



UITM ETHICS REVIEW COMMITTEE: AUDIT GUIDELINE

**Research Ethics Committee (REC)
Universiti Teknologi MARA
2023 (Version 2)**

REC SECRETARIAT
UITM RESEARCH ETHICS COMMITTEE
SHAH ALAM

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| 2 | 15/03/2025 | <p>Content:</p> <ul style="list-style-type: none"> - Added 7.3.3: Responses to Audit Findings (Agreement) - Previously numbered content 7.3.3 and 7.3.4 are relabelled to 7.3.4 and 7.3.5 respectively - The title for 8.2 edited to: Audit Findings (Agreement) Report to REC - The title for item 8.3 is edited to Certificate of Completion <p>Abbreviation. Three abbreviations added: C - Commendation OFI – Opportunity of Improvement NC - Non-compliance</p> <p>Classifications of findings expanded: 7.3.1 Classification of Findings: The explanation is expanded and added 'Commendation (C), Opportunity for Improvement (OFI) and Non-Compliance (NC). A non-compliance is further classified as either Critical, Major or'</p> <p>Three new items added below 7.3.1: 7.3.1.1 Commendation (C) refers to exemplary fulfilment of the SOP. 7.3.1.2 Opportunity for improvement (OFI) refers to the fulfilment of the SOP, however, a more efficient approach to conforming to the requirements can be implemented. 7.3.1.3 Non-compliance (NC) refers to a non-fulfilment of the SOPs and/or regulatory requirements</p> <p>New item added: 7.3.3 ERC Response to Audit Findings (Agreement). The ERC is required to agree or disagree with the audit findings reports within 14 working days. ERC shall ensure that all disagreements with the audit findings are accompanied by detailed rebuttal statements. Rebuttal statements must include valid and substantiated supportive evidence.</p> <p>Previously numbered content 7.3.3 and 7.3.4 are relabelled to 7.3.4 and 7.3.5 respectively</p> <p>Audit flow chart: Two additional flows added and resulting in the estimated length of total audit days to increase from 87 to increase to 122.</p> <p>7.4 Audit Flowchart. New added flows: - Post-Audit: Agreement (14 days) - Post-Audit: Agreement Review (21 days) - Total estimation time of audit = 122 days</p> <p><u>Edited</u></p> | Emeritus Professor Dato' Dr Raymond Azman Ali, Professor Dr Salmi Razali, Professor Dr Nor Azmi Kamaruddin, Professor Dr Rohana Abdul Ghani, Professor Dr Teh Lay Kek, Professor Dr Mohd Hafiz Hanafiah. Professor Dr Ahmad Izuanuddin Ismail, Associate Professor Dr Norziation Ismail Khan, Associate Professor Dr Maria Justine, Associate Professor Dr Thuhairah Hasrah Abdul Rahman, Associate Professor Dr Suraya Abdul Razak, Associate Professor Dr Tarita Taib, Associate Professor Dr Aimi Nadia Mohd Yusof Associate Professor Dr Farha binti Ariffin, Associate Professor Dr Zamzaliza Abdul Mulud, Associate Professor Dr Daleleer Kaur Randawar, Associate Professor Dr Amal Hayati Ishak, Associate Professor Dr Sayang Mohd Deni, Associate Professor Dr Khasnur Abd Malek, Dr Suhana Aiman, Dr Nur Farhani Zamani, Dr Zainal Abidin Abdul Majeed, Dr Shamsul Anuar Ahmad, Ar Saifuddin Ahmad, Mrs Sufina Hisham, ChM Muhammad Hisyam Jamari, Mr Muhamad Amaluddin Fitri Mohd Amin, Nisa Nabila Mohd Ngali , Mrs Ainul Fadilah Johari, Mrs Raiminazihah Osman |

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| | | <p>Item 8.3 relabelled to 8.2 with a new title 'Audit Findings (Agreement)'. The content is reduced to The EAP shall present the outcome of the final audit findings (Agreement or Disagreement) to the REC.'</p> <p>8.2 relabelled to 8.3 and the title is edited to 'Certificate of Completion'</p> <p>Annex 3 edited to annex 2</p> <p>Report to REC Annex 3 : Divided into 3 reports and title is given to each of the report documents</p> <ul style="list-style-type: none"> - ERC Audit Report 1: ERC Audit Attendance Report - ERC Audit Report 2: ERC Audit Findings (AF) Agreement - ERC Audit Report 3: ERC Audit Corrective Action & Preventive Action (CAPA) Evaluation Report <p>ERC Audit Report 3: Corrective Action & Preventive Action (CAPA) is abbreviated as CAPA 1, CAPA 2, CAPA 3 and so on</p> <p><u>Taken out</u></p> <p>Annex 2 : ERC Audit Self-Assessment</p> <ul style="list-style-type: none"> - ERC Report 3: Response to CAPA | |
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ABBREVIATION

