STREET CHILDREN NGO SUPPORT PROJECT
LIFEBANK MICROFINANCE FOUNDATION, INC.

We excel, We share, We care
For Children in Street Situations

presents

BASIC TIPS IN RESEARCH INVOLVING CHILDREN IN STREET SITUATIONS

14 Sept 2021 | Tuesday | 8:30-12:00 noon
VIA ZOOM

RESOURCE SPEAKER:
John Piermont V. Montilla

Member of the Ethics Review Committee of the Western Visayas Health Research Consortium, DSWD VI Planning Officer, President of Kabataang Gabay sa Positibong Pamumuhay (KGP, Inc)

TOPICS:

- What is research
- Why research on CiSS is important
- Research ethics
- Risks involving research with CiSS
- Laws and controls governing research
- Ethical principles
- Good practice protocols

REGISTER AT: HTTPS://BIT.LY/RESEARCHCISS1

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TOPIC

1

WHAT IS RESEARCH

TOPIC

1

OUTLINE

- What is Research
- Research Objectives and Types of Researches

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- # RESEARCH

  - Activity that inquires into a particular subject with the aim to **develop or contribute to generalizable knowledge** (including theories, principles and relationships) or any accumulation of information using **scientific methods**, observation, inference, and analysis.

  - The systematic, rigorous investigation of a situation or problem in order to generate new knowledge or validate existing knowledge.

RESEARCH IS NOT

- medical treatment, surveillance, audit, program evaluation
- unsystematic, disorganized, and without focus

Health Research Stakeholders

refer to the national and the local public and private agencies/ organizations, policymakers, the academe, medical and health societies, people's organizations and others who are concerned with and affected by health and development

– **RA 10532 Sec. 3 b**

DEFINITION OF HEALTH

a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity – World Health Organization

Behavioral Research

studies that apply social and behavioral theories and principles to understand the actions or reactions of persons in response to external or internal stimuli or to an intervention; in health and medicine, it includes studies on basic bio-behavioral mechanisms and social processes that are relevant to public health or disease prevention and promotion, etiology, diagnosis, treatment, and rehabilitation.

– National Ethical Guidelines For Health And Health-related Research 2017

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Health Research

research that seeks to understand the impact of health policies, programs, processes, actions, or events originating any sector; to assist in developing interventions that will help prevent or mitigate the impact; and to contribute to the achievement of health equity, and better health for all.

– National Ethical Guidelines For Health And Health-related Research 2017

PURPOSE AND OBJECTIVE OF RESEARCH

The purpose of research is to discover answers through the application of scientific procedures

The objectives are:

- ✓ To gain familiarity with a phenomenon or to achieve new insights into it
- ✓ To portray accurately the characteristics of a particular individual, situation or a group
- ✓ To determine the frequency with which something occurs or with which it is associated with something else
- ✓ To test a hypothesis of a causal relationship between variables

On a broader perspective, all researches can be classified into two groups: Quantitative and Qualitative researches

Quantitative Research: *refers to the systematic empirical investigation of any phenomena via statistical, mathematical or computational techniques. The objective of quantitative research is to develop and employ mathematical models, theories and/or hypotheses pertaining to phenomena*

Qualitative Research: *refers* to research dealing with phenomena that are difficult or impossible to quantify mathematically, such as beliefs, meanings, attributes, and symbols.

TOPIC

2

Why CiSS Research?

TOPIC

2

OUTLINE

- Why CiSS research?
- Various applicable researches along CiSS

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Statistics

The United Nations estimates there are **up to 150 million street children** in the world. No one knows the exact number because they are often unknown to social care and government organisations. Street children can have complex circumstances and are very vulnerable to exploitation and violence.

Homeless children are among the most vulnerable of the homeless in the Philippines. There are approximately 250 homeless children

https://borgenproject.org/homelessness-in-the-philippines/

- **VARIOUS RESEARCHES (and applications to CiSS)**

1. APPLIED RESEARCH

Applied research refers to scientific study and research that seeks to solve practical problems. Applied research is used to find solutions to everyday problems, cure illness, and develop innovative technologies, rather than to acquire knowledge for knowledge's sake.

Examples of employing applied research for CiSS:

- *Improve access to ALS among CiSS*
- *Prevent sexual exploitation and abuse among CiSS*
- *Mitigate gang violence among CiSS*

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- **VARIOUS RESEARCHES (and applications to CiSS)**

2. BASIC RESEARCH

Basic research is driven by a scientist's curiosity or interest in a scientific question. The main motivation is to expand knowledge, not to create or invent something. There is no obvious commercial value to the discoveries that result from basic research.

Examples of basic science investigations probe for answers to questions such as CiSS:

- ***What are the pull and push factors among CiSS***
- ***What are profile of CiSS in Highly Urbanized Settings?***
- ***What are the specific risks and vulnerabilities of the CiSS in terms of HIV and AIDS?***

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VARIOUS RESEARCHES (and applications to CiSS)

3. CORRELATIONAL RESEARCH

refers to the systematic investigation or statistical study of relationships among two or more variables, without necessarily determining cause and effect. It Seeks to establish a relation/association/correlation between two or more variables that do not readily lend themselves to experimental manipulation.

For example, to test the hypothesis "attending to ALS decreases CiSS risk in involving in crime". T here are 2 ways of conducting research.

- *Experimental – group samples and make one group attend ALS and then compare involvement to crime*
- *Survey – ask group samples of CiSS their involvement in crime? And then compare.*

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VARIOUS RESEARCHES (and applications to CiSS)

4. DESCRIPTIVE RESEARCH

refers to research that provides an accurate portrayal of characteristics of a particular individual, situation, or group. Descriptive research, also known as statistical research. These studies are a means of discovering new meaning, describing what exists, determining the frequency with which something occurs, and categorizing information.

In short descriptive research deals with everything that can be quantified and further explored.

For example, ascertaining the sexual behaviors and the prevalence of sexually transmitted infections among of CiSS. The end user of the research will know what prevention, treatment, and care can be provided for CiSS

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VARIOUS RESEARCHES (and applications to CiSS)

5. ETHNOGRAPHIC RESEARCH

refer to the investigation of a culture through an in-depth study of the members of the culture; it involves the systematic collection, description, and analysis of data for development of theories of cultural behaviour. It studies people, ethnic groups and other ethnic formations, their ethno genesis, composition, resettlement, social welfare characteristics, as well as their material and spiritual culture

For example for CiSS, to understand street families way of life and relationships with other street families in the suburbs of Metro Manila.

- # VARIOUS RESEARCHES (and applications to CiSS)

6. EXPERIMENTAL RESEARCH

is an objective, systematic, controlled investigation for the purpose of predicting and controlling phenomena and examining probability and causality among selected variables.

Advantages: Best establishes cause-and-effect relationships
Disadvantages: Feasibility, requires tedious ethical process & protocols

The simplest experimental design includes two variables and two groups of participants: For example for CiSS, experimental group are CiSS who are sexually active and are given condoms and a control group of CiSS who are sexually active and are not provided with condoms to study condom use and prevalence sexually transmitted infections

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VARIOUS RESEARCHES (and applications to CiSS)

7. EXPLORATORY RESEARCH

is a type of research conducted for a problem that has not been clearly defined. Exploratory research helps determine the best research design, data collection method and selection of subjects. The results of exploratory research are not usually useful for decision-making by themselves, but they can provide significant insight into a given situation. Exploratory research is not typically generalizable to the population at large.

For example for CiSS, "The quality of life of 'children in street situations' accommodated at three LGU-run temporary shelters in Bacolod City: an exploratory study.

