

## **Human Research Protections Program (HRPP)**

### **What is a Human Subject?**

The Medical College of Georgia (MCG) Office of Human Research Protection (OHRP) utilizes the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) definition of Human Subjects:

Health and Human Services (HHS): apply to the organization. The activities subject to the HRPP include “research involving humans as participants” as defined by the HHS regulations. Human Subject: 45 CFR 46.102(f) defines human subject as a living individual 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.

Food and Drug Administration (FDA): Human subject: 21 CFR 56.102(e) defines human subject as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. 21 CFR 56.812 (p) defines a human subject as an individual who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.