

How do I know if my research project requires IRB Review?

All research and other activities, which even in part involve human subject research, regardless of sponsorship, must be reviewed and approved, or acknowledged as Exempt, by the TTUHSC El Paso IRB, prior to initiation. This includes all interventions and interactions with human subjects for research, including advertising, recruitment and/or screening of potential subjects.

Please review the information in this section to understand what activities meet the definition of human subjects research.

Definition of Human Subjects Research

Human subjects research is any research or clinical investigation that involves human subjects.

Investigators conducting human subjects research must satisfy DHHS regulations [\[45 CFR Part 46\]](#) and FDA regulations [21 CFR [Part 50](#) and [56](#)] regarding the protection of human subjects research, as applicable.

Human subject

A living individual about whom an investigator (whether professional or student) conducting research:

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

Research

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A "systematic investigation" is an activity that involves a plan that incorporates data collection in an organized/consistent way, and data analysis to answer a question (for example, a hypothesis).

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

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 is never 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
- Services, courses, or concepts where it is not the intention to share the results beyond the TTUHSC El Paso community
- Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the TTUHSC El Paso community.

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 man-made 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.

Clinical Investigation

FDA regulations define a clinical investigation as any experiment that involves a test article and one or more human subjects and that either is:

Subject to requirements for prior submission to the FDA, or

Not subject to requirements for prior submission to the FDA under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

A test article is any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act.

Intervention

Includes both physical procedures by which information or biospecimens 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 interpersonal contact between investigator and subject.

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.

Identifiable biospecimen

A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

FDA regulations

Define a human subject as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. Examples of clinical investigations include:

Investigational drug clinical trials

- Research testing the safety and effectiveness of an investigational device
- Medical outcomes study comparing approved drugs/devices

Note:

Research testing the safety and effectiveness of an [In Vitro Diagnostic \(IVD\)](#) device using human tissue specimens (identifiable or unidentifiable) requires IRB review per FDA 21 CFR Parts 50 and 56, even though under DHHS regulations research involving unidentified tissue specimens would not be considered human subjects research.