Community Engagement in Research, Evaluation, and Related Activities Workshop

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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

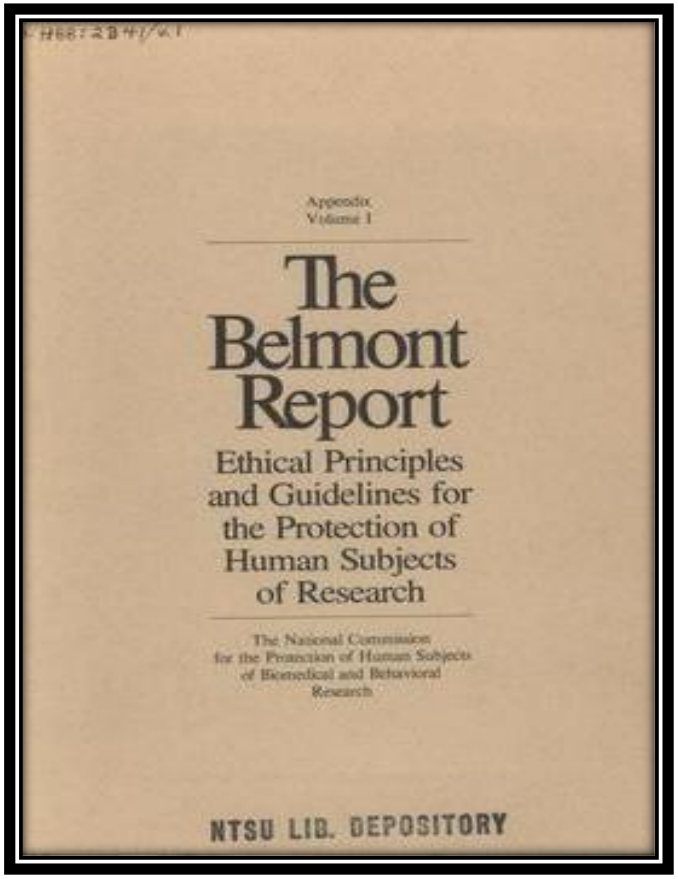
REMINDER: This training **DOES NOT** fulfill the Human Subjects Protection Training and will not address the IRB application process

Brief History of Ethics in Research

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

Books such as *Acres of Skin, The Immortal Life of Henrietta Lacks*, and other resources on ethics in research are available through the DPH Library. For more information visit the library website.

For a full list of available books visit our website: Resources



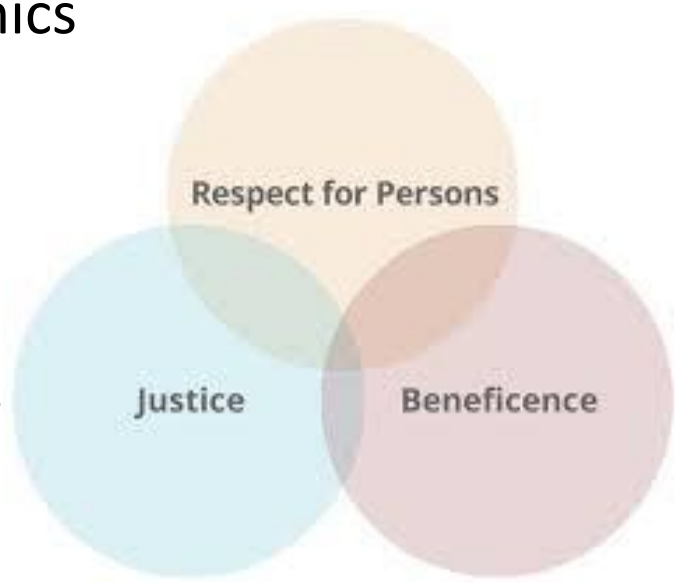
An Ethical Framework

- 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



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

<u>Any project</u> 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

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…"

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

Four Vulnerable Populations Protected by the Regs and our IRB

The IRB provides protection to these vulnerable populations in accordance with the federal regulations, which include:

- Children
- Prisoners, probationers and/or parolees
- Pregnant Persons, Human Fetuses and Neonates
- Individuals with Impaired Decision-Making Capacity (additional)

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."