Data collection methods: FGDs, In-depth interviews, with social workers, houseparents, CiSS and review of case studies

- # VARIOUS RESEARCHES (and applications to CiSS)

7. GROUNDED THEORY RESEARCH

is a research approach designed to discover what problems exist in a given social environment and how the persons involved handle them; it involves formulation, testing, and reformulation of propositions until a theory is developed. Grounded theory is a research method that operates almost in a reverse fashion from traditional research and at first may appear to be in contradiction to the scientific method.

For example for CiSS, "Blended Cognitive-Behavioral Therapy and Rehabilitative Intervention as a Model for Reintegration Process among CiSS who are involved in the crime of murder: grounded theory.

VARIOUS RESEARCHES (and applications to CiSS)

8. HISTORICAL RESEARCH

is research involving analysis of events that occurred in the remote or recent past. Historical research can show patterns that occurred in the past and over time which can help us to see where we came from and what kinds of solutions we have used in the past. Understanding this can add perspective on how we examine current events and educational practices.
Historical research gives a social scientist a better context for making realistic decisions.

For example for CiSS, The Difficult Path in Emancipating from Commercialization of Sex during the American Period: Selling Sex in Olongapo City, Now and Then

VARIOUS RESEARCHES (and applications to CiSS)

9. PHENOMENOLOGICAL RESEARCH

an inductive, descriptive research approach developed from phenomenological philosophy; its aim is to describe an experience as it is actually lived by the person. Phenomenology is concerned with the study of experience from the perspective of the individual, 'bracketing' taken-for- granted assumptions and usual ways of perceiving. As such they are powerful for understanding subjective experience, gaining insights into people's motivations and actions, and cutting through the clutter of taken-for-granted assumptions and conventional wisdom. They are based in a paradigm of personal knowledge and subjectivity, and emphasise the importance of personal perspective and interpretation.

For example for CiSS: Boys and Childhood Sexual Violence Experience and the Sequel of Psychosexual Sterotypes : A phenomenological Study

World Health Organization

TOPIC

3

RESEARCH AND RESEARCH ETHICS

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“Experimenting on human beings is ***morally necessary*** *and* ***necessarily immoral****”*

- Jean Bernard

Ethics are the moral principles that a person must follow, irrespective of the place or time. Behaving ethically involves doing the right thing at the right time. Research ethics focus on the moral principles that researchers must follow in their respective fields of research.

Enago Academy

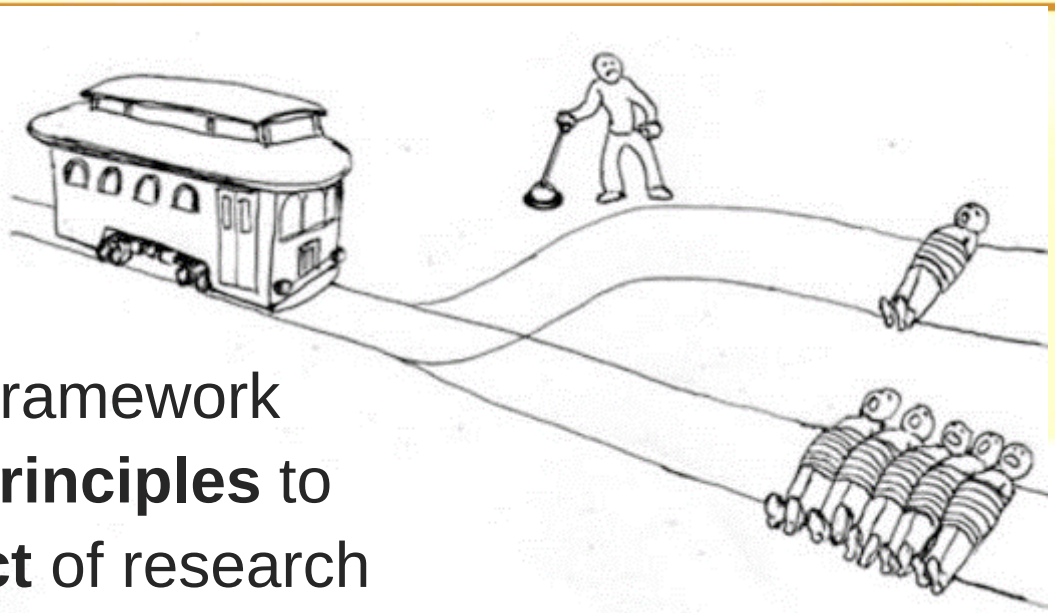
DEFINITIONS

RESEARCH WITH HUMAN BEINGS

Any social science, biomedical, or epidemiologic activity that entails systematic collection or analysis of data with the intent to generate new knowledge in which **human beings are exposed** to manipulation, intervention, observation or other interaction with investigators either directly, or through alteration of their environment, or become **individually identifiable** through investigator's collection, preparation, or use of biological material or medical or other records.

(WHO)

DEFINITIONS



ETHICS: Moral behavior

ETHICS IN RESEARCH: framework applying broad **ethical principles** to the **responsible conduct** of research and to the use of any **outcomes** resulting from research *(University of Reading)*

Focus on research participant

Consider community and environment in ethics

DEFINITIONS

RESEARCHER

A qualified scientist who undertakes **responsibility for the scientific and ethical integrity** of a research at a specific site

INVESTIGATOR

Responsible for the conduct of the **clinical trial** at a trial site

TECHNICIAN

Collector of data

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DEFINITIONS

PROTOCOL

A **document** that provides the background, rationale, and objectives of a research and describes its design, methodology, organization including ethical and statistical considerations *(a research proposal is the submitted protocol for approval)*

DEFINITIONS

SPONSOR

An individual, company, institution or organization responsible for the initiation of a study, clinical investigation, management and/or financing of a clinical trial or a study

IMPORTANCE OF ETHICS IN RESEARCH

Right thing to do

Protects research participants

Provides advocates for research participants

"Rights, safety, and well-being of [research participants] are the most important considerations and should prevail over the interests of science and society." *(ICH-GCP, 2016)*

Preserves credibility, trust, and accountability

Reduces liabilities, wasted time and resources

Turns useless, harmful, worthless to useful, helpful, worthy

Obeys laws

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CONSIDERATIONS

2. Believe that there are correct ways of doing research

CONSIDERATIONS

3. Value the research participant

Indispensable for the research (partner)

Chooses to join

Cannot be worse off by joining research

"While the primary purpose of [research] is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research [participants]" (Helsinki, 2013)

Protection of research participants is a universal concern

Foremost responsibility of researcher is the protection of rights, safety, and welfare of research participants.

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CONSIDERATIONS

3. Value the research participant

As a person with inherent dignity who should be:

