GUIDELINES FOR UCSI UNIVERSITY

INSTITUTIONAL ETHICS COMMITTEE (IEC)

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1.0 GLOSSARY

1.1 Adverse Drug Reaction (ADR)

In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

Regarding marketed medicinal products: a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.2 Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.3 Blinding/Masking

A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

1.4 Case Report Form (CRF)

A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

1.5 Clinical Trial/Study

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s) and/or to identify any adverse reactions to an investigational product(s) and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

1.6 Confidentiality

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

1.7 Conflict of Interest (COI)

In the research context, scientists have a conflict of interest if they stand to achieve personal gain (money or the equivalent) by failing to discharge professional obligations, either to protect the welfare of participants or to uphold the integrity of the scientific process.

1.8 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 subjects are protected.

1.9 Informed Consent

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

1.10 Investigator

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

1.11 Investigator's Brochure (IB)

A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects

1.12 Medical Research Ethics Committee (MREC)

An external committee to provide independent review, advice and decision on health research/specific protocols involving human subjects conducted by staff of MOH or involving MOH facilities. Medical Research and Ethics Committee (MREC) may also act as an independent ethics committee for non-MOH institutions. MREC is composed of scientist and non-scientist and constituted and operated under Director General of Health Malaysia Authority. Extensive clinical research involving human subjects requires prior ethics review and approval by the MREC.

1.13 National Committee for Clinical Research (NCCR)

A committee established for the purpose of coordinating and promoting clinical research in Malaysia, chaired by the Director General of Health, Ministry of Health Malaysia.

1.14 Protocol

A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.

1.15 Randomisation

The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

1.16 Serious Adverse Event (SAE)/Serious Adverse Drug Reaction (Serious ADR)

Any untoward medical occurrence that at any dose: -

- results in death,
- is life-threatening,
- requires inpatient hospitalisation or prolongation of existing hospitalisation,
- results in persistent or significant disability/incapacity, or
- is a congenital anomaly/birth defect (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.17 Sponsor

An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.

1.18 Subject/Trial Subject/Participant

An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

1.19 UCSI Institutional Ethics Committee (IEC)

An independent Institutional committee 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 subjects 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 investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

1.20 Vulnerable/Marginalised Subjects

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, and patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

2.0 INTRODUCTION OF UCSI INSTITUTIONAL ETHICS COMMITTEE (IEC)

Contemporary research ethics guidelines are instituted to ensure that research be subjected to prior ethical review by a competent IEC. Such review is intended to ensure that the ethical principles and practices put forward in the guidelines will be followed in the proposed research. Independent Ethics Committee (IEC) is an independent body constituted of medical/scientific and non-medical/scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a clinical trial.

a) The UCSI University (UCSI) Institutional Ethics Committee (IEC) guidelines is based on principles expressed in Declaration of Helsinki (2013), the 4th Malaysian Guidelines for Good Clinical Practice (ICH-GCP) 2018, WHO's Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, and any other regulatory requirements.

b) The UCSI IEC is also guided by the National and International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS), Operational Guidelines for Ethics Committees That Review Biomedical Research (WHO) and the Belmont Report.

c) UCSI IEC recognises ethical approvals from Medical Research & Ethics Committee (MREC), Ministry of Health Malaysia. Exemptions will be granted for research with MREC approvals.

d) The UCSI IEC establishes its own standard operating procedures based on the 4th Malaysian Guidelines for Good Clinical Practice, 2018.

e) The principal investigator and all co-investigators are deemed responsible and qualified and is/are held liable in ensuring that basic principles of protection for human participants is provided, and is in accordance with this guidelines.

f) For optimal function the IEC will has the following:

- Support staff to carry out its technical and administrative responsibilities;
- Resources such as office space and equipment and supplies (e.g. computers, stationery, telephones, photocopying machines, shredding machine) to conduct administrative business, to store committee files, and to keep documents secure and confidential;
- A dedicated room for meetings and for members to communicate as needed between meetings;
- Adequate financial resources to permit the committee to produce high-quality work.

