



Baylor University
OFFICE OF THE VICE PROVOST FOR RESEARCH

IS THIS HUMAN SUBJECTS RESEARCH? DO I NEED IRB REVIEW?

A Guide for Researchers

baylor.edu/research

This booklet, prepared by the Office of the Vice Provost for Research—Research Compliance, provides guidance to Baylor University investigators who may be uncertain if their study meets the definitions of human subjects research stated in the federal regulations (45 CFR 46.102).

Is This Human Subjects Research? Do I Need IRB Review? offers researchers an explanation of the definitions as well as examples of studies that do or do not qualify as human subjects research.

For further information, please refer to the *Resources* section on page 9 of this booklet.

Credit is given to the University of Southern California Office for the Protection of Research Subjects (OPRS) for the concept and as a primary source of information.

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HUMAN SUBJECTS RESEARCH

Research projects involving human subjects require review by an Institutional Review Board (IRB). An IRB is an ethics committee of scientists and non-scientists who assure that the rights and welfare of human subjects are adequately protected in research. The BU IRB is responsible for reviewing and overseeing human subjects research conducted by BU faculty, staff and students.

The first question a researcher should consider with respect to IRB review is whether the research project fits the definitions of “human subjects” and “research.”

When in doubt, **the investigator should err on the side of caution and consult IRB staff to clarify whether a study is human subjects research or not.**

HOW IS ‘RESEARCH’ DEFINED UNDER FEDERAL REGULATIONS?

Research is defined by federal regulations as “**a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.**”

The term “**research**” means an activity designed to test a hypothesis. Research is usually described in a formal protocol that includes an objective and a set of procedures to reach that objective.

Systematic Investigation is an activity that involves a prospective plan that incorporates data collection (quantitative or qualitative) and data analysis to answer a question.

Generalizable knowledge is information where the intended use of the research findings can be applied to populations or situations beyond those studied. Activities designed to develop or contribute to generalizable knowledge are those designed to draw conclusions, inform policy, or generalize findings beyond a single individual or an internal program. The intent to develop or contribute to generalizable knowledge makes an activity research – it does not need to be published or presented to meet this standard.

Research generally does **not** include operational activities such as defined practice activities in public health, medicine, psychology, and social work (e.g., routine outbreak investigations and disease monitoring) and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services. Research generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge.

Information within this booklet is defined under OHRP “Common Rule” federal regulations only. Activities involving human subjects that are covered under FDA regulations require IRB review.

HOW IS ‘HUMAN SUBJECTS’ DEFINED?

A **human subject** is defined by the Common Rule as “a living individual **about whom** an investigator conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”

This definition can be broken down into several components:

LIVING INDIVIDUAL

The information/biospecimens must be collected from **living** subjects. Cadavers, autopsy specimens, or information/biospecimens from subjects now deceased do not meet the definition of a human subject.

“ABOUT WHOM”

A human subject research project requires the information/biospecimens received from the living individual to be **about** the person.

INTERVENTION

Includes physical procedures, manipulations of the subject, or manipulations of the subject’s environment for research purposes. **Interaction** includes communication between the investigator and the subject. This includes face-to-face, mail, internet, and phone interaction as well as other modes of communication.

PRIVATE INFORMATION

Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation 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 shared or made public (e.g., a health care record).

Identifiable Private Information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Observational studies of public behavior (including social media) do **not** involve human subjects as defined when there is no intervention or interaction with the subjects and the behavior is not private (for social media, this means you don’t have to send a “friend” request or register for a forum). Studies based on data collected for non-research purposes **may not** constitute human subjects research if individuals are not identifiable or the information is publicly available (e.g. data such as service statistics, school attendance data, crime statistics, or election results). The term “**publicly available**” is intended to refer to record sets that are truly readily available to the broad public, such as census data, federal and health, labor, or educational statistics. An investigator should not assume information qualifies as “publicly available” merely because it has been posted on a website and can be accessed without authorization.

HOW DO I IDENTIFY HUMAN SUBJECTS RESEARCH STUDIES?

Certain studies may have the characteristics of human subjects research but may not meet the regulatory definition. Studies which meet the definition require IRB review. There are three categories to consider:

- **Studies that are human subjects research**
- **Studies that may be considered human subjects research (gray area)**
- **Studies that do not qualify as human subjects research**

Any investigator who is unsure of whether their proposal constitutes “human subjects research” should contact a member of the research compliance staff or submit the F-16 Determination of Human Subjects Research form. The research compliance staff will determine if the study is human subjects research. Federal guidelines do not recommend investigators make this determination themselves.

If a study does not qualify as human subjects research, the research compliance staff can issue a formal letter stating that the project does not require IRB review. Once a “Determination of Human Subjects Research form” is submitted to the research compliance staff, a determination letter will be provided to the researcher. **NOTE:** Study sponsors, faculty advisors, or publications/conferences may require a formal determination letter from the IRB/designee.

