Defining Public Health Research vs Public Health Practice

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Authors and Affiliations

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Disclosures: None

Department of Health

- Provides policy direction
- Develops national plans
- Lead agency - health emergencies, catastrophic events
- Technical authority - disease control and prevention
- Agency in charge of monitoring and evaluating health programs, projects, training

Definitions

CDC definition, 2008

Public health practice is the collection and analysis of identifiable health data by a public health authority for the purpose of protecting the health of a particular community, where the benefits and risks are primarily designed to accrue to the participating community.

Public health research is the systematic collection and analysis of identifiable health data by a public health authority or designee for the purpose of generating knowledge that may (or may not) benefit those beyond the participating community that bears the risks of participation.

Public Health Research versus Public Health Practice: Rationale

- Potential conflict exists in two mandated tasks
- Distinction is not addressed by National Ethical Guidelines
- Leads to confusion on the part of the researcher or public health practitioner
- Guideline to be used by both the public health researcher and Ethics committee members

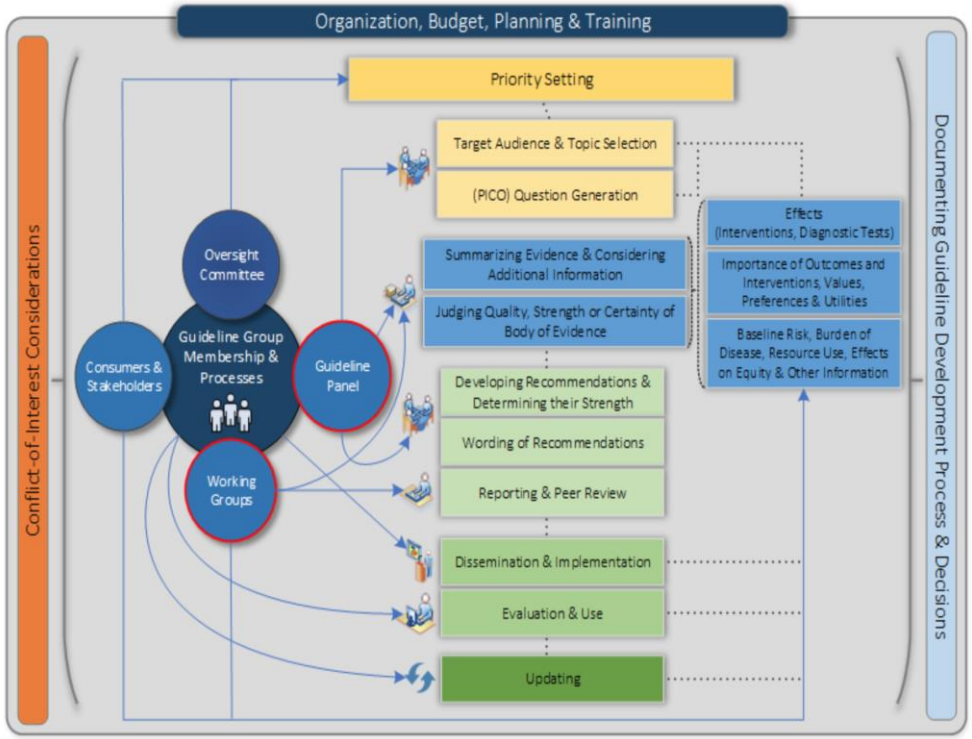
- 4 months study
- Commissioned by the Department of Health and funded through the Philippine Council for Health Research and Development

Objectives

- To develop research ethics guidelines for the conduct and review of public health research and public health practice
- To compile and review international ethics guidelines
- To document and compile the perceptions of public health practitioners, public health researchers, and key opinion leaders on international ethics guidelines

