Community Engagement in Research, Evaluation, and Related Activities Workshop

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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 will be 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 requirement
- 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
- different strategies for engaging members of the community in your projects
- ethical considerations regarding Community Engaged Research

What is Community?

- "A group of people who are linked by social ties, share common perspectives or interests, and may or may not also share a geographic location" (MacQueen et al., 2001)

- 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 - DPH definition

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.

Community-Engaged Research (CEnR)

- Framework/approach, principles, 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)
- Quantitative or qualitative data collection and analysis

Community-Engaged Research (CEnR), continued

Community Engagement (CE)

Examples

High CE:
Collaboration

- Community Advisory Board
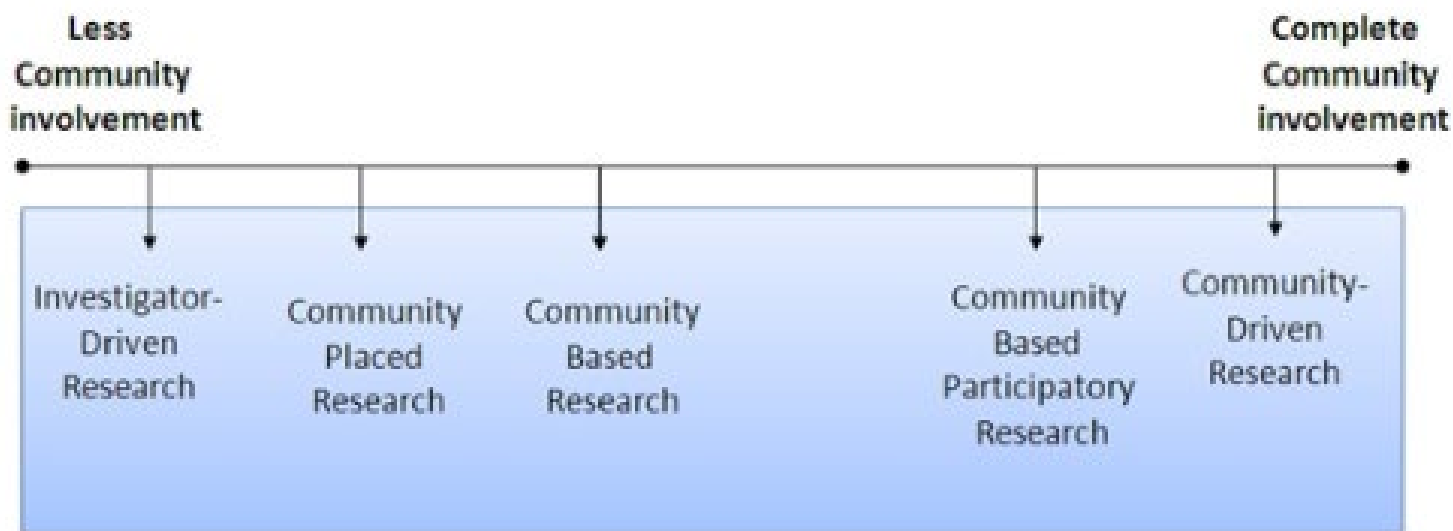- Researcher/community partnership

