



Office of
Research Integrity



Does My Project Require IRB Review?

University of Southern Mississippi Policy and Federal Regulations require that all USM faculty, staff, and students conducting human subjects research apply for and receive approval for their research projects prior to beginning the research. Human subjects research conducted prior to or without IRB approval must be terminated immediately and all collected data must be destroyed.

Not all data involving humans qualifies as human subjects research in the federally defined sense, however. Questions about what does and does not require IRB review hinge on two key terms – what counts as research involving *human subjects* and what counts as *research*. The guidance below is intended to help clarify these two terms, and sample scenarios of projects not qualifying as human subjects research are provided. Note also the decision trees posted on USM’s IRB website: [Decision Tree #1](#) and [Decision Tree #2](#).

Regardless, if you are unsure of whether or not your project requires IRB review, contact the Office of Research Integrity at (601) 266-5997 or irb@usm.edu. Better safe than sorry!

1. Human Subjects

Federal regulatory definition of Human Subject:

“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.” [45 CFR 46.102(e)(1)].

The reference to living individuals means that cadavers, autopsy specimens, or specimens/ information from subjects who are now deceased are not “human subjects.” (The health information of deceased individuals, however, is protected under federal and some state regulations. If you plan to analyze health information of deceased individuals for your project, you should determine whether the health information

associated with the data is “Protected Health Information” (PHI) under the HIPAA Privacy Rule.)

The definition of identifiable private information:

“Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.” [45 CFR 46.102(e)(5)].

“About whom”: To be considered research with “human subjects,” the data received from a living individual must be “about” the person. For example, asking people for information on institutional policies, practices, and characteristics without asking those individuals for their evaluations or opinions of those policies, does not qualify as research with human subjects. (As an example, consider a survey of USM HR employees about the number of USM employees and the types of employee benefits are offered by the University).

When studies involve the use of archival/secondary/existing data (data collected prior to and independent of the research project in question), such as previously collected survey data, census data, or school data, *and* the researcher receives the data in a de-identified form (all identifiers and private information removed), USM IRB approval is NOT required. Some common examples of secondary/existing data that are not considered private information include, but are not limited to:

- Some information on the internet – product reviews on Amazon.com; public tweets and blogs and blog postings; public Facebook page content.
- Archives - identifiable information about individuals in a public archive
- Datasets - anonymous datasets, whether privately held or publicly available

Important: Not all information on the internet is considered publicly available and not all datasets that are characterized as anonymous actually are anonymous. Examples include comments on a non-public chatroom or listserv; restricted-access datasets; or privately held datasets in which individuals may be identified, either directly, through a code associated with a name, or through a combination of variables. In general, the federal Office for Human Research Protections (OHRP) considers private information/specimens to be individually identifiable when they can be linked to specific individuals by the researcher either directly or indirectly through coding systems. "Coded" means that:

- Identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and

- A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

For more information about “coded” information, see

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html>

Also, note that some academic journals require proof of IRB approval for research projects that USM may not consider to involve human subjects. Check journal requirements before conducting the project and contact USM’s IRB with any questions.

2. Research

Federal regulatory definition of research:

"A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" [45 CFR 46.102(l)].

The regulations state that the following activities are not deemed 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) 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).

(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.” [45 CFR 46.102(l)].

To apply the definition of research to an activity, you must look at the “design” or the “intent” of the investigation, the researcher’s relationship with the subjects, and how the data will be used.

Activities at USM that involve human subjects typically fall into one of three categories:

Research - the purpose of the activity is to contribute to “generalizable knowledge” and the data gathered may be shared with a research community or the public at large. USM considers any project conducted for an undergraduate honors thesis, a master’s thesis or a doctoral dissertation to be research.

Evaluation/Assessment/Service/Reporting - the purpose of the activity is to gather data to measure the current situation in regards to a specific phenomenon or condition. Data gathered may be shared only with the sponsor/client/requesting parties or used for internal decision making or informational purposes.

Classroom Assignments/Educational Inquiry/Practice - the purpose of these activities is the education of an individual student through an inquiry or experiential approach to discover known principles or phenomena. Data gathered may be shared only with the course instructor or faculty advisor.

Examples of studies that ARE considered research with human subjects:

1. Studies that utilize test subjects for new devices, products, drugs, or materials.
2. Studies that collect data through intervention or interaction with individuals, if the information is about the individuals (including their opinions/views/thoughts). Examples of this type of research include behavioral interventions, surveys, studies that involve deception, research involving risky behaviors or attitudes, focus groups, 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 human bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if the researcher did not collect these materials for the study. However, such research may not be considered human subjects research if the materials/data are coded and the investigator does not have access to the coding systems.
5. Studies that produce generalizable knowledge about categories or classes of subjects from identifiable private information.
6. Studies that use human beings to evaluate environmental alterations, for example, weatherization options or habitat modifications to their living or working space or test chamber.

Examples of studies that are NOT considered research with human subjects:

1. Data collection for internal departmental or other University administrative purposes. Examples: teaching evaluations, customer service surveys.
2. Information-gathering interviews where questions focus on things, products, or policies rather than people or their thoughts regarding themselves.
3. Program evaluation/quality improvement/quality assurance projects are generally not considered research if these activities are designed specifically to assess or improve performance within a school or classroom setting. The project is not designed or intended to generate conclusions that can be applied more broadly, outside of the immediate environment where the project occurs.

Important: Instructors gathering data from human subjects as part of class evaluations, assessments, service, reporting, classroom assignments, educational inquiries, or practices abrogate their rights to use the data for research purposes *absent* prior review and approval by USM's IRB.

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