



**UNIVERSITI TEKNOLOGI MARA (UiTM)**

**GUIDELINES**

**RESEARCH ETHICS COMMITTEE (REC)  
AND RESEARCHERS  
(Revision 2022 Ver. 2)**

Prepared by:

Research Management Centre (RMC)  
Universiti Teknologi MARA  
Shah Alam

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## **PREAMBLE**

The Research Ethics Committee (REC) Guidelines (Revision 2022) is amended and updated from the original REC Guidelines (Revision 2019, Revision 2015/2016).

All persons conducting research involving human as participants or as human samples must ensure the protection of the rights, dignity and data confidentiality of their participants. Any form of violations of ethics in research is not acceptable. The risks and benefits to participants/researchers/institutions are of utmost importance and must be given due consideration. Therefore, all researchers conducting research involving human participants/samples must be qualified/trained and must obtain ethics approval prior to research commencement.

This REC Guidelines provides assistance and guidance to REC members, researchers and research participants in UiTM. It governs all research involving human participants and samples.

REC works in tandem with the Research Committee at College/Faculties/State Branches/ Entities of Excellence (JPK/JPF/JPN/JEK) to ensure that all research in UiTM is carried out ethically.

The guidelines comply with the Declaration of Helsinki (2013), Malaysian Good Clinical Practice (2018), UiTM Ethics Policy as well as relevant laws in Malaysia.

This revision was validated at REC Meeting on the 15 February 2022, and endorsed by Jawatankuasa Induk Penyelidikan Universiti (JKIPU) on 17 February 2022.

## **1.0 RESPONSIBILITIES OF THE RESEARCH ETHICS COMMITTEE (REC)**

- 1.1 The REC was established to review, approve or reject the ethics application for any research involving human participants conducted in UiTM and/or by UiTM researchers/students. REC upholds high ethical standards to protect the dignity, rights and welfare of research participants, researchers as well as the institutions.
- 1.2 The responsibilities of the REC are to:
- (a) review applications for ethics approval for research involving human; and
  - (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.
  - (c) approve or reject the ethics research application;
  - (d) impose restrictions and conditions on research, if necessary;
  - (e) review submitted progress reports; and
  - (f) suspend or revoke approval of research.

## **2.0 COMPOSITION OF RESEARCH ETHICS COMMITTEE**

- 2.1 The minimum membership of the REC appointed by the Vice Chancellor (VC) is nine (9), represented by both genders, comprising:
- (a) a Chairman;
  - (b) two Deputy Chairman;
  - (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 layman, 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 legal background.

### **3.0 APPOINTMENT OF REC MEMBERS**

#### **3.1 Appointment**

- (a) All REC members are appointed by the Vice Chancellor (VC) of UiTM.
- (b) REC members are appointed based on their expertise as well as on their commitment to perform their duties as stipulated in the REC Terms of Reference.
- (c) Nominated members are required to observe three (3) REC meetings as a prerequisite for their appointment. Re-appointed members whose last appointment as a member of any registered REC was not more than three (3) years ago, are only required to observe one (1) REC meeting. For avoidance of doubt, registered REC means those who are registered with the National Pharmaceutical Regulatory Agency (NPRA).
- (d) Nominated members are required to sign a Confidentiality Agreement prior to joining the REC meetings as an observer.
- (e) Nominated members must give in writing the acceptance or non-acceptance of their appointment, which will be recorded by the Secretariat.

#### **3.2 Terms and Conditions of Appointment**

- (a) 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 renewals.
- (b) An appointed member gives consent to have his/her full name, profession, and affiliation published by REC, where appropriate.
- (c) An appointed member is expected to maintain confidentiality regarding applications, meeting deliberations, information on research participants, and related REC matters.
- (d) REC members will sign a Confidentiality Agreement upon appointment indicating their obligation to maintain confidentiality.
- (e) REC Members must disclose to the Chairman any conflict of interest as soon as they become aware of it.
- (f) REC members who wish to resign should write to the VC at least one month (1) before their resignation.
- (g) REC members who have been found guilty of any professional misconduct will be terminated from the REC committee.
- (h) 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.
- (i) The appointment of REC members can be revoked if they fail to fulfil the two third (2/3)

minimum attendance requirement without valid reasons.

