

Updates on SJREB and PHREN



SJREB



**Jacinto Blas V. Mantaring III, MD,
MSc**
Chair, SJREB and PHREN

DISCLOSURES

- Chair - Department of Clinical Epidemiology, UPCM
- Member of the Health Technology Assessment Council (HTAC) of the DOH
- Sub-investigator of an ongoing clinical trial on the prevention of Respiratory Syncytial Virus (RSV) among infants.

Objectives

- At the end of the lecture, the participant should be able
 - To discuss the rationale for a single joint review
 - To discuss the administrative order that created the SJREB
 - To discuss the scope of authority of the SJREB.
 - To discuss the process for an SJREB review.
 - To discuss the increase in protocols processed by the SJREB since its creation

Objectives

- At the end of the lecture, the participant should be able
 - To discuss the history and role of the PHREN in participant protection
 - To discuss the mission and vision of the PHREN
 - To discuss the roles of the working committees
 - To discuss the activities of the network
 - To discuss the advocacies of the network

SJREB

Single Joint Research Ethics Board

Rationale for a Single Joint Review

- CIOMS - recommends the conduct of single review of multi-site research in one jurisdiction (country) by one ethics committee to avoid lengthy procedures and ensure quality of the review
- FDA (2006) - Guidance on using a Centralized IRB Review for Multicenter Clinical Trials
- NEGHHRR (2017) - provisions for the conduct of a joint review
 - PHREB accredited ethics committees
 - Review abides by a standard operating procedures (SOPs) approved by PHREB

SJREB

- DOH AO 2019-49
- Covers all DOH units, MOH-BARMM, hospitals and attached agencies with research ethics committees
- Other public and private hospital RECs who choose to participate
- SJREB conducts joint review of study protocols to be implemented in at least three (3) sites in the Philippines



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

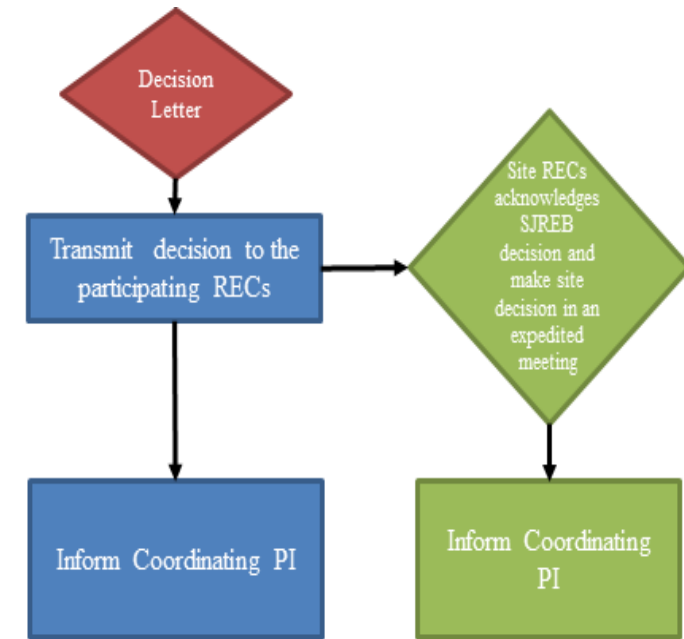
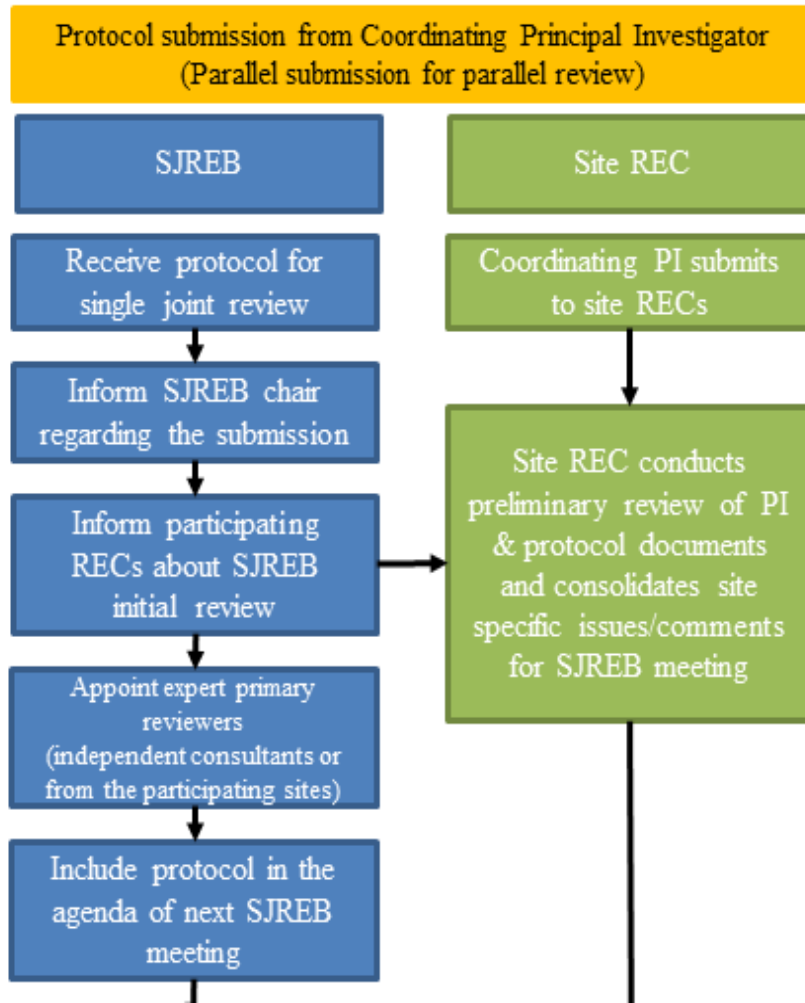
NOV 05 2019