2.1 Responsibilities

a) UCSI IEC will safeguard the rights, safety, and well-being of all trial subjects. Special attention will be paid to trials that may include vulnerable subjects.

b) UCSI IEC will obtain the following documents: trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g., advertisements), and written information to be provided to subjects. Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IEC may need to fulfil its responsibilities.

c) UCSI IEC will review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed and the dates for the following outcomes:

- Approval/favourable opinion;
- Modifications required prior to its approval/favourable opinion; - Disapproval / negative opinion; and
- Termination/suspension of any prior approval/favourable opinion.

d) UCSI IEC will consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB/IEC requests.

e) UCSI IEC may request more information when, in the judgment of the IEC, the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the subjects.

f) When a non-therapeutic trial is to be carried out with the consent of the subject's legally acceptable representative, the IEC will determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.

g) Where the protocol indicates that prior consent of the trial subject or the subject's legally acceptable representative is not possible, the IEC will determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials (i.e. in emergency situations).

h) UCSI IEC will review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject.

i) UCSI IEC will ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form or any other written information to be provided to subjects.

j) UCSI IEC will receive and assess final reports and to disseminate the research findings to relevant authorities, if deemed necessary.

k) UCSI IEC will provide advice and consultancy related to human ethics.

2.2 Scopes

This guideline applies to all UCSI University staff and students, full time, part time, casual or adjunct, from any UCSI University campuses, national and international, who host, conduct, participate in or disseminate the results of research involving human subjects. Visitors to UCSI University who participate in such research are also subjected to this guideline.

a) This guideline is applicable to all investigator-initiated research and industry-initiated research which covers the following types of research:

- Clinical trials
- Epidemiological research
- Social science research
- Research on medical records or any data derived from human
- Research on human samples
- Health systems research
- Implementation research
- Human participants,
- Human samples

b) In essence, these include:

- Studies requiring extra procedures or treatments to be carried out on human subjects *i.e.* any procedure which would not have been normally carried out in the course of the subject's stay/visit to the medical centre and which is proposed to be carried out because of the study.

- Studies, whether retrospective or prospective, using patient data outside of the researcher's department.
- Questionnaires/surveys involving study participants and/or their relatives.

c) Special attention will be given to projects involving but not limited to the following:

- Research involving vulnerable and marginalised groups (children, lesbian, gay, bisexual and transsexual (LGBT), prisoners and adults not competent to give consent). Refer to section 1.2 for full definition.
- Research involving the use of human genetic material.
- Research that may impose an undue disadvantage upon participants.

d) Studies listed below may be granted an expedited review by the UCSI IEC:

- Research solely involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures and data collection in the public domain, and
- Diagnostic and therapeutic procedures that are an accepted part of treatment and are recognised as current practice by the appropriate professional body.

2.3 Authorities and Independency

UCSI IEC may request progress report from any approved study at any point of time during the conduct of said study. Should there be any violation to the responsible and ethical conduct of research, UCSI IEC authorised to:

- Approve any deviation from study,
- Modify previous ethical approval to protect the human subjects,
- Suspend the previous ethical approval,
- Terminate the previous ethical approval.

UCSI IEC also responsible to recommend the following actions to be taken by Research Management Centre:

- Suspend study
- Terminate study
- Place restrictions on the study

To ensure that the IEC cannot be pressured to approve or disapprove particular protocols, the policies of the IEC provide that:

- The IEC's membership includes at least one person with no connection to the organisation that sponsors or conducts the research under review;
- Researchers, sponsors, and funders may attend an IEC meeting to answer questions about their research protocols and associated documents, but they are not present when the IEC reaches decisions about their proposed research;
- Senior decision-makers of the entity creating the IEC, or of any organisation that sponsors or conducts the research reviewed by the IEC (such as the director of an institution, or his or her agent), do not serve as members of the IEC or its Chair;
- The Vice-Chancellor Office will ensures that IEC members are protected from retaliation based on positions taken with respect to IEC-related matters or review of research projects.