A. An **end and not a means**

DO GOOD: BENEFICENCE

B. **Protected against harm and wrong:** ***ABOVE ALL DO NO HARM: NON-MALEFICENCE***

C. **Respected** as a person

AUTONOMY expressed in Informed Consent

D. **Equal** to other persons

JUSTICE – participants, community, society

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CONSIDERATIONS

4. **Value Self**

As honorable and trustworthy

5. **Value Community and Environment**

Impact on community which participants represent both during and after research

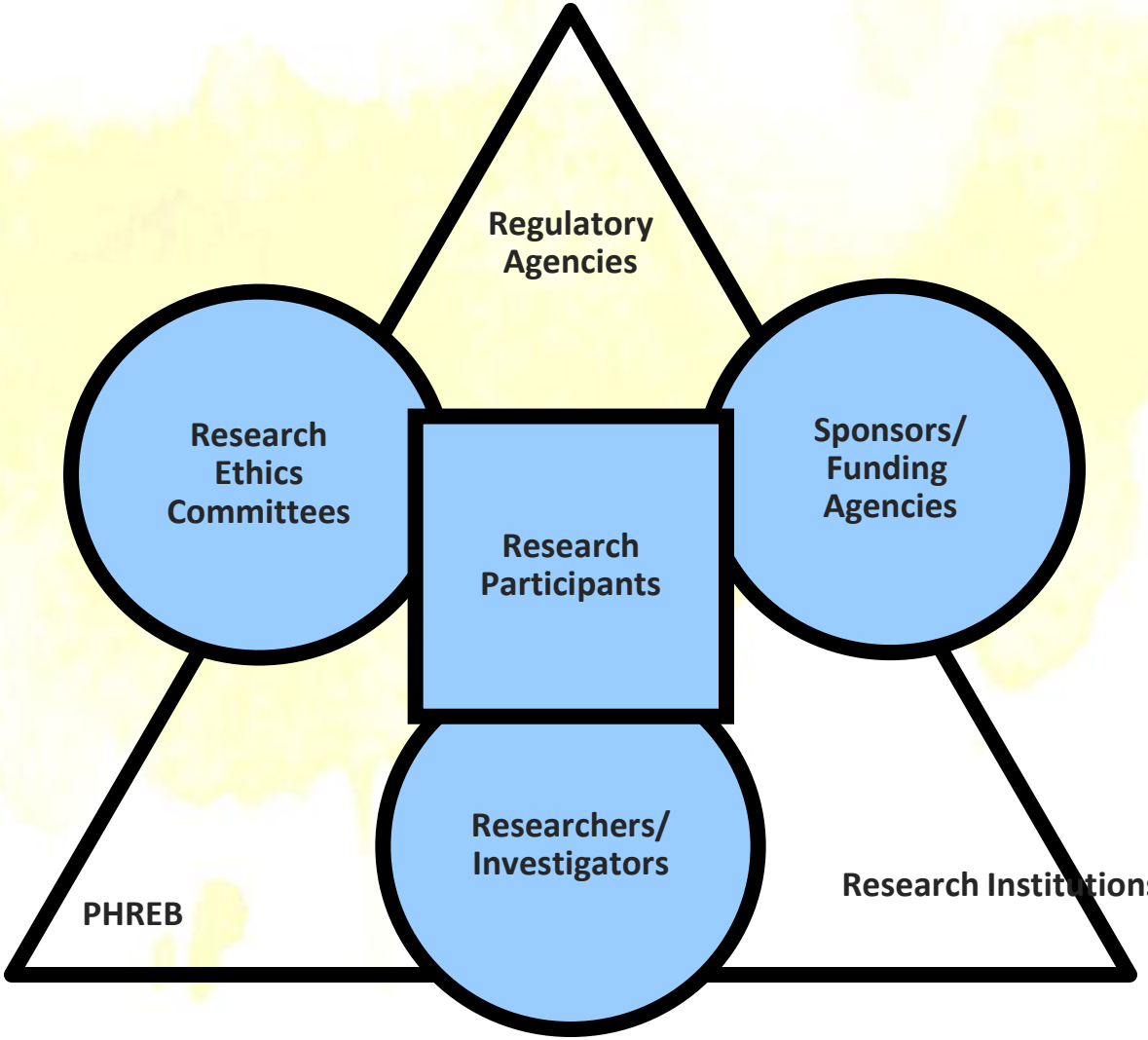
RESEARCH ETHICS SYSTEM

(Shared Responsibility for Ethics in Research)

*The vigilant conscientious **researcher** has **ultimate responsibility** and **accountability**. He must be sensitive and attend to ethical soundness.*

National Structural Framework for Human Protection (Ethics) in Health Research

(2006, 2014, 2016)



SUMMARY

- Ethics in research refers to the moral behavior in the conduct of research and use of its outcomes
- There are ethical ways of doing research
- Ethical conduct makes research helpful and worthy
- Research participants must be valued as persons: protected from harm, benefited, respected, and treated fairly
- Controls and guidelines exist at every level, but the researcher has ultimate responsibility for ethics in research
- Community and environment must not be forgotten

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TOPIC

4

LAWS & CONTROLS

Governing Research and Research Ethics

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1. Enumerate the laws, policies, issuances, and guidelines relevant to research and research ethics and in particular research involving CiSS

2. Identify the regulatory authorities and their vital roles in ensuring a safe and ethical conduct of research in particular research involving CiSS

TOPIC

4

OUTLINE

- International Laws
- National Laws
- Regulatory Authorities

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- **International Laws**

1803: **Percival's Code** "sound reason and consultation"

1833: **Beaumont Code** "voluntary consent"

1947: **Nuremberg Code**: human rights, consent

1964: **WMA Helsinki Declaration**

1966: **UN Declaration of Human Rights**

1974: **The Belmont Report**

1985: **Bernard Williams**: individual more than science

1982: **CIOMS** International Ethics Guidelines *(2015)*

1989: **UN Convention on the Rights of the Child**

1996: **ICH** Harmonized Tripartite Guidelines for GCP *(2016)*

2011: **WHO** Standards and Operational Guidance

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- **National Laws**

1989 RA 6809: Act Lowering the Age of Majority from 21 to 18

1997 RA 8439 Magna Carta for Scientists, Engineers, Researchers and other Science and Technology Personnel in Government

1997 RA 8293 Intellectual Property Code of the Philippines

2008 RA 3573: Reporting of Communicable Diseases (2008)

2009 RA 10055: Philippine Technology Transfer Act - Ownership, Management, Use, and Commercialization of Intellectual Property Generated from Research and Development

2012 RA 10173: Data Privacy Act

2013 **RA 10532: Philippine National Health Research System**

DEFINITION OF HEALTH

a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity – World Health Organization

Health Research Stakeholders

refer to the national and the local public and private agencies/ organizations, policymakers, the academe, medical and health societies, people's organizations and others who are concerned with and affected by health and development

– **RA 10532 Sec. 3 b**

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Regulatory Agencies

DEPARTMENT OF SOCIAL WELFARE AND DEVELOPMENT

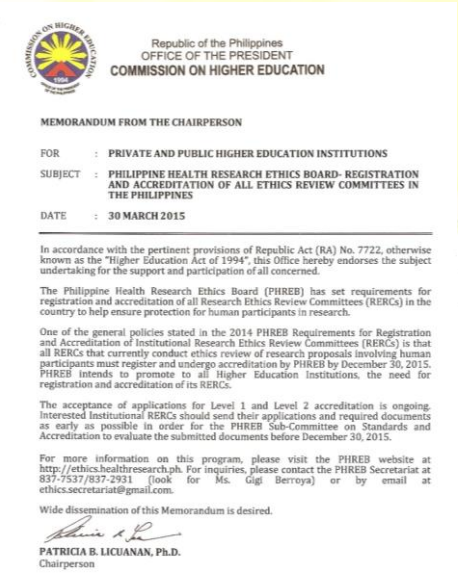
1. MC 009 Series of 2019: Guidelines for the Conduct of Research and Evaluation in the DSWD or the DSWD Research and Evaluation Policy
2. MC 010 Series of 2019: Protocol for the Conduct of Research Studies in DSWD Offices, Centers and Institution, Amending Administration Order N. 19, s. 2011 including Request of SWD Data/Information

- # Regulatory Agencies

QUICK TIP

COMMISSION ON HIGHER EDUCATION

1. CHED Memorandum Dated 30 2015 on Accreditation of all Ethics Review Committees of Higher Education Institutions



Republic of the Philippines
OFFICE OF THE PRESIDENT
COMMISSION ON HIGHER EDUCATION

MEMORANDUM FROM THE CHAIRPERSON

FOR : PRIVATE AND PUBLIC HIGHER EDUCATION INSTITUTIONS

SUBJECT : PHILIPPINE HEALTH RESEARCH ETHICS BOARD- REGISTRATION AND ACCREDITATION OF ALL ETHICS REVIEW COMMITTEES IN THE PHILIPPINES

DATE : 30 MARCH 2015

In accordance with the pertinent provisions of Republic Act (RA) No. 7722, otherwise known as the "Higher Education Act of 1994", this Office hereby endorses the subject undertaking for the support and participation of all concerned.

