



Community Engagement in Research, Evaluation, and Related Activities Workshop

April 8, 2025

Alysia Kwon, ScM

Director, Office of the Institutional Review
Board (IRB)





Ground Rules

- Please keep your microphones on mute
- Please enter your questions in the chat box or raise your hand using the reaction buttons
- Presentation slides are available on the IRB website
- Certificates of completion will be available on Talent Works after the training
- This training **DOES NOT** fulfill the Human Subjects Protection Training and will not address the IRB application process
- Please remember this is a safe space and be respectful of others and their opinions



Training Objectives

After completing this training, you will have a better understanding of:

- The principles underlying Community Engaged Research
- The benefits of engaging the community in research
- Strategies for engaging members of the community in your projects
- Ethical considerations regarding Community Engaged Research
- DPH IRB Health Equity Initiative

REMINDER: This training **DOES NOT** fulfill the Human Subjects Protection Training and will not address the IRB application process

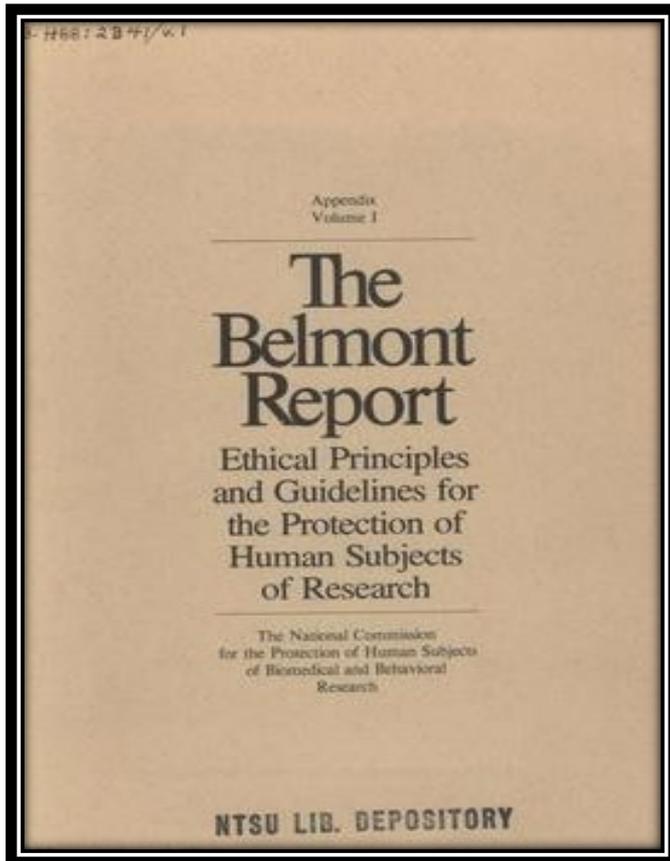


Review: Principles and History

- USPHS Untreated Syphilis Study at Tuskegee, 1932-1972
- Willowbrook Hepatitis Experiments, 1955-1970
- Milgram's experiments on obedience, 1960s

An Ethical Framework

- Belmont Report, 1979
 - National Research Act, 1974 - National Commission of the Protection of Human Subjects of Biomedical and Behavioral Research
 - Provided the foundation for the federal human subjects research regulations known as “the Common Rule” (45 CFR 46)



Principles Outlined in The Belmont Report

Basic Principles of Biomedical Research Ethics

- **Respect for Persons**
 - Autonomy
- **Beneficence**
 - Minimize harm, maximize benefits
- **Justice**
 - Equity of risks and benefits



Legal Basis for the IRB



The “Common Rule” (45 CFR 46)

- Published in 1991, revised in 2017-2018
- Outlines basic requirements for IRBs



LAC Board of Supervisors, 1999

- HIVNet
- Lack of community sensitivity and engagement
- Creation of LAC DPH IRB

What is the DPH IRB?

