Standard Operating Procedures for Single Joint Research Ethics Board (SJREB)

I. Authority, Composition and Structure of SJREB

Purpose

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

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

- To streamline the review process of health-related protocols to be conducted in multiple sites in the Philippines.
- To harmonize the results of ethics review among various site RECs through joint review
- To strengthen the ethics review capacity of PHREB Level 3 RECs to review different types of protocols that are conducted at their sites
- To shorten the turn-around time of ethics review of multi-site protocols

Scope of Authority

1. SJREB is a joint review mechanism among PHREB duly accredited Research Ethics Committees (RECs) of DOH hospitals. SJREB is available to other non DOH RECs from both public and private organizations that will accept the results of SJREB and sign a letter of intent with SJREB. It is a cooperative mechanism, rather than a stand-alone REC, that draws its review authority from RECs duly accredited by the Philippine Health Research Ethics Board.

2. SJREB conducts joint review of study protocols to be implemented in at least three (3) sites in the Philippines. Sponsors and researchers who choose to do their studies in 3 or more sites may submit their protocols to SJREB. 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.

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.

Responsibility

It is the responsibility of HPDPB with authority under DOH to organize the structure and composition of SJREB to enable it to perform its joint review functions.

Terms of Reference

1) HPDPB has the responsibility to set up and support the SJREB office and secretariat to provide support to its activities.
   a) HPDPB allocates space, office equipment, the IT infrastructure and all the necessary logistical support to enable SJREB to conduct its joint review functions efficiently and effectively.
   b) It appoints an appropriate number of persons to form the SJREB secretariat, composed of the regular staff and consultants to manage SJREB operations. It may appoint consultants with relevant skills to help SJREB perform its review functions.
   c) 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. Preferably, The SJREB Chair should come from the University of the Philippines Manila (UPM), provided that UPM Research Ethics Board (REB) signs a Letter of Intent to join SJREB.
   d) It appoints a non-medical/ non-scientific person to serve as non-affiliated SJREB member.
   e) 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.
   f) It invites the Philippine Health Research Ethics Network (PHREN) to nominate its representative with a fixed term, preferably from the private sector. It appoints an appropriate number of designated subject experts/independent consultants who can assist SJREB review multi-site protocols.
   g) 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.
   h) It is responsible for the preparation of SOPs that are compliant with international guidelines [e.g. International Conference on the Harmonization of Good Clinical Practice (ICH-GCP), etc.] as well as national guidelines and regulations to guide the operation of SJREB.
   i) 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.
   j) It provides a monitoring mechanism to regularly assess SJREB performance as basis for continuous quality improvement.

2) 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 a representative from an accredited REC to preside over a meeting that he/ she cannot attend the meeting.

3) The SJREB Secretariat manages the day-to-day activities of SJREB to include office procedures, communication with various stakeholders and ensuring appropriate REC and site representation during the conduct of review.
   a) The SJREB Secretariat invites reviewers from RECs of sites selected by the sponsor or researcher to conduct the study.
   b) It checks whether the site REC has level 2 or 3 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.
   c) It may invite observers from study sites, without RECs, provided that they are listed in the protocol submitted for review.
   d) It prepares the meeting agenda and minutes of all SJREB meetings for approval of the Chair.
   e) It issues a decision certificate that is binding on all DOH Hospital RECs that will conduct subsequent continuing review of protocols initially approved by SJREB. For non DOH hospitals, their RECs should submit a Letter of Intent to participate in SJREB, but they retain the option to accept or reject SJREB decision.

4) The site RECs that participate in SJREB are responsible for the following:
   a) All DOH Hospital RECs are duty bound to accept the results of SJREB review where qualified DOH Hospital RECs participated in the deliberations and decision making.
   b) Non DOH RECs need to submit a Letter of Intent to SJREB to participate in joint review when their sites are selected by the sponsor for the conduct of multi-site researches.
   c) All RECs participating in joint review agree to share their review responsibilities with SJREB as follows:

- 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.
- 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.

- There should be parallel submission of protocol documents to SJREB and all site RECs. Site RECs are expected to conduct a preliminary review of the protocol documents in preparation for the SJREB meeting.
- DOH Hospital RECs accept the results of joint review while non DOH Site RECs are expected to do expedited review and accept the decision of SJREB except when there are strong ethical issues that need to be addressed. All site RECs will issue a Certificate of Approval together with Notice of REC Decision from SJREB.
- 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 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.

