

GUIDELINES FOR RESEARCH ETHICS COMMITTEE (REC) 2015
UNIVERSITI TEKNOLOGI MARA

DISCLAIMER

This guideline aims to provide recommendations for the assistance and guidance of Research Ethics Committee members, researchers and research participants. Universiti Teknologi MARA, Shah Alam does not warrant that the information in it is in every respect accurate or complete, and is not responsible for any errors or omissions or results obtained from the use of such information. Readers are encouraged to consider critically the information and suggestions contained in the guideline and to make up their own minds in relation to the relevant issues and facts. It should be understood that the Malaysian Guidelines for Good Clinical Practices, Ministry of Health Malaysia remains as the primary and definitive source of ethical principles governing the conduct and review of research involving humans.

Endorsed in UiTM REC Meeting on 19 April 2016

1 The Role of Research Ethics Committees

Proper ethical standards should be upheld in scientific research to protect the dignity, rights and welfare of research participants.

The Research Ethic Committees (REC) is a committee established to review the ethics of medical and other health related research involving human participants. The UiTM Research Ethics Committee endorses the use of ICH/ Malaysian Guidelines for Good Clinical Practice as the reference for members of Research Ethics Committee 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:

- 1.1.1 To approve, disapprove or request for modification studies based upon consideration of human subject protection.
- 1.1.2 To request for progress reports from the investigators and oversee the conduct of the study once approval has been granted.
- 1.1.3 To suspend or terminate approval of study.
- 1.1.4 To place restrictions and conditions on studies.

2 Structure of the Research Ethics Committee Members

2.1 Appointment

- 2.1.1 The Vice-Chancellor shall appoint the Chair and Deputy Chair of the REC. Those appointed should have received training in research ethics reviewing and possesses the relevant chairing skills.

2.2 Appointment Procedures for Members

- 2.2.1 Appointment of members can be through consensus and/or direct appointment by the Vice Chancellor.
- 2.2.2 Any of the REC members can nominate a member with reasonable qualifications to serve in the REC.

- 2.2.3 Nominated member will be invited to attend the meeting twice. The nominated member will be required to sign a Confidentiality Agreement and Conflict of Interest Form prior to joining the meetings.
- 2.2.4 Once the nominated member has agreed to be part of the REC, an official letter will be given.
- 2.2.5 Members are appointed based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the work as member of REC.

2.3 Terms and conditions of appointment

- 2.3.1 An appointed member - must be prepared to have his/her full name, profession, and affiliation published. When making appointments, possible conflict of interest should be recorded and published with the personal details.
- 2.3.2 An appointed member is expected to maintain confidentiality regarding applications, meeting deliberations, information on research participants, and related matters.
- 2.3.3 Appointments will be made for a term of two (2) years with provision of re-appointment. There are no limits to the number of renewals.
- 2.3.4 A committee member is normally required to attend in full at least two-thirds of all scheduled meetings in each academic year. Attendance at scheduled meetings should be of sufficient frequency to ensure a member's effective contribution to the work of the committee. Members can be disqualified from their position if they do not attend three consecutive meetings without reason. Members should notify the REC secretariat for any non-attendance.
- 2.3.5 REC members will need to provide a copy of their curriculum vitae.
- 2.3.6 REC Members will be asked to sign a Confidentiality Agreement and Conflict of Interest Form indicating their required assurance to maintain reasonable confidentiality in relation to the information they may become aware of while performing their duty and to report to the Chair of the REC any conflict of interest related to their position as soon as they become aware of it. Confidentiality, however, should not compromise the need for transparency and governance.
- 2.3.7 Members who would like to resign should write to the Vice Chancellor at least one month (1) month before their resignation.
- 2.3.8 Members who are found to be engaged in professional misconduct will be removed from the membership.