3.0 MEMBERSHIP OF UCSI IEC

UCSI IEC ensures that the IEC has a multidisciplinary and multisectoral membership, with a composition that is gender balanced, reflects the social and cultural diversity of the communities from which research participants are most likely to be drawn, and includes individuals with backgrounds relevant to the areas of research the committee is most likely to review. The membership composition includes:

a) **Member:** Individuals with scientific expertise, including expertise in behavioural or social sciences; health care providers; members who have expertise in legal matters and/or ethics.
b) **Lay member:** At least two members who are lay people, who have no affiliation with the institution or organisation, are not currently involved in medical, scientific, or legal work, and who are preferably from the community in which the institution or organisation is located.
c) **Non-affiliated member:** Individuals who are not affiliated with organisations that sponsor, fund, or conduct research reviewed by the IEC.
d) **Independent consultant:** The IEC may call upon independent consultants to provide special expertise to the IEC on specific research protocols, populations, or topics.

UCSI IEC will ensure that multiple perspectives are brought into the discussion. To this end, quorum requirements provide that at least five people, including at least one lay member and one non-affiliated member, are present to make decisions about the proposed research.

3.1 Roles of Member

a) **Chairperson**: The chairperson should be chosen for her or his ability to draw on the experience of all members, including lay members and those with specialist expertise, and is responsible for chairing all IEC-related meetings.

b) **Vice-Chairperson:** Fulfils the role of Chairperson in his/her absence and carries out any additional managerial tasks that may arise.

c) **Secretary:** Provides administrative support, document preparation, minutes of meetings and prepares documents for IEC meetings and its distribution.

d) **Secretariat:** whose functions include

- Informing and advising the principal investigators, sponsors, and new IEC members of applicable regulations, guidelines, processes and procedures.
- Maintain a website ensuring public access to this information.

- Manage the timely progress of protocol review including identifying and requesting missing documentation in applications and preparing the completed file for committee review.
- Prepare the meetings of the IEC, including the distribution of relevant documentation to the members, scheduling the meetings, and ensuring the quorum.
- Follow-up with tasks that the IEC requests the principal investigators to perform such as progress reports, final reports, corrective actions, amendment of the approved protocol or consent documents etc.
- Prepare reports of IEC meetings and annual reports of IEC activities. The annual report includes information about sources of funding and expenses of the IEC.
- Ensures that the confidentiality of IEC records is maintained.
- Facilitate access to literature and educational programmes useful to the members of IEC.
- Updating information about IEC membership, including declarations of potential conflicts of interests.

e) **Members:** individuals with scientific expertise, including expertise in behavioural or social sciences; health care providers; members who have expertise in legal matters and/or ethics.

- 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). There may need to be more than one member in this category depending on type of application. This member is included because such a person has had contact with potential or typical participants in research and has insights into the possible impact of research on such people.
- One optional member who is from the legal profession. This member should have professional qualifications but need not be currently in legal practice. The role of the lawyer on an ethics committee is to advise the committee on legal implications of research considered or decisions taken and whether formal legal advice is necessary.

f) **Lay members:** primary role is to share their insights about the communities from which participants are likely to be drawn.

g) **Independent consultant:** The IEC may call upon independent consultants from other areas of specialisation when deemed necessary for specific studies. The consultant's or independent expert's advice shall be taken into consideration, however decisions on ethical approvals lies solely on the committee.

