Regulatory Definitions

**RESEARCH** [DHHS 45 CFR 46.102(d)]: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**CLINICAL INVESTIGATION** [FDA 21 CFR 50.3(c) and 56.102(c)]: 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 21 CFR 58, regarding nonclinical laboratory studies. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of the FDA.

**RESEARCH** [VA 38 CFR 16; 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.

Additional Considerations:

The Belmont Report provides additional clarification:
"...the term "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."

**Intent to publish**: Publication or intent to publish is not part of the definition of "research". Intent to publish might signify that generalizable results are anticipated. However, activities that do not meet the regulatory definition of research will not be considered research even if published or intended for publication.

The following activities are generally considered to be research in accordance with the regulatory definitions:

- Thesis or dissertation projects conducted to meet the requirements of a degree
- Projects conducted in response to an RFP (Request for Proposal) issued by a federal agency
- Clinical trials
- Behavioral studies
- Projects initiated by Sponsor-investigators and involving FDA test articles

The following activities are generally not considered to be research in accordance with the regulatory definitions:

- Research Practicum or training activities
- Quality assurance (QA), quality improvement (QI), course or program evaluation
- Oral histories*
- Case studies
- Pilot studies**

* An oral history study may not require IRB review because it is not generally thought to be a systematic investigation designed to contribute to generalizable knowledge beyond the individual being interviewed. However, when using oral history as a technique in human subject research it may require IRB review. Researchers proposing such work are strongly encouraged to contact the IRB to determine whether their project requires approval.
** Medical interventions or interactions for research purposes, especially those involving invasive procedures, do require IRB review regardless of the size of the study.

See also the Research Policy Handbook, RPH 7.3.

See also Other Federal Agencies - Additional Requirements [GUI-42] for other regulatory definitions, e.g., Department of Defense, Department of Justice.