## **Historical Background**

The Philippine Heart Center (PHC) has been in existence since its founding in 1975. Through a memorandum order no.234-04 from its Executive Director, Dr. Ludgerio D. Torres dated Aug.20, 2004 the Ethics Committee (EC) was reorganized. It was tasked to act as a super body to formulate policies and guidelines to identify and solve ethical issues, provide a general education program on ethics for PHC staff and make final decision after review of cases submitted to the committee conceiving professional conduct and practices.

Under the EC, two (2) subcommittees were formed. These were Bioethics Committee and research team. The Research Team was tasked to review ethical issues involved in research projects and deliberate on research papers submitted for ethical or legal review in the absence of an IERB. The subcommittee on Bioethics was composed of medical doctors (4), registered nurse (1) and a priest. The Research Team was made up of medical doctors (4) and registered nurse (1).

On May 11, 2006 another memorandum order was issued by the Assistant Director of Medical Services (Memo No. 160-2006). This memorandum contained functions and membership of the EC as well as the subcommittee elements of the EC. The functions of the Bioethics Committee were similar to the previous function. The Research Team was named Institutional Review Board (IRB). This was composed of medical doctors (4), registered nurse (1), layperson (1) and a secretary. Dr. Marcelito L. Durante was appointed as Chair. On Jan 31, 2008 a new composition of the IRB was released. Their appointments were effective from 2008-2010. Again medical doctors (4), registered nurse (1) legal/ lawyer (1) and a layperson comprised the new members of IRB. Ms. Suzette Manuel was the IRB's secretary. Their functions were the same as the functions cited in the earlier memos.

A new memorandum order no.232; 2011 was issued on May 20, 2011 by the new Executive Director of PHC, Dr. Manuel Chua Chiaco Jr. The new memo contains the new members of IERB who will serve a team of two years (2011- 2012). In this

memo IRB was changed to IERB (Institutional Ethics Review Board). Dr. Marcelito L. Durante was appointed to again chair the IERB. The members are:

Marissa A. Orillaza, MD Aileen Guzman Banzon, MD Eva Teodora T. Sison, RN Prof. Aniceta M. Ortireno (Lay Person) Atty. Angelito G. Grande (Lay Person and Legal Consultant)

The new IERB was mandated to provide competent and timely review of the ethics of proposed studies to ensure and safeguard the dignity, rights, safety and wellbeing of all actual or potential human participants in accordance to WHO operational guidelines for Ethics that Review Biomedical Research.

On July 01, 2011 a new member was appointed through a Memorandum Order No. 309:2011 in the person of Eden T. Latosa, MD. She will represent Pediatric Cardiology.

Last August 8-12, 2011 Accreditation Canada International (ACI) surveyed the Philippine Heart Center and a GOLD accreditation was awarded to the institution for the period 2011-2014 for meeting international standards of excellence in quality care and service. The ACI had several positive findings on IERB as follows:

- 1. The center has a clean, well-defined process to review research projects.
- 2. All requests are reviewed scientifically prior to reaching the IERB.
- 3. The committee meets twice a month and receives five (5) requests on average each meeting.

On August 10, 2012, the PHC-IERB received from the Philippine Health Research Ethics Board the certificate of accreditation as a first Level 3 Ethics Review Committee in the country with Accreditation no. 12-001 with registration no. 07-030. The effectivity date of the certificate is 01 August 2012 and the expiry date is 31 July 2015 was given during PNHRS anniversary in Manila, Philippines.

At the same year, the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) in collaboration with the Forum for Ethical Review Committees in Asia and the Western Pacific Region awarded recognition to the PHC-IERB on 12th FERCAP General Assembly in Colombo, Sri Lanka on November 21, 2012, for its compliance with the International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Declaration of Helsinki, Council for International Organization of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Operational Guidelines for Ethics Committees that Review Biomedical Research, EC/IRB Standard Operating Procedures (SOPs) and Local Regulations and Standards in Ethical Review.

