Republic of the Philippines
Department of Health
**OFFICE OF THE SECRETARY**

OCT 30 2017

**ADMINISTRATIVE ORDER**
**NO. 2017-0021**

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

## I. BACKGROUND

As one of the pillars of the Philippine National Health Research System (PNHRS), the Department of Health commits to support the National Ethical Guidelines set forth by the Philippine Health Research Ethics Board (PHREB) stipulating mandatory ethics review for all researches involving human participants.

The Department as one of the primary consumers of research acknowledges the importance of ethics review in conducting various types of studies. However, the influx of health policy and systems research sponsored by the Department has magnified bottlenecks in the conduct of ethics review process. One critical cause of delay is the individual review conducted for multi-site studies.

In 2015, a study to streamline the ethics review structure and process was undertaken and a recommendation to adopt a single joint ethics review mechanism has been proposed. In view of this, the guidelines for the institutionalization of the single joint ethics review is being issued through this Administrative Order.

## II. OBJECTIVES

**General Objective:**

This Order aims to institutionalize the single joint ethics review process in the Department of Health

**Specific Objectives:**

1. To provide general framework and guidelines on the single joint ethics review mechanism for multi-site researches
2. To identify the roles and responsibilities of key actors and stakeholders in the single joint ethics review process

## III. SCOPE AND COVERAGE

This Order shall cover all DOH units including regional offices, hospitals, and attached agencies with research ethics committees. Further, this Order shall apply to private research ethics committees who opted to participate in the single joint ethics review process.

## IV. DEFINITION OF TERMS

A. **Multi-site Research** - refers to researches that will be conducted in three or more sites that utilize the same study protocol.

B. **Single Joint Ethics Review** - refers to reviews for the purpose of approving multi-site research that will be conducted in sites within the purview of the Department of Health. For non-DOH hospitals, participation in this review is voluntary.

## V. GENERAL GUIDELINES

1. **Applicability of Single Joint Review Process in RECs**
   a. All DOH hospital research ethics committees (RECs) shall adhere to the guidelines set forth by this Order in the implementation of single joint review.
   b. All other non-DOH RECs may voluntarily participate in the single joint review.

2. **Standardized Process for Single Joint Review**
   a. All DOH RECs shall adopt and incorporate a chapter of the single joint review mechanism on their Standard Operating Procedures on or before the 4th quarter of 2017.
   b. All non-DOH RECs with the intent to participate in the single joint review shall adopt the same in their SOPs prior to joining any deliberation.
   c. All externally funded research protocols shall require technical review clearance from the funding institution. Institutional RECs may only require technical review for studies funded by the home institution. Ethical review shall apply both for internally and externally funded research studies.

3. **Operationalizing the Single Joint Review**
   a. The single joint review shall be facilitated by a Single Joint Research Ethics Board, participating RECs and supported by a secretariat.
   b. All participants shall be monitored for compliance to standards.

4. **Appropriation of Funds**
   a. The DOH-Health Policy Development and Planning Bureau (HPDPB) shall allocate funds and provide support to operationalize the Single Joint Ethics Review Process.

b. All participating RECs shall allocate funds for the participation of the site representatives specifically with regards to honorarium, transportation, accommodation, and other relevant expenses.

## VI. SPECIFIC GUIDELINES

### A. Single Joint Review Participants' Functions, Qualifications, and Engagement

1. **Single Joint Research Ethics Board (SJREB)** is a group of experts who shall facilitate and provide oversight to the overall operations of the review process. This board shall be convened during full board ethics review and joint ethics review with the participating sites.
    a. **Composition**. The SJREB shall consist of five (5) permanent members which include the chair, independent consultants, lay person, and representative from participating sites. The role of the SJREB members, qualifications and other details of their engagement are outlined in **Annex A**.
    b. **Selection**. The SJRB members shall be appointed by the Office for Policy and Health Systems Cluster Head for a term of 3 years. In order to ensure continuity of functions, at least half of the SJREB shall be retained/re-appointed for at least one (1) year before a new set shall be appointed.

2. **SJREB Secretariat** consists of technical and administrative staff from the DOH who provide support on the day-to-day operations of the single joint ethics review. See **Annex A** for the qualifications and specific roles and responsibilities.

3. **Participating Site RECs** are DOH units (i.e., hospital RECs) that were identified by the sponsors and/or principal investigators to be a study site. See qualifications in **Annex A**.

