

RESEARCH ETHICS COMMITTEE UNIVERSITI TEKNOLOGI MARA
Terms of Reference

DISCLAIMER

This document is intended to serve as a reference for members of the Research Ethics Committee. Universiti Teknologi MARA (UiTM), Shah Alam makes no warranties as to the accuracy or completeness of the information contained therein. UiTM disclaims all liability for any errors or omissions in the results obtained through the use of such information.

1. Terms of Reference

The Research Ethics Committee (REC), UiTM endorses the use of the Malaysian Guideline for Good Clinical Practice as reference for members of the REC to perform their duties to the best of their knowledge. The REC also operates in conformity with the Declaration of Helsinki and the relevant laws and regulatory requirements.

1.1 The purpose of the REC is to:

- (a) review applications for ethics approval for research involving human participants.
- (b) decide the categories of risk into:
 - 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;
 - ii. more than minimal risk – research activities that present greater than minimal risk to human participants; or
 - iii. exempted category

[Note: The Research Risk Classification Form (REC 3/2019) completed by applicants will be used to assist risk categorization.]

- (c) approve or reject research ethics application.
- (d) impose restrictions and conditions on research, if necessary.
- (e) review submitted progress reports.
- (f) suspend or revoke approval of research, if necessary.
- (g) report research ethics transgression to the *Unit Integriti* UiTM.
- (h) provide training and promote research ethics awareness to the academic staff and students at the University.
- (i) ensure expediency deliberation of all research ethics application.

2. The Terms of Appointment for Members

- (a) REC Chairperson, Deputy Chairpersons, Members, Associate Members, and Secretariat are to comply with and abide by the rules and procedures as approved by UiTM Senate.
- (b) The newly appointed or re-appointed REC Members must read, understand, and accept the terms and conditions of their appointment.
- (c) Appointments are made for a term of one (1) or two (2) years subject to re-appointment. There is no limit to the number of re-appointments.
- (d) An appointed member gives consent to have his/her full name, profession, and affiliation published by REC, where appropriate.
- (e) It is mandatory that an appointed member is required to sign a Confidentiality Agreement to maintain confidentiality regarding applications, meeting deliberations, information on research participants, and related REC matters.
- (f) Nominated members with previous experience in IRB/REC are required to observe one (1) REC meeting as a prerequisite for their appointment.
- (g) Nominated members are required to observe three (3) REC meetings as a prerequisite for their appointment.
- (h) Reappointed members (whose 2-year term has ended) are not required to observe the REC meetings as a prerequisite for their reappointment.
- (i) REC Members must disclose any conflict of interest to the Chairperson as soon as they become aware of it.
- (j) REC members who wish to resign should write to the Vice-Chancellor at least one (1) month before their resignation.
- (k) REC members who have been found guilty of any professional misconduct will be terminated from the REC.
- (l) REC members are required to attend no less than two-thirds (2/3) of all scheduled meetings of each year unless exempted or excused by REC. REC members must notify the REC Secretariat in writing for any non-attendance together with valid reasons.
- (m) The appointment of REC members can be revoked if they fail to fulfill the two-third (2/3) minimum attendance requirement without valid reasons.
- (n) External members of REC are entitled to honorarium for each attendance to the REC meeting. The amount of the honorarium will be determined from time to time by the Deputy Vice-Chancellor, Research and Innovation, UiTM. Insurance coverage will also be accorded to external members of REC.

3. Structure of the Research Ethics Committee

The minimum membership of the REC is nine (9). Members appointed by the Vice-Chancellor are represented by both genders, comprising:

- (a) a Chairperson;
- (b) two Deputy Chairpersons;
- (c) at least two academic/professional members who are UiTM staff with knowledge of, and current experience in, the areas of research that are regularly considered by the REC, involved in professional care or treatment of people (e.g. health, medical, social, psychological, epidemiological, as appropriate);
- (d) at least two members who are layperson, not employed by UiTM, not currently involved in medical or scientific work, and preferably from the community in which UiTM is located;
- (e) at least one member who has statistical knowledge;
- (f) at least one member who is from a religious institution or a person who performs a similar role in a community;
- (g) at least one member who has a legal background.

4. Function of Members

4.1 Chairperson

The Vice Chancellor will appoint a Chairperson based on his or her ability to draw on the experience of all members, including lay members and those with specialist expertise, and to demonstrate respect for each member's viewpoint. The Chairperson also has the responsibility for managing the agenda and making sure that all relevant items are covered and adequately recorded. The role of the Chairperson is:

- (a) To preside at all REC meetings.
- (b) To ensure sufficient information is available to enable the REC members to make an informed decision.
- (c) To oversee arrangements for REC meetings.
- (d) To invite research ethics applicants to present their proposal at REC meetings, where required
- (e) To seek advice from experts, if necessary.
- (f) To address any conflict of interest among REC members.