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
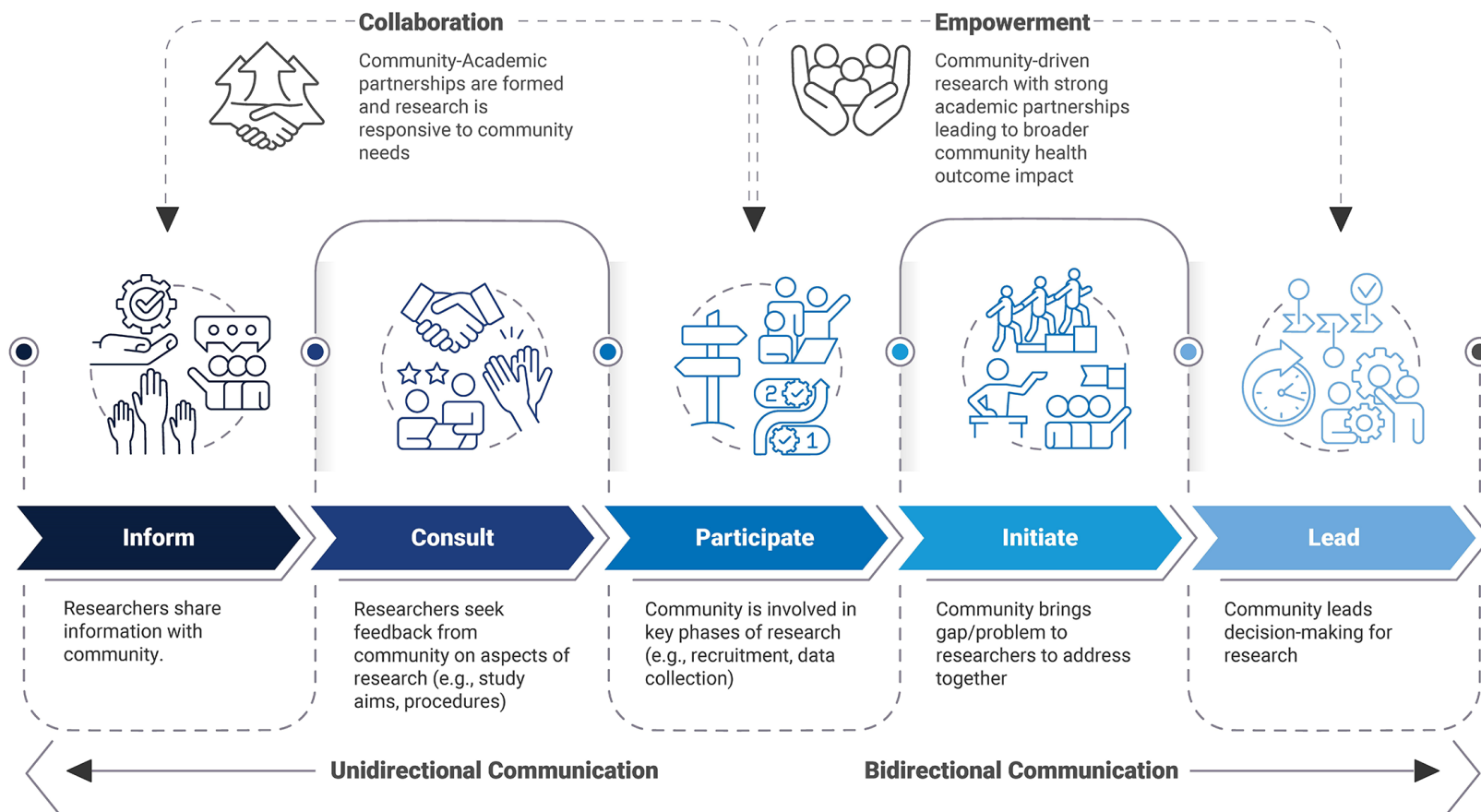- Phone sampling, street intercept interviews

CEnR Continuum

Winkler 2011

CEnR Continuum

Collaboration

Community-Academic partnerships are formed and research is responsive to community needs

Empowerment

Community-driven research with strong academic partnerships leading to broader community health outcome impact

Inform	Consult	Participate	Initiate	Lead
Researchers share information with community.	Researchers seek feedback from community on aspects of research (e.g., study aims, procedures)	Community is involved in key phases of research (e.g., recruitment, data collection)	Community brings gap/problem to researchers to address together	Community leads decision-making for research

← **Unidirectional Communication** → **Bidirectional Communication** →

PennState Clinical and Translational Science Institute, n.d.

CEnR Continuum

DEGREE OF DIFFICULTY AND PUBLIC IMPACT

INFORM — provide balanced, objective info that the public should know and act on

CONSULT — obtain and consider feedback or input on issues, ideas, and decisions

INVOLVE — work with the public to understand the issues and problems and include in identifying options for moving forward

COLLABORATE — partner with the public, seeking advice and innovations that become embedded as much as possible in decisions made

