

Understanding when an activity requires COMIRB review

Our faculty, staff and students are responsible for knowing when they are conducting human subjects research and knowing not to involve human subjects in research without IRB approval. COMIRB review is not required for non-human subjects research activities such as quality improvement, quality assurance or program evaluation. COMIRB review is required for *exempt* human subjects research, and IRB approval is required (e.g., by COMIRB or an external IRB) for non-exempt human subjects research and for “clinical investigations” as defined by the FDA.

The staff and IRB Chairs at COMIRB are happy to consult if there is any question whether an activity is considered human subjects research and what level of review is required. Contact COMIRB at COMIRB@ucdenver.edu or 303-724-1055, or drop in to [COMIRB office hours](#).

Deciding if an activity is considered Human Subjects Research

Human subjects research is any research or clinical investigation that involves human subjects. When considering whether an activity meets the definition of human subjects research per 45 CFR 46.102(e)(1), investigators should consider the federal definitions of both *research* and *human subject*. **Research** is defined as a *systematic investigation*, including research development, testing, and evaluation, designed to *develop or contribute to generalizable knowledge*.

Investigations designed to *develop or contribute to generalizable knowledge* are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publications or presentations). However, research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication. Research that never is published is still research. Participants in research studies deserve protection whether or not the research is published. **Note** Thesis or dissertation projects involving human subjects conducted to meet the requirement of a graduate degree are usually considered generalizable, and require IRB review and approval.

Examples of activities that typically are not generalizable (not research) include:

- Biographies
- Oral histories that are designed solely to create a record of specific historical events
- Service or course evaluations, unless they can be generalized to other individuals
- Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
- Quality assurance (QA) activities designed only to improve the quality or performance of a department or program, and not to contribute to generalizable knowledge
 - If you are unsure whether your activity should be considered QA, use the [QA/Program Evaluation Research Tool](#) on the COMIRB website

A "systematic investigation" is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

Examples of systematic investigations include:

- Surveys and questionnaires
- Interviews and focus groups
- Analyses of existing data or biological specimens
- Epidemiological studies
- Evaluations of social or educational programs
- Cognitive and perceptual experiments
- Medical chart review studies

Per federal regulations, the following activities are deemed not to be research:

- 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.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or manmade disasters).
- 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.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

A **human subject** means a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

- **Intervention** includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction** includes communication or contact between investigator and subject. Interactions also include remote activities such as on-line surveys.
- **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.