

## **TERMS OF REFERENCE**

### **Research Ethics Application Procedures at Branch and Faculty Ethics Review Committee (BERC and FERC)**

This Terms of Reference (TOR) is a document that describes the structure and composition of *Jawatankuasa Penilaian Etika Fakulti* (Faculty Ethics Review Committee) and *Jawatankuasa Penilaian Etika Cawangan* (Branch Ethics Review Committee). The appointment, responsibilities and relevant procedures for ethics application involving the faculty and branch ethics review committees are also outlined in this TOR.

#### **DISCLAIMER**

This TOR aims to assist and guide the Chairperson, committee members and Secretariat of the Faculty Ethics Review Committee and Branch Ethics Review Committee in discharging their respective duties and responsibilities. This TOR does not substitute the Malaysian Guidelines for Good Clinical Practice (GCP), Declaration of Helsinki (Declaration) and other relevant laws and regulatory requirements. The GCP and the Declaration of Helsinki remain as the primary and definitive source of ethical principles governing the conduct and review of research involving human participants.

No.	Description/Procedure
1.1	<p><b>Overview of UiTM Research Ethics Committee (UiTM REC), Branch Ethics Review Committee (BERC) and Faculty Ethics Review Committee (FERC)</b></p> <p>(a) This TOR is applicable to BERC and FERC members.</p> <p>(b) The BERC and FERC must refer to ICH/ Malaysian Guidelines for Good Clinical Practice as the main reference in performing their duties under the TOR.</p> <p>(c) The BERC and FERC must also operate in conformity with the Declaration of Helsinki and the relevant laws and regulatory requirements.</p>
1.2	<p><b>Scope of the BERC/FERC</b></p> <p>(a) To review applications for ethics approval for research involving human for Undergraduate and Postgraduate by Coursework students only;</p> <p>(b) To identify the categories of risk either as:</p> <ul style="list-style-type: none"> <li>i. minimal risk - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests; or</li> <li>ii. more than minimal risk - research activities that present greater than minimal risk to human participants. Any research that falls under this category must be forwarded to UiTM REC;</li> </ul> <p>(c) To approve or disapprove the proposed research;</p> <p>(d) To impose restrictions and conditions on the proposed research, if necessary;</p> <p>(e) To suspend or revoke ethics approval of the proposed research, if necessary.</p> <p>*Note: The Research Risk Classification Section in F/BERC 1/2021 form will be used to assist risk categorization.</p>
1.3	<p><b>Appointment</b></p> <p>(a) The associate members of UiTM REC (Associate Members) will be appointed by the Deputy Vice Chancellor of Research and Innovation.</p> <p>(b) The Chairperson and FERC members will be appointed by the Dean of the respective faculty or equivalent.</p> <p>(c) The Chairperson and BERC members will be appointed by the Rector of the respective branch campus.</p> <p>(d) The FERC/BERC may recommend the appointment of new Associate Member(s) if the need arises.</p>

<p>1.4</p>	<p>(e) The Chairperson and committee members will be appointed based on their scientific knowledge and expertise and their commitment.</p> <p>(f) The duration of the appointment of the Chairperson is according to the terms of appointment as Deputy Dean/Deputy Rector, and for other members are for not less than two (2) years.</p> <p>(g) The appointment of the committee members and Secretariat may be renewed on the recommendation of the Chairperson.</p> <p><b>Responsibilities</b></p> <p>(a) The Chairperson and members of the FERC and BERC, and UiTM employees acting as the FERC and BERC secretariat (Secretariat) must comply with the procedures and guidelines as stipulated by the UiTM REC.</p> <p>(b) The Chairperson, committee members, and the Secretariat must declare their conflict of interests (if any) at the beginning of each FERC/BERC meeting.</p> <p>(c) The Chairperson, committee members, and the Secretariat must sign the Non-Disclosure/Confidentiality Agreement pursuant to their respective appointment.</p> <p>(d) Newly appointed Committee members (including the Chairperson) and Secretariat must attend the relevant training on research ethics.</p> <p>(e) The existing Chairperson, committee members and Secretariat must continuously update themselves and attend relevant skill-development trainings and refresher courses.</p>
<p>2.1</p>	<p><b>Structure of BERC/FERC</b></p> <p>(a) The minimum membership is nine (9), represented by both genders, comprising:</p> <ul style="list-style-type: none"> <li>i. a Chairperson (Deputy Rector/Deputy Dean - Research and Innovation / Academic Affairs);</li> <li>ii. a Deputy Chairperson;</li> <li>iii. at least three Associate Members;</li> <li>iv. at least two academic / professional members who are UiTM employees with knowledge of, and current experience in, the areas of research as appropriate;</li> <li>v. at least one member who has statistical knowledge;</li> <li>vi. a Coordinator (Undergraduate / Postgraduate / Research Coordinator)</li> <li>vii. at least one Secretariat member who is a UiTM employee.</li> </ul> <p>(b) The quorum for FERC/BERC meetings is five (5) including Chairperson or Deputy Chairperson and one Associate Member.</p>
<p>2.2</p>	<p><b>Roles of the FERC/BERC members</b></p>

(a) Chairperson

Chairperson must be able to draw on the knowledge and experience of all members, and demonstrate respect for each member's view. The Chairperson must play an active role in ensuring that all matters in the meeting agenda are covered and duly minuted by the Secretariat. Other roles of the Chairperson include:

- i. To ensure applicants provide sufficient information to enable the members to make an informed decision when necessary;
- ii. To oversee arrangements for meetings;
- iii. To preside over the decision-making process;
- iv. To invite applicants to present their proposal at meetings, if necessary;
- v. To seek advice from experts, if necessary;
- vi. To address any conflict of interest among members;
- vii. To deal with appeals and complaints from all parties;
- viii. To respond to any communications regarding FERC/BERC affairs.