EMPOWER — final decisions are made by the public and are one of the players implementing them
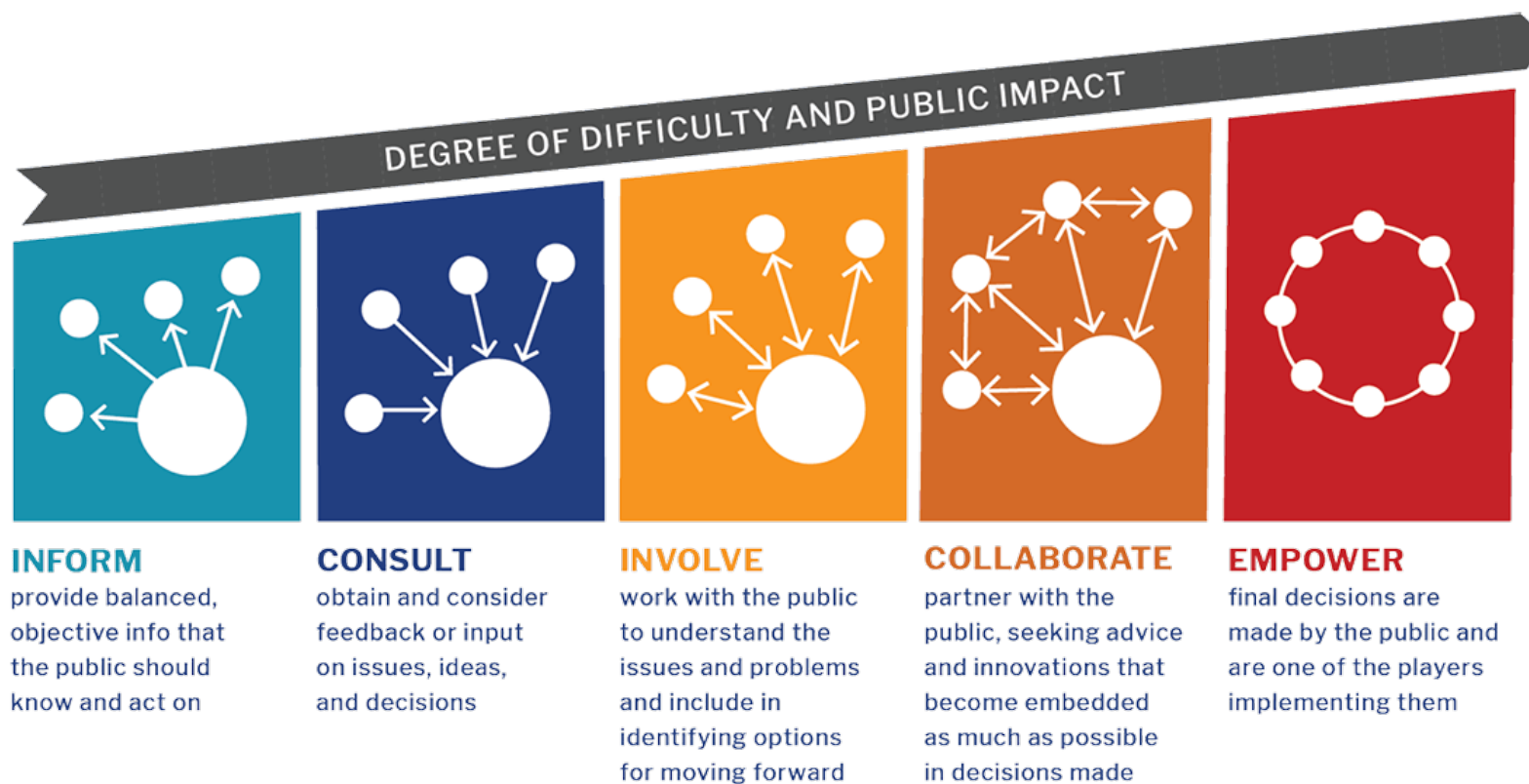
Harvard Catalyst, n.d.

