

Republic of the Philippines
Center for Health Development No. 2
REGION II TRAUMA AND MEDICAL CENTER



REGION II TRAUMA AND MEDICAL CENTER

—

**INSTITUTIONAL REVIEW BOARD
STANDARD OPERATING PROCEDURE**

2022

REGION II TRAUMA AND MEDICAL CENTER

NATIONAL HIGHWAY, BARANGAY MAGSAYSAY, BAYOMBONG, NUEVA VIZCAYA

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**R2TMC- INSTITUTIONAL REVIEW BOARD
ORGANIZATIONAL CHART**



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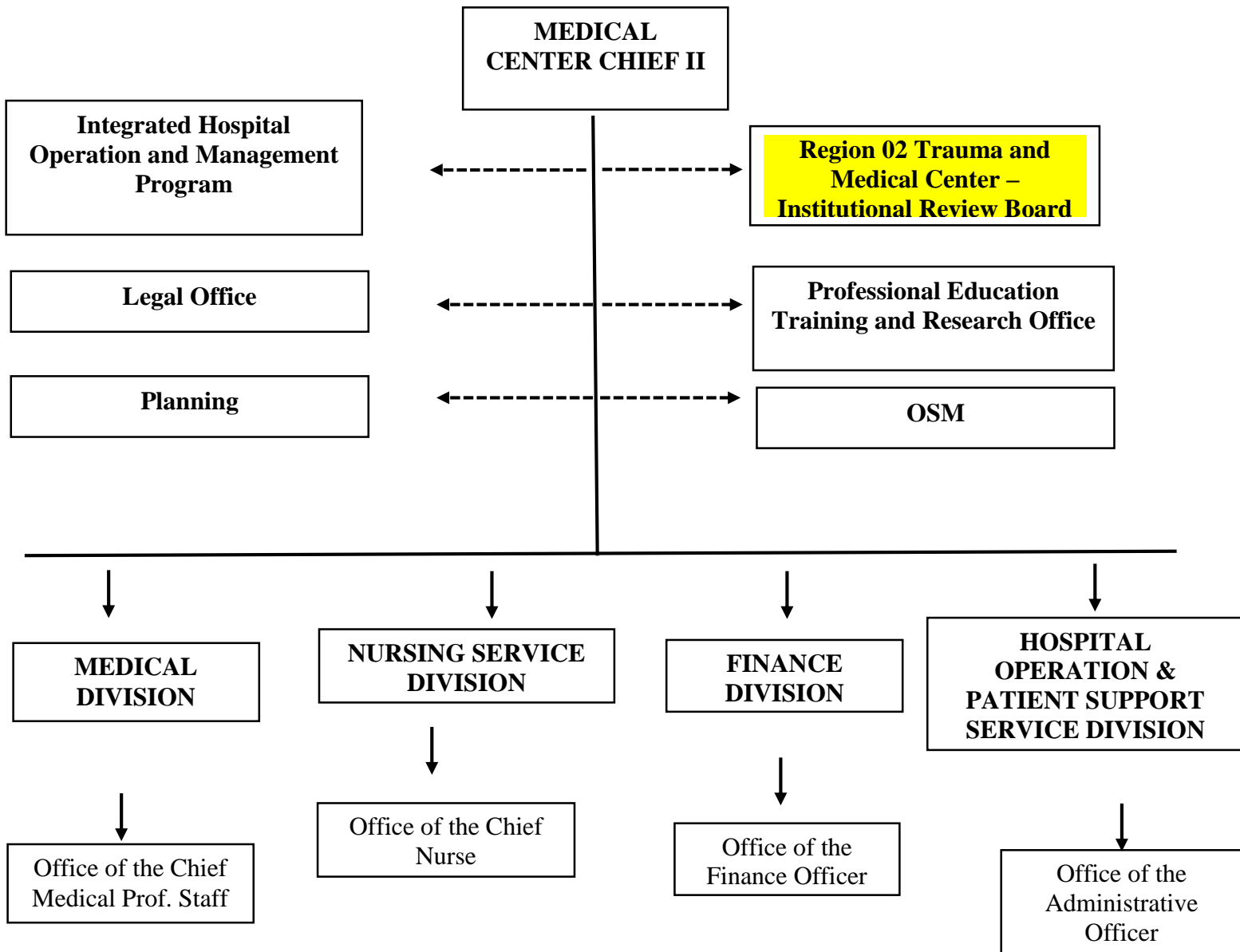


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ORGANIZATIONAL CHART





REGION II TRAUMA AND MEDICAL CENTER
Bayombong, Nueva Vizcaya

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Memorandum
No. 2022-002

Date: September 6, 2022
To: R2TMC – IRB; All Services
From: RAY P. SUANBING, MD, MHA, FPPF, FPCCP
Medical Center Chief II
Subject: Establishment of Region II Trauma and Medical Center – Institutional Review Board (R2TMC-IRB)

The Region II Trauma and Medical Center-Institutional Review Board (R2TMC-IRB) shall review all types of research with humans as subjects with compliance to the core of ethics.

The R2TMC-IRB shall be an independent body constituted of medical, scientific, and non-scientific members. The committee shall be responsible for ensuring the protection of rights, safety, and well-being of human subjects; responsible for reviewing, approving, and providing continuing review protocol within a reasonable time, and obtaining and documenting informed consent of trial subjects.

The R2TMC-IRB shall perform functions according to written procedures and maintain records and decode during announced meetings and required quorum.