- Oversight entity housed in DPH
- Board made up of **15 people**
 - Minimum 5 members
 - Diverse across race, gender, cultural background
 - Scientist, non-scientist
 - Not affiliated with institution (community members)
 - Prisoner advocates
- Meets once a month, every fourth Thursday





DPH IRB Policy on IRB Submission

Any project involving collection or analysis of data from or about individuals, whether “research” or not:

- Needs IRB determination of whether IRB review is needed
- A project is anything involving staff, facilities, clients, patients, funding, databases from DPH, DHS, etc.

The best policy is to **ask** via e-mail if you are not sure... **AND never assume** that a past determination by the IRB will automatically apply to a new project



Related activities requiring review

“Related activities” means any process that involves collecting, accessing or analyzing data from or about individuals other than research, including but not limited to:

- Program evaluation for external use and/or publication
- Program evaluation for internal program use with intention to publish and/or that collect/access data that involve sensitive topics such as substance use/disorder or that collect/access data about persons belonging to vulnerable populations
- Certain quality assurance and quality improvement projects
- Certain non-legally mandated surveillance
- Needs assessments
- Projects using surveys that collect data from the respondent but not necessarily about the respondent



Exceptions to DPH IRB Submission Policy

No submission required if:

- Does not involve humans (e.g., animals only, some lab studies)
- Legally mandated reporting/surveillance
- Information collected/charted as part of clinical care
- Anonymous meeting evaluations
- Authorized operational activities in support of criminal justice or criminal investigative activities or defense/national security
- Environmental investigation
- Staff assessments or other internal queries that pertain to core job duties and skills



Exceptions to DPH IRB Submission Policy, cont.

No submission required if:

- Customer satisfaction surveys that do not collect/access data from vulnerable populations or involve sensitive topics (such as substance use/disorder), OR that do not collect/access personally identifiable information (PII) or protected health information (PHI)
- 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
- Evaluations for internal use for trainings that are linked to receiving CE 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



What is a Vulnerable Population?

- “The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are ***vulnerable to coercion or undue influence***, [emphasis added] such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.” **§46.111(a)(3)**
- **Coercion/undue influence** “The *Belmont Report* states that coercion involves ‘...an overt threat of harm...to obtain compliance, and offer of excessive, unwarranted, inappropriate reward...’
- **Impaired decision-making**
- **Economically or educationally disadvantaged persons**



What is a Vulnerable Population, cont.?

- Other examples:
 - Persons experiencing homelessness
 - Persons with terminal illness or medical vulnerability (life-impacting disorders/illnesses)
 - Non-English-speaking participants
 - Wards of the state
 - Elderly
 - Institutionalized persons
 - Probationers and parolees
 - We apply same protections as prisoners



Community - DPH definition

DPH Community Engagement Policy [407](#):

“The individuals, neighborhoods, geographic areas, groups, organizations, businesses, or agencies who are invested in or affected by the public health issues being addressed; those responsible for addressing the issues; and those holding decision-making authority or influence on the issues.”

What is Community?

- Shared language, occupation, ethnic group, faith, age, activities, goals, sexual orientation
- Organizational membership
- Public, non-profit, or private
- Church, school, club, community-based organization
- Not homogeneous with one voice

