

**Human Subjects Research:** According to IRB policy, research involving human subjects (participants) is defined as any one of the following:

1. ***Human subjects research subject to FDA regulation:***  
Activities are human research subject to FDA regulations when they meet the FDA definition of "clinical investigations" and involve a "subject" as defined in FDA regulation.

Under FDA regulation activities are "clinical investigations" when they involve:

1. Use of a drug other than the use of an approved drug in the course of medical practice
2. Use of a medical device other than the use of an approved medical device in the course of medical practice
3. Gather data that will be submitted to or held for inspection by FDA in support of a FDA marketing permit for a food, including a dietary supplement that bears a nutrient content claim or a health claim, an infant formula, a food or color additive, a drug for human use, a medical device for human use, a biological product for human use, or an electronic product.

In the above criteria "approved" means "approved by the FDA for marketing."

Under FDA regulations, individuals are considered "subjects" when they become a participant in research, either as a recipient of the test article or as a control. If the research involves a medical device, individuals are considered "subjects" when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.

2. ***Human subjects research subject to DHHS regulation:***  
Activities are human subject research subject to DHHS regulations when they meet the DHHS definition of "research and involve a "subject" as defined in DHHS regulations.

Under DHHS regulations activities are "research" when they are a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Under DHHS regulations "subjects" means 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.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the

subject or the subject's environment that are performed for research purposes.

*Interaction* included communication or interpersonal contact between investigator and subject.

*Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research that does not meet the definition of research involving human subjects must be determined by the IRB staff, not an individual investigator. Investigators must complete and submit an IRB new study application with any applicable documents.