Single Joint Research Ethics Board

SJREB

STANDARD OPERATING PROCEDURES

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Department of Health
Health Policy Development and Planning Bureau
Health Research Division

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INTRODUCTION

The Single Joint Research Ethics Board (SJREB) was institutionalized in the Department of Health through the issuance of *Administrative Order (AO) No. 2017-0021* in October 2017. This initiative has been put in place to streamline the ethics review process within the Department and contribute in the improvement of the research ethics governance system in the country.

SJREB has started its operations in March 2018. Its primary role is to host and serve as a platform for joint review of multi-site research studies sponsored by DOH and/or to be implemented across various DOH hospitals. In 2019, with the Board's commitment to further improve its processes and promote transparency, SJREB underwent joint accreditation from PHREB and the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP). This accreditation then led to the issuance of the revised *AO No. 2019-0049: Guidelines for the Operationalization of the Single Joint Ethics Review Process for Multi-Site Researches in the Department of Health* in November 2019 which addresses the issues and gaps identified in its pre-existing procedures and reiterates the processes and procedures in the adoption of the single joint review system in the DOH. Further, recognizing the capacity and core functions of the SJREB, the *Department Order No. 2019-0163: Guidelines on the Implementation of Clinical Research Policy in DOH Hospitals* was also institutionalized in which the Board's primary responsibility is to assist DOH hospitals research ethics committees in identifying and managing conflict of interest and other study-related complaints.

The SJREB's oversight applies to 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. It also covers private research ethics committees who have agreed to participate in the single joint ethics review process. And with its recent designation by the Sub Technical Working Group (TWG) on Vaccine Development and in accordance with PHREB Resolution on the Timelines of Approval for COVID-19 Clinical Trial Proposal, SJREB shall facilitate the ethics review of all COVID-19 vaccine trials to be implemented in the country following the prescribed process flow set forth by the vaccine experts panel.

This SOPs have been developed based on the DOH harmonized research ethics committee SOPs, PHREB and FERCAP standards, and other relevant local and international guidelines on health research ethics such as:

a. *National Ethical Guidelines for Health and Health Related Research (NEGHHRR)*
   - This PHREB document acknowledges the conduct of a joint review of a group of PHREB accredited ethics committees provided that the review abides by a standard operating procedures (SOPs) approved by PHREB

b. *Council for International Organizations of Medical Sciences (CIOMS)*
   - This international guideline highlights 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.

The document contains five (5) important chapters such as: (1) Authority, composition, and structure of SJREB; (2) Joint review process for initial submission; (3) Consolidated post-approval procedures; (4) Documentation and archiving; and, (5) Writing and revising SOPs. This SOP will be periodically reviewed and revised to address new issues and gaps that may arise over time. Also, this document will be updated as new local and international regulations, policies and guidelines are published. Meanwhile, the SJREB encourages stakeholders to send feedback and questions through official SJREB email at sjreb.doh@gmail.com.

ETHICAL FRAMEWORK OF THE SINGLE JOINT RESEARCH ETHICS BOARD

The Single Joint Research Ethics Board is guided by in its review, recommendations, and decisions by the following ethical principles:

1. **Respect for Persons –** principle that states that individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
2. **Beneficence** – principle that requires investigators to protect participants from harm and secure their well-being.
3. **Justice** – principle that refer to the sense of "fairness in distribution" and "what is deserved".

Source: *Belmont Report, 1979*

A. SJREB is guided and informed by the ethical principles, processes and procedures embedded in the following international guidelines:
   - Declaration of Helsinki (2013 and its subsequent revisions)
   - International Conference on the Harmonization of Good Clinical Practice (ICH-GCP) R2
   - Council for International Organizations of Medical Sciences (CIOMS) Guidelines 2016

- Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants (2011) by the World Health Organization (WHO)

B. SJREB shall function in accordance with the existing national laws, policies, regulations, and guidelines such as:
   - National Ethical Guidelines for Health Research set forth by the Philippine Health Research Ethics Board (PHREB)
   - Policy issuances (i.e., Administrative Orders, Department Orders, etc.) from the Department of Health, Philippine Food and Drug Administration (FDA) and other relevant agencies such as:
     - Administrative Order No. 2019-0049
     - Department Order No. 2019-0063

C. SJREB adopts its own standard operating procedures (SOP) based on:
   - Operational Guidelines for Ethics Committees that review Biomedical Research (2000) by the WHO
   - DOH-REC SOP Templates
   - FERCAP-SOP Templates
   - PHREB SOP Workbook 2020

D. In evaluating protocols and ethical issues, SJREB is cognizant of the diversity of the laws, cultures, and practices governing health research in various local sites and countries around the world.

E. SJREB is strictly aware and abide by the relevant Philippine laws in terms of the conduct of various types of research.

F. SJREB attempts to inform itself, whenever possible, of the regulations and requirements of sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of various localities where a proposed research is being considered.

G. SJREB will take the initiative to be informed, as appropriate, by current state-of-the art researches and publications of the impact of the research that it has approved.

A. SOP 1 SJREB STRUCTURE AND COMPOSITION

1.1 Purpose

1.1.1. To describe the authority, composition and structure of the Single Joint Research Ethics Board (SJREB) related to the ethics review of multi-site researches.

1.1.2. SJREB is organized by the Department of Health (DOH) Health Policy Development and Planning Bureau (HPDPB) with the following objectives:

1.1.2.1. To streamline the review process of health-related protocols to be conducted in multiple sites in the Philippines.

1.1.2.2. To shorten the turn-around time of ethics review of multi-site protocols.

1.1.2.3. To harmonize the results of ethics review among various site RECs through joint review.

1.1.2.4. To strengthen the ethics review capacity of PHREB accredited RECs to review different types of protocols that are conducted at their sites.

1.1.2.5. To serve as DOH central ethics committee who shall review DOH funded research.

1.2 Scope of Authority

1.2.1. SJREB is a joint review mechanism for multi-site protocols to be implemented at various sites and as adopted by duly accredited PHREB Research Ethics Committees (RECs).

1.2.1.1. It serves as a common review platform for all DOH RECs that will sign a letter of intent to participate and accept its review.

1.2.1.2. It also covers the non-DOH hospital RECs from both the public and the private sectors that will sign a letter of intent to participate and accept its review.

1.2.2. SJREB conducts joint review of study protocols to be implemented in at least three (3) sites in the Philippines.

1.2.2.1. All DOH funded research studies shall be reviewed by SJREB.

1.2.2.2. Sponsors and researchers who choose to do their studies in 3 or more sites may submit their protocols to SJREB.

1.2.2.2.1. At least one site is a Level 3 PHREB-accredited hospital with letter of intent.

1.2.2.3. It accepts multi-site protocols that are funded by DOH, PCHRD, DOST, PHIC, PHREB, CHED and other local organizations, including industry organizations and other foreign entities.

1.2.2.4. SJREB also accepts and reviews multicenter researches that are community-based.

1.2.3. SJREB requires the site RECs to agree and abide with the procedures that SJREB follows. All research sites should 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.

1.2.4. SJREB facilitates the ethics review of all COVID-19 vaccine trials to be conducted in the country in compliance with its designation by the Sub-Technical Working Group for Vaccine Development and PHREB's Resolution on the Timelines of Approval for COVID-19 Clinical Trial Proposal.

1.2.5. It serves as a Central REC to review DOH Central Office funded researches. It invites all site RECs to participate in the review of DOH protocols. However, SJREB may also review the following; (a) for DOH hospital RECs that lack the required level of PHREB accreditation; and, (b) have lost or have pending reaccreditation according to the following procedures:

1.2.5.1. The site REC shall receive submissions and reports from the site PIs, review the issues through expedited or full board as prescribed in their SOPs, and arrive at a recommended decision. There should be an interim agreement between SJREB and the site;

1.2.5.2. The site REC should forward their recommended decision and attach relevant documents (PI submission, site REC assessment forms, minutes, etc.) to SJREB together with a request for SJREB review and oversight.

1.2.5.3. The SJREB secretariat shall receive the request, determine the appropriate review channels and procedures.

1.2.5.4. SJREB shall review the issues and arrive at an appropriate decision to be forwarded to the site REC which in turn will forward the decision to the site investigator.

1.2.6. SJREB may also be involved in resolving conflict of interest issues and other study-related complaints implicating a DOH REC that may be constrained to fulfill its ethical mandate. SJREB may intervene and recommend the course of action to be implemented by the DOH research unit and/or REC in accordance with Department Order No. 2019-0163: Guidelines on the Implementation of Clinical Research Policy in DOH Hospitals.

1.3 Structure of the Single Joint Research Ethics Board

1.3.1. Organizational Structure. The Single Joint Research Ethics Board shall be placed directly under the Health Policy Development and Planning Bureau (HPDPB), Office of the Director to ensure independence of the board. This Bureau has the responsibility to set-up and support the SJREB office and secretariat to assist the Boards in its day-to-day operations. See Figure 1 for the Organogram of the SJREB.

1.3.2. HPDPB Roles and Responsibilities

1.3.2.1. Administrative support to the Board.

1.3.2.1.1. It ensures the independence of the decision making of SJREB.

1.3.2.1.2. It approves the SJREB Standard operating procedures to ensure that it is in agreement with policies of DOH.

1.3.2.1.3. It ensures that SJREB provides a mechanism to educate its reviewers and staff, including site RECs to develop the necessary knowledge, skills and practice to improve the review of various types of protocols submitted.

1.3.2.1.4. It requires progress report from SJREB to assess performance as basis for continuous quality improvement.

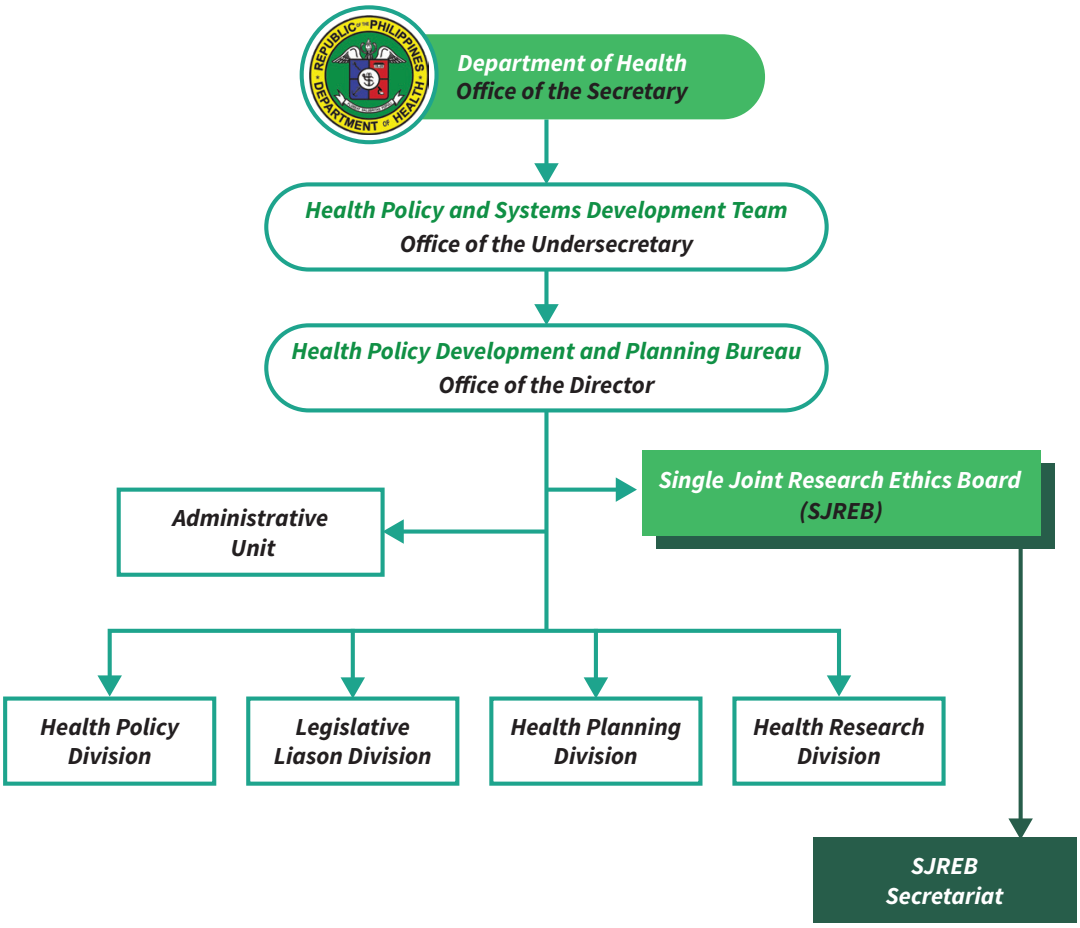
1.3.2.1.5. It provides sufficient staff to support the SJREB operations.

1.3.2.1.6. It allocates space, office equipment, IT infrastructure and all the necessary logistical support to enable SJREB to conduct its joint review functions efficiently and effectively.

1.3.2.1.7. It provides a budget for annual update training to SJREB Members and all DOH RECs and non-DOH RECs that submitted an LOI to the Board.