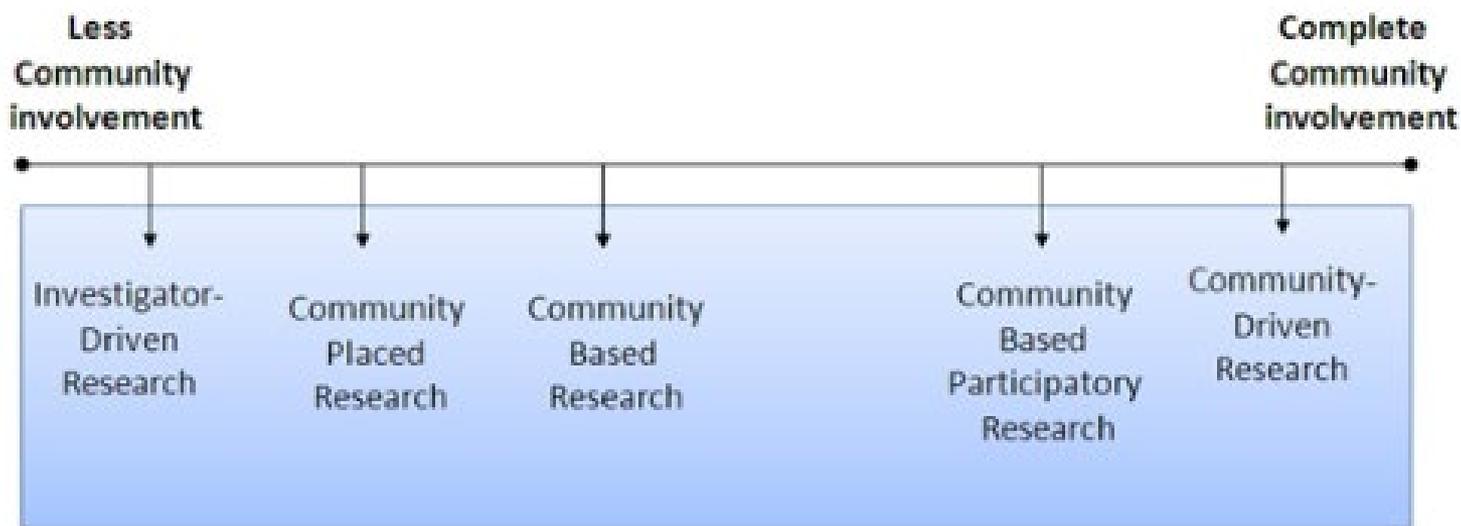




Community-Engaged Research (CEnR)

- Framework/approach, not methodology
- “The process of working collaboratively with groups of people who are affiliated by geographic proximity, special interests, or similar situations with respect to issues affecting their well-being” (CDC 1997)
- Various methodologies used