The Philippine Health Research Ethics Board (PHREB) has set requirements for registration and accreditation of all Research Ethics Review Committees (RERCs) in the country to help ensure protection for human participants in research.

One of the general policies stated in the 2014 PHREB Requirements for Registration and Accreditation of Institutional Research Ethics Review Committees (RERCs) is that all RERCs that currently conduct ethics review of research proposals involving human participants must register and undergo accreditation by PHREB by December 30, 2015. PHREB intends to promote to all Higher Education Institutions, the need for registration and accreditation of its RERCs.

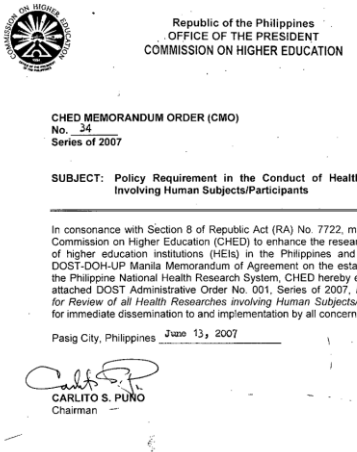
The acceptance of applications for Level 1 and Level 2 accreditation is ongoing. Interested Institutional RERCs should send their applications and required documents as early as possible in order for the PHREB Sub-Committee on Standards and Accreditation to evaluate the submitted documents before December 30, 2015.

For more information on this program, please visit the PHREB website at http://ethics.healthresearch.ph. For inquiries, please contact the PHREB Secretariat at 837-7537/837-2931 (look for Ms. Gigi Berroya) or by email at ethics.secretariat@gmail.com.

Wide dissemination of this Memorandum is desired.

PATRICIA B. LICUANAN, Ph.D.
Chairperson

2. CMO 34 s. 2007: **Policy Requirement** in the **Conduct** of **Health Research Involving Human Subjects / Participants**



Republic of the Philippines
OFFICE OF THE PRESIDENT
COMMISSION ON HIGHER EDUCATION

CHED MEMORANDUM ORDER (CMO)
No. 34
Series of 2007

SUBJECT: Policy Requirement in the Conduct of Health Research Involving Human Subjects/Participants

In consonance with Section 8 of Republic Act (RA) No. 7722, mandating the Commission on Higher Education (CHED) to enhance the research functions of higher education institutions (HEIs) in the Philippines and the CHED-DOST-DOH-UP Manila Memorandum of Agreement on the establishment of the Philippine National Health Research System, CHED hereby endorses the attached DOST Administrative Order No. 001, Series of 2007, *Requirement for Review of all Health Researches involving Human Subjects/Participants*, for immediate dissemination to and implementation by all concerned.

Pasig City, Philippines June 13, 2007

CARLITO S. PUNO
Chairman

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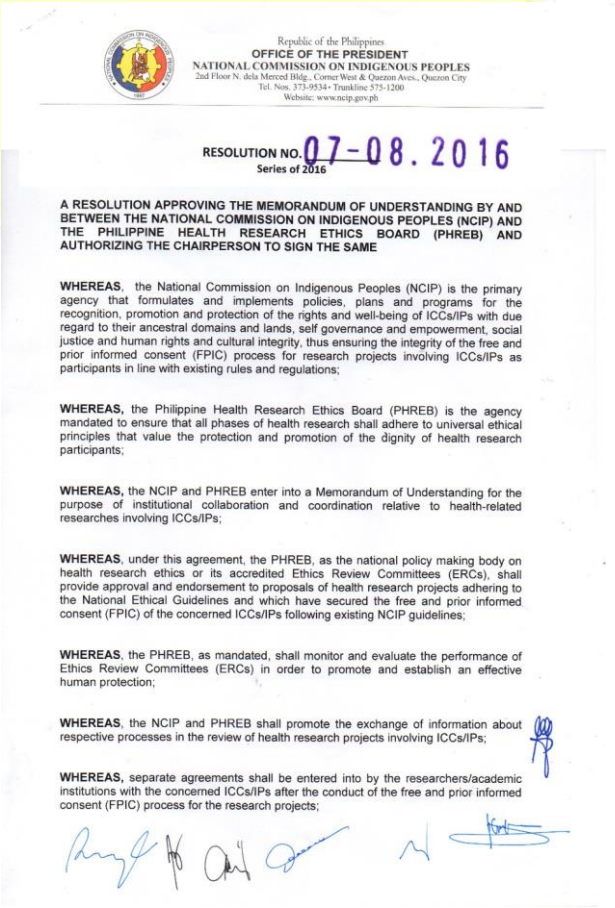
Regulatory Agencies

QUICK TIP

NATIONAL COMMISSION ON INDIGENOUS PEOPLES (NCIP)

1. **NCIP Resolution 07-08.2016:** Policies and Regulations Regarding Research involving Indigenous Peoples / Indigenous Cultural Communities. Not to be confused with the Free And Prior Informed Consent (FPIC)

2. **NCIP AO 01-2012:** Indigenous Knowledge Systems and Practices and Customary Laws Research and Documentation Guidelines



Republic of the Philippines
OFFICE OF THE PRESIDENT
NATIONAL COMMISSION ON INDIGENOUS PEOPLES
2nd Floor N. dela Merced Bldg., Corner West & Quezon Aves., Quezon City
Tel. Nos. 373-9534• Trunkline 575-1200
Website: www.ncip.gov.ph

RESOLUTION NO. 07-08.2016
Series of 2016

A RESOLUTION APPROVING THE MEMORANDUM OF UNDERSTANDING BY AND BETWEEN THE NATIONAL COMMISSION ON INDIGENOUS PEOPLES (NCIP) AND THE PHILIPPINE HEALTH RESEARCH ETHICS BOARD (PHREB) AND AUTHORIZING THE CHAIRPERSON TO SIGN THE SAME

WHEREAS, the National Commission on Indigenous Peoples (NCIP) is the primary agency that formulates and implements policies, plans and programs for the recognition, promotion and protection of the rights and well-being of ICCs/IPs with due regard to their ancestral domains and lands, self governance and empowerment, social justice and human rights and cultural integrity, thus ensuring the integrity of the free and prior informed consent (FPIC) process for research projects involving ICCs/IPs as participants in line with existing rules and regulations;

WHEREAS, the Philippine Health Research Ethics Board (PHREB) is the agency mandated to ensure that all phases of health research shall adhere to universal ethical principles that value the protection and promotion of the dignity of health research participants;

WHEREAS, the NCIP and PHREB enter into a Memorandum of Understanding for the purpose of institutional collaboration and coordination relative to health-related researches involving ICCs/IPs;

WHEREAS, under this agreement, the PHREB, as the national policy making body on health research ethics or its accredited Ethics Review Committees (ERCs), shall provide approval and endorsement to proposals of health research projects adhering to the National Ethical Guidelines and which have secured the free and prior informed consent (FPIC) of the concerned ICCs/IPs following existing NCIP guidelines;

WHEREAS, the PHREB, as mandated, shall monitor and evaluate the performance of Ethics Review Committees (ERCs) in order to promote and establish an effective human protection;

WHEREAS, the NCIP and PHREB shall promote the exchange of information about respective processes in the review of health research projects involving ICCs/IPs;

WHEREAS, separate agreements shall be entered into by the researchers/academic institutions with the concerned ICCs/IPs after the conduct of the free and prior informed consent (FPIC) process for the research projects;