### B. Single Joint Ethics Review Process

a. **Standard Operating Procedures**. The SOP for the single joint review shall be made available through an issuance of a Department Circular. This shall serve as the reference document for the single joint ethics review and will be periodically revised and updated as per the latest PHREB guidelines. A Department Circular will also be issued should there be any updates and revisions in the SOP. The following are the key provisions:
    i. **Frequency of Meeting**. The SJREB shall convene at least once a month, or more frequently depending on the volume of protocol submissions. The secretariat shall assess and recommend the need to conduct meeting.
    ii. **Quorum**. The meeting shall only proceed if the SJREB voting members and at least three (3) participating REC representatives are present.

iii. **Voting Conditions**. Only PHREB-accredited RECs are allowed to cast a vote while independent consultants are not allowed to vote. Decisions are arrived through majority vote of members present.

iv. **Timelines of reviews**. All research protocols subjected for ethics review shall receive the results/decisions of the joint ethics review 30-60 days after the REC submission of complete protocol documents. See **Annex B** for the timelines of the review, the single joint ethics review process flow diagram and description of each of the process.

**C. Appropriation of Funds.**

1. All the permanent SJREB members shall receive honorarium for facilitating the joint ethics review. The honorarium for the members shall be Php 3,000 and Php 5,000 for the Chair, for every meeting attended/facilitated.

2. The DOH-HPDPB shall make available dedicated office space, archiving system, office equipment and supplies and designate full-time administrative support staff.

**D. Roles and Responsibilities of Other Clusters/Offices**

1. Health Policy Development and Planning Bureau
   i. Provide oversight of the single joint ethics review process in the DOH;
   ii. Provide the overall technical and administrative support to SJREB;
   iii. Provide training and other capacity building activities for the single joint review mechanism;
   iv. Monitor the day-to-day operations of the SJREB;
   v. Ensure credibility, acceptability, and validity of reviews coursed through the single joint ethics review process; and
   vi. Ensure compliance and adherence to the national ethics guidelines set forth by PHREB.

2. DOH Hospitals Research Ethics Committees
   i. Adopt the standard operating procedures for single joint ethics review set forth by this Order;
   ii. Develop/update hospital policies in compliance with the provisions recommended by this policy issuance; and
   iii. All DOH research ethics committees shall accept the decision of the single joint ethics review for implementation at the site.

3. Partners from the private sectors and/or other research institutions
   i. Ensure compliance with the standard operating procedures for multi-site research implementation set forth by the Department of Health;

ii. Provide support to the SJREB and its review process mechanism through recognition of its decisions and recommendations; and

iii. All participating private research ethics committees who shall accept the decision of the single joint ethics review for implementation at the site

## VII. EFFECTIVITY

This Order shall be effective immediately.

**PAULYN JEAN B. ROSELL-UBIAL, MD, MPH, CESO II**
Secretary of Health

**Annex A.** Single Joint Ethics Review Operational Structure

## Single Joint Research Ethics Board (SJREB)

1. **Membership**
   a. The **Chair** is a dedicated individual from an REC with experience to review different types of researches with a fixed term as stipulated in the joint review SOPs.
   b. The **Independent consultants** are to be identified based on the following criteria:
      i. Health Systems Consultant for Research Ethics
      ii. Public Health Consultant
   c. Designated **Philippine Health Research Ethics Network (PHREN) Representative** with a fixed term as stipulated in the joint review SOPs
   d. **Subject matter expert from the specialty hospitals** who is a designated representative from DOH specialty hospitals to review a multi-site research within its area of specialization i.e., Philippine Heart Center, National Kidney and Transplant Institute, Lung Center of the Philippines, etc.
   e. The **lay person/non-affiliated** is a non-medical/non-scientific member who shall review the informed consent forms (ICF) and provide inputs from the community/people's perspective.
   f. The **participating site REC representatives** are identified point persons from the sites who are knowledgeable on the study protocols being reviewed.

2. **Qualifications**
   a. Knowledgeable about international and national guidelines and regulations: ICH-GCP 2016 update, Declaration of Helsinki 2013, CIOMS 2016, FDA regulations and procedures, sponsor country regulations, local laws, National guidelines on health research ethics, etc.
   b. Knowledgeable about scientific design and issues in various types of researches including investigational medicinal products (Phase 1, 2, 3, 4) difference between clinical research vs. clinical trials, treatment vs. non-treatment studies, observational vs. interventional methods, biomedical vs. socio-behavioral research, scientific/ statistical analysis tools, etc.
   c. Knowledgeable about analysis of ethical issues such as conflict of interest, vulnerability, risks, benefits, privacy and confidentiality, informed consent issues, etc.
   d. Knowledgeable about good clinical practice (GCP) compliant procedures in research including SOP for joint review.
   e. Subject matter experts on their own fields of practice e.g., health research ethics, epidemiology, social science, medicine, etc.