CEnR Continuum



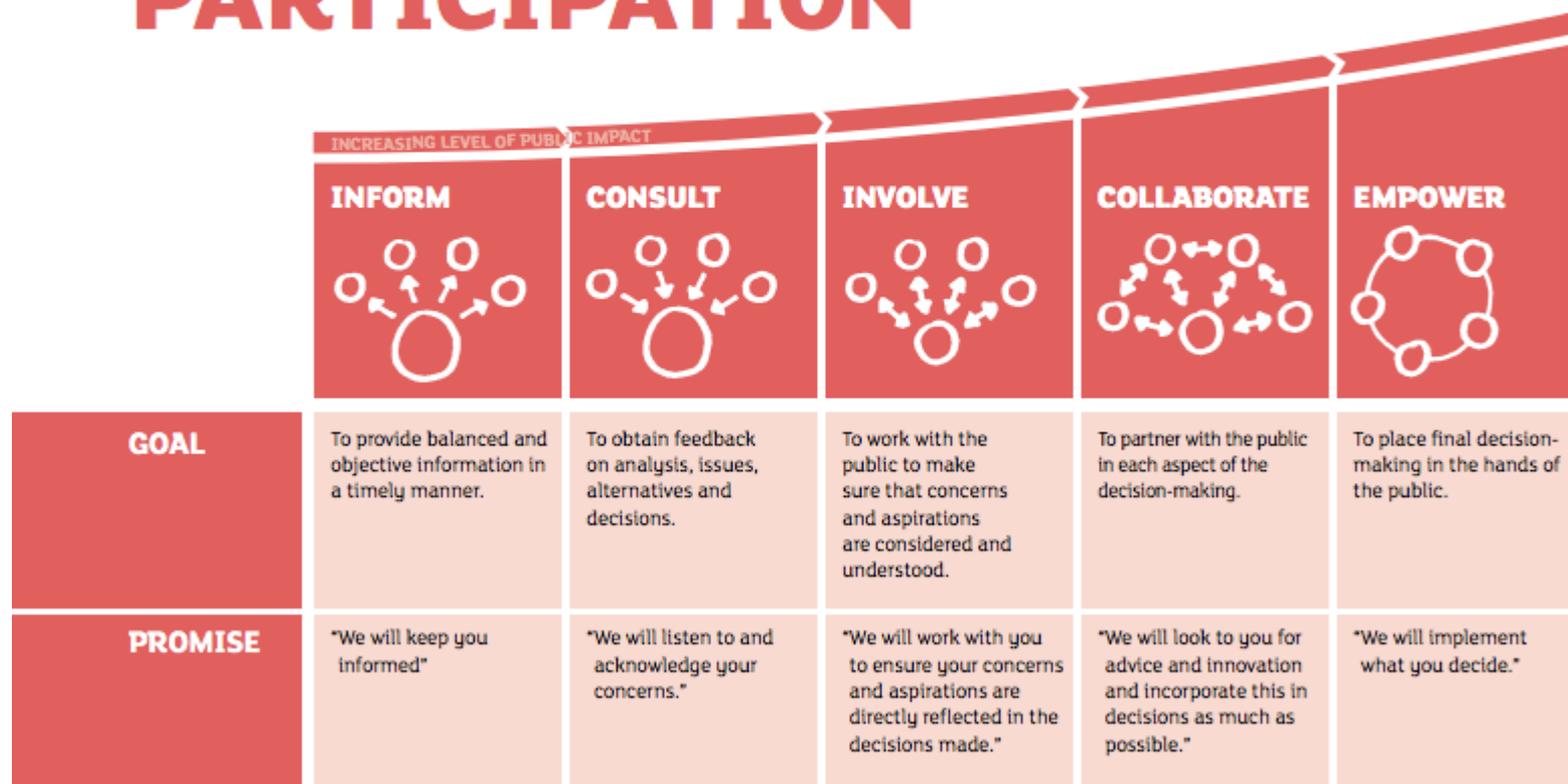
Clinical trials, secondary analyses

Community directly involved in recruitment and/or data collection

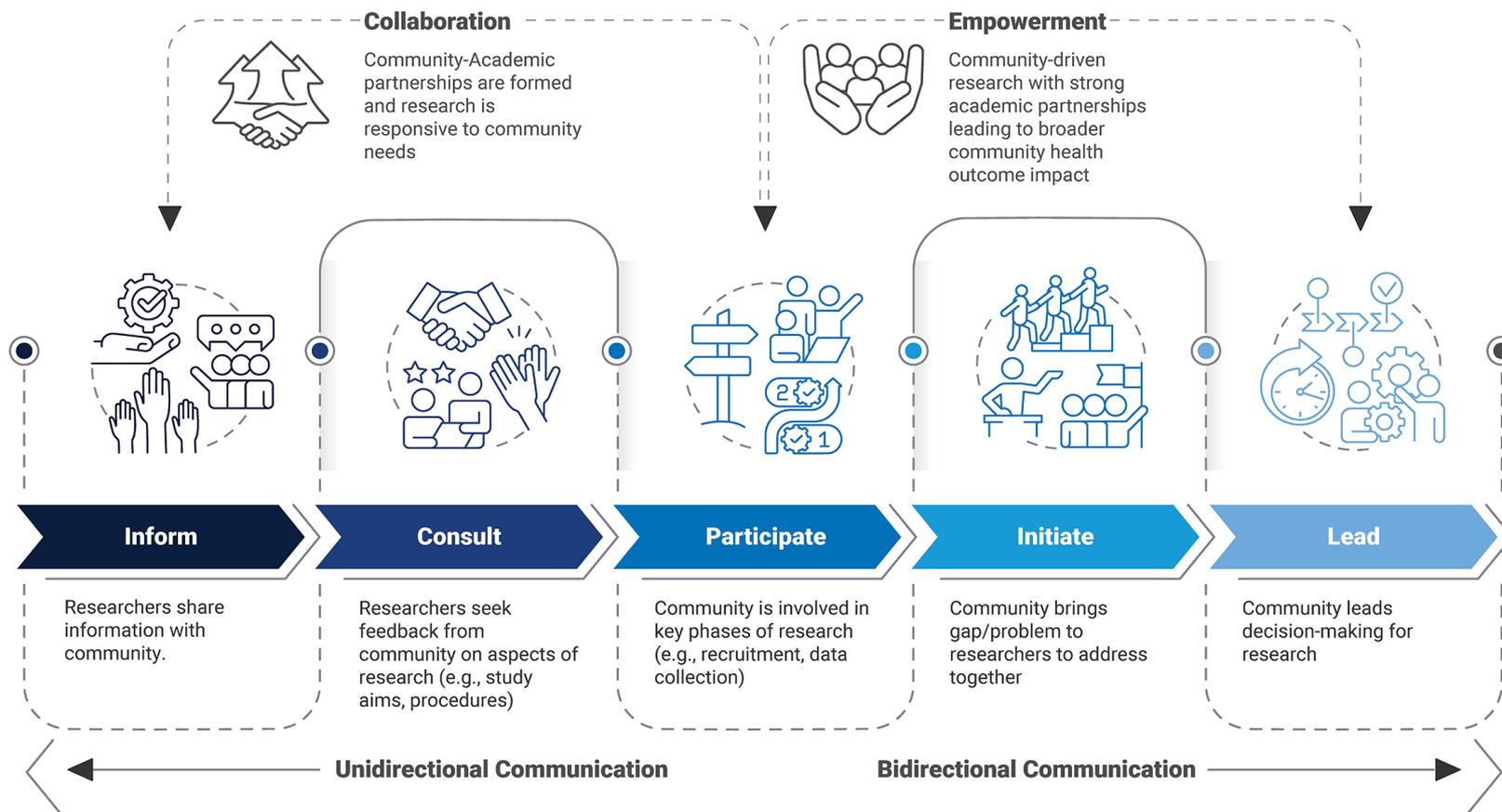
Community provides research questions, assists with data collection/review, final outcomes distributed to community in formats they understand, and partners share funding received for the research



IAP2 SPECTRUM OF PUBLIC PARTICIPATION



CEnR Continuum





Community-Engaged Research (CEnR), continued

Community Engagement (CE)

Examples

High CE:
Collaboration

- Community Advisory Board
- Researcher/community partnership

Moderate CE:
Consultation/Coordination

- Community-based organization assists in implementing a study design
- Church provides site for research activities

Minimal/Lack CE

- Information and education campaigns, outreach
- Phone sampling, street intercept interviews



History and Theoretical Basis

- Theories from Anthropology, Psychology, Education, Sociology, Public Health, Social Work
- “Action research” to overcome social inequality (Kurt Lewin, 1940s)
- Co-learning (Wallerstein and Duran, 2003)
- Empowerment education and community organization (Paulo Freire and Myles Horton)
 - Participatory action research
 - Empowering poor and oppressed groups
 - Solutions coming from communities themselves
 - Adult education: learners are not empty vessels; learning is not one way
 - Socio-political action



Institutionalization of Community Engagement into Research and Funding Mechanisms

Mid-1980s:	CDC recommended community involvement in research and demonstration projects
1997:	Institutes of Medicine formally integrated community involvement into the prevention research framework
Early 2000s:	National Institute of Environmental Health Sciences W.K. Kellogg Foundation
2005:	National Institute on Minority Health and Health Disparities launches Community-Based Participatory Research Program (CBPR)
2006:	NIH initiated Clinical and Translational Science Award (CTSA) Mandated community engagement at biomedical institutions
2016:	Presidential Commission for the Study of Bioethics Report underscores the ethical and practical reasons for community input
2021:	Executive order on “Advancing Racial Equity and Support for Underserved Communities” signed



Mutual Benefits of CEnR

- Research done **IN** and **WITH** communities – a collaboration between partners
- Involvement of those most likely to be impacted: rooted in the concept of justice



Mutual Benefits of CEnR, cont.