The R2TMC-IRB terms of reference have been drawn to ensure that its functions independently and maintains a consistent scientific and ethical framework for health research and integrates ethical values into practice, policy relationships, and organizational ethical values practice, policy relationships, and organizational activities. The constitution of the R2TMC-IRB shall be sufficient to ensure the appropriate expertise, multi-discipline backgrounds, and independence required for competent research ethics review. The membership of the R2TMC-IRB shall include individuals with varying backgrounds and appropriate professional competence to review the diverse types of protocols that are received.

The R2TMC is committed to supporting all the R2TMC-IRB research activities.



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INTRODUCTION

Vision

An established competent and accredited Level III R2TMC-Institutional Review Board by 2023.

Mission

To review all types of researches involving human as subjects with compliance to the core of ethics.



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HISTORY OF R2TMC – IRB

WHEN The Veterans Regional Hospital (VRH) has its Residency Training Programs in Obstetrics and Gynecology, Anatomic and Clinical Pathology and Pediatrics fully accredited in 2014, it sensed the need to establish an Institutional Review Board (IRB) for its research protocols. VRH envisioned the creation of a Research Ethics Committee that conforms to national and international standards. Two members attended trainings on Basic and Advanced Programs for Research Ethics Review at the National Institutes of Health-University of the Philippines, Manila (NIH-UPM).

Dr. Danilo Antonio A. Alejandro and Daisy J. Dulnuan participated in the Training-Workshop on Principles of Health Research Ethics and Good Clinical Practice as well as Standard Operating Procedures for Ethics Review Committees.

On April 15, 2015, Dr. Cirilo R. Galindez, the Medical Center Chief of Hospital formally recognized the VRH-IRB as mandated by the Department of Health (DOH) and Philippine Health Research Ethics Board (PHREB) to be chaired by Dr. Daisy J. Dulnuan and co-chaired by Dr. Danilo Antonio Alejandro. The members were Drs. Richard C. Lopez, Ma. Selina P. Rupisan, Michelle R. Maniquis, Miss Clarita M. Dontogan, Atty. Zozimo P. Kimayong and Mrs. Evelyn Cabanting. Non-affiliate members include Mr. Cesar T. Medulla, Jr and Dr. Bonifacio V. Ramos.

On September 28, 2018, thru Republic Act 11081, the Veterans Regional Hospital changed its name into Region 2 Trauma and Medical Center(R2TMC), so as the name of the Research Ethic Committee into R2TMC-IRB. R2TMC is now a tertiary training hospital with the Departments of Internal Medicine, Family Medicine, Anesthesia and Surgery also became accredited for residency training. Currently, the following members are Dr. Daisy J. Dulnuan, as the chairperson, Dr. Maria Selina P. Rupisan, Dr. Michelle R. Maniquis, Miss Clarita M. Dontogan. Mrs. Thelma V. Tolentino, Atty. Zozimo P. Kimayong, Dr. Jason Arnold Maslang, Mr. Albert Garcia and Ms. Christine Louise N. Andaya as secretary staff.

In line with the hospital's vision, the administration has been very supportive so that all of the R2TMC-IRB members are being sent for trainings, workshops and conventions – both national and international. Upon satisfying all necessary PHREB requirements and recommendations, the R2TMC-IRB was awarded the Certificate of Accreditation as Level 2 until September 2020. R2TMC-IRB aims to maintain and upgrade its accreditation to level 3 in the year 2023.



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Ethical Framework of Region II Trauma and Medical Center- Institutional Review Board

The Region II Trauma and Medical Center- Institutional Review Board (R2TMC-IRB) is guided in its reflection, advice, and decision by the ethical principles as follows:

- Respect for Persons – the principle that states that individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
- Beneficence – the principle that requires investigators to protect participants from harm and secure their well-being.
- Justice – the principle that refers to the sense of “fairness in distribution” and “what is deserved.”

Source: Belmont Report, 1979

- a. It is guided by the ethical principles and procedures as expressed in the following international guidelines:
 - Declaration of Helsinki (2013 and subsequent revisions)
 - International Conference on the Harmonization of Good Clinical Practice (ICH-GCP)
 - CIOMS 2016
 - Standard and Operational Guidance for Ethics Review of Health-related Research with Human Participants (2011) by the World Health Organization (WHO)
- b. The R2TMC-IRB will function in accordance with national laws, regulations, and guidelines.
 - National Ethical Guidelines for Health Research by the Philippine Health Research Ethics Board (PHREB)
 - Administrative Orders from DOH, Philippine FDA, and other relevant agencies
- c. The R2TMC-IRB adopts its own standard operating procedures based on:
 - Operational Guidelines for Ethics Committees that Review Biomedical Research (2000) by the WHO
 - DOH-REC SOP and Template
 - FERCAP SOP and Template
 - PHREB SOP Workbook
- d. The R2TMC-IRB adheres to national and international ethical standards and recognizes that the protocols it approves may have undergone review and approval by other ethics committees including the Multi-Site Research Ethics Board prior to their implementation in specific sites.
- e. In evaluating protocols and ethical issues, the R2TMC-IRB is cognizant of the diversity of laws, cultures, and practices governing health research in various local sites/countries around the world.
- f. It attempts to inform itself, whenever possible, of the regulations and requirements of sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of various localities where proposed R2TMC research is being considered.
- g. The R2TMC-IRB will take the initiative to be informed, as appropriate, by current state-of-the-art research and publications of the impact of the research that it has approved.



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