IS YOUR PROJECT HUMAN SUBJECTS RESEARCH UNDER FEDERAL REGULATIONS?

A Guide for Investigators

Loyola University Maryland Institutional Review Board

This document was prepared using excerpts from the Office for Protection of Research Subjects at University of Southern California and the Institutional Review Board at Skidmore College with permission. This booklet is issued to provide guidance to Loyola investigators who may be uncertain if their study meets the definitions of human subjects research as stated in the federal regulations (45 CFR 46.102).

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 Loyola IRB is charged with the responsibility of reviewing and overseeing human subjects research conducted under the aegis of Loyola University Maryland.

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 the IRB when he/she is uncertain whether the study is human subjects research or not.

DEFINING RESEARCH

Federal Regulations define research as **"a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.**[1]
Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities" (46.102 (1)).

For purposes of this part, the following activities are deemed not to be research:

(1) 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.[2]

(2) Public health surveillance activities, including the collection and testing of information or bio specimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public 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

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

[2] Multiple oral histories conducted to understand general social processes, how social movements generally develop, or how racial ethnic minority group members generally cope with discrimination would be human subject research.

an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, bio specimens, 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.

The term "research" includes any activity designed to test a hypothesis. Research typically involves a formal protocol that includes an objective and a set of procedures to reach that objective. Research may be deductive or inductive and rely on qualitative or quantitative methodologies.

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. 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 obtains (1) 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."** (45 CFR 46.102(f)(1),(2))

Living individual – The specimen(s)/data/information must be collected from live subjects. Cadavers, autopsy specimens or specimens/information from subjects now deceased are not considered human subjects.

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

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

Identifiable private information[3] "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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, health care records or grades)." (45 CFR 46.102(f)(2)).

"Identifiable" means the information contains one or more indirect or direct data elements that can be combined with other reasonably available information to identify an individual (e.g. Social Security #, student ID, cellular phone number, email address, etc.).

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, phone, video conferencing, email, texting, and social media interactions as well as other modes of communication.

IDENTIFYING HUMAN 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 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 contact the IRB at irb@loyola.edu or 410-617-2188. The IRB staff and/or designee will determine if the study is human subjects research. Federal regulations do not allow investigators to make this determination themselves.

STUDIES THAT ARE HUMAN SUBJECTS RESEARCH

1. **Studies that utilize test subjects for 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 asking subjects about risky behaviors or attitudes, and open-ended interviews with minors that contribute to generalizable knowledge.

3. **Studies using private information that can be readily identified with 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 all the materials/data (personal and otherwise) are coded and the investigator does not have and has never had access to the coding systems. Guidance on research involving coded private information or biological specimens is available on the web at: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.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 the impact of altering public or private working and living environments/conditions.**

STUDIES THAT ARE NOT HUMAN SUBJECTS RESEARCH

The following categories of activities typically do not require IRB review, although there may be exceptions. If you have questions, consult the IRB.

1. **Information gathered informally for class discussion or to provide ideas for creative work.** Course-related activities or independent student projects that gather information from people outside of class purely for the purposes of providing material for class discussion, demonstration, or illustration, or as background information for creative writing, theater, or other projects, are not research and do not require IRB review, even if the activity gathers information from people under 18 years of age (or other protected category), so long as the work meets the federal definition of minimal risk and it does not systematically gather information that is intended to contribute to generalizable knowledge.

2. **Class project that involve human participants and systematic research methods, but present no more than minimal risk and do not result in generalizable research.** Frequently, faculty develop course-related activities or students propose independent research projects that are designed to provide opportunities to practice research methods (e.g., interview, observation and survey techniques; data analysis; research design). If such projects are limited in scope, present no more than minimal risk to participants, and results are not generalized, they do not require human subjects review.

3. **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.

4. **Informational interviews and surveys with questions focused on things, products, or policies rather than people or their thoughts/personal opinions.** Projects where the investigator is not collecting data or private information about individual, living human beings are not human subjects research. Examples of these types of projects might include:

   - Interviews of clinical practitioners about the types of therapies available to treat certain conditions.
   - Requests for aggregated, non-identifiable demographic data about specific populations (such as those receiving services at a clinic or enrolled in a school).
   - Interviews with managers/administrators about the structure, purpose, strategies, or environmental challenges of organizations.
   - Surveys or interviews of natural resource managers about policies and practices governing the protection of endangered species.

5. **Biography or oral history research** involving a living individual that will not be generalized 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 including 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 IRB 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. Examples include program evaluations and fiscal or program audits. Any 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 is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.*

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 knowledge is not generalized to a class of individuals.

11. **Publicly available data.** Publicly available, data, such as census data or labor statistics, do not require IRB review. However, the term "publicly available" is intended to refer to record sets that are created for use by the broad public, such as census data, or federal health, labor, crime, 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 such as social media information.

12. **Coded private information or biological specimens that were not collected for the currently proposed projects, 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.

13. **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).

RESOURCES

- **Office for Human Research Protections (OHRP**)
  United States Department of Health & Human Services
  www.hhs.gov/ohrp
- **Chart for Determining if a Project is Human Subjects Research**
  Office of Human Research Protections (OHRP)
  www.hhs.gov/ohrp/policy/decisionchartttext.html
- **Engagement of Institutions in Research**
  Office for Human Research Protections (OHRP)
  www.hhs.gov/ohrp/policy/engage08.pdf
- Family Educational Rights and Privacy Act (FERPA)
  U.S. Department of Education
  https:/www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html
- Federal Policy for the Protection of Human Subjects
  www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- **Guidance on Research with Coded Private Info or Bio Specimens**
  www.hhs.gov/ohrp/policy/cdebiol.html
- The Belmont Report
  www.hhs.gov/ohrp/policy/belmont.html

CONTACT US

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