2.3.9 Members who have resigned or removed from the membership can be replaced by a qualified new member.

2.4 Composition of Research Ethics Committee

The minimum membership of an REC is five, being men and women, comprising:

- a) a Chairperson;
- b) at least two members who are layperson, either man or woman, who have no affiliation with the institution or organization, are not currently involved in medical or scientific work, and who are preferably from the community in which the institution or organization is located;
- c) at least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the REC (e.g. health, medical, social, psychological, epidemiological, as appropriate);
- d) at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people (e.g. medical practitioner, clinical psychologist, social worker, nurse, as appropriate);
- e) at least one member who is from a religious institution or a person who performs a similar role in a community; and
- f) at least one member who is a lawyer.

2.5 Training

2.5.1 REC members will need initial and continuing education and training regarding research ethics, research methodology and research governance. As a condition of appointment, a member should agree to take part in the initial and continuing education appropriate to his or her role as a research ethics committee member (At least once a year).

3 Function of Members

3.1 Chairperson

The VC will appoint a Chairperson for 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 view. The Chairperson also has the

responsibility for managing the agenda and making sure that all relevant items are covered and adequately recorded. Further guidance to the Chairperson's role in relation to committee meetings can be found in other paragraphs of the Malaysian Guidelines for Good Clinical Practices. The role is likely to include:

- a) considering whether the committee is sufficiently informed on all aspects of research protocols
- b) overseeing arrangements for meetings
- c) presiding over decision-making
- d) inviting researchers to attend meetings
- e) seeking advice from experts
- f) monitoring conflict of interest
- g) overseeing recording of decisions
- h) establishing a complaint process

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 multicenter research approval arrangements, and to be required to represent the REC within the institution and in discussions with researchers and other RECs.

3.2 Lay Members

The qualifications of lay members are their independence from the institution and their non-involvement in medical, scientific or legal work. Those recruited from the community in which the institution is located are more likely to understand the said community and how its members would view involvement in research. And those who have no experience in professions associated with research on human beings are more likely to bring a truly lay perspective. There may need to be more than one member in this category.

3.3 Independent consultant

The REC may use independent consultants where additional or specialized expertise is needed to review specific protocols. Independent Consultants may be asked to review an individual protocol or attend a meeting to provide education on any issue of general interest. Consultants do not count as part of a quorum or vote. They will also need to sign the Confidentiality Agreement and Conflict of Interest Form. The use of consultants will be documented in the protocol file and the minutes of the meeting.

The REC or the Chair may invite consultants from inside or outside the UiTM who have special expertise to act as consultants of human research. The reasons for seeking additional or special competence may include but are not limited to the need for:

- additional scientific, clinical or scholarly expertise.
- particular knowledge about potentially vulnerable populations.
- broader understanding of gender or cultural issues.
- greater sensitivity to community perceptions.
- A statistical opinion.

Independent Consultants:

- must have access to all documents submitted to the REC relevant to the specific study under review.
- must affirm that they have no conflict of interest with respect to the specific studies they are invited to review.
- must maintain strict confidentiality with respect to the specific protocol and the meeting's proceedings.
- may provide information about a specific study by written report, attending the meeting, or both.

3.4 The Secretariat

The Secretariat is an administrative unit which is headed by the Secretary. The Secretariat is responsible for maintaining records and other secretarial duties:

- a) Manage the application to conduct research in UiTM.
- b) Giving advice and information regarding rules and regulations within the ethical aspects through communication with the REC members to the investigator.
- c) Preparation for meeting and communication records.
- d) Monitoring protocol implementation.

4 Conduct of Meeting

4.1 Meeting requirements

4.1.1 Meetings will be held every third Tuesday of the month.

2.3.4 Meeting dates will be announced at the beginning of the year for the rest of the year.

4.1.3 Agenda and documents to be discussed during the meeting will be circulated to the REC members/ Reviewers at least a week before every scheduled meeting.

4.1.4 Minutes will be taken in all scheduled meetings.

4.2 Quorum requirements and voting

4.2.1 When there is less than full attendance, decisions will be adopted only under quorum conditions with a minimum number of 5 members. This should include at least one member who is independent of the Faculty where the research is to take place. There also need to be at least one “expert” member and one “lay” member present.