3. **Roles and Responsibilities**
    a. Prepare Standard Operating Procedures (SOPs) for the joint ethics review panel;
    b. Facilitate initial full board review of multi-site protocols with representatives from participating sites;
    c. Provide decisions and/or actions for the scheduled protocols for review through casting of votes
        i. Voting:
            - Chair
            - PHREN Representative
            - Lay Person/Non-affiliated
            - Participating Site Representative
            - Specialty hospitals consultant
        ii. Non-voting:
            - Public health consultant
            - Health research ethics consultant;
    d. Review amendments of approved protocols.

**Single Joint Review Secretariat**

1. **Qualifications**
    a. Technical Staff
        i. Well versed on the ethics review system in the country
        ii. With health-related educational background such as Doctor of Medicine, Nursing, Public Health, Epidemiology, Health Research Ethics
        iii. Has basic knowledge and training on health research ethics which includes:
            1. Good Clinical Practice (GCP) training
            2. Advanced courses on research ethics
            3. CIOMS Guidelines
            4. Other relevant skills and trainings
        iv. Knowledgeable about international and national guidelines and regulations: ICH-GCP 2016 update, Declaration of Helsinki 2013, CIOMS 2016, FDA regulations and procedures, sponsor country regulations, local laws, National guidelines on health research ethics, etc.
    b. Secretary and Administrative Staff
        i. Graduate of any management related course
        ii. Knowledgeable of effective archiving mechanism of protocol submission

2. **Roles and Responsibilities**
    a. Coordinates with SJRB members the submissions of multi-site study protocols

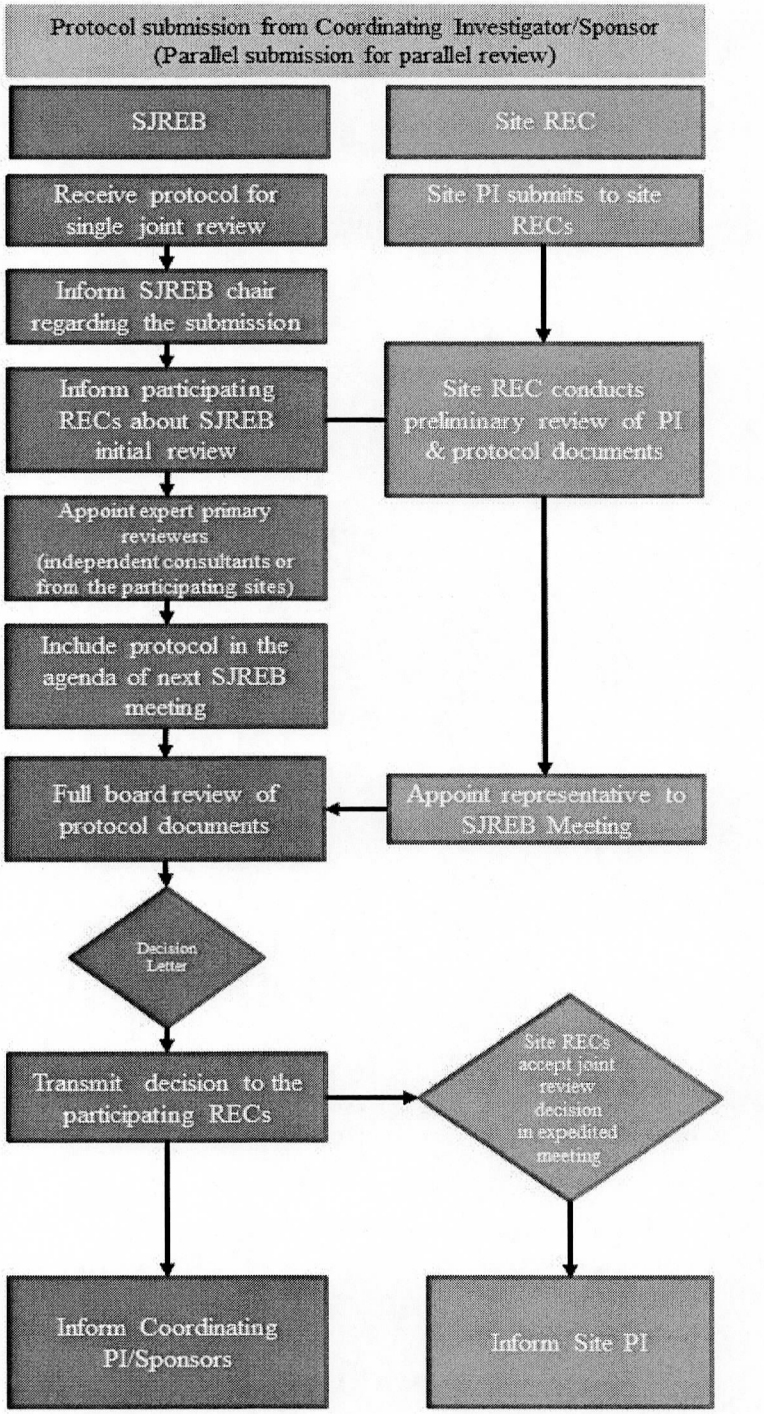
b. Conducts initial screening of submitted protocol documents both new and with amendment
c. Facilitates communication with participating site RECs
d. Monitors implementation of ongoing multi-site studies
e. Prepares administrative support and logistics during meetings e.g., record keeping and documentation of proceedings.
f. Manages protocol submissions, amendments, and archiving of active and inactive researches

