

JOINT DOST-PCHRD, DOH, CHED and UPM-NIH
 ADMINISTRATIVE ORDER NO. 001

THE IMPLEMENTING RULES AND REGULATIONS
 OF
 REPUBLIC ACT 10532
 OTHERWISE KNOWN AS THE
 “PHILIPPINE NATIONAL HEALTH RESEARCH SYSTEM ACT OF 2013”

WHEREAS, Republic Act No. 10532, otherwise known as the “Philippine National Health Research System Act of 2013”, became effective on 1 June 2013;

WHEREAS, the implementing institutions of the Philippine National Health Research System (PNHRS), namely, Department of Science and Technology, Department of Health, Commission on Higher Education and University of the Philippines Manila - National Institutes of Health have signed the following agreements on the development of the Philippine National Health Research System, to wit: Memorandum of Understanding dated 17 March 2003, 11 April 2007, 16 March 2009 and 10 August 2011;

WHEREAS, pursuant to Article III Section 15 of RA 10532, the Department of Science and Technology-Philippine Council for Health Research and Development, the Department of Health, the Commission on Higher Education and the University of the Philippines Manila - National Institutes of Health are mandated to issue and promulgate the rules and regulations to implement the provisions of Republic Act 10532;

NOW THEREFORE, the following Joint Administrative Order of the Department of Science and Technology, Department of Health, Commission on Higher Education and University of the Philippines Manila - National Institutes of Health covering the rules and regulations implementing Republic Act 10532 are hereby adopted and prescribed for the information and guidance of all concerned.

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 MR. JHOVEN G. LITANA
 RECORDS OFFICER
 DEPARTMENT OF SCIENCE AND TECHNOLOGY





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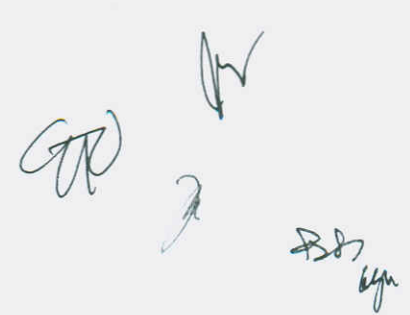
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CHAPTER I

GENERAL PROVISIONS

Rule 1. Title. These Rules shall be known and cited as the Implementing Rules and Regulations of Republic Act No. 10532, otherwise known as the “Philippine National Health Research System Act of 2013.”

Rule 2. Purpose. These Rules are hereby promulgated to prescribe the procedures and guidelines for the implementation of the PNHRS Act in order to facilitate collaboration, cooperation, and convergence among all stakeholders and to achieve the objectives of the Act.

Rule 3. Construction and Interpretation. All doubts in the implementation, construction and interpretation of these implementing rules and regulations shall be resolved in favor of the principle of promoting cooperation and collaboration among stakeholders as well as the integration and convergence of all health research efforts in the country to ensure that research contributes to evidence-informed health-related policies and actions.

Rule 4. Declaration of Policy. – It is hereby declared the policy of the State to protect and promote the right to health of the people, instill health consciousness among them and improve the quality of life of every Filipino through health research and development initiatives.

In pursuit of the above policy, it is the mission of the PNHRS to create and sustain an enabling environment for health research toward evidence-informed health-related policies and actions. Further, the PNHRS shall facilitate and enable the engagement of the stakeholders of the health research community.

Rule 5. Definition of Terms. – For the purpose of this Act, the following terms shall be defined as follows:

- (a) *Act* shall refer to RA 10532.
- (b) *Health* shall refer to a state of optimal physical, mental and social well-being and the ability to function at the individual level.
- (c) *Health Research Stakeholders* shall 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.

