

## CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITIONAL REVIEW BOARD



Version 1

## INTRODUCTION

The Cebu Institute of Medicine – Cebu Velez General Hospital Institutional Review Board (CIM-CVGH IRB) is guided in its reflection, advice, and decision by the ethical principles as follows:

- Respect for Persons principle that states that individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
- Beneficence principle that requires investigators to protect participants from harm and secure their well-being.
- Justice 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 2002, 2009, 2016
  - Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization (WHO)
- b. The 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) 2011, 2017
  - Administrative Orders from DOH, Philippine FDA and other relevant agencies
- c. The IRB adopts its own standard operating procedures based on:
  - Operational Guidelines for Ethics Committees That Review Biomedical Research (2000) by the World Health Organization (WHO)
  - DOH-IRB SOP Template
  - FERCAP SOP Templates
  - PHREB SOP Workbook
- d. The IRB adheres to national and international ethical standards and recognizes hat the protocols it approves may have undergone review and approved by other ethics



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committees including the Multi-Site Research Ethics Board (MREB) prior to their implementation in specific sites.

- In evaluating protocols and ethical issues, the IRB is cognizant of the diversity of laws, cultures and practices governing health research in various local sites/countries around the world.
- e. The IRB respects the confidentiality and privacy of the subjects and their data and abides by the rules and regulations governing Indigenous and marginalized population
- 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 a proposed (CIM CVGH) research is being considered.
- g. The IRB will take the initiative to be informed, as appropriate, by current state of- the-art researches and publications of the impact of the research that it has approved.