| | | |
|--------|---|---|
| AoR | - | Acknowledgement of Receipt |
| Col | - | Conflict of Interest |
| C | - | Commendation |
| CV | - | Curriculum Vitae |
| EAP | - | ERC Audit Panel |
| ERC | - | Ethics Review Committee |
| BERC | - | Branch Ethics Review Committee |
| CERC | - | College Ethics Review Committee |
| FERC | - | Faculty Ethics Review Committee |
| CoEERC | - | Centre of Excellence Ethics Review Committee |
| GCP | - | Good Clinical Practice |
| MCRCR | - | Malaysian Code of Responsible Conduct in Research |
| NC | - | Non-compliance |
| OFI | - | Opportunity for improvement |
| PI | - | Principal Researcher |
| PIC | - | Person in charge |
| REC | - | Research Ethics Committee |
| SOP | - | Standard Operating Procedure |
| ToR | - | Terms of Reference |

INTRODUCTION

The Ethics Review Committee (ERC) is a committee appointed by the Deputy Vice Chancellor of Research & Innovation (TNCPI), upon recommendation by the Assistant Vice Chancellor/ Rector/ Dean/ Director of the College/ Branch/ Faculty/ Cluster of Centre of Excellence (CCoE), which is composed of medical/ scientific and/or non-medical/ scientific members, according to UiTM: Terms of Reference of Ethics Review Committee (UiTM ERC ToR).

The ERC responsibility is to ensure adherence to the stipulated guidelines, procedures and management of ethical approval, with respect to the protection of the rights, safety and well-being of human participants involved in minimal risk research and exempted research, according to the risk category defined in the UiTM: Terms of Reference of Research Ethics Committee (UiTM REC ToR), for undergraduates and master by coursework.

The principles, requirements and standards set out in this document apply to both the Research Ethics Committee (REC), Universiti Teknologi MARA (UiTM) and all its subsidiary ERCs.

The ERC Audit Panel (EAP) is a committee appointed by TNCPI as recommended by REC and the members must be not affiliated with the audited ERC. Their responsibility is to audit the ERC standard of procedure, efficiency of application process, and compliance to the stipulated guidelines. The auditing activities are limited to minimal risk research/ research exempted from ethical review and does not cover for drug-related clinical trials and more than minimal risk research.

2.0 AUDIT FRAMEWORK AND SCOPE

2.1 Audit Framework

This guideline should be read in conjunction with UiTM: Terms of Reference of Research Ethics Committee (UiTM REC ToR), UiTM: Terms of Reference of Ethics Review Committee (UiTM ERC ToR), UiTM Guidelines: Research Ethics Committee (REC) and researchers, *Dasar Etika Penyelidikan Yang Melibatkan Penyertaan Manusia* (UiTM) and Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (WHO).

The Chairperson of REC may issue written directives to the appointed EAP as he/she thinks necessary for the better carrying out the provisions of these auditing practices in a particular ERC.

The REC Chairperson's directive of '7th November 2023 (approved during the 300th UiTM Senate Meeting) stating that all faculties/ colleges/ branches/ clusters of centres of excellence will be audited approximately every six (6) years or earlier (if necessary) to ensure ERC adherence to the stipulated guidelines, procedures and management of ethical approval, with respect to the protection of the rights, safety and well-being of human participants involved in minimal risk research and exempted research for undergraduates and postgraduates by coursework.

2.2 Scope

This guideline addresses the ERC Audit Panel formation and elements/scope of auditing activities to be conducted upon ERC in Universiti Teknologi MARA (UiTM) as per UiTM ERC TOR.

This guideline will be divided into two main parts:

A. ERC Audit Panel Formation

Describes the criteria and process of establishment of the EAP, which elaborates on the composition, competency, key functions of EAP, as well as terms and conditions of EAP appointment.

B. ERC Audit Practice

Describes the type and frequency of an audit, and the procedure of audit itself, as well as reporting and feedback involved.

This scope of audit will be divided into **three (3)**:

i. Assessment of ERC SOP

The Auditors will review the administrative/working procedures for ERC to approve, require amendment of, or reject a research proposal based on ethical grounds. The standard operating procedures of ERC must adhere to the UiTM REC set of procedures adopted from WHO Standards and Operational Guidance for Ethics Review of Health - Related Research with Human Participants. The Auditors will also examine the relevant training provided by the ERC to their respective staff members and the students.

ii. Efficiency of Application Process

The ERC Audit Panel must be satisfied with ERC adherence and implementation of SOP and guidelines, which can be based on a standardized audit checklist provided

iii. ERC compliance to the stipulated guidelines

The ERC Audit Panel assess whether the ERC comply to the UiTM Guidelines: Research Ethics Committee (REC) and Researchers, *Dasar Etika Penyelidikan Yang Melibatkan Penyertaan Manusia and Standards* and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (WHO) and the Terms of Reference for ERC. This also covers the quality control aspects, describing the quality maintenance of ERC establishment as well as competency and training of ERC secretariat.

