SHAHEED ZULFIQAR ALI BHUTTO MEDICAL UNIVERSITY

No.F.2-2/ERB/SZABMU/2025-1910 March 19th, 2025

Subject: **STANDARD OPERATING PROCEDURES FOR CLINICAL TRIALS**

Background:

An Ethical Review Board (ERB) is an Ethics Review Committee that ensures human research subjects' rights are protected, as well as the rights of the patients who ultimately benefit from the research. The ERB has the authority to approve, require modification to, and disapprove research.

ERB Team Members:

The ERB of SZABMU is composed of physicians, scientists, legal advisors, non-scientist personnel, and a representative from the community which is selected to draw the human subjects. The quorum of ERB SZABMU refers to the minimum number of voting members. Members with a conflict of interest regarding a specific study will not participate in deliberations or voting on that study. If the quorum of notified members is not complete the Chairman has the right to add a senior faculty member with prior experience of working in ERB SZABMU.

Role of ERB in Trials:

The Ethical Review Board (ERB) plays a crucial role in clinical research by ensuring studies involving human participants are conducted ethically and in compliance with regulations. Here's a breakdown of the responsibilities:

- Reviewing Research Protocols: ERB meticulously evaluates research proposals before studies can commence, assessing ethical implications, scientific validity, potential risks and benefits to participants. This includes ensuring the research design is sound and methods are appropriate.
- Ensuring Informed Consent: A cornerstone of ethical research is informed consent, where participants are fully aware of the study's nature, risks, benefits, and their rights. ERB reviews consent documents and processes to ensure clarity, comprehensiveness, and understandability, empowering participants to make informed decisions.

- Monitoring Ongoing Research: ERB oversees the progress of studies, reviewing modifications to protocols and assessing reports of adverse events to ensure continued adherence to ethical standards.
- Protecting Vulnerable Populations: ERB pays special attention to research involving vulnerable groups like children, pregnant women, prisoners, and individuals with cognitive impairments, ensuring additional safeguards are in place to prevent exploitation or coercion

Responsibilities:

Informed consent is a critical consideration for ERB in their mission to ensure the protection of the rights and interests of the human subjects of research trials. The ERB is responsible for determining that informed consent forms provided to research subjects include all required information about the nature and extent of the activities involved in the research and that the forms were reviewed and signed by the trial subjects. The ERB must ensure that the study team provides proof that the investigators, medical, and scientific professionals involved in the study fully understand the ethical and technical requirements along with the standards that must be met in conducting the research.

The information required by ERB includes:

- A clear definition and explanation of the activities, procedures, and protocols involved in the research.
- Specific information on the composition of the subject population and the inclusion/exclusion criteria used in the selection of human subjects.
- Proof of informed consent — the voluntary participation of human subjects.
- Documentation of the risks and benefits of the proposed research.

The ERB further protects the interests of human subjects by reviewing the research trial to ensure an appropriate balance of risks and benefits. Risk minimization efforts can include the use of already available data or processes. It also ensures the right of monitory benefits of the subjects in terms of inconvenience allowance, insurance and other implications involving financial burden on the study subjects.

Procedures for ERB Review

The ERB meetings are conducted on a monthly basis in SZABMU. The documents for the ERB review must submitted at least 15 days before the meeting. In case of expedited review at least 7 working days will be required from date of document submission to the final approval. The ERB Review Process is as follows:

- The ERB meeting coordinator assigns the submission to ERB members for initial review.
- The ERB members review the submission and may request additional information or modifications.
- A meeting of ERB is held to discuss the submission and make a decision.
- The ERB Coordinator communicates the decision to the PI through an approval/regret letter.

The reviewers are required to review all submitted documents in advance of convened meetings in depth to be familiar with and be prepared to discuss the protocol. The ERB reviewers of SZABMU are responsible for presenting their findings, providing an assessment of the merits and safety of the protocol, reviewing the consent process (in the absence of a secondary review), and recommending specific actions to the ERB.

The team members must lead the discussion of the study at the convened meeting. For studies qualifying for expedited review, designated expedited reviewers are expected to perform an in-depth review of all documents submitted by the Investigator. Each assigned reviewer describes their findings and determines whether the study meets the minimum criteria for initial approval.

