

Human Subjects

The term *human subject* means a living individual *about whom* an investigator conducting research obtains data through *intervention or interaction* with the individual, *or obtains individually identifiable, private information*.

Intervention includes both physical procedures (*e.g.*, venipuncture) by which data are gathered and manipulations of the subject (*e.g.*, by deception) or the subject's environment (*e.g.*, by introducing extreme heat) that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about a subject that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. It also refers to information that has been provided for specific purposes by an individual with the reasonable expectation that it will not be made public (for example, a medical record).

Information is *individually identifiable* if the identity of the subject is or may be readily ascertained by the investigator or associated with the information.

Research

For IRB purposes, *research* is defined as a systematic investigation, inquiry, or analysis—such as scholarly or critical study or inquiry or scientific investigation, development, testing, or evaluation—designed to develop or contribute to generalizable knowledge. Research includes activities that aim to test a hypothesis, discover or collate facts, principles, or effects, reach new conclusions, or reexamine information by the critical study of a subject or by a course of scientific inquiry. Examples of human subjects *research* include:

- a. studies in which a substance or stimulus is administered to a subject, or responses or states are measured;
- b. studies that involve changes in the subject's physical or psychological state or environment, or changes in diet;
- c. interviews, surveys, tests, inquiries, and observations designed to elicit or obtain nonpublic information; and
- d. studies of existing records where the identity of the subjects is known or could be readily ascertained by the investigator.
- e. Public Benefit/Service Programs which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; or (b) procedures for obtaining benefits or services under those programs; or (c) possible changes in or alternatives to these programs or procedures.

Activities meeting this definition constitute *research* for purposes of human subjects policies, whether or not they are considered research for other purposes.

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If results *are not* disseminated (published, presented, or shared) externally, the term research is *not intended* to apply to data acquisition resulting from:

- a. routine course, workshop, or curriculum development activities using accepted educational practices sponsored by the University of Southern Indiana, including evaluations to determine student or participant satisfaction, attitude change, or knowledge gained during the educational experience; or
- b. aid or services provided by professionals to their clients that are consistent with accepted and established practice, and intended only to meet the clients' own personal needs.

If results from these activities *are* disseminated externally, the activities constitute human subjects research and must receive IRB approval *prior* to the beginning of the research.

Some examples of activities which are not subject to IRB review

1. Activities involving individuals intended solely for internal use, performed to improve services or develop new services or programs, (e.g., satisfaction surveys) *without* plans for presentation or publication performed as a part of organizational operations
2. Biographies
3. Oral histories that are designed solely to create a record of specific historical events
4. Service or course evaluations, unless they can be generalized to other individuals
5. Services, courses, or concepts where it is not the intention to share the results beyond the USI community