# SHAHEED ZULFIQAR ALI BHUTTO MEDICAL UNIVERSITY

No.F.2-2/ERB/SZABMU/2025-1908 March 19th, 2025

Subject: **STANDARD OPERATING PROCEDURE FOR ETHICAL REVIEW BOARD**

**Background:**

An Ethical Review Board (ERB) is an Ethics Review committee that is in place to ensure 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:**

Following the guidelines, the ERB of SZABMU is composed of physicians, a scientist, legal advisor, a non-scientist and a representative from the community from which the human subjects are drawn. 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.

**Meetings of the IARC Ethics Committee:**

- ERB meetings are arranged by the Secretariat, which is responsible for all administrative aspects of the ethics review process including the pre-screening of applications. The Composition of the ERB is provided by the Registrar's Office.
- Meetings to review applications are held once a month in the Syndicate Hall/Vice Chancellor Secretariat. Members that cannot be physically present may attend the ERB meetings remotely by videoconference.
- The quorum for ERB meetings is 5 members. Meetings require the attendance of a majority of the members and of at least one lay member.
- In the absence of the ERB Chair, he/she will nominate one member of the committee who will act as Chair of that meeting.

Declarations of interest of Committee members

To ensure the complete objectivity of ERB in its proceedings, the following is required:

- ERB members must declare any generic potential Conflict of Interest (COI) by completing a "Declaration of Interests" form. They are required to inform the Secretariat of any changes that may occur at any time.
- In advance of each meeting and at receipt of the review assignment, each ERB member must declare any potential COI in relation to specific applications being

evaluated (e.g. he/she is the Principal Investigator – PI, a collaborator, or is in any other way linked to the study being evaluated).

If an ERB member has declared a COI in relation to a particular study, he/she takes no part in the decision on that study. Where the Chair has a potential COI, that item(s) will be chaired by the Vice-Chair or by another member of the committee in his/her absence.

The minutes should record all declarations of interest and decisions of the ERB on the procedure followed.

**Responsibilities**

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 study subjects. ERB committee provides answers with proof that the investigators, medical and scientific professionals involved in a study fully understand the ethical and technical requirements and standards that must be met in conducting the research.

The information the ERB is looking for 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; and
- Documentation of the risks and benefits of the proposed research
- The ERB further protects the interests of human subjects by reviewing the research study in order to insure 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. 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.

- In case of the graduate/post graduate research synopsis, the student responsible for conducting his/her research should attend the meeting in person while the presence of supervisor in not mandatory.
- In case of research projects/articles, the principal investigator or his nominee is required to attend the meeting in person or virtually which should be communicated to the section one week before the meeting.
- The ERB Coordinator communicates the decision to the PI through a 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 methodology to the ERB.

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, sponsored projects/trials 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.

**Post-Approval Monitoring:**

- The PI/supervisor/student must comply with all ERB requirements for ongoing reporting and monitoring.
- The ERB may conduct audits of the study 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.

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**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**

| S. No. | Requirements of SZABMU ERB |
|---|---|
| 1. | Filled and signed Ethical Review board (ERB) Performa |
| 2. | Informed Consent form (English) |
| 3. | Informed Consent form (Urdu) |
| 4. | Information collection tool |
| 5. | Study Synopsis |
| 6. | Declaration for Financial coverage by the PI/Student |

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.