



# Public Health Ethics Oversight

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# Objectives of the Presentation

To discuss the salient features of the proposed policy on Public Health Ethics in the Department of Health (DOH)



# Public Health Research vs Practice



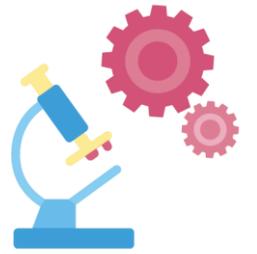
## HPDPPB commissioned study in 2017

- to flesh out *distinction between the two not addressed by the 2017 NEGHR*

## Rationale

- UP Manila Research Ethics Board (Jacinto Mantaring MD MSc, Prof. Edlyn Jimenez)

# When Practice & Research Interests Meet

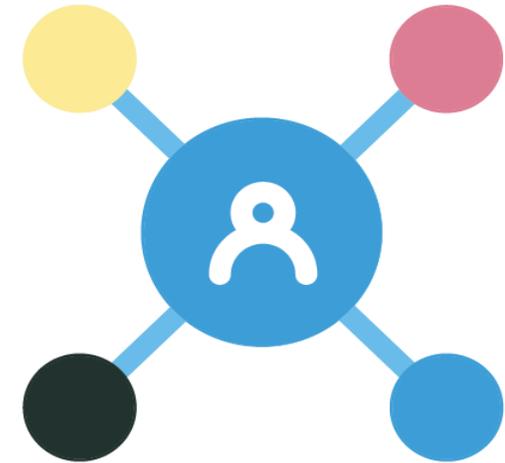


PH ACTIVITY	PH PRACTICE	RESEARCH
<b>Emergency</b>	Identifying displaced residents; health problems encountered	Collecting baseline data with the intention of following up displaced residents and derive generalizable knowledge about post-disaster displacement
<b>Outbreak Investigation</b>	Investigating reported symptoms of measles cases and initiate outbreak prevention protocol	Implementation of an additional non-standard intervention and determining its effectiveness in the prevention of an outbreak
<b>Surveillance</b>	Integrated HIV Behavioral and Serologic Surveillance (routine)	Analyzing IHBSS data to determine correlations between variables
<b>Program Evaluation</b>	Evaluation of the IMCI to assess effectiveness and identify gaps	Determining KAP of parents re the IMCI program



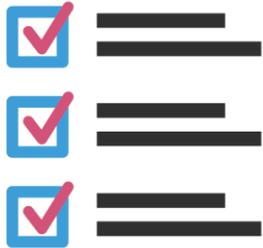
# When Outsourcing Functions blur

- Program monitoring/evaluation is a function/mandate of the institution and is considered *business as usual*
- Some program monitoring/evaluation activities are outsourced to a research institution or individual researcher who do not have legal mandate to conduct such activity i.e., data/sample collection





# Launching a NEW\* Public Health (PH) Program



- Recent controversies raised the question on ethical oversight in rolling out new\* public health programs

❖ \*NEW – no other programs exist in the world, or not yet considered standard by WHO

# Ethics of Health Research

## SINGLE SITE

*Guideline:* NEGHHRR (PHREB, 2017); CIOMS; REC SOP

*Oversight:* PHREB (RA 10532)

