
 <b>PHILIPPINE HEART CENTER</b>  <b>INSTITUTIONAL ETHICS REVIEW BOARD</b>	Document Type	Document Code: POL-E-IRB-010
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<b>REVISION HISTORY</b>			
<b>Rev No.</b>	<b>Review Date</b>	<b>Description of Change</b>	<b>Date of Next Review</b>
0		Original	August 2012
1	May 2012	Change of Format	May 2013
2	March 2015	Change of Format	March 2016
3	November 2015	Change of Format	November 2016
4	January 2017	Change of Format	January 2018
5	March 2017	Change of Format	March 2018
6	June 2017	Change of Format	June 2018
7	July 2017	Change of Format	July 2018
8	December 2018	Change of Format	December 2019
9	July 2019	Change of Format	July 2020
10	December 2020	Change of Format	December 2021
11	June 2022	Change of Format	December 2023
12	November 2023	Change of Format	November 2024

Reviewed by:	<b>MARIA TERESA B. ABOLA, MD</b> Deputy Executive Director for Education Training and Research Services	Approved by:	<b>JOEL M. ABANILLA, MD</b> Executive Director
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## **i. INTRODUCTION**


### **ii. 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:

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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 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 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

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Region awarded recognition to the PHC-IERB on 12<sup>th</sup> 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.

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On November 24, 2015, the PHC-IERB received the renewal of recognition in Nagasaki, Japan during 15<sup>th</sup> 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

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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 a new chair after 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 19<sup>th</sup> 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 a board Secretary member of IERB after resignation of Eva Teodora T. Sison, RN.

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

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The Vision Statement of the IERB is:

An internationally accredited institutional ethics review board that will serve as a model in the review of all medical research and clinical drug studies in the country.

The Mission Statement is:

To provide comprehensive ethical guidelines for a timely review by competent professionals of medical research and clinical drug studies in the country.


The objectives are:

1. To provide ethically-sound review of research protocols
2. To participate in accredited trainings and workshops in research ethics
3. To disseminate information on the ethical conduct of scientific research

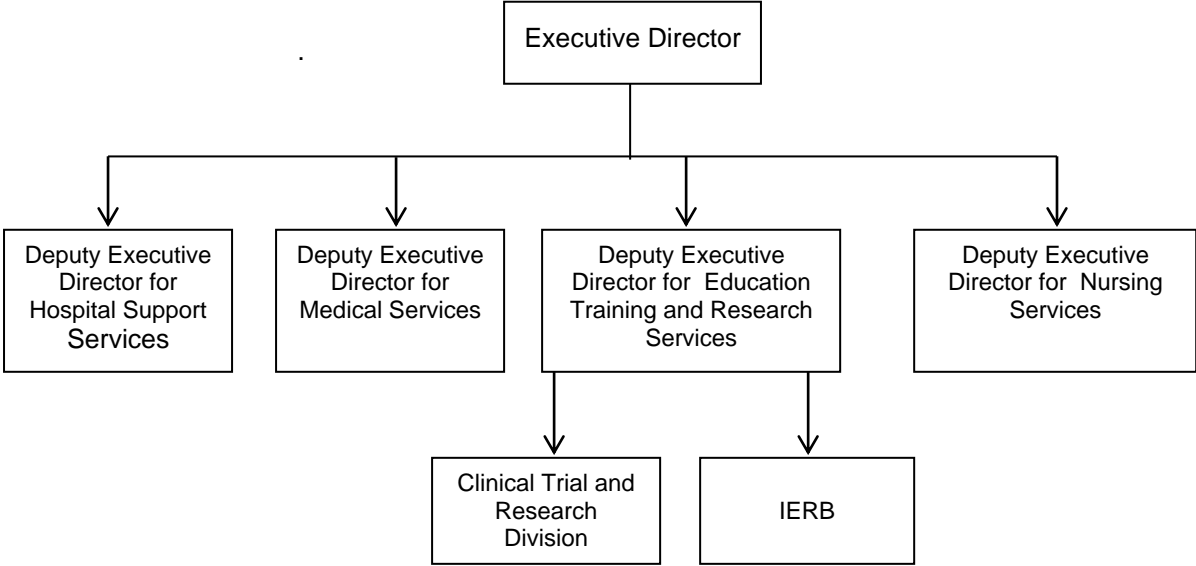
The Institutional Ethics Review Board (IERB) is committed to deliver Quality Service at all times to satisfy all its stakeholders.

The IERB is authorized by the PHC management to operate the board. It defines and manages processes necessary to ensure that its services conform to its customer's requirements. The IERB has established, documented, maintained and improved a management system covering the applicable requirements of the hospital.

