# Regulation on the Use of Human Subjects in Research

***Version 1***

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| **Policy** | REG10.45.04 |
| **Title** | Regulation on the Use of Human Subjects in Research |
| **Category** | Research and Graduate Studies |
| **Sub-category** | Research Compliance |
| **Authority** | Chancellor |
| **History** | Approved by Chancellor February 13, 2017; Non-substantive edits made June 26, 2019. |
| **Contact** | University and Medical Center Institutional Review Board (252) 744 - 2914 |
| **Related Policies** | Related rules and standard operating procedures are available on the University and Medical Center Institutional Review Board (UMCIRB) website: https://rede.ecu.edu/umcirb/ (https://rede.ecu.edu/umcirb/) |
| **Additional References** | 45 CFR 46.102 (http://www.ecfr.gov/cgi-bin/text-idx?SID=aae75c7cb17f345fd554e5cfd55df0c0&mc=true&node=se45.1.46_1102&rgn=div8)<br>45 CFR 46.103 (http://www.ecfr.gov/cgi-bin/text-idx?SID=aae75c7cb17f345fd554e5cfd55df0c0&mc=true&node=se45.1.46_1103&rgn=div8)<br>(http://www.ecfr.gov/cgi-bin/text-idx?SID=aae75c7cb17f345fd554e5cfd55df0c0&mc=true&node=se45.1.46_1102&rgn=div8) |

**1. Introduction**

This regulation establishes the principles and organizational structure governing the use of Human Subjects in research activities and reflects the University's commitment to the protection of those Humans Subjects.

1.1. All activities that meet the definition of Research involving Human Subjects must receive UMCIRB review and approval prior to initiation;

1.2. All research that meets the definition of Research involving Human Subjects must be conducted in accordance with the regulations, rules and standard operating practices of ECU, HHS, and the Food and Drug Administration's (FDA) Code of Federal Regulations governing the use of humans in research (if the research falls within the purview of the FDA), and the applicable regulations set forth by the International Council on Harmonisation.

**2. Definitions**

2.1. Human Subject: means a living individual about whom an investigator (whether professional or student) conducting research (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

2.1.1. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

2.1.2. Interaction includes communication or interpersonal contact between investigator and subject.

2.1.3. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

2.2. Investigator: means any individual who is involved in the conduct of research involving Human Subjects.

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

2.4. Federalwide Assurance: means the written assurance provided by an institution to the Office for Human Research Protections, Department of Health and Human Services (HHS), that the Institution will comply with the requirements set forth in the federal regulations for the protection of humans in research. This assurance must be approved by the Office for Human Research Protections, HHS, for Federalwide use by that office. The Federalwide Assurance is required for ECU to receive federal funding.

2.5. Human Research Protection Program (HRPP): a comprehensive program at ECU that involves all schools and colleges, departments, and individuals who are dedicated to the protection of human research and contribute to areas of compliance that impact those protections. (Ex. Sponsored Programs, Clinical Trials, Radiation Safety, Biosafety, etc.)

2.5.1. The HRPP includes the ECU University & Medical Center Institutional Review Boards (UMCIRB) as set forth in the ECU Federalwide Assurance.

**3. Scope**

This Regulation applies to all Research involving Human Subjects that is conducted at, supported or administered by, or otherwise affiliated with East Carolina University. All individuals, including, but not limited to faculty, staff, students, postdoctoral scholars, and volunteer and affiliated researchers, who conduct Research involving Human Subjects, or research involving private, identifiable information about Human Subjects, shall do so ethically and with responsibility, and in compliance with this Regulation and all applicable laws, regulations, and University policies. The University has a systematic and comprehensive HRPP that is designed to protect the rights, dignity, and welfare of humans who participate in the research programs of the University and its affiliated institutions. The program is based on the ethical principles outlined in the Nuremburg Code and the Belmont Report. Failure to comply with this Regulation may result in disciplinary action, up to and including termination of employment, or expulsion from the University, in accordance with applicable University policies.

**4. Delegation of Authority**

By applying for and receiving a Federalwide Assurance, the U.S. Department of Health and Human Services delegates the authority to ECU to receive federal funds for the conduct of Human Subjects Research.