1.3.2.1.8. It screens nominees and recommends SJREB members to the Secretary of Health.

Figure 1. Organogram of SJREB



1.3.3. Process flow and Steps for Appointment of SJREB members

Table 1. Process flow and Steps for Appointment of SJREB members

NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Nomination and Selection of SJREB Members	SJREB Chair and permanent members
2	Screening of Nominees and Recommendations	HPDPB Director
3	Appointment of the SJREB members	Secretary of Health

1.3.4. Nomination Process

1.3.4.1. The permanent REC members, secretariat, and all participating REC members with an active LOI may nominate potential SJREB members.

1.3.4.2. The identified list of nominees shall be presented to the SJREB members during a regular full board meeting for the Board to finalize such a list.

1.3.4.3. The list of nominees will then be endorsed by the SJREB Chair to the HPDPB Director for final screening.

1.3.5. Screening of Nominees and Recommendations

1.3.5.1. The HPDPB Director, upon receipt of the list of nominees for SJREB membership from the SJREB Chair, shall assess the submitted documents and recommends the final list of proposed new set of SJREB members to the Secretary of Health (SOH).

1.3.5.2. The HPDPB Director has the prerogative to recommend the Chair based on his/her knowledge of the competence and capacity of such nominee. This privilege is guided by the common understanding that despite the nature of such recommendation, the independence of the decision making of the Board should still be strictly observed and exercised at all times.

1.3.5.3. A formal endorsement of the HPDPB's recommendation for the SJREB membership shall be forwarded to the Office of the Secretary for approval.

1.3.5.4. After the approval of the of the SOH, the SJREB Secretariat shall prepare the necessary documentary requirements to formalize appointment of the new SJREB members.

1.3.6. Appointment Process

1.3.6.1. The SJREB Secretariat shall ensure that the appointment documents are completed prior to engaging the SJREB members as described below.

1.3.6.2. SJREB Members

1.3.6.2.1. The Secretary of Health appoints an appropriate number of persons to form the SJREB membership to manage the SJREB operations. It may appoint consultants with relevant skills to help SJREB perform its review functions.

1.3.6.2.2. It appoints the SJREB Chair with a three-year term of office from participating RECs. It ensures that the Chair has sufficient background, training and experience in ethics review of various types of protocols.

1.3.6.2.3. It appoints a non-medical/non-scientific member, depending on the type of review, shall review the informed consent forms (ICF) and provide inputs from the community/ people's perspective.

1.3.6.2.4. It ensures that there is a non-affiliated member (i.e representative not coming from any of the hospital sites specified in the research being reviewed) during the SJREB meetings.

1.3.6.2.5. It invites the Philippine Health Research Ethics Network (PHREN) to nominate its representative with a fixed term, preferably from the private sector.

1.3.6.2.6. It appoints an appropriate number of designated subject experts/independent consultants who can assist SJREB review of multi-site protocols.

1.3.6.2.7. It ensures that a representative from a DOH-specialty hospital (e.g. Philippine Heart Center, National Kidney and Transplant Institute, Lung Center of the Philippines, etc.) is invited to attend review meetings related to their expertise.

1.3.6.2.8. It shall aim for adequate representation of men and women members in order to promote gender sensitivity in its review procedures.

1.3.6.2.9. It shall have representatives from ages below 50 years old and above 50 years old.

1.3.6.2.10. 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.

1.3.7. SJREB Membership and Secretariat

1.3.7.1. SJREB Membership. The SJREB membership is composed of seven (7) permanent and non-permanent members as indicated below. Independent consultants are also engaged for the review of specialized protocols.

1.3.7.1.1. Permanent Members

1.3.7.1.1.1. The **Chair** is a dedicated individual from an REC with experience to review different types of researches with fixed term of three (3) years as stipulated in the joint review SOPs.

1.3.7.1.1.2. A **Vice Chair** may be assigned from the existing permanent members

1.3.7.1.1.3. The **Member Secretary** shall oversee the protocols being reviewed by the Board and ensure the accuracy of the minutes of the meeting. He/she is a plantilla staff affiliated with the DOH.

1.3.7.1.1.4. Designated **Philippine Health Research Ethics Network (PHREN) Representative** from a private institution with a fixed term of three (3) years as stipulated in the joint review SOPs.

1.3.7.1.1.5. The **non-medical or non-scientific member**, depending on the type of protocol submission, shall review the informed consent forms (ICF) and provide inputs from the community/ people's perspective.

1.3.7.1.1.6. Subject matter experts (SME) on Health Systems, Ethics, Social science, and Public Health.

1.3.7.1.2. Non-Permanent Members

1.3.7.1.2.1. The **participating site REC representatives** are identified point persons or subject matter expert from the sites who are knowledgeable on the study protocols being reviewed

1.3.7.1.2.2. 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.

1.3.7.1.3. Independent consultant is an individual who has the specialization that is not present on the permanent members assigned to review a multi-site protocol.

1.3.7.2. Secretariat

1.3.7.2.1. Member Secretary is an affiliated plantilla technical staff who sits as a permanent member of the Board and ensures compliance with the SOP during the entire review process.

1.3.7.2.2. Head of Secretariat (HoS) is a plantilla technical staff who shall supervise the day-to-day operations of the Board

1.3.7.2.3. Administrative Staff is a dedicated staff who provides support to the HoS and Member Secretary in the administrative and clerical management of the SJREB.

1.3.8. Roles and Functions

1.3.8.1. SJREB Members

1.3.8.1.1. The SJREB Chair presides over full board meetings and ensures appropriate review of protocol related documents in accordance with international and national guidelines and regulations. He/she may designate the Vice Chair or a representative from an accredited

REC to preside over a meeting that he/ she cannot attend.

1.3.8.1.2. The SJREB members shall evaluate and manage conflict of interest that cannot be resolved at the institutional level especially for hospitals within the purview of the Department following the processes and procedures in the Department Order No. 2019-0163: Guidelines on the Implementation of Clinical Research Policy in DOH hospitals

1.3.8.2. SJREB Secretariat

1.3.8.2.1. Member Secretary

1.3.8.2.1.1. Oversees the conduct of the full board meeting and ensures that the review process is in accordance with the SOP

1.3.8.2.1.2. Conducts ethical review of assigned protocols as primary reviewer and presents review during expedited or full board meeting

1.3.8.2.2. Head of Secretariat

1.3.8.2.2.1. Manages the day-to-day activities of SJREB to include office procedures

1.3.8.2.2.2. Conducts ethical review of assigned protocols as primary reviewer and presents review during expedited or full board meeting

1.3.8.2.2.3. Conducts screening and identifies type of review of initial protocol submissions and post approval submissions

1.3.8.2.2.4. Recommends exemption for review to the Chair

1.3.8.2.2.5. Reviews all technical and administrative documents relative to SJREB operations to include but not limited to agenda of the meeting, minutes of the meeting, notification of approval/modifications and other post approval communication letters and documents

1.3.8.2.3. Administrative Staff

1.3.8.2.3.1. Communicates with various clients and stakeholders, and ensuring appropriate REC and site representation during the conduct of review.

1.3.8.2.3.2. Invites reviewers from RECs of sites selected by the sponsor or researcher to conduct the study.

1.3.8.2.3.3. Ensures completeness of protocols package submitted by the Coordinating PI for SJREB review.

1.3.8.2.3.4. Checks the site REC's level of PHREB accreditation. Only level 3 REC representatives can vote during full board review of clinical trial protocols intended for FDA registration, while both levels 2 and 3 REC representatives can vote during the review of public health protocols and clinical research not intended for FDA registration. Further, it ensures fair representation in terms of the counts of votes; only one (1) vote per site.

1.3.8.2.3.5. Invites observers from study sites, without RECs or RECs with a level of accreditation not appropriate for the type of protocol being reviewed, provided that they are listed in the protocol submitted for review.

1.3.8.2.3.6. Prepares the meeting agenda and minutes of all SJREB meetings for approval of the Chair.

1.3.8.2.3.7. Checks completeness of all assessment forms accomplished by the designated primary reviewers.

1.3.8.2.3.8. Issues an appropriate decision document (i.e. Notice of Approval, Notice of Protocol Modification, Certificate of Exemption, Notification Letter) to

all participating site RECs as reviewed and approved by the HoS and Member Secretary and duly signed by the SJREB Chair.

1.3.8.2.3.9. Ensures that Letter of Intent to participate in SJREB are secured prior to attendance to any SJREB meetings.

1.3.8.3. SJREB Participating Sites

1.3.8.3.1. DOH Hospital RECs and non-DOH RECs need to submit a Letter of Intent (LOI) to SJREB to participate in joint review when their sites are selected by the sponsor for the conduct of multi-site researches. The LOI shall apply for the entire duration of participation of the RECs in the single joint ethics review. In any given circumstances, the REC may opt to withdraw any time from participation in the review process by submitting a letter of withdrawal to the SJREB Secretariat. Should an REC wish to participate in the joint review after withdrawal, they should submit a new LOI to SJREB.

1.3.8.3.2. All DOH Hospital RECs and non-DOH RECs are expected to accept the results of SJREB review where qualified site RECs participated in the deliberations and decision making except when there are strong ethical issues and/or site specific concerns that cannot be addressed. For non-DOH hospitals, their RECs retain the option to accept or reject SJREB decision.

1.3.8.3.3. All RECs participating in joint review agree to share their review responsibilities with SJREB as follows:

1.3.8.3.3.1. Authority is shared by a duly accredited site REC with SJREB to conduct joint review with representatives from site RECs of multi-site researches. Joint review by SJREB is done only for initial review and renewal of approval. SJREB

conducts full board review of clinical trials for investigational medicinal products intended for FDA registration. All participating sites are invited to send a representative to join the deliberations and arrive at a joint decision. Low risk protocols may be exempted from review or may go through expedited review procedures.

1.3.8.3.3.2. All RECs who will participate in joint review should submit their membership list with their CVs and they should identify representatives qualified to do scientific and ethical review for various types of protocols commonly submitted for review.

1.3.8.3.3.3. All DOH Hospital RECs and non-DOH RECs are expected to accept the results of SJREB review where qualified site RECs participated in the deliberations and decision making except when there are strong ethical issues and/or site specific concerns that cannot be addressed. All site RECs will issue a Certificate of Approval together with the Notice of Decision from SJREB.

1.3.8.3.3.4. The site REC retains its review functions related to protocol amendments, SAE reports, protocol deviation and violation reports and final reports, all of which involve events at specific sites. The site REC, meanwhile, has the prerogative to elevate protocol deviation to SJREB and provide corrective actions.

1.3.8.3.3.5. The site REC maintains active collaboration and communication with SJREB for joint review to achieve its stated objectives and for mutual benefit of improving the research environment in the Philippines.

1.3.8.3.3.6. For site RECs that have lost or pending accreditation, the REC should still conduct review of the protocol. The REC then has the responsibility to submit the result of the review to SJREB for any further discussion or approval.

1.4 SJREB Letter of Intent and Oversight Function

1.4.1. Purpose

To describe the process of engaging participating sites in the joint ethics review process and define the oversight function of the SJREB

1.4.2. Scope

The Letter of Intent (LOI) is an agreement between the participating site(s) and SJREB whereby the site acknowledges and agrees to participate in the joint review process being conducted by the SJREB and abide by all its policies and guidelines set forth in this SOP and other relevant issuances.

1.4.3. Responsibility

1.4.3.1. It is the responsibility of the participating sites to submit a letter of intent (See SJREB Form 12) to SJREB through its Secretariat expressing the interest to participate in the joint review process

1.4.3.2. The SJREB Secretariat shall receive and facilitate the necessary documents to formalize such engagement. The LOI shall then be endorsed to the Director of the HPDPB for conforme.

1.4.3.3. For sites who have been identified to participate in a clinical trial but do not have the required PHREB accreditation level, the SJREB may assume oversight functions following the conditions below:

1.4.3.3.1. Adopt the SJREB standard operating procedures as part of the REC's SOPs in compliance with AO no. 2019-0049;

1.4.3.3.2. Attend SJREB meetings when the indicated protocol is being discussed.
1.4.3.3.3. Accept the decision of the SJREB for implementation at the site.
1.4.3.3.4. Submit results of the REC review of the protocol to SJREB.
1.4.3.3.5. Monitor the study implementation and submit the REC's recommendations to SJREB about action on reports submitted by the PI.
1.4.3.3.6. Inform SJREB at any time that the REC has been given its PHREB accreditation.

1.4.4. Process Flow/Steps

Table 2. Process flow and Steps for LOI and Oversight Fuction

NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Submit LOI to SJREB Secretariat	Participating site(s)
2	Receive and process documents formalizing engagement	Secretariat
3	Issue conforme letter to the participating site	HPDPB Director, Secretariat

1.4.5. Detailed instructions

1.4.5.1. Submit LOI to SJREB Secretariat

1.4.5.1.1. The participating site shall prepare the LOI duly signed by their respective REC Chairperson using SJREB Form 12.
1.4.5.1.2. The signed LOI shall be submitted to the SJREB Secretariat for approval of the HPDPB Director.

1.4.5.2. Receive and process documents

1.4.5.2.1. The SJREB Secretariat shall acknowledge and process the necessary documents

to formalize the engagement with the participating site.

