

ELIZABETH CITY STATE UNIVERSITY
Compliance Policies and Procedures

Preamble

Elizabeth City State University (ECSU) pursues federal, state and local resources to support teaching, research and community outreach activities. Resources are sought and received from federal agencies, state government, foundations, organizations, and individuals. Compliance policies have been established regarding the implementation of sponsored projects which include monitoring research on human and animal subjects and hazardous materials to ensure compliance with federal and state regulations as well as ECSU policies.

A. Human Subjects

The Office of Sponsored Programs, Contracts and Grants (SPCG) shall coordinate the activities of the various compliance committees to govern research experiments at ECSU, whether conducted by faculty, staff, or students. The committees shall be selected by the Vice Chancellor for Academic Affairs in conjunction with the Director of Sponsored Programs. ECSU adheres to all the rules and regulations governing human research as contained in the Department of Health and Human Services (DHHS) Part 46 of Title 45 of the Code of Federal Regulations (45 CFR 46) and the Food and Drug Administration (FDA) 21 CFR Parts 50 and 56. These federal regulations require ECSU to submit to the funding agency, a statement of specific assurance for each research proposal involving human subjects. Therefore, each proposed project involving human subjects shall be reviewed by ECSU's Institutional Review Board (IRB). The IRB shall require a complete copy of the project proposal along with submission of the "Request for Review of Research Involving Human Subjects Form." These forms are available in SPCG and must be completed a minimum of 45 days prior to proposal submission. Except under unusual circumstances, ECSU's IRB shall expedite the review of requests (14 calendar days before submission), thus reducing delays in the proposal submission/award process.

1. Human Subjects Education

All ECSU personnel, whether faculty, staff, or students, shall be IRB-certified before conducting human subjects research. Key personnel are defined as individuals who contribute in a substantive way to the scientific development or execution of a project, whether or not they receive compensation from the grant supporting that project. ECSU key personnel shall take the Collaborative IRB Training Initiative (CITI) online for certification at <https://www.citiprogram.org/default.asp> or provide documentation of certification by other means approved by ECSU's Compliance Officer. Recertification of key personnel will be conducted as required.

2. Social and Behavioral Research

Federal regulations governing human subjects protection also includes social/behavioral research. Social and behavioral science research encompasses a variety of disciplines

including, but not limited to, anthropology, sociology, psychology, political science, education, social work, art education and history, theatre, and, music. Much of this research uses qualitative research methods such as formal and informal interviews, participant observation, questionnaires, surveys, focus group discussions, oral history, ethnographic research, program evaluation and collection or study of existing data, documents and records. However, the research must still be carried out with due consideration of the Ethical Principles regarding research involving human subjects. Therefore, in accordance with federal regulations, all social/behavioral research involving human subjects shall be reviewed and approved by an Institutional Review Board (IRB) for exempt, expedited, or full review status prior to initiation of the research project to assure that the rights and welfare of human subjects are protected. Additionally, all investigators, including faculty and students shall complete the required CITI Human Subjects Protection Certification Training prior to the initiation of research involving human subjects <https://www.citiprogram.org/default.asp>.

a. The Common Rule

The Common Rule states that there are 6 categories of research that are exempt (from full IRB review). The first 4 of the exemptions will be most appropriate for social science research:

1. Research in educational settings involving educational practices.
2. Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior, unless subjects are identified and disclosure of responses would involve more than reasonable risk.
3. Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior not exempt under preceding exemption if human subjects are elected public officials, and if federal statutes require confidentiality of identifiable information.
4. Research involving the collection or study of existing data if publicly available or unidentifiable.
5. Research and demonstration projects designed to study public benefit or service programs.
6. Taste and food quality evaluation and consumer acceptance studies.

b. A designated IRB representative or the entire IRB Committee, not the researcher, shall determine whether the project is exempt. If it so determined, the research shall be free from continued oversight by the IRB.

