SECTION: Scholarly Activity
TOPIC: Human Research Protection Program Statement of Compliance
Approved: Signature on File

Policy: B8530
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POLICY

Statement of Regulatory Compliance

The College shall ensure the protection of human subjects in research through the College's Office of Research & Sponsored Programs (ORSP). The ORSP shall provide administrative oversight of all research conducted at the College and ensures institutional compliance with appropriate federal, state, and local regulations as well as College policies. ORSP responsibilities include providing guidance, assistance, and training to College researchers and providing administrative support for the College Institutional Review Board.

The College Institutional Review Board (IRB) operates in full compliance with the U.S. Department of Health and Human Services, and U.S. Food and Drug Administration regulations for the protection of human subjects as described in 45 Part 46 and 21 CFR Parts 50 and 56 s outlined by the College policies for the conduct of human research. The College IRB is registered with the Department of Health and Human Services Office for Human Research Protection as IRBOOO 10422 and has an approved Federalwide Assurance (FWA00024071) valid through October 3, 2028 (10/3/28).

Membership of the IRB is in compliance with 45 CFR 56.107 and 21 CFR 56.107. It is expected that investigators conducting clinical research adhere to these guidelines.

The College IRB Policies provide written procedures for operation, IRB review, initial and continuing review of research proposals, addendum reporting, and adverse event reporting. The IRB assures compliance with 45 CFR 46.107(e) and 21 CFR 56.107(e) stipulating that no IRB may have a member participate in the IRB's initial or continuing review of a research project in which the member has conflicting interest, except to provide information requested by the IRB.

RESPONSIBLE OFFICIALS:

CEO/President, Authorized Institutional Official for Research, Office of Research and Sponsored Programs, IRB Chairperson, IRB Members, IRB Staff.

DEFINITIONS:

Research is defined by the federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" [45 CFR 46.]

Human subjects are defined by federal regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" [45 CFR 46].

PROCEDURE:

1. The Statement of Regulatory Compliance for the College with regard to protection of human subjects in research projects conducted under the auspices of the College, its faculty, staff, students, and affiliated research entities shall be reviewed annually.

CROSS REFERENCE(S): https://burrell.edu/research/irb/