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- (d) *Health Research Community* shall refer to all stakeholders such as but not limited to policymakers, researchers, funders and/or advocates of research, users and/or beneficiaries of research results at local, national, and/or international levels.
- (e) *Health System shall refer to:* (i) all the activities whose primary purpose is to promote, restore and/or maintain health; and (ii) the people, institutions and resources, organized together in accordance with established policies, to improve the health of the population they serve, while responding to people's legitimate expectations and protecting them against the cost of ill-health through a variety of activities whose primary intent is to improve health
- (f) *International organizations* shall mean the following: (i) United Nations and its specialized agencies, (ii) ASEAN and its specialized agencies, (iii) international development and/or funding institutions recognized by the Philippine Government, and, (iv) all such other international organizations and/or institutions covered by a headquarters agreement and/or an international treaty signed by the Philippine Government.
- (g) *International Networks* shall mean both formal and informal linkages, collaborations, assistance, cooperation, information sharing and other similar activities with non-Filipino individuals or institutions and international organizations subject to existing constitutional and legal limitations and provisions.
- (h) *National Unified Health Research Agenda* shall refer to a set of research priorities determined by the country's stakeholders which addresses the health needs of the population vis-a-vis the health sector's goal for universal health care. This agenda is a platform to advocate for local, national and international support. The term *National Health Research Agenda* shall also have the same definition as the foregoing.
- (i) *Philippine Council for Health Research and Development (PCHRD)* shall refer to one of the sectoral planning councils of the Department of Science and Technology (DOST) which provides central direction, leadership and coordination in health science and technology (S&T). PCHRD shall serve as the national coordinating body for health research.
- (j) *Philippine Health Research Ethics Board (PHREB)* shall refer to the national policymaking body on health research ethics, created under DOST Special Order No. 091, which is mandated to ensure that all phases of health research shall adhere to the

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universal ethical principles that value the protection and promotion of the dignity of health research participants.

- (k) *Philippine National Health Research System (PNHRS)* shall refer to a framework anchored on the principles of Essential National Health Research on inclusiveness, participation, quality, equity, efficiency and effectiveness, which connect to, and converge with, the wider health, economic, political, educational and S&T systems of the country.
- (l) *Philippine National Health Research System Network* shall refer to public and private agencies and institutions which are members of the regional health research and development consortia.
- (m) *Regional Health Research Systems* shall include regional health research consortia or communities in all the regions of the country which mirror the PNHRS framework at the regional level.
- (n) *Research* shall refer to the development of knowledge with the aim of understanding health challenges and mounting an improved response to them. This covers the full spectrum of research in five (5) generic areas of activity: (1) measuring the problem; (2) understanding its cause(s); (3) elaborating solutions; (4) translating the solutions or evidence into policy, practice and products; and (5) evaluating the effectiveness of solutions.
- (o) "*Research for Health*" or "*Health research*" shall refer to the fact that improving health outcomes requires the involvement of many sectors and disciplines. As identified in the work of the Global Forum for Health Research, it is research that seeks to understand the impact of health policies, programmes, processes, actions, or events originating in any sector; to assist in developing interventions that will help prevent or mitigate the impact; and to contribute to the achievement of the Millennium Development Goals, health equity, and better health for all.
- (p) *Regional Unified Health Research Agenda* shall refer to a set of research priorities determined by the regional stakeholders which addresses the health needs of the population *vis-a-vis* the health sector's goal for universal health care. This agenda is a platform to advocate for local, national and international support.
- (q) *Rules* shall refer to these Rules and Regulations.

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(r) *Universal Health Care* shall refer to a focused approach to health reform implementation, ensuring that all Filipinos especially the poor receive the benefits of health reform. This is a deliberate focus on the poor to ensure that they are given financial risk protection through enrollment to PhilHealth and that they are able to access affordable and quality health care and services in times of need.

CHAPTER II

THE PHILIPPINE NATIONAL HEALTH RESEARCH SYSTEM

Rule 6. Institutionalization of the Philippine National Health Research System (PNHRS). – The PNHRS, initiated through a Memorandum of Understanding between the DOST and the Department of Health (DOH) in 2003, and in 2007, is hereby institutionalized within the mandate of the PCHRD, the national coordinating body for health research.

The 2007 Memorandum of Understanding was also signed by the Commission on Higher Education and the University of the Philippines Manila - National Institutes of Health.

Rule 7. Objectives of the PNHRS. – The PNHRS aims to improve the health status, productivity and the quality of life of Filipinos by:

- (a) Ensuring that health research is linked to the health system needs;
- (b) Ensuring that investments in health research yield the most benefit;
- (c) Promoting good governance among health research organizations through efficient, effective, transparent and ethical health research management system;
- (d) Engaging in national and international partnerships and networks for health research development; and,
- (e) Ensuring sustainability of resources for health research.

In achieving these objectives, the PNHRS shall consider the provisions of existing laws.

Rule 8. Formulation of Research Agenda. The process in formulating the research agenda for the present and future requirements of the country's health system should consider alignment with societal goals in science and technology, education, the economy, environment, agriculture and other priority areas of the country. The national and regional research agenda shall be used as a strategic tool to direct research programs, funding priorities, and related activities.

