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

I. BACKGROUND

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

The DOH 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 DOH 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 Single Joint Ethics Review Board (SJREB) was established through Administrative order 2017-0021 entitled, "Guidelines for the Operationalization of the Single Joint Ethics Review Process for Multi-site Researches in the Department of Health" and started its operations in March 14, 2018. Since then, SJREB was able to facilitate review of 45 protocols both clinical research (i.e., clinical trials) and health policy and systems research.

To further improve the efficiency of the current review process, consultations with stakeholders were conducted and various recommendations were raised specifically on addressing issues on quorum. At the same time, SJREB was visited by the Philippine Health Research Ethics Board (PHREB), the accrediting body for ethics committees in the Philippines. Pursuant to the accreditation visit recommendations, along with the recommendations of the stakeholder consultations, Administrative Order No. 2017-0021 is being repealed and the guidelines for the single joint ethics review is being issued through this issuance.

II. OBJECTIVES

General Objective:

This Order aims to provide guidelines for the operation of 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 research
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 Centers for Health Development (CHDs), Ministry of Health – Bangsamoro Autonomous Region in Muslim Mindanao (MOH-BARMM), hospitals, and attached agencies with research ethics committees. This shall apply to the participation of private research ethics committees in the singe joint ethics review process.

The SJREB abides by the RA No. 10532 otherwise known as the Philippine National Research System Act of 2013, its Implementing Rules and Regulations (IRR), RA No. 10173 otherwise known as the Data Privacy Act of 2012, its Implementing Rules and Regulations (IRR), and the guidelines set forth in the most recent National Ethical Guidelines for Health and Health-Related Research. It conducts joint review of study protocols to be implemented in at least three (3) sites in the Philippines and reviews health and health-related research protocols including, but not limited to clinical trials, social science research, public health surveillance, and health policy and systems research; whether involving human participants, identifiable human tissue, biological samples, and data.

IV. DEFINITION OF TERMS

1. **Multi-site Research** - refers to research that will be conducted in three or more sites that utilize the same study protocol. Sites may either be hospital or community based.
2. **Single Joint Ethics Review** - refers to a joint review for the purpose of approving multi-site research, that is participated in by the identified sites where the protocol will be conducted.
3. **Investigator-initiated research** – refers to researches that are funded by the investigator.
4. **Sponsor-initiated research** – refers to researches that are funded by a local or international funding agency.
5. **Site representatives** – refer to participants from hospital research ethics committees (REC) of sites included in the study.
6. **Home institution** – refers to the institution where the coordinating investigator comes from.

7. **Funding institution** – refers to the institution which provided funding for the research project.
8. **Coordinating Investigator** – refers to the point person identified by the sponsor or study team that will facilitate all communications with SJREB.

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 non-DOH RECs may 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 most recent Standard Operating Procedures (SOP).
   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 investigator-initiated and sponsor-initiated research protocols shall require technical review clearance from the funding and/or home institution. For the latter, technical clearance from the sponsor or the Philippine Food and Drug Authority (FDA) shall suffice.
   d. Ethical review shall be required for both internally and externally funded research studies.

3. **Operationalizing the Single Joint Review**
   a. The single joint review shall be facilitated by SJREB, 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, Roles and Responsibilities

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 seven (7) permanent members which include the chair, subject matter experts, non-scientific or non-medical members, and member secretary. It shall ensure the

presence of a non-affiliated member among the Board to ensure quorum. Alternate members may be assigned by the Chair to ensure that quorum is maintained during the full board meeting. On the other hand, the non-permanent/rotating members shall consist of independent consultants, and specialty hospitals and site REC representatives. The qualifications of the SJREB members, and other details of their engagement are outlined in **Annex A**.

b. **Selection**. The SJREB members shall be appointed by the Secretary of Health upon the recommendation of the Health Policy and Systems Development Team 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 - HPDPB who provide support on the day-to-day operations of the single joint ethics review. See **Annex A** for the qualifications.

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 that shall be involved in the joint ethics review, meeting, and votation. See qualifications in **Annex A**.

B. Single Joint Ethics Review Process

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 shall be periodically revised and updated as per the latest PHREB guidelines. A Department Circular shall also be issued should there be any update and revision in the SOP.

C. Appropriation of Funds

1. All the permanent SJREB members shall receive an honorarium for participating in 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 to ensure the optimum operation of the SJREB.

VII. Roles and Responsibilities

1. Single Joint Research Ethics Board shall:
    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; and,
d. Review amendments of approved protocols.

2. Secretariat Staff shall:
    a. Coordinate with SJREB members the submissions of multi-site study protocols;
    b. Conduct initial screening of submitted protocol documents both new and with amendment;
    c. Facilitate communication with participating site RECs;
    d. Monitor implementation of ongoing multi-site studies;
    e. Prepare administrative support and logistics during meetings e.g., record keeping and documentation of proceedings; and,
    f. Manage protocol submissions, amendments, and archiving of active and inactive research.