Modified Guideline Development Process

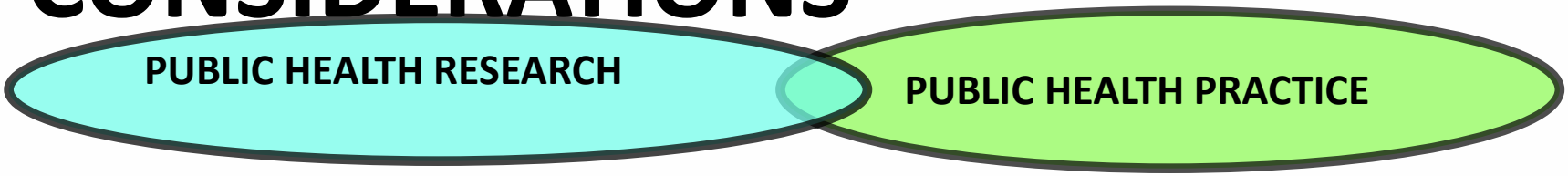
- Extensive search and review of literature
- Key informant interviews (KII) and Focused Groups Discussions
- Compilation and Summary
- Stakeholders meeting
- Draft recommendations



FEATURES

PUBLIC HEALTH RESEARCH	PUBLIC HEALTH PRACTICE
The purpose of the activity is to develop or contribute to **generalizable knowledge** to improve public health practice	The purpose of the activity is to identify and control a **health problem** or improve a **public health program** or service
intended benefits of the project can include study participants, but always **extend beyond the study participants**, usually to society	intended benefits of the project are **primarily or exclusively for the participants (or clients)** or the participants' community
Generalizable knowledge means new information that has **relevance beyond the population or program** from which it was collected, or information that is added to the scientific literature	knowledge that is generated **does not extend beyond the scope of the activity**; and project activities **are not experimental.**

CONSIDERATIONS



Researcher - proponent **Public health practitioner** - co-investigator	**Public Health Official** - proponent **Researcher** - co - investigator
Non - urgent	**Urgent** (with certification of urgency from a higher official / agency)
Primary intent to **publish results / new knowledge** (unethical if unpublished) Secondary intent - **to improve services**	Primary intent to **creation of a policy or bulletin** that is meant to improve the outcomes of the beneficiaries **Secondary intent to publish**

Summary of Key Literature

- Framework for public health practice
- Code of ethics for public health practice
- Distinguishing public health research from practice
- Recommending an oversight committee

Framework for Practice

Nancy E. Kass, ScD . An Ethics Framework for Public Health . Am J Public Health. 2001

"To advance traditional public health goals while maximizing individual liberties and furthering social justice, public health interventions **should reduce morbidity or mortality**; data must substantiate that a program will reduce morbidity or mortality**; burdens of the program must be identified and minimized**; the **program must be implemented fairly** and must, at times, minimize preexisting social injustices; and fair procedures must be used to determine which burdens are acceptable to a community. "

Framework for Practice

Nancy E. Kass, ScD . An Ethics Framework for Public Health . Am J Public Health. 2001

1. What are the **public health goals** of the proposed program?
2. How **effective** is the program in achieving its stated goals?
3. What are the known or potential **burdens** of the program?
4. Can burdens be **minimized**? Are there alternative approaches?
5. Is the program implemented **fairly**?
6. How can the **benefits and burdens** of a program be fairly balanced?

Code of Ethics

James C. Thomas . A Code of Ethics for Public Health. Am J Public Health. July 2002

1. Public health should address principally the **fundamental causes of disease and requirements for health**, aiming to prevent adverse health outcomes.
2. Public health should achieve community health in a way that **respects the rights of individuals** in the community.
3. Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an **opportunity for input from community members**.
4. Public health should advocate for, or work for the **empowerment of, disenfranchised community members**, ensuring that the basic resources and conditions necessary for health are accessible to all people in the community.

Code of Ethics

James C. Thomas . A Code of Ethics for Public Health. Am J Public Health. July 2002

5. Public health should **seek the information needed to implement effective policies and programs** that protect and promote health.

6. Public health institutions should **provide communities with the information** they have that is needed for decisions on policies or programs and should obtain the community's consent for their implementation.

7. Public health institutions should act in a **timely manner** on the information they have within the resources and the mandate given to them by the public.

8. Public health programs and policies should incorporate a variety of approaches that **anticipate and respect diverse values, beliefs, and cultures in the community**.

Code of Ethics

James C. Thomas . A Code of Ethics for Public Health. Am J Public Health. July 2002

9. Public health programs and policies should be implemented in a manner that most **enhances the physical and social environment.**

10. Public health institutions should **protect the confidentiality of information** that can bring harm to an individual or community if made public. Exceptions must be justified on the basis of the high likelihood of significant harm to the individual or others.