- (g) To deal with appeals and complaints.
- (h) To respond to any communications regarding REC affairs.
- (i) To nominate the names of REC members for appointment by the Vice Chancellor
- (j) To report research ethics transgression to *Unit Integriti* UiTM.
- (k) To monitor approved research.

The Chairperson is likely to be called upon to perform duties beyond those related to REC meetings. These could include overseeing procedures, monitoring approved research and receiving reports.

The Chairperson is likely to be called on to communicate with other RECs in multicentre research approval arrangements, and to be required to represent the REC within the institution and in discussions with researchers and other RECs.

4.2 Deputy Chairperson

Deputy Chairperson assumes the responsibilities of the Chairperson in his or her absence.

4.3 Members

Members have the responsibilities to:

- (a) evaluate and deliberate on ethics approval applications;
- (b) provide written feedback for application reviews as requested by the Secretariat;
- (c) attend periodic training and other activities related to research ethics;
- (d) create awareness among the UiTM community on the importance of research ethics.

4.4 Lay members

Lay members are expected to provide their views from the perspective of the community. The qualifications for lay members are their independence from UiTM and their non-involvement in medical, scientific or legal work.

4.5 Secretary

The Secretary has the responsibility to facilitate and support the Chairperson and REC members in ensuring the smooth functioning of the REC. Responsibilities of the Secretary include;

- (a) to lead the Secretariat.

- (b) to assign suitable reviewers for each application and notification received.
- (c) to follow up with applicants and reviewers pertaining to ethics approval applications.
- (d) to call for REC meetings.
- (e) to record the minutes of every meeting.
- (f) to ensure successful execution of the REC meetings as scheduled.
- (g) To execute the decisions made at REC meetings.
- (h) To ensure complete and proper documentation is maintained for the REC.
- (i) To make preparation for audit.
- (j) To plan for the training of REC members.
- (k) To coordinate the ethics awareness drive.

4.6 The Secretariat

The Secretariat has the responsibility to assist the Secretary in the efficient running of REC affairs, including the following:

- (a) To respond to enquiries regarding application processes.
- (b) To receive and process all documents and correspondence addressed to the REC.
- (c) To screen documents and risk categories.
- (d) To ensure that documents submitted for ethics approval are complete and verified by the Research Committee at Faculty or Branch Campuses.
- (e) To organize REC documentation effectively.
- (f) To inform the National Pharmaceutical Regulatory Agency (NPRA) of changes in REC membership within 30 working days.
- (g) To prepare for REC meetings.
- (h) To prepare for audit.
- (i) To assist the secretary in the arrangement of trainings for REC members.

4.7 Independent Consultant

Appointment of Independent Consultant is on 'as needed basis'. An independent consultant is a person who has additional or specialized expertise, beyond that of the REC members.

He/she can be consulted to make recommendations on applications for ethics approval. Independent consultants do not count as part of a quorum or vote. Invitation as an independent consultant will be issued to an identified expert by the REC Chairperson. The appointment of the independent consultant will be recorded in the minutes of the related REC meeting. The responsibilities of an independent consultant are as follows:

- (a) To sign a Confidentiality Agreement.
- (b) To review all documents submitted to the REC relevant to the study under review.
- (c) To declare any conflicts of interest.
- (d) To provide recommendation on the study reviewed through the written report(s) and/or by input during the meeting(s).

4.8 Associate Members

Associate members are appointed by the Deputy Vice-Chancellor (Research and Innovation). Associate members are UiTM staff selected based on their expertise in the area required by the REC. Associate members are not part of the composition of the REC membership.

Their roles include:

- (a) To represent the REC at Faculty/College/Branch/Entities of Excellence Research Committees (JPF/JPK/JPN/JEK) levels in ensuring applications are complete and accurate.
- (b) To assist the REC with reviews of ethics application.
- (c) To train and provide current information to Faculty/College/Branch/Entities of Excellence Research Committees (JPF/JPK/JPN/JEK) or College, Faculty/Branch Ethics Review Committee (C/F/BERC) regarding REC matters.
- (d) To be part of any REC working committee, if necessary.
- (e) To acquire appropriate knowledge and training in the performance of their duties

5. Scope of responsibility

The REC must be satisfied that the study design is capable of producing valid findings while also safeguarding the welfare, dignity, and rights of research participants. The REC may seek or receive assistance from a person, a research committee at UiTM, or an external expert in order to satisfy this requirement.

In the review of applications, the following areas will be considered by the REC:

- (a) *The project*
 - i. Is there a clear hypothesis?
 - ii. Are the research questions useful? Is the research worthwhile?

- iii. Is the research likely to yield new information, enhance understanding or clarify existing uncertainty?
- iv. Has this, or similar research been carried out before in the same or similar, context?
- v. Can the research proposal be supported by a systematic review of literature that would demonstrate the importance of the research question, and does it build upon the results of previous research?
- vi. If indicated, have perspectives of potential participant groups, the wider community, or other disciplines been incorporated into the research proposal?
- vii. Are the aims of the proposal clear?
- viii. Does the value of the project appear to be adequate to justify its conduct with human participants?

