

# Mandates pertaining to the ethical review of researches involving humans, and the establishment and accreditation of research ethics committees

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In 2003, the secretaries of the Department of Health (DOH) and the Department of Science and Technology (DOST) signed a memorandum of understanding to institutionalize the Philippine National Health Research System (PNHRS) for the management of research in the country. One of the groups constituted under the PNHRS was the Technical Working Group (TWG) on Ethics, which created strategies that highlight the role of ethics in a responsible health research system. Among the recommendations of the Ethics TWG was the establishment of the Philippine Health Research Ethics Board (PHREB). In 2006, the PHREB was formally created through DOST Special Order 2006-91 "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." Since then, PHREB has become the country's policy making body on health research ethics.

In 2013, the Republic Act 10532—or the PNHRS Law—was enacted.<sup>4</sup> The Act strengthened the mandate of PHREB to ensure protection of the welfare, rights, and safety of human research participants, and the implementing rules and regulations (IRR) of the Act specified the policies that facilitate the achievement of the PHREB mandate.<sup>5</sup> In 2017, through DOST Special Order 2017-248, DOST established research ethics monitoring boards (REMBs) in Region I, Region VI, and Region XI to assist in the comprehensive and consistent implementation of PHREB policies at the regional level.<sup>6</sup> The creation of PHREB in 2006 initiated several other mandates from PHREB and other agencies that implement the PNHRS. These mandates—shown in the infographic—support human research participant protection through ethical reviews of research protocols, establishment of research ethics committees, and maintenance of quality standards of these committees through accreditation. Many of these mandates are national in scope, but a few are specific to Davao Region (Region XI).

#### Contributors

ASC wrote the original draft and subsequent revisions of this article. CXDL did the layout for the infographics. All authors gave their approval of the final version to be published. All authors agreed to be accountable for all aspects of the work.

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None declared

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# MANDATES PERTAINING TO THE ETHICAL REVIEW OF RESEARCHES INVOLVING HUMANS, AND THE ESTABLISHMENT AND ACCREDITATION OF RESEARCH ETHICS COMMITTEES

2007

approval

2014



**DOST ADMINISTRATIVE** 

protocols for the conduct of

biomedical and behavioral

researches involving human participants shall be submitted

**ORDER 2007-001** 

• requiring that all research

to RECs for coordination

comment, guidance, and

urging all institutions that conduct health research to

establish research ethics committees that evaluate and monitor researches involving

human participants



## 2007 **CHED MEMORANDUM ORDER 2007-34**



• endorsing the DOST Administrative Order 2007-001. which stipulates the requirements for review of all health researches involving human subjects/participants



### 2012







# PHREB REQUIREMENTS FOR REGISTRATION AND



 requiring that all RECs that conduct review for ethical soundness of research proposals (or intend to review researches) involving human participants must register and undergo accreditation by PHREB

**DEPARTMENT ORDER** 

requiring all DOH units with RECs to seek PHREB

2017-0265 BY THE DOH

accreditation: RECs of all Level 3 DOH hospitals are ordered to

have Level 3 PHREB accreditation, while RECs of all

agencies) are ordered to have at least Level 2 PHREB

DOH units (regional offices, hospitals and attached

2015



#### PHREB MEMORANDUM **27 FEBRUARY 2015**

· reiterating the requirement for all RECs in the Philippines to apply for registration and accreditation at the PHREB





 requiring 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

2013





#### PNHRS ACT OF 2013 -**IMPLEMENTING RULES AND REGULATIONS**

- requiring that all researches involving human subjects must undergo ethical review and clearance prior to implementation to ensure the safety, dignity, and well-being of research participants
- stating the task of the PHREB to promote the establishment of functional and effective RECs
- stipulating that accreditation of RECs shall be made mandatory

2017



# 2018





### **RESOLUTION 2018-65 BY** THE REGIONAL DEVEL-**OPMENT COUNCIL XI**

ECIFIC TO REGION XI)

 enjoining all HEIs in Davao Region to establish their respective RECs and apply for PHREB accreditation

#### 2015



#### **MEMORANDUM FROM THE CHAIRPERSON 30 MARCH 2015 BY THE CHED**

 endorsing the PHREB requirement for all RECs that review proposals for doing research involving humans to register and undergo accreditation by PHREB

2015



#### DEPARTMENT CIRCULAR 2015-0059 OF THE DOH

 requesting all DOH RECs to comply with the PHREB requirement for RECs to register and undergo accreditation

accreditation



## 2019 **CHED MEMORANDUM**

**ORDER 2019-15** 

 stipulating that maintaining ethical standards when conducting research involving human participants is one of the minimum requirements to operate a graduate degree program, and requiring HEIs to partner with recognized RECs or to have their own mechanism for the ethical review of researches

2019



## **MEMORANDUM FROM THE DIRECTOR 2019-183 BY** THE CHED REGION XI

C TO REGION XI)

- endorsing the PHREB requirement for all RECs reviewing researches involving humans to register and undergo
- reiterating that checking for PHREB accreditation of RECs will be part of HEI monitoring and

2018



#### **MEMORANDUM FROM THE DIRECTOR 2018-52 BY** THE CHED REGION XI **DIRECTOR**

ECIFIC TO REGION XI)

- endorsing the PHREB requirement for all RECs that review proposals for doing research involving humans to register and undergo accreditation by PHREB
- announcing that PHREB accreditation of RECs will be included in the monitoring and evaluation of HEIs in Davao Region

2019



#### DEPARTMENT ORDER 2019-163 BY THE DOH

requiring that all clinical researches shall undergo ethical review in PHREB-accredited RECs



DIRECTOR

- accreditation by PHREB
- evaluation in Davao Region

CHED - Commission on Higher Education; DOH - Department of Health; **DOST** - Department of Science and Technology; **HEI** - higher education institution; **PHREB** - Philippine Health Research Ethics Board; **PNHRS** - Philippine National Health Research System; REC- research ethics committee; UPM- University of the Philippines Manila









conduct of health research involving human subjects/ participants, CHED Memorandum Order No. 34 series 2007 (2007 June 13).

#### 2012

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#### 2019

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