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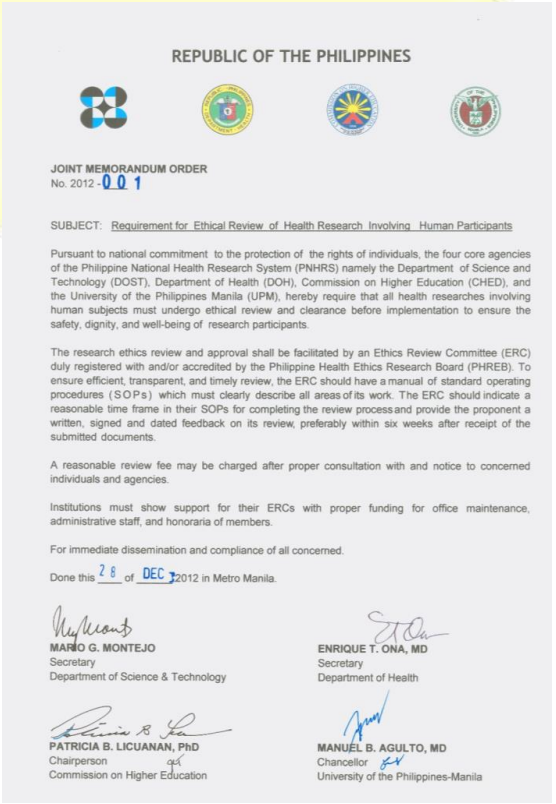
Regulatory Agencies

QUICK TIP

DEPARTMENT OF SCIENCE AND TECHNOLOGY

DOST Administrative Order 001 Series of 2007 on the Requirement for Review of all Health Researches Involving Human Subjects/Participants



REPUBLIC OF THE PHILIPPINES

JOINT MEMORANDUM ORDER
No. 2012 - 001

SUBJECT: Requirement for Ethical Review of Health Research Involving Human Participants

Pursuant to national commitment to the protection of the rights of individuals, the four core agencies of the Philippine National Health Research System (PNHRS) namely the Department of Science and Technology (DOST), Department of Health (DOH), Commission on Higher Education (CHED), and the University of the Philippines Manila (UPM), hereby require that all health researches involving human subjects must undergo ethical review and clearance before implementation to ensure the safety, dignity, and well-being of research participants.

The research ethics review and approval shall be facilitated by an Ethics Review Committee (ERC) duly registered with and/or accredited by the Philippine Health Ethics Research Board (PHREB). To ensure efficient, transparent, and timely review, the ERC should have a manual of standard operating procedures (SOPs) which must clearly describe all areas of its work. The ERC should indicate a reasonable time frame in their SOPs for completing the review process and provide the proponent a written, signed and dated feedback on its review, preferably within six weeks after receipt of the submitted documents.

A reasonable review fee may be charged after proper consultation with and notice to concerned individuals and agencies.

Institutions must show support for their ERCs with proper funding for office maintenance, administrative staff, and honoraria of members.

For immediate dissemination and compliance of all concerned.

Done this 28 of DEC 2012 in Metro Manila.

MARIO G. MONTEJO
Secretary
Department of Science & Technology

ENRIQUE T. ONA, MD
Secretary
Department of Health

PATRICIA B. LICUANAN, PhD
Chairperson
Commission on Higher Education

MANUEL B. AGULTO, MD
Chancellor
University of the Philippines-Manila

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Regulatory Agencies

PHILIPPINE STATISTICAL AUTHORITY

Rule no. 28 of the Implementing Rules and Regulations (IRR) of Republic Act (RA) No. 10625, also known as the "Philippine Statistical Act of 2013"

"The PSA shall establish a Statistical Survey Review and Clearance System (SSRCS) to provide assistance and support to the statistical work of other government agencies in the PSS, including the LGUs and the GOCCs."

Regulatory Agencies

INTELECTUAL PROPERTY OFFICE (IPO)

" 'Published works' means works, which, with the consent of the authors, are made available to the public by wire or wireless means in such a way that members of the public may access these works from a place and time individually chosen by them: Provided, That availability of such copies has been such, as to satisfy the reasonable requirements of the public, having regard to the nature of the work' – Section 171.7

"To require that the authorship of the works be attributed to him, in particular, the right that his name, as far as practicable, be indicated in a prominent way on the copies, and in connection with the public use of his work – Section 193.1.

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Regulatory Agencies

DEPARTMENT OF HEALTH

1. **DOH AO-22-A s1982:** Research Policies and Guidelines in the MOH

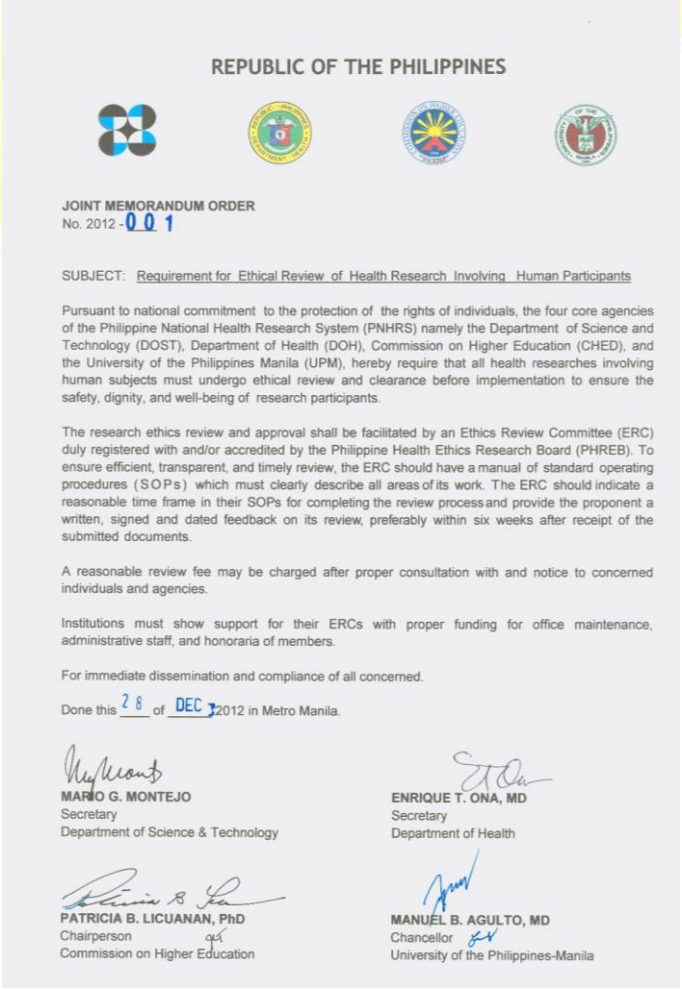
2. **DOH AO 47-A s2001:** Rules and regulations on the registration, including approval and conduct of clinical trials

Regulatory Agencies

QUICK TIP

JOINT MEMORANDA

Joint DOST, DOH, CHED, and UPM Memorandum Order 001 Series of 2012 the Requirement for Ethical Review of Health Research Involving Human Participants



REPUBLIC OF THE PHILIPPINES

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Done this 2 8 of DEC 2012 in Metro Manila.