### **3.3 Resignation, disqualification, and replacement of members**

- (a) REC members may resign from the committee by giving a one (1) month notice to the Vice Chancellor through the REC Chair.
- (b) REC members who have resigned or members who are not re-appointed will be replaced by new members by recommendation from the REC Chair and to be appointed by UiTM Vice Chancellor.
- (c) REC members who fail, neglect and/or refuse to fulfill one or more responsibilities of REC members should not be-reappointed.
- (d) Duration of appointment, disqualification, resignation, and replacement of Secretariat is to be decided by the Vice Chancellor after consulting the Deputy Vice Chancellor, Research and Innovation and the REC Chair.

### **4.0 TRAINING**

- (a) REC members are expected to update themselves with knowledge and skills relevant to their appointment as REC members by attending at least one (1) seminar/workshop/refresher course per year.
- (b) REC members are required to attend professional competency development programs in research ethics and/or related matters organized by REC or via online course that offers certificate that may include any of the followings:
  - 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.
- (c) REC Chair may nominate any REC members to attend professional competency development programs in research ethics and/or related matters organised by the external parties with fees and expenses to be fully paid by UiTM.

### **5.0 OBSERVER**

Persons interested to observe the REC meeting must obtain permission from the Chairman and sign the Confidentiality Agreement Form.

## **6.0 SCOPE OF RESPONSIBILITIES OF REC MEMBERS**

### **6.1 Chairman**

The Chairman is responsible to manage the REC meetings which include ensuring that the meeting agenda is covered and outcomes are accurately minuted. The responsibilities of the Chairman also include the following:

- (a) ensures applicants provide sufficient information to enable the REC members to make an informed decision;
- (b) oversees arrangements for meetings;
- (c) presides over decision making process;
- (d) invites applicants to present their proposal at meetings, if necessary.
- (e) seeks advice from experts, if necessary;
- (f) addresses any conflict of interest among REC members;
- (g) deals with appeals and complaints from all parties;
- (h) responds to any communications regarding REC affairs.

### **6.2 Deputy Chairman**

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

### **6.3 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 trainings and other activities related to research ethics;
- (d) create awareness among UiTM community on the importance of research ethics.

### **6.4 Secretary**

The Secretary has the responsibility to facilitate and support the Chairman in ensuring the smooth functioning of the REC. The responsibilities include:

- (a) leads the Secretariat;
- (b) assigns suitable reviewers for each application and notification received;
- (c) follows up with applicants and reviewers pertaining to ethics approval applications; calls for

- REC meetings;
- (d) records the minutes of every meeting;
  - (e) ensures successful execution of the REC meetings as scheduled.

## **6.5 The Secretariat**

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

- (a) responds to enquiries regarding application processes.
- (b) receives and processes all documents and correspondence addressed to REC.
- (c) screens documents and recommend the category of risks.
- (d) ensures that documents submitted for ethics approval are complete and verified by the Research Committee at Faculty or State Campuses; manages REC documentation efficiently.
- (e) updates the list of REC membership to the NPRA within 30 working days of any changes to the membership.
- (f) makes preparation for REC meetings.

## **7.0 RESEARCH COMMITTEE AT COLLEGE, FACULTY, BRANCH AND RESEARCH EXCELLENCE ENTITIES**

Each College, Faculty, Branch and Research Excellence Entities has its own Research Committee (JPK/JPF/JPN/JPEK) whose responsibility is to ensure that the research agenda of the university is achieved (Pekeliling Timbalan Naib Canselor (Penyelidikan & Inovasi) Bil. 03/2016. Part of the duties of the Research Committee is to provide scientific review and verify applications for ethics approval prior to submission to REC.