1.4.5.2.2. Issue conforme letter to the participating sites

1.4.5.2.3. The signed conforme letter from the HPDPB Director shall be provided and issued to the participating site by the SJREB Secretariat

1.5 Training of SJREB Members and Staff

1.5.1. Purpose

To describe **SJREB** procedures to ensure initial and continuing training of members and staff

1.5.2. Scope

The SJREB recognizes the importance of training and continuing professional development. This SOP describes the training requirements of SJREB members and staff from initial training to continuing education to maintain and update competence in the review of different types of protocols.

1.5.3. Responsibility

1.5.3.1. It is the responsibility of the SJREB members and staff to have themselves educated and trained regularly.

1.5.3.2. It is the responsibility of the SJREB Chair along with the Secretariat to assess the training needs and prepare a training plan for all members, Independent Consultants, and staff. The chair may assign a permanent member to lead capacity building related activities.

1.5.3.3. The Secretariat keeps track of the training records of all members, Independent Consultants, and staff in accordance with the training plan.

1.5.4. Process Flow/Steps

Table 3. Process flow and Steps for LOI and Oversight Fuction

NO.	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Require basic research ethics training for all members and staff	Chair	Needs assessment to be done at the beginning of the year
2	Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses	Chair, Secretariat	
3	Track member and staff participation initial and continuing ethics training and file the documents in the Membership File	Members, Secretariat	

1.5.5. Detailed instructions

1.5.5.1. REC members should maintain competence by ensuring that they have updated knowledge of the following:

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- CIOMS
- Ethical Guidelines
- Relevant laws and regulations
- Relevant developments in science, health and safety, etc.
- International meetings and conferences

1.5.5.2. Require Research Ethics Training for all members and staff

1.5.5.2.1. All members are required to have basic research ethics training that shall consist of research ethics principles, GCP, SOPs, etc. Upon appointment, a new member or staff undergoes orientation, individually or as a group, to cover the following:

1.5.5.2.2. Member's/Staff's responsibilities;

1.5.5.2.3. Confidentiality and Conflict of Interest Agreement;

1.5.5.2.3.1. Review process and use of Protocol and ICF Assessment forms; and,

1.5.5.2.3.2. SOPs.

1.5.5.2.4. The Chair and Member-Secretary shall ensure that initial research ethics training is provided to all new members.

1.5.5.3. Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses

1.5.5.3.1. The Chair provides training opportunities to members/staff through participation in local and national research ethics seminars, conferences and workshops, and allocating funds for this purpose.

1.5.5.3.2. The Chair and Secretariat plan the training activities for individual members based on their training needs.

1.5.5.3.3. The Chair and Secretariat track and facilitate attendance of members and staff of specific training activities needed to ensure that each one gets training at least once a year.

1.5.5.3.4. The members who participate in research ethics training course or seminar-workshops either through personal or through REC efforts/funding are encouraged to:

1.5.5.3.4.1. Share information with other members during meetings; and,

1.5.5.3.4.2. Distribute photocopies/e-copies of relevant materials to the other members.

1.5.5.4. Track member and staff participation in initial and continuing ethics training and file the documents in the Membership File

1.5.5.4.1. For in-house training, the SJREB Staff prepares attendance sheets with relevant information about the topic, duration, date and venue. They ask member-attendees to sign the attendance sheet and keeps a photocopy of the attendance in the membership files, if Training Certificate is not given.

1.5.5.4.2. All members and staff should regularly update their Training Record. They should submit proof of attendance in relevant training or continuing professional education sessions conducted outside of the institution – e.g. certificates of training to the REC Staff for filing.

1.5.5.4.3. Administrative Staff should update the Training Record of individual Member and Staff to reflect their attendance in training activities every time a photocopy of Training Certificate is submitted for filing.

1.5.5.5. The joint review process shall serve as an avenue for building capacity of the RECs by exposing them to wide variety of protocols and best review practices from expert primary reviewers. SJREB may also invite observers from study sites without RECs or RECs with a level of accreditation not appropriate for the type of protocol being reviewed, provided that they are listed in the protocol submitted for review.

B. SOP 2 JOINT REVIEW OF PROTOCOLS

2.1 Purpose

To 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 RECs.

2.2 Scope

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

2.2.1. Sponsors and investigators may submit a protocol to SJREB if it's one of the following:

2.2.1.1. Sponsored or funded by the Department of Health
2.2.1.2. Multi-site protocol to be conducted in at least 3 sites with at least one (1) site identified as site with the ff qualifications:

2.2.1.2.1. Level 3 hospital
2.2.1.2.2. At least one (1) site with a Letter of Intent (LOI) which specifies that:

2.2.1.2.2.1. SJREB reviews the country protocol
2.2.1.2.2.2. PIs shall submit to both SJREB and the sites
2.2.1.2.2.3. Sites accept the SOPs of SJREB for the joint review of protocols
2.2.1.2.2.4. Only site specific modifications shall be allowed. No modifications to the approved country protocol shall be required by the participating sites.
2.2.1.2.2.5. Site accepts the decision of SJREB unless there is compelling ethical, legal or scientific concerns. Reasons for site disapproval shall be submitted to SJREB and must be justified.
2.2.1.2.2.6. Disapproval of protocol shall mean that the site is opting out as a site for the study.

2.2.2. 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.
2.2.3. SJREB requires the site RECs to agree and abide with the procedures of SJREB
2.2.4. 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.
2.2.5. 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.

2.3 Responsibility

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

2.4 Types of Review Classification of Protocols Submitted for Initial Review

SJREB classifies protocols into 3 types to determine the appropriate type of review of multi-site protocols. The Head of Secretariat makes a preliminary assessment of protocols and recommends the type of review to the Chair who approves the classification.

2.4.1. Detailed procedures for the three review types

2.4.1.1. Exemption from Ethics Review:

2.4.1.1.1. The Head of Secretariat makes a preliminary assessment of the protocol using the SJREB Form 6: Checklist for Exemption from Full Ethical Review Form to determine if it meets the exemption criteria as follows:
2.4.1.1.2. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g. meta-analysis protocols)
2.4.1.1.3. Protocols that involve human participants or identifiable human tissue, biological samples, and data provided that the following do not involve more than minimal risks or harm:

2.4.1.1.3.1. Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation

activities, and consumer acceptability tests;

2.4.1.1.3.2. Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:

2.4.1.1.3.3. No disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to their final standing, employability, or reputation; and

2.4.1.1.3.4. Information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant

2.4.1.1.3.5. Protocols that involve the use of publicly available data or information

2.4.1.1.4. The Head of Secretariat and a senior member of the board reviews the protocol and makes a determination for exemption. In certain circumstances, exemption may be discussed in an expedited meeting. The protocol for exemption shall be reported in the full board review for the information of the Board. The reviewer(s) submits the SJREB Form 4: Checklist for Exemption to the Secretariat seven (7) calendar days before the full board meeting.

2.4.1.1.5. SJREB issues a Certificate of Exemption (SJREB Form 4.1) signed by the Chair within seven (7) calendar days after the decision.

2.4.1.1.6. Should there be any major protocol change after the issuance of the Certificate of Exemption, the Coordinating PI shall submit an amendment to SJREB to make a decision about change of classification.

2.4.1.2. Expedited Review:

2.4.1.2.1. The Head of Secretariat makes a preliminary assessment of the protocol and determines qualification for expedited review based on the following criteria:

2.4.1.2.1.1. Does not involve more than minimal risks or harm but does not qualify for exemption
2.4.1.2.1.2. About a topic that should not result in causing social stigma
2.4.1.2.1.3. Does not involve vulnerable populations
2.4.1.2.1.4. Retrospective studies using anonymized data from medical records
2.4.1.2.1.5. Studies using simple questionnaires without identifiers
2.4.1.2.1.6. Proposals such as:

2.4.1.2.1.6.1. Chart review
2.4.1.2.1.6.2. Survey of non-sensitive nature
2.4.1.2.1.6.3. Use of anonymous or anonymized laboratory/pathology samples or stored tissue or data

2.4.1.2.2. The Head of Secretariat recommends the type of review to the Chair who approves the classification.
2.4.1.2.3. The Head of Secretariat identifies two or more primary reviewers from the permanent members and/or participating sites to conduct initial review through expedited procedures. SJREB may also call for a meeting of the sites to expedite the review.
2.4.1.2.4. The primary reviewer(s) should review within seven (7) calendar days using appropriate SJREB assessment forms. The primary reviewers may recommend modifications and decide on the approval of the protocol documents.
2.4.1.2.5. If any of the PR recommends disapproval, it is automatically elevated to full board.
2.4.1.2.6. The Head of Secretariat may recommend to

hold an expedited meeting when necessary, with the attendance of the secretariat and the primary reviewers. The expedited review report shall be finalized by the Member Secretary for reporting in the full board meeting.

2.4.1.2.7. The SJREB Secretariat prepares a Notice of Decision to be signed by the Chair and communicated to the Coordinating Principal Investigator (PI) within fourteen (14) calendar days after protocol submission.

2.4.1.2.8. The SJREB secretariat endorses the decision of SJREB to participating sites. SJREB expects the participating sites to accept its decision. Each site may add site specific recommendation to SJREB Decision.

2.4.1.2.9. The site REC issues a Certificate of Approval.

2.4.1.3. Full-Board Review:

2.4.1.3.1. The Head of Secretariat makes a preliminary assessment of the protocol and identifies more than minimal risk protocols for full board review.

2.4.1.3.2. The Head of Secretariat assigns primary reviewers from site RECs or invites independent consultants to review the protocol and the ICF.

2.4.1.3.3. The SJREB secretariat informs the site RECs of its receipt of protocols for full board joint review. Participating RECs conduct a preliminary assessment of the protocol and prepare comments/ recommendations on the protocol to be presented during the full board review.

2.4.1.3.4. The assigned primary reviewers shall prepare their comments using appropriate SJREB assessment forms and lead the discussion about the protocol during the board meeting. Other SJREB and participating sites representatives contribute to the discussion.

2.4.1.3.5. The SJREB Secretariat schedules the date of the full board meeting, prepares the meeting agenda and informs the members of the board, the site REC representatives, the assigned primary reviewers, as well as SME from necessary fields of experience to attend the meeting.

2.4.1.3.6. The Coordinating PI shall be invited for a clarificatory interview to answer queries about the protocol.

2.4.1.3.7. The board adopts one of the following decisions during joint review:

2.4.1.3.7.6.1. Approval
2.4.1.3.7.6.2. Minor modification required
2.4.1.3.7.6.3. Major modification required
2.4.1.3.7.6.4. Disapproved

2.4.1.3.8. The SJREB Secretariat prepares a Notice of Decision to be signed by the Chair and communicated to the Coordinating PI and to all the participating sites within fourteen (14) calendar days after the Full Board meeting.

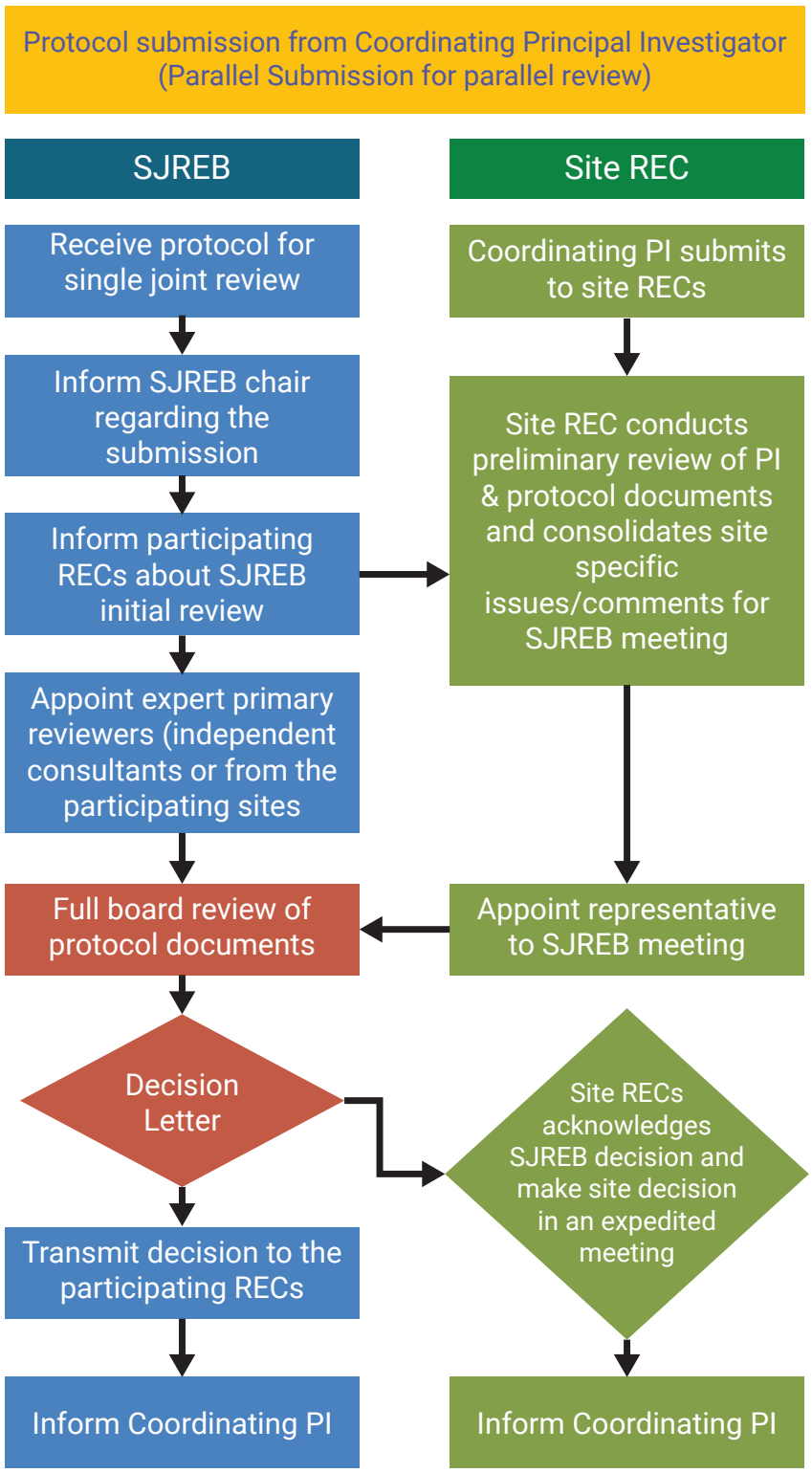
2.4.1.3.9. For protocols with recommendations for modification, the Coordinating PI is given fifteen (15) calendar days to submit a revised protocol.

