

The National Ethical Guidelines for Health and Health-related Research (NEGHHR 2017)

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Chair, Ad Hoc Committee for Updating the National Ethical Guidelines



THE PHREB MANDATE

PNHRS Law 2013 (RA 10532)

DOST Special Order 091 s. 2006: The national policy making body on health research ethics

Formulation of guidelines

- for ethical conduct in health research
- for establishment and management of ERCs

Monitoring performance of ERCs

Providing advice to PNHRS Governing Council... other appropriate entities ... related to ethical issues in human health research...

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Historical Notes: National Ethical Guidelines

1984 PCHRD SO No. 84-053 : National Ethics Committee.

1985 *National Guidelines for Biomedical Research*

1996 *National Guidelines for Biomedical/Behavioral Research*

2000 *National Guidelines for Biomedical/Behavioral Research*

2005 PNHRS Ad Hoc Committee on Revision of Guidelines

2006 *National Ethical Guidelines for Health Research*

2011 *National Ethical Guidelines for Health Research*

2017 *National Ethical Guidelines for Health and Health-related Research*



The Push and Inspiration to Update

1. Time
2. International Developments
 - 2015 Declaration of Helsinki
 - 2016 CIOMS International Ethical Guidelines
3. Local Developments
 - 2013 PNHRS Law
 - 2012 NCIP AO 03
 - 2012 Data Privacy Act

The Push and Inspiration to Update

4. Emerging Local Issues
 - Research in disaster areas
 - Stem Cell Therapy
 - Efficiency of Ethics Review Process
 - etc
5. "Groundswell of public support for ethical health research": "record-breaking participation of various stakeholders in the 1st PHREB National Conference, 2014 and Global Forum on Research and Innovation for Health, 2015.

The Ad Hoc Committee for Updating the National Ethical Guidelines, 13 Jan 2015

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- APPROVAL OF THE “NATIONAL ETHICAL GUIDELINES FOR HEALTH AND HEALTH RELATED RESEARCH 2017”
- 46TH PHREB MEETING, 7 JUNE 2017
- Resolution adopted , 29 July 2017
- Publication in the Official Gazette of the Republic of the Philippines: _____
- Date of Effectivity: _____



Health and Health-related Research

Health Research: research that seeks

- to understand the impact of processes, policies, actions, or events originating in any sector, on the well-being of individuals and communities; and
- to assist in developing interventions that will help prevent or mitigate their negative impact, and in so doing
- contribute to the achievement of health equity and better health for all. (*RA 10532 Joint IRR*)

Health-related Research – research where procedures and outcomes can affect the well-being of participants and the community.

2017 National Ethical Guidelines for Health and Health-related Research

<ul style="list-style-type: none"> ■ General Guidelines <ul style="list-style-type: none"> ■ Elements of Research Ethics ■ Ensuring Quality Research ■ Other Considerations 	<ul style="list-style-type: none"> ■ Special Guidelines <ul style="list-style-type: none"> – Specific Research Areas/Topics – Specific Methods – Discipline-based Research – Specific Populations – International Collaborations – Authorship
<ul style="list-style-type: none"> ■ Appendices 	

General Guidelines:

A. Elements of Research Ethics

- Social Value
- Informed Consent: Elements, Process, Waivers
- Vulnerability
- Risks, Benefits, and Safety
- Privacy and Confidentiality of Information
- Justice
- Transparency

General Guidelines: B. Ensuring Quality Research

- The Research Protocol
- Qualification of Researchers
- The Research Ethics Review: *Governance, Guidelines, Process, Exemptions from Review*
- Responsibilities of and Guidance for Various Stakeholders: *Research Adviser, Research Institutions, Researcher/Investigator, Foreign Researchers, Funder/Sponsor, Guidance for Participants, Community Participation*

General Guidelines: C. Other Considerations

- The National Health Research Agenda
- Externally-funded Collaborative Research
- Protection of the environment and biosafety
- Welfare of animals

Special Guidelines:

- Specific Areas or Topics
- Specific Research Methods
- Health-related Social Research
- Research involving Specific Populations
- Special Concerns
 - International collaborations
 - Authorship

Special Guidelines: A. Specific Areas or Topics

- Clinical Research
- Herbal Research
- Research in CAM
- Reproductive Technology
- Cosmetics
- Environmental Health
- Mental Health
- Genetics and Genomics
- Stem Cell Research
- Emerging Technologies

Special Guidelines: B. Specific Research Methods

- Epidemiology Research
- Use of Online and Digital Tools
- Use of Human Data and Samples from Biobanks, Registries and Databases

Special Guidelines: C. Health-related Social Research

D. Research involving Special Populations

- Indigenous Peoples and Cultural Communities
- Minors/Children
- Older Persons
- Military Personnel
- People with Disabilities
- People Living with HIV and AIDS
- Populations in Disaster Situations

Special Guidelines: E. Special Concerns

- International Collaborative Research
- Authorship

Exemption from Ethics Review

- 3.1.1. No direct human participation nor use of identifiable human tissue, biological samples and data.
- 3.1.2. When the following do not involve more than minimal risk or harms:
 - 3.1.1.1 institutional quality assurance purposes, public health programs, public health surveillance, educational evaluation activities and consumer acceptability tests;

3.1.2.2. Surveys, interviews, or observation of public behavior, provided:

3.1.2.2.1. No disclosure of participants' responses that could place them at risk of criminal/civil liabilities, affect reputation, etc.

3.1.2.2.2. Recording of information non-identifiable.

3.1.2.3. Use of publicly available data or information.

Waiving the Informed Consent Process

- 16.1. Archival research involving publicly available documents.
- 16.2. Research that uses naturalistic observation in data collection provided the following requirements are complied with:
 - 16.2.1. Justification for data collection
 - 16.2.2. Plan for use of data collection
 - 16.2.3. Assurance that risks to participants are unlikely
 - 16.2.4. Mechanism to ensure anonymity and confidentiality

Waiving Signed Informed Consent Form

- When the use of an informed consent form is not feasible or unacceptable to the prospective participant.

Waiving Some Elements of the Informed Consent Form

- 17.1. No more than minimal risk
- 17.2. Not affect rights and welfare of participants
- 17.3. research cannot be practicably carried out without the waiver or alteration
- 17.4. provision of the pertinent information after participation.

Summary

1. Change in Title: Health and Health-related Research.
2. Major Section revisions:
 - Elements of Research Ethics: Social Value, Transparency, Waiving of Informed Consent
 - Ensuring Quality Research : Exemption from Ethics review, Responsibilities of Stakeholders, Gabay para sa mga Kalahok...
 - Expanded Appendices

Summary

3. New Guidelines:
 - Mental Health, Cosmetics, Environmental Health, Stem Cell Research, Use of Online and Digital Tools, Use of Biobanks, Registries and Databases, Research with Military Personnel, with People with Disabilities.
4. Revised Guidelines:
 - Clinical Research, Epidemiology Research, Research in Disaster Situations, Emerging Technologies, International Collaborative Research, Authorship and Publication



Until the next revision....