3.2 Appointment of Member

Authority for appointment of committee members is under the purview of the Vice-Chancellor. Nonetheless, Vice-Chancellor is independent in its decision-making. Conflict of interest will be evaluated prior to making appointments of members.

a) UCSI IEC Chairperson is directly selected and appointed by Vice-Chancellor.

b) Selection of the UCSI IEC member is by majority vote of existing members. The Chairperson reserves the right to recommend the new member to the Vice-Chancellor for appointment.

c) Each member is appointed based on their research interest, experience, ethical knowledge, scientific expertise and their commitment to UCSI IEC.

d) All IEC members are appointed for a term of two years that is renewable.

e) Renewal of membership is by consensus of each individual member. The Chairperson reserves the right to recommend the renewal of membership to the Vice-Chancellor.

f) UCSI IEC member(s) can be disqualified and removed if he/she is absent for three consecutive meetings without prior notification or without valid reasons given to the chairperson. Selection of replacement candidates is by majority vote of existing members. The Chairperson reserves the right to recommend new UCSI IEC member(s) to the Vice-Chancellor for replacement.

g) Member who wish to resign must write in officially to Chairperson, with a serving notice of 30 calendar days.

h) All IEC members will be published on the UCSI IEC website with his/her full name, gender and affiliations.

i) The appointment of IEC members will be recorded and made available to the public upon request.

j) All IEC members are required to sign conflict of interest (COI) declaration form and non-disclosure agreement (NDA) regarding sensitive aspects of protocols, meeting deliberations and related matters.

k) The independent consultant shall also sign the conflict of interest (COI) declaration form and non-disclosure agreement (NDA) to ensure confidentiality and non-bias evaluations are carried out.

l) All members are required to attend at least one ethics-related training or orientation in a year to keep themselves updated with current knowledges and practises.

m) IEC member should withdraw him/herself from the decision-making process if there is any conflict of interest

4.0 UCSI IEC ETHICS APPLICATION

4.1 Conduct of UCSI IEC Meeting

a) The UCSI IEC shall meet once every two months. At the discretion of the Chairman, additional meetings may be convened or a scheduled meeting postponed.

b) Secretariat will call the meeting at least 14 calendar days before the meeting date, via email, attaching together with the agenda of the meeting.

c) The Chairperson shall conduct all UCSI IEC meetings. In the absence of the Chairperson, an *ad hoc* co-Chairperson or vice-Chairperson nominated by the Chairperson can conduct the meeting.

d) When there is less than full attendance, decisions will be adopted only under quorum conditions with a minimum number of five members, including at least one lay member and one non-affiliated member.

e) Only UCSI IEC members who are independent of the investigation and the sponsor of the study may be eligible to vote.

f) Any vested interest or involvement in research which is to be discussed, reviewed and approved by the UCSI IEC should be disclosed prior to project discussion.

g) Members of the secretariat are non-voting members but are allowed to give comments and opinions.

h) UCSI IEC may invite Independent consultant with expertise in special areas for advices but the invitee shall not be entitled to vote.

i) Chairperson of UCSI IEC can allow an observer to be present in the meeting but the observer shall not be entitled to vote.

j) Principal investigator may be required (or asked to standby) to be present at the meeting by UCSI IEC to provide further clarifications.

k) To avoid conflict of interest, UCSI IEC member(s) that is/are involved directly or indirectly in the research should not participate in discussion or decision making for ethical approval.

l) Minutes of the meeting shall be recorded by the Secretariat of UCSI IEC and countersigned by the Chairperson. Minutes of each reviewed protocol shall include the following but not limited to:

- Decision by the meeting
- Presentation by the Principal Investigator (PI), if available
- Recusal of member due to Conflict of Interest

m) Confirmation of the meeting minutes may be done through e-mail circulation and reconfirmation during the subsequent meeting.

n) The quorum requirement for approval by e-mail circulation involving arising matters or applications should at least constitute of a minimum number of five members, including at least one lay member and one non-affiliated member. Each e-mail circulation will be granted a timeline of one week prior to final approval. Among which, independent consultant may be included should the needs arises.

