

TERMS OF REFERENCE

Research Ethics Application Procedures at College, Faculty, Branch, Cluster of Centre of Excellence Ethics Review Committee (CERC, FERC, BERC, CoEERC)

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) and *Jawatankuasa Penilaian Etika Kluster Pusat Kecemerlangan* (Cluster of Centre of Excellence Ethics Review Committee, CoEERC). 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>Overview of UiTM Research Ethics Committee (UiTM REC), College Ethics Review Committee (CERC), Faculty Ethics Review Committee (FERC), Branch Ethics Review Committee (BERC) and Cluster of Centre of Excellence Ethics Review Committee (CoEERC)</p> <p>(a) This TOR is applicable to CERC, FERC, BERC and CoEERC members. (b) The CERC, FERC, BERC and CoEERC must refer to ICH Malaysian Guidelines for Good Clinical Practice as the main reference in performing their duties under the TOR. (c) The CERC, FERC, BERC and CoEERC must also operate in conformity with the Declaration of Helsinki and the relevant laws and regulatory requirements.</p>
1.2	<p>Scope of the CERC, FERC, BERC and CoEERC</p> <p>(a) To review applications for ethics approval for research involving human for Undergraduate and Postgraduate by Coursework students only; (b) To identify the categories of risk either as: 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 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; (c) To approve or disapprove the proposed research; (d) To impose restrictions and conditions on the proposed research, if necessary; (e) To suspend or revoke ethics approval of the proposed research, if necessary.</p> <p>*Note: The Research Risk Classification Section in C/F/B/CoEERC 1/2022 form will be used to assist risk categorization.</p>
1.3	<p>Appointment</p> <p>(a) The Members and Associate Members of UiTM REC will be appointed by the Deputy Vice Chancellor of Research and Innovation. (b) The Chairperson and the Deputy Chairperson (who is a Member or an Associate Member or REC) and other CERC/FERC/BERC/CoEERC 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. (c) The CERC/FERC/BERC/CoEERC may recommend the appointment of new</p>

<p>1.4</p>	<p>Associate Member(s) if the need arises.</p> <p>(d) The Chairperson and committee members will be appointed based on their knowledge and expertise and their commitment.</p> <p>(e) The duration of the appointment of the Chairperson and other members are for not less than two (2) years.</p> <p>(f) The appointment of the committee members and Secretariat may be renewed on the recommendation of the Chairperson.</p> <p>Responsibilities</p> <p>(a) The Chairperson and members of the CERC/FERC/BERC/CoEERC, and UiTM employees acting as the Secretariat of CERC/FERC/BERC/CoEERC 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 CERC/FERC/BERC/CoEERC 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 and successfully complete 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>Structure of CERC/FERC/BERC/CoEERC</p> <p>(a) The minimum membership is seven (7), comprising:</p> <ul style="list-style-type: none"> i. A Chairperson (a Member or Associate Member of REC); ii. A Deputy Chairperson (a Member or Associate Member of REC); iii. At least another (1) Member or Associate Member of REC; 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; v. At least two (2) lay persons who are UiTM employees <p>(b) The quorum for CERC/FERC/BERC/CoEERC meetings is five (5) including Chairperson or Deputy Chairperson and one Member or Associate Member of REC.</p> <p>(c) Member(s) of Secretariat and a Coordinator will be assigned to assist with the application processes and meetings, but not in the decision making.</p>

2.2

Roles of the CERC/FERC/BERC/CoEERC members

(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 CERC/FERC/BERC/CoEERC affairs.

The Chairperson is likely to be called upon to perform duties beyond those related to CERC/FERC/BERC/CoEERC 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 CERC/FERC/BERC/CoEERC;
- ii. To ensure the application form is complete and filled in correctly;
- iii. To provide the latest information related to the UiTM REC to CERC/FERC/BERC/CoEERC;
- iv. To evaluate research ethics application forms;