## **8.0 INDEPENDENT CONSULTANT**

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 recommendation on related applications for ethics approval. Independent consultant does not count as part of a quorum or vote.

### **8.1 Appointment**

Invitation as an independent consultant will be issued to an identified expert by the REC Chairman. The appointment of the independent consultant will be recorded in the minutes of the related REC meeting.

### **8.2 Responsibilities**

The responsibilities of an independent consultant are as follows:

- (a) agrees to and sign a Confidentiality Agreement;
- (b) reviews all documents submitted to the REC relevant to the study under review;
- (c) declares any conflict of interest;
- (d) provides recommendation on the study reviewed through written report(s) and/or by input during meeting(s).

## **9.0 CONDUCT OF REC MEETING**

REC meetings are conducted as follows:

- (a) The meetings are scheduled at least once a month.
- (b) Meeting dates are announced at the beginning of the year.
- (c) Agenda and documents to be discussed during the REC meeting are circulated electronically to the REC members/reviewers at least one (1) week before every scheduled meeting.
- (d) Minutes are taken by the Secretary in all REC meetings.
- (e) The minimum required quorum is 5 members.
- (f) At least one member whose primary area of interest is in a non-scientific area.
- (g) At least one member who is independent of the institutional/trial site.
- (h) Applications under the category of 'More Than Minimal Risk' require oral presentation by the researchers or students in the presence of research supervisor.
- (i) Applications under the category of 'Minimal Risk' will be reviewed by members of REC without any oral presentation.

## **10.0 CONFLICT OF INTEREST**

- 10.1 REC members must disclose any conflict of interest to the Chairman and leave the room during discussion of the application and the related decision, except if the member is providing information at the REC's request. The Secretariat must minute the recusal.
- 10.2 The duty to disclose conflict of interest also applies to independent consultants and ad-hoc reviewers. This policy applies to all ethics approval applications reviewed by the REC, including initial application and ongoing reviews. A conflict of interest includes but is not limited to the following:
- (a) participation in a study where the REC member is listed as an investigator or is a member of the research team;
  - (b) where the REC member is the supervisor or co-supervisor of the study;
  - (c) REC member has a personal relationship/kinship with the applicant;

- (d) REC member or his/her immediate family members has any fiduciary relationship to the research sponsor;
- (e) REC member has an interest that will unfairly influence the REC's ability to review an application objectively;
- (f) any other reason for which the REC believes its member has a conflict of interest with the application.

10.3 Procedures for handling conflict of interest:

- (a) REC member with a conflict of interest must not review the application and return it to the Secretariat for assignment to another reviewer;
- (b) Chairman must ensure that the REC member who discloses a conflict of interest neither deliberate nor vote on the application and must leave the room.
- (c) Notwithstanding to the above, REC member with a conflict of interest can remain during the presentation of the application to provide information.
- (d) The Secretariat will record in the minute the name of the REC member leaving the meeting due to a conflict of interest.

## **11.0 SUBMISSION OF APPLICATION FOR ETHICS APPROVAL**

A researcher conducting research involving human has the responsibility to obtain ethics approval prior to commencement of the research project. Application must be submitted to the REC through the Research Committee at College/Faculties/State Branches/Entities of Excellence (JPK/JPF/JPN/JEK) according to the prescribed procedures and guidelines.