Rule 9. Determination of Benefit. In ensuring that investments in health research will yield the most benefit, the health research should be anchored on the country's health agenda and emerging health issues, result in improved health outcomes, and optimize the resources invested.

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Rule 10. Sustainability of Resources for Health Research. To ensure sustainability of resources for health research and development, the PNHRS implementing institutions shall allocate in their respective annual budget as well as in their work and financial plan the appropriate resources to support the plans and programs of the PNHRS.

Public and private organizations who are members of the PNHRS Network shall likewise allocate in their respective annual budget as well as in their work and financial plan the appropriate resources to support the plans and programs of the PNHRS.

PNHRS shall tap other funding sources including any government revenues generated through various legal instruments or laws.

Public or private local, national or international institutions or organizations may contribute resources, such as funds, expertise, technical assistance, logistics, and facilities.

Rule 11. Composition of the PNHRS. – The PNHRS shall be institutionalized within the mandate of the PCHRD, the national coordinating body for health research. It is composed of the Governing Council (GC), the Steering Committee, the Technical Working Committees (TWC) and the Secretariat, as described in Section 9 hereof. The whole health research community shall be deemed an indispensable partner and contributor in the effort to strengthen the PNHRS.

Rule 12. The PNHRS Governing Council. – The PCHRD Governing Council, created under Executive Order (EO) No. 784 of 1982 and EO No. 128 of 1987, shall be the Governing Council of the PNHRS. The PNHRS Governing Council shall be composed of the following:

- (a) The Secretary of the DOST, as Chair;
- (b) The Secretary of the DOH, as Co-Chair;
- (c) The Chair of the Commission on Higher Education (CHED);
- (d) The Chancellor of the University of the Philippines Manila (UPM);
- (e) The National Nutrition Council Executive Director;
- (f) The PCHRD Executive Director; and
- (g) Five (5) representatives from the private sector.

Rule 13. Private Sector Representatives. The five (5) private sector representatives shall be appointed by the President of the Philippines for a term of two years. The criteria and terms of the appointment of four representatives shall be governed by EO 128, Section 16 while the fifth private sector representative shall represent a recognized health civil society organization.


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Rule 14. Meetings of the Governing Council – The meetings of the PNHRS Governing Council shall follow the existing procedures of the PCHRD Governing Council.

Rule 15. Powers and Functions of the PNHRS Governing Council. – The PNHRS Governing Council shall:

- (a) Set policies and directions for the PNHRS;
- (b) Periodically review and approve the long-term plans and programs of the PNHRS;
- (c) Evaluate and approve the National Unified Health Research Agenda, and identify areas that will serve as the foci of the National Health Research Agenda;
- (d) Review, approve or disapprove research programs; and
- (e) Create committees as the need arises to facilitate and ensure the achievement of its objectives.

Rule 16. The GC shall develop its own guidelines in reviewing, approving, and disapproving research programs.

Rule 17. The PNHRS Secretariat. – The PCHRD Secretariat, headed by an Executive Director, shall serve as the PNHRS Secretariat. The Executive Director shall be responsible for, among others, the smooth implementation of programs and projects and shall, in pursuit thereof, exercise an oversight function over the PNHRS.

The Secretariat shall provide technical and administrative support to the Technical Working Committees, Steering Committee and the Governing Council in the following areas:


- (a) Research and Development Management;
- (b) Institution Development;
- (c) Research Information, Communication and Utilization; and
- (d) Finance and Administration.





Rule 18. PNHRS Secretariat Staff and Budget. – The PNHRS Secretariat's staffing and budget shall be included in the PCHRD staffing and budget.

Rule 19. Creation and Functions of the Steering Committee. – (a) The Governing Council (GC) shall create an advisory group, the Steering Committee, to be headed by the PCHRD Executive Director. It shall be composed of the following:

- (a) The Executive Director, DOST-PCHRD;

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- (b) The Director, Department of Health-Health Policy Development and Planning Bureau (DOH-HPDPB);
- (c) The Director, Commission on Higher Education, Office of Policy, Planning, Research and Information (CHED-OPPRI);
- (d) The Executive Director, University of the Philippines Manila - National Institutes of Health (UPM-NIH);
- (e) The Director of the Social Development Services of the National Economic and Development Authority (NEDA);
- (f) The Chair of the Philippine Health Research Ethics Board (PHREB);
- (g) A representative from the Philippine Health Insurance Corporation (PHIC);
- (h) A representative from the National Statistics Office (NSO);
- (i) A representative from the Professional Regulation Commission (PRC);
- (j) A representative from the Department of Transportation and Communications-Land Transportation Office (DOTC-LTO);
- (k) A representative from the Department of Environment and Natural Resources-Environment Management Bureau (DENR-EMB);
- (l) A representative from the local government units (LGUs); and
- (m) The Chairpersons of relevant PNHRs TWC.