4.1. The Chancellor has delegated authority and responsibility of the HRPP to the Senior Associate Vice Chancellor for Research, Economic Development, and Engagement. The Senior Associate Vice Chancellor serves as the Institutional Official for ECU's Federalwide Assurance and is responsible for the oversight and compliant operation of the HRPP, to include the following as defined in the ECU Federalwide Assurance:

4.1.1. ECU Biomedical Institutional Review Board (IRB #1); and

4.1.2. ECU Behavioral and Social Sciences Institutional Review Board (IRB #2).

4.2. The University Medical Center Institutional Review Boards (UMCIRBs) are granted authority through federal regulations to review Human Subjects Research proposals and take any of the following actions:

4.2.1. Approve;

4.2.2. Require modifications to secure approval;

4.2.3. Disapprove;

4.2.4. Suspend or terminate approval of on-going studies;

4.2.5. Suspend or terminate the ability of research personnel to conduct human research;

4.2.6. Observe or have a third party observe consent processes or the conduct of research; and

4.2.7. Conduct routine Post-IRB Approval Monitoring evaluations and for-cause investigations of on-going and closed research studies.

4.3. No official of ECU or its Affiliates can:

4.3.1. Support the conduct of human research activities that do not have approval from the UMCIRBs; or

4.3.2. Overturn a decision of disapproval issued by the UMCIRBs.

**5. Responsibilities**

5.1. The Vice Chancellor for Research, Economic Development and Engagement:

5.1.1. Serves as the Institutional Official and has the authority to speak for the institution in matters regarding human research. The Vice Chancellor is ultimately responsible for the oversight and appropriate operations of the HRPP;

5.1.2. Maintains open and direct channels of communication with UMCIRBs members and staff, investigators and research personnel, and administrators to address questions, concerns, or suggestions regarding the HRPP;

5.1.3. Provides the UMCIRBs with sufficient meeting space, staff, and budgetary resources to support review and record keeping responsibilities;

5.1.4. Reviews an annual report drafted by the Director of the UMCIRB Office to ensure adequate resources are available to support required activities;

5.1.5. Notifies the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), the Office of Research Integrity (ORI) as appropriate and any relevant agencies of incidents of serious or continuing noncompliance with UMCIRBs procedures, federal regulations, or state laws as well as any

unanticipated problems, or suspensions or terminations of UMCIRBs approval;

5.1.6. Protects UMCIRBs from undue influence or threat of retaliatory actions so that UMCIRBs can function independently, basing decisions on ethical principles, regulations, and institutional policies;

5.1.7. Approve recommendations and appoints IRB members - including alternate and ex-officio members as well as continuing consultants; and

5.1.8. Receives annual evaluations and recommendations from the Director of the University and Medical Center Institutional Review Board (UMCIRB) office of:

5.1.8.1 UMCIRBs Members, staff, board composition and number of protocols reviewed;

5.1.8.2 Adequacy of resources, program continuity, scientific and professional expertise of members as relevant to the business conducted;

5.1.8.3 Delegates to the UMCIRB the sole authority to make determinations of expedited and exempt status; and

5.1.8.4 Timeliness in review, decisions made on applications submitted, and quality of reviews.

5.2. The ECU Director of UMCIRB:

5.2.1. Serves as the overall administrator for the HRPP;

5.2.2. Holds responsibility for ensuring that the UMCIRBs function and operate in compliance with all federal, state, and local laws and regulations that govern the protection of humans involved in research activities;

5.2.3. Provides notification to the Vice Chancellor for Research, Economic Development, and Engagement and, as applicable, other administrative and affiliated officials of any injury, breach of trust, unanticipated problems involving risks to participants or others, serious or continuing noncompliance, and suspension or termination of UMCIRBs approval;

5.2.4. Investigates all issues of undue influence or threats of retaliation directed to the UMCIRBs members or staff and provides recommendations for resolution to the Vice Chancellor; and

5.2.5. Presents an Annual Report to the Senior Associate Vice Chancellor regarding the status of the HRPP program that includes review of resources, continuity of operations, and adequacy of scientific and professional expertise available to carry out requirement of the HRPP.