

**Do I need IRB Review? Is This Human Subjects
Research?**

A Guide for Investigators

***Human Subjects Office/IRB
Office of the Vice President for Research***

This booklet, prepared by the Human Subjects Office/IRB, provides guidance to University of Iowa investigators who may be uncertain if their study meets the definitions of human subjects research stated in the federal regulations (45CFR46.102). The HSO/IRB recognizes that the definition may not always provide a straightforward answer.

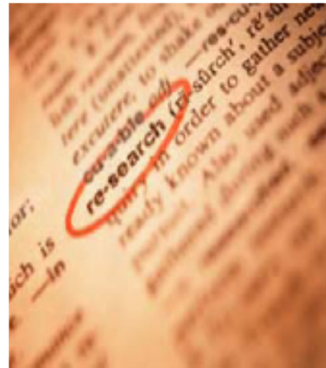
Do I need IRB Review? Is This Human Subjects Research? A Guide for Investigators offers investigators an explanation of the definitions as well as examples of studies that do or do not qualify as human subjects research. For further information, please refer to the *Resources* section in the back of this booklet. Credit is given to the University of Southern California Office for the Protection of Research Subjects (OPRS) for the concept and as a primary source of information. Credit is also given to the IRB Chairs and HSO staff for their contributions to this booklet.

HUMAN SUBJECTS RESEARCH

Research projects involving human subjects require review and approval by an Institutional Review Board. The mission of the University of Iowa Institutional Review Boards is to assure that the rights and welfare of human subjects in research are adequately protected. The IRB is responsible for reviewing and overseeing human subjects research conducted under the aegis of The Office of the Vice President of Research. The first question a researcher should consider with respect to IRB review is whether the research project fits the definition of human subjects research. To protect human subjects, and ensure that the regulatory requirement of obtaining IRB review and approval for applicable projects is fulfilled, **the investigator should err on the side of caution and submit a Human Subjects Research Determination Form when he/she is uncertain whether the study meets the regulatory definition of human subjects research.**

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(l)). As described in the Belmont Report² “...the term 'research' designates an activity designed to test a hypothesis or answer a research question(s) [and] permit conclusions to be drawn... Research is usually described in a formal protocol that



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.

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. However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge.

****Information within this booklet is defined under Office of Human Research Protections (OHRP) federal regulations only. Activities that involve clinical investigations covered under Food and Drug Administration (FDA) regulations involving human subjects require IRB review.**

DEFINING HUMAN SUBJECTS

Federal Regulations define a **human subject** as “**a living individual about whom an investigator (whether professional or student) conducting research: (1) obtains 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\(e\)\(1\)\(i\)\(ii\)\]](#)



Living individual – The specimen(s)/data/information must be collected from or be about live subjects. Research on cadavers, autopsy specimens or specimens/information from subjects now deceased is not human subjects research.

About whom – a human subject research project requires the

data received from the living individual to be **about** the person.

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. (i.e. for example, exercise, or use of a computer mouse).

Interaction includes communication or interpersonal contact between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as other modes of communication, such as completion of a questionnaire, survey, interview procedures, or focus groups.

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 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(e)(5)) **“Identifiable”** private data or biospecimens are those for which the identity of the subject is or may readily be ascertained by the investigator or associated with the data/specimen.

Observational studies of public behavior (including television and open internet chat rooms) do **not** involve human subjects as defined above 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).

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.

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. Due to the ambiguous nature of the above examples, it is fair to say the IRB will make a final determination of whether or not a specific set of data meets the requirements of publicly available.

IDENTIFYING HUMAN RESEARCH STUDIES

Some studies have characteristics of human subjects research and may or may not meet the regulatory definition listed above. There are three categories to consider:

- **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**

Investigators are responsible for obtaining IRB approval before beginning any human subjects research that meets definition above. Federal regulations do not specify who at an institution may determine that research is human subjects research. However, Office of Human Research Protections (OHRP) recommends that institutions adopt policies to ensure knowledgeable individuals assist investigators in making the appropriate decision about the status of their project and ensure that an IRB reviews all projects research that are determined to be human subjects research.



As a result, the Human Subjects Office (HSO) developed the “Human Subjects Research Determination” or HSRD Form.

This abbreviated form allows researchers to submit specific information to the IRB and receive documentation of the IRB's determination. Any investigator who is unsure of whether his/her proposal constitutes "human subjects research" should contact the HSO office and submit this Form via HawkIRB. <https://hawkirb.research.uiowa.edu/hawkirb>

The HSRD is not yet required but is highly recommended. When an investigator submits a HSRD, the IRB Chair and/or Chair designee reviews the responses to determine if the study meets the definition of human subjects research. If the IRB Chair/designee has questions about the responses, s/he will correspond with the investigator in workflow.

If the IRB Chair/designee determines the study does not qualify as human subjects research, HawkIRB will issue a memo stating that the project does not require IRB review or approval. The Principal Investigator (PI) will receive an email with a link to this memo. The PI can access the memo by logging into his/her HawkIRB Inbox, scrolling down to 'Projects', changing the filter on the project status to 'Any', and logging into the specific project. This aspect is very beneficial for researchers that require a formal determination from the IRB, i.e., grant offices, faculty advisors, or journals.