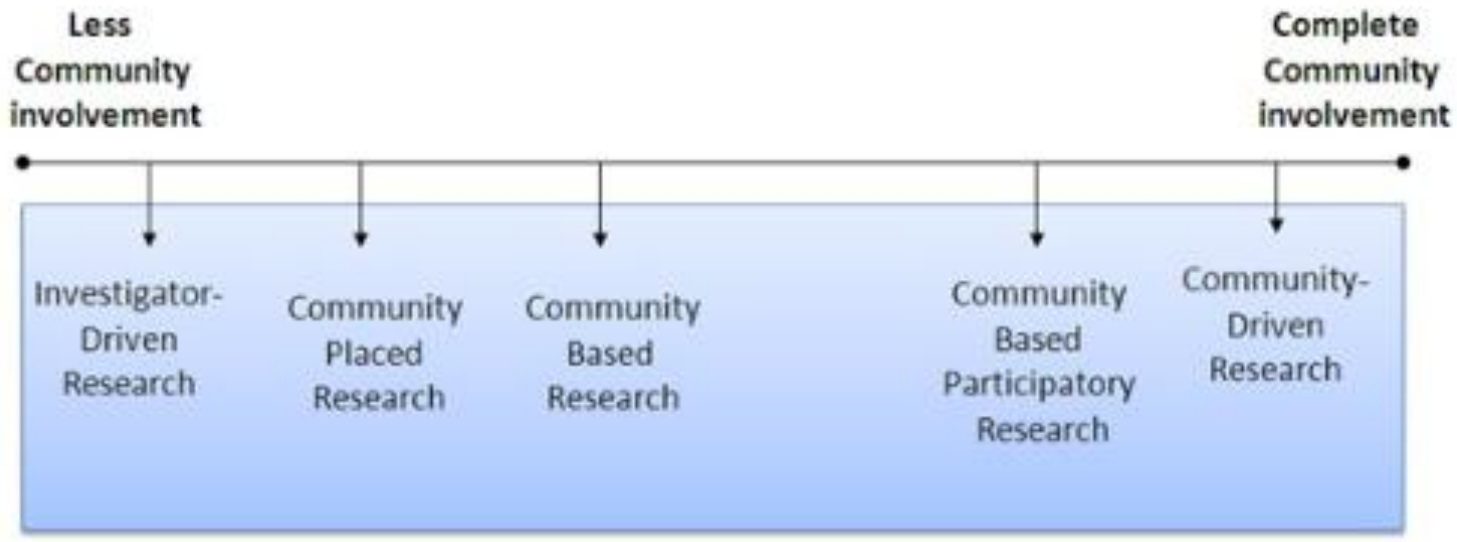
What is Community?

