

Is it Human Subject Research?

NOTE: CHS policy charges the IRB with determining whether an activity conducted or supported by OSU CHS faculty, staff, or students, is research involving human subjects. OSU CHS policy does not authorize investigators to make a determination of exemption for their own.

Research is defined by DHHS as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities" Research is defined differently by the FDA and has additional requirements.*

Is it a Human Subject?

A **Human Subject** is defined by DHHS as "a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through **intervention** or **interaction** with the individual, or
- (2) Identifiable **private information**

Human Subjects is defined differently by the FDA and has additional requirements.*

Intervention includes both physical procedures by which data are gathered (for example, 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).

Identifiable 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 or accessed for research purposes. It 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.

Is it a systematic investigation?

There are two aspects of this definition that make a research project regulated, and both aspects must be present in a research project for it to be reviewed and approved by the IRB. These aspects include the practice of a systematic investigation, and the contribution to generalizable knowledge.

Is data be obtained in a systematic imanner (some or all)?

A systematic investigation is the gathering and analysis of information according to a fixed plan, system or method.

Qualities of a project involving a systematic investigation include:

- One or more specific questions of interest, often framed as hypotheses, that the project will seek to answer;
- Data collection methods appropriate to address the question(s);
- Data analysis plans appropriate for the type(s) of data collected;
- An ability to use the analyzed data to answer the questions(s).

Does it contribute to generalizable knowledge?

- Generalizable knowledge is knowledge that is expressed in theories, principles, or statements of relationships that can be generally applied to our experiences. A study designed to develop or contribute to generalizable knowledge intentionally likes to, applies, and/or expands upon existing knowledge. The methods allow for replication and for comparisons with data collected from different samples of the same population, and the results apply to people beyond those directly studied.
 - Activities designed to contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual(s) or an internal program(s)
 - The information is collected to share with others and is created for the purpose of making a broad statement (conclusion) about a group of people, procedures, or programs.
- The *intent* to develop or contribute to generalizable knowledge makes an activity research
 - The intent to contribute to “generalizable (scholarly) knowledge” makes and 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.

A research project is considered “contributing to generalizable knowledge” when any of the following activities will occur:

- The information contributes to a theoretical framework or an established body of knowledge
- The information expands the knowledge base of a scientific discipline or scholarly field of study
- The primary beneficiaries of the study are other researchers, scholars, stakeholders, and practitioners in the field of study where they may use the end product to inform their daily practices, policy, or their research design, instruments, devices, data collection methods, and drugs or biologics
- Publication, presentation or other distribution of the results are intended to inform the field of study. Distribution of results may involve an oral presentation such as a lecture or conference talk, a written presentation such as a published research article, scholarly book, conference poster, podcasts, magazines, news articles, or other display that is made available to persons beyond the University
- The findings are intended to be replicated in or transferable to other settings.
 - Generalizability is applied by researchers in an academic setting. It can be defined as the extension of research findings and conclusions from a study conducted on a sample
 - Transferability is applied by the readers of research. Although generalizability usually applies only to certain types of quantitative methods, transferability can apply in varying degrees to most types of research including Qualitative research. Unlike generalizability, transferability does not involve broad claims, but invites readers of research to make connections between elements of a study and their own experience
- The findings are intended to inform a larger study, the design of a device, drug, or biologic, or to aid in future planning of research activities
- If it is likely that members of the public will make inferences from the data you are collecting and findings you plan to share, this is an indicator the research is designed to contribute to generalizable knowledge
- Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships. This includes pilot work and some feasibility studies (please see pilot/feasibility guidance found on the IRB website)

The following projects are not considered research

- Internal reporting activities to sponsors, supervisors, and offices
- Program assessment and evaluation where the intention is for program improvement or measurements of outcomes and not intended to generalize to others. For example, a

quality assurance/quality improvement/organizational effectiveness study where the intent is to assess, improve, or develop programs or services for an organization is not research, because outcomes will remain specific to the organization, programs or services, although other organizations may use the results for their own programs

- 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
 - An oral history or journalistic piece is published materials that are limited to documenting or reporting on events, situations, policies, institutions, or systems without the intent to form hypotheses, draw conclusions, synthesize information about, or generalize findings
 - Such oral histories or journalism will not involve stories that will or may draw broad conclusions about the population, cultures, norms, and practices
 - Note that an article reporting on findings from a project may be considered contributing to generalizable knowledge
- 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
- Classroom or educational research activities and class projects assigned and conducted to teach methods, not to contribute to generalizable knowledge. The intent may be to provide the student with practical experiences, information gathering techniques, and report writing. However, when the primary focus and initial intent of the class activities are to collect data to be used by students or other researchers beyond the classroom thereby contributing to “generalizable knowledge,” IRB review may be needed. Please see Research as a class Requirement for additional guidance.
- Biography research involving a living individual that is not generalizable beyond that individual