



Policy Title:	Human Subject Research
Policy Number:	ACAD- 138
Revision Date:	October 2021
Policies Superseded:	None
Policy Management	Research

SUMMARY:

This policy is set forth to protect the rights and welfare of research participants to assure a favorable climate for scientific inquiry while protecting the interests of the University when conducting research involving human subjects.

POLICY:

- I. Coastal Carolina University (CCU) is committed to ethical principles for the protection of human subjects in research. CCU recognizes and accepts responsibility, which it shares with its investigators and other researchers, for determining that research involving human subjects fulfills these ethical principles. The following general guidelines apply equally to all research involving human subjects, whether carried out solely with University resources or with external funds.

This policy has been established to meet the compliance standards set forth in the Belmont Report of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research and the Federal Common Rule 45 CFR 46.101.

II. DEFINITIONS

- A. Federal Wide Assurance (FWA) - Under the Department of Health and Human Services (DHHS) human subjects protection regulations (at C.F.R. 46.103), every institution engaged in human subject research that is funded or conducted by the DHHS must obtain an Assurance of Compliance approved by the Office of Human Research Protections (OHRP). NOTE: CCU assumes responsibility and obligations to ensure that all research activity involving human subjects will be regulated under this assurance, regardless of whether activity is funded or unfunded.
- B. Human subject - means a living individual about whom a faculty, staff or student investigator conducting research obtains data through intervention or interaction with the individual or collects identifiable private information, 45 CFR 46.102 (F), Code of Federal Regulations (CFR.), 46.102(f). Human subject under United States Food and Drug Administration (FDA) regulations includes an individual who is or

becomes a participant in research, either as a recipient of a test article or as a control. A “subject” may be a healthy human or a patient, 21 CFR 56.102(e).

- C. Institution Review Board (IRB) - an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.
- D. Research - “*a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge.*” 45 CFR 46.102(d). Research includes surveys and interviews, behavioral investigations, retrospective reviews of medical information, experiments with blood and tissue, demonstration and service programs, and clinical trials. In addition, FDA includes under the definition of reviewable research, any use of an FDA-regulated product except for use of a marketed product in the practice of medicine. Under this definition of Research, CCU includes the collections of historical data and reviewing records, observations and questionnaires that will be used shared or published outside the campus.

III. HUMAN SUBJECT RESEARCH

- A. For research involving human subjects, the University uses as its guide the Federal Common Rule (45 CFR 46) entitled “Federal Policy for the Protection of Human Subjects Code,” Federal Register, June 18, 1991. Also those regulations include in 45 CFR, Part 46, entitled “Protection of Human Research Subjects” (HHS regulation), 21 CFR Part 50, entitled “Protection of Human Subjects” (FDA regulation), and 21 CFR Part 56, entitled “Institutional Review Boards” (FDA regulation). Other applicable FDA regulations, which the IRB and the investigator must follow, depending on the study, include 21 CFR Part 312, “Investigational Drugs” and 21 CFR Part 812, “Investigational Devices.” NOTE: The NIH and FDA occasionally publicize additional guidelines for the conduct of certain types of research.
- B. Under federal regulations as prescribed by the Common Rule, the FWA and the OHRP, the University has established an Institutional Review Board (IRB), charged with reviewing all research at CCU that involves human subjects. The IRB is required to review all human subject research before it may begin, and may approve only that research which meets the established regulatory and ethical criteria.

IV. AUTHORITY AND JURISDICTION

- A. The President of CCU has delegated the Associate Provost for Research as CCU’s official responsible for oversight of all human subject research activity.

- B. The Associate Provost for Research has delegated the following responsibilities to the IRB to fulfill CCU's obligations to ensure compliance.

- C. The IRB has the following authority and responsibilities:
 - 1. Review all research projects that will involve human subjects prior to contact of subjects or involvement of human subjects.
 - 2. Conduct continuing review of research involving human subjects at intervals appropriate to the degree of risk, but no less than once a year.
 - 3. Approve, disapprove or require changes in all research (including the protocol, consent document, etc.) and notify the researcher in writing of this status.
 - 4. Review proposed changes in activities to determine which projects need verification from sources other than the investigator and that no material changes have occurred since previous IRB review.
 - 5. Monitor additional safeguards when vulnerable subjects are involved in the research in order to protect against coercion or undue influence. Vulnerable populations to include, but not limited to: minors, prisoners, pregnant women and fetus in utero.
 - 6. Ensure prompt reporting to the IRB by investigators of noncompliance with the IRB, federal or other policies or regulations and report serious or continuing noncompliance to appropriate agencies.
 - 7. Ensure prompt reporting to the OHRP, as well as any sponsoring agency, of unanticipated problems involving risk to subjects or others.
 - 8. Suspend or terminate a previously approved project and notify applicable agencies.
 - 9. Establish, update and change operational procedures as deemed necessary to meet federal, state and University regulations and requirements.

- D. The IRB Administrator, Director of the Office of Sponsored Programs and Research Services (OSPRS) is responsible for oversight of the IRB administrative and operational functions.