2. Joint Review of Initial Submission

Purpose

To describe the Single Joint Research Ethics Board's (SJREB) procedures in conducting initial and continuing review of multi-site protocol related documents.

Scope

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

1. The SJREB accepts protocols to be implemented in at least three (3) sites in the Philippines. Sponsors and researchers who choose to do their studies in 3 or more sites may submit their protocols to SJREB.
2. SJREB 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.
3. SJREB requires a Letter of Intent to regularly participate in joint review from non DOH Research Ethics Committees when their sites are selected by the sponsors to conduct the study.
4. SJREB requires the site RECs to agree and abide with the procedures that SJREB follows.
5. 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.

Responsibility

The SJREB Secretariat manages all protocol submissions to the SJREB. It covers the actions to be done from the time of submission to the filing of the initial protocol documents in the SJREB office.

2.1 Classification of Protocols Submitted for Initial Review

SJREB classifies protocols into 3 types to determine the appropriate type of review of multi-site protocols.

Detailed procedures for classification into 3 types of review

2.1.1 For Exemption from Ethics Review:

SJREB will issue a Certificate for Exemption.
The SJREB Secretariat in consultation with the Chair or research ethics consultant makes a determination if the protocol meets the exemption criteria as follows:

- Research about public behavior (voting trends, opinion surveys, etc)
- Evaluation of public programs by the agency itself
- Quality control studies by the agency itself
- Standard educational tests and curriculum development
- Surveillance functions of DOH
- Historical and cultural events
- Research involving large statistical data without identifiers
- Research not involving humans

2.1.2 For Expedited Review:

SJREB Secretariat in consultation with the Chair or research ethics consultant checks if the protocol qualifies for expedited review based on the following criteria:

- About a topic that should not result in causing social stigma
- Does not involve vulnerable populations
- Retrospective studies using anonymized data from medical records
- Studies using simple questionnaires without identifiers
- Laboratory research that uses anonymized human tissue/specimen

SJREB Secretariat identifies two or more primary reviewers from the participating sites to conduct initial review through expedited procedures. SJREB may also call for a meeting of the sites to expedite the review. If there is agreement among the reviewers that the protocol is approvable through expedited means, the protocol remains with the expedited reviewers until the protocol documents are modified and finally approved by the primary reviewers.

SJREB Secretariat prepares a Notice of Decision to be signed by the Chair and communicated to the sponsor/ coordinating investigator that submitted the protocol for review and all the participating sites. SJREB expects the participating sites to accept its decision. Each site REC will issue a Certificate of Approval.

2.1.3 For Full-Board Review:

- SJREB Secretariat classifies more than minimal risk protocols for full board review and consults SJREB Chair to confirm its classification.

- SJREB Secretariat informs the site RECs of its receipt of protocols for full board of joint review.

- SJREB appoints primary reviewers from site RECs or invites independent consultants to prepare their comments using SJREB assessment forms and lead the discussion about the protocol during the board meeting.