11. Public health institutions should ensure the **professional competence** of their employees.

12. Public health institutions and their employees should engage in collaborations and affiliations in ways that **build the public's trust and the institution's effectiveness.**

Research vs Practice

Hodge and Gostin. Public Health Practice vs Research: A Report for Public Health Practitioners including cases and guidance. 2004

- **General legal authority**
  - Public health authorities may conduct activities pursuant to general legal authorization
- **Specific intent**
  - given that the public health authority provides an accurate and honest assessment of the intent
- **Responsibility**
- **Participant benefit**
- **Experimentation**
- **Subject selection**

Research vs Practice

Hodge and Gostin. Public Health Practice vs Research: A Report for Public Health Practitioners including cases and guidance. 2004

Steps and Related Assumptions and Questions	Yes	No	Next Action	
			If Yes, then	If No, then
Step 1: Check Key Assumptions				
Assumption 1.A: Are you a governmental public health official, agent, agency, or entity at the federal, tribal, state, or local level (or an authorized partner conducting public health activities via contract or other agreement)?			Go to **A 1.B.**	**Stop**. This Checklist does not apply.
Assumption 1.B: Does your activity involve the acquisition, use, or disclosure of identifiable health data (i.e., individually-identifiable data that relate to a person's past, present, or future physical or mental health or condition or provision or payment of health care, or identifiable bodily tissues or biological samples)?			Go to **Step 2.**	**Stop**. This Checklist does not apply.
Step 2: Assess the Foundations of Public Health Practice				
Assumption 2.A: In general, does your activity involve the collection and analysis of identifiable health data for the purpose of protecting the health of a particular community, where the benefits and risks are primarily designed to accrue to the participating community?			Go to **Q 2.A.**	Go to **Step 3.**
Question 2.A: Is there a *specific* legal authorization (via statute, administrative regulation, or other law) and corresponding governmental duty to use identifiable health data for a public health purpose that underlie the activity?			**Stop**. This activity is practice.	Go to **Q 2.B.**
Question 2.B: Does your activity involve direct performance or oversight by a governmental public health authority (or its authorized partner) and accountability to the public for its performance?			Go to **Q 2.C.**	Go to **Step 3.**

Research vs Practice

Hodge and Gostin. Public Health Practice vs Research: A Report for Public Health Practitioners including cases and guidance. 2004

Steps and Related Assumptions and Questions	Yes	No	Next Action	
			If Yes, then	If No, then
Question 2.C: Does your activity legitimately involve persons who must participate in the activity or did not specifically volunteer to participate (i.e., they did not provide informed consent absent a waiver under the Common Rule?)			**Stop**. This activity is practice.	Go to **Step 3**.
Step 3: Assess the Foundations of Human Subjects Research				
Assumption 3.A: In general, does your activity involve the collection and analysis of identifiable health data for the purpose of generating knowledge that will benefit those beyond the community of persons who bear the risks of participation?			Go to **Q 3.A**.	The activity is likely practice. Go to **Step 4**.
Question 3.A: Does your activity involve living individuals?			Go to **Q 3.B**.	**Stop**. This is not human subjects research.
Question 3.B: Does your activity involve, in part, private information as defined in the Common Rule?			Go to **Q 3.C**.	**Stop**. This is not human subjects research.
Question 3.C: Does your activity involve persons who voluntarily participate via informed consent or the consent of their guardian, absent a waiver of informed consent under the Common Rule?			Go to **Step 4**.	**Stop**. This activity is practice.