3. Participating Site RECs shall:
    a. Designate permanent and alternate representatives to attend during joint ethics review meeting;
    b. Communicate the results of the ethics review from their respective sites during the joint ethics review; and,
    c. Actively participate in the joint ethics review and meeting as well as in the votation for acceptance/non-acceptance of the protocol.

4. Health Policy Development and Planning Bureau shall:
    a. Provide oversight of the single joint ethics review process in the DOH;
    b. Provide the overall technical and administrative support to SJREB;
    c. Provide training and other capacity building activities for the single joint review mechanism;
    d. Monitor the day-to-day operations of the SJREB;
    e. Ensure credibility, acceptability, and validity of reviews coursed through the single joint ethics review process; and,
    f. Ensure compliance and adherence to the national ethics guidelines set forth by PHREB.

5. DOH Hospitals Research Ethics Committees shall:
    a. Adopt the SOP for single joint ethics review set forth by this Order;
    b. Develop/update hospital policies in compliance with the provisions recommended by this policy issuance; and,
    c. Acknowledge the decision of the single joint ethics review for implementation at the site.

6. Partners from the private sectors and/or other research institutions shall:
    a. Adopt the SOP for multi-site research implementation set forth by the Department of Health;

b. Provide support to the SJREB and its review process mechanism through recognition of its decisions and recommendations; and,
c. Acknowledge the decision of the single joint ethics review for implementation at the site

VIII. REPEALING CLAUSE

Administrative Order No. 2017-0021 dated October 30, 2017 is hereby repealed.

IX. SEPARABILITY CLAUSE

If any of the provisions under this Order is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected thereby shall remain valid and effective.

X. EFFECTIVITY

This Order shall be effective immediately.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

Annex A. Single Joint Ethics Review Operational Structure

Single Joint Research Ethics Board (SJREB) and Participating Site Research Ethics Committees (RECs)

1. **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 shall be periodically revised and updated as per the latest PHREB guidelines. A Department Circular shall also be issued should there be any update and revision in the SOP. The following are the key provisions:
        i. **Frequency of Meeting**. The SJREB shall convene at least once a month 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 there are at least five (5) SJREB voting members inclusive of the presence of at least 4 out of 7 permanent members and at least one (1) participating site representative. Further, there should be at least one (1) member who is non-medical/ non-scientific and at least one (1) member who is non-affiliated.
        iii. **Voting Conditions**. Only the SJREB permanent members, and representatives from PHREB-accredited site RECs shall be allowed to cast a vote while independent consultants and representatives from non-PHREB accredited site RECs are non-voting. Decisions are arrived through majority vote of the voting members present which are the following:
            1. Chair
            2. PHREN Representatives
            3. Non-scientific or non-medical member
            4. Participating Site Representative
            5. SME on Pediatrics
            6. SME/Non-medical representatives from specialty hospitals
            7. Member secretary
        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.

2. **Membership**
    a. The **Chair** is a dedicated individual from REC with experience to review different types of research with a fixed term as stipulated in the joint review SOPs.
    b. A **Vice Chair** may be identified from the existing permanent members and assumes the Chair's responsibilities whenever necessary.
    c. Designated **Philippine Health Research Ethics Network (PHREN) Representative** with a fixed term as stipulated in the joint review SOPs to represent the private sector
    d. **Subject Matter Expert (SME)/Non-medical member from the specialty hospitals** who is a designated representative from the DOH specialty hospitals to review a multi-site research i.e., Philippine Heart Center, National Kidney and Transplant Institute, Lung Center of the Philippines, etc.
    e. The **non-scientific or non-medical member**, depending on the type of protocol submission, shall review the informed consent forms (ICF) and provide inputs from the community/people's perspective.
    f. The **Member Secretary** is an affiliated member who shall oversee the protocols being reviewed by the Board and ensure the accuracy of the minutes of the meeting.
    g. **Subject Matter Expert (SME)** on Pediatrics, Health research ethics and Public health are to be identified.
    h. The **participating site REC representatives** are identified point persons from the sites who are knowledgeable on the study protocols being reviewed.