Additional documents are required when a study necessitates additional consideration by the ERB (e.g., the study involves a vulnerable group, the use of a medical device, the use of an investigational drug, etc.). Completed review documents are submitted and become a part of the electronic record and form the basis for communication with the Investigator.

Notification of ERB Review

The ERB coordinator of SZABMU notifies the Investigator of the ERB's determination within seven working days of the convened board meeting. The written notification includes the ERB's decision with requested revisions or requested clarification when applicable. Approval will not be

granted until all of the board or expedited reviewer recommendations and requests are appropriately addressed.

Ongoing Reporting Requirements and Timelines:

To ensure continued compliance and monitoring of the clinical trial, the following ongoing reporting requirements and timelines are established:

- **Annual Progress Report Submission for Renewal:** Investigators are required to submit detailed progress reports every three months. These reports should include enrollment numbers, adverse events, protocol deviations, and any preliminary findings.
- An annual review and re-approval of the study are required. Investigators must submit an annual report that includes a summary of the study's progress, any modifications made, and plans for the coming year.
- **Serious Adverse Event (SAE) And Suspected Unexpected Serious Adverse Reactions (SUSARs) Reporting:** All SAEs and SUSARs must be reported to the ERB within 24 hours of occurrence. A detailed follow-up report must be submitted within seven days.
- **Amendments in study related documents:** Any changes to the study related documents including protocol, ICF, etc. must be submitted for ERB review and approval before implementation. This includes changes in study design, procedures, or consent documents.
- **Safety Reports:** Periodic safety reports must be submitted to the ERB, following ICH E2F guidelines, to provide updated information on the safety of the investigational product.
- **Final Report:** Upon completion of the study, a comprehensive final report must be submitted to the ERB within 60 days. This report should include all findings, conclusions, and any issues encountered during the study.
- **Changes in Key Personnel:** The ERB must be notified of any changes in the study's principal investigator or other key personnel.

The ERB will review these documents/reports to ensure the study is progressing as planned and that the rights and welfare of the participants are protected.

Post-Approval Monitoring:

- The PI must comply with all ERB requirements for ongoing reporting and monitoring.
- The ERB may conduct audits or site visits to ensure compliance with approved protocols and regulations.

Non-Compliance:

- Any instances of non-compliance with ERB requirements must be reported immediately.
- The ERB will review non-compliance reports and take appropriate action, which may include suspension or termination of the study.

Review of Reports:

- The ERB will review all submitted reports to ensure the study is progressing as planned and that the rights and welfare of the participants are protected.

Review of Requested Revision: Based on the terms of approval at the time of initial review, the ERB will review the Investigator's request for revisions and will approve the revised versions upon submission of the revised documents after consultation with all members during the meeting.

List of Documents

The following documents are required for submission to the Ethical Review Board for approval:

S. No.	Requirements of SZABMU ERB
1.	Filled and signed Ethical Review Board (ERB) Proforma
2.	Trial Protocol/Study Synopsis
3.	Informed Consent form (English)
4.	Informed Consent form (Urdu)
5.	Data Collection Tool/ Original Record / Worksheet
6.	Agreement/MoU/Affidavit of financial management (signed pages showing Patients Inconvenience Allowance and Insurance if the other details are confidential)

7.	Insurance policy
8.	Approval of National Bioethics Committee/ DRAP (if applicable)
9.	Case monitoring records (English)if applicable
10.	Cue cards (English) if applicable
11.	Cue cards (Urdu) if applicable
12.	Contact card vaccination approval (English) if applicable
13.	Contact card vaccination approval (Urdu) if applicable
14.	Diary Card - Urdu if applicable
15.	Diary Card - English if applicable
16.	Any other and/or Updated versions of the protocol in case of any amendment made and all other documents used in clinical trials.
17.	Adverse Reactions (ARs), Adverse Events (AEs), Severe Adverse Reactions (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSARs) And Development Safety Update Report (DSUR) if applicable

This is issued with approval of the Vice Chancellor

(Prof. Dr. Moosa Khan)
Vice Chancellor

Distribution:

- All Members of ERB

Copy for information:

- PSO to Vice Chancellor, SZABMU
- PA to Registrar, SZABMU
- Senior Biostatistician, SZABMU
- Deputy Director, IT, with request to upload on official website of SZABMU
- Office File.