3.0 DEFINITIONS

Audit

The act by appointed auditor(s) of conducting an official review of ERC documents, facilities, records, and any other resources that are deemed by the auditor(s) to be related to the research that may be located at the site/facilities of the faculty/branch/college/cluster of centres of excellence, or at other establishments deemed appropriate by the auditor(s).

Compliance

The state of conformity of a regulated party with a legislative or regulatory requirement or a recognized standard or guideline.

Confidentiality

Prevention of disclosure, to other than authorised individuals, of a sponsor's proprietary information or of a participant's identity.

Direct Access

Permission to examine, analyse, verify and reproduce any records and reports that are important to evaluation of a study or ethical approval procedure. Any party (e.g., regulatory authorities, staff and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of participants' identities and proprietary information.

Ethics Review Committee (ERC)

Ethics Review Committee (ERC) is an appointed committee by Deputy Vice Chancellor (Research & Innovation), upon recommendation by Dean/ Rector/ Assistance Vice Chancellor (AVC), which is constituted of medical/scientific or non-medical/non-scientific members. The ERC responsibility is to ensure adherence to the stipulated guidelines, procedures and management of ethical approval, with respect to the protection of the rights, safety and well-being of human participants involved in minimal risk research and exempted research for undergraduates and postgraduates by coursework. The principles, requirements and standards set out in this document apply to ERC reviewing related research that relates to areas of responsibility of the Research Ethics Committee (REC), Universiti Teknologi MARA (UiTM).

Exempted (risk)

Human participants studies that present no greater than minimal risk to participants and fit into one or more exempt categories, as described in UiTM: Terms of Reference of Research Ethics Committee (UiTM REC ToR).

Findings

A deviation or deficiency noted by an auditor during an audit.

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial participants are protected.

Informed Consent

A process by which a participant voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the participant's decision to participate. Informed consent is usually documented by means of a written, signed and dated informed consent form, unless the study is conducted via an online platform or survey.

Audit

The act by an auditor(s) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the auditor(s) to be related to the study, and the approval procedure, at the ERC facilities, or at other establishments deemed appropriate by the auditors.

Auditor

Any person appointed to be an auditor by TNCPI, with the relevant training or qualifications as recommended by REC and must be not affiliated with the audited ERC.

Investigation

Specific response to known or suspected non-compliance. Investigations typically are undertaken when there are reasonable grounds to suspect that non-compliance has occurred and that enforcement measures may be necessary (e.g. quality complaints, reports from other researchers or relevant bodies, or etc.).

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, as described in UiTM: Terms of Reference of Research Ethics Committee (UiTM REC ToR).

More than minimal risk

Research activities that present greater than minimal risk to human participants, as described in UiTM: Terms of Reference of Research Ethics Committee (UiTM REC ToR).

Protocol / research methodology

A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a study. The protocol usually also gives the background and rationale for the study, but these could be provided in other protocol referenced documents.

Protocol Amendment

A written description of a change(s) to or formal clarification of a protocol.

Researcher

A person responsible for the conduct of the research.

Research Ethics Committee (REC)

An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical/scientific professionals and non-medical/non - scientific

members, whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on the trial protocol, the suitability of the researcher(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial participants. The legal status, composition, function, operations and regulatory requirements pertaining to Research Ethics Committees may differ among countries but should allow the Independent Ethics Committee to act in agreement with GCP as described in Malaysian Guideline for GCP.

Study

Any investigation involving human participants intended to answer research questions and research objectives.

The Malaysian Code of Responsible Conduct in Research (MCRCR)

A comprehensive, robust, and contextually-appropriate guideline which is aligned to the best practices in research and in accord with international standards and practice, yet congruent with local ethical and cultural milieu and legal requirements.

4.0 ESTABLISHMENT OF ERC AUDIT PANEL

4.1 Directive to Establish ERC Audit Panel

The directive to establishment of Ethics Review Committee (ERC) is by the Deputy Vice Chancellor of Research & Innovation (TNCPI), upon recommendation by the REC UiTM, and the implementing officer is Assistant Vice Chancellor (AVC) / Rector / Dean / Director of the College/Branch/Faculty/Cluster of Centre of Excellence (CCoE), according to UiTM: Terms of Reference of Ethics Review Committee (UiTM ERC ToR).

It is the responsibility of the REC to ensure that the ERCs adhere to the guidelines and perform their duties as stipulated in the ERC ToR. The EAP is therefore established by the Senate's directive to ensure that an audit panel can carry out the duty of auditing the ERCs.

4.2 Appointment of ERC Audit Panel

Members of EAP are appointed by the TNCPI, by the recommendation of REC.

