I. Purpose

In order to protect the rights of all human participants involved in research at Georgia Southern University, the University operates its human participant research programs under a Federalwide Assurance (FWA) with the Office of Human Research Protection (OHRP) within the Department of Health and Human Services. The FWA represents a fundamental commitment to the protection of human participants and applies to all Georgia Southern University (GS) research involving human participants, regardless of the location of the research or its sources of funding, be they governmental agencies, nonprofit organizations, industry, or University funds. In addition, the FWA applies to all research that is conducted at Georgia Southern University or using GS resources regardless of who is conducting the research. As part of its mission, GS maintains a Human Research Protection Program that adheres to the principles outlined in the Belmont Report, the Declaration of Helsinki (as amended in 1989), and the Nuremberg Code as well as with the federal regulations, outlined in 45 CFR 46 and its Subparts A, B, C, and D, and the FDA regulations, outlined in 21 CFR 50 and 21 CFR 56 and related regulations. In addition, the University complies with Georgia States and University System of Georgia policy and procedure concerning the use of human participants in research.

II. Policy Statement

It is GS policy that no research involving human subjects may be undertaken until approval has been granted by the Institutional Review Board (IRB). This includes research conducted by GS faculty, staff, and students from all campuses as well as any research involving members of the GS community as subjects, whether or not the researchers are affiliated with GS.

III. Definitions

Research is as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A “systematic investigation” is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

A human subject is a living individual or a biospecimen about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information.
IV. Exclusions
There are no exclusions to this policy.

V. Procedures
Procedures for the application, review and governance of the Institutional Review Board are located on the Office of Research Integrity website.