300.4.1.4
Adopted: 03/08/07

**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.