4.2.1 Responsibilities

In performing the ERC audit, the appointed auditor(s) should always strive to be objective in their assessment and judgment. The audit member should comply fully with the rules, regulations and ERC audit guidelines. The assessment and reporting should be conducted professionally without fear of favour. In addition, auditors must avoid making false, unsupported or misleading statements that tend to injure or discredit the reputation of the audited ERC. Nonetheless, ethical audits require full disclosure of any finding (or observation) with responsible members of REC and the audited ERC. During the conduct of the audit, auditors often have access to proprietary information of the audited ERC. Henceforth, auditors have a moral obligation to treat such information as confidential. This requirement is self-evident and must be adhered to in every respect.

4.2.2 Duration of Appointment

The duration of appointment for ERC Audit Panel is three (3) to twelve (12) months for pre-audit, audit, post-audit procedures (until the audit exit report is finalized and endorsed).

4.2.3 Deliverables

The EAP tasks involve:

- a. obtaining and examining the pre-audit documents from ERC;
- b. conducting the audit on-site, providing feedback to ERC;
- c. preparing the audit reports to ERC;
- d. reviewing the CAPA (corrective action, prevention action) report from ERC;
- e. preparing the final report to REC.

4.2.4 Confidentiality

The Auditors must sign the confidentiality statement to treat the audit findings as confidential and not to disclose the information to other parties without REC's permission. The confidentiality statement will be embedded in the appointment acceptance letter to be signed by the appointed ERC Audit Panel.

4.2.5 Liability

The ERC Audit Panel shall not be held liable for their responsibilities as entrusted by UiTM. Under no circumstances will the ERC Audit Panel be held responsible or liable in any way for any claims, damages, losses, expenses, costs or liabilities whatsoever resulting or arising directly or indirectly from their assigned tasks.

5.0 CRITERIA OF AUDIT PANEL

5.1 Composition of ERC Audit Panel

The members of the EAP shall be appointed by the TNCPI, which may include:

- i. Lead Auditor, ONE (1) - a member of the REC
- ii. Secretary, ONE (1) - a member / the secretary of the REC
- iii. Auditor, AT LEAST TWO (2) - a member or associate member of the REC
- iv. Secretariat, AT LEAST ONE (1)

A minimum of TWO (2) members and ONE (1) secretary/secretariat should be present during each audit.

A minimum of ONE (1) member who is GCP and/or MCRCR certified is required if the ERC is involved in clinical/health science-related studies.

5.2 Criteria of ERC Audit Panel

The members of the EAP should be/have:

- i. appropriately trained and qualified to review ethical review practices.
- ii. experience in working with quality evaluation (auditing), preferably within ethical review systems.
- iii. demonstrated communication skills and preferably experience in research.
- iv. thoroughly familiar with the SOP, requirements, practices, and needs of ERCs, and

- they should be knowledgeable of the legislative and regulatory framework in which the ERC to be reviewed is working.
- v. signed confidentiality and COI agreements.

5.3 Competency and Training

5.3.1 Competency

Fundamental understanding of audit panel competency:

- i. Core competencies are viewed as collective.
- ii. It should not be expected that EAP members of the panel should possess all competencies because the experience and expertise of the individual member complement one another in the group.

5.3.2 Training

- i. Must be regularly trained with the relevant guidelines and SOPs, especially with those of UiTM REC and ERC.
- ii. Optionally, undergoes regular training related to audit or systematic process/management.

5.4 Key Function

- i. To provide continuous support and advice on ethical dimensions of the individual case.
- ii. To investigate if the recommendation was followed through from the previous meeting findings.
- iii. To continue to identify the ethical problem(s) and facilitate their resolution within the context of, but not limited to, current legal and professional requirements.

Aspiration for all members to possess a basic level of skill and knowledge, and some members possess an advanced level of knowledge and skills necessary for specific functions, e.g., leading a case consultation.

Individuals providing consultation services should possess all the basic skills and knowledge. All members of the case consultation team should acquire at least basic competencies.

6.0 TYPE AND FREQUENCY OF THE AUDIT

6.1 Routine Audit

A Routine Audit is an audit conducted on the ERC to ensure that the ERC functions in accordance with the Malaysian and UiTM regulatory requirements and other established guidelines. Approximately 10-20% of the ERCs will be audited by the EAP each year. The ERC must be audited every 6 years or earlier if required.

6.2 Triggered Audit

A Triggered Audit is an audit that is only triggered when specific concerns are raised to the REC, thus it may be conducted at any time deemed necessary.

These specific concerns are:

- i. Complaints or reports on ERC regarding possible misconduct, ethical or safety issues.

- ii. Non-adherence to regulatory and legal requirements
- iii. Other issues deemed appropriate by the REC

7.0 PROCEDURE OF THE AUDIT

An audit shall be conducted according to the established procedure and proposed timeline based on the flowchart detailed in **Section 7.4**. During the audit, documents as listed in **Annex 1** (but not limited to) may be requested by the auditors to be inspected. Auditors will attempt to reconstruct the work process involved in the core activities of the ERC based on available SOP, documents and records.

