DEFINITION OF RESEARCH

**RESEARCH** - VA regulations at 38 CFR 16.102(d) and the Common Rule define **research** as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

**Note:** FDA regulations at 21 CFR 56.102(c) define research as "any experiment that involves a test article and one or more human subjects." FDA regulations note that "the terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part."

**HUMAN SUBJECT** - VA regulations at 38 CFR 16.102(f) and the Common Rule define 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."

VA policy at VHA Handbook 1200.5(3.g) clarifies that human subjects include investigators, technicians, and other assisting investigators when they serve a "subject" role by being observed, manipulated, or sampled.

**Note:** FDA regulations at 21 CFR 56.102(e) define **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."