- 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



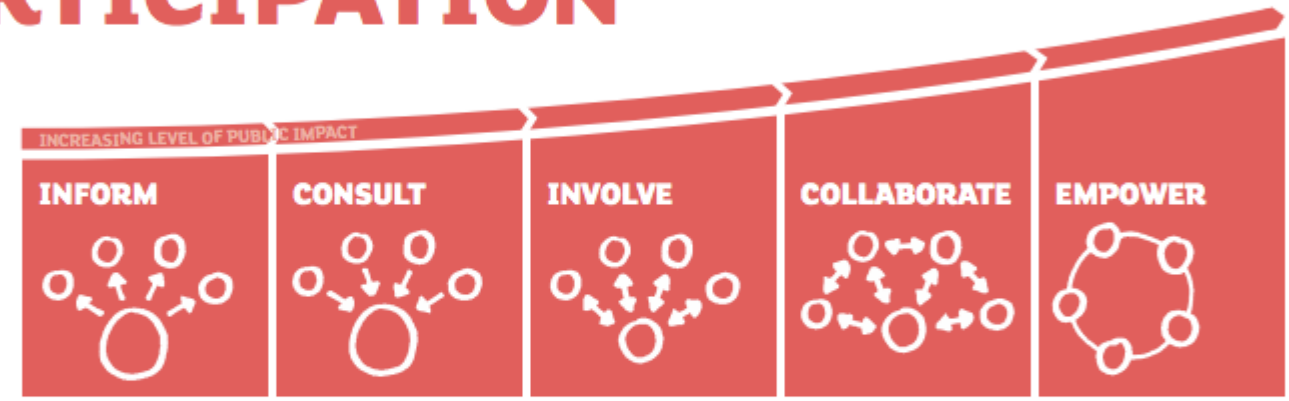
Clinical trials, secondary analyses

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

Winkler 2011

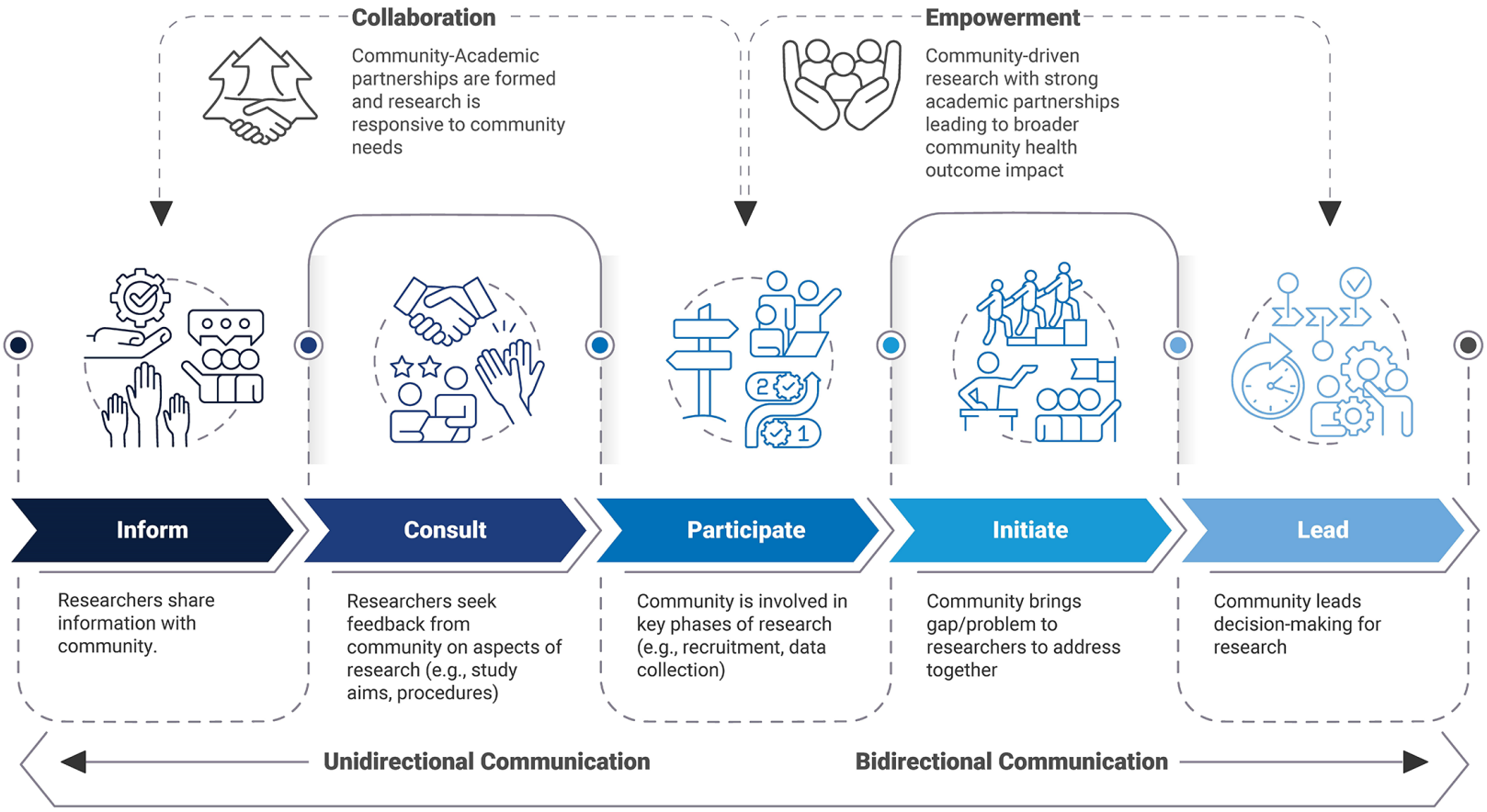
IAP2 SPECTRUM OF PUBLIC PARTICIPATION



	INFORM	CONSULT	INVOLVE	COLLABORATE	EMPOWER
GOAL	To provide balanced and objective information in a timely manner.	To obtain feedback on analysis, issues, alternatives and decisions.	To work with the public to make sure that concerns and aspirations are considered and understood.	To partner with the public in each aspect of the decision-making.	To place final decision-making in the hands of the public.
PROMISE	"We will keep you informed"	"We will listen to and acknowledge your concerns."	"We will work with you to ensure your concerns and aspirations are directly reflected in the decisions made."	"We will look to you for advice and innovation and incorporate this in decisions as much as possible."	"We will implement what you decide."

International Association for Public Participation (IAP2), n.d.

CEnR Continuum



PennState Clinical and Translational Science Institute, n.d.

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.