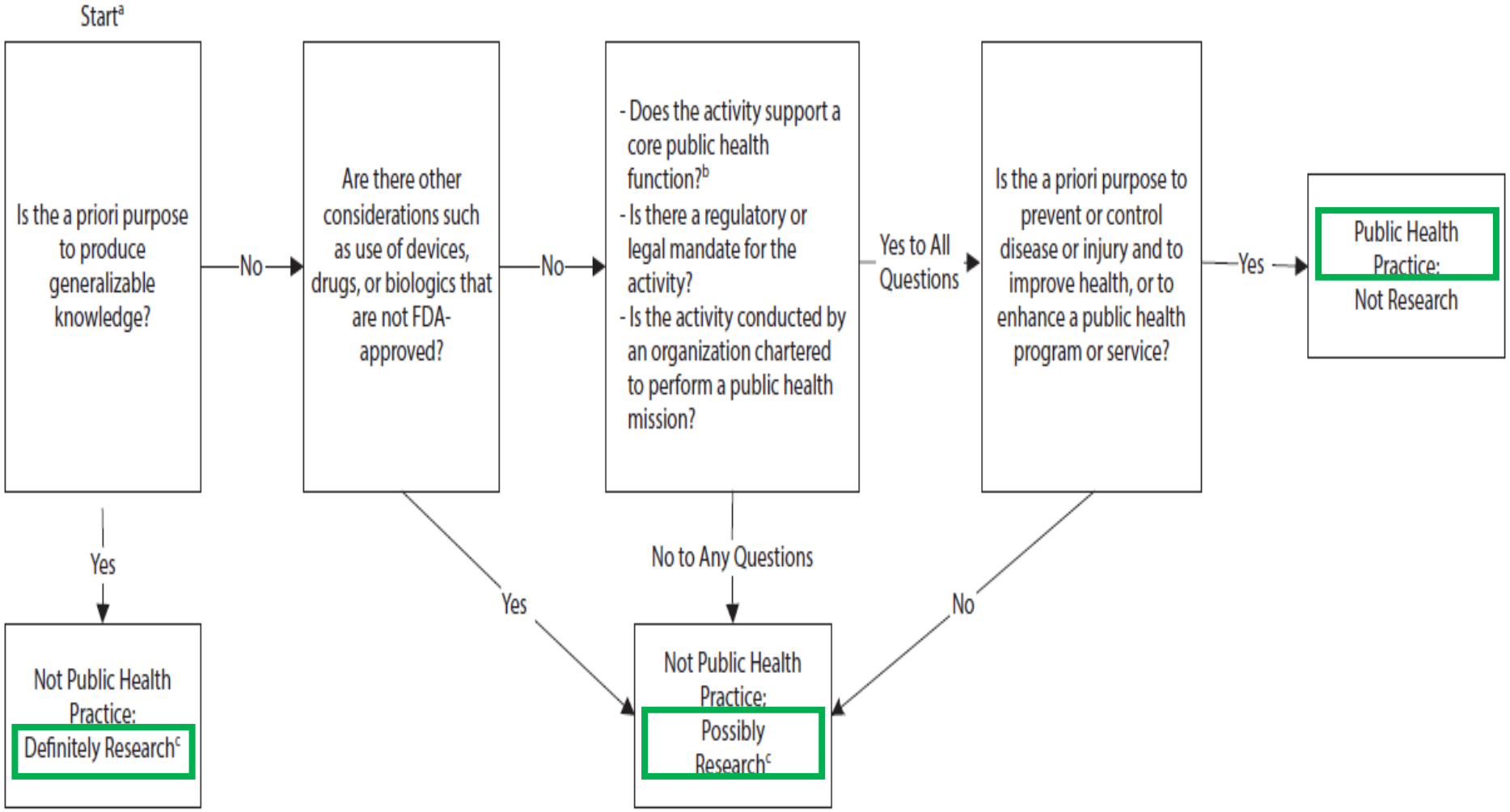
Research vs Practice

Distinguishing Public Health Research and Public Health Non-research. CDC Policy Guidelines. 2010

- Specific features that **cannot distinctly** separate public health research versus practice:
  - publication of findings
  - statutory authority
  - methodological design
  - selection of participants
  - hypothesis testing or generating
- **Public health surveillance, emergency response, and evaluation** are three activities that can present a dilemma as to whether the activity is research or non-research

Research vs Practice

Otto, et. al, Research or Practice? Public Health Research is not Practice, 2014



Research vs Practice

Pratt, B, Paul A, Hyder AA, and Ali J. Ethics of health policy and systems research: a scoping review of the literature. Health Policy and Planning, 2017

Key criteria that may distinguish public health research vs practice.

