

**OHRP
45 CFR
46.102**

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

Human subject 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 includes 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.

**FDA
21 CFR
50.3 (c), (j)**

Clinical Investigation means any research experiment that involves a drug, device, or biologic and one or more human subjects and is subject to requirements for prior submission to the FDA (e.g., a change in labeling) or the results of the research (e.g., safety and efficacy) are intended to be submitted to the FDA as part of an application for a research or marketing permit. Such research requires both IRB and FDA reviews. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for this definition.

Human Subject means 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.

**Belmont
Report:
Boundaries
Between
Practice
and
Research**

Practice refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals.

Research designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

**MD
Anderson
HRPP
Manual**

For information on the types of protocols that qualify as human subjects research, please refer to [Chapter 1.4](#) of the Human Research Protection Program (HRPP) manual.

The Quality Improvement Assessment Board (QIAB) reviews all MD Anderson quality Improvement projects to: assure patient safety; optimize the potential benefits being sought; and discern which projects may be more appropriately designed or categorized as research studies requiring Institutional Review Board (IRB) oversight.