Is Your Project Human Subjects Research?

A Guide for Investigators

Skidmore College Institutional Review Board

This document was prepared using excerpts from the Office for the Protection of Research Subjects at University of Southern California and the Institutional Review Board at Evergreen State College with permission. This booklet is issued to provide guidance to Skidmore 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. An IRB is an ethics committee composed of scientists and non-scientists who serve as advocates for human subjects involved in research. The Skidmore IRB is charged with the responsibility of reviewing and overseeing human subjects research conducted under the aegis of Skidmore College. 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 development, testing, and evaluation, designed to develop or contribute to generalizable knowledge**[1]" (45 CFR 46.102(d)).

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.

"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.

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

DEFINING HUMAN SUBJECTS

A **human subject** is defined by Federal Regulations as **"a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."** (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.

Identifiable private information[2] "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, a health care record)." (45 CFR 46.102(f)(2)).

"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 #).

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, and phone interaction as well as other modes of communication.

[2] 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.

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 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. The IRB Chair and/or designee will determine if the study is human subjects research. Federal regulations do not allow investigators to make this determination themselves.

If a study does not qualify as human subjects research, the IRB can issue a letter stating that the project does not require IRB review or approval.

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 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 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 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: www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf

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,** such as weatherization options or habitat modifications to their living or working space or test chamber.

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 do not lead to generalizable results, they do not require human subjects review.

3. **Informational interviews and surveys that are not about individual human beings.** 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:

- Surveys or interviews of natural resource managers about policies and practices governing the protection of endangered species.
- 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 about the structure, purpose, strategies, or environmental challenges of organizations.

4. **Oral histories and biographies.** Oral histories and biographies that describe or document particular lives, phenomena, or historical events are exempt from IRB review. However, oral histories and similar investigations that are intended to produce generalizable conclusions (e.g., that serve as data collection intended to test economic, sociological, or anthropological models/theories) *do* require IRB review.

5. **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.

6. **Research involving cadavers**, **autopsy material or bio-specimens from now deceased individuals.** However, some research in this category, such as genetic studies providing private or medication information about relatives, may need IRB review. Please contact the IRB for further information.

7. **Institutional assessment, quality assessment, quality improvement.** Gathering data and information for purposes of institutional assessment, quality assurance, or quality improvement (e.g., surveys about student satisfaction with college services, analyses of the effectiveness of academic programs, market surveys) does not generally require IRB review or approval, because such activities usually serve to assess and document matters specific to the college, rather than contribute to generalizable knowledge. The privacy of participants in these projects should be protected and participation must be voluntary. The treatment of private student information of the type frequently used in assessment is protected by the provisions of the Family Educational Rights and Privacy Act (FERPA). In some instances, assessments of this kind can have a broader applicability (such as through presentations to outside entities, or participation in multi-institutional studies that compare and contrast student characteristics) and should undergo IRB review.

8. **Case studies.** Case studies – explorations of particular individuals or small groups in very specific contexts – generally do not involve systematic investigation or lead to generalizable results and, therefore, do not meet the definition of research involving human subjects and do not require prior IRB review and approval. However, a report of a series of cases may qualify as human subjects research and should be submitted for review and approval.

9. **Publicly available data.** Publicly available, data, such as census data or labor statistics, do not require IRB review. However, investigators should contact the IRB if they are uncertain as to whether the data qualifies as "publicly available."

10. **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.

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/decisionchart text.html
  Select: *Chart 1: Is an Activity Research Involving Human Subjects?*

- **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
  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

- **Skidmore College: Institutional Review Board**
  www.skidmore.edu/irb

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