1) having a primary aim of creating **generalizable knowledge**
2) intent to **publish** in a peer reviewed journal,
3) use of **research methods**
4) challenge to clinical practice with **risk** for patient
5) being conducted by a **person not normally having access to patient records**
6) **information gathering beyond** that gathered in routine clinical practice, and/or
7) involving **randomization or use of placebo**.

Oversight committee

MacQueen KM and Buehler JW. Ethics, Practice and Research in Public Health. Am J Public Health. 2004

- For public health activities that are considered as non-research, then IRB procedures may not apply, hence the **interests of the participants and communities** are protected under public health laws.
- Emphasized the **ethical conduct of activities**
- There is a need for public health ethics review mechanisms that are **sensitive to risks and burdens to participants** and **offer flexible and timely responses** to emergent situations or crises.

Oversight committee

Drue H. Barrett, Roger H. Bernier , et al. Strengthening Public Health Ethics at the Centers for Disease Control and Prevention. 2008

- In 2005, the Center for Disease Control and Prevention (CDC), saw the need to strengthen **public health ethics.**
- As a result, the CDC created an **external ethics subcommittee** of the Advisory Committee to the director, an internal **CDC Public Health Ethics Committee (PHEC)** and the office of the CDC public health **Ethics Coordinator.**

Oversight committee

Pearlman D. Rethinking local IRB review at state health departments: Implications for a consolidated independent public health IRB. J of Medicine Law and Ethics. 2012

Addresses fundamental problems in state DOHs

- Problem 1: Do DOHs Collectively Have an Adequate Research Ethics Infrastructure?
- Problems 2 and 3: Application and Interpretation of Public Health Laws at DOHs
- Problem 4: Conflicts of Interest and Commitment at DOH IRBs

The author proposes the adoption of a **consolidated independent IRB** in the USA

Summary of Key Informant Interviews

Distinguishing Public Health Research vs Practice

- It is difficult to distinguish public health research versus public health practice.
- The following attributes may but cannot effectively distinguish between research and practice: (1) the **proponent** (2) the main **intent** or primary objective of the activity, (3) intended **beneficiaries** of the activity, and (4) **urgency** of the activity.
- **Publication** as a distinguishing factor between research and practice is also a grey area.

Summary of Key Informant Interviews

Distinguishing Public Health Research vs Practice

- Both research and practice have **risks** and will require **ethics oversight**.
- Urgent programs are clearly public health practice and may proceed without ethical clearance. The implementation of these programs should be **ethical**.
- We tend to err on the side of commission, to treat the project as a research, so that the **privacy** and **confidentiality** of the concerned individual or community is protected.

Summary of Key Informant Interviews

Distinguishing Public Health Research vs Practice

- The administrative roles of public health practitioners should be **separate** from their participation in research undertakings.
  - One's interest as a practitioner should be ahead of research interest, for public health officials.
- Potential **conflicts** may also exist when a researcher would like to use existing public health data such as surveillance data (which was initially intended to be used for research purposes).

Summary of Key Informant Interviews

Ethical guidelines for public health research and public health practice:

Project Proponent and conflicts of interest

- If the researcher will wish to use data from public health practice, he should get a **co-investigator who is from a public health office** so that a "check and balance" may be provided, and that privacy of subjects and confidentiality of data are maintained.

- For public health practice, the major proponent is the **public health official**, but he may also seek a co-investigator who is researcher.

- A public health official **cannot simultaneously** assume the role of both researcher and public health official, as he should be primarily fulfill the mandate to address the public health concerns, and make research component secondary.

Summary of Key Informant Interviews

Ethical guidelines for public health research and public health practice:

Ethical Review

- Both public health research and public health practice activities may have to be **subject to ethics review and clearance** before the start of the activities.
- The ethics review of public health practice activities may not be in the same process or format as that conducted by health research ethics boards.
- An **ethics board** exists for public health researches, but none exists presently for the review of public health practice.
- IRBs should have **training** on distinguishing research from practice.

Summary of Key Informant Interviews

Ethical guidelines for public health research and public health practice:

Risks and Burdens

- Risks are present for both public health practice and public health research.
- In cases wherein public health surveillance data is to be used for research purposes, the data may be collated as an **aggregate**, and personal or identifying data needs to be **de-identified** so as not to encroach on privacy and confidentiality.
- The **optimal standard** of care in interventions for public health practice should be given, but public health researchers may provide interventions that are not the usual standards of care.