2.4.1.3.10. Site RECs acknowledges SJREB decision and make site-specific decisions in an expedited meeting.

2.4.1.3.11. All DOH Hospital RECs and non-DOH RECs with LOI are expected to accept the results of SJREB review where qualified site RECs participated in the deliberations and decision making except when there are strong ethical issues and/or site specific concerns that cannot be addressed. Each site REC shall issue a Certificate of Approval, or a notice of its decision clearly stating the ethical issues, if it chooses to disapprove the protocol.

2.4.1.3.12. The site in general can no longer introduce major modification on the country protocol. However, the site RECs can disapprove the protocol only when they think that there are strong ethical issues or site specific concerns that were not addressed. Reasons for disapproval should always be stated in the decision letter. Meanwhile, the ICF may be revised in any manner the site REC requires.

Figure 2. Initial and Annual Renewal of Approval Review Procedures



Note: The target turn around time for the entire review process is 30-60 calendar days

LEGEND:

Orange - Coordinating PI
Blue - SJREB Secretarial
Red - Joint Review
Green - Site RECs

2.5 Management of Initial Protocol Submissions

2.5.1. Receive the initial protocol package for review and check the completeness of the documents submitted

2.5.2. SJREB Secretariat ensures that SJREB Form 1: Application for SJREB Initial Review and SJREB Form 1.2: Protocol Summary Sheet are completely filled out, signed and dated by the Coordinating PI submitting the protocol documents.

2.5.3. The following documents should be submitted in the initial protocol package:

2.5.3.1. Basic Documents:

2.5.3.1.1. Application Form [SJREB Form 1 - Application Form]
2.5.3.1.2. Protocol Summary Sheet [SJREB Form 1.2 - Protocol Summary Sheet]
2.5.3.1.3. Study Protocol
2.5.3.1.4. Informed Consent Forms
2.5.3.1.5. Recruitment and Advertisement Materials
2.5.3.1.6. Data Collection Forms
2.5.3.1.7. Curriculum vitae of principal investigators
2.5.3.1.8. Study Budget
2.5.3.1.9. Technical Clearance
2.5.3.1.10. Proof of submission to at least three (3) study sites

2.5.3.2. Study-specific Documents (submit as needed)

2.5.3.2.1. FDA Approval/ Proof of submission (for clinical trials)
2.5.3.2.2. Patient Information Sheet (for clinical trials)
2.5.3.2.3. Investigator Brochure (for clinical trials)
2.5.3.2.4. Basic Research Ethics Training Certificates of PIs (for non-clinical trials)
2.5.3.2.5. GCP certificates of PIs (for clinical trials)
2.5.3.2.6. Other protocol-related documents

2.5.4. SJREB may require Coordinating PI to submit to SJREB specific protocol-related documents submitted to the local RECs.

2.5.5. SJREB requires proof of submission of protocol to at least three (3) sites, with at least one (1) DOH hospital or a level 3 REC with LOI identified as site, prior to acceptance for ethics review.

2.5.6. One (1) hard copy and soft copy (sent either via email, flash drive, or CD) of the above documents shall be submitted to the SJREB.

2.5.7. The SJREB full board meeting is scheduled every second Wednesday of the month. The deadline for protocol submission for full board meeting is fourteen (14) calendar days prior (last Wednesday of the preceding month) to the next meeting.

2.5.8. Assign a permanent code to the protocol package

2.5.8.1. For efficient file management, it is necessary for SJREB staff to use a unique identifier to refer to this file, the Protocol Code Number. This code number is given as follows: SJREB-yyyy (year) –number (chronological number based on order of receipt).

2.5.8.2. For example, if the protocol entitled “Clinical Drug Trial of XYZ on Pediatric Patients” is the first protocol received in 2017, the code SJREB-2017-01 should be used to identify this protocol. The code shall be used on all communications regarding the protocol.

2.5.9. Determine the Type of Review and assign primary reviewers

2.5.9.1. The Head of Secretariat makes a determination about the appropriate type of review and seeks approval of the Chair on the review classification.

2.5.9.2. The Head of Secretariat identifies one (1) protocol reviewer and one (1) as ICF reviewer from the permanent members or from members of participating site RECs for full board and expedited protocols.

2.5.10. Distribute the Initial Protocol Documents to the Primary Reviewers

2.5.10.1. The SJREB Staff sends copies of protocol documents together with the SJREB Form 2: Protocol Assessment Form and SJREB Form 3: Informed Consent Assessment Form, with the transmittal letter to the primary reviewers.

2.5.10.2. The initial protocol documents should be distributed to the Primary Reviewers seven (7) calendar days before the full-board meeting.

2.6 Full-Board Review Procedures

2.6.1. Before Full-Board Meeting

2.6.1.1. The Coordinating PI submits the multi-site protocol documents to the identified sites at least two (2) weeks prior to submission to SJREB.

2.6.1.2. The site RECs conduct their preliminary review of the protocol documents and identify a representative who will participate in the discussion during the Full-Board SJREB meeting to reflect the views of their own REC.

2.6.1.3. The SJREB staff schedules the Joint Review meeting and checks the availability of the regular SJREB members, independent consultants, and representatives of the participating RECs to determine if quorum will be met. Quorum requires attendance of 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 (from a non-DOH site).

2.6.1.4. Attendance of members through video conference is allowed.

2.6.1.5. The SJREB secretariat prepares and sends the agenda to all participating sites. Prior to dissemination, the HoS should review the prepared agenda of the meeting to check if items are properly classified and presented. The agenda should include information about the following: a. date, time, and venue of the joint SJREB full-board meeting, b. full details about the protocol (number, title, sponsor, coordinating PI, sites) for initial review and renewal of approval.

2.6.1.6. The SJREB full board meeting is regularly scheduled on the second Wednesday of the month or more frequently depending on the volume of protocol submissions. An emergency meeting may also be conducted to facilitate review of urgent protocols (See Appendix B. Guidelines for review procedures during a public health emergency or during an epidemic) and critical issues needing the Board's immediate decision.

2.6.2. During Full-Board Meeting

2.6.2.1. A full-board SJREB meeting is convened to discuss and recommend a decision about the protocol and related documents. The SJREB members attending the full board meeting have to review and comment on the following:

2.6.2.1.1. Protocol;
2.6.2.1.2. Informed Consent;
2.6.2.1.3. PI and research team;
2.6.2.1.4. Study sites covered by the application;
2.6.2.1.5. Advertisements, etc.

2.6.2.2. Designated primary reviewers shall submit the accomplished and signed SJREB Form 2: Protocol Assessment Form and SJREB Form 3: Informed Consent Assessment Form during the full-board meeting.

2.6.2.3. The SJREB secretariat invites the Coordinating PI to attend the meeting for clarificatory interview to answer questions about the protocol.

2.6.2.4. The SJREB members discuss protocol documents and vote on specific items to arrive at a decision as follows (voting requirements are discussed in Chapter 1):

2.6.2.4.1. Approval (when no further modification is required)
2.6.2.4.2. Minor modification (requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.)

2.6.2.4.3. Major modification (requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data)

2.6.2.4.4. Disapproval (due to ethical, legal or scientific concerns). Reasons for vote of disapproval should be noted in the minutes and communicated to the PI.

2.6.2.5. If the study is approved, SJREB determines the frequency of continuing review. All meeting deliberations and decisions regarding a protocol shall be noted in the meeting minutes.

2.6.2.6. Copies of meeting minutes and SJREB decision pertaining to the specific protocol are sent to the site RECs for their information.

2.6.2.7. Site RECs shall submit to SJREB copies of their Certificate of Approval/Notice of Decision.

2.6.3. After the Full-Board Meeting

2.6.3.1. The SJREB secretariat communicates the notice of modification decision to the Coordinating PI.

2.6.3.2. Once the SJREB board approves the protocol related documents, the decision of SJREB is communicated to the Coordinating PI and all the participating site RECs.

2.6.3.3. Investigators may appeal the decision of SJREB by writing a letter requesting for reconsideration with reasons clearly stated and submission of a new protocol. Any appeal shall be taken up at full board meeting.

2.6.3.4. All DOH Hospital RECs and non-DOH RECs with an LOI are expected to accept the results of SJREB review where qualified site RECs participated in the deliberations and decision making except when there are strong ethical issues and/or site specific concerns that cannot be addressed. The site REC conducts an expedited review of the approved protocol to address site specific concerns and inform the PI of the local site of the outcome of the SJREB review as well as the outcome of the local REC review. All site REC decisions should be reported to

SJREB and copy of decisions should be provided to the SJREB Secretariat.

2.6.3.5. The SJREB secretariat prepares the Minutes of the SJREB Full-Board Meeting as follows:

2.6.3.5.1. The SJREB secretariat fills out the basic information about each protocol submission for review in the SJREB Meeting Minutes template with identifying information (Protocol number, title, PI, sponsor, etc.) before the meeting date.

2.6.3.5.2. As the SJREB meeting proceeds, the SJREB Secretariat takes minutes of the meeting on real time according to the prescribed format and projects this on the multimedia screen to enable the SJREB Members to closely follow the proceedings, and to facilitate the recapitulation of discussion points by the SJREB Chair/ Presiding Officer. The SJREB decisions and recommendations are collective in nature. No attribution to specific SJREB member is stated in the minutes. The meeting minutes should include the following items:

2.6.3.5.2.1. Date and venue of the meeting
2.6.3.5.2.2. Presiding Officer
2.6.3.5.2.3. Attendance of REC representatives (medical/scientific; non-medical/non-scientific; non-affiliated with the study site)
2.6.3.5.2.4. Attendance of independent consultants
2.6.3.5.2.5. Attendance of coordinating PI and guests or observers, if any
2.6.3.5.2.6. Time when the meeting was called to order
2.6.3.5.2.7. Status of quorum at the start of the meeting and before every decision making
2.6.3.5.2.8. Discussion of items based on the order in the meeting agenda

2.6.3.5.2.9. Summary of technical and ethical discussion points and recommendations

2.6.3.5.2.10. SJREB decision and voting results according to decision categories, abstention and votes for disapproval with reasons given.

2.6.3.5.2.10.1. If the review decision (for initial and continuing reviews) is "approved", the frequency of submission of progress reports are determined.

2.6.3.5.2.10.2. If the review decision is disapproved, the reasons for the disapproval are stated.

2.6.3.5.2.10.3. If the review decision (for initial and continuing reviews) is "for modification", the items to be revised are identified and the type of review for the resubmission is defined.

2.6.3.5.2.11. Attach the list of protocols for exemption and protocols approved through expedited review report for the information of the board.

2.6.3.5.2.12. Name and signature of the person who prepared the minutes

2.6.3.5.2.13. Name and signature of the Chair who approved the minutes with the date of approval

2.6.3.6. The SJREB secretariat sends the draft meeting minutes to the SJREB Members for their review and comments within 7 calendar days before the succeeding meeting. Prior to dissemination of the minutes of the meeting, the secretariat shall seek approval from the HoS for the release of the document.

2.6.3.7. During the next full board meeting, the Chair asks the members to approve the Minutes.

2.6.3.8. The SJREB Staff files approved meeting minutes in the online database of Meeting Minutes.

2.7 Continuing Review Procedures

2.7.1. The following documents shall be submitted to SJREB for continuing review:

2.7.1.1. Amendment of the country protocol
2.7.1.2. Progress report
2.7.1.3. Final report
2.7.1.4. Protocol violation/ deviation
2.7.1.5. Early termination report

2.7.2. The SJREB secretariat keeps the continuing review application package together with the review comments of the primary reviewer/s and the SJREB decision in the protocol file folder and updates the Online Database of Active Study Files.

