

Human Research Protections Program (HRPP)

What is Research?

HHS regulations define *research* at 45 CFR 46.102(d) as follows: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

A systematic investigation is an activity that involves a prospective research plan which incorporates data collection, both quantitative and qualitative, and data analysis to answer a research question.

Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), form policy, or generalize findings.

FDA regulations at 21 CFR 56.102 (c) defines research as any experiment that involves a test article and one or more human subjects. The FDA regulation further states that "...The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part.

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 Federal Food, Drug, and Cosmetic 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 non-clinical laboratory studies.