PURPOSE

This policy serves as the Statement of Regulatory Compliance for the Burrell College of Osteopathic Medicine with regard to protection of human subjects in research projects conducted under the auspices of BCOM, its faculty, staff, students, and affiliated research entities. The Policy also establishes and empowers the BCOM Institutional Review Board as the responsible administrative body for reviewing and approving research involving human subjects.

SCOPE

This policy applies to all research involving human subjects that is conducted by administrators, faculty, staff and students of BCOM as well as any researcher/agent of BCOM conducting human subject research.

RESPONSIBLE OFFICIALS

BCOM CEO/President, Dean, Authorized Institutional Official for Research, Director of Research, 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" [Federal Policy 45CFR46. l 02(d)J.*

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" [Federal Policy 45CFR46.102(f)].*

POLICY

Statement of Regulatory Compliance

The Burrell College of Osteopathic Medicine (BCOM) ensures the protection of human subjects in research through the College's Office of Research Compliance and Protection (ORCP). The ORCP provides administrative oversight of all research conducted at BCOM and ensures institutional compliance with appropriate federal, state, and local regulations as well as BCOM policies. ORCP responsibilities include providing guidance, assistance, and training to BCOM researchers and providing administrative support for the BCOM Institutional Review Board.

The BCOM 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 as outlined by the BCOM policies for the conduct of human research. The BCOM 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 (FWA0002407l) valid through October 4, 2022 (10/4/22).

Membership of the IRB is in compliance with 45 CFR 56.107 and 21 CFR 56.107. The IRB also adopts the standards for conducting clinical research studies as defined in the International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practice. It is expected that investigators conducting clinical research adhere to these guidelines.

The BCOM 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.