

8.1 Is it research?

DHHS regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)). FDA regulations define clinical investigation as “any experiment that involves a test article and one or more human subjects” as described in 21 CFR 50.3 (see Definitions for further details). Activities that meet either definition constitute research for the purposes of UNC-Chapel Hill policy.

As described in the Belmont Report, “...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn...” Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”

Thus, a key aspect of research is that there be a systematic design in advance, generally utilizing a scientific approach or protocol, for the defined purpose of contributing to generalizable knowledge. Research can encompass a wide variety of activities, including: experiments, observational studies, surveys, tests, and recordings. Studies assigned an Investigational New Drug (IND) number or an Investigational Device Exemption (IDE) by the FDA are by definition research that requires IRB review. (21 CFR 56.103)

“Research” generally does not include such operational activities as: defined practice activities in public health, medicine, psychology, and social work (e.g., routine outbreak investigations and disease monitoring in public health); studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, or marketing studies. It generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where there is clear advance intent to contribute to generalizable knowledge with a scientific protocol. Intent to publish is one possible indication of intent to contribute to generalizable knowledge.