This document, prepared by the Investigational Review Committee (IRC), provides guidance to Palomar Health investigators and academic students who may be uncertain if their study meets the definitions of human subjects research stated in the federal regulations (45CFR46.102). The IRC recognizes that the definition may not always provide a straightforward answer.

*Is Your Project 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 on the last page of this document.
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. At Palomar Health, the IRC is charged with the responsibility of reviewing and overseeing human subjects’ research. The first question a researcher should consider with respect to IRC 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 IRC review and approval, the investigator should choose to err on the side of caution and consult the IRC 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” (45CFR46.102(d)). As described in the Belmont Report, “...the term ‘research’ designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that 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. 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 knowledge that is generalizable across different settings.

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)). For clarity, an explanation of key terms is included below.

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 human subjects. Human subjects are often called “research participants” to further indicate voluntary participation in a study.

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.
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. "Generalizable knowledge" is information where the intended use of the research findings can be applied to populations or situations beyond the setting in the proposed study.

Identifiable private information 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 #).

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).

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. 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 of research require IRC 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 IRC office. The IRC staff, Chair and/or designee will determine if the study is human subjects research. Federal regulations do not allow investigators to make this determination themselves but must do so in agreement with other trained reviewers.

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3Researchers 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.
If a study does not qualify as human subjects research, the IRC can issue a letter stating that the project does not require IRC review or approval. NOTE: Grant offices, faculty advisors, or publications may require a determination letter from the IRC. The researcher or project coordinator should be aware if this requirement exists, and allow sufficient time for such correspondence to be generated.

STUDIES THAT ARE NOT HUMAN SUBJECTS RESEARCH

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

1. **Data collection** for internal departmental, school, or other University administrative purposes. Examples: teaching evaluations, customer service surveys, information-gathering interviews where questions focus on things, products, or policies rather than people or their thoughts regarding themselves. Example: canvassing librarians about inter-library loan policies or rising journal costs.

2. **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 IRC is only required to review studies that meet the Federal definitions of research and human subject, or “engaged in research.”

3. **Biography or oral history research** involving a living individual that is not generalizable beyond that individual.

4. **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.

5. **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 IRC review. Please contact the IRC for further information.

6. **Quality improvement projects** are generally not considered research unless there is a clear intent to contribute to generalizable knowledge and 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 IRC 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 IRC. All Quality Improvement projects must undergo IRC review, but may meet the criteria for expedited review.

7. **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.

8. **Publicly available data** do not require IRC review. Examples: census data, labor statistics. Note: Investigators should contact the IRC if they are uncertain as to whether the data qualifies as “publicly available.”

9. **Coded private information or biological specimens** that were not collected for the currently proposed projects do not need IRC 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 IRC.

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Footnotes:

4. hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
5. hhs.gov/ohrp/humansubjects/assurance/engage.htm
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: 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)
  hhs.gov/ohrp/

- US HHS Office of Human Research Protections (OHRP) Decision chart to assist in determining whether a project is human subjects research. 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
  hhs.gov/ohrp/humansubjects/assurance/engage.htm

- United States Food and Drug Administration
  fda.gov/

- Federal Policy for the Protection of Human Subjects (Common Rule)
  hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

- Guidance on Research Involving Coded Private Information or Biological Specimens
  hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf

- The Belmont Report hhs.gov/ohrp/humansubjects/guidance/belmont.htm

*This document was adapted with permission from the USC Office for the Protection of Human Subjects.