4.2 Application for Ethical Approval

a) All documents need to be given a reference as per stipulated in Standard Operating Procedures for the Coding of IEC Documents (**Appendix 1**)

b) All clinical trials involving intervention must first be registered in National Medical Research Registry (NMRR) before submitting to UCSI IEC.

c) List of investigators should include all investigators who are involved in the research and their contact information.

d) All information required for a thorough and complete review of the ethics of proposed research need to be submitted, including disclosures about researchers' conflicting interests, if any.

e) The principal investigator must sign the application form and present his/her research proposal to UCSI IEC, if required.

f) The investigators are responsible to comply with any other relevant regulatory requirements.

g) An application or review of the ethics of proposed health-related research is submitted by a researcher qualified to undertake the particular study, who is directly responsible for the ethical and scientific conduct of the research. In certain jurisdictions, the sponsor of a study is responsible for submitting the research protocol to the IEC.

h) Student applications are submitted under the responsibility of a qualified advisor/faculty member involved in the oversight of the student's work.

4.3 Documents Needed for Ethical Approval

a) All applications must be attached with Ethics Application Form, Conflict of Interest (COI) Declaration Form and Submission Checklist, provided by UCSI IEC.

b) Informed Consent Form

- In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the IEC's written approval/favourable opinion of the written informed consent form and any other written information to be provided to subjects.

- Informed consent form should include the followings:
  - the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
  - the monitor(s), the auditor(s), the IEC, and the regulatory authority will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorising such access.
  - records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

- Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.

- Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.

- For retrospective studies, permission must be obtained from the data owner prior to commencement of study.

- Consent form should be translated into Bahasa Malaysia, English or any other languages relevant to patients or participants.

c) Participant/Patient Information Sheet (PIS)

- Researchers have a responsibility to inform participants on the study details and keep them and their communities informed of the progress of research by appropriate means, at suitable time-frames in simple and non-technical language.

- PIS is needed for all studies, with the exception of retrospective studies.

- PIS should include the followings:
  - The purpose of the trial.
  - The trial treatment(s) and the probability for random assignment to each treatment.
  - The trial procedures to be followed, including all invasive procedures.
  - The subject's responsibilities.
  - Those aspects of the trial that are experimental.
  - The reasonably foreseeable risks or inconveniences to the subject and when applicable, to an embryo, foetus, or nursing infant.
  - The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
  - The alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks.
  - The compensation and/or treatment available to the subject, in the event of trial related injury.
  - The anticipated prorated payment, if any, to the subject for participating in the trial.
  - The anticipated expenses, if any, to the subject for participating in the trial.
  - The subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in this trial.
  - The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of the trial-related injury.
  - The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
  - The expected duration of the subject's participation in the trial.
  - The approximate number of subjects involved in the trial.

- The source(s) and component(s) of the investigational product(s) that may be culturally unacceptable.

- PIS is encouraged to be translated into Malay or English or relevant languages deemed necessary in order to provide a better understanding to patients or participants.

d) Research Proposal

- Research Proposal is required to provide substantial information for review by UCSI IEC. A detailed proposal is necessary for all types of study (refer to GCP Malaysia 4th Edition, Section 6).

- The investigator/institution should conduct the trial in compliance with the proposal agreed to by the sponsor and, if required, by the regulatory authority and which was given approval/favourable opinion by the IEC.

- The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favourable opinion from the IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change in monitor(s), change of telephone number(s)).

- The investigator should follow the randomisation procedures stated in approved proposal, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s).

e) Curriculum Vitae

- Curriculum Vitae of the principal investigator needs to be submitted to UCSI IEC.

- All principal investigators conducting clinical, interventional or sampling-related studies must be certified with Good Clinical Practice (GCP).

f) Investigator's Brochure (if applicable) (refer to GCP Malaysia 4th Edition, Section 7)

- The Investigator's Brochure (IB) is a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects.

- Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration and safety monitoring procedures.

