1. Purpose

This SOP shall describe the Single Joint Research Ethics Board (SJREB) requirements and procedures in conducting initial and continuing review of multi-site protocol related documents, vis-a-vis the site Research Ethics Committee/s.

2. Scope

This procedure applies to all multi-site protocols submitted to the SJREB for initial ethics review.

1. Sponsors and investigators may submit a protocol to SJREB if it's one of the following:
    a. Sponsored or funded by the Department of Health
    b. Multi-site protocol to be conducted in at least 3 sites with at least one (1) site with the following qualifications:
        i. Level 3 hospital
        ii. At least one (1) site with a Letter of Intent (LOI) which specifies that:
            - SJREB reviews the country protocol
            - Pis shall submit to both SJREB and the sites
            - Sites accept the SOPs of SJREB for the joint review of protocols
            - Only site specific modifications shall be allowed. No modifications to the approved country protocol shall be required by the participating sites.
            - Sites accept the decision of the SJREB unless there are compelling ethical, legal or scientific concerns. Reasons for site disapproval shall be submitted to SJREB and must be justified
            - Disapproval of protocol shall mean that the site is opting out as a site for the study

2. SJREB requires an LOI to regularly participate in joint review from all Research Ethics Committees when their sites are selected by the sponsors as a study. The LOI shall be effective unless a withdrawal of the intent to participate is submitted in writing.
3. SJREB requires the site RECs to agree and abide with the procedures of SJREB.
4. All research sites agree to provide the necessary environment to ensure the safe and ethical conduct of research, including oversight and stewardship functions as necessary, to monitor the conduct of the study.
5. In sites with no REC or has a functional REC with PHREB accreditation that is not appropriate for the type of protocol being reviewed, SJREB may either assume the oversight function of the site or choose to assign a PHREB-accredited REC to do the review and oversight. The determination will depend on the type and nature of the protocol to be implemented. The designated oversight REC shall issue the certificate of approval and assume stewardship and monitoring functions.

3. Responsibility (Please Refer to attached SOP)

1. The permanents members, independent consultant, and participating sites representatives act as primary reviewers and attend board meeting
2. The members review and decide make decisions on the protocol
3. The SJREB Secretariat manages all protocol submissions to the SJREB.

4. Flowchart

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1: Receive protocol from Coordinating PI protocol for single joint review	CHH IRB Staff	To be done within 60 Calendar Days
Step 2: Receive information about SJREB Initial Review	CHH IRB Staff	
Step 3: Conduct preliminary review of PI and protocol documents and consolidates site specific issues/comments for SJREB meeting	CHH IRB Chair, Member Secretary, IRB Members	
Step 4: Appoint representative to SJREB meeting	CHH IRB Chair	
Step 5: Representative attends Full Board review of protocol documents in SJREB meeting	CHH IRB Member appointed	
Step 6: Receives and acknowledges SJREB decision and make site decision in an expedited meeting	CHH IRB Chair, Member Secretary, IRB members, CHH IRB Staff	
Step 7: Inform Coordinating PI	CHH IRB Staff	
Step 8: File copies of the documents in the protocol file folder and update the protocol database	CHH IRB Staff	

5. Procedures

Step 1- Receives from coordinating PI protocol for Single Joint Review: CHH IRB Staff receives protocol for initial review from Coordinating PI.

Coordinating PI informs CHH IRB Staff that protocol is for Single Joint Review.

Step 2- Receive information about SJREB initial review: SJREB informs participating CHH IRB about the protocol for SJREB Initial Review.

Step 3- Conduct preliminary review of PI and protocol documents and consolidates site-specific issues/comments for SJREB

- The CHH IRB Chair/Member Secretary assigns a designated Primary Reviewers.
- The CHH IRB Staff prepares the notice to the Primary Reviewers, the protocol package and the corresponding study assessment forms and forwards them to the designated reviewers.
- The CHH IRB Chair calls for a special meeting for the conduct of preliminary review of PI and protocol documents and consolidates site-specific issues and/or comments for SJREB.s

Step 4- Appoint representative to SJREB meeting: The primary reviewer is appointed representative of CHH IRB to attend the SJREB meeting. In the event the primary reviewer is unavailable, CHH IRB Chair or Member Secretary attends the SJREB meeting.

Step 5- Representative attends Full Board review of protocol documents in SJREB meeting: Appointed representative for CHH IRB attends the SJREB Single Joint Review meeting and discusses site-specific issues during the meeting.

Step 6- Receives and acknowledges SJREB decision and make site decision in an expedited meeting

- CHH IRB Staff receives the SJREB decision.
- CHH IRB Chair calls for a special meeting to acknowledge the SJREB decision.
- CHH IRB makes site decisions on site-specific issues in the said special meeting.

Step 7- Inform Coordinating PI: Coordinating PI is informed of all decisions regarding site-specific issues and site decisions of the CHH IRB.

Step 8- File copies of the documents in the protocol file folder and update the protocol database.

- The CHH IRB Staff files copies of the SJREB review documents and the CHH IRB site decision on site-specific issues in the protocol file folder.
- Update the protocol file index of the protocol file folder.
- The CHH IRB Staff updates the protocol database.

6. History of SOP

Version No.	*Date*	*Authors*	*Main Change*
8	04 January 2024	Dr. Manuel Emerson Donaldo	– New – Refer to annexed SOP on SJERB
8.01	21 August 2024	Dr. Manuel Emerson Donaldo	No Change
9	21 August 2024	Atty. Dean Decal	Changed Title of SOP to SJREB review.

7. References:

- ADMINISTRATIVE ORDER NO. 2019 - 0044 NOV 05 2013 SUBJECT: Guidelines for the Operationalization of the Single Joint Ethics Review Process for Multi-Site Researches in the Department of Health
- Single Joint Research Ethics Board SJREB STANDARD OPERATING PROCEDURES Department of Health Policy Development and Planning Bureau Health Research Division Department of Health 2021 Published by Health Policy Development and Planning Bureau Department of Health San Lazaro Compound Rizal Avenue, Sta. Cruz Manila 1003, Philippines