

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.

VHA  
Handbook  
1200.5.3

**Pilot Studies** are full-fledged research studies that must be approved by the IRB when human subjects are involved. They are not considered to be activities preparatory to research.

**Preparatory to Research** refers to activities that are necessary for the development of a specific protocol. PHI from data repositories or medical records may be reviewed during this process without IRB approval, subject authorization, or a waiver of authorization, but only aggregate data may be recorded and used in the protocol application (e.g., potential number of subjects meeting study criteria at each site). Within VHA, an activity preparatory to research does not include the identification of potential subjects and recording of data for the purpose of recruiting these subjects or to link with other data. The preparatory to research activity ends once the protocol has been submitted to the IRB for review.

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.

Stanford  
Research  
Policy  
Handbook  
[RPH 5.4](#)

**Student Projects: Research Practica** (research training) do not require Panel review. **Directed or independent research projects** (e.g., honors or graduate theses) do require prospective IRB review and approval.

**Pilot Study:** A preliminary investigation of the feasibility of a study, usually on a small scale (e.g., fewer than 10 subjects) and exploratory in nature. It is designed to help the investigator refine data collection procedures and instruments or prepare a better, more precise research design. (However, see FDA definitions of Clinical Investigation and Investigation, as well as VHA Handbook definition of Pilot Study)

**Oral History:** A technique in which the researcher conducts taped interviews with the participants in a particular historical event or period. Often, interviews will be historical recollections of the character of a society or institution rather than the interviewee's subjective perceptions. Such activities may or may not be considered human subjects research. Such projects should be submitted to the IRB to determine the appropriate level of review.

**QA/QI and Other Study Types:** Research conducted in conjunction with *program evaluations* or [quality assurance](#) measures may or may not fall under the jurisdiction of the IRB. See [Quality Assessment & Quality Improvement \(QA/QI\)](#). A project to be conducted with the intent to develop or contribute to generalizable knowledge, should be submitted for IRB review.