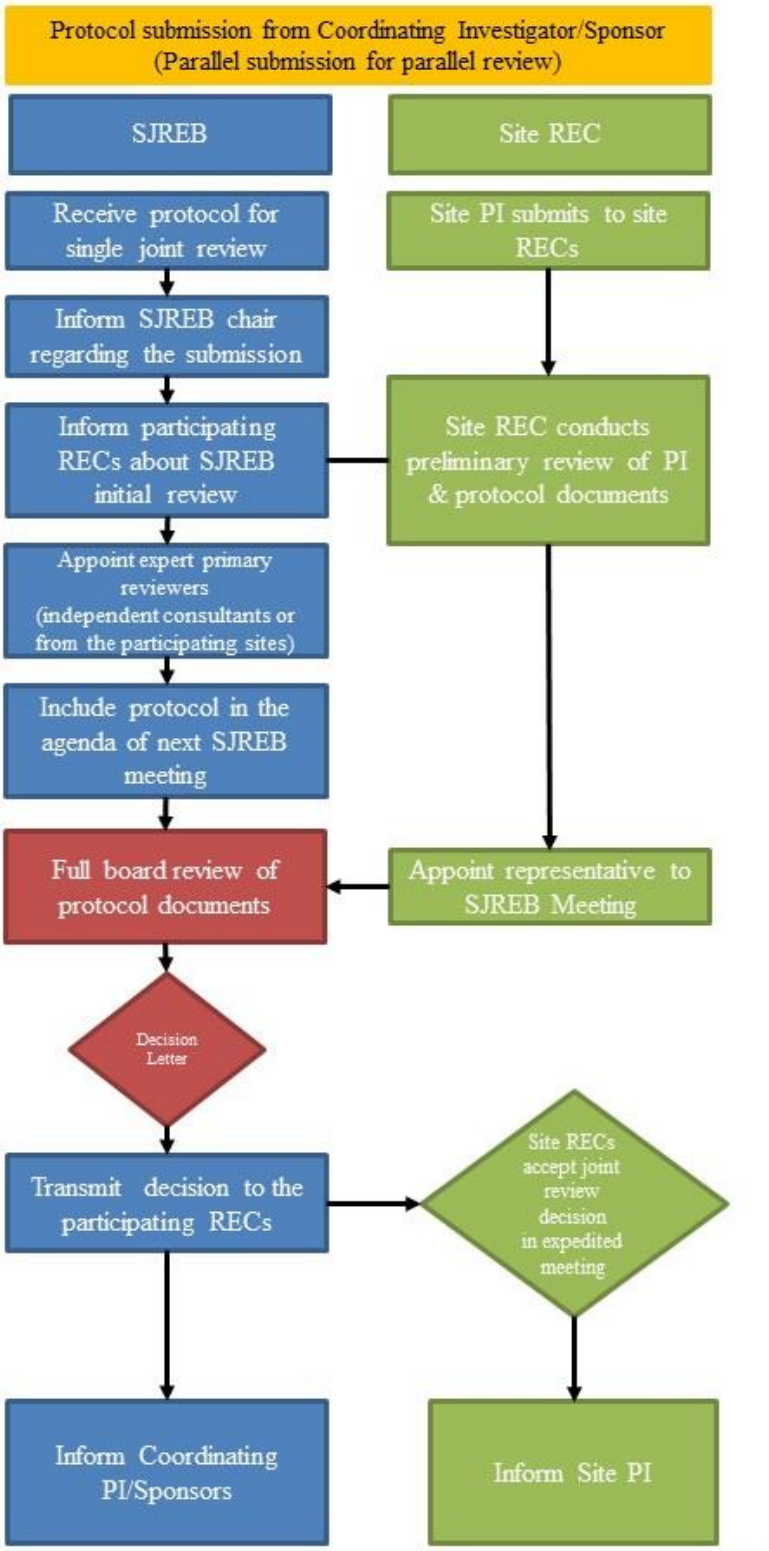
- SJREB Secretariat schedules the date of the full board meeting, prepares the meeting agenda and informs the SJREB Chair, PHREN representative, representatives of site RECs representatives of DOH specialty hospitals, as well as independent consultants to attend the meeting.

- The Coordinating PI, together with the Sponsor representatives are also invited to answer queries about the protocol.

    - Full board adopts one of the following decisions during joint review.
        - Approval
        - Minor modification required
        - Major modification required
        - Disapproved

- SJREB Secretariat informs the Coordinating PI and Sponsor of the results of Joint Review, including recommendations for modification, if any.

- SJREB Secretariat informs all the sites selected to conduct the study of its decision for endorsement of site RECs that are expected to accept the SJREB decision. Each site REC will issue a Certificate of Approval or a notice of its decision if it chooses to disapprove the protocol. The site RECs can disapprove the protocol only when they think that there were strong ethical issues that were not addressed. Reasons for disapproval should always be stated in the decision letter.



Initial and Annual Renewal of Approval Review Procedures

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

2.2 Management of Initial Protocol Submissions

Detailed Procedures

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

- SJREB Secretariat ensures that the Review Application Form and the Protocol Summary Sheet are completely filled up, signed and dated by the sponsor/ researcher submitting the protocol documents.
- The following documents should be submitted in the initial protocol package:
    - Sites where the protocol will be implemented
    - CVs of the coordinating PI and site PIs
    - Research Protocol
    - Versions of informed consent forms (including those translated in the local language)
    - Recruitment and advertisement materials
    - Investigator brochure
    - Other protocol-related documents

- SJREB may require sponsors/coordinating PI to submit to SJREB specific protocol-related documents submitted to the local RECs.
- Only softcopies of the above documents should be submitted to the SJREB.
- Upon submission of the initial protocol for SJREB review, the coordinating principal investigator or his/her representative should ensure that the protocol follows the standard protocol format and contains a Protocol Summary Sheet

2.2.2 Assign a permanent code to the protocol package

- 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).
- 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 will be communicated to the researcher/coordinating investigator in all communications regarding the protocol.

