Parallel Session on:
Strengthening Research Ethics Review
Marco Polo Hotel, Mindanao Room, Ground Floor
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Lecture 2:
Ethical Principles in Research
National Regulatory System for Human Protection in Research

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Ethical Principles (*Belmont Report 1974*)

- Respect for Persons
- Beneficence
- Non-maleficence
- Justice

Principle of Respect for Persons

1. Autonomy
   - Capable decision-makers
   - Respect for the vulnerable
   - "Informed Consent"
2. Truth telling
3. Confidentiality
4. Fidelity

Beneficence

A positive duty providing benefits
Balancing benefits and harms

Helsinki 2008:

"It is the duty of the physician to promote and safeguard the health of the people."

"Every patient… in the study should be assured of access to the best prophylactic, diagnostic and therapeutic methods identified in the study."

"Populations… stand to benefit from the results."

Non-maleficence

"Do no harm"

Avoid risks unless potential results justify them.

Helsinki 2008:

"Risks involved must be adequately assessed and can be satisfactorily managed."

"Cease if risks outweigh potential benefits."

"No use of placebo or no treatment as controls…"

Justice

- ***Rawls***: Fairness,

  Person gets what is due her.

- ***Aristotle***: Equals treated equally,

  unequals unequally.

WHO- CIOMS 2001 Guidelines

Research with women, pregnant, lactating

Research with the poor

Authorship

Ethical Issues

- Conflict of interest
- Disproportion between importance of objectives and resource utilization
- Product availability
- Post-research care of participants
- Bias, use of control arms
- Uninformed participation of individuals, community
- Errors, honest mistakes, negligence
- Misconduct: fabrication, falsification, plagiarism

Importance of Guidelines

"To ensure quality and consistency in the ethical review of health research involving humans."

(WHO Operational Guidelines)

- Strengthen institutional capacity for ethical review.
- Protect (enhance) credibility of ERCs.
- Ensure independence from political, institutional, professional and market influences.
- Ensure impartiality.
- Promote consistency.

International and National Guidelines

1964 Declaration of Helsinki of WMA,… 2008

1982 International Guidelines for Biomedical Research Involving Human Subjects WHO & CIOMS… 1993, 2001

1985 National Ethical Guidelines for Health Research ... 2006

1996 ICH Guidance E6: Good Clinical Practice Guidelines

2000 WHO Operational Guidelines for Ethics Committees that Review Biomedical Research

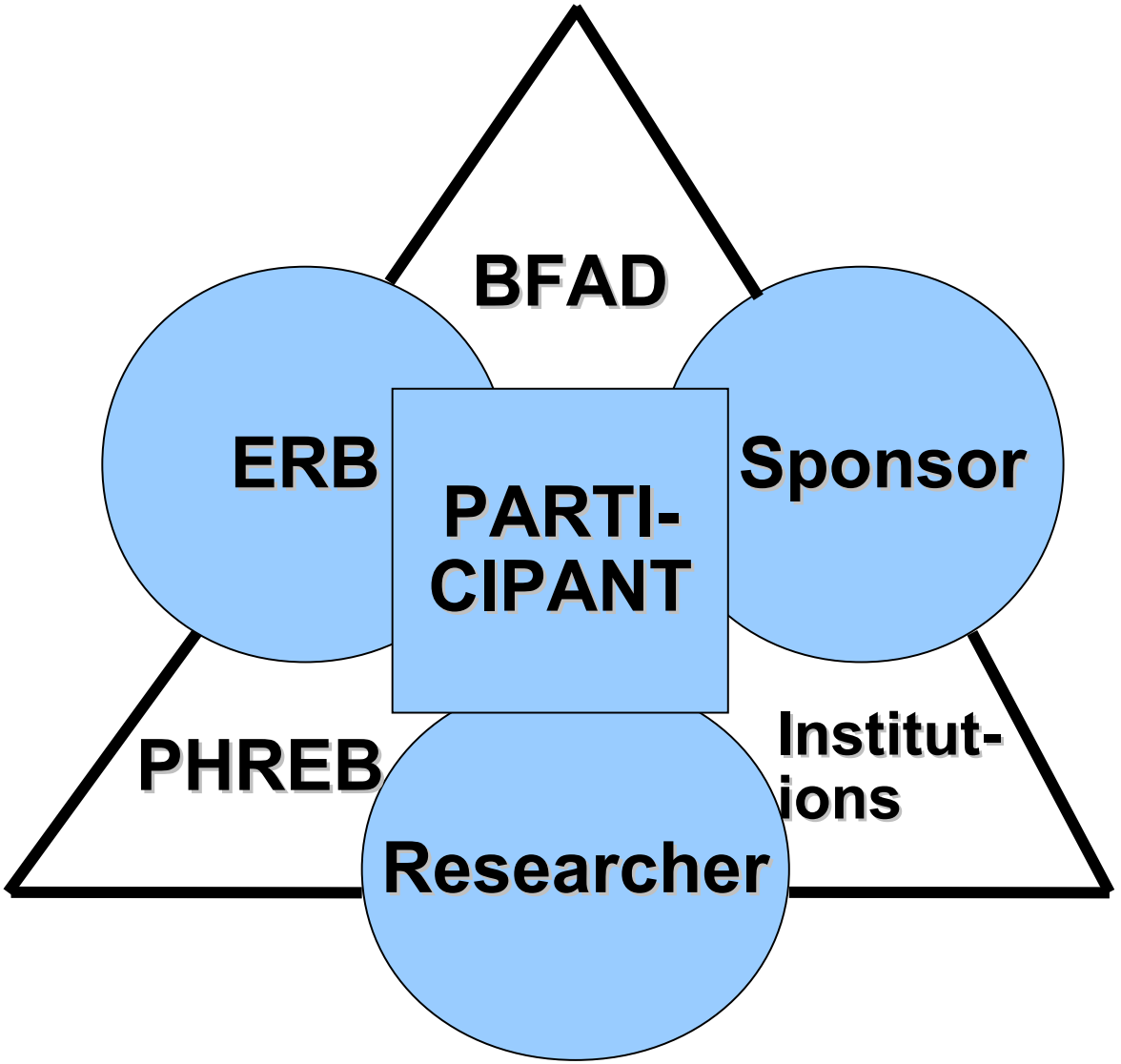
Regulatory System for Protection of Human Participants in Health Research

3- layered system

1. Individual informed consent
2. Ethics Review Committees
3. National regulatory authorities

The National Research Ethics Review System

Defining the Framework



Values in Health Research

- Equity in health needs appropriate priority setting and ethical conduct in health research and health care provision.
- There is a humane imperative to ensure that health research have meaningful outcomes *(Juntra Karbwang, 2007)*- i.e., those in the interest of patients and public health.
- Health research must be respectful of the dignity of persons and protective of human rights.