

## TERMS OF REFERENCE

### RESEARCH ETHICS APPLICATION PROCEDURES AT COLLEGE, FACULTY, BRANCH, ETHICS REVIEW COMMITTEE (CERC, FERC, BERC)

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| Relevant documentation to read in conjunction:                                | <ol style="list-style-type: none"><li>1. Declaration of Helsinki (2013)</li><li>2. Malaysian Guideline for Good Clinical Practice. (2018)</li><li>3. Malaysian Code of Responsible Conduct in Research (2017)</li></ol> |

Updated : 11 March 2025

## **TERMS OF REFERENCE**

### **Research Ethics Application Procedures at College, Faculty, Branch, Ethics Review Committee (CERC, FERC, BERC)**

This Terms of Reference (TOR) is a document that describes the structure and composition of *Jawatankuasa Penilaian Etika Kolej* (College Ethics Review Committee, CERC), *Jawatankuasa Penilaian Etika Fakulti* (Faculty Ethics Review Committee, FERC), *Jawatankuasa Penilaian Etika Cawangan* (Branch Ethics Review Committee, BERC). 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  |
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| 1.1 | <p><b>Overview of UiTM Research Ethics Committee (UiTM REC), College Ethics Review Committee (CERC), Faculty Ethics Review Committee (FERC), and Branch Ethics Review Committee (BERC)</b></p> <p>Any research project involving human participants, human data, or human tissue must undergo ethical review by an independent, competent, and properly constituted ethics committee. Universiti Teknologi MARA (UiTM) operates a two-tier independent ethical review system, comprising a university-wide Research Ethics Committee (REC) and localized Ethics Review Committees (ERCs) situated within its Colleges, Branches, and Faculties. The REC and ERC are dedicated to maintaining high ethical standards to protect the dignity, rights, and welfare of research participants, researchers, and the institution itself.</p> <p><b>Tier 1 System:</b> The Research Ethics Committee (REC), is responsible for reviewing applications from postgraduate students engaged in full research, staff, external applicants, and any proposals categorized as posing more than minimal risk.</p> <p><b>Tier 2 System:</b> The Ethics Review Committee (ERC) is responsible for reviewing proposals from undergraduate and postgraduate by coursework (Master and PhD) students that involve minimal risk or qualify for exemption.</p> <p><b>The Ethics Review Committee (ERC)</b> was established in 2021, with its Term of Reference presented at the <i>Jawatankuasa Induk Penyelidikan Universiti</i> (JKIPU) Bil 04/2022 and endorsed by the UiTM Senate in its 282nd meeting on the 4th April 2022. The ERC is an independent body appointed by the Department of the Deputy Vice-Chancellor (Research and Innovation). The primary purpose of the ERC is to review, approve, or reject ethics applications involving human participants from undergraduate students and postgraduate students by coursework (Master and PhD), specifically those involving minimal risk or qualifying for exemption. Proposals deemed to involve more than minimal risk are to be forwarded to the Research Ethics Committee (REC) for an independent review. In addition to these responsibilities, each ERC is tasked with monitoring ongoing projects and ensuring that review committees, staff, and students receive appropriate training in ethical principles.</p> <p>(a) This TOR is applicable to CERC, FERC, and BERC members.<br/> (b) The CERC, FERC, and BERC must refer to ICH Malaysian Guidelines for Good Clinical Practice as the main reference in performing their duties under the TOR.<br/> (c) The CERC, FERC, and BERC must also operate in conformity with the Declaration of Helsinki and the relevant laws and regulatory requirements.</p> |