	<p>Detailed TOR for Associate Member is outlined in Terms of Reference Associate Members.</p> <p>(d) Members of CERC/FERC/BERC/CoEERC</p> <p>The responsibilities include:</p> <ul style="list-style-type: none"> i. To assist Associate Members in evaluating the ethics approval applications; ii. To take part in the deliberation of the CERC/FERC/BERC/CoEERC meetings. <p>(e) Secretariat</p> <p>The Secretariat facilitates and supports the Chairperson in ensuring the smooth functioning of the CERC/FERC/BERC/CoEERC.</p> <p>The roles include:</p> <ul style="list-style-type: none"> i. To ensure that the ethics approval applications are complete and all related documents are included; ii. To assign suitable reviewers for each application and notification received; iii. To follow up with applicants and reviewers pertaining to ethics approval applications; iv. To call and make preparations for meetings when necessary; v. To record the minutes of every meeting and circulate them to the committee members; vi. To respond to enquiries regarding the application processes; vii. To receive and process all documents and correspondences addressed to the CERC/FERC/BERC/CoEERC; viii. To ensure that documents submitted for ethics approval are complete and verified by the Department / Postgraduate Research Committee; ix. To manage CERC/FERC/BERC/CoEERC documentation effectively.
<p>3.1</p>	<p>Working procedures</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>

	<ul style="list-style-type: none"> i. C/F/B/CoEERC 1 - Application Form; ii. C/F/B/CoEERC 2 - Participant Information Sheet; iii. C/F/B/CoEERC 3 - Assent Form (if applicable); OR iv. C/F/B/CoEERC 4 - Exemption Form. <p>(c) The duly completed forms must be endorsed and categorized as either minimal risk or more than minimal risk research by the KPP / Coordinator (or equivalent entity) prior to submission to CERC/FERC/BERC/CoEERC. Detailed standard operating procedure for CERC/FERC/BERC/CoEERC is outlined in the SOP CERC/FERC/BERC/CoEERC document titled 'Flowchart: Research Ethics Approval Application for Undergraduates or Postgraduates by Coursework Research'.</p> <p>(d) CERC/FERC/BERC/CoEERC meetings/ assessment will be conducted at regular intervals according to the number of application or as defined by the faculty or branch.</p> <p>(e) The CERC/FERC/BERC/CoEERC may approve, require amendment of, or reject a research proposal on ethical grounds.</p> <p>(f) The CERC/FERC/BERC/CoEERC must record their decisions in writing and should include reasons for rejection.</p> <p>(g) The CERC/FERC/BERC/CoEERC 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 CERC/FERC/BERC/CoEERC may reach the decision by general agreement.</p> <p>(l) The Secretariat shall communicate with the researchers according to the procedures outlined by the CERC/FERC/BERC/CoEERC.</p> <p>(m) The CERC/FERC/BERC/CoEERC must provide any data or information on their records and processes during REC Audit.</p>
<p>3.2</p>	<p>Trainings</p> <ul style="list-style-type: none"> a) CERC/FERC/BERC/CoEERC 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. b) CERC/FERC/BERC/CoEERC 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

	<p>any of the followings:</p> <ul style="list-style-type: none"> i. Basic Research Ethics Course & Good Clinical Practice; ii. REC UiTM Standard Operating Procedures; iii. Continuing Ethics Education; iv. Other educational activities on international trends including international specialists' meetings organized for the exchange of experiences and information.
<p>4.1</p>	<p>Resignation, disqualification, and replacement of Committee Members</p> <ul style="list-style-type: none"> (a) The Chairperson, Deputy Chairperson and Committee Members may resign by submitting a letter of resignation to the Deputy Vice Chancellor, Research and Innovation through the respective Dean/Rector or equivalent. (b) The Deputy Vice Chancellor, Research and Innovation reserves the rights of not reappointing the Chairperson, Deputy Chairperson and Committee Members. (c) New committee members shall be recommendation by the CERC/FERC/BERC/CoEERC Chairperson to replace members who have resigned, or have not been re-appointed, or when necessary. (c) New committee members shall be appointed on the recommendation of the CERC/FERC/BERC/CoEERC Chairperson to replace members who have resigned or have not been reappointed, or as needed.
<p>5.1</p>	<p>Data Maintenance and Reporting to UiTM REC</p> <ul style="list-style-type: none"> (a) The CERC/FERC/BERC/CoEERC is required to submit a list of approved ethics applications from the undergraduate and postgraduate by coursework students to the REC by the third week of each month. (b) The submitted report must be prepared in accordance with the reporting template provided by the REC. (c) The REC as and when deemed necessary may conduct an audit on the CERC/FERC/BERC/CoEERC.