**Representatives from Participating Sites**

1. **Qualifications**
   a. PHREB accredited RECs
   b. Should have Level 3 accreditation for interventional new drugs (IND) studies
   c. Should have at least Level 2 accreditation for public health researches
   d. For sites with REC but is not PHREB accredited, attendance and participation in the discussion is allowed. The only limitation is that these RECs are not allowed to vote.
   e. For sites with no REC, affiliation to hospitals with PHREB accredited REC is allowed.

2. **Roles and Responsibilities**
   a. The participating sites shall designate permanent and alternate representatives to attend during joint ethics review meeting.
   b. The representative shall communicate the results of the ethics review from their respective sites during the joint ethics review.
   c. The representative shall actively participate in the joint ethics review and meeting as well as in the votation for acceptance/non-acceptance of the protocol.

**Annex B**. Single Joint Ethics Review Process and Timelines for Review




**Initial and Annual Renewal of Approval Review Procedures**
**Note:** The target turnaround time for the entire review process is 30-60 days

**Description of each of the process in the joint ethics review:**

1. **Protocol submission from PI/Sponsors**. The PI and/or sponsors shall submit study protocol package to both the SJREB Secretariat and all the identified participating sites.

2. **Receive protocol for single joint review**. SJREB Secretariat shall acknowledge the receipt of the study protocol from the principal investigators and/or the sponsors.

3. **Inform SJRB chair regarding submission**. The secretariat ensures completeness of the documents submitted by the proponents (i.e., investigator brochure, protocol package, curriculum vitaes, advertisements and recruitment materials, and complete versions of informed consent forms) and shall notify the chair for the new protocol submission and protocol amendments. The chair is responsible for the conduct of the entire review process.

4. **Inform participating RECs about SJREB initial review**. The SJREB shall conduct a full board review of the submitted multi-site study protocol. The participating site RECs shall conduct a parallel preliminary review of the protocol submission.

5. **Appoint expert primary reviewers (independent consultants or from the participating sites)**. The SJREB secretariat shall identify appropriate primary reviewers for the submitted research protocol. The reviewers shall reassess the package for completeness of documents and conduct review based on the timeline set forth in the SOPs. The expert primary reviewers may be the identified independent consultants of the SJREB and/or subject matter experts from the participating sites.

6. **Include protocol in the agenda of next SJREB meeting**. The SJREB secretariat shall be responsible in convening the SJREB members and the participating REC representatives for a meeting. The secretariat shall ensure quorum prior to the scheduled date of the meeting.

7. **Full board review of protocol documents**. SJREB shall facilitate initial full board review of all protocol submissions. Decisions on this review shall be communicated to participating RECs during the meeting.

8. **Decision**. The SJREB secretariat shall communicate the results of the review to the PI and/or sponsors after the scheduled meeting. The decision will either be:
    a. Acceptance of the protocol submission
    b. With minor or major revisions. The PI and/or sponsors shall be requested to address revisions as deemed necessary by the board and participating RECs. Resubmission of revised protocol shall follow the timeline set by the SJRB SOPs.

c. Non-acceptance/disapproval

**Timelines for Review**

| ACTIVITY | | TIMELINE |
|---|---|---|
| **FROM** | **TO** | |
| Submission of research protocol from Sponsors/Principal Investigators | Assessment of the research protocol and endorsement to the Single Joint Review Board | 7 – 15 calendar days |
| Single Joint Research Ethics Board | Review of the Single Joint Research Ethics Board and primary reviewers | 7 – 15 calendar days |
| Single Joint Research Ethics Board Decision | Sponsor/Principal Investigator (if there are any revisions) | 7 – 15 calendar days |
| Revised research protocol from the Sponsors/Primary Investigators | Single Joint Research Ethics Board (for final decision) | 7 – 15 calendar days |