ADMINISTRATIVE ORDER

NO. 2019 - 0049

**SUBJECT: Guidelines for the Operationalization of the Single Joint Ethics
Review Process for Multi-Site Researches in the Department of Health**

SJREB Process Flow



Initial and Annual Renewal of Approval Review Procedures

Note: The target turnaround time for the entire review process is 30-60 days

Legend:
 Orange – Coordinating PI
 Blue – SJREB Secretariat
 Red – Joint Review
 Green – Site RECs

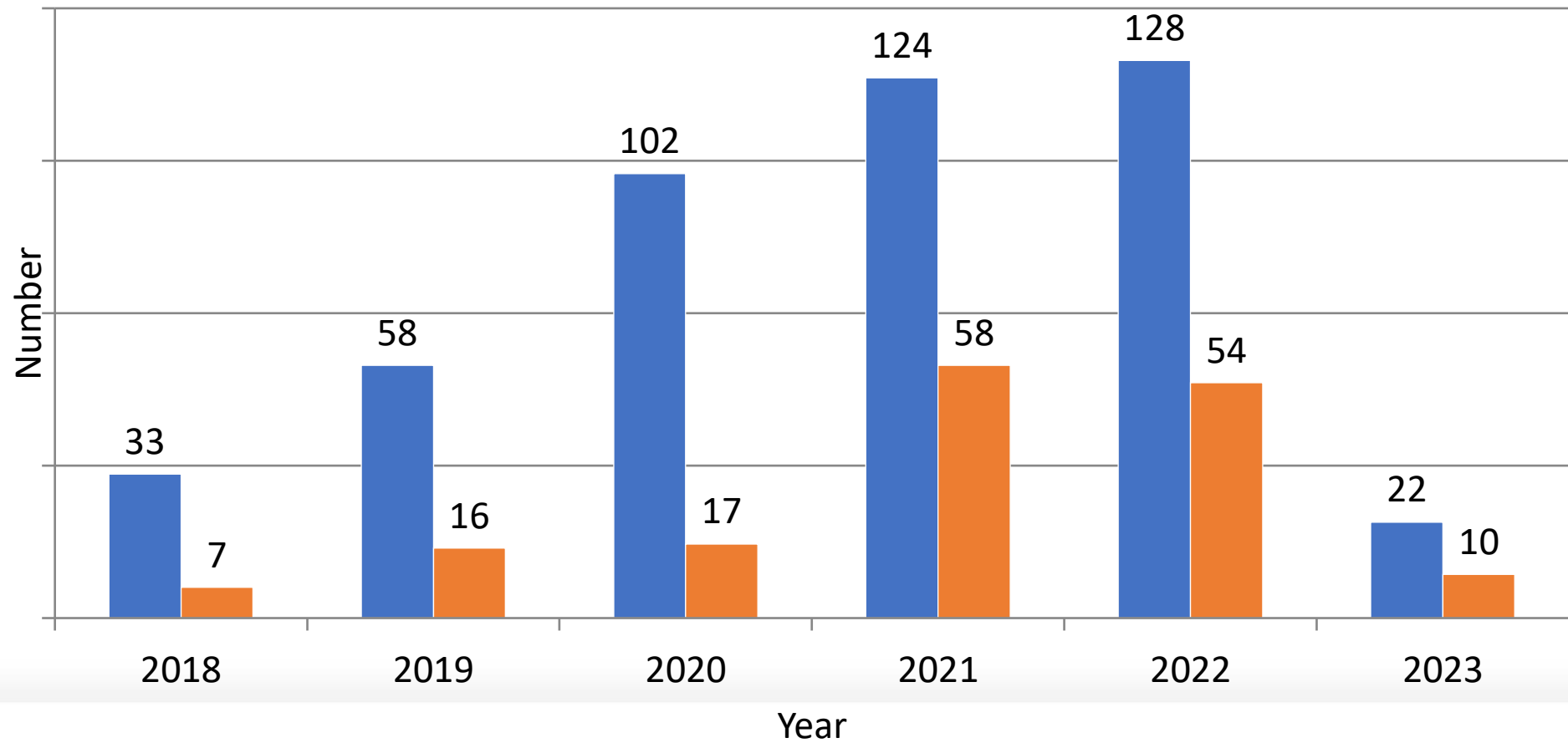
Hospitals that have participated in SJREB

1. Amang Rodriguez Memorial Medical Center
2. Baguio General Hospital and Medical Center
3. Batangas Medical Center
4. Corazon Locsin Montelibano Memorial Regional Hospital
5. Southern Philippines Medical Center
6. East Avenue Medical Center
7. Governor Celestino Gallares Memorial Hospital
8. Jose R. Reyes Memorial Medical Center
9. Lung Center of the Philippines
10. National Kidney and Transplant Institute
11. Philippine Children's Medical Center
12. Philippine Heart Center
13. Quirino Memorial Medical Center
14. Research Institute for Tropical Medicine
15. Valenzuela Medical Center
16. Veterans Regional Hospital
17. San Lazaro Hospital
18. Dr. Jose Fabella Memorial Medical Center
19. Tondo Medical Center
20. Southern Isabela General Hospital
21. Ilocos Training and Regional Medical Center
22. Ospital ng Palawan
23. Rizal Medical Center
24. Bicol Regional Training and Teaching Hospital
25. Vicente Sotto Memorial Medical Center
26. National Children's Hospital
27. Western Visayas Medical Center
28. Bataan General Hospital & Medical Center

Hospitals that have participated in SJREB

1. Cardinal Santos Medical Center
2. Manila Central University – Filemon D. Tanchoco Medical Foundation, Inc
3. Makati Medical Center
4. Veterans Memorial Medical Center
5. Manila Doctors Hospital
6. Mary Chiles General Hospital
7. Philippine General Hospital – University of the Philippines Manila
8. University of the East Ramon Magsaysay Memorial Medical Center, Inc.
9. Far Eastern University - Nicanor Reyes Medical Foundation
10. De La Salle Health Sciences Institute
11. Mary Mediatrix Memorial Hospital
12. The Medical City
13. Manila Medical Center
14. St. Luke’s Medical Center (Per Protocol)
15. University of Santo Tomas
16. Perpetual Succour Hospital

Number of protocols (2018-2023)



