

Clarification of “Research” Definition

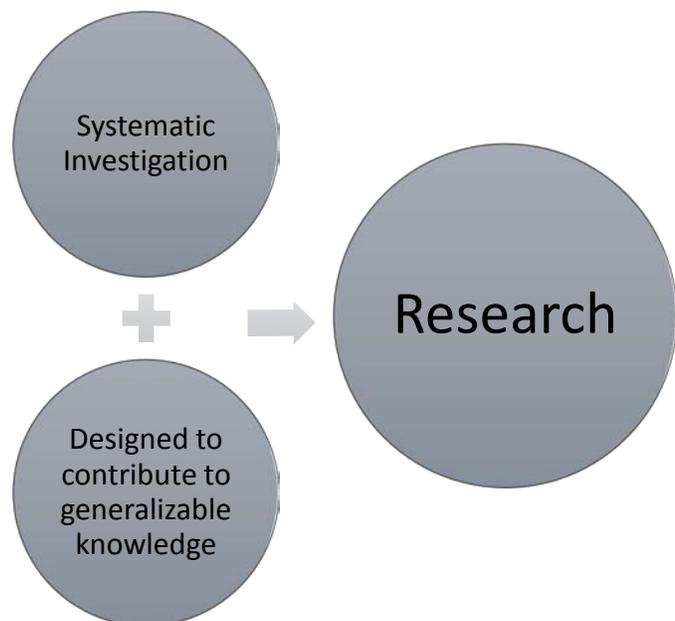
While the definition of “research” is unchanged, the regulations have been expanded to provide **examples** of circumstances in which activities may be deemed not to be research.

This change in is intended to clarify what activities may be excluded from IRB oversight because they do not meet the federal definition of research.

This change does not substantively alter Iowa State IRB’s interpretation the federal definition of research.

46.102 (I) Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

- (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.*



* The fields of study listed in the regulations are given as **examples** of specific activities that collect and use information about specific individuals themselves, rather than generalizing to other individuals or groups. The examples are not intended to imply that all activities within those fields fall outside of IRB oversight.

To illustrate, an ethnographic or observational study in which an investigator gathers information from individuals to understand their beliefs, customs, and practices, and the *findings apply to the studied community or group* (i.e., not just the individuals from whom the information was obtained) *would* fall within the scope of the definition of research and therefore *would require IRB oversight*.

Addition clarifications of activities not meeting the definition of research, included in the 2018 Common Rule:

46.102(l)

- (2) public health surveillance activities when conducted supported, requested, ordered, required, or authorized by a public health authority* (e.g. State Health Departments, Food and Drug Administration (FDA), etc.);
- (3) the collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes; and
- (4) authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.

**Public health authority* means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. 45CFR46.102(k)

Note: The FDA definition of research/clinical investigation is not updated at this time.

“...any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration...or ... the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.”

[21 CFR 56.102(c)]

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