International Association for Public Participation (IAP2), n.d.
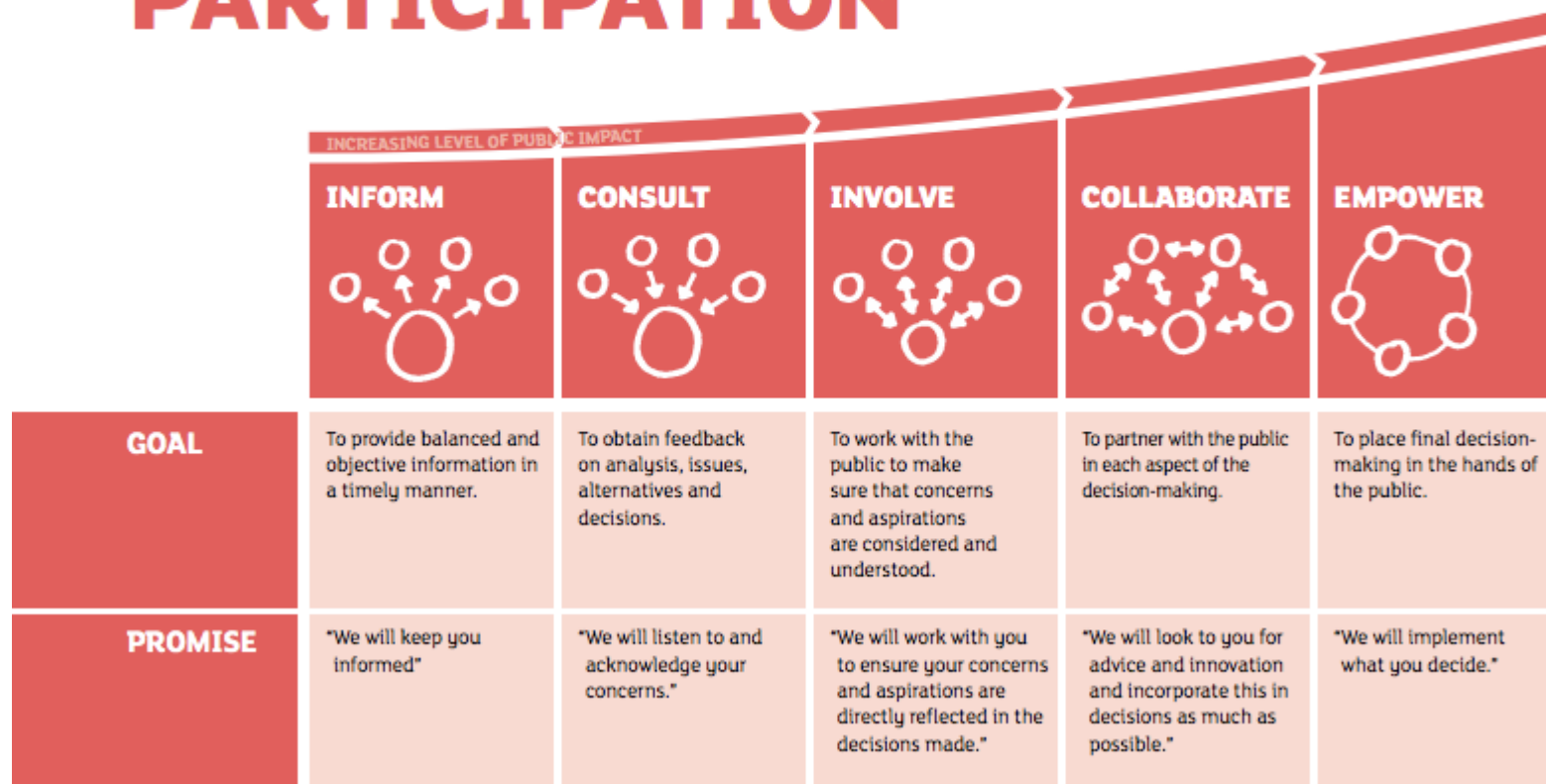
History and Theoretical Basis

- 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

- Subject has become participant (NEJM, AJPH)

- Input of those most likely to be impacted: rooted in the concept of justice

- Recognizes unique strengths
  of each party using an assets-based
  approach to research

- Empowerment: strengthening
  community assets and capacity
  building

Mutual Benefits of CEnR, continued

- 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, continued

- 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

- Contributions from the community may vary depending on community context, experience and background of researchers
  - Infrastructure and capacity of community organization
  - Funding
- Partnerships with organizations
  - Address local health issues important to community
  - The people affected by the issue
  - Development of a solution
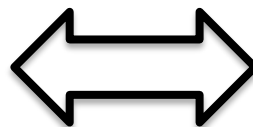 - Way to "give back" to the community

Collaboration, continued

Respect, cooperation, time, build on strengths of participants

Community advisory board

Co-learning, bi-directional

Process: long-term commitment to sustainability

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

Multiple Dissemination Strategies: Be Creative!

What Are Potential Challenges In Community Engagement?

- Can equal partnership be achieved?

  - Unequal distribution of power

  - Time considerations

- What are some solutions to these challenges?

Potential Solutions

- Unequal distribution of power
  - Funding sources/finances
  - Infrastructure that supports research
  - Invest in building trust in researchers
- Time Considerations
  - Build infrastructure and capacity to work as research collaborators
  - Understand community processes, gain trust and initiate/maintain relationships

Group Exercise

Scenario: A group of researchers wants to work on obesity prevention in a local neighborhood where high rates of obesity have been found.

- **Question 1:** What would you do before actually designing the project? What would you do before putting together the IRB application?

- **Question 2:** The project is funded. What would do you to make sure there is maximum community engagement in the operationalization of it?

Group Exercise

Scenario: A group of researchers wants to work on obesity prevention in a local neighborhood where high rates of obesity have been found.

- **Question 3:** The project is underway but participants are not finishing the surveys. What should you do to solve this problem and be able to collect complete data?

- **Question 4:** How would the project members plan to disseminate the results? What would you do if you found some results that were counter-intuitive and/or stigmatizing?