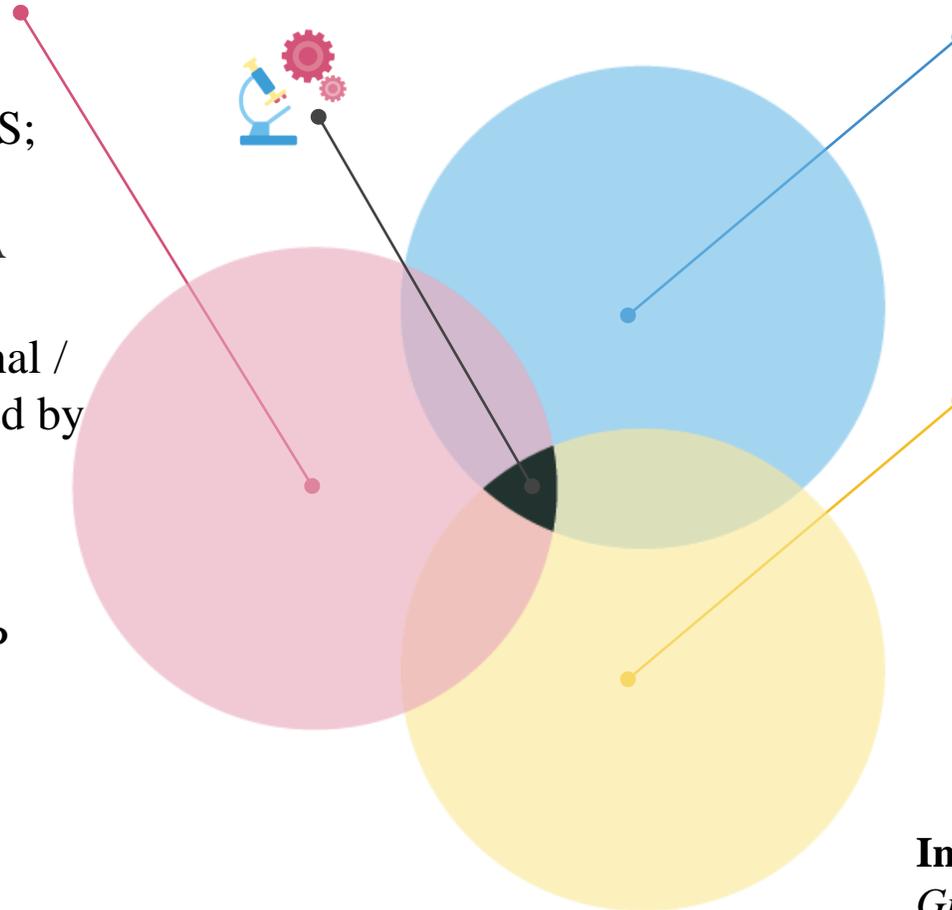
*Implementer:* Institutional / hospital RECs accredited by PHREB

## MULTIPLE SITES

*Guideline:* SJREB SOP (DOH, 2018)

*Oversight:* PHREB

*Implementer:* SJREB, secretariat @ DOH



## ETHICS OF PUBLIC HEALTH PRACTICE

*Guideline:* Code of Conduct of Public Health Workers (R.A 7305)/ Code of Conduct and Ethical Standards for Public Officials and Employees (R.A. 6713)

*Oversight:* Civil Service

*Implementer:* None

## ETHICS OF CLINICAL PRACTICE PROFESSIONAL vs INSTITUTIONAL

*Guideline:* Mexico and Kuala Lumpur Principles; Code of Ethics of the Medical Profession; Code of Conduct per health practitioner (e.g. Code of Medical Ethics [RA No. 4224])

*Oversight:* PRC; PMA (Medical Act of 1959)

*Implementer:* PMA; Professional Societies

## Institutional

*Guideline:* Hospital REC SOP

*Oversight:* PHREB

*Implementer:* Hospitals through Hospital RECs



# Goal of any Ethics Inquiry



Protecting the rights, welfare and well-being of human participants in...

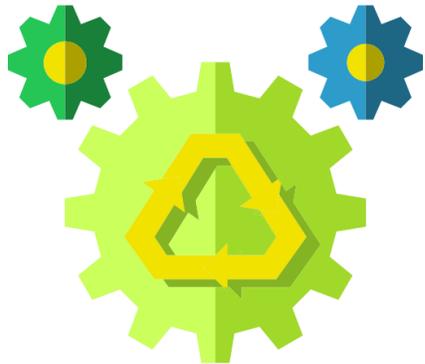
- Research or research-related activities
- Public health program
- Clinical encounter

Provide guidance on ‘best course of action’ to

- Researchers
- Policymakers
- Clinicians



# Salient Features of the Policy



To provide general framework and guidelines on the PHEC's review of public health policies and programs



To institute a monitoring and evaluation mechanism for the review process



To identify roles and responsibilities of key actors and stakeholders in the PHEC's review process

## OBJECTIVES



# Salient Features of the Policy

## Scope and Coverage

This order shall cover all DOH units (DOH Central Office Bureaus, DOH Regional Offices, DOH-ARMM, DOH Hospitals, including specialty hospitals and corporate hospitals, and DOH Treatment and Rehabilitation Centers), and attached agencies involved in the design, implementation and evaluation of public health programs and researches.