7.1 Pre-Audit

7.1.1 Audit Plan & Timeline

The appointed EAP shall outline the scope, plan and timeline of audit according to the guidelines and terms given by the REC

7.1.2 Audit Notification

The EAP shall communicate with the ERC Secretariat to determine the appropriate date of the audit. The EAP shall issue a notification letter to the ERC Secretariat. The EAP shall inform the agendas, requirements, and the conduct of audit to the auditee. The ERC shall be given a self-assessment form.

7.2 During the Audit

7.2.1 Opening

The Lead Auditor of EAP shall open the meeting, attended by the EAP members and the chairperson or other members and the secretariat of the ERC.

The purpose of an opening meeting is to (but not limited to):

- i. Highlight the scope of the audit
- ii. Explain the regulatory framework for the conduct of the audit
- iii. Explain the methods and procedures to be used during the audit
- iv. Confirm that the resources, documents and facilities needed by the auditor(s) are made available
- v. Confirm the time and date for the closing meeting and interim meetings, if any.

This shall be followed by a presentation from the representative of the ERC on the current activities, workload and function of the ERC. Attendance will be kept by the EAP.

7.2.2 Audit Activities

The audit activities will be detailed in the audit plan. During the audit, the auditors reserve the right to adjust the plan to ensure all the audit objectives are achieved. The secretary or at least one representative from the secretariat who is familiar with the functions of the ERC should be present throughout the conduct of the audit. Auditors shall be granted direct access to all source data/documents, books, records and reports in hardcopy or softcopy that are relevant to the audit. During the audit, documents as listed in Annex I (but not limited to) may be requested by the auditors to be inspected. Auditors will attempt to reconstruct the work process involved in

the core activities of the ERC based on available SOP, documents and records. ERC shall ensure that its management and other key personnel are available during the audit in the event that their input is required by the auditors. The ERC shall also make available a room for document examination as well as assist in any other audit related activities.

7.2.3 Exit Meeting

The exit meeting shall be attended by the EAP members and the chairperson or other members and the secretariat of the ERC. During this meeting, the EAP shall have the draft of the audit report and the Lead Auditor shall verbally present all the findings and observations made during the audit to the ERC representatives. At the end of the session, representatives from the ERC shall be allowed to clarify the observations made by the auditors, if possible. Attendance will be kept by the auditor and an acknowledgement will be obtained from the representatives of the ERC on the evidence collected during the audit.

7.3 Post-Audit

7.3.1 Classification of Findings

The classification of the audit findings is intended to help classify the severity of observations. Overall, the evaluation will commensurate with the nature, extent and severity of the deviations. The classification of findings includes Commendation (C), Opportunity for Improvement (OFI) and Non-Compliance (NC). A non-compliance is further classified as either Critical, Major or Minor.

7.3.1.1 Commendation (C) refers to exemplary fulfilment of the SOP.

7.3.1.2 Opportunity for improvement (OFI) refers to the fulfilment of the SOP, however, a more efficient approach to conforming to the requirements can be implemented.

7.3.1.3 Non-compliance (NC) refers to a non-fulfilment of the SOPs and/or regulatory requirements.

i. Critical

Conditions, practices or processes that adversely affect the rights, safety or wellbeing of the participants. Critical observations are considered totally unacceptable

ii. Major

Conditions, practices or processes that might adversely affect the rights, safety or wellbeing of the participants. Major observations are serious deficiencies and are direct violations of GCP principles and regulatory requirements.

iii. Minor

Conditions, practices or processes that would not be expected to adversely affect the rights, safety or wellbeing of the participants. Observations

classified as minor, indicate the need for improvement of conditions, practices and processes.

7.3.2 Audit Exit Report

All findings shall be classified as per definitions in **Section 7.3.1** will be presented as a written audit report based on **Section 8.1** and **Annex 2 and Annex 3**. The ERC shall receive a written **Audit Findings** detailing the findings and observations within 21 working days from the last day of audit.

7.3.3 ERC Response to Audit Findings (Agreement)

The ERC is required to agree or disagree with the audit findings reports within 14 working days. ERC shall ensure that all disagreements with the audit findings are accompanied by detailed rebuttal statements. Rebuttal statements must include valid and substantiated supportive evidence, until the findings are agreed by both the EAP and the ERC.

7.3.4 Corrective Action and Preventive Action (CAPA)

The ERC shall provide the CAPA based on the Audit Report, within 14 working days. If the reviewed CAPA is deemed unsatisfactory, a subsequent CAPA may be requested and submitted within 14 working days under normal circumstances, until the CAPA is deemed satisfactory by the EAP.

7.3.5 Audit Completion

An ERC Audit Certificate of Completion (refer **Section 8.3** and **Annex 5**) shall be issued to the successful ERC to indicate good practice and compliance with the regulations and guidelines.