MARIO G. MONTEJO
Secretary
Department of Science & Technology

ENRIQUE T. ONA, MD
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STREET CHILDREN NGO SUPPORT PROJECT

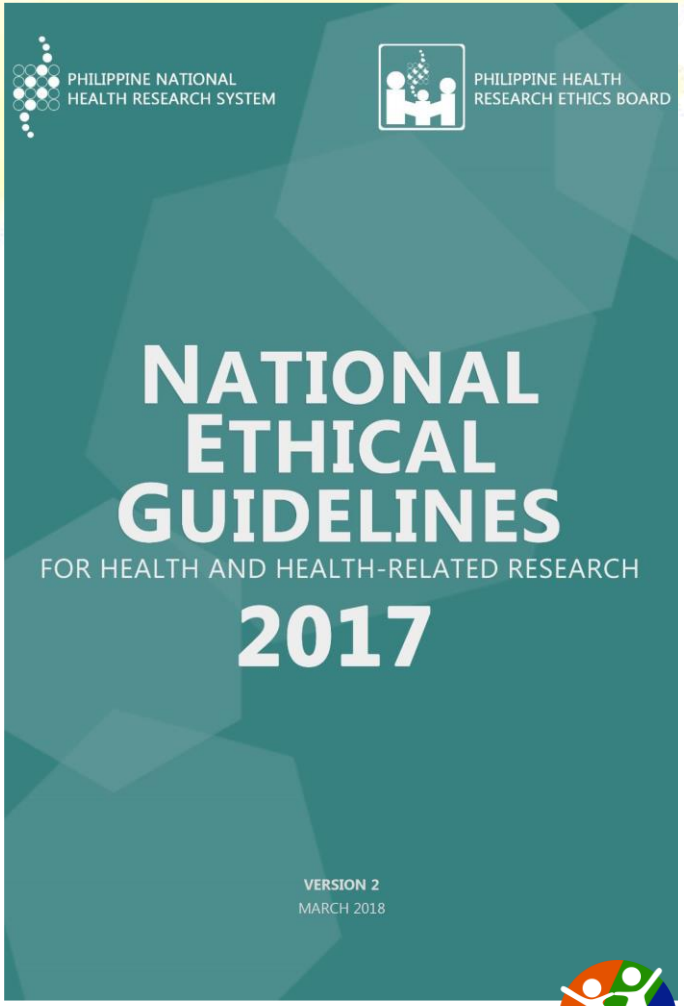
- # Regulatory Agencies

QUICK TIP

PHILIPPINE HEALTH RESEARCH ETHICS BOARD (PHREB)

Philippine Health Research Board (PHREB) 2017 edition of the National Ethical Guidelines for Health and Health-Related Researches which is downloadable at

https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg



STREET CHILDREN NGO SUPPORT PROJECT

World Health Organization

TOPIC

4

ETHICAL PRINCIPLES

In Research

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TOPIC

4

OUTLINE

- Respect of Persons
- National Laws
- Regulatory Authorities

The Principle of RESPECT OF PERSONS

INFORMED CONSENT

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COMPONENTS OF OF ETHICAL RESEARCH INVOLVING CiSS

1. For the good of the person (Social Value)
2. Scientific soundness
3. **Ethical soundness**
4. Researcher competence
5. Community involvement

RESPECT FOR PERSON

Manifested by:

- Courtesy
- Cultural sensitivity
- Gender sensitivity
- Free and informed consent

FREE AND INFORMED CONSENT

- ✓ Based on the principle of **AUTONOMY** or **SELF-DETERMINATION**
- ✓ The right of a competent person (capable of deliberation and personal choice) to decide what is in his or her best interest.
- ✓ A process by which one gives permission to another to invade one's privacy
- ✓ Obtained with respect, honesty and concern
- ✓ Given by one who knows what s/he is giving and freely chooses to do so
- ✓ Neither a "now or never" nor a "forever"
- ✓ Always a TRUST

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INFORMED CONSENT IN RESEARCH

Voluntary agreement to participate in research

Not merely a form that is signed but is a process

GOAL OF INFORMED CONSENT PROCESS

To provide **sufficient** information so that a participant can make an informed decision

To ensure that a participant freely chooses to enroll in a study or to continue participation

INFORMED CONSENT IN RESEARCH

Must be obtained for **ALL** types of research involving human participants

- Diagnostic
- Therapeutic
- Interventional
- Social
- Behavioral

- May be waived by the REC under certrain conditions.

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ELEMENTS OF INFORMED CONSENT IN RESEARCH

NECESSARY INFORMATION

1. Information

   Informing the participant about:

   - His or her rights
   - Purpose of the study
   - Procedures to be undergone
   - Potential risks and benefits of participation

2. Comprehension: Language, Technology

ELEMENTS OF INFORMED CONSENT IN RESEARCH

3. Voluntariness

- Participants must choose **FREELY** and **WILLINGLY** to join study
- Minimize presence of undue coercion or influence

4. Documentation:

Signature or thumb mark on the ICF

Alternative: Description of the process, attested by a witness

ELEMENTS OF INFORMED CONSENT IN RESEARCH

5. Alternatives to participation
6. Length of time the participant is expected to be in the study
7. Statement regarding the participant's right to privacy and confidentiality
8. Data retention limits
9. Statement indicating that refusal to participate will not result in any consequences or any loss of benefits that is otherwise entitled to receive
10. Person to contact for answers to questions or in the event of a research-related injury or emergency

ELEMENTS OF INFORMED CONSENT IN RESEARCH

CONDITIONAL INFORMATION

- Vulnerable populations must receive extra protections
- The legal rights of participants may not be waived.
- Participants may not be asked to release or appear to release the researcher, the sponsor, the institution or it's agents from liability for negligence.
- The participant must be given sufficient time to think and consider participation

CONDITIONAL INFORMATION

- Payment for participation
- Additional costs from participation
- Risks to vulnerable participants (e.g., embryo, fetus, mentally ill, etc.)
- Circumstances when researcher may "withdraw" participants
- Early withdrawal consequences
- Statement regarding how significant new findings will be communicated

REQUIREMENTS OF INFORMED CONSENT IN RESEARCH

- The informed consent document must be written in language easily understood by the participant.
- It must minimize the possibility of **coercion** or **undue influence**.
- The process of consenting is ongoing and must be made clear to the participant that it is their right to withdraw or opt-out of the study or procedure at any time not just at the initial signing of paperwork.

TYPES OF INFORMED CONSENT

CONSENT - an adult participant, capable of giving permission to participate in a research study, can provide consent. The participant must be 18 years of age and competent to make the decision to participate.

PARENTAL CONSENT - when children are included in research, the parent or guardian must sign a parental permission consent document. Some situations require permission from at least one parent, while other situations require permission from both parents.

TYPES OF INFORMED CONSENT

ASSENT - a child's affirmative agreement to participate in research. If the participant is 7-17 years of age, assent must be obtained. The assent form must be written at the appropriate reading level of the youngest participant in the age range and use simple terminology.

VERBAL CONSENT- contains all elements of written consent, however, the participant has verbally read the elements and verbally agrees to join. Verbal consent may require corroborating documentation

When the Informed Consent Process and/or Form may be waived, either-

Archival research involving publicly available documents, or

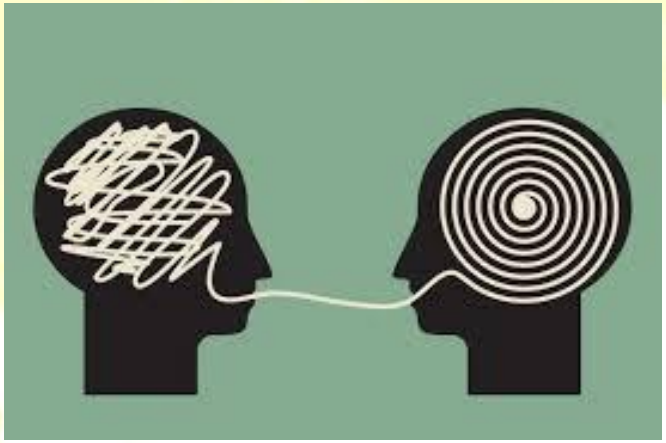
Use of naturalistic observation

- Justification
- Description of how data will be used
- Risks to participants unlikely
- Keeping confidentiality and protection of privacy

When some of the elements of IC may be waived, ALL conditions are present

- Research cannot be practicably carried out without the waiver , and
- No more than minimal risk, and
- Rights and welfare of participants are not adversely affected, and
- Additional information is given to the participants after participation

SHORT FORM - generally used when there is a language barrier and an English REC-approved consent is orally translated in the native language of the research participant.