2.2.3 Determine the Type of Review and assign primary reviewers

- The Head of SJREB Secretariat (HoS) in consultation with the SJREB Chair or research ethics consultant makes a determination about the appropriate type of review.
- The HoS identifies primary reviewers from the members of RECs of sites selected to conduct the protocols. Each REC that agrees to participate in joint review should submit its membership roster with corresponding expertise to SJREB.

2.2.4 Distribute the Initial Protocol Documents to the Primary Reviewers

- The SJREB Staff sends copies of protocol documents together with the SJREB Protocol Assessment Form and Informed Consent Assessment Form, with the transmittal letter to the primary reviewers.
- The initial protocol documents should be distributed to the Primary Reviewers within 7 days after submission of documents.

2.3 Full-Board Review Procedures

Detailed Procedures

2.3.1 Before Full-Board Meeting

- The Sponsor/ Coordinating PI submits the multi-site protocol documents to be reviewed to SJREB and to all duly accredited RECs of all the sites selected to conduct the study.
- 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.
- 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 5 members (from participating site RECs) together with the Chair, PHREN representative, specialty hospital representative, and non-affiliated member. Joint review complies with the ICH-GCP quorum requirements.
- The SJREB staff prepares and disseminates the agenda to all participating sites. The agenda includes 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.
- The SJREB full board meeting is regularly scheduled on the second Wednesday of the month.

2.3.2 During Full-Board Meeting

- 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:
  - Coordinating PI
  - Protocol
  - Informed Consent
  - Advertisements or recruitment materials
  - Study sites covered by the application

- The SJREB calls the Coordinating PI/ Sponsor to answer questions about the protocol related documents.
- The SJREB members vote on specific items to arrive at a decision to be recommended to the site RECs as follows:
  - Approval (when no further modification is required)
  - Minor modification (requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.)
  - Major modification (requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data)
  - Disapproval (due to ethical or legal concerns) Reasons for vote of disapproval should be noted in the minutes and communicated to the PI.

- If the study is approvable, SJREB determines the frequency of continuing review. All meeting deliberations and decision regarding a protocol are noted in the meeting minutes.
- Copies of meeting minutes are sent to the site RECs for their information. Site RECs should submit to SJREB copies of their Certificate of Approvals/Notice of Decision.

2.3.3 After the Full-Board Meeting

- Communicate the SJREB decision to the Sponsor/ Coordinating PI for proper action, in case modification is required.
- Minor modification of protocol documents goes to SJREB expedited review while major modification has to go back to full board.
- Once SJREB full board approves the protocol related documents, the decision of joint review is communicated to the Sponsor/ Coordinating PI and all the participating site RECs.

  - Approval: The SJREB Staff prepares the Notice of Approval to be signed by the SJREB Chair.
  - Minor modification: The SJREB Staff prepares the Notification Letter to inform the Sponsor/ Coordinating PI of the required revisions in the protocol, ICF or any related document. The resubmitted documents undergo Expedited Review before approval is granted. The SJREB Chair/Secretariat reviews and checks compliance to recommendations of the resubmitted documents, before granting approval.
  - Major Modification: The SJREB Staff prepares the Notification Letter to inform the PI of a required revisions in the protocol, the ICF or related document. The resubmitted documents are referred to Primary Reviewers and discussed at Full Board Review, once more before approval is granted.
  - Disapproval: The SJREB Staff prepares the Notification Letter to inform the PI of SJREB decision. The reasons should be clearly stated in the notice.

- The local RECs are expected to accept the SJREB decision except when there are strong ethical issues that still need to be addressed. The local RECs have the responsibility to

inform the PI of the local site of the outcome of the SJREB review as well as the outcome of the local REC review.

- The SJREB Staff prepares the Minutes of the SJREB Full-Board Meeting as follows:
    - The SJREB Staff fills up the basic information about each protocol submission for review of the SJREB Meeting Minutes template with identifying information (Protocol number, title, PI, sponsor, etc.) before the meeting date.
    - 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:
        - Date and venue of the meeting
        - Presiding Officer
        - Attendance of REC representatives (medical/scientific; non-medical/non-scientific; non-affiliated with the study site
        - Attendance of independent consultants
        - Attendance of coordinating PI/ sponsor and guests or observers, if any
        - Time when the meeting was called to order
        - Status of quorum at the start of the meeting and before every decision making
        - Discussion of items based on the order in the meeting agenda
        - Summary of technical and ethical discussion points and recommendations
        - SJREB decision and voting results according to decision categories, abstention and votes for disapproval with reasons given.
            - If the review decision (for initial and continuing reviews) is “approved”, the frequency of submission of progress report are determined.
            - If the review decision is disapproved, the reasons for the disapproval are stated.
            - 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.