7.4 Audit Flowchart

| FLOWCHART | PARTY-IN-CHARGE | PROCEDURE | PROPOSED TIMELINE |
|-----------|-----------------|--|-----------------------|
| | - | START | - |
| | EAP | Pre-Audit: Audit plan | 14 days |
| | EAP, ERC | Pre-Audit: Audit Notification | 7 days prior to audit |
| | EAP, ERC | Audit: Opening | 3 days |
| | EAP, ERC | Audit: Inspection | |
| | EAP, ERC | Audit: Closing | |
| | EAP | Post-Audit: Audit Report | 21 days |
| | ERC | Post-Audit: Agreement | 14 days |
| | EAP | Post-Audit: Agreement Review | 21 days |
| | ERC | Post-Audit: Corrective Action and Preventive Action (CAPA) | 14 days |
| | EAP | Post-Audit: CAPA Review | 21 days |
| | EAP | Post-Audit: Audit Completion | 7 days |
| | - | FINISH | |

Total estimation time of audit = 122 days

8.0 REPORT AND FEEDBACK OF AUDIT

8.1 ERC Audit Report

The Lead Auditor must ensure that all the information provided is accurate and valid.

The ERC Audit Report (refer **Annex 2, Annex 3 and Annex 4**) shall include at least the following:

- i. The ERC official name, address, phone number and email address.
- ii. The EAP auditors present.
- iii. The attendance record of the auditors and auditees during the audit.
- iv. A summary of the ERC activities: list of full meetings held during the audited years, including their dates and the number of members attending.
- v. The number of sampled applications audited.
- vi. The details of the sampled applications.
- vii. Overview and details of audit findings/observations agreement or disagreement
- viii. Clarification of CAPA, its review and resolution status.

8.2 Audit Findings (Agreement) Report to REC (Annex 3)

The EAP shall present the outcome of the final audit findings (Agreement or Disagreement) to the REC before proceeding to Report 3 (Annex 4).

8.3 Certificate of Completion

Once the audit has been completed successfully, the ERC will be given the ERC Audit Certificate of Completion (refer **Section 9.1 and Annex 5**).

9.0 MAINTENANCE OF ETHICS REVIEW COMMITTEE (ERC) ESTABLISHMENT AND QUALITY CONTROL

9.1 Maintenance of ERC Establishment

Once an ERC has been issued the Audit Certificate of Completion, its information will be made available as an active ERC to the public via the UiTM REC website. The ERC's name, address, contact number and email address, as well as the chairperson's name, will be available on the UiTM REC website.

9.2 Revision of Registration Information

The ERC is responsible for notifying the UiTM REC of any amendment(s) or information updates pertaining to the ERC. The ERC shall notify the UiTM REC within 30 working days if any of the following information is altered:

- i. The ERC's details, such as name, address, contact number and email address.
- ii. The chairperson's name and details.
- iii. Any change of membership or composition of the ERC.

The REC may request further supplementary information and/or documentation if deemed necessary. The REC reserves the right to reverse/amend any revision made by the ERC if necessary.

9.3 The ERC Termination/Suspension of Approved Research Ethics Application

The ERC should promptly notify REC with detailed written information if the ERC terminates/suspends a study that has been given approval.

ERC shall have the authority to suspend or terminate studies that have been given approval of research ethics in cases such as:

- i. Research that is not conducted in accordance with the REC's requirements.
- ii. Research that has been associated with unexpected serious harm to participants.
- iii. Any suspension or termination of approval shall include a statement of the reasons for ERC's action and shall be reported promptly to the researcher, REC, and appropriate institutional officials (ANC, Rectors, Deans, or Directors).
- iv. Any suspension or termination of studies will be informed to REC and documented.

9.4 Notification of Administrative Requirement

- i. All the notifications from 9.2 shall be submitted in soft copy via email to REC.
- ii. The information received from ERC will be archived in the official UiTM REC's online cloud storage.

9.5 Competency and Training of ERC Secretary and Secretariat

9.5.1 Competency

- i. Minimum of a Diploma holder
- ii. Excellent communication and presentation skills
- iii. Excellent report writing skills
- iv. IT and computer literate
- v. Updated training records (yearly)
- vi. Ability to work in multi-disciplinary and multi-cultural settings
- vii. Understand and sign a confidentiality, and COI agreements are maintained

9.5.2 Training

- i. Must be regularly trained with the relevant guidelines and SOPs, especially with those of UiTM REC and ERC.
- ii. Optionally, undergoes regular training related to administrative or secretarial work.

10.0 ANNEX

Annex 1: Audit Review of Documentation

The aim is to assess if ethical review of research proposals is carried out according to the ERC's own written standard operating procedures (SOP). It is also to assess whether ERC operates in conformity with the Declaration of Helsinki, the ICH/Malaysia GCP Guidelines, UiTM guidelines, other relevant laws and regulatory requirements.

