Institutional Review Board
Compliance
Elizabeth City State University

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Research Compliance Office

Exists to:

✓ 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 research institution
Objectives

Historical Events
Role of IRB
Training Requirements
Types of Reviews
IRB Approval Process
Historical Events

Nazi Medical War Crimes

“Medical Experiments” were conducted by Nazi physicians during WWII-performed deadly studies and torture on thousands of concentration camp prisoners

- injections of gasoline and live viruses
- immersions in ice water
- forced ingestion of poisons

(1939-1945)

Nuremberg Code

The first international code of research ethics that established basic principles that must be observed in order to satisfy moral, ethical, and legal concepts in the conduct of human subject research

(1947)
Historical Events

**Syphilis Study at Tuskegee**

Most notorious example in the US of the violation of the rights and welfare of human subjects. It was a long-terms study conducted by Public Health Services on black males in Tuskegee, Alabama.

Approximately 600 African-American men were recruited without informed consent and led to believe that some of the procedures were done in the interest of research as “special free treatment.”

(1932-1972)

**National Research Act of 1974**

Created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to develop guidelines for human subject research and to oversee and regulate the use of human experimentation in medicine.

It was partly a response to the infamous Tuskegee syphilis study.

(1974)
Historical Events

**National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research**

Charged to identify ethical principles to guide all research and develop guidelines for the conduct of ethical research involving human subjects

(1979)

**The Belmont Report**

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Identified three essential principles

- Respect of Persons
- Beneficence
- Justice

(1979)
Respect of Person

Treat individuals as autonomous agents
Protect persons with diminished autonomy

Understanding risks and benefits without influence

Requirements for IRB Approval
✔ Voluntary consent to participate in research
✔ Informed consent to participate
✔ Privacy and confidentiality protection
✔ The right to withdraw from research without penalty
Beneficence

Minimize the risks of harm and to maximize the potential benefits of research

Do No Harm

Requirements for IRB Approval

✓ Risks are justified by potential benefits to the individual or society
✓ The study is designed to minimize the risks and maximize the benefit
Justice

Distribute the risks and benefits of research equally among those who may benefit from the research

Individuals are treated fairly and equitably - inclusion/exclusion

Requirements for IRB Approval
- Vulnerable subjects are not targeted for convenience
- People who are likely to benefit from research participation are not systematically excluded
The primary responsibility of the Institutional Review Board (IRB) is to protect the rights and welfare of research subjects. It provides assurances that the University will comply with all applicable federal laws and regulations related to research involving the use of humans as participants.
Role and Responsibilities

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.
Role and Responsibilities

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).

Requirements

In June 2000, the Department of Health and Human Services (DHHS) issued a mandatory training requirement for all individuals working in human research.

You must take the training before a research project with human subjects can begin.
CITI Training

https://www.citiprogram.org/default.asp

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

- Human Subjects Research
- Animal Care and Use
- Biosafety and Biosecurity
- Export Controls
- Information Privacy and Security
- Responsible Conduct of Research
- Conflict of Interest
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.
CITI Training

All key personnel must complete training requirements in human subject protections from CITI Program. Refresher Courses must be taken every two years after initial certification.

(Social and Behavioral Responsible Conduct of Research and Social Behavioral Research Key Investigators and Key Personnel)

Timely review of your protocol is based upon your completion of the required training modules.
Definitions

Research - a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.

Human Subject - a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
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 Categories

1) Clinical studies of drugs and medical devices
2) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture
3) Prospective collection of biological specimens for research purposes by noninvasive means
4) Collection of data through noninvasive procedures (no general anesthesia or sedation)
5) Research involving materials that have been collected, or will be collected solely for non-research purposes
6) Collection of data from voice, video, digital or image recordings made for research purposes
7) 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
8) Continuing review of research previously approved by the convened IRB
Federal regulations require that the IRB give special consideration to protecting the welfare of particularly vulnerable subjects such as children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons.
Full Board Review

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 Review Process

The IRB Approval Process can take at least two to four weeks, therefore applications should be submitted in a timely manner.
IRB Review 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 (110 McLendon).

All key personnel must complete training requirements in human subject protections from CITI Program.
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) See Informed Consent Checklist for all required elements
5. A copy of your Certificate of Completion for CITI training
Forms & Applications

located on the website

www.ecsu.edu/osp

Forms and Documents
Final Report

IRB Applications are approved for a period of one year. Once research project is complete, PI should submit the End of Project Form to conclude that research involving human subjects was performed according to the procedures approved by the IRB.

If PI needs more time or should there be changes to approved protocol, a Revision or Continuation Request form should be submitted.
Contact Information

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