4.2.2 The REC must review initial and continuing studies at full-committee meetings at which a quorum is present.

4.3 Quorum and voting requirements:

4.3.1 A quorum must be maintained for each vote. If a quorum fails, applications cannot be approved and must be held over until the next convened meeting.

4.3.2 Any member with a conflict of interest with respect to a specific study must leave the room during deliberations and decision-making relating to the study. This member may not vote on the study. This should be documented in the minutes of the meeting.

4.3.3 Any person not listed on the official Committee membership roster, as a regular or alternate member, may not vote.

4.3.4 Voting by proxy is not allowed.

4.3.5 Independent Consultants may not vote.

4.3.6 Generally, decision-making at full committee meetings is by consensus. At the Chair’s discretion, voting may be decided by a show of hands.

4.3.7 The Committee may:

4.3.7.1 Approve a study as submitted. An investigator need not change any aspect of the protocol or consent forms.

4.3.7.2 Require that conditions are met before a protocol is approved. All protocols requiring amendments must be resubmitted to a committee meeting for a decision.

4.3.7.3 Not approve a study in its present form.

4.3.7.4 Defer a decision until the following meeting. A protocol may be held over to the next convened meeting for one or more of the following reasons:

- a) Lack of appropriate expertise at the meeting.
- b) Insufficient information to conduct an adequate review.
- c) Loss of a quorum.

4.4 Conflict of Interest

Any Research Ethics Committee member must disclose a conflict of interest to the Chair and leave the room during discussion of the study and the related decision, except if the member is providing information at the committee's request. The meeting minutes will document the recusal. The definition of conflict of interest extends to consultants and ad hoc reviewers who are asked to review a study because of their expertise. This policy applies to all research reviewed by the Committee, including initial and continuing reviews.

4.4.1 Definition of Conflict of Interest

A conflict of interest generally includes the following:

4.4.1.1 Participation in a study where the REC member is listed as an investigator or is a member of the research team.

4.4.1.2 Supervision of a study where the REC member is the faculty supervisor.

4.4.1.3 The REC member has a 'personal relationship' with the investigator. This means the member has an immediate family relationship or other close relationship with the investigator ('immediate family' means the REC member's spouse or domestic partner and dependent children).

4.4.1.4 The Committee member has a fiduciary relationship to the sponsor. This means the Committee member serves as an executive to a company sponsoring the research or serves on the company's board of directors.

4.4.1.5 Other examples of conflict of interest include but are not limited to the following:

- a) REC member has an interest that he or she believes conflicts with the member's ability to review a project objectively.
- b) Any other reason for which the Committee member believes he or she has a conflict of interest with the research.

4.5 Procedures for handling Research Ethics Committee member's conflict of interest:

- 4.5.1 The REC member with a conflict of interest should not accept the protocol for review and should return it for assignment to another reviewer.
- 4.5.2 The Chair must ensure that a Committee member who discloses a conflict of interest does not participate in the deliberative discussion or vote on the protocol and leaves the room.
- 4.5.3 If committee members need information on the study from the member with a conflict of interest, then the member may remain in the meeting room during the presentation of the study. The member must then leave the meeting room during the deliberative discussion and voting on the protocol.
- 4.5.4 The Committee member with a conflict of interest will not be counted as part of the quorum for the review of the study. If the quorum fails, the Committee cannot take further action or vote on the study.
- 4.5.5 The name of the person leaving the room due to a conflict of interest will be recorded in the minutes of the meetings.

5 Submitting an application

A qualified researcher responsible for the ethical and scientific conduct of the research should submit an application for review to the REC.

5.1 Application requirements

The submission of a research project for ethical review should contain the following:

- a) Study protocol and investigators' brochure/ REC 1 Form, written informed consent form (REC 2 and 3 Forms), recruitment procedures, safety information, information about payment and compensation available to subjects (can be included in REC 1 Form), investigators' curriculum vitae (CV) (only Principal Investigator or Supervisor's CV) and any other relevant documents. Note: for clinical trial research, all investigators involved in the trial will be required to submit a copy of their CV and Good Clinical Practice (GCP) Certificate as required by the Malaysian Guideline for GCP. The application should be sent to the REC secretariat in hardcopy and softcopy.
- b) Required application forms (e.g. REC forms) must be submitted two (2) weeks

before the monthly REC meeting.