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| <p><b>1.2</b></p> | <p><b>Scope of the CERC, FERC, and BERC</b></p> <p>(a) To review applications for ethics approval for research involving human for Undergraduate and Postgraduate by Coursework (Master &amp; PhD) students only;</p> <p>(b) To identify the *categories of risk 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> <li>iii. Exemption from ethical review</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>(f) To ensure that any research involving subjects and facilities of the Ministry of Health Malaysia (MOH) is approved by the Medical and Research Ethics Committee (MREC).</p> <p><i>*Note: The Research Risk Classification Part E in C/F/B ERC1 Rev5 (2025) form will be used to assist risk categorization.</i></p> |
| <p><b>1.3</b></p> | <p><b>Appointment Criteria</b></p> <p>The criteria for appointment to an Ethics Review Committee include having relevant expertise and knowledge as well as practical experience in research, clinical practice, or ethical review. Members must be willing to commit the necessary time and effort to review research proposals and attend committee meetings. It is important that members do not have any conflicts of interest that could affect their impartiality. Additionally, committees often seek diverse membership to ensure a range of perspectives and expertise.</p> <p>(a) The Chairperson and the Deputy Chairperson (who is a Member or an Associate Member or REC) and other ERC members will be appointed by the Deputy Vice Chancellor of Research and Innovation upon the recommendation of the Dean/Rector of the respective college/faculty/branch or equivalent.</p> <p>Ensuring the independence and impartiality of ethics committees is crucial for fair, unbiased, and lawful assessments. Consequently, the Chairperson and Deputy Chairperson of the ERC should not simultaneously hold any senior decision-making positions, such as deputy dean, rector, director, or higher post. This measure protects the ERC's operations from external pressures and safeguards the committee's decision-</p>   |

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|     | <p>making process, ensuring that proposals are evaluated on their merits alone.</p> <p>(b) The ERC may recommend the appointment of new Associate Member(s) if the need arises.</p> <p>(c) The Chairperson and committee members will be appointed based on their knowledge and expertise and their commitment.</p> <p>(d) The duration of the appointment of the Chairperson and other members are for not less than two (2) years.</p> <p>(e) The appointment of the committee members and Secretariat may be renewed on the recommendation of the Chairperson.</p>  |
| 1.4 | <p><b>Responsibilities</b></p> <p>(a) The Chairperson and members of the ERC, and UiTM employees acting as the Secretariat of ERC must comply with the procedures and guidelines as stipulated by the UiTM REC.</p> <p>(b) The ERC Members must read, understand, and accept the terms and conditions of their appointment.</p> <p>(c) The Chairperson, committee members, and the Secretariat must declare their conflict of interests (if any) at the beginning of each ERC meeting and leave the room during discussion of the application and the related decision, except if the member is providing information at the ERC's request. The Secretariat must minute the recusal.</p> <p>(d) The Chairperson, committee members, and the Secretariat must sign the Non-Disclosure/Confidentiality Agreement pursuant to their respective appointment.</p> <p>(e) Newly appointed Committee members (including the Chairperson) and Secretariat must attend and successfully complete relevant training on research ethics.</p> <p>(f) The existing Chairperson, committee members and Secretariat must continuously update themselves and attend relevant skill-development training and refresher courses.</p> <p>(g) The ERC members are required to train and guide non-ERC reviewers within the Branch/College/Faculty in reviewing and ensuring adherence to ethical standards, best practices, and institutional policies during the evaluation of research proposals and academic submissions.</p> |