- The IB also provides insight to support the clinical management of the study subjects during the course of the clinical trial.

- The information should be presented in a concise, simple, objective, balanced, and nonpromotional form that enables a clinician, or potential investigator, to understand it and make his/her own unbiased risk-benefit assessment of the appropriateness of the proposed trial.

g) Letter of Permission or Approval (if applicable)

- Letter of permission or approval is required from the owner of research venue.

- If the proposed research will be conducted within an area involving a specific jurisdiction (e.g. Ministry of Education, Municipality, etc.), a letter of permission or approval shall be attached with the Application for Ethical Clearance.

h) Questionnaire Survey Form (if applicable)

i) Case Report Form (if applicable)

j) Decisions from other Ethics Committee (EC) (if applicable)

k) Proof of NMRR Registration (if applicable)

l) Insurance/protection of subject for any medical incidence (if applicable)

4.4 Review Procedures of Regular Ethics Review

a) All ethics application documents from individual applicant will first be submitted to Head of Research from each respective Faculty. Head of Research is responsible to cross-check the documents and ensure all documents are coded and in order before submitting to Secretariat of UCSI IEC. Deadline of submission to Secretariat is 21 calendar days before the next IEC meeting.

b) All submissions will be circulated to designated reviewers at least 14 calendar days prior to meeting. Reviewers will be given maximum period of 14 calendar days to complete their reviews.

c) The following components will be taken into consideration during review process:

- Competency of research team in carrying out the study
- Research scope, aims, questions, design and methods
- Recruitment process, target population and vulnerability of participants
- Informed consent and participants information sheet
- Potential benefits and harms of the study
- Collection, use and management of data and information
- Communication of research findings and results to participants
- Funding of the study

d) The following decisions may be made by UCSI IEC:

- Approved.
- Approved upon revision. Will require re-submission to UCSI IEC together with all corrected documents and clarifications.
- Rejected.

e) In the event where a revision of ethical clearance application is needed, first revision is given a maximum period of 14 calendar days to resubmit. Similarly, second revision (if applicable) is also given a maximum period of 14 calendar days to resubmit.

f) The decisions will be communicated within 14 calendar days from the review meeting, together with the decision letter signed by Chairperson.

g) Decision letter will be issued for approval, conditional approval and rejected application, with the following components:

- Decision by UCSI IEC
- List of reviewed documents
- List of attended IEC members
- The duration for which the approval is valid, and the procedures to be followed to renew the approval at the end of that period, if applicable.
- A statement of the responsibilities of the principal investigator, which include notification to UCSI IEC in the event of deviations from initial approved protocols.

h) Should there be any delay in the above mentioned time frame due to unforeseen circumstances, applicants will be notified accordingly.

m) All approvals are valid for 12 months, during which an extension can be requested. Extension request (using the continuing review form - CRF) is under the responsibility of the PI and must be done at least 30 calendar days prior to the expiry date. If no extension request is done, the study approval will be terminated automatically.

n) Any changes, deviation, modifications and amendments to research should be informed in writing to the UCSI IEC by the PI. Failing which the ethical approval will be void.

4.5 Review Procedures for Expedited Review

a) All ethics application documents from individual applicant will first be submitted to Head of Research from each respective Faculty. Head of Research is responsible to cross-check the documents and ensure all documents are coded and in order before submitting to Secretariat of UCSI IEC.

b) Reviewers will be given 14 calendar days to review the submission, reviewers will be given maximum of 14 calendar days to complete their reviews. Final decision will be determined by Chairperson without going through UCSI IEC meeting.

c) The following decisions may be made by UCSI IEC:

- Approved.
- Approved upon revision. Will require re-submission to UCSI IEC together with all corrected documents and clarifications.
- Rejected.

d) In the event where a revision of ethical clearance application is needed, first revision is given a maximum period of 14 calendar days to resubmit. Similarly, second revision (if applicable) is also given a maximum period of 14 calendar days to resubmit.