- c) Submission should be in Malay or English while consent forms to be in English & Malay (Tamil & Mandarin as per required).
- d) Faculties submitting application forms in bulk (more than 10) should submit at least a month before the monthly REC meeting to give time for the secretariat to process the forms.

5.2 Procedures for changes or amendments of proposal/protocol

- 5.2.1 Any changes made to already approved research proposals, related documents, or instruments must be approved by the UiTM REC prior to their implementation. To request a review of proposed changes, the researcher must write a letter with the amended document.

6 Review of protocols

All properly submitted applications will be reviewed in accordance to the procedure established by the UiTM REC.

The primary task of the REC is to review research proposals and their supporting documents, with special attention given to the informed consent process, documentation, and the sustainability and feasibility of the protocol. REC will take into account prior scientific reviews, if any, and the requirements of applicable laws and regulations.

The following should be considered, as applicable:

- a) Scientific design and conduct of the study
- b) Recruitment of research participants
- c) Care and protection of research participants
- d) Protection of research participants' confidentiality
- e) Informed consent process
- f) Community considerations

7 Decision making procedure

In making decisions on applications for the ethical review of human related research, an REC should take the following into consideration:

- a) a member should withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest; the conflict of interest should be indicated to the chairperson prior to the review of the application and recorded in the minutes;
- b) a decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g., the investigator, representatives of the sponsor, independent consultants) from the meeting, with the exception of REC members;
- c) decisions should only be made at meetings where a quorum (as stipulated in the REC's written operating procedures) is present;
- d) the documents required for a full review of the application should be complete and the relevant elements mentioned above should be considered before a decision is made;
- e) only members who participate in the review should participate in the decision;
- f) there should be a predefined method for arriving at a final decision acceptable to all (e.g., by consensus, by vote); it is recommended that decisions arrived at a group consensus, where possible; when a consensus appears unlikely, it is recommended that the REC vote;
- g) advice that is non-binding may be appended to the decision;
- h) in cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified;
- i) a negative decision on an application should be supported by clearly stated reasons.

8 Communication of decision

A decision should be communicated in writing to the applicant according to the REC procedures, preferably within two weeks from the date of the meeting at which the decision was made. The communication of the decision should include, but is not limited to, the following:

- a) the exact title of the research proposal reviewed;
- b) the clear identification of the protocol of the proposed research or amendment, date, and version number (if applicable) on which the decision is based;
- c) the names and (where possible) specific identification numbers (version numbers/dates) of the documents reviewed, including the participant information sheet/material and informed consent form;
- d) the name and title of the applicant;
- e) the name of the site(s);
- f) the date and place of the decision;
- g) the name of the REC taking the decision;
- h) a clear statement of the decision reached;
- i) any advice by the REC;
- j) in the case of a conditional decision, any requirements by the REC, including suggestions for revision and the procedure for having the application re-reviewed; in the case of a positive decision, a statement of the responsibilities of the applicant; for example, confirmation of the acceptance of any requirements imposed by the REC; submission of progress report(s); the need to notify the REC in cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study); the need to notify the REC in the case of amendments to the recruitment material, the potential research participant information, or the informed consent form; the need to report serious and unexpected adverse events related to the conduct of the study; the need to report unforeseen circumstances, the termination of the study, or significant decisions by other RECs; the information the REC expects to receive in order to perform an ongoing review; the final summary or final report;
- k) the schedule/plan of the ongoing review by the REC;
- l) in the case of a negative decision, the clearly stated reason(s) for the negative

decision;

m) signature (dated) of the Chairperson (or other authorized person) of the REC.