PHREN

Philippine Health Research Ethics Network

Historical Timeline

Nov 2013

FERCAP
Bali, Indonesia
Philippine
recognized
ethics
committees (9)
committed to
unite

Mar 2014

Formally
launched
during the 32nd
Anniversary of
the PCHRD

Sep 2015

Incorporated
with the
Securities and
Exchange
Commission

Apr 2016

Strategic
Planning
Workshop

First
organizational
meeting

Memorandum
of agreement
signed by 9
Institutional
Ethics
Committees

First National
Assembly
and addition of
4 more
institutional
members

Dec 2013

Mar 2015

Oct 2015

Bali Declaration



Vision - Mission

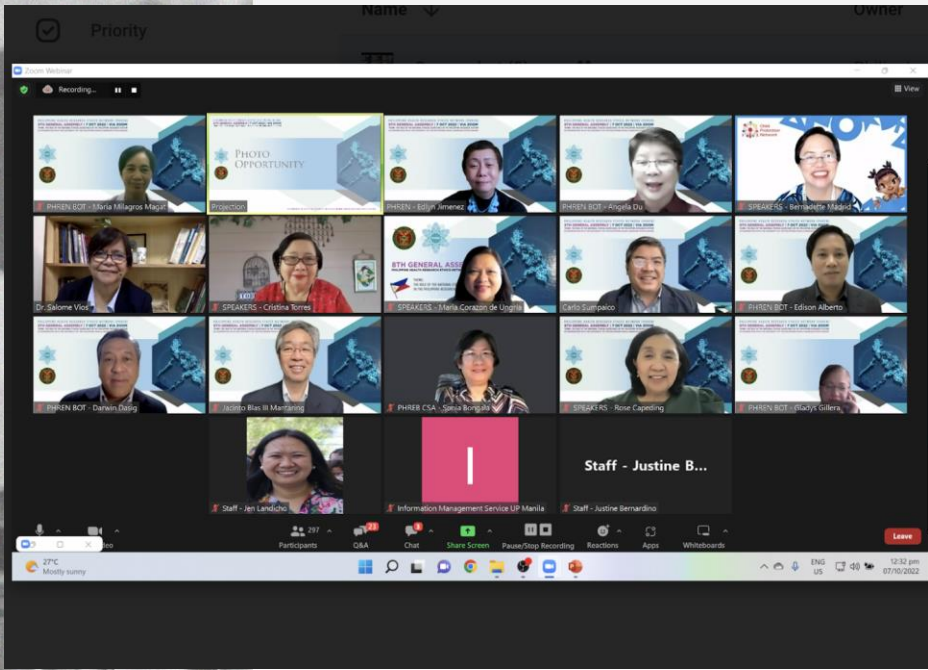
- Vision: “The leading collaboration of ethics advocates for quality health research in Asia”
- Mission:
 - Cognizant of its mandate to protect human research participants:
 - We promote and sustain policies and initiatives in health research ethics
 - We empower ethics groups and individuals through networking, education and research
 - We address the challenges confronting ERCs in the Philippines

Standing Committees

- Structure and Membership
- Finance
- Research and Publication
- Standards and Guidelines
- Advocacy
- Capacity building and Training

Activities

- Annual Assembly - (8th) October 2022
- Conduct / Participation in collaborative research on best practices
- Training Programs
 - Ethics Training
 - Responsible conduct of Research
 - Good Clinical Practice
 - Secretariat training for Research Ethics Committees





PHREN Participation in Research

- Streamlining Ethics Review in the Philippines. PI: Prof Cristina Torres (PCHRD funded; commissioned by DOH). PHREN participated in FGDs
- Study on Post-trial access. PI: Rosemarie de la Cruz Bernabe, PhD, University of Oslo. PHREN participated in FGDs
- Study on Important contents of the ICF. PI: Dr. Nut Koonrungsomboon (for FERCAP). PHREN participated in data collection, reviewing the analysis and manuscript (Prof. Jimenez and Dr. Mantaring)
- Development of guidelines for public health practice and research. PI: Dr. Jacinto Blas V. Mantaring. (PCHRD funded, commissioned by DOH). PHREN participated in an FGD.