- Recognizes unique strengths of each party using an assets-based approach to research
- **Empowerment:** strengthening community assets and capacity building



Mutual Benefits of CEnR, cont.

- Addresses limitations of “traditional” research
 - A research sample that more closely reflects the larger community yields more generalizable data and is better positioned to inform public policy
 - Create sustainable partnerships that can build trust among the community
- Uses knowledge to bring about action
 - Directly influence health outcomes
 - Tailor interventions to specific communities
 - Effect social change and eliminate/mitigate disparities in health outcomes



Mutual Benefits of CEnR, cont.

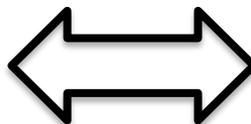
- Participants can understand purpose of the research and how the results may affect them
 - Informed consent process
 - Response rates
- Improve reliability and validity of data collection instruments
- Produce culturally sensitive questions and design
- Yields important and culturally sensitive explanations, local interpretation of findings
- Is an intervention in and of itself
- Results likely to be translatable to similar communities

Collaboration

**Respect, cooperation,
time, build on strengths
of participants**

Community
advisory board

**Co-learning,
bi-directional**



**Process: long-term
commitment to
sustainability**





Collaboration, cont.

- Contributions from the community may vary depending on community context, experience and background of researchers
 - Infrastructure and capacity of community organization
 - Funding

Collaboration, cont.

- Partnerships with organizations
 - Address local health issues important to community
 - The people affected by the issue
 - Development of a solution
 - Way to “give back” to the community



Putting it Into Practice

- Research plus capacity-building
 - Vulnerable populations/ communities with lack of resources, high risk for poorer health outcomes
 - Equality in some or all phases of research and decision-making
 - Identify problems and work together to build mutual skills and develop solutions
- Not just:
 - For qualitative research
 - After the proposal is written





Terms of Engagement

- Mutually agreed upon
 - Memorandum of Understanding (MOU)
 - Financial support
 - Research activities, roles and responsibilities, outcomes
 - Data ownership and sharing
 - Developing research tools
 - Data collection methods, analysis and interpretation
- Methods for disseminating research results to both academic and community audiences
 - Products may be collaboratively owned
 - Participants review and contribute



Dissemination

Community-informed strategies more likely to lead to *action*, more time urgent

- **Community members:**

- Local newspapers, magazines, radio programs
- Joint community meetings
- Peer-to-peer sharing
- Social media

- **Researchers:**

- Peer-reviewed journals
- Program implementation, evidence in legal or legislative campaigns, grant applications
- Some journals may not publish articles whose findings have previously been published in the newspaper, TV or other media

Use Multiple Dissemination Strategies: Be Creative!



What Are Potential Challenges In Community-Engaged Research?

Potential Challenges In Community-Engaged Research

- Can equal partnership be achieved?
 - Unequal distribution of power
 - Time considerations
 - Infrastructure
 - Mistrust of researchers
 - Scientific jargon





What Are Potential Solutions to These Challenges?

Potential Solutions



- Distribute funding sources/finances
- Invest in building trust in researchers
- Build time into research plan



Potential Solutions, cont.

- Build infrastructure and capacity to work as research collaborators
- Understand community processes, gain trust and initiate/maintain relationships
- Create materials at appropriate reading levels using lay language



The Role of the Institutional Review Board (IRB):

Ethical Considerations



Where Does the IRB Fit?

