**LIST OF SOPS 2024 PHREB**

SOP 01 Selection and appointment of members (regular and alternate),

SOP 02 Designation of officers

SOP 03 Appointment of independent consultants

SOP 04 Management of Initial Submissions

SOP 05 Exemption from Review

SOP 06 Expedited Review

SOP 07 Full Review

SOP 08 Joint review (if applicable)

SOP 09 Review in Public Health Emergencies

SOP 10 Other types of review

SOP 11 Management of Re-submissions

SOP 12 Management of Appeals

Management of Post Approval Submissions

SOP 13 Review of Progress Reports

SOP 14 Review of Amendments

SOP 15 Review of Protocol Deviations and Protocol Violations

SOP 16 Review of Safety Reports

SOP 17 Review of Final Reports

SOP 18 Review of Early Termination Reports

SOP 19 Management of Applications for Continuing Review

SOP 20 Conduct of Site Visit

SOP 21 Management of Queries, Complaints and Feedback

SOP 22 Preparation for a Meeting

SOP 23 Preparation  of the Meeting Agenda

SOP 24 Conduct of Meeting

SOP 25 Preparing the Minutes of Meeting

SOP 26 Communicating REC Decisions

SOP 27 Management of Incoming and Outgoing Communications

SOP 28 Management of Active Files

SOP 29 Archiving of Files

SOP 30 Access to Confidential Files

SOP 31 Communication and coordination with other research ethics

oversight stakeholders (committees, regulatory authorities, and

others)

SOP 32 Annual Performance Evaluation (Internal AUDIT) on: Members,

Staff, Compliance to SOP, Quality of work, Complaints and

Feedback

SOP 33 Other SOPs

SOP 34 Writing and Revising SOPs

**Functioning REC Website or webpage in MM website should have on the following items available:**

1. Current membership list
2. Schedule of meetings
3. SOP and downloadable and editable REC forms,
4. MMERC Review Process flowchart,
5. Instructions for protocol submissions for researcher and sponsor-initiated protocols
6. List of approved protocols, date of approval, and PIs,
7. Platform on Queries/Complaints/Feedback/Survey Forms
8. Frequently Asked Questions (FAQ)
9. Funding information available upon request,
10. Research participant’s rights (PHREB CPFCE informational materials and other
11. institutional materials)
12. Link to the international and national references

**The institutional issuance shall contain the following:**

1.  all research involving human participants shall undergo ethics review by the REC;

2.  the REC shall adhere to international, national and institutional guidelines and regulations;

3.  Policy/guidelines on compliance with the Data Privacy Act of 2012;

4. the institution has a mechanism to investigate allegations of unethical conduct by researchers and to impose consequences or to establish a Research Integrity Office;

5.  requirement that all researchers affiliated with it be  trained in their responsibilities for ethical conduct of  research;

6.  statement on the responsibility of the institution and researchers  (i.e., faculty, staff, students and trainees) to provide mechanisms for care for research related injuries.

    7.  constitution, functions, and responsibilities of the REC;

8.  terms of Reference (TOR) of REC Members;

9. REC members and chairs are protected from being removed  prior to the expiration of their terms, except for good cause;

10.  the independence of the REC in decision-making, decisions cannot be overruled except in cases of abuse of authority as determined by a regulatory agency or court

   11.  authority of REC to terminate or suspend studies; and

1. commitment to support the operations of the REC (legal, administrative, financial, technological)