

Burrell College of Osteopathic Medicine Faculty Handbook Research 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 IRB00010422 and has an approved Federal-wide Assurance (FWA00024071) valid through 04/12/2021.

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 member may 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.

For more information regarding the research program at the College and all related policies please see the Office of Research and Sponsored Programs website at:

<https://bcomnm.org/research/>.