        - Attach the list of protocols granted exemption and protocols approved through expedited review for the information of SJREB members.
        - Name and signature of the person who prepared the minutes
        - Name and signature of the Chair who approved the minutes with the date of approval

    - The SJREB Staff group-e-mails the copy of the provisional meeting minutes to the SJREB Members for their review and comments within 7 days from the meeting date. The SJREB Members are expected to e-mail their corrections to the group for their approval.

- The SJREB Staff distributes the final version of the minutes of the meeting together with the Notice of Meeting for the next SJREB meeting.
- During the next full board meeting, the Chair asks the members to approve the Minutes.
- The SJREB Staff files approved meeting minutes in the online database of Meeting Minutes.

III. Continuing Review Procedures

Detailed Procedures

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

The Coordinating PI/ Sponsor submits to SJREB the latest versions of the Investigator Brochure (IB), current versions of the protocol, informed consent forms (ICF) and summarizes in the progress report form all protocol amendments, protocol deviations/ violations and on-site SAEs/SUSARs etc., as well as participant recruitment since the last SJREB approval.

3.2 The SJREB Staff notifies all site RECs about the continuing review submissions.

The Site REC representative collects 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.

3.3 The SJREB Staff sends the progress report package to the primary reviewers at least 7 days before full-board meeting.

- Primary reviewers refer to the IB and progress report document to check if the protocol and the ICF contain updated information related to patient safety. Review comments should consider the following:
    - 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.
    - 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)
    - 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.
    - 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)

3.4 The SJREB staff includes all progress report submissions in the agenda of the full board meeting for discussion of participating representatives from site RECs.

3.5 SJREB members are convened in a Full-Board Meeting to discuss the issues and arrive at any of the following decisions:

- Renew approval
- Request additional information
- Recommend modification
- Suspend: enrollment of new subjects; research procedures in currently enrolled subjects; entire study;
- Disapprove renewal

- Approval of progress report reviewed by the Primary Reviewers by expedited procedure is reported to the board meeting by the Chair/Head of SJREB Secretariat.

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

- 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.

3.7 The SJREB Staff 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.

IV. Documentation and Archiving

Detailed Procedures

4.1 SJREB Staff maintains a protocol file to contain all action taken on protocols submitted for review.

The SJREB Staff properly labels active and inactive files in the database.
It maintains a database that contains complete and updated information about all protocol submissions.

4.2 SJREB will follow the following archiving procedures:

- Studies are considered to be completed and inactive when the closure/final report of the study has been reviewed and approved by the site REC and forwarded to SJREB. Studies are also classified as inactive when no further communication has been received by SJREB after two years.
- The SJREB Staff requests all site RECs to notify SJREB about final reports submitted to them. Once the Sponsor/ Coordinating confirms completion of the clinical trial in the various Philippine sites, the SJREB Staff removes the protocol file folders from the database for active studies, to be transferred to the inactive files database.
- Protocols are archived for 3 years. After 3 years in the archive, the protocol files may be transferred to an offline hard disk

Appendix A. Forms

SJREB FORM 1

APPLICATION FOR SJREB INITIAL REVIEW

To be filled up by the Coordinating Investigator

		Protocol Number:	
Sponsor Protocol Number:		Submission Date:	
Protocol Title:			

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

Study Duration:			
Sponsor:			
Coordinating Investigator:			
Telephone number:		Fax:	
E-mail:		Preferred means of contact	☐ Phone ☐ Fax ☐ Email
Institution:			

Declaration of Conflict of Interest (COI)				
Are you an employee of the sponsor/s?	☐	Yes	☐	No
Did you do consultancy or part time work for the sponsor/s?	☐	Yes	☐	No
In the past year, did you receive P500,000 or more from the sponsor/s?	☐	Yes	☐	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:

- ☐ Protocol summary
- ☐ Patient information sheet
- ☐ Informed consent form
- ☐ Advertisement
- ☐ CVs
- ☐ GCP certificates
- ☐ Study budget
- ☐ Revised protocol

Received by SJREB Secretariat:
(name)
Date:

SJREB Form 2
PROTOCOL EVALUATION FORM

To be filled up by primary reviewer

Instructions: Please do literature search to update your knowledge about this protocol

