

Not Human Subjects Research/Human Subjects Research: Purpose of this Worksheet

This worksheet provides assistance for individuals who wish to determine whether an activity is or is not human subjects research. If it is not human subjects research, IRB review and approval are not required. USC policy allows researchers to make this determination themselves, using this Worksheet as a guide.

NOTE IN ALL CASES: if excluded activities involve interaction (in-person or remotely) with individuals under the age of 18 you must still comply with and consider policies and regulations pertaining to research involving children.

To ask the IRB to make the determination: Please see [Not Human Subjects Research \(NHSR\)](#) page on our website.

Table of Contents

Not Human Subjects Research/Human Subjects Research: Purpose of this Worksheet.....	1
Not Human Subjects Research.....	2
Human Subjects Research	3
Definitions, Explanations, and Examples.....	4
Scholarly and journalistic activities	4
Public health surveillance activities (PHSA)	5
Exceptions	5
Public Data Sets	6
Exceptions: The following uses of data sets listed require USC IRB review	6
Examples of Class Specific Research Where IRB Approval is not required	7
Exceptions:	7
Definition of Research.....	8
Exceptions	9
Terms used in Research.....	10
Identifiable:	10
Individuals who "screen out:"	10
Interaction:	10
Intervention:	10
Obtain:.....	10
Private:	10

Not Human Subjects Research

Specifically, the Federal Common Rule (45 CFR 46 Subpart A) calls out “Scholarly and Journalistic activities” and “Public health surveillance activities” as not meeting the definition of research. This means that these activities are considered Not Human Subjects Research (NHSR) and **therefore do not need IRB review**.

If your project fits one of these criteria, you do not need to submit your study for IRB review.

- ☐ **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 (PHSA)** Public health surveillance involves collecting, testing, analyzing, and using information or biospecimens to improve public health and prevent disease. *A defining characteristic of these activities is a direct link to decision making and action by a public health authority.*
 - The activity is being conducted, supported, requested, ordered, required, or authorized by a public health authority.

Other activities that are considered Not Human Subject Research NHSR and do not require submission to the USC IRB include activities using public data sets and class-specific research activities/projects. The activity must fulfill all criteria defined.

- ☐ **Public Data Set** Information that is available to any one regardless of occupation, purpose, or affiliation. These data sets are “legitimately attained such status” (i.e., those individuals who are responsible for posting the dataset had legitimate access to the data and have employed the necessary mechanisms to ensure the privacy and confidentiality of the individuals about whom the data were collected). The data are not accessed through the “Dark Internet.”
- ☐ **Class-Specific Research** Class activities/projects (individual or group) that are designed for pedagogical purposes only. That is, the primary purpose of the activity is skill development. There is no intent to publish the work. There is *no intent* to present the work outside of the university setting (no public presentations).

Human Subjects Research

Review and complete steps 1 -3.

1. If both boxes below are checked the activity is considered [research](#).

- ☐ **Systematic investigation:** A detailed or careful examination that has or involves a prospectively identified approach to the activity based on a system, method, or plan.
- ☐ **Generalizable knowledge:** The information is expected to expand the knowledge base of a scientific discipline or other scholarly field or study and yield one or both of the following:
 - Results that are applicable/transferrable to a larger population beyond the site of data collection or the specific participants studied.
 - Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships or to inform policy beyond the study.

2. To determine if the activity is human subjects research, review the criteria. If both boxes below are checked, **IRB review is required**.

- ☐ **Living Individuals:** Individuals who are alive according to applicable local and national regulations and laws. For specimens, data, and other information gathered without direct interaction with the individual, it is assumed that the individuals are alive unless the researcher specifically knows otherwise.
- ☐ **About whom:** The data or information relates to the person. Asking what they think about something, how they do something, or similar questions is usually about the individuals. This contrasts with questions about factual information not related to the person. Biospecimens are always considered to be about the person.

3. If *any* of the following boxes below are checked, **IRB review is required**.

- ☐ **Obtain information or biospecimens** through intervention or interaction with the individual, and use, study, or analyze the information or biospecimens.
- ☐ **Obtain and use**, study, analyze, or generate identifiable [private information](#) or [identifiable](#) biospecimens.
- ☐ **An individual** on whom or on whose specimen an investigational device is used or as a control. This is true even if the specimen is anonymous.

