

IS YOUR PROJECT HUMAN SUBJECTS RESEARCH?

A Guide for Investigators



Institutional Review Board (IRB)

This guidance, prepared by the Office for the Protection of Research Subjects (OPRS) at University of Southern California (USC), has been modified by Saint Louis University's Institutional Review Board with permission. This booklet provides guidance to SLU investigators who may be uncertain if their study meets the definitions of human subjects research as stated in the federal regulations (45CFR46.102). The SLU IRB recognizes that the definition may not always provide a straightforward answer. *Is Your Project Human Subjects Research? A Guide for Investigators* offers investigators 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 in the back of this booklet.

HUMAN SUBJECTS RESEARCH

Research projects involving human subjects require review and approval by an Institutional Review Board (IRB). An IRB is an ethics committee composed of scientists and non-scientists who serve as advocates for human subjects involved in research. The IRB is charged with the responsibility of reviewing and overseeing human subjects research conducted under the aegis of Saint Louis University. The first question a researcher should consider with respect to IRB review is whether the research project fits the definition of human subjects research. In light of the mission to protect human subjects, and the potential regulatory consequences of not obtaining IRB review and approval, **the investigator should choose to err on the side of caution and consult with the IRB when he/she is uncertain whether the study is human subjects research or not.** The [SLU IRB Human Subjects Research Determination Form](#) should be submitted for official determinations.

DEFINING RESEARCH

Federal Regulations define **research** as **“a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”** (45CFR46.102(d)). As described in the Belmont Report² “...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”

“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. It 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.



DEFINING HUMAN SUBJECTS

A **human subject** is defined by Federal Regulations as **“a living individual about whom an investigator 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.** (45 CFR 46.102e1) (ii)

Living individual – The specimen(s)/data/information must be collected from live subjects. Cadavers, autopsy specimens or specimens/information from subjects now deceased is not human subjects. *Note: The SLU IRB also acts as the Privacy Board and therefore, because HIPAA requirements apply, the SLU IRB may need to review research activities with deceased individuals.*



¹ "Generalizable knowledge" is information where the intended use of the research findings can be applied to populations or situations beyond that studied.

² [The Belmont Report](#) is a statement of ethical principles (including beneficence, justice, and autonomy) for human subjects research by the U.S. Department of Health, Education, and Welfare.

“About whom” – a human subject research project requires the data received from the living individual to be **about** the person.

Intervention includes physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as other modes of communication.

Identifiable private information³ “includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place,” (such as a public restroom) “and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a health care record).” (45 CFR 46.102(e)(4)) **“Identifiable” means the information contains one or more data elements that can be combined with other reasonably available information to identify an individual** (e.g. Social Security #).

Identifiable biospecimen is a biospecimen for which the identity of the subjects is or may be readily ascertained by the investigator or associated with the biospecimen.

Observational studies of public behavior (including television and internet chat rooms) do **not** involve human subjects as defined when there is no intervention or interaction with the subjects and the behavior is not private. Also, studies based on data collected for non-research purposes may **not** constitute human subjects research if individuals are not identifiable (e.g. data such as service statistics, school attendance data, crime statistics, or election returns).

Studies based on data that are individually identifiable but are also publicly available may **not** constitute human subjects research. However, the term “publicly available” is intended to refer to record sets that are truly readily available to the broad public, such as census data, or federal health, labor, or educational statistics. An investigator should **not** assume information qualifies as “publicly available” merely because it has been posted on an electronic website and can be accessed without authorization.



IDENTIFYING HUMAN RESEARCH STUDIES

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

- 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 his/her proposal constitutes “human subjects research” should complete the [SLU IRB Human Subjects Research Determination Form](#) for an official determination.

³ Researchers must take caution since disclosure of private information may place the subjects at risk of criminal or civil liability and/or damage their financial standing, employability, or reputation.