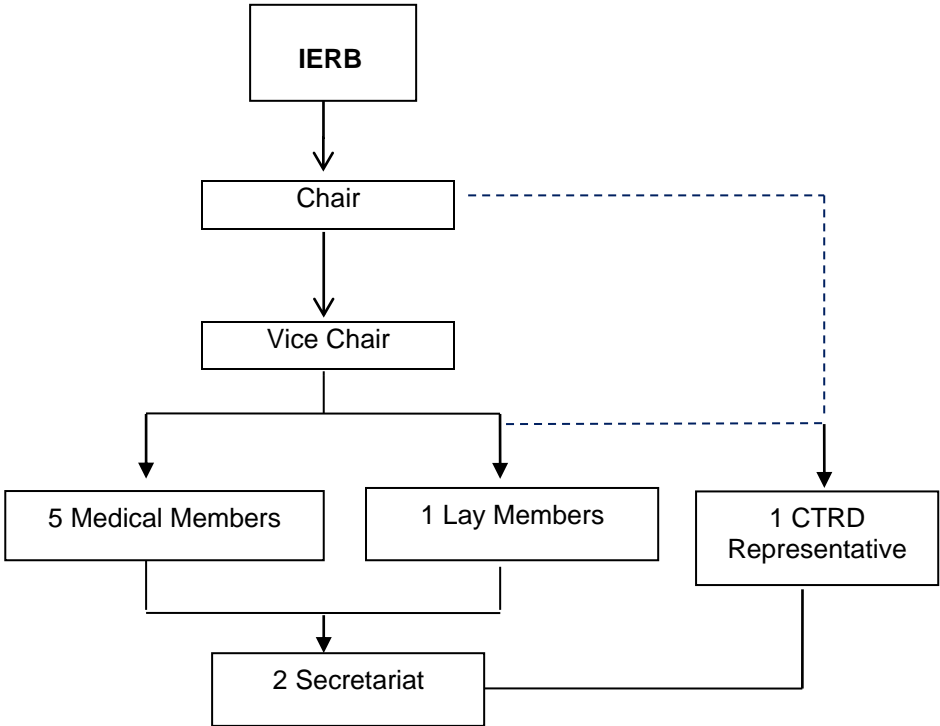
The organizational chart is one of the most important management tools that outlines the accountability of the Chair, Members of the Board and the Secretariat. The Chair signs the organizational chart for approval prior to use. Authority interrelation and responsibilities are on file in the form of job description including the responsibilities of the Chair, Medical members, Non-medical members (lay person) and the Secretariat.

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**Institutional Ethics Review Board Organizational Structure 1**



**Institutional Ethics Review Board Organizational Structure 2**





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### iii. HOSPITAL VICINITY MAP




The IERB is located at the 8<sup>th</sup> floor of the Medical Arts Building of the Philippine Heart Center along East Avenue, Quezon City. All official functions of IERB as well as its documents are in this office

The IERB is an independent board of the Philippine Heart Center. It is a board with nine (9) members and two (2) secretariats that offers services to fulfill and satisfy the needs of the principal investigators, patients, and corporate organizations. A Liason Officer from the Clinical Trial and Research Division attends the board meeting since majority of the protocols are from Fellows and Residents. The IERB has an email address of: [irbphc@gmail.com](mailto:irbphc@gmail.com)


The board services comprise the following review of PHC – Funded protocols (In House):