2.7.3. Detailed Procedures

2.7.3.1. Amendment of the country protocol
2.7.3.2. The Coordinating PI submits to SJREB any amendments to the previously approved protocol documents.
2.7.3.3. The Head of Secretariat makes a preliminary assessment of the amendment and determines the type of review necessary.
2.7.3.4. Amendments that may potentially alter the risk/ benefit ratio is referred to full board review for discussion, including but not limited to the following:

2.7.3.4.1. Change in study design
2.7.3.4.2. Change in the number of subjects
2.7.3.4.3. Change in the inclusion or exclusion criteria
2.7.3.4.4. Addition or removal of treatments
2.7.3.4.5. Change in the method or route of drug administration
2.7.3.4.6. Change in drug dosage

2.7.3.5. Minor changes that does not potentially alter the risk/benefit ratio is referred to the original Primary Reviewers.

2.7.3.6. The SJREB secretariat sends the amendment report to the primary reviewers at least seven (7) calendar days before full-board meeting.

2.7.3.7. The SJREB secretariat notifies all site RECs about the amendment application.

2.7.3.8. Approval of amendment application reviewed by the Primary Reviewers by expedited procedure is reported to the board meeting.

2.7.3.9. The SJREB staff communicates the decision of the SJREB to the Sponsor/ Coordinating PI, and local RECs.

2.7.3.10. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required and prepares Notification of SJREB Decision – Progress/Annual Report for signature of SJREB Chair.

2.7.4. Progress report

2.7.4.1. Progress reports shall be submitted annually unless an earlier or more frequent schedule is decided by the board.

2.7.4.2. The SJREB secretariat communicates to the Sponsor/ Coordinating PI about the need to submit progress report 30 calendar days before the expiry of the Notice of Approval.

2.7.4.3. The Coordinating PI submits to SJREB the latest versions of the Investigator

2.7.4.4. Brochure (IB), current versions of the protocol, informed consent forms (ICF) and other relevant documents, along with a summary of all protocol amendments, protocol deviations/ violations and on-site SAEs/SUSARs etc., as well as participant recruitment since the last SJREB approval.

2.7.4.5. The SJREB secretariat notifies all site RECs about the continuing review submissions. The Site RECs collect specific information from their site about protocol amendments, protocol deviations/ violations and local SAEs/ SUSARS, including participant recruitment data to provide inputs during joint review.

2.7.4.6. The SJREB secretariat sends the progress report package to the primary reviewers at least seven (7) calendar days before full-board meeting.

2.7.4.7. Primary reviewers refer to the progress report document to determine whether they contain updated information related to patient safety. Review comments should consider the following:

2.7.4.7.1. Risk Assessment: the risks to the subjects are minimized; the risks to the subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be expected to be gained from the study.

2.7.4.7.2. Adequacy of Informed Consent: Informed consent/Assent forms current (most recent); appropriate, new significant findings since the last continuing review that may be related to the subjects' willingness to continue participation provided to enrolled subjects (e.g., important toxicity or adverse event information)

2.7.4.7.3. Local Issues: Changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, medical license; involvement in numerous clinical trials); Evaluation, investigation and resolution of complaints related to the research, if any; Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable national law, or standards of professional conduct of practice.); Report from third party observation of the research (including the informed consent process) carried out; Investigator concerns about trial conduct at the local site (e.g., study coordinator ineffectiveness, inability of subjects to understand sections of the informed consent document required by institutional policies), if any.

2.7.4.7.4. Trial Progress: Start date of the study and expected duration; Total subject enrollment (expected enrollment, actual enrollment, enrollment issues), subject withdrawal (number of subjects who withdrew, lost to follow-up, summary of reasons for withdrawal at local site)

2.7.4.8. Progress report of protocols reviewed through full board shall be included in the agenda for discussion in the full board meeting where members arrive at any of the following decisions:

2.7.4.8.1. Renew approval
2.7.4.8.2. Request additional information
2.7.4.8.3. Recommend modification
2.7.4.8.4. Suspend:
2.7.4.8.5. Enrollment of new subjects
2.7.4.8.6. Research procedures in currently enrolled subjects
2.7.4.8.7. Entire study
2.7.4.8.8. Disapprove renewal

2.7.4.9. Approval of progress report reviewed by the Primary Reviewers by expedited procedure is reported to the board meeting.

2.7.4.10. SJREB staff communicates the decision of the SJREB to the Sponsor/ Coordinating PI, and local RECs.

2.7.4.11. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required and prepares Notification of SJREB Decision – Progress/Annual Report for signature of SJREB Chair.

2.7.5. Final report

2.7.5.1. Final reports shall be submitted by the Coordinating PI upon completion of the study using SJREB Form 9. Closure/Final Report Form. The final report shall contain consolidated information from all the sites included in the study.

2.7.5.2. The SJREB secretariat communicates to the Coordinating PI about the need to submit progress report 30 calendar days before the expiry of the Notice of Approval.

2.7.5.3. The SJREB head of secretariat classifies the submission as either for full board or for expedited review based on the original protocol review classification.

2.7.5.4. The SJREB secretariat sends the final report package to the primary reviewers at least seven (7) calendar days before the full-board meeting.

2.7.5.5. Primary reviewers refer to the final report document to determine whether they are in accordance with the protocol and related documents approved by the SJREB during initial review and review of amendments, as applicable.

2.7.5.6. Final report of protocols reviewed through full board shall be included in the agenda for discussion in the full board meeting where members arrive at any of the following decisions:

2.7.5.6.1. Approve final report and classify the protocol as inactive

2.7.5.6.2. Request additional information from the coordinating PI

2.7.5.7. Approval of progress report reviewed by the Primary Reviewers by expedited procedure is reported during the board meeting.

2.7.5.8. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required

2.7.5.9. The SJREB Secretariat prepares the Notice of Approval for signature of SJREB Chair.

2.7.5.10. The SJREB staff communicates the decision of the SJREB to the Coordinating PI and site RECs.

2.7.6. Protocol Violation/ Deviation

2.7.6.1. Protocol violation or deviation, whether minor or major, from any of the sites included in the study shall be reported to the SJREB by the coordinating PI through the Progress Report Form including relevant documents needed to explain or provide details for the information indicated in the report.

2.7.6.2. The Head of Secretariat classifies the submission as either for full board or for expedited review:

2.7.6.3. Minor Protocol Deviation- are non-systematic protocol noncompliance with minor consequences to the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature

2.7.6.4. Major Protocol Deviation or Protocol Violation - are persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk

2.7.6.5. The SJREB secretariat sends the protocol non-compliance report package to the primary reviewers at least seven (7) calendar days before the full-board meeting.

2.7.6.6. Primary reviewers refer to the protocol non-compliance report package to determine the appropriate course of action depending on the seriousness of the non-compliance.

2.7.6.7. Non-compliance identified for full board shall be included in the agenda for discussion in the full board meeting where members arrive at any of the following decisions:

2.7.6.7.1. Uphold Original Approval
2.7.6.7.2. Request Further Information
2.7.6.7.3. Suspension of Ethical Clearance
2.7.6.7.4. Cancellation of Ethical Clearance
2.7.6.7.5. Deferred Action pending major clarification

2.7.6.8. Non-compliance report reviewed by the Primary Reviewers by expedited procedure is reported during

the board meeting.

2.7.6.9. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required

2.7.6.10. The SJREB Secretariat prepares the Notification of Decision for signature of SJREB Chair.

2.7.6.11. The SJREB staff communicates the decision of the SJREB to the Coordinating PI and site RECs.

2.7.7. Early Termination

2.7.7.1. Early termination of protocol implementation shall be reported to the SJREB by the coordinating PI through the Early Termination Application Form (SJREB Form 11).

2.7.7.2. The SJREB secretariat sends the early termination report to the primary reviewers at least seven (7) calendar days before the full-board meeting.

2.7.7.3. Primary reviewers refer to the early termination application to determine the appropriate recommendations

2.7.7.4. Early termination application shall be included in the agenda for discussion in the full board meeting to determine the early termination's implication to the participants and arrive at recommendations for continued protection of study participants including follow-up plan to those who are still actively enrolled.

2.7.7.5. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required

2.7.7.6. The SJREB Secretariat prepares the Notification of Decision for signature of SJREB Chair.

2.7.7.7. The SJREB staff communicates the decision of the SJREB to the Coordinating PI and site RECs.

C. SOP 3 DOCUMENTATION AND ARCHIVING

3.1 Purpose

3.1.1. To describe the Single Joint Research Ethics Board (SJREB) procedures in documenting all protocol submissions and archiving completed and inactive studies.

3.2 Scope

3.2.1. This procedure applies to documentation and archiving of all protocols submitted to SJREB for ethics review.

3.3 Process Flow and Procedures for Documentation

Table 4. Process Flow and Procedures for Documentation

NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Input of protocol submission in the online database	Secretariat staff
2	Input digital and hard copy of protocol related files in their respective storage areas	Secretariat staff

3.4 Documentation

The secretariat staff maintains a protocol file to contain all submissions and action taken on protocols submitted for SJREB review.

3.4.1. Online database

3.4.1.1. The secretariat staff It maintains an online database that contains complete and updated information about all protocol submissions.

3.4.1.2. The database should contain the following information:

3.4.1.2.1. Protocol code
3.4.1.2.2. Protocol title
3.4.1.2.3. Type of protocol
3.4.1.2.4. Sponsor
3.4.1.2.5. Study sites
3.4.1.2.6. Coordinating investigator
3.4.1.2.7. Submission date
3.4.1.2.8. Type of review
3.4.1.2.9. Primary reviewers
3.4.1.2.10. Date of meeting
3.4.1.2.11. Review decision
3.4.1.2.12. Date of issuance of decision
3.4.1.2.13. Resubmission date
3.4.1.2.14. Date of decision of resubmission
3.4.1.2.15. Approval date
3.4.1.2.16. Expiration date
3.4.1.2.17. Due date for progress report
3.4.1.2.18. Date of submission of progress report
3.4.1.2.19. Submission of amendment report
3.4.1.2.20. Date of approval of amendment report
3.4.1.2.21. Submission of final report Date of approval of final report
3.4.1.2.22. Other reports (SAEs, protocol violations, etc.)

3.4.1.3. All protocol submissions should be logged in the database.

3.4.2. Digital and hard copies of protocol related files should be submitted to the secretariat staff.

3.4.2.1. All protocol submissions should be properly labeled with protocol code (Refer to chapter 2 on proper labelling, *see 2.5.8*).

3.4.2.2. Digital copies are stored in their separate google drive folders that are password protected.

3.4.2.3. Hard copies are kept in separate folders in the cabinet with locks and keys

3.4.2.3.1. All protocol submission should be stored in separate folders.

3.4.2.3.2. Folders should be properly labeled with their protocol code. For protocols with multiple folders, the label format should be: Protocol Code + letter (in chronological order based on the oldest files).

3.4.2.3.3. Folders should be stored in cabinets properly labeled with active or inactive status. All cabinets should be secured by a lock and key. Only the secretariat staff should have the key and its duplicate.

3.4.2.3.4. Each folder should contain an index at the beginning of the file to identify the protocol documents found in the folder

3.4.2.4. Any document submitted by the investigator is added to the protocol files

3.5 Process Flow and Procedures for Archiving

Table 5. Process Flow and Procedures for Archiving

NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Identify inactive protocols files	Secretariat staff
2	Update protocol database	Secretariat staff
3	Affix appropriate label to files for archiving	Secretariat staff
4	Transfer files to the proper cabinet	Secretariat staff

3.6 Archiving

The secretariat staff will follow the following procedures:

3.6.1. Studies are considered to be completed and inactive when the closure/final report of the study has been reviewed and approved by SJREB.

3.6.2. Incomplete studies are classified as inactive when no further communication or submission has been received by SJREB after two years. Studies that are terminated earlier before completion will also be classified as inactive files.

3.6.3. Once the final report has been approved, the Secretariat staff marks the database as completed.

3.6.4. Digital file folders are marked with an I or C to indicate that they are incomplete and complete respectively. Hard copy folders are marked with a red sticker to indicate that they are inactive.

3.6.5. At the end of the year, the secretariat staff transfers all completed/inactive protocol folders to the archive.

3.6.6. Protocols are archived for 3 years. After 3 years in the archive, the protocol files may be transferred to a password protected offline hard disk

3.7 Process Flow and Procedures for Retrieval of Documents

Table 6. Process Flow and Procedures for Retrieval of Documents

NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Receive requests to access SJREB protocol documents	Secretariat staff
2	Approve and input all requests and transaction in the database	Secretariat staff
3	Supervise the use of retrieved documents	Secretariat staff
4	Return of document to the protocol file folder	Secretariat staff

3.8 Retrieval

The secretariat staff will follow the following procedures:

3.8.1. Receive requests to access SJREB protocol documents.

3.8.1.1. Access to SJREB files is subject to the following limitations:

3.8.1.1.1. Participating site members with a signed Confidentiality Agreement and Conflict of Interest Disclosure can access documents outside of regular protocol review access, upon request.

3.8.1.1.2. Non-members can access specific documents by submitting a formal request. The secretariat staff will require a signed Confidentiality Agreement and Conflict of Interest Disclosure. This request needs to be approved by the Member Secretary.

3.8.1.1.3. Regulatory authorities (e.g. Philippine FDA) can have full access to SJREB documents provided it is within their mandate and within a reasonable notice to make the files available.

