

**RESEARCH: A systematic investigation designed to develop or contribute to generalizable knowledge**

**Systematic Investigation:** [OHRP] Research development, testing and evaluation, i.e., the gathering and analysis of information.

**Generalizable:** Intent to draw conclusions from the research which will develop or contribute to a general body of knowledge.

**Clinical investigation:** [FDA] means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies. [21 CFR 50.3(c)]

**Research:** [VA] Per VHA Handbook 1200.5: “testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. Also by the Common Rule (38CFR 16).

All protocols involving "research" and "human subjects" must be reviewed and approved by the IRB before recruitment and data collection may start. However, it might be difficult to tell whether some protocols qualify as human subject research.

Activities are **generally considered to be research** if they:

1. Involve a systematic investigation, i.e. an approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory, and
2. Are designed to contribute to generalizable knowledge.

The following are **generally considered to be research**:

- **Thesis or dissertation projects** conducted to meet the requirements of a degree *are* considered generalizable and meet the regulatory definition of research.
- **Intent to publish** (although not automatically an indication of intent to do research) might signify that generalizable results are anticipated, and is taken into consideration when making a determination of research.

The following are **generally not considered to be research**:

- **Research Practica or training activities:** individuals are being trained to perform a certain technique or therapy, such as art therapy, psychotherapy, interview technique
- **Classroom exercises:** the objective of the activity is to teach proficiency in performing certain tasks, such as design of research, implementation, or analysis
- **Quality assurance (QA), quality improvement (QI), course or program evaluations:** activities designed to continuously improve the quality or performance of a department or program, where the intention is not to share results beyond that department or program
- **Oral histories:** activities which are solely designed to create a record of specific historical events without intent to draw conclusions or generalize findings
- **Case studies:** publications that are descriptive in nature, involve fewer than three cases, and are not meant to contribute to generalizable knowledge, such as a description of an unusual surgical outcome or an unusual anatomical abnormality
- **Pilot studies:** preliminary investigation of the feasibility of a study, usually done on a small scale (usually 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.

See also [Examples of “Not Research”;](#)  
[Definitions.](#)