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| <p><b>2.1</b></p> | <p><b>Structure of ERC</b></p> <p>(a) The minimum membership is seven (7), comprising:</p> <ul style="list-style-type: none"> <li>i. A Chairperson (a Member or an Associate Member of REC);</li> <li>ii. A Deputy Chairperson (a Member or an Associate Member of REC);</li> <li>iii. At least another (1) Member or Associate Member of REC;</li> <li>iv. At least two (2) 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 two (2) lay members who are UiTM employees</li> </ul> <p>(b) The minimum quorum for ERC meetings is five (5) including a Chairperson or Deputy Chairperson, one Member or Associate Member of REC, and one lay member.</p> <p>(c) The ERC's Secretary and Secretariat can be assigned to coordinate the application processes and meetings, but not in the decision-making.</p>  |
| <p><b>2.2</b></p> | <p><b>Roles of the ERC members</b></p> <p>Members of the Research Review Committee (ERC) should possess a robust understanding of ethics and research ethics to ensure that all research adheres to ethical and scientific standards. They are entrusted with protecting the safety and well-being of human participants and maintaining the integrity of Universiti Teknologi MARA (UiTM). ERC members must exhibit passion and dedication, meticulously execute their responsibilities, and uphold the highest standards of integrity, reflecting the trust vested in them. Additionally, they must accept full accountability for every decision and action they undertake.</p> <p>(a) Chairperson</p> <p>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:</p> <ul style="list-style-type: none"> <li>i. To ensure applicants provide sufficient information to enable the members to make an informed decision when necessary;</li> <li>ii. To oversee arrangements for meetings;</li> <li>iii. To preside over the decision-making process;</li> <li>iv. To invite applicants to present their proposal at meetings, if necessary;</li> <li>v. To seek advice from experts, if necessary;</li> <li>vi. To address any conflict of interest among members;</li> <li>vii. To deal with appeals and complaints from all parties;</li> <li>viii. To respond to any communications regarding ERC affairs.</li> </ul> |

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

The Chairperson is likely to be called on to communicate with UiTM REC to discuss 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 ERC;
- ii. To ensure the application form is complete and filled in correctly;
- iii. To provide the latest information related to the UiTM REC to ERC;
- iv. To evaluate research ethics application forms;

Detailed TOR for Associate Member is outlined in Terms of Reference Associate Members.

(d) Members of ERC

The responsibilities include:

- i. To assist Associate Members in evaluating the ethics approval applications;
- ii. To take part in the deliberation of the ERC meetings.

(e) Lay members

- i. Lay members are expected to provide their views from the perspective of the community. The qualifications for lay members are non-academic from UiTM and are non-involvement in medical, scientific or legal work.
- ii. A layperson on an ethics committee is someone who isn't a professional in the field being evaluated. Their role is to provide a fresh, unbiased perspective, representing the views and concerns of the general public. This helps ensure that decisions made by the committee are fair and consider the broader societal impact.

(f) Secretary and Secretariat

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|            | <p>The Secretary and Secretariat facilitate and support the Chairperson in ensuring the smooth functioning of the ERC.</p> <p>The roles include:</p> <ol 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 ERC;</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 ERC documentation effectively.</li> </ol>  |
| <b>3.1</b> | <p><b>Working procedures</b></p> <p>(a) The relevant Head of School/ Program (KPP)/ Coordinator of Undergraduate/ Postgraduate/ Research/ equivalent entity at the college, faculty or 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 Head of School/ Program (KPP)/ Coordinator of Undergraduate/ Postgraduate/ Research/ equivalent entity at the college, faculty or branch campus are as follows:</p> <ol style="list-style-type: none"> <li>i. C/F/B 1 - Application Form;</li> <li>ii. C/F/B 2 - Participant Information Sheet;</li> <li>iii. C/F/B 3 - Assent Form (if applicable); OR</li> <li>iv. C/F/B 4 - Exemption Form.</li> <li>v. C/F/B 5 - Post-Approval Amendment Form</li> </ol> <p>(c) The duly completed forms must be endorsed and categorized as either minimal risk or more than minimal risk research or exempted from ethical review by the KPP / Coordinator (or equivalent entity) prior to submission to ERC. Detailed standard operating procedure for ERC is outlined in the <b>SOP ERC</b> document titled Flowchart III: Research Ethics Approval Application for Undergraduate or Postgraduate by Coursework (Master &amp; PhD) for Minimal Risk, More Than Minimal risk and Exemption</p> <p>(d) ERC meetings/ assessment will be conducted at regular intervals according to the number of applications or as defined by the faculty or branch. Meetings of the ERC</p> |