### **11.1 Ethics Approval Application Procedure**

- (a) The flow of process for ethics approval application is as stipulated in the Flowchart I Research Ethics Approval Application for Minimal Risk (MR) Research and Flowchart II: Research Ethics Approval Application for More than Minimal Risk (MMR) Research.
- (b) The application must be submitted online to the Secretariat.
- (c) All applications must include the following documents:
  - i. Covering letter addressed to the Chairman of REC;
  - ii. Application Form for Ethics Approval;
  - iii. Research Risk Classification Form;
  - iv. Participant Information Sheet;
  - v. Informed Consent Form and/or Assent Form;
  - vi. Applicant Checklist;

vii. Other relevant documents (e.g., research proposal, validated questionnaires, survey form, interview protocol)

(d) For Clinical Trial Applications must include the following additional documents:

- i. Study protocol, amendments & sample Case Report Form (CRF);
- ii. Signed agreement between involved parties;
- iii. Investigator's Brochure;
- iv. Financial agreement with sponsor;
- v. Insurance statement & documents;
- vi. Clinical Trial Agreement;
- vii. Curriculum Vitae of all investigators;
- viii. Good Clinical Practice certificates of all investigators;
- ix. Annual Practicing Certificate.

(e) For Application for Exemption from Ethics Review:

- i. Application for Exemption from Ethics Review Form;
- ii. Other relevant documents (e.g., research proposal).

**11.2 Justification for Exemption from Ethics Review** includes but not limited to the following:

- (a) Research does not involve human participants, human tissues and/or biological samples;
- (b) Research does not collect sensitive and identifiable secondary data of an individual;
- (c) Research involves content analysis / textual analysis / meta-analysis. (E.g.: non-identifiable data lawfully collected, public/private records, published/unpublished reports, and documents available in libraries, repositories, archives, websites);
- (d) Case study / doctrinal study / policy study that utilizes a qualitative approach that does not involve human participants / sensitive / identifiable data of an individual;
- (e) Concept paper which synthesizes knowledge from the previous study on a particular topic and presents it in a new context with the aims to fill knowledge gaps. This research does not involve human participants and does not collect sensitive and / identifiable data of an individual;
- (f) Market survey, opinion poll / online vote, and consumer acceptability tests that do not collect:  
a) sensitive or b) identifiable data of an individual;
- (g) Studies based on video recording obtained from public domains that do not collect: a) sensitive, or, b) identifiable data of an individual;
- (h) Filming of documentary / documentation of cultural / traditional practices that have obtained prior approval from the relevant parties / authorities and does not collect: a) sensitive\* or b) identifiable data of an individual (random video/photo);

- (i) Activities for quality assurance purposes (e.g., clinical audit, communication audit, compliance audit) related to the evaluation of public service programs, public health surveillance, educational evaluation.

### **11.3 Terms of Submission of Ethics Approval Application**

- (j) All required documents must be submitted two (2) weeks before the scheduled REC meeting.
- (k) Faculties submitting application forms in bulk (more than 10 applications) must submit at least one (1) month before the scheduled meeting to allow for timely processing by the Secretariat.
- (l) Submission of all forms prescribed by REC must be in English with exception to the research conducted in other languages with Senate approval.
- (m) Any data collection instruments that require the participants to complete must be prepared in the Malay and English languages and other language(s) understood by the participants.

## **12.0 DECISION MAKING**

- (a) Decisions at REC meetings will be reached by consensus or voting.
- (b) Any REC member with a conflict of interest with respect to a specific application must leave the room during deliberations and decision-making relating to the application. This recusal must be documented in the minutes of the meeting.
- (c) The following matters will be considered by the reviewer:
  - i. scientific design and conduct of the study;
  - ii. recruitment of research participants;
  - iii. care and protection of research participants;
  - iv. protection of research participants' confidentiality;
  - v. informed consent process;
  - vi. community considerations;
  - vii. public policy considerations.
- (d) Voting by proxy is not allowed.
- (e) Independent Consultants are not allowed to vote.
- (f) Four (4) categories of decision are made on ethics approval applications:
  - i. Approved
  - ii. Conditional Approval
  - iii. Re-present

iv. Rejected

- (g) Decision on applications that are not presented due to absence of presenter will be deferred to the next meeting.

### **13.1 APPROVALS**

- 13.1 Applicants whose application is subject to conditional approval must submit the duly amended documents within ninety (90) days from the date of letter issued by the REC informing the same.
- 13.2 In the event the amended documents are not submitted within the prescribed period, a fresh application has to be made, unless otherwise instructed by the Chairman.
- 13.3 The amended documents will be tabled at the meeting for discussion by REC members before a decision is made.

