what you need to know

Research Compliance

Elizabeth City State University
Office of Sponsored Programs, Contracts and Grants
110 McClendon Hall, ECSU Campus
Michelle Moore, Research Compliance Officer
- Ensure the ethical conduct of research
- Protect the University’s opportunity to compete for research funding
- Uphold the University’s ethical responsibility to the public as a high research institution

- Compliance Policies and Procedures 300.4.1.4
Elizabeth City State University (ECSU) pursues federal, state and local resources to support teaching, research and community outreach activities.

Compliance policies have been established regarding the implementation of sponsored projects (300.4.1.4).
Sponsored Programs’ goal is to facilitate the research process by providing information, guidance and training.
Areas of Research Compliance

- Safety, Hazardous Waste and Biohazards
- Export Controls
- International Travel
- Animal Care and Use
- Human Subjects Protection and the IRB
- Responsible Conduct of Research

Sponsored Programs Compliance Policies and Procedures 300.4.1.4
Process

- Submit Intent and Internal Processing Form
- Proposal Submission
- Proposal Review
- Contact PI
- Application and Approval
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 (polychlorinated biphenyls) waste, asbestos waste or other specially regulated waste that is no longer of use.
Hazardous waste practices are regulated by

- Environmental Protection Agency
- Occupational Safety and Health Administration
- State of North Carolina
Procedures

- all projects involving the use of hazardous materials shall adhere to normal chemical hygiene procedures outlined in policy

- Contact your departmental operations manager and/or ECSU Office of Safety and Health prior to generation and disposal of hazardous materials for guidance
Sheryl Bradford—Research Operation Manager
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Purpose of Export Controls

- Control the export (and import, and re-export) of certain categories of commercial items and **defense-related articles and services**
- Control access of certain technology to **foreign nationals** whether in US or abroad
- Safeguard **US national security**
- Facilitate **US foreign policy objectives**
Each ECSU faculty, staff, and student who is involved in research must take reasonable precautions for safeguarding sensitive and export controlled data and information from disclosure to foreign persons without proper authorization.

- All research proposals are subject to Export Controls review ECSU policy

- To identify if export license is required complete Export Controls Checklist with submission of proposal
Export is defined not only as a physical transfer/disclosure of an item outside the United States but also as a transfer/disclosure in any form of a controlled item or information within the U.S. to anyone who is a foreign national (not a U.S. citizen or permanent resident), better known as the “deemed export” rule.
Export Controls

Exporting Methods

Mailing, Shipping or Transporting

- Biological, Chemicals, Reagents
- Equipment, materials, prototypes
- Manuals and Data
Exporting methods cont....

- Electronically
- Verbally
  - Teaching
  - Presentations
  - Deem Export
Regulatory Agencies

Department of Commerce
Export Administration Regulations (EAR)

State Department
International Traffic in Arms Regulations (ITAR)

US Treasury
–Office of Foreign Assets Control (OFAC)
Exclusions

- Fundamental Research Exclusion
- Educational Information Exclusion
- Public Domain/Public Availability
- Contractual Negotiation
When exporting does not fall under Fundamental Research or Educational Exemption, the PI will initiate the export application process through the Office of Sponsored Programs, Contracts and Grants.
If International Travel will be a part of your research, an international travel briefing for all travelers needs to be schedule prior to traveling
International Travel Briefing

- Tactical information about the Country
- Review of Current Travel Alerts
- Safety and Security Tips
- Registration and Embassy Location
- Contact and Emergency Information
A license would only be required if you are taking an item found on:

- Dept of State’s Munitions List (USML)
- Bureau of Industry and Security (BIS)
- BSI Commerce Control List (CCL)

Travel to certain embargoed or sanctioned countries (laptop would required license)
When hiring personnel especially consultants on awarded proposals, we are required to screen them utilizing the Visual Compliance Screening tool
The major responsibility for maintaining standards of intellectual integrity rests with the individual scholars and with the departments in which they work. ECSU expects the highest standards of professional and ethical conduct.

To that end, unethical behavior in research represents a breach of the confidence among faculty, staff, and students as well as other research scientists that is central to the advancement of knowledge. (ECSU Policy 300.4.1.6)
Shared Values

- **Honesty**—conveying information truthfully and honoring commitments
- **Accuracy**—reporting findings precisely and taking care to avoid errors
- **Efficiency**—using resources wisely and avoiding waste
- **Objectivity**—letting the facts speak for themselves and avoiding improper bias

Information for this portion of the training was based on ORI Introduction to the Responsible Conduct of Research (N.H Steneck, 2003)

http://ori.dhhs.gov/education/products/RCRintro/
Foundation regulations dealt with humans and animals in research and research misconduct

- 1966 Animal Welfare Act
- 1974 National Research Act
- 1985 Health Research Extension Act
- 1989 DHHS established what is now Office of Research Integrity
Research Misconduct

- “fabrication, falsification or plagiarism in proposing, performing or reviewing research, or reporting research results” -- Actions must represent a “significant departure from accepted practices;” have been committed intentionally, or knowingly, or recklessly; and be “proven by preponderance of evidence.”