3.8.2. Approve and input all requests and transaction in the database.

3.8.2.1. All requests are put into the online database. The following information should be included:

3.8.2.1.1. Protocol code
3.8.2.1.2. Date borrowed
3.8.2.1.3. Name of borrower
3.8.2.1.4. Document requested or copied
3.8.2.1.5. Number of copies made
3.8.2.1.6. Date returned of borrowed documents

3.8.3. Supervise the use of retrieved documents.

3.8.3.1. Access to SJREB documents is generally for room use only, but requests to make copies can be accommodated on a case to case basis.

3.8.3.2. The secretariat staff makes only the exact number of copies requested.

3.8.4. Return document to the protocol file folder.

3.8.4.1. The secretariat staff is responsible for returning the documents in the protocol file folder in the cabinet after making sure that all documents are complete as per protocol file index

D. SOP 4 WRITING AND REVISING STANDARD OPERATING PROCEDURES

4.1 Writing SOPs

4.1.1. Purpose

To describe the procedure for writing and revising SOPs used by the Single Joint Research Ethics Board

4.1.2. Scope

This SOP provides instructions on how the new SJREB SOPs are prepared.

4.1.3. Responsibility

4.1.3.1. It is the responsibility of the Chair of SJREB to organize an SOP Team to formulate the SOPs of the REC.

4.1.3.2. The SOP Team is an ad hoc committee composed of designated SJREB members and invited resource persons. The team is responsible for drafting new SOPs and revising existing SOPs when necessary. The team must follow existing institutional procedures when drafting SOPs in consultation with the Secretariat and Chair. The team submits the draft SOPs to the Chair.

4.1.3.3. The Chair convenes an SJREB meeting to review and finalize the draft SOPs and ensures that all SJREB members have an access to current versions of SOPs to guide them in the performance of their functions.

4.1.4. Process Flow

Table 7. Process Flow for Writing SOPs		
NO.	**ACTIVITIES**	**PERSON/S RESPONSIBLE**
1	Organize an SOP Team	SJREB Chair
2	Identify reference templates with corresponding layout	SOP Team
3	Draft revised SOPs and submit to Chair	SOP Team
4	Review and finalize revised SOP in an SJREB meeting and submit to the HPDPB Director	Chair, SJREB Members
5	Approve and sign revised SOPs	HPDPB Director
6	Distribute approved SOPs and keep copies in the SJREB files	Secretariat

4.1.5. Detailed Instructions

4.1.5.1. Organized an SOP Team

4.1.5.1.1. HPDPB Director assigns members of the SOP Team, and invites resource persons as needed.

4.1.5.1.2. The SOP Team receives an orientation from the Chair regarding its duties and responsibilities.

4.1.5.1.3. The Chair may organize a SOP Team workshops to facilitate the drafting of SOPs.

4.1.5.2. Identify reference templates with corresponding layout

4.1.5.2.1. Identify reference templates with corresponding layout from SOPs of other RECs to guide the SOP Team in drafting new SOPs.

4.1.5.2.2. An SJREB SOP have the following format:

4.1.5.2.2.1. SOP Number

4.1.5.2.2.2. Title

4.1.5.2.2.3. Purpose of the SOP
4.1.5.2.2.4. Scope which defines the extent of coverage of the SOP and its limitations
4.1.5.2.2.5. Responsibility identifies the persons assigned to perform specific tasks during SOP implementation
4.1.5.2.2.6. Process Flow/ Steps
4.1.5.2.2.7. Detailed instructions which elaborates the steps outlined in the process flow
4.1.5.2.2.8. Standard forms and checklist to be used
4.1.5.2.2.9. Glossary
4.1.5.2.2.10. References
4.1.5.2.2.11. List of Acronyms

4.1.5.2.3. Each SOP should be given a number and a title that is self-explanatory and is easily understood.
4.1.5.2.4. The SOP Document History describes the different versions of the document by version no., version date, and description of main changes. This is attached with the SOP Masterfile.
4.1.5.2.5. The typical SOP uses a header with the following elements

4.1.5.2.5.1. Institutional seal or logo
4.1.5.2.5.2. Name of institution
4.1.5.2.5.3. SOP Identifier
4.1.5.2.5.4. SOP Title
4.1.5.2.5.5. Effectivity date
4.1.5.2.5.6. Page number

4.1.5.3. Draft new SOPs and submit to the Chair

4.1.5.3.1. The SJREB SOPs should contain details under the following main topics:

4.1.5.3.1.1. Introduction - contains a statement of ethical principles that will guide SJREB
4.1.5.3.1.2. Authority, Composition, and Structure of SJREB - describes the composition of SJREB Membership with specific review functions

4.1.5.3.1.3. Joint Review of Initial Submission - describes types of review and initial review procedures
4.1.5.3.1.4. Continuing Review Procedures - describes how SJREB conducts post-approval review procedure
4.1.5.3.1.5. Documentation, and Archiving - describes administrative procedures that support the review functions
4.1.5.3.1.6. Writing and Revising SOPs - describes how to draft and revise SOPs

4.1.5.3.2. The SOP Team submits completed SOP draft to the Chair.

4.1.5.4. Review and finalize new SOPs in an SJREB meeting and submit to the HPDPB Director

4.1.5.4.1. The SJREB Chair or any permanent member presents the draft SOPs during an SJREB meeting for the member to discuss and finalize the draft
4.1.5.4.2. The SJREB Chair submits the approved draft to the Director of HPDPB for approval.

4.1.5.5. Approve and sign new SOPs

4.1.5.5.1. The HPDPB Director reviews and approves the SOPs by signing in the designation section.
4.1.5.5.2. The approved SOPs will be implemented after approval by the HPDPB Director.

4.1.5.6. Distribute approved SOPs and keep copies in the SJREB files

4.1.5.6.1. The SJREB Secretariat distributes the new SJREB SOPs to all SJREB Members, participating site RECs with active LOI, and Staff and files the original copy in the SJREB storage cabinet.
4.1.5.6.2. The SOP Manual with downloadable forms are uploaded on the SJREB website for the use of and guidance of researchers.

APPENDICES AND FORMS

APPENDIX A

Appendix A.	
SJREB FORM 1	Application for SJREB Initial Review
SJREB FORM 1.2	Protocol Summary Sheet
SJREB FORM 2	Protocol Assessment Form
SJREB FORM 3	Informed Consent Assessment Form
SJREB FORM 4	Checklist of Exemption
SJREB FORM 4.1	Certificate of Exemption from Ethics Review
SJREB FORM 5	Notice for Protocol Modification
SJREB FORM 5.1	Protocol Resubmission Form
SJREB FORM 6	Notice of Approval
SJREB FORM 7	Progress or Annual Report for Philippine Sites
SJREB FORM 7.1	Progress Report for Government Funded Protocols
SJREB FORM 8	Protocol Amendment Application Form
SJREB FORM 9	Closure or Final Report Form
SJREB FORM 9.1	Early Study Termination Application
SJREB FORM 10	Notice for Post-Approval Modification
SJREB FORM 11	Onsite Serious Adverse Event Report
SJREB FORM 12	Protocol Violation_Deviation Report
SJREB FORM A	Declaration of Conflict of Interest

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SJREB FORM 1
APPLICATION FOR SJREB INITIAL REVIEW

To be filled up by the Coordinating Investigator

SJREB Protocol Number *(to be filled-up by secretariat staff)*:	

Sponsor Protocol Number:		Submission Date:			

Protocol Title:	

Type of Research:	☐	Clinical Research	☐ Clinical Trial	☐	Laboratory Research
	☐	Genetic Research	☐ Socio-behavioral	☐	Public health
	☐	Others (*specify)*: _____			

Study Duration:	

Sponsor:	

Coordinating Investigator: *(Please assign one person only)*	

Sites and Site Principal Investigators: *(List all sites and site investigators)*	

Telephone number:		Email	

Institution:	

Declaration of Conflict of Interest (COI)				
Are you an employee of the sponsor/s?	x	Yes	x	No
Did you do consultancy or part time work for the sponsor/s?	x	Yes	x	No

In the past year, did you receive P500,000 or more from the sponsor/s?	x	Yes	x	No	
Other ties with the sponsor:					
Ethical Responsibility and COI Statement I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Coordinating Investigator (CI).					

CI Signature:	

Documents submitted: *(Please check the documents submitted)*

Basic documents:	
	Application Form [SJREB FORM 1 – APPLICATION FORM]
	Protocol Summary Sheet [SJREB Form 1.2 – Protocol Summary Sheet]
	Informed Consent Forms (in English and in local language)
	Recruitment and Advertisement Materials
	Data Collection Forms
	CVs of PIs
	Study Budget
	Study Protocol
	Technical Clearance
	Proof of parallel submission to at least three (3) study sites

Study-specific Documents (submit as needed):	
	FDA Approval/Clearance (for clinical trials)
	Patient Information Sheet (for clinical trials)
	Investigator Brochure (for clinical trials)
	GCP Certificates of PIs (for clinical trials)
	Other protocol-related documents (please specify):

Received by:
(SJREB Secretariat)

Date:

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FORM 1.2
PROTOCOL SUMMARY SHEET

SJREB Protocol No.	Protocol Title

Coordinating Investigator	Sponsor

Rationale	
Objectives	
Study Design/Methodology	
Inclusion Criteria	
Exclusion Criteria	
Data Analysis Plan	
Study Outcomes	
Ethical Consideration	

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SJREB FORM 2
PROTOCOL ASSESSMENT FORM

To be filled up by primary reviewer
Instructions: Please do literature search to update your knowledge about this protocol

SJREB Protocol No.:		Date (D/M/Y.):	
Protocol Title:			
Coordinating Investigator:			
Institution:			
Total No. of Participants:		No. of Study Sites:	
Expected no. from Philippine sites:			
Sponsor:			

Duration of the Study:		Status:		New		For Renewal of Approval

Reviewers:	

☐	Intervention	☐	Epidemiology	☐	Observational study
☐	Document review	☐	Case study	☐	Genetic
☐	Social Survey	☐	Others *(specify):*		

Review Type:	☐	Full Board	☐	Expedited	☐ Exempted

Description of the Study in brief: Mark whatever applies to the study.					
	Randomized		Drug		Use of Genetic Materials
	Double-blind		Medical Device		Multicenter Study
	Single-blind		Vaccine		Global Protocol
	Open-label		Diagnostics		Sponsor-initiated
	Observational		Questionnaire		Investigator-initiated

A. PROTOCOL DOCUMENT REVIEW (*please put an X before your choice and N/A on the comments if there are no further comments)*

Questions	Comment/s:
1. Objectives of the study Clear / Not clear	
2. Need for human participants Clear / Not clear	
3. Background information Sufficient / Not sufficient	
4. Methodology Clear / Not clear	
5. Sufficient number of participants Yes / No	
6. Control arms (placebo, if any) Yes / No	
7. Data analysis plan Appropriate / Not Appropriate	
8. Study outcomes Defined / Incomplete / Not defined	
9. Level of risk Low / Medium / High	
10. Risk mitigation in the protocol Appropriate / Not Appropriate	
11. Benefits of the participants in the protocol Appropriate / Not Appropriate	
12. Inclusion criteria Appropriate / Not Appropriate	
13. Exclusion criteria Appropriate / Not Appropriate	
14. Withdrawal criteria	

	Appropriate		Not Appropriate	
15. Involvement of vulnerable participants				
	Yes		No	
16. Protection of vulnerable participants				
	Appropriate		Not Appropriate	
17. Voluntary, non-coercive recruitment of participants				
	Yes		No	
18. Are the qualifications and experience of the coordinating investigators/participating investigators, research team appropriate?				
	Yes		No	
19. Disclosure of potential conflicts of interest				
	Yes		No	
20. Facilities and infrastructure of participating sites				
	Yes		No	
21. Community consultation				
	Yes		No	N/A
22. Involvement of local researchers and communities in the protocol preparation and implementation				
	Yes		No	N/A
23. Contribution to local capacity building				
	Yes		No	N/A
24. Benefit to local community				
	Yes		No	N/A
25. Sharing of study results				
	Yes		No	N/A
26. Are blood or tissue samples sent abroad				
	Yes		No	N/A

B. RECOMMENDATION

Decision:		Approval		Minor Revision
		Major Revision		Disapproval

Summary of comments:	

Reviewer's Name:		Date:	

Signature:	

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SJREB FORM 3
INFORMED CONSENT ASSESSMENT FORM

To be filled up by primary reviewer

SJREB Protocol No.		Date (D/M/Y):	
Protocol Title:			
Coordinating Investigator:			

A. INFORMED CONSENT DOCUMENT REVIEW (*please put an X before your choice and N/A on the comments if there are no further comments)*

Questions				Comment/s:
1. Does the Informed Consent document state that the procedures are primarily intended for research?				
	Yes		No	
2. Are procedures for obtaining Informed Consent appropriate?				
	Yes		No	
3. Does the Informed Consent document contain comprehensive and relevant information?				
	Yes		No	
4. Is the information provided in the protocol consistent with those in the consent form?				
	Yes		No	
5. Are study related risks mentioned in the consent form?				
	Yes		No	
6. Is the language in the Informed Consent document understandable?				
	Yes		No	
7. Is the Informed Consent translated into the local language/dialect?				

