following CITI courses most relevant to their proposed research: 1) Social & Behavioral Research or 2) Biomedical Research.

   NOTE: do not submit the the student CITI certificates to the CUHSR. Only the IRB Members course certificates from course instructors are required to be submitted.

   Instructions for completing the CITI training courses are posted here (see the section at the end titled "Additional CITI courses" to add the IRB Members course. The IRB Members course is an option in Question 1: Human Subjects Research). Note: if you have already completed either the Social & Behavioral Research or Biomedical Research course, you will have already completed approximately half of the CITI IRB Members course as they share modules. When you add the IRB Members course, any modules you have already completed in another CITI course will show as completed in the IRB Members course.

   Upon successful completion of the IRB Members course, you can download a PDF certificate of completion. One copy of this for each instructor must be included with the IRB-4 Protocol Application submission; save a copy and/or the CITI login information for future submissions. The CITI course certificate of completion is valid for three years.

4. A copy of the consent form or consent form template to be signed by each participant in a student research project must accompany the Protocol Application. There is a sample consent form that may be downloaded from the CUHSR website. The consent form should be written directly to the participants in lay language (which many IRBs set at the 6th-8th grade reading level). It needs to contain the following information:
   a) A statement of the purpose and procedures of the research.
   b) An explanation of the subject's responsibilities and the duration of participation.
   c) A description of any foreseeable risks and benefits to the subject**.** If the research poses only minimal risk, this should be clearly stated. For studies posing minimal risks, use the IRB standard minimal risk statement, "I do not anticipate any risks to you as a result of participating in this study other than those normally encountered in day-to-day life."
   d) A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
   e) A statement indicating that participation is voluntary, and that the subject can refuse to participate or terminate his/her participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

f) A statement that the results of the investigation will be made available to the subject upon request.
g) A statement of whom to contact for answers to pertinent questions about the research, or to request a copy of the research results, and the contact information for that person to be contacted. The name and contact information of the course instructor must also be included.
h) A statement of whom to contact with questions about one's rights as a research subject. The CUHSR recommends the following: "If you have questions about your rights as a research participant, please contact Dr. Melanie Evans Keyes, Chair of the Committee on the Use of Human Subjects in Research at Eastern Connecticut State University (Ph: 860-465-0070; Email:CUHSR@easternct.edu)."

5. If the students will be collecting anonymous data using an information sheet instead of a signed consent form, the section on Waiver or Alteration of Consent needs to be completed. A copy of the information sheet must accompany the Protocol Application. Note: information sheets should contain the same information as listed in number 4 a-h above.

6. If a research project is to take place in a controlled facility (school, daycare center, nursing home, etc.) the student investigator(s) must submit an IRB-1 Protocol Application.

7. If a research project will enroll as subjects members of a vulnerable population, the student investigator(s) must submit an IRB-1 Protocol Application. Vulnerable populations include: children (under age 18), prisoners, pregnant women, handicapped or mentally disabled persons, economically or educationally disadvantaged persons.

8. Instructors must complete the Student Research Projects within a Course Review Sheet 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. This form may downloaded from the CUHSR website.

9. Instructors 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 Protocol Application. These copies must be submitted to the CUHSR if requested.

10. Please submit the completed Protocol Application and any supporting documents by email to: Dr. Melanie Evans Keyes, Chair, CUHSR (CUHSR@easternct.edu)

11. IRB-4 review typically takes 2-3 weeks. If revisions are required, the approval process will take longer. Please plan accordingly to ensure your students have time to collect data.

12. The CUHSR includes faculty (science and non-science), administrative faculty, and a non-Eastern affiliated community member. As such, your application must be clear to someone outside of your discipline.

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