



# **NATIONAL CHILDREN'S HOSPITAL STANDARD OPERATING PROCEDURES**

**VERSION NO: 4**  
**EFFECTIVE DATE:**  
**11/01/2018**

## **INTRODUCTION**

Research must not only be for the advancement of science and health, it must also ensure the protection, safety and well-being of human participants. International and National Guidelines for health research are available to protect human participants and to uphold their dignity and rights. The National Children's Hospital is a tertiary retained hospital of the Department of Health geared towards the improvement of specialty health care for children.

The National Children's Hospital- Institutional Review Board (NCH-IRB) was originally created in 2009 carrying the name National Children's Hospital- Institutional Review Board/Institutional Ethics Committee (NCH-IRB/IEC). It was created by the late Dr. Robert Enriquez with only a handful of members who were chosen on the basis of their background in research. The original Standard Operating Procedures (SOP) was patterned after international SOPs. In the year 2012, through a hospital order issued by our present Medical Center Chief, Dr. Epifania S. Simbul, the creation of the present Institutional Review Board was formalized. Regular trainings provided by the Department of Health (DOH) and University of the Philippines- National Institutes of Health (UP-NIH) on Good Clinical Practice (GCP) and Standard Operating Procedures (SOP) were regularly attended by the members. It was then that the 2012 SOP was formulated and patterned after the UP-Manila's Research Ethics Board Standard Operating Procedures as well as the SOP of the UP-Manila REB, FEU-NRMF- IERC and Makati Medical Center REC, which were based on International and National Guidelines and policies. SOP formulation was also based on the NCH's guidelines and policies.

In line with the vision of the Philippine Health Research Ethics Board (PHREB) that all Research Ethics Committees be accredited by December 2015, the NCH-IRB/IEC finally adopted the name NCH-IRB. The NCH-IRB has full administrative support in the performance of its functions.

The NCH-IRB adheres to ethical standards of practice in research. It protects research participants from harm, helps minimize risks and prevents their exploitation. It also protects the participants' rights. It provides measures in monitoring conduct of research, researchers' as well as NCH-IRB members' qualifications.

The NCH-IRB performs its functions based on the NCH-IRB SOP. We also adhere to PHREB standards for maintaining their accreditation and SIDCER standards for its continued recognition.



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The revised NCH-IRB SOP of 2018 has been adopted from the revised SOP 2017 as recommended by the DOH. It also included the recommendations by PHREB and FERCAP during the joint re-survey held last July 2018.

The 2018 NCH-IRB SOP includes the appointment of alternate members with their duties and responsibilities. The different categories of members were defined, specifically, medical/ non-medical, scientific/non-scientific and lay members. Heads of the different sections in the hospital can recommend members to the NCH-IRB. The timeline of review and approval had been revised. The decision is based on consensus, and in the absence of a consensus, by a majority vote. The principal investigators are informed of the expiration of Ethics approval two months before the due date for Continuing Review Application. The revised 2018 SOP also includes the membership of NCH-IRB to the DOH's Single Joint Research Ethics Board (SJREB) and the SOP of the SJREB. The revised 2018 SOP was implemented on Nov. 5, 2018.

## 1. Objectives

This SOP describes the Terms of Reference (TOR) which provide the organizational framework for the structure and composition of the National Children's Hospital-Institutional Review Board (NCH-IRB). This SOP also describes and provides the procedures, templates, and forms that are related to nomination, appointment, privacy and confidentiality, training, and compensation; and identifies who should read, agree to, sign, and date these forms.

## 2. Scope

This SOP applies to the constitution of the NCH-IRB and the composition of subcommittees within the NCH-IRB, which will carry out the task of providing an independent review of research protocols involving human participants submitted to the NCH-IRB by the students, hospital staff, residents, fellows and other trainees and employees of the National Children's Hospital (NCH), and non-NCH principal investigators (PIs).

This SOP describes the general ethical basis or values on which the NCH-IRB is based, the composition and appointment of NCH-IRB members, duties and responsibilities including attendance, training, expected review deliverables, and disclosure of conflict of interest of NCH-IRB members.

## 3. Responsibilities

It is the responsibility of the Medical Center Chief to constitute and establish the NCH-IRB. The Medical Center Chief is also responsible for appointing the Members and Secretariat; and providing the terms of reference for these appointments in accordance with prevailing policies, guidelines, and regulations.



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It is the responsibility of the Members to study, comprehend, comply with, and respect the procedures and guidelines set by the NCH-IRB as approved by appropriate officials. The Members shall vote among themselves the NCH-IRB Chair, Vice Chair and Member-Secretary to serve for a term of three (3) years.