- Revised Common Rule does not specifically address CEnR
 - Lack of IRB experience with CEnR
 - IRB Policies and Procedures do not specifically address community risks



Ethical Challenges

- Community risk vs. individual risk - is associating participants with research harmful to community or individuals?
- Reinforcing negative stereotypes?
- Disrupting community cohesion?
- Privacy and confidentiality when community members are part of research team
 - Community members of research team may know the individuals they are recruiting



Ethical Challenges, cont.

- Community consent – how is it to be obtained?
- Compensation for participation (in addition to funding for organizations)
- Conflicts of interest
- How are community leaders involved in decision-making?
- Avoiding exploitation



Some Solutions



- Build incentives into grants
- Work with community partners to help discuss stereotypes of the community and advise on how best to approach groups
 - Informed consent about potential of stigma

Some Solutions, cont.



- Use non-technical language in informed consent, or translating appropriately
- Train community members about data storage and access
- Careful consideration and transparency of what possible conflicts of interest could be



What the IRB Requires

- How is the IRB going to apply this to evaluate/approve projects?
- What should “minimum criteria” of level of engagement be?
 - Demonstrated consciousness or frank acknowledgement of the importance of CEnR
 - Outline of the steps that were taken to achieve adequate CEnR
 - Consultation with the community on ways to disseminate findings

IRB Health Equity Initiative

LAC DPH defines health equity as ***“when everyone has a fair and just opportunity to attain their optimal health and well-being.”***

- Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on certain social conditions.



IRB Health Equity Initiative, cont.

- Matter of justice and necessary to ensure that research and related activities produce quality (robust and generalizable) data that can better inform action at all levels.
- As a research goal, health equity is a lens through which all research activities should be viewed.
 - From study design all the way to dissemination of results



IRB Health Equity Initiative, cont.

Key Informant (KI) Interviews

- KIs with known health equity work
- Semi-structured interviews
- A Health Equity Report summarizing results from the interviews is available on the IRB website

Annual Health Equity Survey

- Recruitment: snowball and internet search
- Eligibility: 18+ years, English speaking
- 18-item survey

Internal Health Equity Standard of Practice (SOP)

- Applies to DPH projects and provides guidance for reporting progress toward meeting health equity objectives, including the methods used to measure health equity



IRB Health Equity Initiative – Key Informant Interviews

“ *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.* ”

- Seven informants noted that the research field must do a better job of involving community members and community-based organizations throughout the research process - from the development of the research question and study design to the dissemination of results.
- Of these seven informants, four highlighted the value of and need for researchers to integrate principles of CEnR into their work.
- Five informants noted that the research field must do a better job with recruitment and retention of under-served communities by offering study documents that are in appropriate languages and reading levels.

IRB Health Equity Initiative – Health Equity Survey Year 1 and Year 2 Results

The most commonly used **methods of community engagement**:

1. Community engaged in research design
(68.5% and 62.1%, respectively)
2. Community engaged in recruitment
(62.9% and 57.6%, respectively)
3. Community engaged in data collection
(60.1% and 53.0%, respectively)
4. Community Advisory Board convened regularly
(51.8% and 40.9%, respectively)

The top 2 barriers to **addressing health equity in research**:

1. Availability of funding
(38.9% and 36.4%, respectively)
2. Lack of trust between community and research field
(34.9% and 33.6%, respectively)





IRB Health Equity Initiative – Health Equity Survey Year 1 and Year 2 Results, cont.

The top 2 **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



IRB Health Equity Initiative, cont.

- **New:** Health Equity SOP regarding health equity, diversity and inclusion in research and related activities reviewed by the DPH IRB
 - [Internal version](#) available on IRB intranet
 - [External version](#) available on IRB website
- SOP informed by key informant interviews and health equity survey completed as part of IRB's Health Equity Initiative
- Please refer to our [Health Equity Initiative](#) page for more information about our efforts to develop this SOP



More Resources - Toolkits

- [Engage for Equity](#)
- [Urban Institute Community Engagement Resource Center](#)
- [Scripps Translational Science Institute Community-Engaged Research Toolbox](#)
- [Minnesota Department of Health Community engagement assessment tool](#)
- [University of Kansas Community Toolbox Box](#)
- [Penn State Engagement Toolbox](#)

There are many more out there!



