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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-3 Research with Human Subjects Assessment Form**

Read these important notes before completing this form:

1. There may be periodic updates to this form, so please be sure to use the current version.
2. Only complete forms will be reviewed.
3. Do not alter this form/convert it to another format (PDF, etc.). Altered forms 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 information must be clear to someone outside of your discipline.
5. Research Assessment decisions from the CUHSR typically take 2-3 weeks.
6. If your project is determined to be research, you must submit either an IRB-1 or IRB-2 Application (as appropriate) and receive approval from the CUHSR before research activities may begin.

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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.  **Principal Investigator (PI) Information**  *Note: only complete one of the boxes below for Faculty/Staff or Student.* | |
| **Faculty / Staff PI**  **Name:** 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 PI**  ***(Only for student-initiated research; students working on faculty/staff-initiated research should be listed as Research Personnel below).***  **Name:** 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. |

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| **Section 2: Common Rule Research Assessment** |
| **Federal Policy for the Protection of Human Subjects – Common Rule – 45 CFR 46**  Please complete the following questions to assess whether the proposed study involves research under the federal Common Rule.  1. Is this study limited to scholarly or journalistic activity, such as oral history, journalism, biography, literacy criticism, legal research, or historical scholarship, including the collection and use of information, that focuses directly on the specific individuals about whom the information is collected? [45 CFR 46.102(l)(1)]  NOTE: Scholarly and journalistic activities, including the collection and use of information, are not considered research when they focus directly on the specific individuals about whom the information is collected. These types of activities as performed in anthropology or sociology are likely to be considered research as defined by the human subjects regulations if they focus more broadly than just the specific individuals about whom the information is collected. For example, it is considered to be research when studies use methods such as participant observation and ethnographic studies to gather information from individuals in order to understand their beliefs, customs, and practices, and the findings are applied to the studied community or group and not just the individuals from whom the information was collected.  Yes → Stop here. This is not research as defined by the Common Rule. Proceed to Section 3.  No → Continue to Question 2.  2. Is this a public health surveillance activity, including the collection and testing of information or biospecimens that meets both of the following criteria?   * is conducted, supported, requested, ordered, required, or authorized by a public health authority, AND * is limited to activity necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public healthy importance (involving trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). [45 CFR 46.102(l)(2)]   NOTE: A public health authority is:   * an agency or authority of the United States Government, a State, a territory, a political subdivision of a State or territory, or an Indian tribe that is responsible for public health matters as part of its official mandate, OR * a person or entity acting under a grant of authority from or contract with such public agency * <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/is-recipient-public-health-authority/index.html>   Yes → Stop here. This is not research as defined by the Common Rule. Proceed to Section 3.  No → Continue to Question 3.  3. Is this activity limited to collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes? [45 CFR 46.102(l)(3)]  Yes → Stop here. This is not research as defined by the Common Rule. Proceed to Section 3.  No → Continue to Question 4.  4. Is this activity limited to authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions? [45 CFR 46,102(l)(4)]  Yes → Stop here. This is not research as defined by the Common Rule. Proceed to Section 3.  No → Continue to Question 5.  Information for Questions 5 and 6:   * Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(l)] * Systematic investigation is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question. * Generalizable knowledge means the information is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:   + Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.   + Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.   5. Is this activity a systematic investigation?  Yes → Continue to Question 6.  No → Stop here. This is not research as defined by the Common Rule. Proceed to Section 3.  6. Is this activity designed to develop or contribute to generalizable knowledge?  Yes → This activity is research as defined by the Common Rule. Proceed to Section 3.  No → Continue to Section 3. |

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| **Section 3: Study Information** |
| **Study Objective (Provide summary of purpose, specific aims, or objectives. Describe any hypotheses being tested):** Click or tap here to enter text.  **Who will be involved in this study? How will they be selected and recruited?**  Click or tap here to enter text.  **Please provide a rationale for why your activity is not considered research.** Click or tap here to enter text. |