STUDIES THAT ARE NOT HUMAN SUBJECTS RESEARCH

Studies that fit **any** of the categories below do not need IRB review:

1. **Data collection** for internal departmental, school, or other University administrative purposes. Examples: teaching evaluations, customer service surveys.
2. **Service surveys** issued or completed by University personnel for the intent and purposes of improving services and programs of the University or for developing new services or programs for students, employees, or alumni. This would include surveys by professional societies or University consortia. *Note: If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, IRB review may be required before the data could be released to the researcher of the new project.*
3. **Information-gathering interviews** with questions focused on things, products, or policies rather than people or their thoughts/ personal opinions. Example: canvassing librarians about inter-library loan policies or rising journal costs.
4. **Course-related activities** designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment, but are not intended for use outside of the classroom. Example: instruction on research methods and techniques.
5. **Biography or oral history research** involving a living individual that is not generalizable beyond that individual.
6. **Independent contract for procedures** carried out for an external agency. Examples: personnel studies, cost-benefit analyses, customer satisfaction studies, biological sample processing (for a fee and not authorship or other credit), public park usage, IT usage, and software development.
7. **Research involving cadavers**, autopsy material or bio-specimens from deceased individuals. *Note: Some research in this category, such as genetic studies providing private or medical information about live relatives, may need IRB review. Please contact the research compliance staff for further information.*
8. **Innovative therapies** except when they involve “research” as defined by the above criteria. (An innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individuals.)
9. **Quality improvement** projects are generally **not** considered research unless there is a clear intent to contribute to generalizable knowledge **and** use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice. Any individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the research compliance staff for guidance. If the data is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the research compliance staff.
10. **Case histories** which are published and/or presented at national or regional meetings are **not** considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge.
11. **Publicly available data** do **not** require IRB review. Examples: census data, labor statistics. *Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as “publicly available.”*

NON-HUMAN SUBJECTS RESEARCH EXAMPLES

EXAMPLE 1

A researcher wants to interview veterans about their deployment experiences. The researcher plans to get written consent from the veterans and will not collect any identifying information. The researcher plans to publish the interviews in their paper, "Perspectives of the Deployed."

Example 1 is not human subjects research because the interviews are done only to document the veterans' life histories and do not contribute to generalizable knowledge.

EXAMPLE 2

A researcher wants to know how people's social media usage changed after a recent election. The researcher plans to track the number of posts of 100 public Twitter accounts and 100 public Facebook accounts. The researcher does not need to login or request permission to access the public accounts.

Example 2 is not human subjects research because the social media accounts are publicly accessible.

EXAMPLE 3

A nurse wants to know how a sanitation protocol works. The nurse plans on interviewing 35 nurses about the sanitation protocol. The interviews will include the nurses' names, departments, and positions.

Example 3 is not human subjects research because the nurse's questions will be about a specific protocol and not include personal opinions. Additionally, the outcomes of the interviews would not be generalizable as they are for quality improvement/quality assurances purposes.

EXAMPLE 4

An administrator of a university wants to survey students about the use and improvement of counselling options offered by the university. The administrator plans to use the data to inform current counselling options and make any appropriate changes.

Example 4 is not human subjects research because the administrator is not using the data to contribute to generalizable knowledge, rather, they are only using the data to improve their current counselling offerings (i.e. program evaluation).

HUMAN SUBJECTS RESEARCH EXAMPLES

EXAMPLE 1

An undergraduate exercise kinesiology student wants to survey 250 personal trainers about their opinions on vegan diets and performance. The undergraduate plans to email a 15-minute survey to the personal trainers.

Example 1 is human subjects research because the survey is asking the personal trainers about their opinions and the outcomes of the survey contribute to generalizable knowledge.

EXAMPLE 2

A professor wants to record how different chat forums react to new members. The professor will create 100 accounts and send requests to join 100 different chats. The chat forum managers will either accept or deny the requests.

Example 2 is human subjects research because the professor must be given access to the chat forums.

EXAMPLE 3

A researcher wants to know how diet effects sleep. The research study will require the participants to abide by a strict diet and sleep in a lab for monitoring.

Example 3 is human subjects research because the researcher is manipulating the participants' diets and the study outcomes contribute to generalizable knowledge.

EXAMPLE 4

A nurse wants to write a paper about the correlation of type 2 diabetes and lifestyle choices. The nurse acquires data sets from local hospitals that list patient's medical ID numbers, addresses, and medical conditions.

Example 4 is human subjects research because the data being used contains identifying information.

IS AN EXEMPT DETERMINATION THE SAME THING AS A NON-HUMAN SUBJECTS RESEARCH DETERMINATION?

An exempt determination is not the same thing as a non-human subjects research determination. Exempt determinations are made by the research compliance staff and only apply to human-subjects research that falls within one or more of the exempt categories found in 45 CFR 46.104(d). Even though exempt studies do not need to follow the Common Rule (45 CFR 46), researchers are expected to abide by the ethical principles of **Respect for Persons**, **Beneficence**, and **Justice** as discussed in the Belmont Report and Baylor policies.

RESOURCES

OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP)

United States Department of Health & Human Services
<http://www.hhs.gov/ohrp/>

CHART FOR DETERMINING IF A PROJECT IS HUMAN SUBJECTS RESEARCH

<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html>
Select: “Chart 1: Is an Activity Research Involving Human Subjects?”

ENGAGEMENT OF INSTITUTIONS IN RESEARCH

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

UNITED STATES FOOD AND DRUG ADMINISTRATION

www.fda.gov

FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS

www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

THE BELMONT REPORT

www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

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www.baylor.edu/research/resources/irb

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