(b) The Steering Committee shall perform the following functions:


- (a) Recommend policies to the GC;
- (b) Perform oversight function on the implementation and harmonization of the PNHRs activities and the allocation of the PNHRs fund;
- (c) Coordinate and harmonize the activities of the six (6) PNHRs TWCs; and
- (d) Monitor and report to the GC the progress of the PNHRs programs.

The Steering Committee may also coordinate and harmonize the activities of the other PNHRs TWCs.

Rule 20. Guidelines of the Steering Committee – The Steering Committee shall promulgate its guidelines for the conduct of its meetings.

Rule 21. Creation of the Technical Working Committees (TWC). – The GC shall create TWC aligned with research themes which are based on the country's health needs, and the six (6) building blocks of the World Health Organization (WHO) to attain universal health care. The Committees shall develop and monitor their respective strategic plans. They shall work closely with the stakeholders and the Secretariat. Other international references may also be used to determine the aforesaid research themes.

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The number of PNHRS TWCs shall be increased or decreased depending on the circumstances as may be determined by the Governing Council. In doing this, the Governing Council may consider the original six PNHRS TWCs on research agenda, ethics, capacity building, research utilization, resource mobilization, structure and organization, monitoring and evaluation.

Representation of the private sector, civil society and regional, national or international institutions or organizations shall be considered in the creation of national technical working committees.

Rule 22. *Interrelationships of the PNHRS Components* – The PNHRS Governing Council shall be the highest policymaking body. As such, its day-to-day operation shall be subsumed within the mandate, staff and budget of the PCHRD. The mode of operation of the PNHRS is through cooperation and collaboration between and among consortia, organizations, individuals and experts within the health research community. Engagement of stakeholders is through, but not limited to, the formation of advisory bodies, study groups, working groups, task forces, or similar bodies by the Governing Council or the Secretariat.

Rule 23. *The Philippine Health Research Ethics Board (PHREB)*. – The PHREB, created under DOST Special Order No. 091 s. 2006, shall ensure adherence to the universal principles for the protection of human participants in research.

The constitution of PHREB shall be governed by the same terms of reference contained in the above DOST Special Order.

The PHREB shall, among other, things:

- (a) Formulate and update guidelines for the ethical conduct of human health research;

The National Ethical Guidelines for Health Research shall be regularly updated every five years or whenever necessary. For this purpose, PHREB shall constitute a committee which shall be responsible for this undertaking.

- (b) Develop guidelines for the establishment and management of ethics review committees and standardization of research ethics review;

All 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 shall be facilitated by an Ethics Review Committee duly registered with and/or accredited by PHREB as provided for in the Joint

Memorandum Order 2012-001 of the Department of Science and Technology,

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Department of Health, Commission on Higher Education and the University of the Philippines Manila.

The National Ethical Guidelines for Health Research shall include the standards for the establishment and management of ethics review committees and the standards for research ethics review.

PHREB may conduct the necessary training activities for researchers, ERC members, and administrator which, may function at the national, regional, or local levels; or as cluster or individual committees.

- (c) Monitor and evaluate the performance of institutional ethics review committees in accordance with procedures outlined in a prior agreement;

In carrying out its monitoring and evaluation function, PHREB shall establish or designate Regional Ethics Monitoring Boards. These Regional Ethics Monitoring Boards may be located within existing regional DOH, DOST, CHED offices or designated institutions; and shall directly supervise the Ethics Review Committees established in their regional area of responsibility.

PHREB and the Regional Ethics Monitoring Boards, in consultation with ethics review committees shall develop and agree on indicators of good performance which shall be used in ensuring and monitoring quality ethics review in health research.

- (d) Promote the establishment of functional and effective ethics review committees;

The standards for the establishment of functional and effective ethics review committee shall be included in the National Ethical Guidelines for Health Research for reference of institutions and organizations.