SUMMARY

Respect for person is expressed in the Informed Consent Process.

A valid informed consent process:

- involves a potential participant who is competent and is given all the necessary information.
- is free from coercion and undue influence
- is facilitative of expression of decision
- adapts to changes in circumstances

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NON-MALIFICENCE & BENEFICENCE

Weighing Benefits and Risks

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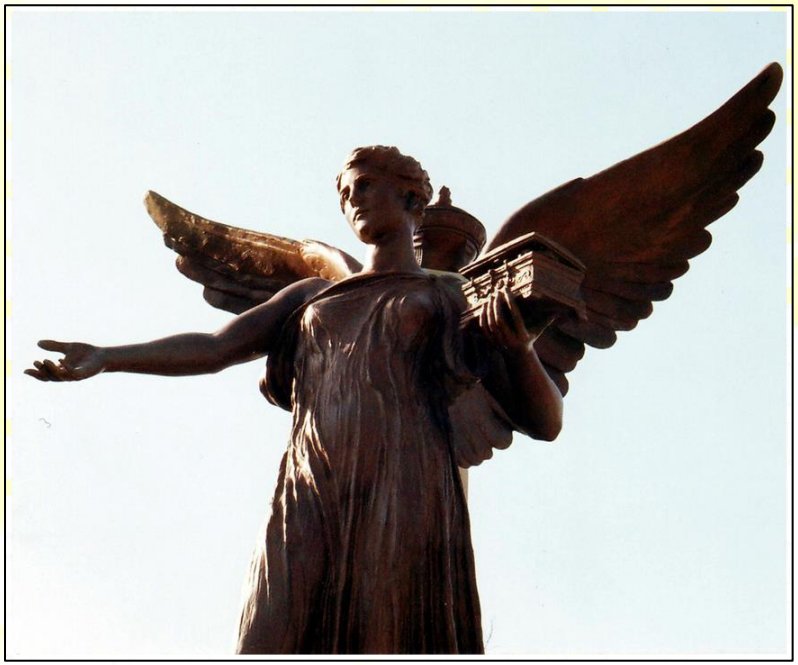
DEFINITIONS

BENEFICENCE is action that is done for the benefit of others.

Beneficent actions can be taken to help prevent or remove harms or to simply improve the situation of others.



Beneficence statue *at the campus of Ball State University, IN*

DEFINITIONS

BENEFICENCE

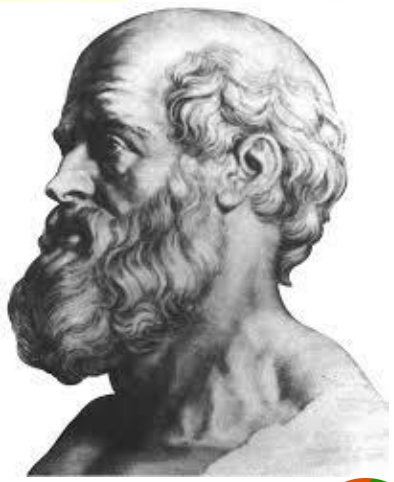
a concept in research ethics which states that **researchers should have the welfare of the participants as a goal of any research.**

DEFINITIONS

NON-MALEFICENCE means to above all "do no harm."

- The pertinent ethical issue is whether the benefits outweigh the burdens/risks.

Primum non nocere



DEFINITIONS

BENEFIT: a valued or desired outcome; an advantage

RISK: the probability and magnitude of harm or injury occurring as a result of participation in a research study

BENEFICENCE is applied to:

Research Participants

Community

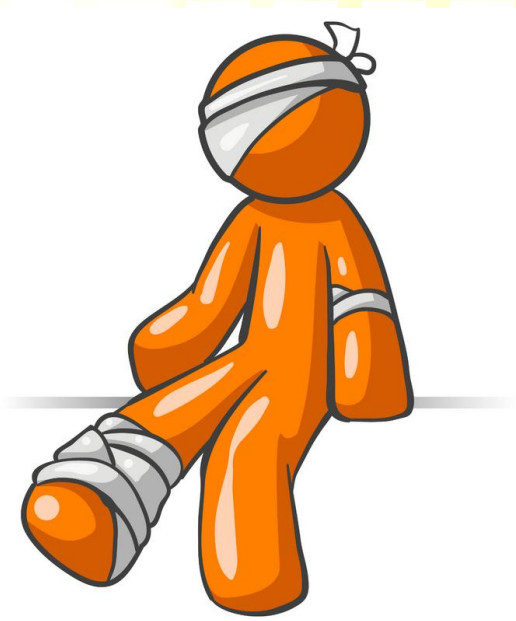
Society

TYPES OF RISKS

1. Physical
2. Psychological
3. Social
4. Economic

PHYSICAL RISK

- Usually minor discomfort or pain
- Potentially serious or disabling
- Transient or permanent



PSYCHOLOGICAL RISK

- Stress, feeling of guilt or embarrassment, depression, loss of self-esteem, trauma, confusion, etc.
- From minimal or transient, to serious

PSYCHOLOGICAL RISK

INVASION OF PRIVACY

- Access to a person's body or behavior without consent

BREACH OF CONFIDENTIALITY

- Inability to safeguard information that has been given voluntarily by one person to another

SOCIAL HARM

"**Labelled** or **Stigmatized**"

May cause embarrassment or criminal prosecution

ECONOMIC HARM

- Actual costs
- Loss of employment

REQUIREMENT

Two of the required criteria for REC approval of a research:

- Risks to participants are **minimized**
- Risks to participants are **reasonable**

MINIMIZED RISKS

Minimize risks by using procedures:

- Consistent with sound research design
- Do not unnecessarily expose participants to risk
- When appropriate, already being performed for diagnosis and treatment

DEFINITIONS

- **MINIMAL RISK**: where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in **daily lives** of the general population or during the performance of **routine** physical or psychological examination or test.

REASONABLE RISKS

Risks must be reasonable in relationship to:

- Anticipated benefits, if any, to participants themselves
- The importance of the knowledge that may reasonably be expected to result

WAYS TO MINIMIZE RISK

- Provide complete information in the research proposal regarding the experimental design and the scientific rationale underlying the proposed research
- Assemble a research team with sufficient expertise and experience to conduct a research

WAYS TO MINIMIZE RISK

- Ensure that the projected sample size is sufficient to yield useful results
- Collect data from standard-of-care procedures to avoid unnecessary risk, particularly for invasive or risky procedures (e.g., spinal taps, cardiac catheterization)

WAYS TO MINIMIZE RISK

- Incorporate adequate standards into the research design such as an appropriate data safety monitoring plan, the presence of trained personnel who can respond to emergencies and procedures to protect the confidentiality of the data (e.g., encryption, codes, and passwords).

RISKS & BENEFITS Assessment

- To avoid confusion, speak of risks and benefits in terms of probabilities.
- Researchers should provide detailed information about potential risks and benefits associated with the research, as well as probability, magnitude and potential harms associated with each risk.