Official determinations regarding whether or not IRB review is required are documented on the Human Subjects Research Determination Form and/or in correspondence from the IRB. *Note: Grant offices, faculty advisors, or publications may require documentation from the IRB.*

EXAMPLES OF ACTIVITIES THAT ARE **NOT** HUMAN SUBJECTS RESEARCH

Activities 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, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary. 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 new project.*
3. **Information-gathering interviews** (through interviews, surveys, etc.) where questions focus on things, products, or policies rather than people or their thoughts. Example: asking company officers to provide data about company facts (such as number of employees) or to provide copies of company policies. *Note: If the study involves collecting the officers' opinions of company policies (e.g. in your opinion, is the policy effective?), then the study will need IRB review.*
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. *Note: The IRB is only required to review studies that meet the Federal definitions of research and human subject⁴, or "engaged in research"⁵.*
5. **Scholarly and journalistic activities** (e.g., oral history, 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.
6. **Activities involving cadavers**, autopsy material or bio-specimens from now deceased individuals. *Note: Some research activities in this category, such as genetic studies providing private or medical information about live relatives, may need IRB review. The SLU IRB also acts as a Privacy Board, and may require a "Notification of Decedent Research" form which is located on the SLU IRB website under HIPAA. Please contact the IRB for further information.*
7. **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.) *Note: When innovative therapies differ significantly from routine practice it should be viewed and treated as such with appropriate safeguards in place to protect the rights and welfare of the patients.*
8. **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

⁴ <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

⁵ <http://www.hhs.gov/ohrp/policy/engage08.html>



individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the IRB for guidance. If the data are re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.

9. **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. SLU IRB policy states that 5 cases may be studied before submitting to the IRB.
10. **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 are not considered research. 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).
11. **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.
12. **Authorized operational activities** (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
13. **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”.
14. **Coded private information or biological specimens** that were **not** collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the coded data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects (e.g. subjects’ names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator. *Note: Investigators are not allowed to make this determination. These projects require verification from the IRB.*
(<http://www.hhs.gov/ohrp/policy/cdebiol.html>)
15. Some examples of **Non-Engagement in Research** include: when an institution’s employees or agents act as consultants on research but at no time obtain, receive, or possess identifiable private information; perform commercial services for the investigators (e.g. non-collaborative services meriting neither professional recognition nor publication privileges); or simply inform prospective subjects about the availability of research, but at no time obtain consent or act as authoritative representative of the investigator(s). *Note: The examples above are not an all inclusive listing.* (<http://www.hhs.gov/ohrp/policy/engage08.html>)

EXAMPLES OF STUDIES THAT ARE HUMAN SUBJECTS RESEARCH

1. Studies that involve human subjects for testing new devices, products, drugs, or materials.
2. Studies that collect data through intervention or interaction with individuals. Examples of this type of research include drug trials, internet surveys about alcohol consumption, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews with minors that contribute to generalizable knowledge.
3. Studies using private information that can be readily linked to individuals, even if the information was not collected specifically for the study in question.
4. Studies that use bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if one did not collect these materials for the study. However, such research may be considered exempt or not human subjects research if the materials/data are coded and the investigator does not have access to the coding systems. Guidance on research involving coded private information or biological specimens is available on the web at: (<http://www.hhs.gov/ohrp/policy/cdebiol.html>)
5. Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information.
6. Studies that use human beings to evaluate environmental alterations. For example, making changes to a living or working space (e.g. changing the temperature).

RESOURCES

- United States Department of Health & Human Services: Office for Human Research Protections (OHRP) <http://www.hhs.gov/ohrp/>
- US HHS Office of Human Research Protections (OHRP) Decision chart to assist in determining whether a project is human subjects research. <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html> select: *Chart 1: Is an Activity Research Involving Human Subjects?*
- US HHS Office for Human Research Protections (OHRP) Engagement of Institutions in Research <http://www.hhs.gov/ohrp/policy/engage08.html>
- United States Food and Drug Administration <http://www.fda.gov/>
- Federal Policy for the Protection of Human Subjects (Common Rule) <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>
- Guidance on Research Involving Coded Private Information or Biological Specimens <http://www.hhs.gov/ohrp/policy/cdebiol.html>
- The Belmont Report <http://www.hhs.gov/ohrp/policy/belmont.html>
- Pritchard, Ivor A. Searching for “Research Involving Human Subjects”: What is Examined? What is Exempt? What is Exasperating; *IRB: Ethics and Human Research* 23, no.3 (2001), 5-12
- Saint Louis University’s Institutional Review Board Website <https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/index.php>
- University of Southern California: Institutional Review Board website <http://www.usc.edu/admin/provost/oprs/upirb/>

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