Los Angeles County Department of Public Health Institutional Review Board (IRB)
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Los Angeles County Department of Public Health Institutional Review Board (IRB) Policy 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, which serves as the IRB of record for the Department of Public Health (DPH), Department of Health Services (DHS) Ambulatory Care Network (ACN), Correctional Health Services (CHS) and Health Services Administration (HSA), and select community-based organizations (CBOs), reviews all human subjects research and related activities. This policy applies to all research and related activities that are sponsored by, or involve, ACN, HSA, CHS and select CBOs, 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, ACN, CHS , HSA, and select CBOs, 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") as informed by the guiding ethical principles described in the Belmont Report.[1] This policy further sets forth expansions of these protections as permitted by 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, conducting local, state or federal statutorily mandated surveillance, environmental or criminal investigations, or activities in support of national security measures.

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.

[1] Written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979, the Belmont Report identifies the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects. Citation: Belmont Report (1979). The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research.

"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, accessing or analyzing data from or about human subjects, other than those activities meeting the regulatory definition of "research." Examples of "related activities" include but are not limited to activities that may not be considered research such as 1) program evaluation for external use and/or publication; 2) certain quality assurance and improvement projects; 3) certain non-legally mandated surveillance;[2] and 4) needs assessments. This excludes 1) anonymous meeting evaluations; 2) customer satisfaction surveys that do not collect/access data about persons belonging to vulnerable populations such as minors; 3) customer satisfaction surveys that do not collect/access data that involve sensitive topics such as substance use/disorder; 4) customer satisfaction surveys that do not collect/access personally identifiable information (PII) or protected health information (PHI); 5) staff assessments or other internal queries that pertain to core job duties and skills; 6) program evaluation for internal use with no intention to publish and that do not collect/access data that involve sensitive topics such as substance use/disorder or that do not collect/access data about persons belonging to vulnerable populations; or 7) evaluations for internal use for trainings that are linked to receiving Continuing Education units or certificates of completion or that do not involve vulnerable populations and/or where the IRB determines that informed consent is not required for participation in the trainings.

A "principal investigator" (PI) is the person responsible for all aspects of research, including methodology, recruitment, data collection, data analysis, ethical conduct, and compliance with all local, 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. A study/project should designate no more than one co-PI, but a co-PI is not required.

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

"Key personnel" includes all staff who help carry out the project including recruitment of participants, obtaining consent from participants (if applicable), data collection and management, data analyses (including aggregated data), and dissemination of results.

A "reliance agreement" is a document, signed by two or more institutions engaged in human subjects research, that permits one or more institutions to cede review to another IRB. The signed agreement permits a single IRB to review human subject research activities for more than one site, as is required by the Revised Common Rule for certain types of federally-supported studies involving multiple sites [45 CFR 46.114(b)].

[2] This may include surveillance data used for other than its original purpose.

"Engagement" [3] means when employees or agents of ACN, HSA, CHS or the CBOs mentioned above , including staff, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation, for the purposes of a research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATORS/PROJECT LEADS:

Prior to initiation of any research or related activities, PIs/project leads will submit the appropriate application, training certificates, protocol, and pertinent study materials via the electronic platform IRBManager 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 informed consent will be obtained using a process that ensures voluntariness of participation for each prospective participant (or the participant's legally authorized representative), unless otherwise waived by state or federal law. When waived 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 (or participants' legally authorized representative). The informed consent process will also include adequate protection of those who are likely to be vulnerable to coercion, undue influence or heightened risks, including but not limited to 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 a waiver of authorization (if strongly justified and approved by the IRB), will be obtained for data collection/analysis involving Protected Health Information (PHI).

4. Adequate provisions will ensure protection of individual participant's privacy and data confidentiality. Approval by the Departmental Information Security Officer (DISO) must be obtained for DHS projects.

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 health equity, including but not limited to equitable participant inclusion criteria and participant recruitment/selection; [4] 7) provide incentives and/or reimbursement as appropriate.

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[3] "Engagement" defined according to the 45 CFR 46; not to be confused with "community engagement."

[4] Please refer to the Los Angeles County Department of Public Health Institutional Review Board (IRB) Policy Regarding Health Equity, Diversity and Inclusion in Research or Related Activities Reviewed by the IRB, available here: http://publichealth.lacounty.gov/irb/Docs/DPH_IRB_Health_equity_policy_3_26_2024_FINAL.pdf

6. PIs/project leads and all key 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 through the IRB's Teams training or online CITI training, or on-demand Spanish-language training available upon request from the IRB. In addition, all such personnel will also be trained in the HIPAA Privacy, Security, and Breach Notification Rules every two years (accessible through the CITI website).