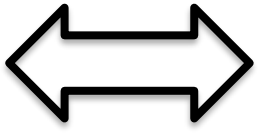
- Participants can understand purpose of the research and how the results may affect them
  - Informed consent process
  - Response rates
- Improve reliability and validity of data collection instruments
- Produce culturally sensitive questions and design
- Yields important and culturally sensitive explanations, 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

Collaboration, cont.

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

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*

- **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
    - Trainings
  - 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

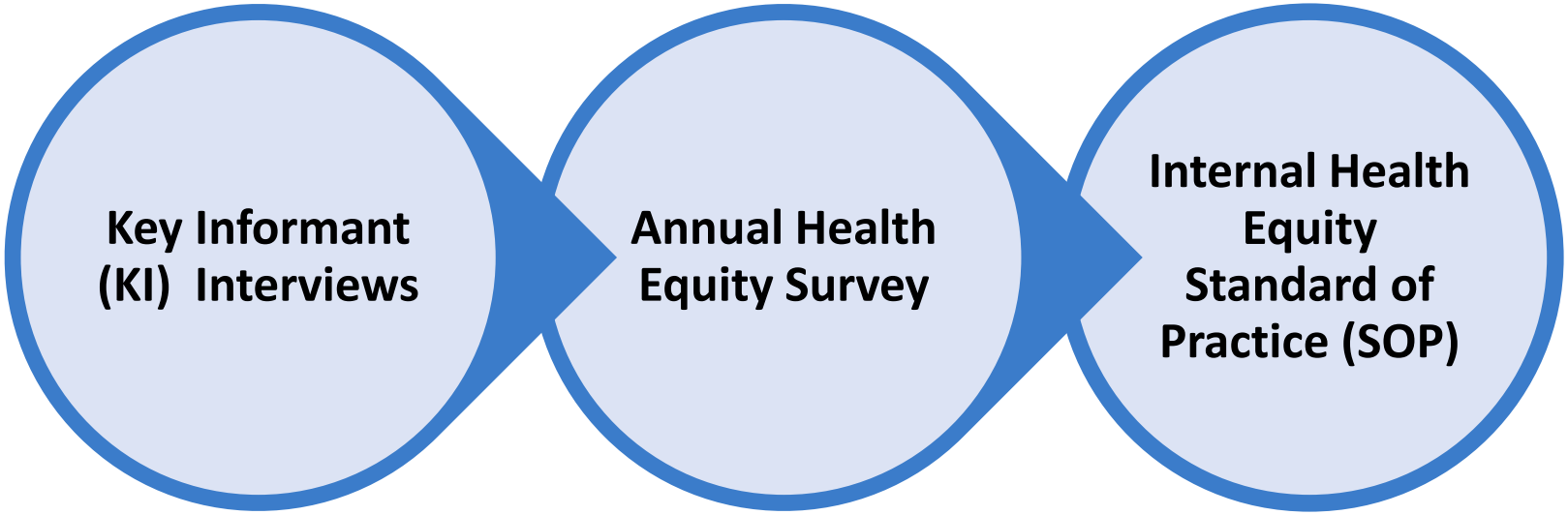
What the IRB Requires

- 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, 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.



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

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

- 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 – 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 Standard of Practice

- **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

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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/YGZ7GNX