Definitions, Explanations, and Examples

Scholarly and journalistic activities

Example: In these activities, the ethical requirement is to provide an accurate and evidence-based portrayal of the individuals and not necessarily to protect them from public scrutiny. For example, a biographer might collect and present factual information to support the biographer's opinion about the character of a public official.

These fields of research typically have their own codes of ethics and may be performed in different fields (e.g., anthropology, history, journalism, legal research, or sociology).

Please consider:

When these activities *may be* considered research:

If the focus includes generalizing to other individuals, then the activity may be research and should be evaluated against the definition of research.

When these activities *are considered* research:

Studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals to understand their beliefs, customs, and practices, and the findings apply to the studied community or group (not just the individuals from whom the information was obtained) are considered to be research and subject to the Common Rule, therefore submission to the USC IRB is required.

Public health surveillance activities (PHSA)

A defining characteristic of these activities is a direct link to decision making and action by a public health authority. Some activities may be a combination of public health surveillance components and research components.

This PHSA exclusion depends on the project purpose, the context in which it is conducted, and the role of the public health authority. It is not necessary to consider the standard Common Rule definition of research (i.e., whether the activity is a systematic investigation designed to develop or contribute to generalizable knowledge).

Rationale. Public health surveillance activities are deemed not to be research because federal agencies do not want to impede a public health authority's ability to accomplish its mandated mission to protect and maintain the health and welfare of the population(s) for which it is responsible. Other laws, regulations, policies, or standards may be applicable to the conduct of these activities, such as HIPAA.

Other public health activities. Public health activities that do not meet the definition of **surveillance** activities should be evaluated against the definition of research. Note that there are many types of public health activities that may be neither research nor surveillance. Examples: Providing public service health messages; conducting vaccination campaigns.

Examples of public health surveillance activities that *are not* considered to be research.

- Safety and injury surveillance activities designed to enable a public health authority to identify, monitor, assess, and investigate potential safety signals for a specific product or class of products (e.g., the surveillance activities of FDA's Adverse Event Reporting System, the Vaccine Adverse Event Reporting System).
- Surveillance activities designed to enable a public health authority to identify unexpected changes in the incidence or prevalence of a disease in a defined geographic region where specific public health concerns have been raised (e.g., the U.S. influenza surveillance system).
- Surveillance activities designed to enable a public health authority to identify the prevalence or incidence of known risk factors associated with a health problem in the context of a domestic or international public health emergency.
- Surveillance activities designed to enable a public health authority to locate the range and source of a disease outbreak or to identify cases of a disease outbreak.
- Surveillance activities designed to enable a public health authority to detect the onset of disease outbreaks or provide timely situational awareness during an event or crisis that threatens the public health, such as a natural or man-made disaster.
- Surveillance activities designed to enable a public health authority to identify the prevalence or incidence of a condition of public health importance, known risk factors associated with the condition, or behaviors or medical practices related to prevalence of the condition (e.g., surveillance of the prevalence of tobacco use, exposure to secondhand smoke, lung cancer, or use of smoking cessation treatments).

Exceptions

Researchers are not allowed to self-determine whether this exclusion applies to their activities.

- For NIH-funded research, the researcher must request the determination from NIH. This policy and process is described in NIH notice NOT-OD-22-011
- For all other research, USC IRB must make the determination. Researchers may request this determination. Please see [Not Human Subjects Research \(NHSR\)](#) page on our website.

Public Data Sets

The IRB has determined that research projects involving only the analysis of de-identified datasets available from the following institutions do not meet the definition of involving human subjects and IRB submission is not required.