10.1 ESTABLISHMENT OF THE ERC

The main points to consider are the following:

- i. The authority under which the ERC was established
- ii. A statement that the ERC operates in conformity with the Declaration of Helsinki, the ICH/Malaysia GCP Guidelines, UiTM guidelines, relevant laws and regulatory requirements
- iii. Adequate provisions to protect the privacy of participants and to maintain the confidentiality of data

10.2 THE MEMBERSHIP OF THE ERC

The main points to consider are the following:

- i. The membership requirements, including the duties and responsibilities of member
- ii. The terms for the appointment of members of the ERC (for example, duration, renewal procedure; disqualification, and resignation and replacement procedures)
- iii. The conditions of appointment (for example, withdrawal from the decision-making process if there is a conflict of interest; willingness to publicise his/her full name, profession and gender; and the signing of confidentiality agreement)
- iv. The procedure for making appointment including the individual or party that makes the appointment, selection of candidates (for example, by consensus, by majority vote, or by direct appointment)
- v. A listing of current and previous members of the ERC
- vi. The curriculum vitae of the current and past members of the ERC
- vii. A description of the requirements for the ERC offices (for example, chairperson, secretary)
- viii. The quorum requirements, including the minimum and maximum numbers of ERC members to be present
- ix. If an ERC regularly reviews research that involves a vulnerable category of participants, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those participants.

10.3 APPLICATIONS MADE TO THE ERC

The main points to consider are the following:

- i. The published guidelines for submission of application for the review by the ERC

- ii. The maintenance of records for communications regarding the application
- iii. The review procedure timelines

10.4 REVIEW PROCEDURES OF THE ERC

The main points to consider are the following:

- a. The meeting procedures
- b. The elements of the review of the application
 - 1. Scientific design and conduct of the study
 - 2. Risks and potential benefits
 - 3. Selection of study population and recruitment of research participants
 - 4. Inducements, financial benefits and financial costs
 - 5. Protection of research participants' privacy and confidentiality
 - 6. Informed consent process
 - 7. Community considerations
- c. The decision-making procedure
- d. The procedure for communicating a decision
- e. The documentation and archiving procedures; including an inventory of all documents archived and the length of storage of the documents

10.5 ACTIONS TAKEN BY THE ERC

The main points to consider are the following:

- a. The screening of documents submitted by applicants
- b. The correspondence regarding applications, decisions, and follow-ups
- c. The agenda of ERC meetings
- d. The minutes of ERC meetings with detail to show attendance at the meetings and recusal
- e. The decisions and advice provided to applicants
- f. Notifications of completion or premature study suspensions/terminations, if deemed required.

10.6 RECORDS AND REPORTS

The main points to consider are the following:

- a. Maintain adequate documentation of ERC activities, including the following:
 - Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by researchers, and reports of injuries to participants.
 - Minutes of ERC meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the ERC; the vote on these actions including the number of members voting for, against, and abstaining; recusal; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

- A list of ERC members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe EAPh member's chief anticipated contributions to ERC deliberations.
 - Written procedures/standard operating procedures (SOP)
- b. The records required by this regulation shall be retained for at least 6 years and shall be accessible for audit at reasonable times and in a reasonable manner.

Annex 2 : ERC Audit Report 1: ERC Audit Attendance Report

| | | | |
|------------|-----------------------------|--------------|--|
| EAP | ERC Audit Panel | Document No: | |
| | ERC Audit Attendance Report | Issue Date | |
| | | Version | |
| | | Page | |

| No. | Name | Day 1 [Date] | Day 2 [Date] |
|---------------------|------|-----------------|-----------------|
| ERC Audit Committee | | | |
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |
| [ERC Name] | | | |
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |
| 7 | | | |

Annex 3: ERC Audit Report 2: ERC Audit Findings (AF) Agreement

| | | | |
|------------|--------------------------------------|--------------|--|
| EAP | ERC Audit Panel | Document No: | |
| | ERC Audit Findings (AF) Agreement | Issue Date | |
| | | Version | |
| | | Page | |

| | |
|--------------------------|----------------------------|
| ERC Audited Site | |
| Address | |
| Members of EAP Present | 1. 2. 3. 4. 5. |
| Date of Audit | |
| Studies Audited | 1. 2. 3. 4. |
| Date of Closing Meeting | |
| Date of Audit Completion | |

| Overview of Findings: | | | | |
|-----------------------|----------------------------|---------------------|---------------------|---------------------|
| No. | Classification of Findings | Summary of Findings | Date of AF Received | Date of AF Accepted |
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |
| 5 | | | | |

| | | | |
|-----|--|---------------------|--|
| EAP | ERC Audit Panel | Document No: | |
| | ERC Audit Findings (AF) Agreement | Issue Date | |
| | | Version | |
| | | Page | |