e) The decisions will be communicated within 7 calendar days, together with the decision letter signed by Chairperson.

f) Decision letter will be issued for approval, conditional approval and rejected application, with the following components:

- Decision by UCSI IEC
- List of reviewed documents
- List of attended IEC members
- The duration for which the approval is valid, and the procedures to be followed to renew the approval at the end of that period, if applicable.
- A statement of the responsibilities of the principal investigator, which include notification to UCSI IEC in the event of deviations from initial approved protocols.

g) All approvals are valid for 12 months, during which an extension can be requested. Extension request (using the continuing review form - CRF) is under the responsibility of the PI and must be done at least 30 calendar days prior to the expiry date. If no extension request is done, the study approval will be terminated automatically.

h) Any changes, deviation, modifications and amendments to research should be informed in writing to the UCSI IEC by the PI. Failing which the ethical approval will be void.

4.6 Post-Approval Submissions

All post-approval requests and submissions will be treated the same as normal ethics application, processed in accordance to the procedures outlined in section 4.4, unless otherwise stated. Circumstances that will trigger post-approval reviews, in addition to those that are regularly scheduled, including the following:

- any protocol amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study
- serious unexpected adverse events related to the conduct of the study or study product
- any event or new information that might affect the potential benefits or risks of harm involved in the study
- decisions made by a data safety monitoring board (DSMB) or other monitoring or regulatory authorities to suspend a study in whole or in part

Post-approval request may include any of the followings but not limited to:

a) Continuing Review Form (CRF)

- All PI is responsible to report the progress of study to UCSI IEC at least once a year via submission of continuing review form (CRF).

- CRF can also be used to request for extension on the approved period of study.

b) Protocol Amendment Form

- Protocol amendment form is used to request any amendment to the prior approved protocols, or any ethics related documents.

c) Protocol Deviation Report

- The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IEC approval/favourable opinion. Nonetheless, as soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be reported using protocol deviation report and submitted to:

    - To the /IEC for review and approval/favourable opinion,
    - To the sponsor for agreement and, if required,
    - To the regulatory authority.

d) Adverse Event Reporting Form

- Principal Investigator should promptly report to the IEC all adverse events (AE), serious adverse events (SAE), suspected unexpected serious adverse events (SUSAR) within 24 hours from the time of the event using Adverse Event Reporting Form. Failing which the ethical approval will be void.

- The procedures to handle adverse event reporting are following expedite review process, as per outlined in section 4.5.

e) Project Closure Form

- Project closure form is used to notify the IEC when a study is completed (i.e. when interactions with participants have concluded) or prematurely suspended/terminated, and to provide the IEC with a final report.

- Project closure request will be endorsed in IEC meeting without any prior review from the members.

Decision should be issued and communicated to the applicant, indicating either that the original decision is still valid or that there has been a modification, suspension, or withdrawal of the IEC's original decision. In the case of a conditional decision, any requirements by the IEC, including suggestions for revision and the procedure for having the application re-reviewed will be communicated. In the case of a negative decision, reasons related specifically to ethical considerations will be communicated. Advice or suggestions that are non-binding may be appended to the decision but should clearly be marked as advice separate from any stipulations or determinations of the IEC.

5.0 ARCHIVING

All of the IEC's documentation and communication records will be dated, filed, and archived in electronic format according to the committee's policies and written procedures. Such policies should be consistent with any relevant local laws or institutional policies.

5.1 Purposes

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

5.2 Responsibility

It is the responsibility of the UCSI IEC secretariat to ensure that all study files are prepared, maintained, and kept securely for a period of five years after completion of study.