On March 25, 2015 another memorandum order was issued by the Assistant Director of Medical Services, Gerardo S. Manzo, MD. The Memorandum Order No. 121:2015 stated that the Institutional Ethics Review Board (IERB) members is reconstituted for a term of three (3) years (2015-2018) with the following composition:

Chair:	Marcelito L. Durante, MD
Members:	Marissa A. Orillaza, MD
	Aileen Guzman-Banzon, MD

Eden D. Latosa, MD Rafael R. Tenorio, MD Ronaldo C. Manuel, MD Eva Teodora T. Sison, RN Rev. Nelson G. Domingo Ma. Theresa A. Villanueva Renewal/replacement of IERB member has occurred. Dr. Bernice Ong-Dela Cruz replaced Aileen Guzman-Banzon, MD for Pulmonology and Dr. Iris Garcia replaced Dr. Ronaldo Manuel for Adult Cardiology, include other replacement.

On November 24, 2015, the PHC-IERB received the renewal of recognition in Nagasaki, Japan during 15th FERCAP General Assembly for its compliance with the International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Declaration of Helsinki, Council for International Organization of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Operational Guidelines for Ethics Committees that Review Biomedical Research, EC/IRB Standard Operating Procedures (SOPs) and Local Regulations and Standards in Ethical Review.

On March 17, 2016, the PHC-IERB received from the Philippine Health Research Ethics Board the certificate of re-accreditation for another three (3) years as a Level 3 Ethics Review Committee with Accreditation no. L3-2016-030-02. The effectivity date is March 10, 2016 and the expiry date is March 10, 2019 was given during PCHRD anniversary in New World Hotel, Makati City, Philippines.

On April 17, 2018, the Philippine Heart Center received the much coveted Diamond Accreditation for meeting international standards of excellence in quality care and service from the Accreditation Canada International (ACI). PHC is the first and only government hospital in Asia to receive the highest level of recognition from an international accrediting body that passionately adheres to healthcare safety and quality service. The ACI Diamond award is a strong testament of PHC's adherence to excellent delivery of cardiovascular healthcare, the institution being dedicated to quality service and good governance. The IERB was included in the assessment and was given excellent findings and comments by the assessors having a robust quality management system.

On January 10, 2019, another memorandum order was issued by the Executive Director. The memorandum order no. 017:019 stated the Institutional Ethics Review Board (IERB) members is reconstituted for a term of three (3) years (2019-2021) with the following Composition:

Chair: Marcelito L. Durante, MD Members: Marissa A. Orillaza, MD Eden D. Latosa, MD Rafael R. Tenorio, MD Eva Teodora T. Sison, MD Bernice Ong-Dela Cruz, MD Eva Teodora T. Sison, RN Leahdette O. Padua, MD Iris M. Garcia, MD Ma. Theresa M. Villanueva

On June 2019, Dr. Benjamin Jose C. Quito was appointed as a regular IERB member while Dr. Rafael R. Tenorio was appointed the new chair after the resignation of Dr. Marcelito L. Durante.

On August 16, 2019, the PHC-IERB received from the Philippine Health Research Ethics Board the certificate of re-accreditation for another four (4) years as a Level 3 Ethics Review Committee with Accreditation no. L3-2019-030-03. The effectivity date is July 31, 2019 and the expiry date is June 30, 2023 was given during PNHRS week in Limketkai Luxe Hotel, Cagayan de Oro City, Philippines.

On November 27, 2019, the PHC-IERB received the renewal of recognition in Penang, Malaysia during 19th FERCAP General Assembly for its compliance with the International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Declaration of Helsinki, Council for International Organization of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Operational Guidelines for Ethics Committees that Review Biomedical

Research, EC/IRB Standard Operating Procedures (SOPs) and Local Regulations and Standards in Ethical Review.

On November 2020, Edreck D. Estioko, RN was appointed as the board Secretary member of IERB after resignation of Eva Teodora T. Sison, RN.

On June 2022, Dr. Benjamin Jose C. Quito was appointed as the new Vice-Chair of IERB while Dr. Marissa A. Orillaza was appointed as a regular IERB member.