If the IRB Chair/designee determines the study constitutes human subjects research, the PI will receive an email notifying of this determination. HawkIRB automatically imports the information from the HSRD into the appropriate sections of a HawkIRB application – so the email also informs the PI that a New Project application is in the Draft Forms section of his/her HawkIRB Inbox. The PI must then complete the New Project Application and submit it for IRB review and approval before implementing the study procedures.

STUDIES THAT ARE NOT HUMAN SUBJECTS RESEARCH

Studies that fit any of the categories below typically do not need IRB review.

1. The 2018 revised definition of ‘research’ deems these four categories not human subjects research:
 - a. 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.
 - b. 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.
 - c. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
 - d. Scholarly and journalistic activities – such as such as biography, oral history, journalism, and historical scholarship - including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
[OHRP Guidance](#) clarifies that the objective should not be to develop generalized knowledge. If the activity involves using the information for purposes of drawing general conclusions about the overall group, then the activity *would* be considered research for the purposes of the regulations. 2) the determination about whether an activity is research should be made by looking at the specific activities in question, rather than by looking at the academic discipline in which that activity is situated.

2. **Data collection** for internal departmental, school, or other University administrative purposes. Examples: teaching evaluations, customer service surveys.

3. **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.

4. Information-gathering interviews where questions focus on things, products, or policies rather than people, their opinions, or their thoughts regarding themselves.

Examples: canvassing librarians about their libraries' inter-library loan policies or periodical purchases or interviews with company engineers or managers about how a product is made.



5. Course-related activities⁴ designed specifically for educational or teaching purposes, where data are collected as part of a class exercise or course requirement but are **not** intended for use outside of the classroom. *Note: Review the Guide for Human Subjects Research under Section II, Part 12.D, Course Related Student Projects for the criteria that **must** be met for this condition to be applicable. If you have **any** question as to whether or not your project meets this definition, contact the HSO at irb@uiowa.edu prior to beginning the project.*

6. Research involving cadavers, autopsy material or biospecimens from now 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.*

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

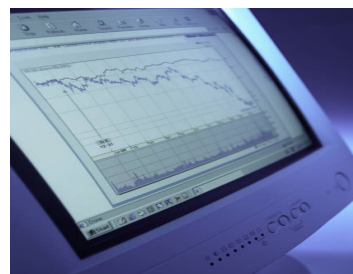
⁴ *Course work as part of a Master's Theses, Dissertation, or other Honor's Program would not fall under this category.*

therapy to particular individuals, or when the innovative therapy is investigational.) *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 individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the IRB for guidance.

Examples of QI/QA that may not need IRB review:

- A clinic implements a procedure known to reduce pharmacy prescription error rates and collects prescription information from medical charts to assess adherence to the procedure to determine whether medication error rates have decreased as expected. If so, this will be implemented as standard practice.
- A newly approved procedure has been demonstrated to reduce over-exposure in patients having multiple X-rays. Patient data are collected from medical records and entered into the database to monitor exposure to radiation. The department will analyze the data to determine if over-exposures have decreased after implementation of the new method. If so, this will be implemented as standard practice.
- Planning to publish an account of a QI/QA project does not mean that it fits the definition of research or requires IRB approval. Individuals publish results to share their knowledge about non-research topics as well. Alternately, a QI/QA project may involve research even if there is no intent to publish the results.



9. **Case history or Case Study** 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 three or fewer patients and **do not contribute to generalizable knowledge**. *Note: Investigators should contact the IRB if they are uncertain as to whether or not they are contributing to generalizable knowledge.*

10. **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.”*

11. **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 (the identity of the subject is not or may not be readily ascertained on the data or specimens). 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 cannot independently make this determination. These projects require verification from the IRB Chair or their designee.*
(<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>)

12. 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, or inform prospective subjects about the availability of research. *Note: these examples are not an all-inclusive listing.*
(<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>)

STUDIES THAT ARE HUMAN SUBJECTS RESEARCH

1. Studies that **utilize test subjects or their specimens 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 associated with individuals (or the identity may be ascertained), 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/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, for example, weatherization options or habitat modifications to their living or working space or test chamber.

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.**
www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm
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/humansubjects/assurance/engage.htm>
- 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.htm>
 - **Guidance on Research Involving Coded Private Information or Biological Specimens**
<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>
 - **The Belmont Report**
<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
 - 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

How to submit a Human Subject’s Research Determination form:

- University of Iowa: IRB Submission and Tracking Review System, HAWKIRB
<https://hawkirb.research.uiowa.edu/hawkirb>

Note: To access the Request for Human Subjects Determination application, you must login to HawkIRB and click the “Human Subjects Research Determination” tab located in the black and gold tool bar after log in.

WHOM TO CONTACT

Human Subjects Office (HSO)

University of Iowa
600 Newton Rd
105 Hardin Library for the Health Sciences (HLHS)
Iowa City, IA 52242
www.research.uiowa.edu/hso
Phone: 319-335-6564 Fax: 319-335-7310
Email: irb@uiowa.edu