

DISCLAIMER

This guideline only 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 contained in them is in every respect accurate or complete, and it is not responsible for any errors or omissions or the results obtained from the use of such information. Readers are encouraged to consider critically the information and suggestions contained in the guidelines and to make up their own minds in relation to the relevant issues and facts. It should be understood that 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

Terms of Reference

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

Purpose of the REC:

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

The Terms of Appointment for Members

- a) Membership Renewal: 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.
- b) Disqualification: 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 meeting 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.
- c) Resignation: Members who would like to resign should write to the Vice Chancellor at least one month (1) month before their resignation.
- d) Removal of member: Members who are found to be engaged in professional misconduct will be removed from the membership.
- e) Replacement of member: Members who have resigned or removed from membership can be replaced by a qualified new member.

Structure of the Research Ethics Committee

Members:

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

- (a) a Chairperson;
- (b) at least 2 members who are lay people, 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, counseling or treatment of people (e.g. medical practitioner, clinical psychologist, social worker, nurse, as appropriate);
- (e) at least one member who is from a religion institution, or a person who performs a similar role in a community; and
- (f) at least one member who is a lawyer.

Function of Members

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

Lay members

The qualifications for 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.

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:

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

Independent Consultants:

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

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.

Scope of responsibility

REC need to be satisfied that the research design can produce valid results and can protect the welfare, dignity and rights of research participants. To be satisfied, an REC may seek or receive advice from an individual, a scientific committee in its institution, an external expert, or it may include an *additional* person who has specific expertise in the particular type of research.

As it is not possible to provide a comprehensive list of relevant considerations for every research approval, the following matters will usually require consideration:

(a) The project

- Is there a clear hypothesis?
- Is the research question useful? Is the research worthwhile?
- Is the research likely to yield new information, enhance understanding or clarify existing uncertainty?
- Has this, or similar, research been carried out before in the same, or similar, contexts?
- Can the research proposal be supported by a systematic review of the literature that would demonstrate the importance of the research question and that it builds upon the results of previous research?
- If indicated, have perspectives of potential participant groups, the wider community, or other disciplines been incorporated into the research proposal?
- Are the aims of the proposal clear?
- Does the value of the project appear to be adequate to justify its conduct with humans?

(b) The researchers

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

obligations?

(c) The funding

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

(d) Research methodology

- Are all aspects of the research methodology clearly described?
- Is the REC satisfied that the methodology is appropriate to the achievement of the aims of the project?

(e) Recruitment of participants

- Is it clear how participants will be recruited?
- Do the recruitment methods respect participants' rights to the confidentiality of their affairs?
- Are the proposed participants appropriate in number and kind?

(f) Burdens of research

- Are the burdens and risks of research to participants clearly identified and have appropriate measures been taken to minimize these?
- Is the balance between the burdens and risks to participants and the aims and benefits of the project such as to warrant approval?

(g) Incentives for participation

- Are financial or other rewards proposed to be given to participants?
- Are these of such a size or value that they may unduly influence the freedom of participants to withdraw or otherwise protect themselves from risks?

(h) Consent

- Are the ways in which participants will be approached clearly described?
- Is the information to be provided to potential participants adequate in content and appropriate in form?
- Do the proposed methods of securing consent to participate provide a) sufficient time to consider the decision; b) evidence that participants understood their choices, and c) sufficient opportunities to ask questions and re-consider?

(i) Discontinuing participation

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

(j) Information protection

- Is it clear who will (and who will not) have access to information collected during the project?
- Are the proposed storage and security measures adequate?
- Are participants clearly informed that information they provide will be used only for the project?
- What measures are proposed to protect the confidentiality of information in the course of the project and are these adequate to give the degree of protection promised to participants?
- Are the manner and form in which results will be published clearly described, and do they adequately protect the confidentiality of information and privacy of participants?

(k) Legal issues

- Does the project involve subject matter or conduct which may give rise to legal vulnerability of participants or researchers? Are adequate precautions to be taken?
- 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 persons in dependent or unequal relationships;
- research involving collectivities;
- research involving indigenous or special groups.

Procedures

Working procedures:

Meetings will be conducted once every month. Meetings of an 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.

An 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. REC should inform researchers in writing of decisions and, in the event of rejections or recommended amendments, the reasons for those decisions.

The agenda, including copies of research proposals, would be distributed to all members prior to the meeting, allowing sufficient time for reading.

When there is less than full attendance at a meeting, the Chairperson must be satisfied, before a decision is reached, that the minimum of 5 members, including a member who is independent of the Faculty where the research is to take place, an “expert” member and a “lay” member have received all papers and have had an opportunity to contribute their views and that these

have been recorded and considered.

Members who are unable to attend a particular meeting can contribute, prior to those meeting, views on each protocol to be considered. Written comments may be communicated by any convenient method, including email or facsimile. The Chairperson is responsible for ensuring that these views are recorded and considered at the meeting. A quorum of 5 members serves the important purpose of ensuring a degree of discussion, but needs to be realistic.

The REC endeavors to reach decisions by general agreement. This need not involve unanimity, but failure to agree may require an extension of time to reconsider the research protocol and its possible amendment, especially when any member is not satisfied that the welfare and rights of participants are protected.

Committees are encouraged to respect the expression of a diversity of views and to allow the time necessary to review all concerns. Full consideration of all relevant perspectives fosters greater confidence in the committee's decisions and the advice it offers.

An REC may invite the researcher(s) to be present for discussions of the research and may request amendments to the research protocol.

REC need to be sufficiently informed about each research protocol. Interviewing researchers is one means to this end.

REC would invite researcher for interviews to proposals involving contentious ethical issues, invasive or potentially risky procedures, or the need for clarification. Interviews provide opportunities for detailed assessment of the proposed research, for provision of information about its conduct, for clarifying the capacity of the researchers to fulfill their responsibilities and for negotiating possible amendments to research proposals. Interviews can contribute to a cooperative working relationship. Communication between individual REC members and researchers should be in accordance with procedures established by the REC.

Confidentiality of protocols and proceedings

Documents are submitted to an REC for the sole purpose of consideration and, if thought fit, approval. RECs should regard this as confidential material. They should take care to prevent it being disclosed outside of the REC except for the purpose for which it was provided, for example obtaining an opinion from an expert. Where a committee thinks consultation within the research or wider communities is desirable, or where it wishes to share its experiences with other committees, it should seek the consent of the parties involved or omit potentially identifying information.

An REC shall ensure that no member of the committee adjudicates on research in which that 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 an REC member has, or could be seen to have, a conflict of interest, that member should withdraw from the meeting when that project is being assessed. The absence of the member concerned should be recorded in the minutes. In addition, a committee member in this situation should not discuss the project 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 project before the member withdraws 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. The REC must consider the extent to which it should disclose that information about funding sources. Researchers must disclose funding sources, affiliations or financial interests so that RECs may consider whether there is any actual or perceived conflict between the researcher's personal and professional involvement in the proposed research. Disclosure of such conflict is a recognized means of protecting a person from later criticism. For this

reason, the REC must consider whether the affiliation or financial interest, or any payments to be received by the researcher, ought to be disclosed to the research participants. An explanation of the REC's reasons for so deciding should be provided to the researcher.

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.