### **14.0 COMMUNICATION OF DECISION**

- 14.1 A decision should be communicated in writing or email to the applicant, preferably within two weeks from the date at which the decision was made.
- 14.2 The communication of the decision includes, but is not limited to the following:
- (a) title of research proposal reviewed;
  - (b) reference number, version numbers and dates of application;
  - (c) name of research site(s);
  - (d) decision made by REC;
  - (e) date of decision;
  - (f) list of attendees during related REC meeting;
  - (g) a clear statement of the decision reached;
  - (h) list of actions that are required to improve the application (if any);
  - (i) any other recommendations made by the REC (if any);
  - (j) duly dated signature of the Chairman or other signatory.
  - (k) In cases of conditional approval, clear suggestions/instructions should be specified to the applicant and the grounds of disapproval of an application should be clearly stated.
- 14.3 In cases of disapproval, the REC must clearly state the grounds for the disapproval.

### **15.0 DUTIES OF INVESTIGATORS**

- 15.1 Upon approval, a letter will be issued to the applicant outlining duties of the investigator with regards to the approved research, inter alia:

- (a) Submission of annual progress report(s) using the Monitoring of Ongoing Studies Form due notification in cases of: a) serious and unexpected adverse events or b) early termination using the Monitoring of Ongoing Studies Form.
- (b) application amendments/ protocol deviations using the Amendment of Application/Protocol Form and Research Project Membership Amendment Form.
- (c) changes in research team membership using the Research Project Membership Amendment Form.
- (d) significant decisions by REC of other institutions
- (e) completion of research project using the Project Completion Report Form.

## **16.0 FEEDBACK ON ONGOING STUDIES**

- 16.1 The first progress report must be submitted by the investigator within twelve (12) months upon approval and continue to be submitted annually until the completion of the approved research.
- 16.2 Receipt of the progress reports will be acknowledged by the Secretariat and to be reviewed by an assigned REC member.
- 16.3 The reviewed progress report will then be deliberated at the REC meeting.
- 16.4 Chairman may approve the request by investigator to terminate annual progress reporting in situations where research has completed recruitment and intervention, but requires long periods of follow-up.

## **17.0 MAINTENANCE, ARCHIVING AND DISPOSAL PROCEDURES**

### **17.1 Responsibility**

The Secretariat is responsible for the maintenance, archiving and disposal of all documents received pertaining to the ethics approval process.

### **17.2 Maintenance and Access of Active Research Files**

- (a) Documents of active research files must be properly updated.
- (b) All active files will be kept in a cabinet with controlled access.
- (c) The documents are only accessible by personnel authorized by the Chairman.
- (d) The Secretariat must maintain a logbook containing particulars of personnel authorized to access the documents.

### **17.3 Archiving of Completed Research**

- (e) Documents of approved research which have been completed will be separately archived.
- (f) All archived files will be kept in a cabinet with controlled access.
- (g) The archived documents are only accessible by any person through authorization from the Chairman.
- (h) Secretariat must maintain a logbook containing particulars of personnel authorized to access the archived documents.

#### **17.4 Disposal of Documents Completed/Non-Active Research**

The documents of completed/non-active research will be disposed of by the Secretariat after a retention period of three (3) years.

#### **18.0 APPEALS**

- (a) Applicants aggrieved by the decision of the REC have the right to appeal for reconsideration.
- (b) Appeals must be submitted in writing within two (2) weeks of decision notification, and include all supporting documents.
- (c) The REC will deliberate and decide on the appeal in the next scheduled meeting.
- (d) The REC reserves the right to invite the applicant to appear before the Committee during the appeal.
- (e) Appeal will be settled in a timely manner and the decision made by the REC is final.

#### **19.0 REPORTING BY COLLEGE, FACULTY, AND BRANCH REVIEW ETHICS COMMITTEE**

- 19.1 Each College, Faculty and Branch will form a Research Ethics Review Committee whose responsibilities is to approve minimal risks research ethics applications from undergraduate and full course work postgraduate students.
- 19.2 The College, Faculty and Branch Review Ethics Committee 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.
- 19.3 The submitted report must be prepared in accordance with the reporting template provided by the REC.
- 19.4 The REC as and when deemed necessary may conduct an audit on the College, Faculty and Branch Review Ethics Committee.

## REFERENCES

- i. Malaysian Code of Responsible Conduct in Research (2017), National Science Council.
- ii. Ministry of Health Malaysia (2018). Malaysian Guideline for Good Clinical Practice. 4th edition.
- iii. World Health Organization (2000). Operational Guidelines for Ethics Committees Reviewing Biomedical Research.
- iv. World Medical Association (2000). Ethical Principles for Medical Research Involving Human Subjects. World Medical Association. Declaration of Helsinki (2013).

### Drafting Committee

	Members	Department/Institution
1.	Professor Dato' Dr Abu Bakar Abdul Majeed	Director Research Management Center (RMC) Universiti Teknologi MARA
2.	Emeritus Professor Dato' Dr Raymond Azman Ali	Faculty of Medicine Universiti Teknologi MARA
3.	Professor Dr Teh Lay Kek	Deputy Director iPROMISE Universiti Teknologi MARA
4.	Professor Dr Rohana Abdul Ghani	Faculty of Medicine Universiti Teknologi MARA
5.	Professor Dr Rohana Ahmad	Lecturer Faculty of Dentistry Universiti Teknologi MARA
6.	Professor Dr Nor Azmi Kamaruddin	Department of Cardiology National Heart Institute
7.	Associate Professor Dr Ahmad Izuanuddin Ismail	Faculty of Medicine Universiti Teknologi MARA
8.	Associate Professor Dr Haswira Nor Mohamad Hashim	Deputy Legal Advisor Legal Advisor Office Universiti Teknologi MARA
9.	Associate Professor Dr Salmi Razali	Lecturer Faculty of Medicine Universiti Teknologi MARA
10.	Associate Professor Dr Mohd Hafiz Mohd Hanafiah	Deputy Dean (Research, Linkages & Innovation) Faculty of Hotel and Tourism Management Universiti Teknologi MARA
11.	Associate Professor Dr. Thuhairah Hasrah Abdul Rahman	Deputy Dean (Research, Linkages & Innovation) Faculty of Medicine Universiti Teknologi MARA
12.	Associate Professor Dr Maria Justine	Lecturer Faculty of Health Sciences Universiti Teknologi MARA
13.	Associate Professor Dr Norziation Ismail Khan	Lecturer Faculty of Accountancy Universiti Teknologi MARA
14.	Dr Zainal Abidin Abdul Majeed	Malaysian Institute of Integrity
15.	Dr Suhana Aiman	Lecturer Faculty of Sports Science & Recreation, Universiti Teknologi MARA
16.	Dr Amirah Abdul Rahman	Lecturer Faculty of Medicine

		Universiti Teknologi MARA
17.	Dr Zalina Zahid	Lecturer Faculty of Computer and Mathematical Sciences Universiti Teknologi MARA
18.	Dr Yogheswaran Gopalan @ Gopal	Lecturer, Faculty of Pharmacy Universiti Teknologi MARA
19.	Dr Aimi Nadia Mohd Yusof	Lecturer Faculty of Medicine Universiti Teknologi MARA
20.	Dr Nur Farhani Zarmani	Lecturer Academy of Contemporary Islamic Studies Universiti Teknologi MARA
21.	Dr Shamsul Anuar Ahmad	Oral Maxillofacial Surgeon & Oral Implantologist KPJ KL Dental Specialist Centre
22.	Puan Sufina Hisham	HappiKoffee (Lay member)