References and Additional Resources

- Centers for Disease Control and Prevention (CDC). 1997. *Principles of Community Engagement (First Edition)*. Atlanta, GA: CDC/ATSDR Committee on Community Engagement.
- Collaborative Institutional Training Initiative (CITI Program). 2019. Introduction To Community-Engaged Research (CEnR) module. Accessed March 21, 2019.
- Clinical and Translational Science Awards Consortium Community Engagement Key Function Committee Task Force on the Principles of Community Engagement. 2011. *Principles of Community Engagement (Second Edition)*. Bethesda, MD: National Institutes of Health.
- Freire, Paulo 1970. *Pedagogy of the Oppressed*. New York: Herder and Herder.
- George, Cynthia. 2014. "[Frequently Asked Questions: Community-Engaged Research \(CEnR\) and VCU's Institutional Review Board \(IRB\)](#)." Accessed April 3, 2019.
- Hacker, Karen and J. Glover Taylor. 2011. "Community-Engaged (CEnR) and the Institutional Review Board: Principles, Challenges, and Opportunities," Presentation at the Office for Human Research Protection Conference, Protecting Human Subjects: Blending Regulatory Requirements and Best Practices, Boston, Massachusetts, June 21, 2011.
- Harvard Catalyst. N.d. [Community Engagement](#). Accessed May 13, 2024.
- Horton, Myles, Paulo Freire, Brenda Bell, John Gaventa, and John Marshall Peters. 1990. *We make the road by walking: conversations on education and social change*. Philadelphia: Temple University Press.
- International Association for Public Participation (IAP2). N.d. [IAP2 Spectrum of Public Participation](#). Accessed May 13, 2024.
- Lewin, Kurt. 1946. "Action research and minority problems." *Journal of Social Issues* 2(4):34-46.
- MacQueen, Kathleen M., Eleanor McLellan, David S. Metzger, Susan Kegeles, Ronald P. Strauss, Roseanne Scotti, Lynn Blanchard, and Robert T. Trotter II. 2001. "What is community? An evidence-based definition for participatory public health." *American Journal of Public Health* 91(12):1929-38.
- McDonald, Mary Anne. 2007. "Practicing Community-Engaged Research." Accessed March 21, 2019.
- Minkler, Meredith, Analilia P. Garcia, Victor Rubin, and Nina Wallerstein. 2012. [Community-Based Participatory Research: A Strategy for Building Healthy Communities and Promoting Health through Policy Change](#). Berkeley, CA: PolicyLink.
- PennState Clinical and Translational Science Institute. N.d. [Section 2: What is Community-Engaged Research](#). Accessed May 13, 2024.
- Wallerstein, Nina and Bonnie Duran. The conceptual, historical and practice roots of community-based participatory research and related participatory traditions In: Meredith Minkler and Nina Wallerstein (editors) *Community-Based Participatory Research for Health* (1st ed , pp 27-52) San Francisco: Jossey-Bass; 2003
- Winkler, Sabune. 2011. "Community Engaged Research Continuum." Presentation at the Office for Human Research Protection Conference, Protecting Human Subjects: Blending Regulatory Requirements and Best Practices, Boston, Massachusetts, June 21, 2011.
- NYC Department of Health and Mental Hygiene, Dec. 2021. [Health of Indigenous Peoples of the Americas Living in New York City Indigenous peoples of the Americas](#), Epi Research Report Workgroup. Accessed May 24, 2023

Any Questions??



Visit our website:

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

Write us with questions:

irb@ph.lacounty.gov



Thank you!

We value your feedback!

Please take a minute to complete the evaluation.

Evaluation link:

<https://www.surveymonkey.com/r/XKW5YFP>