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|  | <p>should be arranged to ensure that, whenever possible, all members receive relevant documents in advance and have the opportunity to attend.</p> <p>ERC's meeting agenda must at least include the following:</p> <ul style="list-style-type: none"> <li>i. Declaration of conflict of interest</li> <li>ii. Confirmation of ERC's past minutes meeting</li> <li>iii. Matters Arising <ul style="list-style-type: none"> <li>- This covers any pending agenda from the previous ERC meetings</li> </ul> </li> <li>iv. Application (Must include research proposal titles) <ul style="list-style-type: none"> <li>a. Presentation - for research proposals that require further assessment by the ERC</li> <li>b. Approval - For applications that are given the status "Recommend to approve" by the reviewers.</li> <li>c. Reporting - Approval list for group / batch of students of interest</li> </ul> </li> <li>v. Endorsement of post-approval amendment - Post-approval amendment list including the current status and the category of amendment. (Change of PI, methodology, title, supervisor, or extension)</li> <li>vi. Annual plan and status of completion/report. The activity includes <ul style="list-style-type: none"> <li>a. ERC meeting planned</li> <li>b. Training/briefing to applicants and reviewers (if any)</li> </ul> </li> <li>vii. Other Matters</li> </ul> <p>(e) The ERC may approve, require amendment of, or reject a research proposal on ethical grounds.</p> <p>(f) The ERC must record their decisions in writing and should include reasons for rejection.</p> <p>(g) The ERC should inform researchers in writing of the decision and, in the event of rejection or recommended amendments, the reason/s for the decision.</p> <p>(h) The meeting agenda, including relevant documents such as application forms and related documents, must be shared with all members prior to the meeting.</p> <p>(i) Written comments may be communicated through any convenient method, including email.</p> <p>(j) The Chairperson is responsible for ensuring that all views and reports are recorded and considered at the meeting.</p> <p>(k) The ERC may reach the decision by general agreement.</p> <p>(l) The Secretariat shall communicate with the researchers according to the procedures outlined by the ERC.</p> |
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|            | (m) The ERC must provide any data or information on their records and processes during the REC Audit.   |
| <b>3.2</b> | <p><b>Training</b></p> <p>a) ERC members are expected to update themselves with knowledge and skills relevant to their appointment by attending at least one (1) seminar/ workshop/ refresher course per year.</p> <p>b) ERC members are required to attend professional competency development programs in research ethics and/or related matters organized by REC UiTM or via online course that offers certificate that may include any of the followings:</p> <ul style="list-style-type: none"> <li>i. Basic Research Ethics Course &amp; Good Clinical Practice;</li> <li>ii. REC UiTM Standard Operating Procedures;</li> <li>iii. Continuing Ethics Education;</li> <li>iv. Other educational activities on international trends including international specialists' meetings organized for the exchange of experiences and information.</li> </ul>    |
| <b>4.1</b> | <p><b>Resignation, disqualification, and replacement of Committee Members</b></p> <p>(a) The Chairperson, Deputy Chairperson and Committee Members may resign by submitting a letter of resignation to the Deputy Vice Chancellor, Research and Innovation, or the Dean/Rector or the ERC Chairperson.</p> <p>(b) The Deputy Vice Chancellor, Research and Innovation and the REC Chairperson reserve the rights of not reappointing a Chairperson, Deputy Chairperson and Committee Members of ERC.</p> <p>(c) New committee members shall be recommended by the ERC Chairperson to replace members who have resigned, or have not been re-appointed, or when necessary.</p> <p>(d) New committee members shall be appointed on the recommendation of the ERC Chairperson to replace members who have resigned or have not been reappointed, or as needed.</p> |
| <b>5.1</b> | <p><b>Data Maintenance and Reporting to UiTM REC</b></p> <p>(a) The ERC is required to submit a list of approved ethics applications from the Undergraduate and Postgraduate by coursework (Master and PhD) students to the REC by the third week of each month.</p>  |

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|  | <p>(b) The submitted report must be prepared in accordance with the reporting template provided by the REC.</p> <p>(c) The Research Ethics Committee (REC) reserves the right to conduct audits on the Ethics Review Committee (ERC) whenever deemed necessary.</p> |
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