THE INVESTIGATIONAL REVIEW COMMITTEE PRESENTS

CONDUCTING RESEARCH USING HUMAN SUBJECTS

A GUIDE FOR PRINCIPAL INVESTIGATORS

PALOMAR HEALTH
HUMAN SUBJECTS RESEARCH

The Palomar Health (PH) Investigational Review Committee is responsible for making final decisions as to what constitutes human subjects research and how human subjects’ research protections must be implemented. PH adheres to the Federal Regulation 45 CFR 46 Protection of Human Subjects1 which states:

RESEARCH is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

HUMAN SUBJECT is a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual, or
2. identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place 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 medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

WHAT CONSTITUTES HUMAN SUBJECTS RESEARCH?

› Studies that use people to test devices, products, or materials that have been developed through research; to evaluate environmental alterations.

› Studies that collect data through intervention or interaction with individuals. Intervention includes not only physical procedures (e.g., drawing blood) but also manipulation of a subject’s environment (e.g., surveys, questionnaires, interviews, and focus groups). Data collection using non-individually identifiable information may be exempt.2

› Studies using private information that can be readily identified with individuals, even if the information was not collected specifically for your study.

› Studies that use bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if you did not collect these materials. However, such research may be considered exempt if materials are not personally identifiable.3

› Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information.

If your research belongs to any of the above categories, you must comply with Federal Regulations and PH’s policies for the protection of human subjects. These requirements apply if the research is conducted using PH facilities or property, supported with PH funds, or performed by PH faculty, staff, or students.

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1 See Federal Policy for the Protection of Human Subjects (45 CFR 46) for more information.

hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

2 Only the IRC has the authority to determine exemptions.

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PALOMAR HEALTH

PALOMAR HEALTH IRC REVIEW BOARD

The IRC at Palomar Health must review and approve research, quality improvement projects and evidence based practice projects if they involve human subjects or their health information. This process is designed to ensure that research and projects protect the rights and welfare of human subjects by minimizing risks, selecting subjects equitably, obtaining informed consent, and ensuring privacy and confidentiality.

IRC approval is valid for one year. If the research continues, the IRC must review and approve the study again prior to its expiration. The investigator is required to notify the IRC if subjects experience: physical injury, unexpected or adverse events, improper disclosure of private information, economic loss, and other harmful or potentially harmful occurrences.

TYPES OF IRC REVIEW

Full Board Review – Some studies involve more than minimal risk⁴ and merit Full Board Review.

These studies require a review of the proposed research at a convened meeting at which a quorum of IRC members is present. For the research to be approved, it must receive the approval of a majority of those members present.

Expedited Review – Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research. Expedited review is performed by the IRC chair, a designated voting member, or a group of voting members rather than by the entire convened IRC. Studies previously approved by IRBs with which PH has a Memorandum of Understanding are eligible for expedited review.

Exemption – When it is determined that the study does not involve human subjects (as defined in 45 CFR 46) or the involvement of human subjects is in one of the six exempt categories listed in the Regulation (45 CFR 46.101(b))⁵, it is exempt. The exempt categories include certain educational practices and tests, some studies of existing data, public service programs, and food evaluations.

Any research study involving human subjects thought to be exempt must be submitted to the IRC for a determination.

⁴Minimal risk – The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

⁵See Federal Policy for the Protection of Human Subjects (45 CFR 46.101(b) for a detailed description of exemption categories.

hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
INFORMED CONSENT

Informed consent is the process of informing potential volunteers about the key facts of a research study. The human subjects in your study must participate willingly, after having been adequately informed about the research. If the human subjects in your study are part of a vulnerable population, such as prisoners or children, special protections are required. For more information on vulnerable populations, please consult the Office of Human Research Protection (OHRP) website.

Voluntary participation means that subjects have enough information to give true informed consent. Such information includes:

- Purpose of the research.
- Benefits of the research to society and possibly to the individual human subject.
- Procedures involved in the research.
- Alternatives available should a subject decide not to participate in the research.
- All foreseeable risks or discomforts to the subject. *Note that these include not only physical injury but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- Length of time the subject is expected to participate.
- Person to contact for answers to questions or in the event of a research-related injury or emergency.
- Statement that participation is voluntary and that refusal to participate will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive.
- Subjects’ right to confidentiality and right to withdraw from the study at any time without any consequences.

Consent documents must be clearly written and understandable to subjects. The language must be nontechnical (comparable to the language in a newspaper or general circulation magazine). Scientific, technical, and medical terms must be plainly defined. It is often recommended that the informed consent be written at the sixth to eighth grade reading level. The same recommendation applies to the assent forms for minors and study recruitment materials.

Informed consent may not include language that appears to waive subjects’ legal rights or appears to release the investigator or anyone else involved in the study from liability or negligence. Templates and model consent forms are available from the IRC office upon request.

TO LEARN MORE:

- U.S. Department of Health and Human Services (DHHS): hhs.gov
- Office for Human Research Protections (OHRP) hhs.gov/ohrp/
- U.S. Food and Drug Administration (FDA) fda.gov/
- U.S. Department of Education: ed.gov

WHOM TO CONTACT:

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