9 Conditional Approvals

- 9.1 Investigator is required to submit the amended documents within 90 days from the date of letter given by the REC secretariat.
- 9.2 Should amendments not submitted within 90 days from the date of the letter, a fresh application has to be made to the REC.
- 9.3 All submitted documents will be brought into the meeting to be discussed by members before approval can be made.

10 Follow-up reviews/progress report

- 10.1 Progress reports on all research with a favorable opinion should be submitted to the main REC at least annually. The first annual report should be submitted twelve (12) months after the date on which the ethical approval was given. Reports should continue to be submitted at least annually until the end of the study is notified.
- 10.2 The REC may request that more regular reports should be submitted, or may request an additional progress report at any time.
- 10.3 Reports may be submitted by the sponsor or the Principal Investigator, but should always be signed by the Principal Investigator.
- 10.4 Progress reports should be acknowledged by the Secretariat and reviewed at least by the Chair or, at the Chair's discretion, by one or more members of the Committee (for example, the lead reviewer for the study) or a Scientific Officer. The Committee should be notified of the receipt of the report. Copies or summaries may be distributed to members.
- 10.5 Following receipt of the first progress report, the Chairperson has the discretion to waive the requirement for further reports on receipt of a written request from the Principal Investigator. This might be appropriate where a study has completed recruitment and intervention, but has a long period of follow-up with minimal involvement of participants.

11 Documentation and Archiving

11.1 Purpose

To provide instructions for preparation and maintenance of active study files and other related documents approved by UiTM REC and storing closed files and retrieval of documents.

11.2 Scope

This SOP applies to all protocols/study files and their related documents that are maintained in the REC/IRMI office and closed files.

11.3 Responsibility

It is the responsibility of the UiTM REC secretariat to ensure that all study files are prepared, maintained, and kept secured for a period of three years after the completion of a study.

11.4 Maintaining active study files and related documents

- a) Minutes/records/notes of the meetings of the UiTM REC will be maintained.
- b) Minutes/records/notes must document the reasoned decision. The minutes must be accessible to authorized representatives of the institution, researchers, and funding agencies.
- c) Any other documents that are submitted to permit review of a proposal will be kept on file. Written feedback about the results of a review must be provided to the faculty member(s) involved in the research.
- d) Master file is the file comprising of all essential documents and correspondence related to the study/protocol. The master files will be established at the beginning of the trial by the REC secretariat.
- e) All related documents will be gathered, classified and combined together of the approved study files.
- f) All active files will be kept in a secured cabinet with controlled access. A logbook of authorized individuals accessing the files will be maintained.
- g) In the event that an internal or external audit is performed to determine whether ethical practices are upheld, documents and records must be stored for three years after completion of the study.

- h) All closed study files will be separately archived.
- i) Final disposal of study/master files on completion of an archival period.

11.5 Disposal of closed files and copies of protocols and documents submitted for UiTM REC review

The master file will be maintained in REC/IRMI office for a period of three years following closure of study. After the completion of an archival period, the closed files will be shredded and disposed of. A logbook of disposed documents will be maintained.

11.6 Accessibility / Retrieval

Master files will be made available for inspection and copying by authorized representatives of regulatory authorities after receiving the request in writing.

12 Appeals

- a) Faculty researchers have a right to appeal negative decisions.
- b) An appeal regarding a negative decision about a graduate or undergraduate project must be activated by the faculty member responsible for the project.
- c) Appeals must be made in writing and include all supporting documents. The appeal must be forwarded to the REC Secretariat within two (2) weeks of issuance of the letter that outlines the reasons for the negative decision. REC Secretariat will include these documents in the next monthly REC meeting for deliberation.
- d) The Committee reserves the right to invite the researcher to appear before the committee in the next REC meeting. Appeals will be settled in a timely fashion and the appeal decision is final.

References

World Medical Association. Declaration of Helsinki.1964.

World Medical Association. (2000). Ethical principles for medical research involving human subjects.

World Health Organization. (2000). Operational guidelines for ethics committees reviewing biomedical research.

Ministry of Health Malaysia (2004). Malaysian Guidelines for Good Clinical Practice. 2nd edition.