# Salient Features of the Policy

## General Guidelines

- The DOH shall uphold the principles of public health ethics at all times.
- The PHEC review shall only cover interventional public health policies and activities that are identified as high risk.
- The PHEC review shall be a prerequisite for approval of new policies, programs, and other public health activities.



# Salient Features of the Policy

## Principles of Public Health Ethics

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 and work for the empowerment of disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.



# Salient Features of the Policy

## Principles of Public Health Ethics

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.



# Salient Features of the Policy

## Principles of Public Health Ethics

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 collaboration and affiliation in ways that build the public's trust and the institution's effectiveness.



# Salient Features of the Policy

## High Risk Public Health Activities

1. Endanger participants' safety that increase risk for death, disability or injury
2. Perform life threatening interventions;
3. Collect pertinent subject identifiers;
4. Provide threat to the privacy and confidentiality of participant's data;
5. Recruit participants without informed consent; and
6. Collect human samples (blood, saliva, tissue, etc.)



# Salient Features of the Policy

## General Guidelines

The DOH shall constitute a public health ethics committee (PHEC), which shall function as an advisory body that:

- Reviews and determine the ethical soundness of public health activities;
- Recommends risk mitigation measures;
- Determines frequency of monitoring;
- Assesses compliance to recommendations; and
- Conducts inquiries as may be necessary to address ethics-related support on public health programs and/or activities required by the Office of the Secretary.



**Program protocol submission  
from DOH cluster/  
program  
manager**

**Initial screening to identify PH  
research from PH program/non  
research**

**Research Ethics  
Review**

**With RESEARCH  
COMPONENT or considered  
RESEARCH**

**PHREB-accredited  
Research Ethics  
Committees (RECs)**

**PHREB-accredited  
Research Ethics  
Committees (RECs)**

**PH Activity with high risks**

**Expedited Review**

**Full Board Review**

# **PHEC Review Process**



**Evidence review and synthesis**



**Stakeholder Mapping, 1<sup>st</sup>  
Stakeholder Consultation**



**Draft Policy Issuance**



**2<sup>nd</sup> Stakeholder Consultation**



**PHEC  
Review**



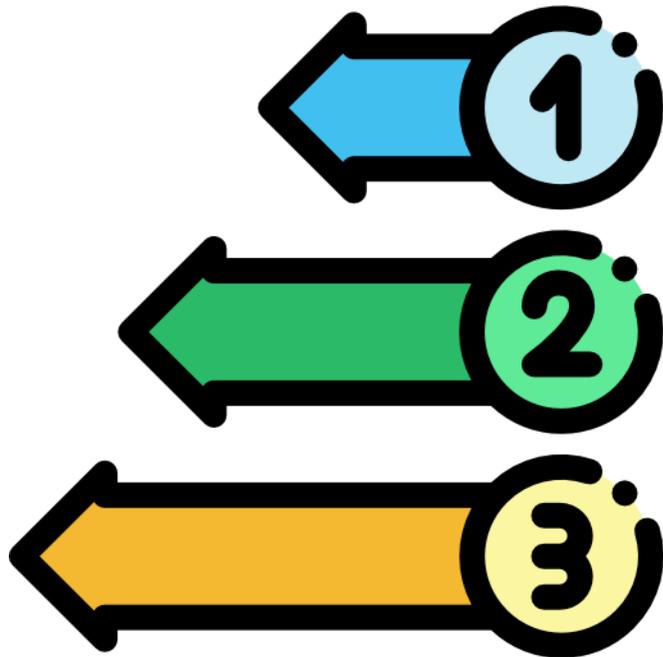
**Cluster and ManCom  
Approval**



**DO: Endorsement to OSEC  
AO: Presentation to Execom**



# Way Forward



- Policy Issuance on Operationalizing Public Health Ethics Committee
- Development of the Standard Operating Procedures for PHE Review

# *Thank you.*

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