

Development of an Institutional Review Board Health Equity Policy

Los Angeles County Department of Public Health (LACDPH)



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Objectives

In this presentation you will learn about:

- The ethical principles underlying research and health equity and corresponding federal regulations
- LACDPH IRB's role as a public health IRB
- LACDPH IRB's Health Equity Initiative and key findings
- LACDPH IRB health equity standard of practice/policy



A HEALTH EQUITY FOCUS



- LACDPH prioritizes health equity
 - Mission: ***“Advance the conditions that support optimal health and well-being for all”***



- Internal Standards of Practice (SOP) data collection guidance to support health equity
 - Race/Ethnicity
 - Disability status
 - Sexual orientation and gender identity



ESTABLISHMENT of the LACDPH IRB and ETHICAL PRINCIPLES

- Creation of IRB mandated by LAC Board of Supervisors in 1999
 - HIVNet
 - Enabled research to continue in our communities
- The Belmont Report
 - Respect for persons
 - Beneficence
 - Justice
- The federal regulations
 - The “Common Rule”

A PUBLIC HEALTH IRB



- Expanded purview of the Common Rule as permitted by Health and Human Services (HHS) Office of Human Research Protections (OHRP)
 - The Common Rule is the floor, not the ceiling
 - We review “related activities” as well
 - Evaluations
 - Needs assessments
 - Certain QA/QI projects



- Who our IRB serves
 - LACDPH
 - LAC Department of Health Services
 - Correctional Health Services
 - Ambulatory Care Network
 - Community and population health programs
 - Select Los Angeles-based community-based organizations via MOUs

THE LEGAL BASIS for HEALTH EQUITY in RESEARCH: THE COMMON RULE

- **45 CFR 46.116[a](3)**
“The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.”
- **45 CFR 46.111[3]**
“Selection of subjects is equitable.”



Source: <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46?toc=1>



THE LEGAL BASIS for HEALTH EQUITY in RESEARCH (CONT.)

- **45 CFR 46.107(a)**

“The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.”

Source: <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46?toc=1>

HEALTH EQUITY INITIATIVE (HEI)



- Draft SOP submitted to Chief Science Officer in mid-2021
- HEI working group established in late 2021 to collect data to inform revision of the SOP
- Shared goals:
 - Collect qualitative and quantitative data to inform revision
 - Roadmap for DPH investigators
 - Ensure accountability

HEALTH EQUITY INITIATIVE (CONT.)

- Meeting structure
 - Vice Chair, Chair, Chair Emeritus, IRB analyst, MPH student workers, MPH-trained fellow (one year)
 - Met every 2 weeks virtually
- Research activities to inform SOP
 - Literature review
 - Key informant interviews
 - Annual survey
- IRB approval obtained for initial research activities and amendments (e.g., addition of evaluation)
- Regular IRB activities continued



KEY INFORMANT INTERVIEW (KII) METHODOLOGY

- To assess:
 - Shared definitions of health equity
 - Organizational commitment to health equity
 - Individual commitment/involvement
- Sample
 - 14 individuals interviewed via Teams
 - Known involvement in research and other data-gathering activities or health equity work in Los Angeles County
 - Professional contacts
- Thematic domains
 - *Defining health equity*
 - *Health equity in research*
 - *Barriers to health equity in research*
 - *Measuring health equity in research*
 - *Organizational support for health equity*
 - *Funding for addressing health equity in research*



KII KEY FINDINGS

“Did you check in with community members and a diverse set of community members? Because I think what happens oftentimes is we assume that one organization has a pulse on an entire community, but they may only interact with a segment of it.”

-Key informant



- All 14 informants reported their **organizations are supportive**; extent varied
 - Respondents' organizations needed to do a better job of **providing training** related to community engagement in research and conducting research in and with diverse populations (8 informants)
- Major barrier to health equity in research is a **lack of trust** between the community and researchers (8 informants)
 - Other barriers:
 - **Inadequate funding** and resources (8 informants)
 - **Lack of study materials** offered in appropriate languages and reading levels (4 informants)



ANNUAL SURVEY METHODOLOGY

- To serve as annual cross-sectional “temperature check” informed by KII
- Sample
 - 18+ years of age, English-speaking
 - Current or previous involvement in research or other data-gathering activities in LA County
- Survey period
 - Early November 2022 and 2023
 - Survey link and 3 reminder emails sent throughout a 2-week period
 - \$10 gift card offered in 2023
- Example questions
 - Biggest barriers to achieving equity in research?
 - Actions the IRB can take to help ensure that research is conducted more equitably?
 - Methods of community engagement you have utilized in your research?

ANNUAL SURVEY - YEAR 1 and YEAR 2 KEY FINDINGS

Response rate:

Year 1 – 24.5% (n=155)

Year 2 – 18.2% (n=66)

Sector	Year 1 (n=153)	Year 2 (n=66)
Academic	49%	58%
Governmental	20%	23%
Independent Research		
Organization	20%	11%
Non-Profit	11%	9%

Top 2 barriers to addressing health equity in research:

1. Availability of funding
2. Lack of trust between community and researchers

Top 3 most commonly used methods of community engagement were:

1. Community engaged in research design
2. Community engaged in recruitment
3. Community engaged in data collection



ANNUAL SURVEY - YEAR 1 and YEAR 2 KEY FINDINGS (CONT.)