RISKS & BENEFITS Assessment

Research Ethics Committees (RECs) should:

- Evaluate potential risks
- Weigh the probability of the risk occurring
- Weigh the magnitude of harm that may result
- Judge whether the anticipated benefit (either new knowledge or of improved health for the research participant) justifies inviting any person to undertake the risks

RISKS & BENEFITS Assessment

Research Ethics Committees (RECs) should:

- Identify the risks associated with the research, as distinguished from the risks of therapies the participants would receive even if not participating in research
- Determine that the risks will be minimized to the extent possible
- Identify the probable benefits to be derived from the research

RISKS & BENEFITS Assessment

Research Ethics Committees (RECs) should:

- Determine that the risks are reasonable in relation to the benefits to participants, if any, and the importance of the knowledge to be gained
- Assure that potential participants will be provided with an accurate and fair description (during consent) of the risks or discomforts and the anticipated benefits.

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The Principle of

SOCIAL JUSTICE

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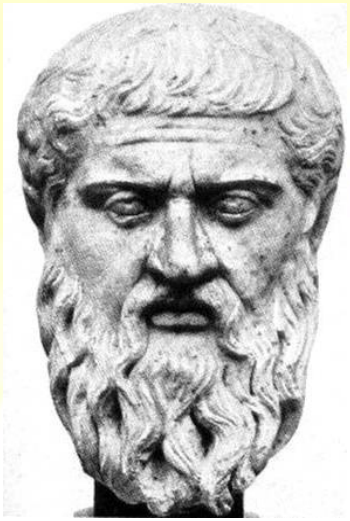
MEANING

"Rightness" of persons' interactions and relationships

Golden rule: what one would have others do to oneself **(NATURAL LAW)**

"Fair if I were in need; Fair if I were to give"



JUSTICE APPLIED

1. FOR ALL STAKEHOLDERS

- Research must reduce inequalities (CIOMS)
- Equal standards for developing and developed countries; rich or poor in healthcare, control, follow-up care, review
- Truth-telling

2. FOR RESEARCH PARTICIPANTS

- Fair recruitment, sampling, assignments
- Just compensation
- Benefit (Good outcomes) sharing
- Children's participation in research

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JUST COMPENSATION

Not exploitive: proportionate to contribution of participant, research budget, and local conditions

Not undue: either excessive or inappropriate

"Monetary or in-kind compensation for research participants must not be so large as to persuade them to volunteer against their better judgment or deeply held beliefs" (CIOMS, 2016)

JUST COMPENSATION

Reimbursement, compensation, incentive:

- **If no direct benefit**: additional compensation for discomfort, inconvenience, lost time
- **If difficult to invite, recruit:** provide incentive
- **If harm, wrong, or injury**: additional compensation for correction

Replacement Income

- **Payment provided to research participants which may include reimbursement for lost earnings, travel costs, and other expenses incurred as a study participant and recompense inconvenience and time spent**

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JUSTICE APPLIED

3. Community

- Relevant topic, capacity to utilize
- Conservation of time, energy, environment, and resources
- Consultation before and during implementation: respect for values, consent of leaders
- Capacity building
- Fair share of results: availability and affordability of successful product

JUSTICE APPLIED

4. Society

- Compliance with law
- Timely and truthful publication after peer review
- Influence policy change

TRUTHFUL PUBLICATION

- No data fabrication (making up), falsification (changing or omitting, “cooking”, “trimming”), statistical misuse, plagiarism, (appropriation of another’s ideas, words, processes without giving appropriate credit) unfounded claims, redundancy, “salami slicing”, trivial studies, + and – findings (gag clause)

- Cite literature, reference, original source, or previous publication

TRUTHFUL PUBLICATION

Correct Authorship

- **Lead author (Guarantor)** - responsible for integrity of whole paper.
- **All Other Authors:** (ICMJE Guidelines)
- Not funding, data collection, general supervision, inspiration, gratitude
- Acknowledgement of other contributors

Research Publication Ethics

enago academy
Learn. Share. Discuss. Publish.

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PEER REVIEW

- ✓ Expert reviewer not known to author
- ✓ Scientific process and value
- ✓ Ethical integrity
- ✓ Grammar and writing style
- ✓ Suitability for journal

JUSTICE APPLIED

4. Society

Compliance with law

Timely truthful publication after peer review

"Whistle blow"

5. Researcher

Compensation and autonomy of research

6. Institution

Compensation and protection of reputation

7. Sponsor

No conflicts of interest

SUMMARY

- Give or not deprive others their due
- Follow the principles of non-maleficence, beneficence, and respect for persons
- Fair selection, assignment, and compensation for research participants
- Be truthful
- Disclose results timely
- Share benefits with community and institution
- No conflict of interest

Professional boundary along divided Loyalty

CONFLICT OF INTEREST

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CONFLICT OF INTERESTS

Who?

Person or group

Your organization

The researchers

The sponsor

CONFLICT OF INTERESTS (COI)

Set of conditions in which professional judgment concerning a **primary interest** (such as a patient's welfare or the validity of research) tends to be influenced by a **secondary interest** (such as financial gain) (Thompson, 1993).

Set of circumstances that creates a risk that professional judgement or actions regarding a **primary interest** will be unduly influenced by a **secondary interest** (Lo & Field, 2009).

Those of any kind that could undermine the objectivity, integrity or perceived value of a publication through their potential influence on behavior or content or from perception of such potential influence (Nature, Competing Interest, 2017).

CONFLICT OF INTERESTS

Conflict of interest (COI) may be:

Actual,

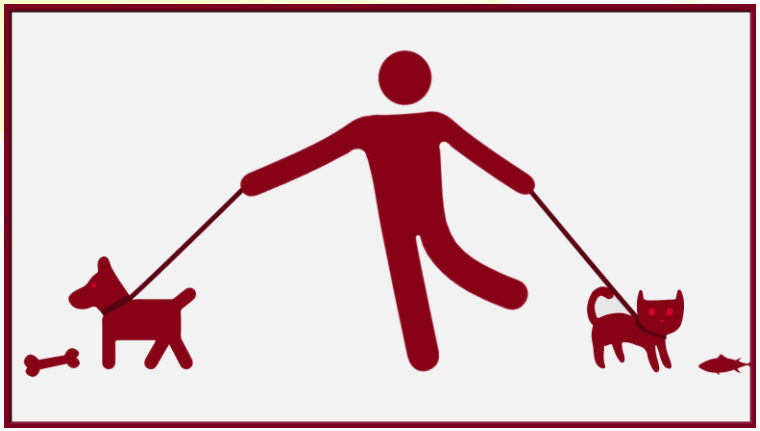
Apparent,

Potential,

Perceived,

Tangible, or Intangible,

For or against



CONFLICT OF INTERESTS

Intrinsic to research

Not necessarily unethical

Becomes unethical when the person with COI behaves unethically

Not dependent on underlying motives

Action in context of particular situation

"Could a reasonable person conclude that the secondary interest could influence the investigator's professional conduct?"

POSSIBLE HARMS

1. **Injury to participants**
   - Report and attribution of adverse effects.
   - Care given (including prescriptions) of investigator or clinician.
2. **Damage to Research Credibility: Bias**
   - Selection and retention of participants.
   - Collection and reporting of data.
   - Selective attendance or misperceived critical observations.
   - Peer review and publication.

POSSIBLE HARMS

3. **Reduced trust from:**
   - Research participants
   - Colleagues
   - Government
   - Sponsors or Funding Agency
   - Public

MANAGEMENTS

Vigilance:

- Recognize (likelihood and consequence),

Deal with:

- Remove
- Declare
- Recuse
- Third party system of review

MANAGEMENTS

Prevent

- Conscientious ethical soundness: participant's best interest
- Scientist: honesty and responsibility
- Institution: environment of integrity and responsible conduct

MANAGING COI

Disclosure - Sources of financial or economic support for the research shall be disclosed to give those who would be affected, or who are otherwise in a good position to assess the risks, information they need to make their decisions.

Abstention - Conflicted parties shall withdraw from cases in which they have substantial secondary interests

Divestiture

Mediation - Use of devices such as blind trusts that insulate parties from the secondary interests