Ethics review committees (ERCs) shall be categorized as follows:

- (a) Institution-based ERCs like those in hospitals, academic and research institutions
- (b) Government Agency-based ERCs
- (c) Organization-based ERCs
- (d) Cluster-based ERCs
- (e) Research site-based ERCs

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PHREB shall oversee and recognize functional and effective ERCs through the mechanisms of registration and accreditation as provided for in the Joint Memorandum Order 2012-001 of the Department of Science and Technology, Department of Health, Commission on Higher Education and the University of the Philippines Manila. Registration procedures must be described in the National Ethical Guidelines for Health Research and in the website of PHREB.

In coordination with the CHED and DOH-Food and Drug Administration, accreditation shall be made mandatory such that ERCs can be classified into different levels based on a set of criteria that shall determine the type and nature of researches the ERC is qualified to review.

- (e) Provide advice and make recommendations to the PNHRS Governing Council and other appropriate entities regarding programs, policies and regulations as they relate to ethical issues in human health research;
- (f) Initiate and contribute to discourses and discussions on ethical issues in human health research; and

PHREB shall institutionalize a Forum for Ethics Review Committees that shall meet at least annually during the PNHRS week, for discussions of ethical issues in human health research and other concerns.

- (g) Network with relevant local, national and international organizations.

PHREB shall link and cooperate with local, national and international organizations in furtherance of its goals and objectives to foster ethical health researches for the protection of human participants and promotion of the integrity of research data.

Rule 24. Regional Health Research Systems. – The PNHRS framework of cooperation and collaboration, strategic directions and programs, shall be mirrored in all the regions of the country, forming a network of regional research consortia. The consortium setup varies depending on the culture and resources of the region. Each regional health research system shall address concerns relating to health research agenda, development of human resource in health research, conduct of researches, dissemination of research results, research utilization, resource mobilization, leadership and management.

The PNHRS Network will be strengthened to ensure equitable distribution of health research resources as well as to achieve full coverage within regions. Strategies to increase and sustain commitment of member institutions to participate in and share resources shall be pursued.

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Rule 25. Inter-regional collaboration shall be encouraged through joint projects, information and resource sharing, participation in, and hosting of, the annual Philippine National Health Research System Week celebration, among other things.

CHAPTER III

MONITORING, EVALUATION, ACCOUNTABILITIES AND ANNUAL REPORT

Rule 26. *Monitoring, Evaluation, Accountabilities and Annual Report.* Regular monitoring and evaluation mechanism shall be done by the Governing Council, through the Secretariat, to determine the accountabilities of the PNHRS to the contributing agencies.

Rule 27. The Secretariat, with the Technical Working Committees and the Steering Committee, shall develop and implement a monitoring and evaluation plan, with appropriate indicators, for approval of the Governing Council.

Rule 28. All health researches shall be registered in the Philippine Health Research Registry, and when published, to the national repository (HERDIN) of published health researches. The Secretariat shall develop and disseminate guidelines to enable institutions to share their research information to these registries and databases.

Rule 29. The PNHRS Network and implementing institutions shall develop policies and guidelines to institutionalize and operationalize their participation in the PNHRS.

Rule 30. The Secretariat shall submit an annual report of the accomplishments of the PNHRS to the Governing Council. This report shall be presented during the PNHRS Week celebration.

CHAPTER IV

MISCELLANEOUS AND FINAL PROVISIONS

Rule 31. *Amendments to the Rules.* Any amendment to these Rules can only be done in writing by any of the implementing agencies which shall be effective upon approval of all the implementing agencies.

Rule 32. *Review of the Rules.* This IRR shall be reviewed every three years.

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Rule 33. Repealing Clause – All existing rules and regulations, or parts thereof which may be contrary to or inconsistent with these rules are hereby repealed or modified accordingly.


Rule 34. Separability Clause. – If any provision, or parts, of these Rules are held invalid or unconstitutional, the remainder of the Rules not otherwise affected shall remain valid and subsisting.


Rule 35. Effectivity Clause. – These Rules shall take effect fifteen (15) days after its publication in any newspaper of general circulation and upon filing at the UP Law Center in accordance with existing law.

NOW THEREFORE, the Parties have herein below affixed their signatures to the Joint DOST-PCHRD, DOH, CHED and UPM-NIH Administrative Order No. 001 this 30 day of JUL, 2013


MARIO G. MONTEJO
Secretary
Department of
Science & Technology


ENRIQUE T. ONA
Secretary
Department of Health


PATRICIA B. LICUANAN
Chairperson
Commission on Higher
Education


MANUEL B. AGULTO
Chancellor
University of the
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Department of Science and Technology
Records Management Section (GSD)



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