It is the responsibility of all appointed Members to read, understand, accept, and sign required appointment forms at the start of their appointment or reappointment to the NCH-IRB.

It is the responsibility of members and the secretariat to undergo training during the course of their appointment and existing members and the secretariat to continuously update themselves and train on relevant knowledge and skills. The NCH-IRB Chair shall enjoin members and the secretariat to attend trainings/seminars/workshops as needed, and ensure that adequate resources are provided for continuing professional development.

Therefore NCH management is responsible for allocating an annual budget for specific trainings and other educational activities needed in the performance of their roles and functions as members

## **4. Constitution and Functions**

### ***4.1. Organizational Structure of the NCH IRB***

4.1.1. The Medical Center Chief appoints the Members to facilitate the discharge of functions of the NCH-IRB along the line of authority indicated by the following chart:



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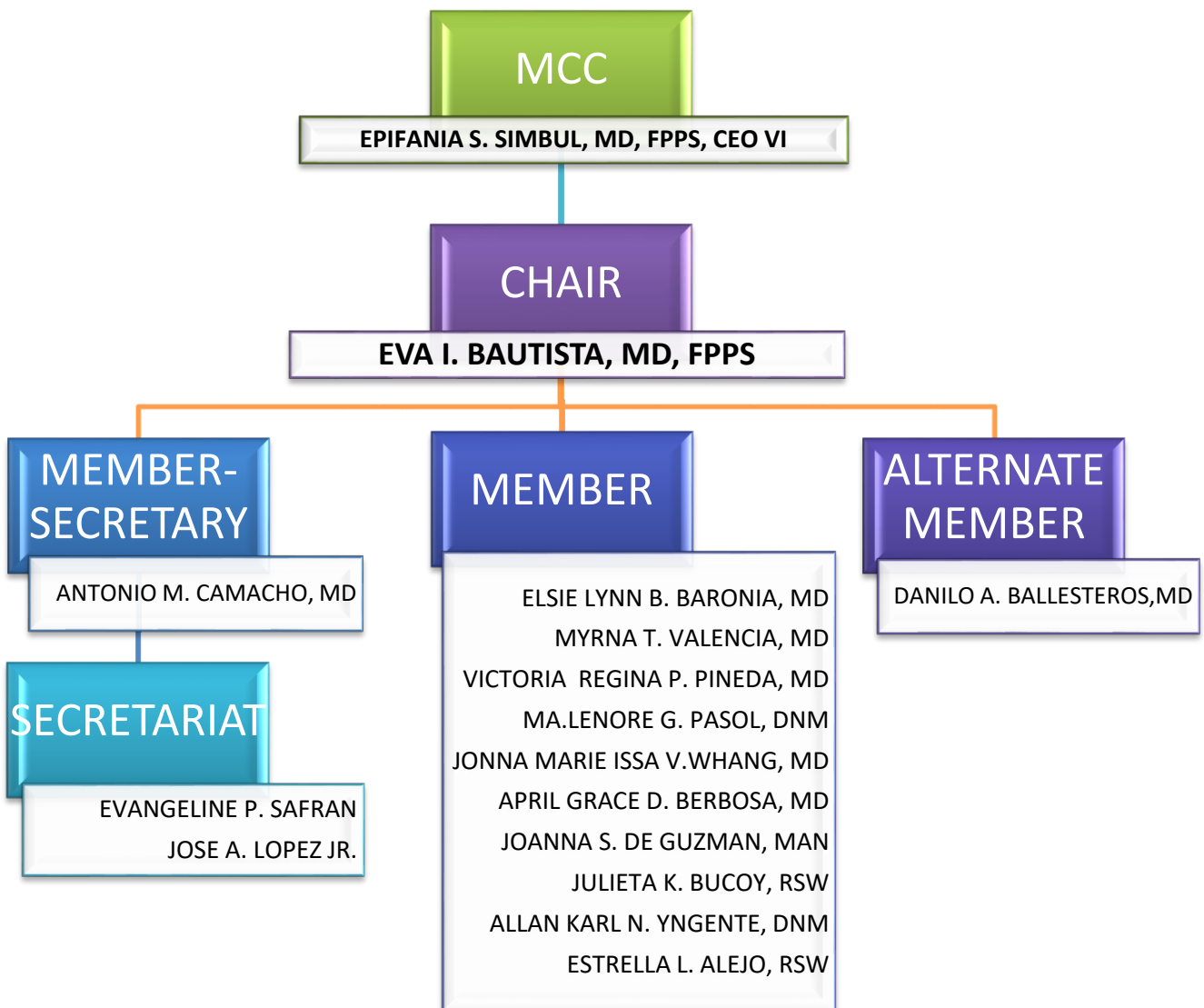


Figure 1: Organizational Chart