



UNIVERSITY OF SOUTH ALABAMA

Institutional Review Board

**STATEMENT OF REGULATORY COMPLIANCE
Federalwide Assurance (FWA) FWA00001602 (Expires 10/16/2023)**

The University of South Alabama 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 CFR Part 46 and 21 CFR Parts 50 and 56 and as outlined in the University's policies for the conduct of human subject research.

The membership of the IRB is in compliance with 45 CFR 56.107 and 21 CFR 56.107. Specifically, the IRB is comprised of clinicians, researchers, scientists, non-scientists, and unaffiliated members both internal and external to the University of South Alabama. Any individual with a conflicting interest in the research does not deliberate or vote on protocols under review.

The IRB also adopts the standards for conducting clinical research studies as defined in the International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice. It is expected of all investigators conducting clinical research to adhere to these guidelines.

The IRB has 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.