B. Animal Subjects

Federal regulations require ECSU, when using animals as research subjects, to carefully monitor their care and use. ECSU is committed to observing federal regulations pertaining to animal care. ECSU's Institutional Animal Care and Use Committee (IACUC) shall make recommendations to the ECSU administration on all matters of animal care. Forty-five (45) days prior to the submission of proposals that incorporate the use of laboratory animals, ECSU's "Protocol for the Use of Live Vertebrates for Research, Teaching or Demonstration" shall be completed. This protocol shall be reviewed by members of the IACUC. Animal research shall be further governed as follows:

1. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible institutional official shall ensure that these principles are adhered to:
 - a. The transportation, care, and use of animals should be in accordance with the *Animal Welfare Act (7 U.S.C. 2131 et. seq.)* and other applicable Federal laws, guidelines, and policies.
 - b. Procedures involving animals shall be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
 - c. The animals selected for a procedure shall be of an appropriate species and quality and the computer simulation and in vitro biological systems shall be considered.

C. Hazardous Materials

ECSU conducts academic research and other activities that involve the use of hazardous materials. The purpose of this policy is to ensure compliance with all local, state, and federal regulations regarding hazardous materials. Hazardous material is defined as radioactive waste, biohazard waste, PCB waste, asbestos waste or other specially regulated waste that is no longer of use. These materials, if not properly used, stored, transported, and disposed of, may pose a risk to persons or the environment by virtue of properties such as toxicity, corrosiveness, reactivity, flammability, or infectivity among others. It is ECSU's position that it shall provide an environment free from recognized, significant hazards and comply with local and federal regulations regarding environmental and occupational safety and health, such as those promulgated by the Occupational Safety & Health Administration (OSHA) and the Environmental Protection Agency (EPA). Accordingly, all projects involving the use of hazardous materials shall adhere to normal chemical hygiene procedures as follows:

1. Contact the ECSU Office of Safety and Health (OSH) prior to generation of hazardous materials for guidance.

2. Contact the OSH for disposal of all hazardous materials.
3. Supervisors shall:
 - a. maintain a list of waste that will be generated, including the route of disposal for each waste.
 - b. Inform employees, students, and others as appropriate if they are generating waste and instruct them on the appropriate route of disposal.
 - c. Maintain a registry of AHCs (acutely hazardous materials) in each laboratory with information regarding its hazards, physical and chemical properties, antidotes, precautions, and clean-up procedure. The registry and chemicals shall be discussed with personnel that will work in that laboratory prior to allowing them access to the laboratory. A copy of the registry list shall be sent to OSH and updates telephoned in when an AHC is added or discontinued.
 - d. Ensure that all waste is identified, packaged, and removed in accordance with the appropriate manual and guide on a continuous basis.
 - e. Inspect areas under their supervision that are generating or have generated waste, to insure that the area is clear of all waste prior to termination of responsibility in that area.
4. Each waster generator shall:
 - a. Limit ordering of waster source materials to the amounts needed. The disposal cost of waste typically exceeds the purchase price of the material.
 - b. Be cognizant that steps can be taken to detoxify and/or neutralize waste and include those steps in the generation procedures as practical.
 - c. Practice waste reduction in accordance with the appropriate manual.
5. Any unclaimed waste shall remain the liability of the generating supervisor or the supervisor's department. OSH will work in a cooperative effort to identify and dispose of such waste but shall not assume responsibility for any unclaimed waste.

These procedures shall serve as a guide for laboratory researchers, professors, students, and other ECSU personnel who generate less than 50 kg of hazardous waste per month. This is referred to as a Small Quantity Generator and therefore, is regulated. ECSU is so categorized and shall comply with the hazardous waste disposal procedures issued by the Environmental Protection Agency and the Department of Transportation. PIs applying for grants and contracts and

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proposing the use of hazardous materials shall cite the specific policy to guide the research. Project proposals involving hazardous materials shall also include the name of the company with which ECSU has contracted for the disposal of hazardous chemicals. All generators of waste shall include a line item in their budget for disposal of waste.