IRB-1 and IRB-2 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. Researchers (faculty, staff, and students) planning to conduct research on human subjects must submit an IRB-1 or IRB-2 Protocol Application for the Involvement of Human Subjects in Research. These forms may be obtained from the CUHSR Chair (contact information given below), or downloaded from the CUHSR website.
   a. IRB-1 forms are for expedited or full board review.
   b. IRB-2 forms are for research that falls into one of the 6 exempt categories as defined by 45 CFR 46.104.

Submitting an IRB-1 or IRB-2 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. All investigators and research personnel must provide documented evidence of having completed within the past three years one of the following CITI courses most relevant to your proposed research: 1) Social & Behavioral Research, 2) Biomedical Research. If

you have non-Eastern research personnel, they can complete the CITI course through our subscription. They do not need an Eastern address to create their account.

Instructions for completing the CITI training courses are posted here.

Upon successful completion of the course, you can download a PDF certificate of completion. One copy of this must be included with each 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.

3. A copy of the consent form to be signed by each subject or the subject's legally authorized representative must accompany the Protocol Application. There is a sample consent form that may be downloaded from the CUHSR website. The consent form should be printed on official letterhead and should be written directly to the participants in lay language (which many IRBs set at the 6-8th grade reading level) to ensure participants' ability to make an informed decision. 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. (NOTE: IRB-2 Protocol Applications may not have more than minimal risk). 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 an institutional address for the person to be contacted. For student projects, the name and contact information of a faculty supervisor must 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)."

Note: Consistent with the 45 CFR 46.116(f)(3) the requirement for an informed consent document signed by the subject may be waived **if** the following is documented:

i. The research involves no more than minimal risk to the subjects;
ii. The research could not practicably be carried out without the requested waiver or alteration;
iii. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
iv. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
v. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Note: Investigators using human subjects under the age of 18 must obtain signed consent from the child's parent or guardian and written/oral assent from the child. Samples of all necessary consent forms (e.g., from parents, teachers, administrators, daycare supervisors) and assent forms should accompany Protocol Applications using children as subjects. There is information on assent forms on the CUHSR website.

Note: In certain exceptional cases, investigators using children as research subjects may be exempt from the requirement for obtaining informed consent from parents or guardians; investigators should refer to the 45 CFR 46.401-409 for more information.

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

5. IRB-1 expedited review and IRB-2 exempt review typically take 2-3 weeks, and a decision is not tied to a convened meeting of the CUHSR. Full board review typically takes 4-5 weeks. If revisions are required, the approval process will take longer.

6. 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.

7. If you have questions about conducting research on human subjects at Eastern Connecticut State University, please contact the CUHSR Chair, Dr. Melanie Evans Keyes, Department of Psychological Science, Eastern Connecticut State University (Ph: 465-0070; Email: CUHSR@easternct.edu).

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