

## IRB RESEARCH EVALUATIONS, PROCEDURES, CRITERIA AND ACTIONS

### 8.0 Determination if a project constitutes human subjects research subject to UNC-Chapel Hill IRB review

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The IRB has been charged with the responsibility for reviewing and monitoring human subjects research conducted under the aegis of UNC-Chapel Hill. Therefore, the first question with respect to IRB review of a project is a determination of whether the project fits this definition. In light of the mission to protect human subjects, the IRB should err on the side of conducting an IRB review when the determination is not clear. The definitions of “research” and “human subjects” for this purpose are derived from federal research regulations. The criteria for “under the aegis of UNC-Chapel Hill” have been determined by the campus and may extend beyond what is required by federal regulations.

#### 8.1 Is it research?

Federal Regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy, whether or not they are supported under a program that is considered research for other purposes.” (45 CFR 46.102(d)) As described in the Belmont Report, “...the term 'research' designates an activity designed to test an 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. An intent to publish is one possible indication of an intent to contribute to generalizable knowledge.