Conflicts of Interest

Legitimate research interests can create competing responsibilities and lead to conflicts of interest—competing obligations and interests—three crucial areas... Financial gain, work commitments, intellectual and personal matters

Special steps are needed to assure that conflicts are managed so not to interfere with the responsible practice of research
Planning Research

Human Subjects & Animal Welfare

- Know what research is subject to regulation
- Understanding and following rules for project approval
- Getting appropriate training
- Accepting continuing responsibility for compliance through all stages of a project
Conducting Research

Data Management Practices—how researchers should collect, store, protect and share data, mindful of the need to maintain its integrity, validity and accuracy.

Mentor and Trainee Responsibilities—covers the role of the researcher as a teacher.

Collaborative Research—explores responsibilities that arise when researchers work with colleagues, whether in their own discipline or in other disciplines, at other institutions, and in other countries.
Reporting and Reviewing Research

**Authorship and Publication**—covers responsibilities researchers have when they share results with others through informal communications, oral presentations, scholarly publications, and public statement.

**Peer Review**—responsibilities researchers have when they review the work of other researchers.
ECSU is committed to observing federal regulations pertaining to animal are.

However we do not conduct research involving animal subjects on campus at this time.

In such cases, collaborations, we require a copy of the approved IACUC application used by institution where the research is being conducted (governed by Office of Laboratory Animal Welfare).
IRB reviews all research involving the use of human subjects and implements institutional policies and procedures regarding such research in compliance with Office of Human Research Protections (OHRP) 45CFR 46 and the Food and Drug Administration (FDA) 21CFR 50 and 56.
IRB Approval

All research involving the use of human subjects conducted by researchers (ECSU faculty, staff, or students), or sponsored, in part or in whole, by ECSU, must be reviewed and approved by the IRB prior to start of the project; and

Then conducted in full compliance with IRB guidelines and procedures regardless of funding.
Types of Reviews

Exempt Review – little or no risk

Expedited Review – minimal risk

Full Board Review – greater than minimal risk
EXEMPT REVIEW CATEGORIES

1) Normal Educational Practices and Settings
2) Anonymous Educational Tests, Surveys, Interviews, or Observations
3) Identifiable Subjects in Special Circumstances
4) Collection or Study of Existing Data
5) Public Benefit or Service Programs
6) Taste and Food Evaluation and Acceptance Studies
Expedited Review Categories

- Clinical studies of drugs and medical devices
- Collection of blood samples by finger stick, heel stick, ear stick or venipuncture
- Prospective collection of biological specimens for research purposes by noninvasive means
- Collection of data through noninvasive procedures (not involving general anesthesia or sedation)
- Research involving materials that have been collected, or will be collected solely for non-research purposes
- Collection of data from voice, video, digital or image recordings made for research purposes
- Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
- Continuing review of research previously approved by the convened IRB
RESEARCH INVOLVING

special populations
sensitive behavioral research
deception
ingestion of substances
research that is potentially harmful to the subjects
research that involves undue stress to subjects

automatically requires full IRB review
IRB APPROVAL PROCESS

The IRB Approval Process can take at least two to four weeks, therefore applications should be submitted in a timely manner to reduce delays in proposal submission / award process.
The Principal Investigator must complete the ECSU IRB Application and e-mail a copy to the IRB Chair and IRB Administrator/Research Compliance Officer (RCO).

The researcher’s Department (College/School) must approve the protocol/proposal before it is forwarded to the IRB for approval.

The PI must deliver a signed application with all supporting documentation to the IRB Administrator/RCO in the Office of Sponsored Programs, Contracts and Grants (107 McLendon).
PROTOCOL PACKAGE

1. A signed IRB application from your Department or School
2. An attached survey, questionnaire, or data collection instrument
3. A copy of your recruitment instrument (flyer, advertisement, poster, brochure, contact letters, etc)
4. A copy of the Informed Consent Document – letter, oral script or information sheet (include a statement directing research subjects to contact IRB or IRB Administrator pertaining to their rights as research subject)
5. A copy of your Certificate of Completion for CITI training
June 2000 the Department of Health and Human Services (DHHS) issues mandatory training requirements for all individuals working in human research.

January 2010 National Institutes of Health (NIH) and the National Science Foundation (NSF) require training in Responsible Conduct of Research (RCR). The requirement went into effect on January 4, 2010 for NSF and January 25, 2010 for NIH.
The University requires all relevant parties to complete compliance training prior to conducting any research (funded or unfunded).
The Collaborative Institutional Training Initiative (CITI) program has been recognized to meet the federal requirements for investigators conducting educational research in the protection of human subjects.
CITI Training

CITI Training offers Basic (initial), Refresher, and International course modules for:

- Social Behavioral Research Investigators and Key Personnel
- Biomedical Research Investigators and Key Personnel
- Social and Behavioral Responsible Conduct of Research
- Animal Care and Use
CITI Training

All modules are extensively peer reviewed and user feedback provides a focus for semi-annual updates

All modules include quizzes and learners have the opportunity to complete a user satisfaction survey when all course requirements are met.
Recertification

Refresher Courses must be taken every two years after initial certification for Human Subjects Protection

Recertification for Responsible Conduct of Research is required every four years.
Forms & Applications

www.ecsu.edu

Forms and applications can be located on the website

EXEMPT STATUS, EXPEDITED OR FULL REVIEW, CONTINUING REVIEW, REQUEST FOR REVISION

Links -- Sponsored Programs – Forms

or

Faculty and Staff – Forms and Documents – Sponsored Programs
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