

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 elemental 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 Chiacco Jr. The new memo contains the new members of IERB who will serve a term 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 is mandated to provide competent and timely review of the ethics of proposed studies to ensure and safeguard the dignity, rights, safety and well-being 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 findings on IERB were divided into positive comments and observations. The positive comments were:

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.

The observations and recommendations were:

1. The committee minutes reflect only approval. It is suggested the committee be briefed on status of current approved projects. More specifically an update on intension reports and/or a report on completed projects showed be provided.
2. In the event of adverse sentinel event, or a significant patient safety issue as part of the approval process, PI's should be encouraged to provide a certification to the committee outlining the event and subsequent actions taken.
3. The committee is encouraged to review its current costing to ensure the center is recouping the full edit of participating in research projects

Upon receipt of the ACI findings on IERB, the board scheduled a management review on Sept. 07, 2011 after its regular meeting. This was presided by the Chair with all members in attendance. An action plan was proposed and finalized.

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

Suzette R. Manuel (Secretariat)