1. [Inter-University Consortium for Political and Social Research \(ICPSR\)](#)
2. [U.S. Bureau of the Census](#)
3. [National Center for Health Statistics](#)
4. Life Tables
5. LSOAs: Longitudinal Studies of Aging
6. NHANES: National Health and Nutrition Examination Survey
7. Health and Retirement study (Public Data)
8. NHCS: National Health Care Survey
9. NHIS: National Health Interview Survey
10. NIS: National Immunization Survey
11. NSFG: National Survey of Family Growth
12. SLAITS: State & Local Area Integrated Telephone Survey
13. Vital Statistics: National Vital Statistics System
14. [National Center for Education Statistics](#)
15. [National Election Studies](#)
16. Fatality Analysis Reporting System (FARS)
17. American Hospital Association Annual Survey
18. Behavioral Risk Factor Surveillance System (BRFSS; public data only)
19. Comprehensive Hospital Abstract Reporting System (CHARS; public data only)
20. dbGaP (NIH GWAS Database of Genotypes and Phenotypes)
21. Demographic Health Survey (DHS), Standard and Interim Surveys
22. Healthcare Cost and Utilization Project (HCUP) healthcare databases
23. The Nationwide Inpatient Sample (NIS)
24. The Kids Inpatient Database (KID)
25. The State Inpatient Databases (SID)
26. The State Ambulatory Surgery Databases (SASD)
27. The State Emergency Department Databases (SEDD)
28. HIV Prevention Trials Network D01: Vaccine Preparedness Study/Uninfected Protocol Cohort-4 files
29. Hospital Compare
30. Medicare Healthcare Cost Report Information System (HCRIS)
31. National Automotive Sampling System (NASS) General Estimates System (GES)
32. National Hospital Ambulatory Medical Care Survey (NHAMCS)
33. National Epidemiological Survey on Alcohol and Related Conditions (NESARC) – Wave 1 & Wave 2
34. National Longitudinal Survey (NLSY)
35. National Longitudinal Survey of Youth 1997 (NLSY97)
36. National Longitudinal Survey of Youth 1979 (NLSY79)
37. NLSY79 Children and Young Adults
38. National Longitudinal Survey of Young Women and Mature Women
39. National Longitudinal Survey of Young Men and Mature Men
40. National Survey of Children's Health (public version)
41. National Survey of Children with Special Health Care Needs (public version)
42. Organ Procurement and Transplantation Network (OPTN)
43. Roper Center for Public Opinion Network (OPTN)
44. Survey of Consumer Finances (SCF)
45. U.S. Bureau of Labor Statistics

****This is an incomplete list****

Exceptions: The following uses of data sets listed require USC IRB review

- Merging data sets in such a way that individuals may be identified.
- Enhancing a data set with identifiable or potentially identifiable data.
- Research that consists of using one or more data sets on this list and also (1) the collection or use of private, identifiable data and/or (2) interactions or interventions with humans.
- A Data Use Agreement (DUA) is needed to access the data set.
- Documentation is required for research sponsors, funding agencies, or a journal.
- Publicly available data are not considered private. For example, there are many large data sets that are widely available. These are not considered to involve "human subjects" as defined by the Common Rule. See [USC HRP Policies and Procedures 14.3 Secondary Data Analysis - Identifiable Information and Biospecimens for Secondary Research](#).

WORKSHEET Human Subjects or Not Human Subjects Research (NHSR) Determination

Examples of Class Specific Research Where IRB Approval is not required

Examples of Student Projects Where IRB Approval is not required.
A student in a psychology 300 class wants to interview 12 peers individually on campus about gender identity and family support for a research paper. The student will use quotes from the interviews in their research paper.
An advanced undergraduate Kinesiology class has a research project where students in the class are interviewing student athletes on campus about the effects of injuries have had on their athletic career. They are recruiting students from other Kinesiology classes. The students in the classes will discuss what they found from their interviews and write a report together. They will share the report with the class project participants and present it at on-campus research symposium.
A group of students in a marketing class design a survey that will be sent out through their social media channels. The survey will have questions about the effectiveness of advertisements in social media. The students are also collecting basic demographics such as age, race, and year in college as part of the survey. This data will be presented to other class members.
Pre-service student teachers in a 6–12 th grade teach preparation program, are going to try one week of using individual gamification to learn pre-algebra and one week of using small groups made of 3–4 students to learn pre-algebra. The students will take pre and posttests for each curricula type. All students in a teachers' class will do all activities. The school supports student teachers trying new thing to help the 6–12 th student populations. The Pre-service student teachers will present their findings to other pre-service teachers in their program and the to the school administrators and staff where they are doing their student teaching.
Students in a psychology class are learning to how to interview. Their instructor has given them 8 interview questions to practice with ranging from "How did you chose your major?" to "What classes do you plan on taking in the future?" The students will record and transcribe the interviews. Next, they will include what they learned about the process in a class assignment.
Students in physics class will be experimenting with different ways to get AI to help them with efficiency of electrical circuits. Their instructor will give all students a short survey (10 questions) to see if they believe the AI was helpful in the experiment. The instructor will present the survey to the class.
Students in a biology class will be learning to figure out their blood type. After they collect their blood, they will be graphing the averages of blood type by gender to see if there are any trends.
Graduate Students in an educational research methods course are learning how to do collect and analyze data. With support from their instructor, they have decided they are going practice facilitating a focus group. The focus groups will be recorded, transcribed, and the data will be analyzed and presented to the class. Gun violence in middle schools is the focus group topic. Previous to this assignment one of the students revealed that her art teacher in middle school was in the library at the Columbine shooting in Colorado.
Students in graduate criminal justice methodology class want to interview formally incarcerated people about their experience with the criminal justice system. Participants will be recruited via a local non-profit that serves formally incarcerated individuals. The participants will be asked to come to the class for a Q&A session with the students. Only one participant will come at a time to the class. All interviews will be recorded. The students will then code all the data from the participants and present the information to other at the university on what they learned.