	Yes		No	
8. Are there vulnerable participants?				
	Yes		No	
9. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants?				
	Appropriate		Not appropriate	
10. Are names and contact numbers from the research team and the REC in the informed consent?				
	Yes		No	
11. Does the ICF provide privacy & confidentiality protection?				
	Yes		No	
12. Is there any undue inducement for participation?				
	Yes		No	
13. Is there provision for medical/psychosocial support?				
	Yes		No	N/A
14. Is there provision for treatment of study-related injuries				
	Yes		No	N/A
15. Is the amount paid to participants stated?				
	Yes		No	N/A

B. RECOMMENDATION

Decision:		Approval		Minor Revision
		Major Revision/ Resubmission		Disapproval

Summary of comments:	

Reviewer's Name:		Date:	

Signature:	

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SJREB FORM 4
CHECKLIST FOR EXEMPTION FROM FULL ETHICAL REVIEW FORM

To be filled up by primary reviewer

SJREB Protocol No.		Date (D/M/Y):	

Protocol Title:	

Coordinating Investigator:	

A. Protocol Assessment

Questions	Comment/s:
1. Does this research involve human participants?	
☐ Yes ☐ No	
2. Does this research involve use of non-identifiable human tissue/ biological samples?	
☐ Yes ☐ No	
3. Does this research involve use of non-identifiable publicly available data?	
☐ Yes ☐ No	
**Protocols that neither involve human participants, nor identifiable human tissue, biological samples and data shall be exempted from review (NEGHHR 2017)*	
4. Does this research involve interaction with human participants	
☐ Yes ☐ No	
5. Type of research (*please tick appropriate box)*	
a. Institutional quality assurance	
☐ Yes ☐ No	
b. Evaluation of public service program	
☐ Yes ☐ No	
c. Public health surveillance	
☐ Yes ☐ No	
d. Educational evaluation activities	
☐ Yes ☐ No	

e. Consumer acceptability test				
	Yes		No	
**These 5 have been identified in the NEGHHR as exemptible, as long as it does not involve more than minimal risk.*				
6. What is/are the method/s of data collection *(please tick appropriate box)*				
a. Surveys and/or questionnaire				
	Yes		No	
b. Interviews or focus group discussion				
	Yes		No	
c. Public observations				
	Yes		No	
d. Research which only uses existing data				
	Yes		No	
e. Audio/video recordings				
	Yes		No	
**These 5 have been identified in the NEGHHR as exemptible, as long as anonymity and/or confidentiality is maintained.*				
7. Will the collected data be anonymized or identifiable?				
	Anonymized		Identifiable	
	De-identified			
8. Is this research likely to involve any foreseeable risk of harm or discomfort to participants; above the level experienced in everyday life? (NEGHRR 2017) **Please refer to section B. Risk Assessment, prior to answering this item*				
	Yes		No	
**If YES, then this protocol does not qualify for exemption*				

B. Risk Assessment

Questions	Comment/s
1. Does this research involve the following: *(please check all that applies)*	
a. Any vulnerable groups?	
Yes / No	
b. Sensitive topics that may make participants feel uncomfortable *(i.e. sexual behaviour, illegal activities, racial biases, etc.*	

	Yes		No	
c. Use of drugs				
	Yes		No	
d. Invasive procedure (e.g. blood sampling)				
	Yes		No	
e. Physical stress/distress, discomfort				
	Yes		No	
f. Psychological/mental stress/distress				
	Yes		No	
g. Deception of/or withholding information from subjects				
	Yes		No	
h. Access to data by individuals or organizations other than the investigators				
	Yes		No	
i. Conflict of interest issues				
	Yes		No	
j. Or any other ethical dilemmas				
	Yes		No	
k. Is there any blood sampling involved in the study				
	Yes		No	

C. RECOMMENDATION

Decision:		Qualified for Exemption
		Unqualified for Exemption

Summary of comments:	

Reviewer's Name:		Date:	

Signature:	

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 4.1
CERTIFICATE OF EXEMPTION FROM ETHICS REVIEW

Date:

This is to certify that the following protocol and related documents have been reviewed and granted exemption from review by the SJREB for implementation

SJREB Protocol No.:		Sponsor Protocol No.:	
Coordinating Investigator:		Sponsor:	
Title:			
Protocol Version No.:		Version Date:	
ICF Version No.:		Version Date:	
Other Documents:			

This protocol is exempted from review for the following reasons: *(check the NEGHHR)*

1.

SJREB Chair	Signature	Date

NOTE:

- Final/Closure Reports should be submitted at the end of the study.
- Any amendment to the protocol should be submitted to SJREB for re-evaluation of exemption.

Received by:

Name: _____

Signature: _____ Date: _____

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 5
NOTICE OF PROTOCOL MODIFICATION

Date: 2020

To *(name of PI)*: _____

Contact Details: _____

Protocol Title: _____

SJREB Protocol Code _____

Sponsor Protocol No. _____

Protocol Version No. and Version Date: _____

ICF Version No. and Version Date _____

Type of Submission
- ☐ Initial Submission
- ☐ Resubmission
- ☐ Others

This is to inform you of the SJREB decision related to the documents you have submitted:

ITEMS FOR REVISION	REVISION/INFORMATION REQUIRED FROM THE PRINCIPAL INVESTIGATOR
Protocol	
Informed Consent Form	
Others	

Please submit the revised documents on or before _____

Type of review	
	Exempted
	Expedited
	Full Board

SJREB Decision			
	Minor revisions required		Approved
	Major revisions required		Others:
	More information required		

Meeting Date:	

SJREB Chair	Signature	Date
Dr. Jacinto Blas Mantaring III		

Republic of the Philippines
Department of Health

SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 5.1
PROTOCOL RESUBMISSION FORM

To be filled by investigator

SJREB Protocol Number	

Sponsor Protocol Number		Submission Date	

Protocol Title:	

Documents revised		Protocol (*latest version number and date*)		ICF (*latest version number and date*)	
		Others (specify):			

Type of Initial Review		Exempted		Expedited		Full Board	

Channel of review for resubmission		Expedited		Full Board

Coordinating PI		Sponsor	

Contact Numbers		Email	

Institution	

REC Recommendations	Revisions made by the PI	Reviewer Comments *(to be filled up by primary reviewers)*

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

Co-PI Signature:	Date:
Received by SJREB Secretariat:	Date:

FOR REC USE:	
Summary of comments:	

Recommendations:	
	Approve
	Request for further information/modification
	Others

Name of reviewer:		Signature:		Date:	

Final Decision:	

SJREB Chair	Signature	Date

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 6
NOTICE OF APPROVAL

Date:

This is to certify that the following protocol and related documents have been granted approval by the SJREB for implementation in accordance with the International Conference on the Harmonization of Good Clinical Practice and the National Ethical Guidelines on Health and Health-related Research

SJREB Protocol No.:		Sponsor Protocol No.:	
Coordinating Investigator:		Sponsor:	
Title:			
Protocol Version No.:		Version Date:	
ICF Version No.:		Version Date:	
Other Documents:			
Members of research team:			
Study sites:			

Type of Review:	☐ Expedited ☐ Full Board Meeting date:	Duration of Approval From – To *(date)* December 28, 2018 to December 28, 2019	Frequency of continuing review Annual

SJREB Chair	Signature	Date

Investigator Responsibilities after Approval:

- Submit country protocol amendments to the SJREB and site REC for approval before implementing them;
- Submit site-specific amendments to site REC for approval before implementing them;
- Submit annual report for renewal of approval to SJREB;
- Submit SAE and SUSAR reports to the site REC within 7 days;
- Submit progress report every 12 months;
- Submit final report after completion of protocol procedures at the study site;
- Report protocol deviation/violation to the REC study sites;
- Comply with all relevant international and national guidelines and regulations; and
- Abide by the principles of good clinical practice and ethical research

Received by:

Name: _____

Signature: _____ Date: _____

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 7
PROGRESS/ANNUAL REPORT FOR PHILIPPINE SITES

SJREB Protocol No.:		Initial Approval Date:	

Protocol Title:	

Coordinating Investigator:		Sponsor:	

Any amendment since the last review? Describe briefly.		Yes		No
Any change in participant population, recruitment or selection criteria since the last review? Explain the changes.		Yes		No
Any change in the Informed Consent process or documentation since the last review? Please explain.		Yes		No
Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? Summarize.		Yes		No
Any unexpected complication or side effect noted since the last review? Summarize.		Yes		No

Were there protocol deviation/ violation reports? Summarize. What corrective actions were taken?		Yes		No
Any new investigator that has been added to or removed from the research team since the last review? Please identify them and submit the CVs of new investigators.		Yes		No

Summary of recruitment:	
	Accrual ceiling set by REC
	New participants accrued since last review
	Total participants accrued since protocol began
	No. of participants who are lost to follow up
	No. of participants withdrawn from the study
	No. of participants who experienced SAEs/ SUSARs

Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion.		Yes		No

---

FOR SJREB USE

Name of Primary Reviewer	

Assessment by the Primary Reviewer:

Questions:	**Yes**	**No**	**Comments:**
Do the risks to the study participants remain reasonable in relation to anticipated benefits?			
Are there new findings in the IB or literature (e.g., important toxicity or adverse event information) that need to be included in the informed consent?			

Is there need to revise the ICF?			
Is there need to re-consent subjects enrolled in the study?			
Are there concerns about conduct of the research team (e.g., suspension of medical license, frequent protocol violation, patient or third party complaints, etc.) or institutional commitment that may affect patient safety?			
Are there concerns about patient safety, inability to comply with the protocol, high dropout rate that affect study implementation?			

Check the protocol file to ensure consistency of the progress report with actual reports (SAE, protocol deviation/ violation, etc.) submitted by the PI

Recommended Action:	
	Approve
	Request further information, *specify*
	Recommend further action, *specify*
Other comments:	

Primary Reviewer:	Signature:	Date:

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 7.1
PROGRESS REPORT FOR GOVERNMENT FUNDED PROTOCOLS

SJREB Protocol No.:		Initial Approval Date:	

Protocol Title:	

Coordinating Investigator:		Sponsor:	

Summary of Accomplishments			
Objectives	Activities (for each objective)	Targets	Accomplishments

Results and Discussion (Detailed discussion of outputs / findings for the period based on target activities)

Problems / Difficulties Encountered (Obstacles/hurdles met and experienced during implementation, explanatory notes for deviation(s) in targets and accomplishments, changes in dates of implementation, etc.)

Proposed or Suggested Solutions (Proposed action(s) to solve problems encountered)

Please submit an endorsement letter from the end-user/sponsor that they have fully received and accept the progress of the study

FOR SJREB USE

Name of Primary Reviewer	

Assessment by the Primary Reviewer:

Recommended Action:	
	Approve
	Request further information, *specify*
	Recommend further action, *specify*
Other comments:	

Primary Reviewer:	Signature:	Date:

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 8
PROTOCOL AMENDMENT APPLICATION FORM

Date of submission	SJREB Protocol No.	Sponsor Protocol No
Principal Investigator	**Email/ Mobile No.**	**Sponsor**

Title of Study	

Study Site/s:		Date of Initial Approval	
		Type of Initial Review: *(Full Board, Expedited, Exempted)*	

Items to be Amended	List of Amendments	Reasons

Signature of PI:	
Date:	

FOR REC USE:				
Assessment of Primary Reviewers	1. Type of amendments:			
		Minor		Major
	Comment/s:			
	2. Does the amendment decrease the risks to participants			
		Yes		No
	Comment/s:			
	3. Does the amendment decrease the benefits to participants?			

		Yes		No
	Comment/s:			
	4. Is there favorable benefit/ risk ratio?			
		Yes		No
	Comment/s:			

Recommendations:	
	Approve
	Request for further information/modification
	Others

Type of review	
	Expedited
	Exempted
	Full Board

Name of reviewer:		Signature:		Date:	

Final Decision:	

SJREB Chair	Signature	Date

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

FORM 9
CLOSURE/FINAL REPORT FORM

(Consolidated report from all sites included in the study)

PROTOCOL CODE:			
PROTOCOL TITLE:			
(INITIAL) APPROVAL DATE:			
COORDINATING INVESTIGATOR:			
Email:		**Mobile:**	
STUDY SITES:			
SPONSOR:			
SPONSOR CONTACT PERSON:		**Email:**	

1. Study Arms:	
2. Summary of Recruitment:	
Accrual ceiling set by REC	
• New participants accrued since last review	
• Total number of participants accrued since protocol began	
• No. of participants who are lost to follow up	
• No. of participants withdrawn from the study	
• No. of participants who experienced SAEs/SUSARs	
3. Number of participants who completer the study:	
4. Amendments to the original protocol (including dates of approval):	
5. Summary of onsite SAEs reported:	
6. Summary of participants' complaints or grievances documented regarding conduct of study:	

7. Summary of benefits to participants:	
8. Summary of indemnifications of study related injury (If Applicable):	
9. If terminated early, specify reason for termination:	
10. Progress reports submitted (with dates of approval):	
11. Duration of the study (months):	
12. Informed consent form used (with version no./date) and attach most recent version:	
13. Study objectives and summary of results:	

SIGNATURE OF PI:	
DATE:	
RECEIVED BY:	
REPORT SUBMISSION DATE: (to be filled out by REC)	

FOR REC USE ONLY:
COMMENTS OF PRIMARY REVIEWER (i.e. compliance with the terms of the approved protocol including post- approval review requirements, and overall assessment of risks against benefits in the conduct of study)

Recommendations:	
	Approve
	Request for further information/modification
	Others

Type of review	
	Expedited
	Exempted
	Full Board

Name of reviewer:		Signature:		Date:	

Final Decision:	

SJREB Chair	Signature	Date

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 9.1
EARLY STUDY TERMINATION APPLICATION

(Consolidated report from all sites included in the study)

SJREB PROTOCOL CODE:			
PROTOCOL TITLE:			
(INITIAL) APPROVAL DATE:			
COORDINATING INVESTIGATOR:			
Email:		**Mobile:**	
STUDY SITES:			
SPONSOR:			
SPONSOR CONTACT PERSON:		**Email:**	
TERMINATION DATE:			

1. No. of participants	
2. No. of enrolled	
3. Reason/s for early termination	
4. Summary of results	
Accrual data	
• How many have completed the study?	
• How many are still active?	
• What are the plans for those who are still active in the study?	