Top 3 **actions the IRB can take** to help ensure research is conducted more equitably:

1. Provide written guidelines/policies for addressing equity in a research protocol/proposal
2. Provide education/training on how to integrate health equity into research process
3. Provide metrics/indicators to track adherence to equitable research practices



“IRB should offer consultations, education, and training on how to incorporate health equity principles into research projects.”

-Survey Respondent



LIMITATIONS

- Convenience sampling
- Non-response bias
- Self-reported data



DEVELOPMENT of INTERNAL STANDARD of PRACTICE and EXTERNAL POLICY

- **Revisions to original draft of SOP included a focus on:**
 - Community engagement
 - Equity of recruitment
 - Appropriate languages and reading levels
 - Collection of health equity data
 - Dissemination
- **Edits/levels of review**
 - Addition of resources, articles, toolkits



SOP/POLICY EVALUATION PLAN

- Evaluation survey administered to IRB applicants before and after SOP/policy dissemination
- SOP/policy link embedded in electronic IRB application
- Evaluation survey link embedded in electronic IRB application
- Key questions:
 - How are projects addressing health equity
 - How are projects following SOP/complying with policy
 - What barriers prevent projects from following SOP/complying with policy
- Completely voluntary; has no bearing on IRB review



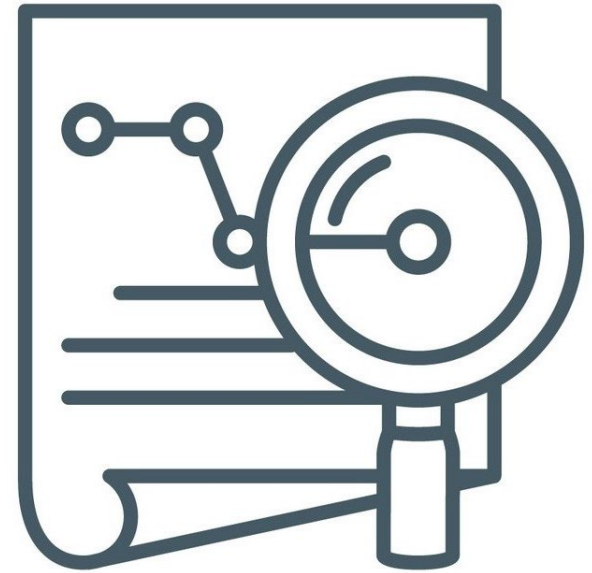
BASELINE EVALUATION KEY FINDINGS

- Response rate: 59% (n=42)
- Respondents from governmental organizations: 86% (n=36)
- Top 3 **methods for addressing health equity** researchers planned to use in their project (n=38)
 1. Study data collected is relevant to the examination of health equity (66%)
 2. Project materials are available in reading levels that are appropriate to the target population (63%)
 3. Research question addresses health equity (61%)
- Top 3 **methods of community engagement** researchers planned to use in their project (n=26)
 1. Community member(s)/organization(s) consulted during research design (58%)
 2. Community member(s)/organization(s) actively involved in recruiting research participants (50%)
 3. Research findings disseminated via lay fact sheet made available to public (50%)



BASELINE EVALUATION KEY FINDINGS (CONT.)

- Top 3 ways researchers **planned to track** whether project is addressing health equity (n=20)
 1. Research question addresses health equity (65%)
 2. Study data collected is relevant to the examination of health equity (60%)
 3. Project materials are available in reading levels that are appropriate to the target population (55%)



DISSEMINATION



- Posters/Sessions:
 - Public Responsibility in Medicine and Research (PRIM&R) 2022, 2023
 - Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) 2024, 2025
- Networking with partners
 - Government
 - Academia
- Manuscript



RECAP: TIMELINE and DELIVERABLES

- **July 2021:** Draft SOP submitted to Chief Science Officer
- **December 2021:** Health Equity Initiative working group established
- **April-May 2022:** Key informant interviews conducted
- **November-December 2022:** Key informant interview report completed, Year 1 cross-sectional survey administered, poster presented at PRIM&R
- **August 2023:** Baseline evaluation data collection started
- **November 2023:** Year 2 cross-sectional survey administered
- **February 2024:** SOP revised and approved by Chief Science Officer; adapted for external policy
- **August 2024:** Baseline evaluation data collection completed
- **September 2024:** Evaluation post-test data collection started
- **October 2024:** Year 1 and Year 2 cross-sectional survey reports completed and evaluation baseline findings report submitted for review



NEXT STEPS

- Complete evaluation data collection and analysis
- Continued guidance/technical assistance for researchers
- Tracking health equity metrics





“Capacity building needs to happen on the community side for research to be more equitable, or community representation could be performative. Community members seem to be very engaged in research studies when they see the benefits and outcomes of research, so researchers need to do a better job in explaining [how] communities are benefiting from all of these research projects.”

– Key informant



FOR YOUR REFERENCE:

- [The Belmont Report](#)
- [The Federal Regulations \(The Common Rule\)](#)
- [LACDPH IRB Policy Regarding Health Equity, Diversity and Inclusion in Research or Related Activities Reviewed by the IRB](#)
- [LACDPH IRB Health Equity Initiative reports](#)



Any questions?





Thank you!

Email us:

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Visit our website:

<http://publichealth.lacounty.gov/irb/index.htm>