1. Medical services
2. Clinical Research Fellows
3. Fellow
4. Residents
5. Nursing services

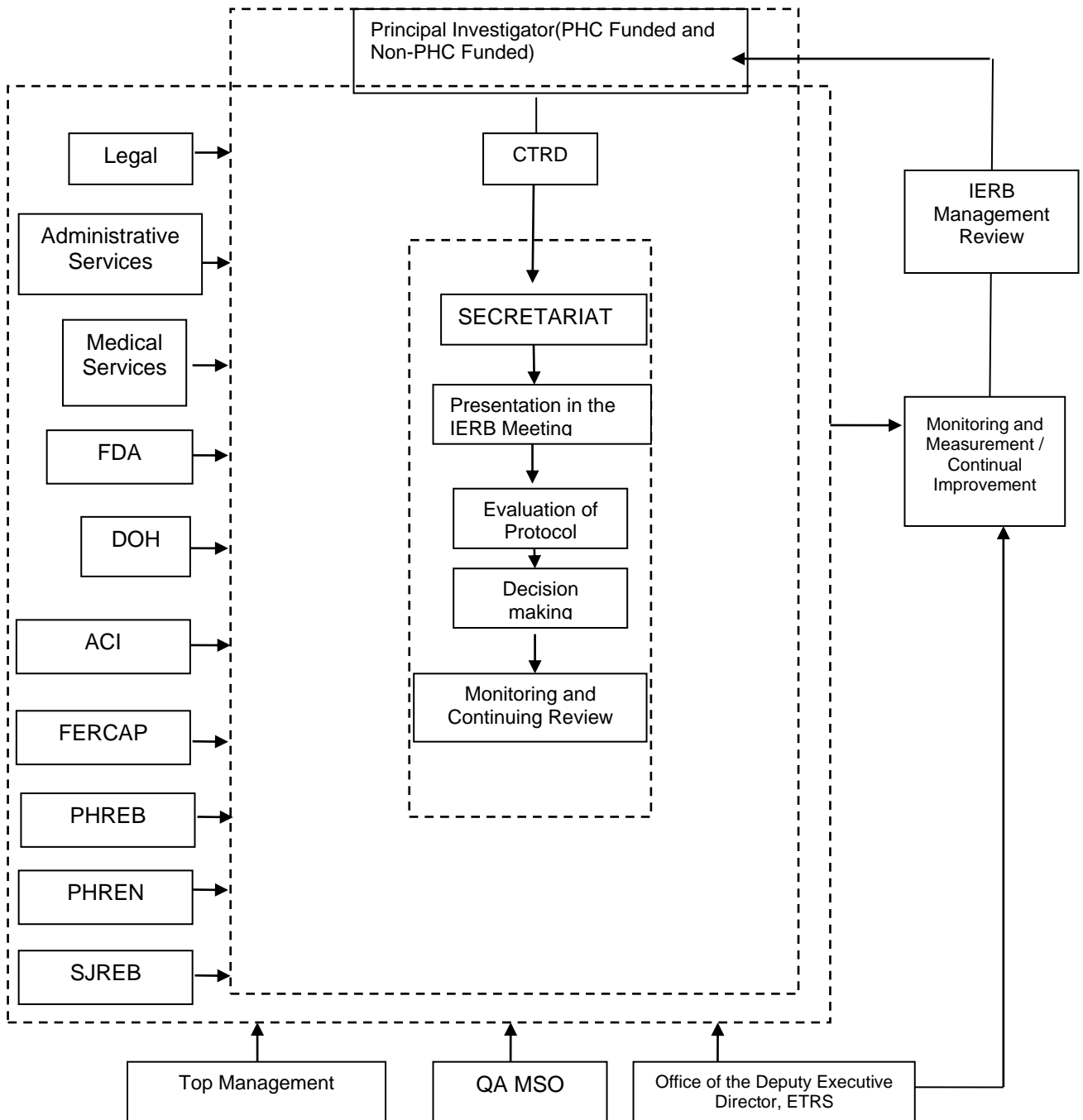
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The review of NON-PHC Funded protocols are usually referred protocols.

1. Clinical Trial
2. FDA

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The different processes involved are mapped in the following diagram.



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The formulation of the Policies/Standard Operating Procedures (SOPs) is in line with the thrust and partial fulfillment of the requirements and intent of the Philippine Health Ethics Review Board (PHREB, SIDCER Recognition Programme thru FERCAP and Accreditation Canada International (ACI) and just recently ISO 9001:2015 to achieve quality management system in the conduct of ethics review of research protocols based on the established international, national, local ethical standards and other relevant regulations. The quality management system covers the different aspects of operations from defining the requirements of the Principal Investigator up to the approval of the protocols and monitoring them to the fullest possible means. in order to achieve consistency in arriving at impartial and independent decisions on the ethical integrity of research protocols


The SOPs contain the detailed policies and procedures for those who are involved in providing ethics review functions of the IERB. Each Policy/SOP is presented in a special context containing its purpose, scope, responsibility, policy statements, procedure, Flow Chart, glossary, annex and references.

The system follows the SIDCER RECOGNITION PROGRAMME requirements and is categorized into five (5) major sections for SIDCER Recognition Programme namely:

1. Structure and Composition of EC
2. Adherence to specific policies
3. Completeness of its review process
4. After review process
5. Documentation and Archiving.

Similarly, it follows the PHREB Accreditation requirements namely:

- 1) Structure and Composition of the REC
- 2) Adherence to international, national, institutional and guidelines and policies
- 3) Adequacy of the Standard Operating Procedures and consistency in its implementation
- 4) Completeness of review process
- 5) Adequacy of the after-review procedures
- 6) Administrative support

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7) Efficiency of the recording and archiving system

From the 5 categories from FERCAP and 7 categories from PHREB, 5 major sections of the policies and procedures were prepared following the sequence SOP from DOH.

SOP 1 IERB Structure and Composition

SOP 2 Initial Review Procedures

SOP 3 IERB Monitoring Procedures

SOP 4 Documentation and Archiving

SOP 5 Writing and Revising of SOP

The SOPs have been carefully prepared by Dr. Marissa A. Orillaza, the Vice-Chairman of IERB and judiciously peer critiqued by the members of the IERB with special mention to Ms. Noreen Malaca, the Secretariat for her efforts, inputs and final layout of the SOP. Likewise, we are deeply grateful to the Executive Director Dr. Joel M. Abanilla and Deputy Executive Director for Training Education and Research Services Dr. Maria Teresa B. Abola for its approval.



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