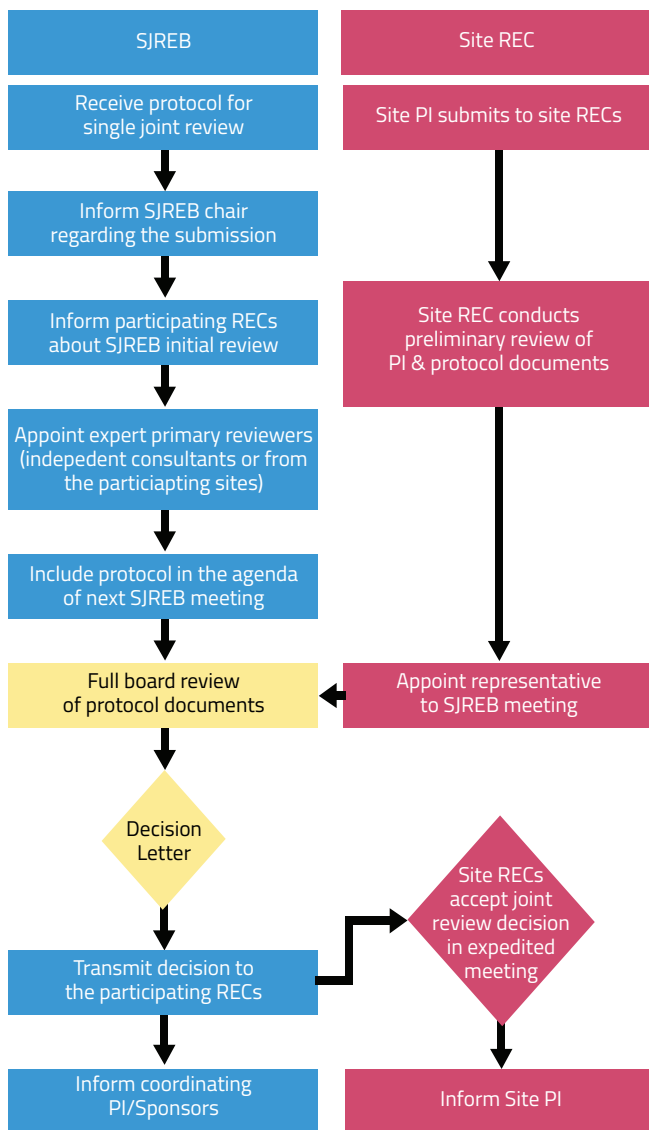


**Protocol submission from
Coordinating Investigator/Sponsor
(Parallel submission for parallel review)**



Legend:
 Black - PI/Sponsors
 Blue - SJREB Secretariat
 Yellow - Joint Review
 Red - Site RECs

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

**Access the Standard
Operating Procedures (SOP)
from Department Circular
2017-0354**



**Single Joint
Research Ethics Board**

For inquiries, please contact:

SJREB Secretariat

Health Policy Development and Planning Bureau
 Department of Health - Philippines

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FAQs

1. What is the Single Joint Research Ethics Board?

Single Joint Research Ethics Board or SJREB is organized by the Department of Health to conduct a *harmonized review* of health-related research protocols involving three (3) or more sites to shorten turnaround time of review.



2. When should investigators/sponsors submit their protocol to SJREB?

Protocols must be submitted *on or before the 4th Wednesday of the month* for it to be included in the succeeding month's meeting agenda. The board meets every *2nd Wednesday of the month*.



3. What documents should be submitted and to whom should the requirements be submitted?

The following are requirements for application to SJREB review:

BASIC DOCUMENTS:

- Application Form [SJREB FORM 1 - APPLICATION FORM 1]
- Protocol Summary Sheet [SJREB FORM 1.2 - PROTOCOL SUMMARY SHEET]
- Informed Consent Forms (in English and in local language)
- Recruitment and Advertising Materials
- Data Collection Forms
- CVs of PIs
- Study Budget
- Study Protocol

STUDY-SPECIFIC DOCUMENTS (SUBMIT AS NEEDED):

- Technical Clearance/FDA Approval
- Patient Information Sheet (for clinical trials)
- Investigator Brochure (for clinical trials)
- GCP certificates of PIs (for clinical trials)
- Other protocol-related documents

Please e-mail sjreb@doh.gov.ph for templates of SJREB Forms 1 and 1.2. The investigator/sponsor shall submit the protocol documents to the SJREB and to the participating site RECs simultaneously. SJREB only accepts soft copies of protocols.



4. How much does the review cost?

While the SJREB *does not* charge any fee, the investigator/sponsor shall still pay the ethics review fees of each participating site.

5. How does the SJREB review protocols?

SJREB classifies protocols into three types to determine the appropriate type of review: exempt from ethics review, expedited review, full board review.

6. Who conducts the review?

- For protocols that qualify for *expedited review*, two or more primary reviewers shall conduct initial review.
- For protocols that require *full board review*, SJREB permanent members who are appointed by the Secretary of Health and representatives from the participating site RECs shall review the protocol together. Decisions are arrived at through majority vote of members present.



7. Does the investigator/sponsor need to be present during the SJREB meeting?

The investigator/sponsor may be required to attend to answer clarificatory questions.

8. How will I know the decision of the SJREB?

- For protocols *exempted* from review, the SJREB secretariat shall issue a Certificate of Exemption.
- For protocols that have undergone *expedited* and *full board* review, the SJREB secretariat shall forward a Notice of Decision to the participating site RECs and the investigator/sponsor. The participating site RECs shall then issue the corresponding Certificates of Approval to the investigator/PI.

9. For protocols deemed suitable for expedited or full board review, what are the possible types of decision by the SJREB?

- Approved
- Minor modification required
- Major modification required
- Disapproved



10. How long does it take for the SJREB to come up with a decision?

Decisions shall be received by the investigator/sponsor within 7-15 days after the SJREB meeting.

11. Is the SJREB accredited by the Philippine Health Research Ethics Board?

Since no accreditation mechanisms currently exist for joint reviews, the SJREB draws its powers from the accredited participating sites, i.e. participating sites issue Certificate of Approval.

12. Does SJREB accept protocols that are not multi-site?

No.