The Chairperson is likely to be called upon to perform duties beyond those related to F/BERC meetings. These could include overseeing procedures and receiving reports.

The Chairperson is likely to be called on to communicate with UiTM REC to discuss on related research ethics issues.

The ethics approval letter for Undergraduate and Postgraduate by Coursework applications will be signed by the Chairperson.

(b) Deputy Chairperson

Assumes the responsibilities of the Chairperson in his or her absence.

(c) Associate Member

- i. To act as the representative of the UiTM REC in the FERC/BERC;
- ii. To ensure the application form is complete and filled in correctly;
- iii. To provide the latest information related to the UiTM REC to FERC/BERC;
- iv. To be a member of the UiTM REC subcommittee (when necessary);
- v. To evaluate ethical approval application forms (when necessary);

Detailed TOR for Associate Member is outlined elsewhere.

(d) Members of FERC/BERC

	<p>The responsibilities include:</p> <ul style="list-style-type: none"> <li>i. To assist Associate Members in evaluating the ethics approval applications;</li> <li>ii. to take part in the deliberation of the FERC/BERC meetings.</li> </ul> <p>(e) Secretariat</p> <p>The Secretariat facilitates and supports the Chairperson in ensuring the smooth functioning of the FERC/BERC.</p> <p>The roles include:</p> <ul style="list-style-type: none"> <li>i. to ensure that the ethics approval applications are complete and all related documents are included;</li> <li>ii. to assign suitable reviewers for each application and notification received;</li> <li>iii. to follow up with applicants and reviewers pertaining to ethics approval applications;</li> <li>iv. to call and make preparations for meetings when necessary;</li> <li>v. to record the minutes of every meeting and circulate them to the committee members;</li> <li>vi. to respond to enquiries regarding the application processes;</li> <li>vii. to receive and process all documents and correspondences addressed to the FERC/BERC;</li> <li>viii. to ensure that documents submitted for ethics approval are complete and verified by the Department / Postgraduate Research Committee;</li> <li>ix. to manage FERC/BERC documentation effectively.</li> </ul>
<p>3.1</p>	<p><b>Working procedures</b></p> <p>(a) The relevant Department or Postgraduate Research Committee (D/PRC) at the faculty/equivalent entity and branch campus must ensure that all application forms are complete and verified by the supervisor/representative of the research team.</p> <p>(b) The forms to be screened by the D/PRC are as follows:</p> <ul style="list-style-type: none"> <li>i. FERC/BERC 1 - Application Form;</li> <li>ii. FERC/BERC 2 - Participant Information Sheet;</li> <li>iii. FERC/BERC 3 - Assent Form (if applicable);</li> </ul> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> <li>iv. F/BERC 4 - Exemption Form.</li> </ul>

	<ul style="list-style-type: none"> <li>(c) The duly completed forms must be endorsed by the Coordinator of D/PRC prior to submission to FERC/BERC. Detailed standard operating procedure for F/BERC is outlined in the <b>SOP FERC/BERC</b> document titled '<b>Flowchart: Research Ethics Approval Application for Undergraduates or Postgraduates by Coursework Research</b>'.</li> <li>(d) FERC/BERC meetings will be conducted at least once a month. (has to be once a month as according to the flow chart this can be completed within 4 weeks).</li> <li>(e) The FERC/BERC may approve, require amendment of, or reject a research proposal on ethical grounds.</li> <li>(f) The FERC/BERC must record their decisions in writing and should include reasons for rejection.</li> <li>(g) The FERC/BERC should inform researchers in writing of the decision and, in the event of rejection or recommended amendments, the reason/s for the decision.</li> <li>(h) The meeting agenda, including relevant documents such as application forms and related documents, must be shared with all members prior to the meeting.</li> <li>(i) Written comments may be communicated through any convenient method, including email.</li> <li>(j) The Chairperson is responsible for ensuring that all views and reports are recorded and considered at the meeting.</li> <li>(k) The FERC/BERC may reach the decision by general agreement.</li> <li>(l) Committee members are encouraged to respect the wide range of viewpoints and to take the time necessary to consider all issues.</li> <li>(m) The Chairperson, committee members and Secretariat shall communicate with the researchers only according to the procedures outlined by the FERC/BERC.</li> </ul>
4.1	<p><b>Resignation, disqualification, and replacement of Committee Members</b></p> <ul style="list-style-type: none"> <li>(a) An Associate Member may resign by submitting a letter of resignation to the Deputy Vice Chancellor, Research and Innovation through the UiTM REC Chairperson.</li> <li>(b) The Chairperson, committee members, and Secretariat of the FERC/BERC may resign by submitting a letter of resignation to the respective Dean/Rector.</li> <li>(c) The Chairperson, committee member, or Secretariat may not be reappointed for non-compliance of duties and responsibilities stated herein.</li> <li>(d) A new committee member shall be appointed upon recommendation by the FERC/BERC Chair to replace a member who has resigned or not been re-appointed.</li> </ul>