| Detailed Findings and Feedback: | | |
|---------------------------------|--|--|
| No. | Detailed Findings | ERC Rebuttal with Evidence |
| 1 | [filled by auditor, after audit] | [only to be filled by Auditee when there is evidence to suggest otherwise] |
| | Agreement with these Audit Findings: Yes / No | |
| 2 | [filled by auditor, after audit] | [only to be filled by Auditee when there is evidence to suggest otherwise] |
| | Agreement with these Audit Findings: Yes / No | |
| | | [only to be filled by Auditee when there is evidence to suggest otherwise] |
| | Agreement with these Audit Findings: Yes / No | |

| | |
|---|--|
| Prepared by: | Verified by: |
| [signature] [name] Secretary ERC Audit Panel | [signature] [name] Lead Auditor ERC Audit Panel |
| Responded by: | Accepted by: |
| [signature] [name] Secretariat [ERC Name] | [signature] [name] Chairperson [ERC Name] |

Annex 4: ERC Audit Report 3: ERC Audit Corrective Action & Preventive Action (CAPA) Evaluation Report

| | | | |
|------------|--|--------------|--|
| EAP | ERC Audit Panel | Document No: | |
| | ERC Audit Corrective Action & Preventive Action (CAPA) Evaluation Report | Issue Date | |
| | | Version | |
| | | Page | |

| | |
|--------------------------|----------------------|
| ERC Audited Site | |
| Address | |
| Members of EAP Present | 1. 2. 3. 4. |
| Date of Audit | |
| Studies Audited | 1. 2. 3. 4. |
| Date of Closing Meeting | |
| Date of Audit Completion | |

| Overview of Findings: | | | | |
|-----------------------|----------------------------|---------------------|-----------------------|-----------------------|
| No. | Classification of Findings | Summary of Findings | Date of CAPA Received | Date of CAPA Resolved |
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |

| | | | |
|------------|--|--------------|--|
| EAP | ERC Audit Panel | Document No: | |
| | ERC Audit Corrective Action & Preventive Action (CAPA) Evaluation Report | Issue Date | |
| | | Version | |
| | | Page | |

| | | | |
|---|----------------------------------|--|--|
| Detailed Findings and Feedback: | | | |
| No. | Detailed Findings | Corrective Action & Preventive Action (CAPA) | |
| 1 | [filled by auditor, after audit] | [filled by auditee, after receiving audit report] [clarify all CA & PA taken to address the findings] CAPA 1: CAPA 2: CAPA 3: | |
| CAPA Review Comment: Resolved: Yes / No | | | |
| 2 | [filled by auditor, after audit] | [filled by auditee, after receiving audit report] [clarify all CA & PA taken to address the findings] CAPA 1: CAPA 2: CAPA 3: | |
| CAPA Review Comment: Resolved: Yes / No | | | |
| 3 | [filled by auditor, after audit] | [filled by auditee, after receiving audit report] [clarify all CA & PA taken to address the findings] CAPA 1: CAPA 2: CAPA 3: | |
| CAPA Review Comment: Resolved: Yes / No | | | |
| Prepared by: | | Verified by: | |
| [signature] [name] Secretariat [ERC Name] | | [signature] [name] Chairperson [ERC Name] | |
| Responded by: | | Verified by: | |
| [signature] [name] Secretary ERC Audit Panel | | [signature] [name] Lead Auditor ERC Audit Panel | |

Annex 5: ERC Audit Certificate of Completion



JAWATANKUASA ETIKA PENYELIDIKAN (JEP)
RESEARCH ETHICS COMMITTEE (REC)

UNIVERSITI TEKNOLOGI MARA (UiTM)

SIJIL PENYEMPURNAAN AUDIT JAWATANKUASA PENILAIAN ETIKA
ETHICS REVIEW COMMITTEE AUDIT CERTIFICATE OF COMPLETION

ID SIJIL :
CERTIFICATE ID

JAWATANKUASA PENILAIAN ETIKA :
ETHICS REVIEW COMMITTEE

TARIKH AUDIT :
DATE OF AUDIT

TEMPOH SAH SIJIL :
CERTIFICATE VALIDITY

Jawatankuasa Penilaian Etika ini telah lulus audit dan dimasukkan ke dalam senarai aktif Jawatankuasa Penilaian Etika, oleh Jawatankuasa Etika Penyelidikan, Universiti Teknologi MARA.
This Ethics Review Committee has passed the audit and entered the active list of the Ethics Review Committee, by the Research Ethics Committee, Universiti Teknologi MARA.

[SIGNATURE]

[SIGNATURE]

[NAMA / NAME]

Ketua Auditor / *Lead Auditor*
Panel Audit ERC (PAE) /
ERC Audit Panel (EAP)
Universiti Teknologi MARA (UiTM)

[NAMA / NAME]

Pengerusi / *Chairperson*
Jawatankuasa Etika Penyelidikan (JEP) /
Research Ethics Committee (REC)
Universiti Teknologi MARA (UiTM)