Summary of Key Informant Interviews

Ethical guidelines for public health research and public health practice:

Emergency situations

- In emergency situations or situations relevant to national security, there is no need for ethical review for public health practice activities. Ethical review may be **waived**.
- However, a **higher agency or authority** (such as the Secretary of Health or a government official) needs to certify that the activity indeed warrants emergency consideration.
    - The public health practitioner who will conduct the activity should not be the one to also declare its urgency.

Summary of Key Informant Interviews

Ethical guidelines for public health research and public health practice:

Emergency situations

- Public health interventions during emergency situations **should not be delayed** due to researches and should not be in conflict with research activities, as the latter may potentially delay interventions.
- In cases of emergency programs with attached research components in which data may be generated, it is recommended that **two informed consents** be obtained from participants, one is for the emergency response (which may be waived) and the other for research (which is mandatory).
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Summary of Key Informant Interviews

- Difficult to distinguish clearly the difference between public health practice vs research
  - Cannot be distinguished by type of knowledge that is generated
  - Cannot be distinguished by intent to publish and output
- Current definitions have overlaps
- Conflicts exist when public health practitioners have secondary research interests
- A body is needed to decide to implement public health guidelines

Recommendations

Creation of a Public Health Ethics Committee (PHEC)

- Public health research ethics has been addressed by the National Ethical Guidelines for Health and Health Related Research, 2017.
- Public health practice ethics is observed mainly by having proponents practice ethically.
- This project proposes the creation of a Public Health Ethics Committee (PHEC), that will be tasked to provide guidance in seeing to it that public health research and practice activities adhere to the ethical principles.

