IS YOUR PROJECT HUMAN SUBJECTS RESEARCH, OR NOT?...

USC

Office for the Protection of Research Subjects (OPRS)

Office of Research

This booklet, prepared by the Office for the Protection of Research Subjects (OPRS), provides guidance to USC investigators who may be uncertain if their study meets the definitions of human subjects research stated in the federal regulations (45CFR46.102).

Is Your Project Human Subjects Research, Or Not? 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.

HUMAN SUBJECTS RESEARCH

Research projects involving human subjects require review and approval by an Institutional Review Board. IRB is an ethics committee of scientists and non-scientists who advocate for human subjects in research. The IRB is responsible for reviewing and overseeing human subjects research conducted by USC or with USC faculty.

The first question a researcher should consider with respect to IRB review is whether the research project fits the definition of "human subjects and research".

When in doubt, **the investigator should err on the side of caution and consult the IRB staff to clarify whether a study is human subjects research or not.**

RESEARCH DEFINED

Research is defined by federal regulations as **"a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge"**[1].

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.

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

Research 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.

HUMAN SUBJECTS DEFINED

A **human subject** is defined by Federal Regulations[2] as **"a living individual <u>about whom</u> an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."**[3]

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

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

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. Interaction also includes face-to-face, mail, and phone interaction as well as other modes of communication.

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[2] The Department of Defense defines "Research Involving a Human Being as an Experimental Subject" as: "*An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f), reference (c)). Examples of interventions or interactions include, but are not limited to, a physical procedure, a drug, a manipulation of the subject or subject's environment, the withholding of an intervention that would have been undertaken if not for the research purpose.* (DoDD 3216.02, E2.1.3)

[3] (45 CFR 46.102(f)(1),(2))

Identifiable private information[4] "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 shared or 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 #).

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. 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 results).

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, federal and 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.

[4] 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.

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 consider:

- **Studies that <u>are</u> human subjects research**
- **Studies that <u>may be</u> considered human subjects research (gray area)**
- **Studies that <u>do not</u> qualify as human subjects research**

Any investigator who is unsure of whether his/her proposal constitutes "human subjects research" should contact the IRB office or submit an online "Request for Human Subjects Research Determination" through iStar (istar.usc.edu). The IRB staff, Chair and/or designee will determine if the study is human subjects research. Federal regulations do not recommend 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. Once a "Request for Human Subjects Determination" is submitted through iStar, a decision letter will be sent to the investigator via email. NOTE: Grant offices, faculty advisors, or publications may require a determination letter from the IRB.

STUDIES THAT <u>ARE</u> 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/policy/cdebiol.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 environmental alterations, for example, weatherization options or habitat modifications to their living or working space or test chamber.

STUDIES THAT ARE NOT HUMAN SUBJECTS RESEARCH

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

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

2. **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. 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.

3. **Information-gathering interviews** with questions focused on things, products, or policies rather than people or their thoughts/ personal opinions. Example: canvassing librarians about inter-library loan policies or rising journal costs.

4. **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. *Note: The IRB does not review classroom studies.*
5. **Biography or oral history research** involving a living individual that is not generalizable 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 involving 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 **<u>not</u>** considered research unless there is a clear intent to contribute to generalizable knowledge ***<u>and</u>*** 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. 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 do not contribute to generalizable knowledge.
11. **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".*

12. **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. 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 are not allowed to make this determination. These projects require verification from the IRB
www.hhs.gov/ohrp/policy/cdebiol.html

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/regulations-and-policy/decision-trees/index.html
  Select: *Chart 1: Is an Activity Research Involving Human Subjects?*
- **Engagement of Institutions in Research**
  www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.htmll
- **United States Food and Drug Administration**
  www.fda.gov
- **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/regulations-and-policy/belmont-report/index.html
- ***Searching for "Research Involving Human Subjects": What is Examined? What is Exempt? What is Exasperating***; Pritchard, Ivor A. *IRB: Ethics and Human Research* 23, no.3 (2001), 5-12
- **USC Office for the Protection of Research Subjects**
  oprs.usc.edu
- **University Park, Institutional Review Board, USC**
  oprs.usc.edu/upirb
- **Health Sciences, Institutional Review Board, USC**
  oprs.usc.edu/hsirb
- **USC IRB Submission Tracking and Review System (ISTAR)**
  istar.usc.edu
  To access the Request for Human Subjects Determination application, login to ISTAR and click the "request information" button under "Should I Submit My Project to HSIRB or UPIRB?"

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