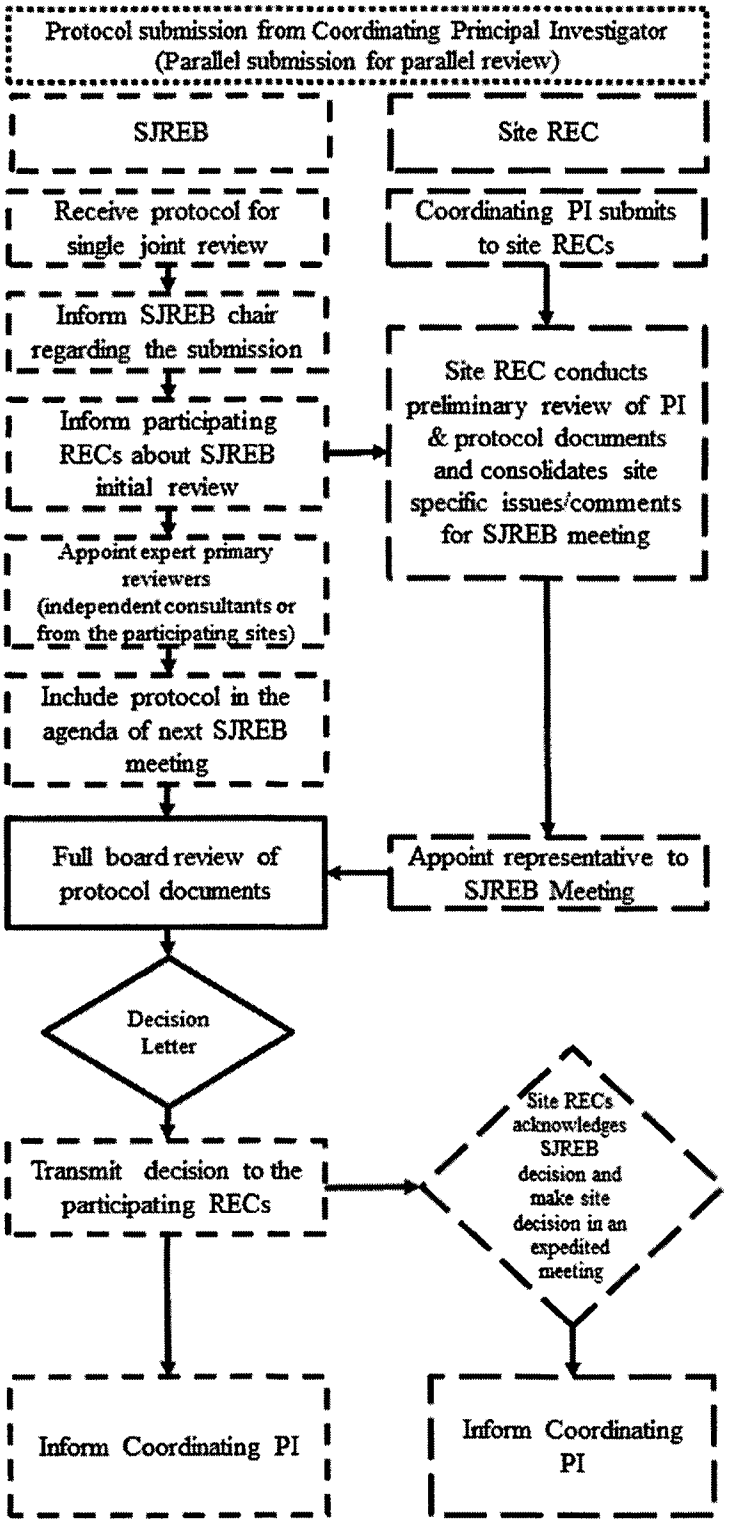
3. **Qualifications**
    a. Knowledgeable about international and national guidelines and regulations: ICH-GCP 2016 update, Declaration of Helsinki 2013, CIOMS 2016, FDA regulations and procedures, sponsor country regulations, local laws, 2017 National Ethical Guidelines for Health and Health Research, etc.
    b. Knowledgeable about scientific design and issues in various types of research 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.

Single Joint Review Secretariat

1. **Qualifications**
    a. Head of Secretariat
        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 and other related courses
        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

Representatives from Participating Sites

1. **Qualifications**
    a. PHREB accredited RECs
    b. Should have Level 3 accreditation for interventional new drug (IND) studies
    c. Should have at least Level 2 accreditation for public health research
    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, partnership to hospitals with PHREB accredited REC is allowed.



Initial and Annual Renewal of Approval Review Procedures

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

Legend:

——————— – Coordinating PI
- - - - - - - - - - - - - – SJREB Secretariat
——————— – Joint Review
— — — — — — — – Site RECs

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

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

1. **Protocol submission for PI/Sponsors.** The Coordinating Principal Investigator (PI) 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 Coordinating PI.

3. **Inform SJREB chair regarding submission**. The secretariat shall ensure 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 and submit their review to SJREB.

5. **Appoint expert primary reviewers.** 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 for 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.

8. **Decision**. The SJREB secretariat shall communicate the results of the review to the Coordinating PI 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 SJREB 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