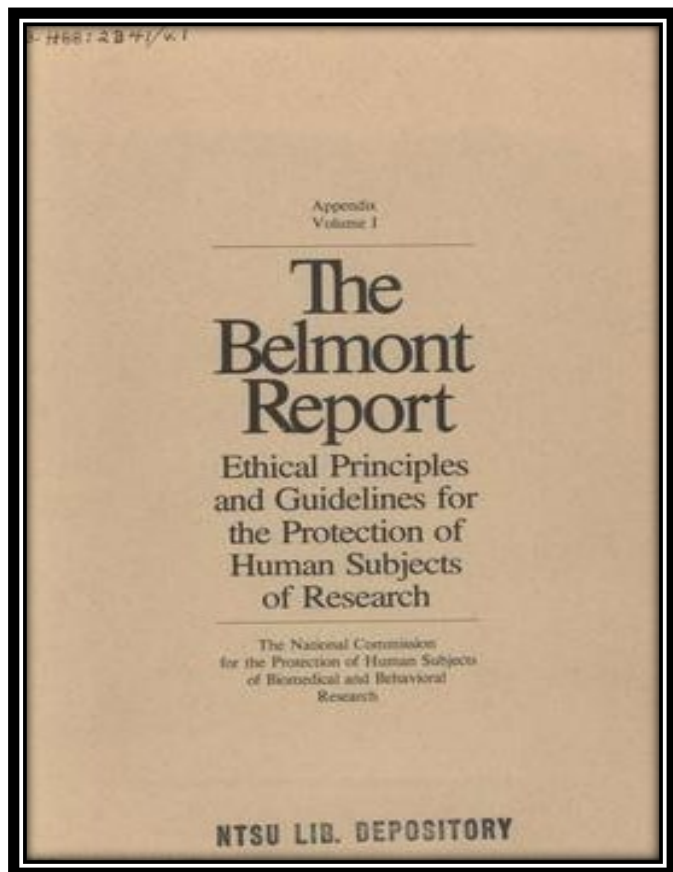# The Role of the Institutional Review Board (IRB):

Ethical Considerations

Review:
Principles and History

- Tuskegee Syphilis Experiment, 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
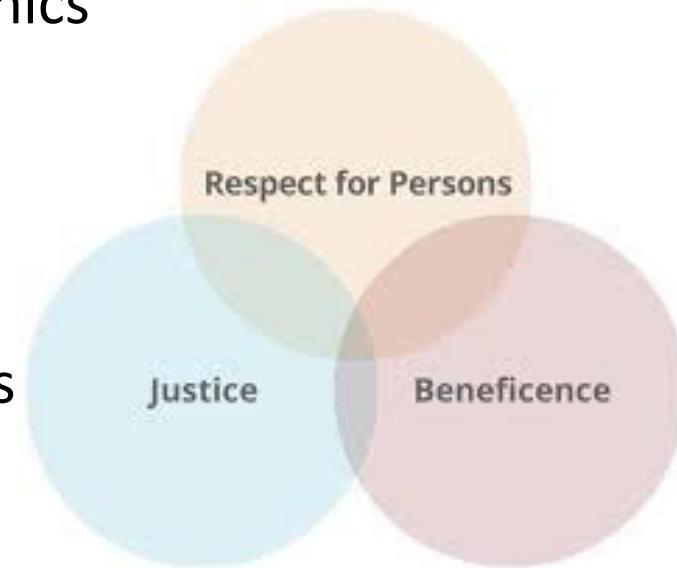
Legal Basis for the IRB

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 consultation for 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, including evaluation for internal program use;

  - certain quality assurance and 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
- Customer satisfaction surveys that do not collect/access data from vulnerable populations such as minors or persons experiencing homelessness or involve sensitive topics such as substance use/disorder
- Customer satisfaction surveys that do not collect/access personally identifiable information (PII) or protected health information (PHI)
- Environmental investigation

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, continued

- 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

- Minimize possibility of community members interacting with study participants who are friends or neighbors

  - Hire data collectors who are not part of community if needed

- 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

- Use non-technical language in informed consent, or translating appropriately

- Train community members about data storage and access

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

- Addressing health equity in research is a matter of justice and is 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

Key Informant (KI) Interviews

Annual Health Equity Survey

Internal Health Equity Standard of Practice (SOP)

- 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

- Apply to DPH projects and will provide 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.

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

The most commonly used methods of community engagement were:

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)

Top 2 top 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)

In year 1 and year 2 survey, the top 2 actions the IRB can take to help ensure research is conducted more equitably were:

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

- **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 (HEI).

- Please refer to our Health Equity Initiative page for more information about the HEI and 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/KHWSPJH