7. PIs/project leads will be qualified to conduct research and disseminate findings. This may include appropriate training and professional experience but does not necessarily require an advanced or terminal degree for principal investigators. For DHS projects, students may serve as PIs/project leads for projects related to their academic programs as appropriate so long as supervision is clear and an experienced permanent DHS employee serves as co-PI and will take ultimate responsibility for compliance with this policy and federal regulations 45 CFR 46. Junior-level staff, contractors, interns and volunteers may also serve as PIs/project leads under appropriate supervision from an experienced permanent DHS employee as co- PI. For CBOs, a permanent member of the CBO research staff must serve as co-PI for projects with students, interns, junior-level staff, contractors and volunteers serving as PI.

8. PIs/project leads will not have financial and/or intellectual property interests in any financial sponsor(s) of the project or any product(s) 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/spouse), including gifts, meals, and financial interests of any amount, involving financial sponsor(s) of the project or product(s) used in the research project.

9. PIs/project leads will demonstrate adequate plans to include collection of data on health equity, diversity, and inclusion in accordance with the Los Angeles County Department of Public Health Institutional Review Board (IRB) Policy Regarding Health Equity, Diversity and Inclusion in Research or Related Activities Reviewed by the IRB unless there is a compelling justification not to collect these data and this justification is documented in writing by the PI/project lead.

10. PIs/project leads will also: 1) submit an annual continuing review for projects if requested or required by the IRB; 2) submit an amendment request to notify the IRB of any changes or modifications to project activities or key personnel changes, regardless of whether continuing review is required; 3) submit an amendment request to notify the IRB of any changes to the PI/project lead, co-PI, or the organization's program/division director as soon as possible and before they vacate their positions, as they are required signatories for IRB applications and future applications may be delayed due to inaccurate personnel information or inability to contact individuals; 4) notify the IRB of an adverse/reportable event, such as participant injury or data breach, as soon as known by the PI/project lead or Co-PI and no later than 7 days from occurrence; 5) 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 the project; 6) not begin study activities until the IRB has granted approval and the PI/project lead has received the formal approval letter; and 7) adhere to all procedures set forth by the IRB.

11. PIs/project leads will ensure that their research team is prepared to comply with an internal audit request as initiated by the Office of the IRB.

12. PIs/project leads will contact the IRB to receive a letter of determination of Not Research, Not Human Subjects Research or Not Engaged (i.e., DHS/CBOs not considered to have a significant role in the project activities) prior to beginning any such activities. Most non-legally mandated surveillance or standard public health practice will be exempt from this requirement; however, the IRB must be informed of surveillance activities involving prisoners, minors and pregnant women before such activities begin. Letters of determination will not be issued after manuscripts have been completed and

are ready for submission for publication. PIs/project leads will provide a description of the project activities including the purpose of the project, source(s) of data, method(s) of data collection, data elements to be collected/accessed, and the name(s) of the key personnel who will have access to the data. The PI/project lead will notify the IRB prior to implementation of any changes to project activities by way of an email to irb@ph.lacounty.gov so that the IRB can re-assess whether the original determination continues to be appropriate in light of the proposed changes.

13. PIs/project leads who wish to request, via a reliance agreement, that DPH IRB serve as reviewing/relying IRB will reach out to the Office of the IRB as soon as they make plans for collaborative research.

RESPONSIBILITIES OF THE IRB/OFFICE OF THE IRB:

1. The IRB will convene once a month to review projects deemed full board review projects by the Chair or Vice Chair of the IRB. Projects involving prisoners, parolees or probationers will be brought to the full board with the exception of secondary data analysis involving any of these populations, which will be reviewed as expedited or full board according to the determination of the IRB's prisoner advocate(s). Otherwise, exempt and expedited review projects will be reviewed and acted upon by the Chair, Vice Chair and IRB analyst without waiting for convened meetings**.** Those projects classified as exempt or expedited will be reported to the IRB membership at the next convened meeting, and some may be scheduled for consultative discussion with Board members, as deemed necessary by the Chair or Vice Chair or any IRB member.

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

3. The Office of 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.

4. The Office of the IRB will offer quarterly or as-needed training on the rights and welfare of human subjects.

5. The Office of 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.

6. When needed, the Office of 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.

7. When the Office of the IRB determines that the appropriate conditions have been met, the Office agrees to act as the IRB of record (as "reviewing IRB") allowing other institutions to cede review to DPH IRB, and also agrees to cede review (as "relying IRB") to an external IRB, as applicable. The IRB's agreement to serve as reviewing/relying IRB will be documented via a reliance agreement in the online documentation website SMART IRB or a signed reliance agreement.

The Office of the IRB will post this document on its website at: http://www.publichealth.lacounty.gov/IRB/