Advocacies

- Participation in accreditation / recognition activities
- Participation in government efforts and policy
- Participation in Single Joint Research Ethics Committees
- Issuance of statements



PHREN Philippine Health Research Ethics Network

Browse

Manage 2



Community home



Overview

Admin tools



Community chats

4 chat suggestions for your group



Admin Assist

0 actions, 0 criteria



Member requests

0 new today



Feed channel requests



Badge requests

0 new today



Edit

PHREN Philippine Health Research Ethics Network

Private group · 235 members



+ Invite

Discussion

Featured

Topics

Members

Media

Reels



PHREN Statement on Unethical Conduct of Genomic Research



STATEMENT OF THE PHILIPPINE HEALTH RESEARCH ETHICS NETWORK (PHREN) ON THE UNETHICAL CONDUCT OF GENOMIC RESEARCH BY DR. MAXIMILIAN LARENA AND PROF. MATTIAS JAKOBSSON OF UPPSALA UNIVERSITY

The Philippine Health Research Ethics Network (PHREN) is the network of accredited research ethics committees in the Philippines, established in 2015 to uphold and protect the rights of the research participants. PHREN supports the statement issued on 6 July 2021 by the Philippine Health Research Ethics Board (PHREB) entitled "Statement on Upholding Ethical Standards in Research". The PHREB asserted its "...right to conduct local ethics review of foreign-funded research..." conducted "...within the framework of our national guidelines and our system for the accreditation of ethics review committees consistent with Article 21 of the Universal Declaration on Bioethics and Human Rights."

The PHREN condemns the actions of Dr. Maximilian Larena and Prof. Mattias Jakobsson, who have continuously disregarded regulations and guidelines in the conduct of their "Genomic Study on Filipinos", collecting samples for genetic analysis without first acquiring a proper ethical clearance. This statement comes after serious deliberation and consideration of the issuances of the National Commission on Indigenous Peoples (NCIP), PHREB, and the Philippine Genome Center (PGC) of the University of the Philippines. The NCIP and the PHREB have been raising these ethical concerns since 2015.

We likewise support the University of the Philippines statement and disagree with the claim of Dr. Larena and Prof. Jakobsson's that the conduct of their research has complied with ethical standards. We seriously put forward that the "investigation" that absolved them of misconduct was conducted by entities outside of the Philippines who are not knowledgeable of the local context and local stakeholders important to the issue.

PHREN issues this statement of support for the information of all its individual and institutional members to collectively stand as one with PHREB to call for compliance with local regulations. These regulations took decades to formulate and establish through the dedication of stakeholders working together with the ultimate goal of human subject protection in the country.

Chair of the PHREN Board of Trustees:


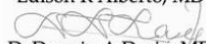


Jacinto Blas V. Mantaring III, MD

Members of the PHREN Board of Trustees:


Angela A. Du, MD


Carlo Emmanuel J. Sumpalco, MD


Maria Milagros U. Magat, MD


Edison R. Alberto, MD

D. Darwin A. Dasig, MD

Gladys L. Gillera, MD

PHREN Present Status

- 29 Institutional members
- 75 Individual members
- 8 Annual Assemblies - 300 - 400 participants per assembly
- 4 Trainings conducted per year
- Participation in 3 international collaborative studies
- Participation in 4 local collaborative studies
- Lead partner in the organization

PHREN During COVID

- Assemblies were held online
- Training activities were held online
- Continued to participate in accreditation / recognition activities
- Continue to participate in collaborative research

Summary

- At the end of the lecture, the participant should be able
 - To discuss the rationale for a single joint review
 - To discuss the administrative order that created the SJREB
 - To discuss the scope of authority of the SJREB.
 - To discuss the process for an SJREB review.
 - To discuss the increase in protocols processed by the SJREB since its creation

Summary

- At the end of the lecture, the participant should be able
 - To discuss the history and role of the PHREN in participant protection
 - To discuss the mission and vision of the PHREN
 - To discuss the roles of the working committees
 - To discuss the activities of the network
 - To discuss the advocacies of the network

**Thank you for
your
attention!!!**