(b) *The researchers*

- i. Do the researchers have the necessary qualifications, competence and experience?
- ii. Are there adequate arrangements to ensure that members of the research team are aware of relevant ethical and legal obligations?

(c) *The funding*

- i. What is the relationship between the source of the funding and the aims of the project?
- ii. Does that relationship have any implications for the ethical conduct of the project, especially the recruitment of participants, the type of information sought, or the freedom to publish the results?

(d) *Research methodology*

- i. Are all aspects of the research methodology clearly described?
- ii. Is the methodology scientifically sound?
- iii. Is the REC satisfied that the methodology is appropriate to achieve the aims of the project?

(e) *Recruitment of participants*

- i. Is it clear how participants will be recruited (e.g. advertisement, etc.)?

- ii. Do the recruitment methods respect participant rights to the confidentiality of their affairs?
- iii. Are the proposed participants appropriate in number and kind?
- iv. Is there a fair selection of participants?

(f) *Incentives for participation*

- i. Are financial or other rewards proposed to be given to participants?
- ii. Are these of such a size or value that they may unduly influence the freedom of participants to participate or withdraw.

(g) *Consent*

- i. Is the participant information sheet adequate in content and appropriate?
- ii. Is assent form provided to participants below the age of 18 years?
- iii. Do the proposed methods of securing consent to participate provide:
 - sufficient time for comprehension and decision,
 - evidence that participants understood their choices, and
 - sufficient opportunities to ask questions and re-consider?

(a) *Withdrawal of participation*

- i. Are the ways in which participants are advised of their freedom to withdraw sufficient in content?

(h) *Risks and benefits of research*

- i. Have the risks and benefits of research to participants been identified clearly, and have appropriate risk mitigation measures been taken?
- ii. Do the risks to the participants outweigh the benefits?

(i) *Data protection*

- i. Is it clear who will have access to information collected during the project?
 - Are the proposed storage and security measures adequate?

- Are the participants clear that the information provided will be used only for the project?
- What are the measures used to protect the privacy and confidentiality of participants?
- Are the manner and form in which results will be published clearly described, and do they adequately protect the privacy and confidentiality of participants?

(j) *Special Considerations*

i. Does the project involve subject matter or conduct which may give rise to the legal vulnerability of participants or researchers? Have adequate precautions been taken?

ii. In addition to these recurrent issues, some research requires particular additional attention, either because of the vulnerability of the intended participants or the type of research. Research with vulnerable participants that needs additional consideration includes:

- research involving children.
- research involving participants with intellectual or mental impairment, including temporary impairment, for example as a result of alcohol or drug- induced intoxication.
- research involving persons in highly dependent medical care situations.
- research involving indigenous or special groups.

6. Procedures

Working procedures:

Meetings will be conducted at least once a month. Meetings of the REC would be so arranged as to allow, wherever possible, all members to be fully informed by receipt of all relevant papers and the opportunity to attend.

The REC may approve, require amendment of, or reject a research proposal on ethical grounds. The REC must record decisions in writing and should include reasons for rejection. The REC should inform researchers in writing of decisions and, in the event of rejections or recommended amendments, the reasons for those decisions.

The agenda should be distributed to all members at least one (1) week before the meeting.

When there is less than full attendance at a meeting, the Chairperson must be satisfied that a quorum of five (5) members is met. The quorum must include a member who does not have any conflict of interest with the proposed research, an external member and a lay member.

Members who are unable to attend a particular meeting can contribute, prior to those meetings, views on each protocol to be considered. Written comments may be communicated by any convenient method, including email. The Chairperson is responsible for ensuring that these views are recorded and considered at the meeting.

The REC endeavors to reach decisions by general agreement. When unanimity is not achieved, a majority vote can be considered.

The REC will invite researcher(s) to present their proposals involving contentious ethical issues, invasive or potentially risky procedures, or when there is a need for clarification. Full board presentations provide opportunities for a detailed assessment of the proposed research.

7. Confidentiality of protocols and proceedings

All documents submitted to the REC should be regarded as confidential materials. Information should only be disclosed beyond REC when deemed necessary, for example, when obtaining an opinion from an expert.

The REC shall ensure that no member of the Committee adjudicates on research in which the member has any conflict of interest including any personal involvement or participation in the research, any financial interest in the outcome or any involvement in competing research.

When the REC member has a conflict of interest, that member should recuse from the meeting when that research is being deliberated. The absence of the member concerned should be recorded in the minutes. In addition, a committee member in this situation should not discuss the research with other members or attempt to influence the committee in any way. Where a member is an investigator, the REC may choose to invite that member to answer questions about the research before the member recuses from the meeting.

A researcher must disclose to the REC the amount and sources or potential sources of funding for the research and must declare any affiliation or financial interest when proposing and when reporting the research.

All documents and other material used to inform potential research participants should be approved by the REC, including plain language information sheets, consent forms, questionnaires, advertisements, and letters of invitation.