Exceptions:

- Senior Thesis
- Master's Thesis
- Dissertations Research
- Class research activities/projects or coursework when your initial desire is to publish the findings

WORKSHEET Human Subjects or Not Human Subjects Research (NHSR) Determination

Definition of Research

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

Definition of Human Subject means 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.
 - **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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical 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.
 - **An identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Examples of research:

- A survey of elementary school teachers that asks them factual questions about class size, classroom features, and availability of classroom materials is not about the teachers and would therefore not involve human subjects unless they are also asked to provide information about themselves (such as "How long have you been teaching?" or "How old are you?")
- A survey of elementary school teachers that asks them for their opinions about the standard curriculum would be about the teachers.
- A researcher is developing a new user interface for a computer program. Their research uses the "think aloud" method whereby they ask college students to verbally express their thought processes as they use the interface. Though the object of the researcher's interest is the interface, not the students, they are nonetheless collecting data about the students.
- Suppose you ask individuals, "How does your hospital respond to confidentially breaches?" If you are seeking information about the hospital and are asking people who oversee medical record privacy and security, then the question is not about the person being asked. If you are seeking to find out how often hospital employees know the correct answer, then the question is about the employees.

WORKSHEET Human Subjects or Not Human Subjects Research (NHSR) Determination

Exceptions

- See [USC HRPP Policies and Procedures 6.1 Human Subjects Research: What is and What is Not](#) for discussion of other types of activities that may or may not be research, such as classroom activities, quality improvement, program evaluation.
- See [USC HRPP Policies and Procedures 14.1 Chart Reviews / Case Studies](#) for information about how to identify which case reviews/studies do, or do not, meet the definition of “research.”
- **The Common Rule** provides clarifying information:

The following activities are deemed not to be research:

1. Scholarly and journalistic activities.
2. Public health surveillance activities.
3. 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.
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

WORKSHEET Human Subjects or Not Human Subjects Research (NHSR) Determination

Terms used in Research

Identifiable:

- a. The identity of the individual is or may readily be ascertained or associated with the information or biospecimen by a member of the research team.
- b. A member of the research team could readily identify the individual through a combination of the data or information.
- c. Note that the definition of "identifiable" is not the same as in the HIPAA Privacy Rule about health care records. Information that is an "identifier" by HIPAA regulations may not be "identifiable" according to the Common Rule, depending upon the context.
- d. Third party or secondary subject situations. These are situations in which a researcher obtains private identifiable information about one individual through an interaction with another individual. The individuals to which the private identifiable information pertains are considered human subjects.

Individuals who "screen out:" Individuals who screen out of a study because an interaction or intervention (such as a screening phone call or lab test) reveals that they do not meet the study eligibility criteria are considered humans subjects.

Interaction: Communication or interpersonal contact between a member of the research team and the individual. Surveys, whether in person, by mail, email, phone, or social media are an example of interaction between researchers and individuals.

Intervention: Physical procedures, or manipulations of the individuals or the individual's environment, that are performed for research purposes. Manipulations may be physical, social, psychological, or emotional. "Environment" includes an individual's social and virtual environments as well as physical environment.

Obtain: Record in any way (writing, video, email, voice recording, photography, etc.) for research purposes and retain for any length of time.

Private:

- a. Information or biospecimens about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.
- b. Information or biospecimens that have 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 or a residual medical specimen that is "left over" from a health care procedure).
- c. Information about an individual or biospecimen from an individual that is collected specifically for the proposed research through an interaction or intervention with the individual by the investigator or other member of the research team is always considered to be private.
- d. If permission is required to obtain information, then the information is almost always considered to be private.
- e. There are many gray areas in distinguishing "private" from "non-private." For example, there are some situations that are best considered "semi-private"—for example, some behaviors, communications, and interactions that occur in electronic or social media. It is also important to consider that a specific type of information may be considered private for one group of individuals but for not for others.