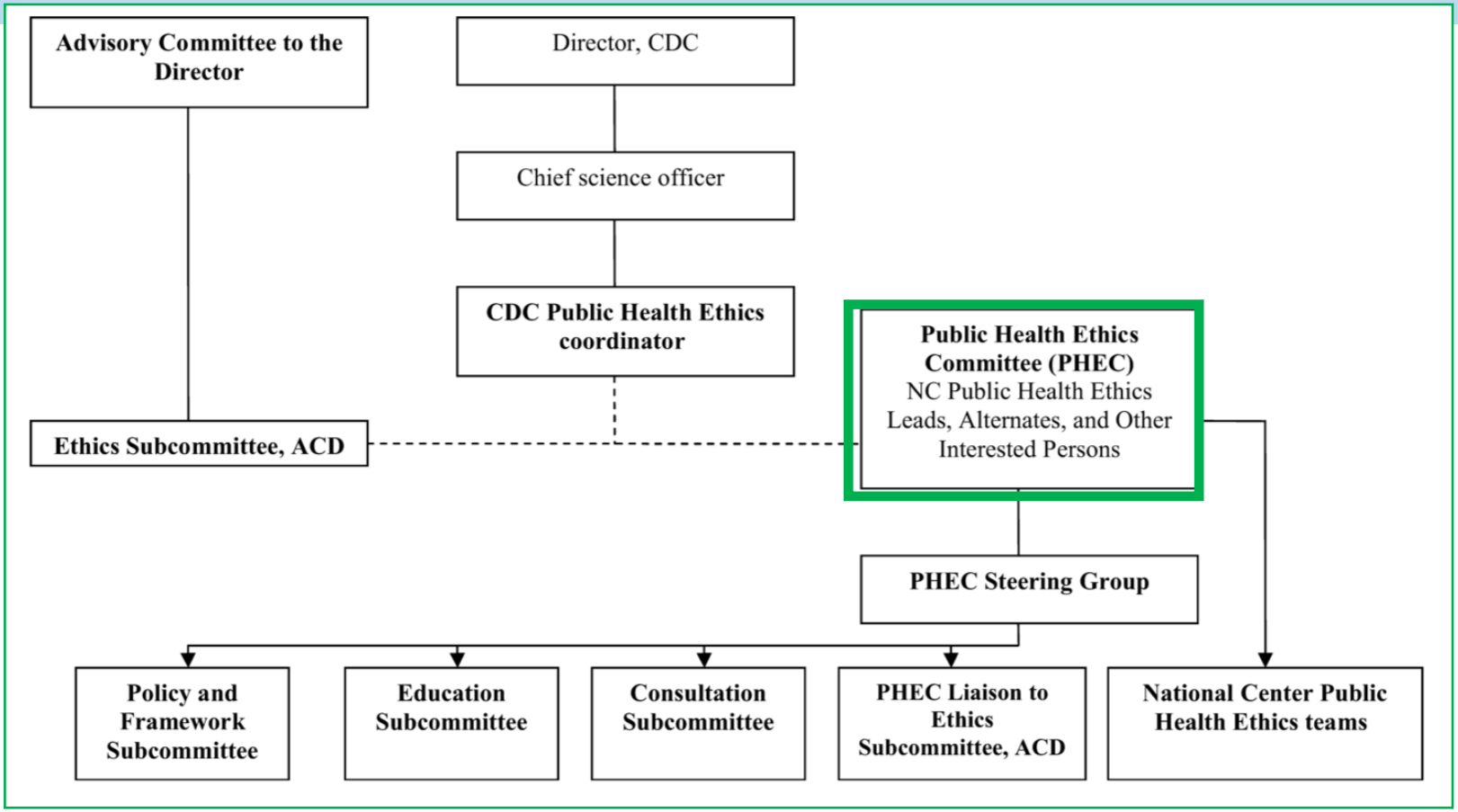
Recommendations

Functions of the proposed Public Health Ethics Committee (PHEC)

- The PHEC will be tasked to **provide ethical clearance and implement the ethical guidelines** of any public health activity whether it be for research or for practice or for both.
- The PHEC will decide on the **ethical merits** of a program that has the dual intent of practice and research
- The PHEC can **decide on situations wherein there may be conflicts of interest**. (The secondary objective of the research may conflict with the primary practice activities.)

Recommendations

Public health ethics model adopted by the CDC in 2005



Recommendations

Scope of Authority of proposed Public Health Ethics Committee (PHEC)

- The created Philippine PHEC should be appointed by the highest authority of the institution.
    - This will ensure institutional support that includes an operational budget, manpower and organizational resources such as an office and adequate staff.
- The PHEC should have a clear mandate and exist within the organization's structure while insulating it from influence and conflicts of interests.

Recommendations

Operating Procedures of proposed Public Health Ethics Committee (PHEC)

- The created PHEC should develop **standard operating procedures (SOPs).**
  - The SOPs should describe the organizational scope, authority and structure, and should detail administrative and review processes as well.
  - SOPs will ensure transparency of review, accountability of decisions and promote efficiency.

Recommendations

Composition of proposed Public Health Ethics Committee (PHEC)

- Similar to the composition of an ethics committee, the composition should include **scientific and non-scientific members and non-institutional members.**
- Considering that the committee will evaluate and approve both research and practice, it is suggested that the composition be **in compliance with the National Ethical Guidelines for Health and Health Related Research (2017).**
- However, because the PHEC should concern itself with public health practice activities as well, among the scientific members, there should be **public health researchers and practitioners**.
- All members should be **trained** in health research ethics and public health ethics principles.

Recommendations

Functions and Responsibilities of proposed Public Health Ethics Committee (PHEC)

- The PHEC should have the competence to review and decide on the ethical merits of both public health research and public health practice.
- In reviewing the public health research, the PHEC should balance the interests of the participants of the research without compromising the objectives of the research and the interests of the researchers.
- The PHEC should review public health research in accordance with existing local applicable guidelines, laws and regulations (eg. NEGHHR, 2017).
- In the event of the the lack of guidelines, the PHEC shall likewise consider international guidelines (eg. Declaration of Helsinki, CIOMS).

Recommendations

Functions and Responsibilities of proposed Public Health Ethics Committee (PHEC)

- In reviewing public health practice, the PHEC should balance national interests with that of the individual participants and the community.
- Depending on the urgency of the practice (eg. prevention and / or control of a disease outbreak, emergency response, etc), national interests may have to take precedence over the interests of the individual. Only the PHEC can decide on this.

Thank you for listening.