



Los Angeles County Public Health, Ambulatory Care Network and
Health Services Administration Institutional Review Board
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Los Angeles County Department of Public Health Policy Regarding Institutional Review Board Review of Research and Related Activities Involving Human Subjects

The purpose is to establish policy for the Los Angeles County Department of Public Health (DPH), that the Public Health, Ambulatory Care Network (ACN) and Health Services Administration (HSA) Institutional Review Board (IRB) review all human subjects research and related activities that are sponsored by, or involve, the Department.

DEFINITIONS

A “human subject” is a living individual from whom an investigator conducting research obtains (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 “Research” is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.¹ “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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

“Identifiable private information” is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

N. B. This is a policy document for the Department of Public Health. All the basic principles in this policy and nearly all of the specific provisions also apply not only to all of DPH but also to the Department of Health Services (DHS) programs and divisions that rely on this IRB as well as the other public agencies and community-based organizations that have signed agreements to rely on this IRB. However, each agency may determine its own policies as to exactly which types of projects must be submitted for IRB review and thus there may be some variation. The IRB office or the individual department officials responsible for signing off on projects can help clarify for particular types of projects.

¹ “Non-research” is defined as 1) scholarly and journalistic activities that focus directly on the specific individuals about whom the information is collected; 2) public health surveillance activities limited to those necessary to identify, monitor, assess, or investigate conditions of public health importance; 3) collection and analysis of materials for criminal justice purposes; and 4) authorized operational activities for national security purposes.

“Related activities” means any process that involves collecting data from or about individuals other than that related to provision of clinical care or conducting statutorily mandated surveillance and disease or environmental investigation.

ETHICAL PRINCIPLES

The IRB is guided by the ethical principles for research involving human subjects stated in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report). DPH specifically recognizes the Belmont Report’s principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice and applies these principles in all research covered by these policies and procedures.

In addition, all DPH-funded or conducted research must meet the requirements stated in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) often referred to as the “[Revised Common Rule](#).” Any research involving products regulated by the U. S. Food and Drug Administration (FDA) must meet the requirements of 45 CFR 46 and FDA regulations for protecting human subjects, 21 CFR 50 and 56.

DPH abides by all criteria as set forth by the federal regulations for protecting human subjects and defines their ethical principles in keeping with and beyond the Final Rule’s mandates as well as state and local laws. This includes but is not limited to requiring a commitment by principal investigators to disseminate the findings to stakeholders and the community from which the subjects are recruited, e.g., through community-level outlets and methods.

POLICY

DPH acknowledges and accepts its responsibility for protecting the rights and welfare of human research subjects and all individuals from or about whom it collects individual-level data.

DPH acknowledges that it and especially its investigators bear full responsibility for performing all research covered by this policy, including complying with federal, state, and local laws as they apply to such research.

The boundary between “research” and other activities that may be considered “practice” or otherwise not research, e.g., systematic program evaluation, quality improvement and needs assessment, is often hard to delineate; the methods and intent are overlapping. DPH acknowledges its responsibility for protecting the rights and welfare of all individuals with whom we interact and from or about whom collect data whether in a formal research project. Furthermore, the federal Final Rule and the oversight U.S. Department of Health and Human Services (HHS) Office of Human Research Subjects Protections (OHRP) explicitly grant authority to institutions such as DPH to expand protections and procedures beyond the minimum required by law. Therefore, DPH explicitly considers these ethical principles and these review and oversight procedures to apply to all activities in which individual-level data are collected, with the exception of the collection of data in the course of providing clinical care or conducting statutorily mandated surveillance and disease outbreak or environmental investigations. The DPH IRB may simplify or otherwise modify the specific manner of complying with the following requirements for projects classified as “non-research,”¹ but the principles must be embodied in an appropriate form in all projects and all projects are subject to IRB review and oversight.

DPH assures that it and its investigators will satisfy the following requirements before involving human subjects:

1. Risks to participants are minimized: a) by using procedures that are consistent with sound research design but do not unnecessarily expose participants to risks, and b) whenever appropriate, researchers do not duplicate procedures that are already being performed on participants for prevention, diagnostic, or treatment purposes.
2. Risks to participants are reasonable compared to the knowledge that might reasonably be expected to result.
3. Participant selection is equitable.
4. The principal investigator will acquire informed consent appropriate to the project from each prospective participant or the participant's legally authorized representative, unless otherwise exempted by state or federal law.
5. When required, the principal investigator will appropriately document informed consent and will retain it in a secure manner such as a locked file cabinet or protected computer server.
6. The research plan ensures participant safety.
7. Each research project will have adequate provisions to protect individual participant's privacy and maintain data confidentiality.
8. DPH recognizes that for those who are likely to be vulnerable to coercion, undue influence or heightened risks, such as children, prisoners, pregnant women, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, the research plan needs appropriate additional safeguards. Aforementioned potentially vulnerable subjects are defined by federal regulations; however, DPH requires principal investigator to identify other study subjects who may belong to vulnerable groups and create measures to protect these subjects.
9. DPH encourages and promotes constructive communication among its administrators, research supervisors, research investigators, and all other relevant parties to maintain a high level of awareness for safeguarding research subjects' rights and welfare.
10. DPH oversees projects by reviewing each open full board review project at least annually to assure that investigators are effectively applying its practices and procedures designed for the protection of the rights and welfare of human subjects. Exempt and expedited review projects' annual review will be required if Chair of the IRB or Staff designates it as such at time of original approval. Justification criteria will be documented such as 1) potential vulnerability of the population, 2) potential controversy of findings, 3) potential sensitivity of data if breached and other criteria deemed appropriate by DPH. The principal investigator is still obligated to notify DPH of any changes or modifications to study protocol regardless if continuing review is required.
11. DPH posts this statement of ethical principles and policy on its Web page as a separate document.
12. DPH requires that principal investigators and other key project staff be trained in the rights and welfare of human subjects.
13. DPH additionally requires that each project approved by the IRB: a) addresses an important public health or health services problem; b) employs an appropriate methodology and analysis plan capable of

yielding valid information about the problem; c) describes means by which the resulting data will be utilized and/or shared with community and other stakeholders; d) includes appropriate community consultation and engagement and communicating risks and potential harms to the community; and e) includes provisions for being conducted in or translated/interpreted into whatever languages are primarily spoken by a significant proportion of the source or target population.

14. DPH requires that principal investigators be appropriately qualified for conducting research and disseminating findings. This may include appropriate training, professional experience and activities, and presentations/publication efforts but does not necessarily require a terminal degree for principal investigators.

RESPONSIBILITIES

The director of each bureau, division, program or office in DPH is responsible to ensure that the Chair of the IRB is consulted on any project or activity in his or her jurisdiction that may involve human subjects research or related data-collection activities not explicitly exempt by law, i.e., clinical care and statutorily mandated surveillance or investigation.

Unless the Chair of the IRB determines that a proposed project or activity is legally exempt from review, the proposal will be submitted for the appropriate level of review by the IRB. The IRB must approve or exempt the proposed project or activity before it can begin.

The director of each bureau, division, program or office in DPH shall ensure that all IRB requirements are fulfilled, including prompt reporting of modifications to approved protocols, complaints, and adverse events. He or she shall ensure that approved projects are submitted for re-approval prior to the approval expiration date, if the project will continue past this date, and that the IRB is notified when all activities have been completed, including analyses and preparation of manuscripts or reports, and a final report submitted.