Protocol No.:		Date (D/M/Y.):	
Protocol Title:			
Coordinating Investigator:			
Institution:		Contact no./ Email:	
Co – PI/ Members of the Research Team:		Contact no./ Email:	
Total No. of Participants: Expected no. from Philippine sites:		No. of Study Sites:	
Sponsor:		Contact No/ Email:	
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 ☐ **Exempt**

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

1. Objectives of the Study	**Comments/what should be improved?**
☐ 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	
☐ Negligible ☐ Low ☐ Medium-High	
10. Risk mitigation in the protocol	
☐ Appropriate ☐ Not appropriate	
11. Benefits to 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 ☐ N/A	
15. Involvement of Vulnerable Participants	
☐ Yes ☐ No	

16. Protection of Vulnerable Participants	**Comments/what should be improved?**
☐ 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 communities	
☐ Yes ☐ No ☐ N/A	
25. Sharing of study results	
☐ Yes ☐ No ☐ N/A	
26. Are blood/tissue samples sent abroad	
☐ Yes ☐ No ☐ N/A	

B. RECOMMENDATION

DECISION:	☐	Approval	☐	Minor Revision
	☐	Major Revision/ Resubmission	☐	Disapproval

Summary of comments:	

Reviewer's Name:		Date:	

Signature:	

SJREB FORM 3

INFORMED CONSENT EVALUATION FORM

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

A. INFORMED CONSENT DOCUMENT REVIEW	COMMENTS/ WHAT SHOULD BE IMPROVED?
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 contained comprehensive and relevant information? ☐ Complete ☐ Incomplete	
4. Is the information provided in the protocol consistent with those in the consent form? ☐ Consistent ☐ Inconsistent	
5. Are study related risks mentioned in the consent form? ☐ Complete ☐ Incomplete	
6. Is the language in the Informed Consent document understandable? ☐ Clear ☐ Unclear	
7. Is the Informed Consent translated into the local language/dialect? ☐ Yes ☐ No	

	COMMENTS/ WHAT SHOULD BE IMPROVED?
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? ☐ Complete ☐ Incomplete	
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? ☐ Appropriate ☐ Inappropriate ☐ N/A	
14. Is there provision for treatment of study-related injuries ☐ Appropriate ☐ Inappropriate ☐ N/A	
15. Is the amount paid to participants stated? ☐ Appropriate ☐ Inappropriate ☐ N/A	

B. Recommendation

DECISION:	☐ Approval	☐ Minor Revision
	☐ Major Revision/ Resubmission	☐ Disapproval

Summary of comments:	

Reviewer's Name:		Date:	

Signature:	

SJREB Form 4
SJREB NOTICE FOR PROTOCOL MODIFICATION
(for initial and continuing review)

Date _____

To: (Name of CI) _____
Contact No.: _____
Protocol Title: _____
Protocol No./ Version Date: _____
ICF Version No./ Version Date: _____
Sponsor Protocol No.: _____

Type of Submission:

☐	Initial Review	☐	Resubmission
☐	Amendment	☐	Progress Report
☐	Final Report	☐	Others

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

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

Please submit the revised documents within 15 days from receipt of this notice.

Type of review		SJREB Decision	
☐	Expedited	☐	Approved
☐	Full board	☐	Minor revisions required
☐	Exempt	☐	Major revisions required
Meeting Date:		☐	More Information Required
		☐	Others

SJREB Chair Person	Name	Signature	Date

SJREB FORM 5
Notice of Approval

Date _____

This is to certify that the following protocol and related documents have been granted approval by the SJREB for implementation

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 (date) To	Frequency of continuing review

SJREB Chair Person	Name	Signature	Date

Investigator Responsibilities after Approval:

- Submit document amendments to the site REC 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 ____ 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 _____

SJREB FORM 6

PROGRESS/ANNUAL REPORT FOR PHILIPPINE SITES

To be filled up by the Coordinating Investigator

Protocol No.:		Initial Approval Date	
Protocol Title:			
Coordinating Investigator:		Sponsor:	

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

Summary of recruitment:

- ☐ Accrual ceiling set by SJREB
- ☐ 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. ☐ No ☐ Yes

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For SJREB USE
Comments of Primary Reviewer

Name of Primary Reviewer:		Date Received:	

Assessment by the Primary Reviewer:

	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 reconsent 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
_____ (e.g. Require protocol/ ICF amendment, re-consent) to address concerns about patient safety)

Other Comments:

Primary Reviewer:	Signature:	Date: