UNIVERSITI TEKNOLOGI MARA (UiTM)

GUIDELINES

RESEARCH ETHICS COMMITTEE (REC) AND RESEARCHERS (Revision 2019)

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PREAMBLE

The REC Guidelines (Revision 2019) is amended and updated from the original REC Guidelines (2015/2016).

All persons conducting research involving human as respondents/subjects/participants must take steps to protect the rights, dignity and data confidentiality of their respondents/subjects/participants. There should be no violation of ethics in any research activities. The risks and benefits to respondents/subjects/participants/ researchers are of utmost importance and must be given due consideration. Therefore, it is compulsory for all researchers conducting research involving human to obtain ethics approval prior to research commencement.

This document aims to provide assistance and guidance to Research Ethics Committee (REC) members, researchers and research participants in UiTM. It governs all research involving human, either as respondents, subjects or participants.

REC works in tandem with the Research Committee at Faculties and State Campuses 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.

The revision was validated at REC Meeting on the 18th of December 2018, and presented at Jawatankuasa Induk Penyelidikan Universiti (JKIPU) for endorsement in January 2019.

1.0 ROLE OF THE RESEARCH ETHICS COMMITTEE (REC)

1.1 The Research Ethics Committee was established to review the ethics of any research involving human participants conducted in UiTM premises and/or by UiTM researchers. REC should uphold proper ethical standards in scientific research to protect the dignity, rights and welfare of research participants as well as the researchers.

1.2 The roles of the REC are to:

(a) review applications for ethics approval for research involving human;

(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 subjects.

[Note: The Research Risk Classification Form (REC 2/2019) completed by applicants will be used to assist risk categorization.]

(c) approve or disapprove of the proposed research;

(d) impose restrictions and conditions on research, if necessary;

(e) review submitted progress reports;

(f) suspend or revoke approval of research, if necessary.

2.0 COMPOSITION OF RESEARCH ETHICS COMMITTEE

2.1 The minimum membership of the REC is nine (9), represented by both genders, comprising:

(a) a Chairman who is the current Assistant Vice Chancellor (Research and Innovation);

(b) a Deputy Chairman;

(c) at least two academic/professional members who are UiTM employee 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 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.

(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 of appointment or otherwise, which should 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 third (2/3) of all scheduled meetings of each year. REC Members must notify the REC Secretariat for any non-attendance.

(i) REC members can be disqualified from their positions if they fail to fulfill the two third (2/3) minimum attendance requirement without valid reasons.

4.0 TRAINING

REC members are required to attend periodic training in research ethics and/or related matters.

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) To ensure applicants provide sufficient information to enable the REC members to make an informed decision.

(b) To oversee arrangements for meetings.

(c) To preside over decision making process.

(d) To invite applicants to present their proposal at meetings, if necessary.

(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 from all parties.

(h) To respond 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) 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.

6.5 The Secretariat

The Secretariat has the responsibility to assist Secretary in the smooth 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 REC.

(c) To screen documents and recommend the category of risks.

(d) To ensure that documents submitted for ethics approval are complete and verified by the Research Committee at Faculty or State Campuses;

(e) To manage REC documentation effectively.

(f) To update the list of REC membership to the National Pharmaceutical Regulatory Agency (NPRA) within 30 working days.

(g) To make preparation for REC meetings.

7.0 RESEARCH COMMITTEE AT FACULTY AND STATE CAMPUS

Each Faculty and State Campus has its own Research Committee 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 is to 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) To agree to and sign a Confidentiality Agreement.

(b) To review all documents submitted to the REC relevant to the study under review.

(c) To declare any conflict of interest.

(d) To provide 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 ethic approval applications reviewed by the REC, including initial application and ongoing reviews.

10.3 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.

10.4 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 Faculty or State Campus 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 of Research Ethics Approval Application (REC 1/2019 Rev. 1).

(b) The application must be sent to the Secretariat in hard and soft copies.

(c) All applications must include the following documents:

i. Cover letter addressed to the Chairman of REC

ii. Application form (REC 2/2019 Rev. 1)

iii. Research Risk Classification Form (REC 3/2019);

iv. Subject Information Form and Consent Form (REC 4/2019 Rev. 1)

v. Checklist for Applicant (REC 5/2019 Rev. 1)

vi. Research proposal

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

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

viii. Study protocol, amendments & sample Case Report Form (CRF)

ix. Signed agreement between involved parties

x. Investigator's Brochure

xi. Financial agreement with sponsor

xii. Insurance statement & documents

xiii. Clinical Trial Agreement

xiv. Curriculum Vitae of all investigators

xv. Good Clinical Practice certificates of all investigators

xvi. Annual Practicing Certificate

11.2 Terms of Submission of Ethics Approval Application

(a) All required documents must be submitted two (2) weeks before the scheduled REC meeting.

(b) 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.

(c) Submission of all forms prescribed by REC must be in English with exception to the research conducted in other languages with Senate approval.

(d) Any data collection instruments that require the respondents/subjects/participants to complete must be prepared in the Malay and English languages and other language(s) understood by the respondents/subjects/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. Not approved

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

13.0 APPROVALS

13.1 Applicant 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 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.

14.3 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.

14.4 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:

15.2 Submission of annual progress report(s) using the Monitoring of Ongoing Studies form (REC 6/2019) due notification in cases of:

(a) serious and unexpected adverse events or early termination using the Monitoring of Ongoing Studies form (REC 6/2019)

(b) application amendments/ protocol deviations using the Amendment of Application/Protocol form (REC 7/2019)

(c) changes in research team membership using the Research Project Membership Amendment form (REC 8/2019)

(d) significant decisions by REC of other institutions

(e) completion of research project using the Project Completion Report form (REC 9/2019)

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 a 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 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 Chairman.

(d) Secretariat must maintain a logbook containing particulars of personnel authorized to access the documents.

17.3 Archiving of Completed Research

(a) Documents of approved research which have been completed will be separately archived.

(b) All archived files will be kept in a cabinet with controlled access.

(c) The archived documents are only accessible by any person through authorization from the Chairman.

(d) 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 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.

REFERENCES

Malaysian Code of Responsible Conduct in Research (2017), National Science Council.

Ministry of Health Malaysia (2018). Malaysian Guideline for Good Clinical Practice. 4th edition.

World Health Organization (2000). Operational Guidelines for Ethics Committees Reviewing Biomedical Research.

World Medical Association (2000). Ethical Principles for Medical Research Involving Human Subjects.

World Medical Association. Declaration of Helsinki (2013).

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