SIGNATURE OF PI:	
DATE:	
RECEIVED BY:	
REPORT SUBMISSION DATE: (to be filled out by REC)	

FOR REC USE ONLY:
COMMENTS OF PRIMARY REVIEWER (i.e. compliance with the terms of the approved protocol including post- approval review requirements, and overall assessment of risks against benefits in the conduct of study)

Recommendations:	
	Approve
	Request for further information/modification
	Others

Type of review	
	Expedited
	Exempted
	Full Board

Name of reviewer:		Signature:		Date:	

Final Decision:	

SJREB Chair	Signature	Date

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 10
NOTICE OF POST-APPROVAL MODIFICATION

Date:

To *(name of PI)*: _____

Contact Details: _____

Protocol Title: _____

SJREB Protocol Code _____

Sponsor Protocol No. _____

Protocol Version No. and Version Date: _____

ICF Version No. and Version Date _____

Initial Approval Date _____

Type of Submission

- ☐ Annual Progress Report
- ☐ Amendment
- ☐ Final Report

This is to inform you of the SJREB decision related to the documents you have submitted:

ITEMS FOR REVISION	REVISION/INFORMATION REQUIRED FROM THE PRINCIPAL INVESTIGATOR
Protocol	
Informed Consent Form	
Others	

Please submit the revised documents on or before _____

Type of review	
	Exempted
	Expedited
	Full Board

SJREB Decision			
	Minor revisions required		Approved
	Major revisions required		Others
	More information required		

Meeting Date:	

SJREB Chair	Signature	Date

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 11
ONSITE SERIOUS ADVERSE EVENT REPORT

Coordinating Principal Investigator:	
SJREB Protocol Code:	
Study Title:	
Sponsor:	
Name of Study Medicine:	
Report Date:	
Onset Date:	
Date of First Use:	

Patient Number	Age	Sex

Patient's History:	
Laboratory Findings:	
SAE:	
Treatment Outcome:	
Management of Adverse Reaction:	

Please check the ones applicable:

Seriousness:		Relation to:					
	Life Threatening		Drug		Device		Study
	Death		Not related				
	Hospitalization		Possibly				
	Disability/Incapacity		Probably				
	Congenital Anomaly		Definitely related				

	Others (please specify)		Unknown

*Please attach standard CIOMS report form

FOR REC USE

Reviewer's Name	Signature	Date

Changes in the protocol recommended?		Yes	Comments:
		No	
Changes to the informed consent form recommended?		Yes	Comments:
		No	

REC Final Action	
	Request an amendment to the protocol or the consent form
	Request further information
	Suspend enrollment of new research participants
	Suspend all trial-related procedures
	Termination of study
	Take note and continue monitoring
	Conduct study site visits
	Others (please specify)

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 12
PROTOCOL VIOLATION/DEVIATION REPORT

Coordinating Principal Investigator:	
SJREB Protocol Code:	
Study Title:	
Sponsor:	
Date of Submission:	
Reported by:	

Protocol deviation:	
Corrective measures done:	

FOR REC USE

Reviewer's Name	Signature	Date

Please check the ones applicable:

Deviation from the protocol:		Participant non-compliance:	
	Minor		Yes
	Major		No
			N/A

REC Recommendation:	
	Noted (no further action needed)
	Correction action needed
	Site visit needed
	Others (please specify)

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM A
DECLARATION OF CONFLICT OF INTEREST

Coordinating Principal Investigator:	
SJREB Protocol Code:	
Study Title:	
Sponsor:	

Declaration of Conflict of Interest				
Are you an employee of the sponsor/s?		Yes		No
Have you done consultancy or part time work for the sponsor/s in the past?		Yes		No
In the past year, did you receive P500,000 or more from the sponsor/s?		Yes		No

Other information	
Do you have other financial or non-financial ties with the sponsor (e.g. employment of relative to the 4th level of consanguinity)	
Are you a member of a policy-determining/recommendatory body that is convened by the DOH, DOST, and other national agencies who lead on COVID-19 response?	

List of all studies you are currently managing			
Title of study	**Sponsor**	**Status of implementation**	**% of time allotted for the study**

Ethical Responsibility and COI Statement

I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Coordinating Investigator (CI)

SIGNATURE	**DATE**

APPENDICES AND FORMS

APPENDIX B

Appendix B.	
	Guidelines for Review of Protocols during Emergency Outbreak

APPENDIX B. Guidelines for Review of Protocols during Emergency Outbreak

Adapted from the WHO Guidelines for Rapid Review of COVID-19 Research

Background

To date, there are no approved treatments or prophylactic products known to be safe and effective for COVID 19, which is similar to previous outbreaks such as Ebola, Zika, or Lassa fever. Consequently, conducting research on new medications or vaccines during this pandemic is essential. Research conducted during pandemics or outbreaks, while in the best interests of communities that are presently affected or could be affected in the future, raises many unique ethical issues.

Different countries will be in different stages of readiness to review epidemic-relevant research. Regardless of preparatory work that has been done so far, there are things that ethics committees can and should do now to prepare for rapid review of COVID-19 protocols. It is necessary that research ethics committees be prepared to rapidly review COVID-19 research.

There have been many articles and reports published after the 2014 Ebola outbreak that address ethical issues in research during outbreaks and research ethics governance[1,2,3,4,5]. Of note, issues were raised about time sensitivity and the balance between the quality and time to review and ensuring the protection of participants in clinical trials, many of whom are in desperate need for any management protocols, lest they lose their lives.

Recently, two workshops were held to address important issues in this context: 1) "Ethics preparedness": Facilitating *Ethics Review During Outbreaks*, organized by ALERRT[6] (**A**frican coa**L**ition for **E**pidemic **R**esearch, **R**esponse and **T**raining)& WHO (World Health Organization) in Dakar, Senegal in March 2018, and 2) "*Ethics review of research on Lassa & other infectious disease outbreaks*", organized by WHO in Abuja, Nigeria in October 2018. These workshops provided

recommendations for addressing how National/Institutional (Research) Ethics Committees (N(R)ECs) and other research review committees should prepare for changes that may be necessary to their Standard Operating Procedures (SOPs) in order to respond efficiently during this pandemic.

Specific Guidelines

To facilitate the rapid or time-sensitive reviews, the following additions or changes to the ethics committees' existing standard operating procedures are being recommended.

> **It is important to note that this guidance should come into action once an outbreak is declared as a public health emergency. This declaration will come from the public health authority of the country. To speed up time to start the research, many processes (e.g., drafting documents, translations, approvals, etc.) will be happening in parallel rather than sequentially as is the case in non-emergencies.**

When a protocol is being considered for submission in a language different from that in which the review is conducted, the synopsis, plan, documents of consent/assent, and data collection tools/ forms at a minimum should be submitted in the official language of the country where the review will take place. Other documents in the reviewing country's language should be submitted as soon as possible.

---

1 World Health Organization (WHO). Guidance for Managing Ethical Issues in Infectious Disease Outbreaks. WHO 2016. ISBN 978 92 4 154983 7

2 Schopper D, Ravinetto R, Schwartz L, et al. Research Ethics Governance in Times of Ebola. Public Health Ethics 2016; doi: 10.1093/phe/phw039 First published online: November 1, 2016.

3 Nuffield Council of Bioethics. Conducting research and innovation in the context of global health emergencies: what are the ethical challenges? Notes of workshop held on 9 December 2016: 10:00–13:30 28 Bedford Square, London WC1B 3JS.

4 Upshur R, Fuller J. Randomized controlled trials in the West African Ebola virus outbreak. Clinical Trials 2016: 1-3. DOI: 10.1177/1740774515617754.

5 The Challenge of Timely, Responsive and Rigorous Ethics Review of Disaster Research: Views of Research Ethics Committee Members. Matthew Hunt, Catherine M. Tansey, James Anderson, Renaud F. Boulanger, Lisa Eckenwiler, John Pringle, Lisa Schwartz. PLOS ONE | DOI:10.1371/journal.pone.0157142 June 21, 2016.

6 Abha Saxena, Peter Horby, John Amuasi, Nic Aagaard, Johannes Köhler, Ehsan Shamsi Gooshki, Emmanuelle Denis, Andreas A. Reis. The ALERRT-WHO Workshop and Raffaella Ravinetto. Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel. BMC Medical Ethics 2019; 20:29

Documentary Requirements

A checklist including the following items should be included in addition to the ethics review form (if used by the research ethics committee):

An option to identify the research as epidemic/outbreak-related in order to facilitate fast-tracking;

An opportunity to describe whether prior research data about the disease exists;

Inclusion of at least one PI or co-PI of the country where research and review is taking place;

Qualification of key investigators, including a description of previous track record with outbreak-relevant research among the research group; and,

An indication whether the protocol is part of a multicenter trial. If yes, an opportunity should be provided to describe the status of ethics approval of the master protocol or the ethics approval of the sponsoring country.

Apart from the basic documents submitted for review (Protocol, CVs, etc.), the following should also be submitted:

Letter of collaboration in the form of a Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA) with sponsor institution(s) and the funder(s) of the research along with declarations of Conflict of Interest when possible;

Monitoring and safety management plan for the project, as provided by the study sponsor;

Both data sharing and material transfer agreements (MTA) for data and human biological material, especially if samples are being exported out of the country, while honoring the laws of the land (a draft may be submitted initially);

Clear processes and procedures/expectations for follow-up dissemination and publication, co-authorship, co-presentation, and Intellectual Property Rights;

Procedures for dissemination of findings to the affected community (important to ensure maintaining contact and upholding trust of the

affected populations, especially research participants); and,

May include local requirements on insurance policies, particularly on trials/interventions.

Meeting Requirements and Procedures

Considerations

To prepare for the review of COVID-19 research, RECs should agree on a process for rapid review and communicate this to researchers (and communicate any anticipated delays for non-COVID-19 research).

Also, practical aspects like: identify surge capacity for review, set up systems for remote discussions (which software platform, does everybody who needs it have access and know how to use it, what will you do if internet isn't functioning etc.)

Membership and Quorum

It is essential that a certain number of members be pre-identified who will share the major burden of review. These members would require specialized training (or equivalent experience) in reviewing research in outbreaks so that they are able to rapidly review research proposals without compromising the ethics. Additional members should be identified and called for review at times when demand increases.

Once an outbreak is imminent or ongoing, the chair or the secretary of the review committee should alert members and ascertain which members would be available for the rapid review.

Identification as well as contacting in advance subject experts (technical) and people with strong knowledge of ethics (both in-country and abroad) willing to serve as ad hoc or co-opted members during outbreaks, as there is a likelihood of receiving multiple projects that need to be reviewed in a short time.

The quorum shall abide by the ICH-GCP requirements.

If pre-identified REC member submits their review but is unable to join the meeting, they should be considered as part of the quorum requirement.

Procedures

The new SOPs should be circulated to all members of the review committee.

The review meetings could be virtual or electronic especially if the risk of face-to-face meeting in highly infectious outbreak like COVID-19 may be risky to the members.

Protocol submission **should** be done electronically to save time with submission of the hard copy, which if mandatory can follow. PIs should contact RECs as soon as possible to communicate their intention to submit as well as a high-level overview of research (is it a trial of new medicine, vaccine, observational study, survey, etc.) so that RECs are aware of protocols that may be forthcoming.

Face to face meetings with the PIs should not be mandatory and if necessary electronic and or virtual venues may be adopted.

Timelines

Protocols should be sent to reviewers within **24-hours of submission**.

Each reviewer should complete their reviews within a specified period of time (usually **3 calendar days** is sufficient and appropriate during an outbreak).

Consolidated review and suggestions (or approval) should be communicated to the PI within a specified period of time (usually **within 5 calendar days**).

The complete review process until issuance of approval should not exceed **14 calendar days**.

Communication

Electronic or telephonic communication with PIs **should** be initiated to seek clarifications, thus saving time.

The PI **should** respond to the review within 48-hour

Focal points/persons for communication in respective institutions and RECs/NECs should be identified as early in the process as possible.

Documentation and Archiving

All communications **should** be documented and archived following the research ethics committee's standard operating procedures.

Department of Health
Health Policy Development and Planning Bureau
Health Research Division