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 factsIt 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 18 December 2018

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) 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.

The Terms of Appointment for Members

(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.

Structure of the Research Ethics Committee

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.

Function of Members

Chairman

The VC will appoint a Chairman 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 Chairman also has the responsibility for managing the agenda and making sure that all relevant items are covered and adequately recorded. Further guidance to the Chairman'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) 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.

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.

Deputy Chairman

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

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

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. 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. 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).

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.

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.

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.