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Los Angeles County Department of Public Health Institutional Review Board Policy (IRB) Regarding IRB Review of Research and Related Activities Involving Human Subjects

PURPOSE:

To set forth procedures through which the Institutional Review Board (IRB) for the Los Angeles County Department of Public Health IRB, which serves as the IRB of record for the Department of Public Health (DPH), Department of Health Services Ambulatory Care Network (ACN) and Health Services Administration (HSA) and select community-based organizations (CBOs) and health departments, reviews all human subjects research and related activities. This policy applies to all research and related activities that are sponsored by, or involve, DPH, ACN, and HSA, and select CBOs and health departments, including subjects who receive clinical care and community-based services.

SCOPE:

This policy ensures that research and related activities that are sponsored by, or involve, DPH, ACN, and HSA, meet the requirements stated in Code of Federal Regulations (CFR) Title 45, Subtitle A, Subchapter A, Part 46: Protection of Human Subjects ("Revised Common Rule"). This policy further sets forth expansions of these protections as permitted by the Revised Common Rule and the oversight of the U.S. Department of Health and Human Services (HHS) Office of Human Research Protections (OHRP). Closely related are the U.S. Food and Drug Administration (FDA) regulations for protecting human subjects, 21 CFR 50 and 21 CFR 56. This policy excludes the collection of data in the course of providing clinical care or conducting statutorily mandated surveillance and disease outbreak or environmental investigations.

DEFINITIONS

A "human subject" is a living individual from whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or their legally authorized representative, or (2) identifiable private information.

"Research" is (1) a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, or (2) a systematic collection or analysis of data with the intent to generate new knowledge.

"Related activities" means any process that involves collecting or analyzing data from or about individuals other than that related to provision of clinical care or conducting statutorily mandated surveillance and disease or environmental investigation. Examples of "related activities" include but are not limited to: 1) activities that may be considered "practice" or otherwise not research, 2) program evaluation, 3) quality assurance and improvement, 4) non-legally mandated surveillance, and 5) needs assessments.

A "principal investigator" (PI) is the person responsible for all aspects of research and related activities, including methodology, recruitment, data collection, data analysis, ethical conduct, and compliance with all state and federal regulations as well as the policies of this IRB. For related activities, the term "project lead" can be used to refer to the person with the same responsibilities as a PI.

A "co-principal investigator," or "co-PI," is a person who 1) has an equally shared responsibility with the PI for the conduct of a project; and/or 2) has delineated responsibilities such as being the local investigator for a site on a multi-site study. Each study/project should designate no more than one co-PI.

A "DPH or DHS liaison" is a person who is responsible for the conduct of a project when the PI, project lead or co-PI is not a DPH or DHS permanent employee.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATORS/PROJECT LEADS:

Prior to initiation of any research or related activities, principal investigators PIs/project leads will submit the appropriate application forms, certificates, and protocol to inform the IRB that their research or related activities will ensure the following:

1. Risks to participants will be minimized. Risks to participants will be reasonable compared to the benefits to the subjects and/or scientific community. Participant safety will be ensured.

2. Documentation of an informed consent process appropriate to the project for each prospective participant or the participant's legally authorized representative will be obtained to ensure voluntariness of participation, unless otherwise exempted by state or federal law. When exempted from the requirement of a written informed consent document, some form of "effective" consent (e.g., verbal consent, consent language embedded in a data collection instrument, simplified written consent) will be obtained from the participants. Informed consent will also include adequate protection of those who are likely to be vulnerable to coercion, undue influence or heightened risks, such as children, prisoners, pregnant individuals, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Informed consent will be appropriately obtained and stored in a secure manner.

3. A Health Insurance Portability and Accountability Act (HIPAA) authorization or waiver of authorization if approved by the IRB.

4. Adequate provisions will ensure protection of individual participant's privacy and data confidentiality.

5. The projects will: 1) address an important public health or health services problem; 2) employ an appropriate methodology and analysis plan capable of yielding valid information about the problem; 3) describe the means by which the resulting data will be utilized and/or shared with community and other stakeholders; 4) include appropriate community consultation and engagement and communication of risks and potential harms to the community; 5) include provisions for a project to be conducted in or

translated/interpreted into those languages which are primarily spoken by a significant proportion of the source or target population and at a reading level for all study documents at an appropriate level for the target population; 6) address and ensure healthy equity, including, but not limited to, equitable participant inclusion criteria and participant recruitment/selection; and 7) provide compensation and/or reimbursement as appropriate.

6. PIs/project leads and all personnel accessing, collecting, analyzing, or otherwise working with data will be trained in the rights and welfare of human subjects and provide documentation of such training every three years.

7. PIs/project leads will be qualified for conducting research and disseminating findings. This may include appropriate training and professional experience but does not necessarily require an advanced or terminal degree for principal investigators. Students may serve as PIs/project leads for projects related to their academic programs as appropriate so long as supervision is clear and a DPH or DHS staff member is serving as liaison or co-PI and will take ultimate responsibility for compliance with these policies. Junior-level staff and contractors may also serve as PIs/project leads under appropriate supervision of an experienced DPH or DHS staff person.

8. PIs/project leads and the home institution will not have financial and/or intellectual property interests in the sponsor or the products used in the project. PIs/project leads and other research personnel shall disclose any conflict of interest (including potential conflicts involving their immediate family/domestic partner), including gifts, meals, and financial interests of any amount, involving the sponsor or products used in the research project.

9. When needed, PIs/project leads will coordinate with Program Contracts and Grants Liaisons to obtain appropriate data use agreements to use DPH or DHS data.

10. PIs/project leads will demonstrate adequate plans to include collection of data on health equity, diversity, and inclusion unless there is a compelling justification not to collect these data and this justification is documented in writing by the PI/project lead.

11. PIs/project leads will also: 1) request an annual continuing review for projects if requested or required by the IRB; 2) notify the IRB of any changes or modifications to the project protocol regardless of whether continuing review is required; 3) notify the IRB of an adverse event as soon as known by the PI/project lead and no later than 7 days from occurrence; 4) submit an annual progress report and a final report upon completion of the project, including any summary reports or manuscripts or risk automatic closure of project; 5) not begin study activities until the IRB has granted approval; and 6) adhere to all policies and procedures of the IRB.

12. PIs/project leads will ensure that their research team is prepared to comply with an audit request.

RESPONSIBILITIES OF THE IRB:

The IRB will convene once a month to review projects deemed full board review projects by the Chair or Vice Chair of the IRB. Otherwise, exempt and expedited review projects will be reviewed and acted upon by the Chair and Vice Chair without waiting for convened meetings**.** Those projects classified as exempt or expedited will be brought to the IRB membership, and some may be scheduled for consultative discussion, as deemed necessary by the Chair or Vice Chair or any IRB member.

The IRB will reserve the right to determine the level of review of a project at time of initial review or amendment submission.

The IRB will reserve the right to require an annual continuing review for exempt or expedited review projects if the Chair or Vice Chair of the IRB designates it as such at time of original approval. Justification criteria will be documented such as vulnerability of the population, sensitivity of the data if breached, and other criteria deemed appropriate by the IRB. The IRB will offer quarterly or as-needed training on the rights and welfare of human subjects.

The IRB will reserve the right to perform routine audits of approved research and related activities, including but not limited to a review of project documents utilized in such activities.

When needed, the IRB will provide technical assistance regarding IRB principles and their applications, and other areas, including but not limited to best practices regarding study design and procedures for engaging the community.

The IRB will post this document on its website at: http://publichealth.lacounty.gov/irb/.