5.3 Maintenance of study files and documents

a) Minutes/records/notes of the meetings of the UCSI IEC will be maintained and only accessible to authorised representatives of the institution, researchers, and funding agencies.

b) All documents and records will be saved in PDF format. All documents generated by external party need to be attributed to its original sources. Meeting minutes from Top Management Meeting needs to be verified by the Secretariat of the said meeting.

c) Master file is the file comprising of all essential documents and correspondence related to the study/protocol. Any other subsequent documents submitted to support an existing study will be kept on the same file.

d) All active files will be kept one copy in an online cloud and one copy in the university's shared network folder (\\fileserver.ucsihq.edu\UCSI IEC) with controlled access. All closed study files will be separately archived.

e) 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 five years after completion of the study.

f) Final disposal of study/master files will only be done upon completion of the archival period.

5.3 Disposal of closed files

The master file of ethics applications will be archived and kept for a period of five years after completion. After completion of archival period, the closed files will be erased from online cloud and shared network folder. A log book of disposed documents will be maintained.

6.0 REFERENCES

1. 4th Malaysian Guideline for Good Clinical Practice (GCP) 2018.
2. WHO's Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (WHO 2011).
3. Guidelines for Stem Cell Research and Therapy, MOH/P/PAK/177.08(GU) July 2009
4. Guideline Of The Malaysian Medical Council, MMC Guideline 009/2006, Clinical Trials And Biomedical Research
5. Declaration of Helsinki (2013)
6. Handbook For Good Clinical Research Practice (GCP) (WHO 2005)

APPENDIX A - Standard Operating Procedure (SOP) For Coding Of IEC Documentations

Applicant is to get an **IEC reference code** from respective Faculty Head of Research (HOR)

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For **NEW** application

FMHS	- IEC-2023-FMHS-0001
FAS	- IEC-2023-FAS-0001
FPS	- IEC -2023-FPS-0001
FOSSLA	- IEC-2023-FOSSLA-0001
GBS	- IEC-2023-GBS-0001
FBM	- IEC-2023-FBM-0001
IMUS	- IEC-2023-IMUS-0001
ICSDI	- IEC-2023-ICSDI-0001

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Applicant should use the reference code assigned for labelling the UCSI IEC STANDARD FORMS during the submission

For example

Adverse Event Reporting (AER) Form	IEC-2023-FMHS-0001/AER/Ver1
Conflict Of Interest Declaration Form	IEC-2023-FMHS-0001/COI/Ver1
Continuing Review Form (CRF)	IEC-2023-FMHS-0001/CRF/Ver1
Cover Letter	IEC-2023-FMHS-0001/CL/Ver1
Curriculum Vitae Researcher 1	IEC-2023-FMHS-0001/CV1/Ver1
Curriculum Vitae Researcher 2	IEC-2023-FMHS-0001/CV2/Ver1
Ethic Clearance Application Form	IEC-2023-FMHS-0001/APPLICATION/Ver1
Final Report	IEC-2023-FMHS-0001/FR/Ver1
Informed Consent Form (ICF)	IEC-2023-FMHS-0001/ICF/Ver1
Participant Information Sheet (PIS)	IEC-2023-FMHS-0001/PIS/Ver1
Protocol Amendment Form	IEC-2023-FMHS-0001/AMENDMENT/Ver1
Protocol Deviation Report (PDR)	IEC-2023-FMHS-0001/PDR/Ver1
Project Closure Form	IEC-2023-FMHS-0001/PCF/Ver1
Proposal/Protocols	IEC-2023-FMHS-0001/PROPOSAL/Ver1

Note: For the next revise version will be Ver2

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Applicant should use the reference code assigned for labelling the additional document(s)* during the submission

For example

Additional document 1	IEC-2023-FMHS-0001/ADD1/Ver1
Additional document 2	IEC-2023-FMHS-0001/ADD2/Ver1

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All the document's code needs to be inserted as header at the top left corner

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Applicant submit his/her application to Faculty Head of Research (HOR)

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Applicant should use the assigned code for future corresponding

*Additional document(s) refer to any other document that is not under UCSI IEC Standard Forms