GLOSSARY

Terms	Definition
A	
Adverse Event	Any unfavorable change that may affect a subject during or after a clinical trial, the change is not necessarily caused by the investigational product. Includes physical signs and symptoms, abnormal laboratory findings, change in vital signs, a new condition or illness, or the worsening of a condition or illness that was present before product use. Also called adverse experience. When a causal relationship has been established between a product and the AE, the AE is referred to as an adverse drug reaction (causal relationship with a drug) or an adverse device effect (causal relationship with a medical device)
Amendment	See protocol Amendment
Applicant	The person who completes the ethics application form.
Approval	The affirmative decision of the Institutional Review Boards that the clinical trial has been reviewed and may be conducted at the institution site within the constrains set forth by the Institutional Review Boards, the institution, Good Clinical Practices (GCP), and the applicable regulatory requirement.
C	
Case Report Form (CRF)	A printed, optical, or electronic document used to record protocol-required information for each subject in the study
Clinical Practice	A form of research designed to find out the effects of an intervention, including treatment of diagnostic device.
Clinical Trial	A written description of a trial/study of any therapeutic, prophylactic, diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report
Compensation	Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research
Compliance	Adherence to protocol requirements, standards of good clinical practice, and applicable regulations
Confidentiality	Prevention of unauthorized disclosure of a sponsor's proprietary information or of a subject's identity and personal medication information
Conflict of Interest	Where personal interest may have the potential to influence the conduct of the research. This may include a personal, professional or financial interest in the outcomes of the research.
Consent	In this context, where a person has agreed to participate in research. Consent must be freely given (without coercion or pressure) and fully informed. Consent may be written, oral, implied or in certain circumstances may be given by a third party on behalf of the participant. See 'Informed Consent'.

Consent Form	Consent form is a document signed by the potential participant acknowledging their understanding of the information provided in the Letter to Participants and their agreement to participate in the research. In some cases, consent forms are read out loud and consent is given verbally.
Curriculum Vitae (CV)	A summary of an investigator's education, training, and experience, similar to a resume
D	
Data	Pieces of information. In relation to research this can include measurements, personal details and information, recorded conversations and interviews, surveys, observations and databases
Documentation	All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or result of a trial, the factors affecting a trial, and the actions taken.
E	
Exclusion Criteria	Rules of eligibility that exclude an individual from participation in a study
Expedited Review	An expedited review is defined as an application that is not required to undergo the interview process. These applications will be circulated among members for comments and decision making.
F	
Full board review	Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting
G	
Good Clinical Practice	The standards for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials. The standards provide assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentially of trial subjects are protected.
Guardian	An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care
Guidelines	Written principles and practices pertaining to applying the regulations. Although guidelines are an accepted standard of practice, they are not enforceable by law. FDA guidelines are

	applicable in the United States while International Conference on Harmonization (ICH) guidelines reflect an international movement to standardize practices across national borders.
H	
Harm	Harm may be physical, psychological, reputational or social
I	
Inclusion Criteria	Rules of eligibility that an individual must meet in order to participate in a clinical study.
Independent Consultant	A person who is not a member of JKEUPM and has special skill or knowledge/expertise in a particular field
Informed Consent	A process by which a subject voluntarily confirms his or her willingness to participate in a clinical trial/ non-clinical trial after having been informed of all aspects relevant to the subject's decision to participate. The Declaration of Helinski states that in any human research, each potential subject must be adequately informed of the aims, methods, anticipated benefits, potential hazards, and discomforts that study participation might entail. Informed consent is typically documented via a written, signed and dated consent form.
Institution	Any public or private entity or agency or medical or dental facility where clinical trials are conducted
Investigators	An individual who conducts a clinical study and directs the use, administration, and distribution of the investigational agent to a subject. When a team of individuals at a specific location conducts an investigation, the investigators is the responsible leader of the group. The investigator holds regulatory responsibility for the conduct of the trial at the investigative site. A c0-investigator is an individual who shares equal responsibility in conducting the trial at a site.
Investigators Brochure	A brochure compiled by the sponsor providing all known information about the test article or investigational agent. In includes the formulation of the investigational agent, pharmacology, toxicology, pharmacokinetics, safety and effectiveness data, possible side effects and risks. Both pre-clinical and clinical data are included. Also called investigators drug brochure and investigational drug brochure.
Investigational Product	A pharmaceutical form of an active ingredient including plant /animal-derived medicinal products or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication (off-label use), or when used to gain further information about an approved use.
L	
Low risk	The National Statement defines low risk research as where the only foreseeable risk is one of discomfort.
M	

Medical Device	A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment
Monitoring	The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections
Monitoring report	A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs.
P	
Protocol	A document that identifies the plan or set of rules for conducting a specific clinical trial, and states the objectives, design, methodology, statistical considerations, and organization of a trial
Protocol Amendment	A written description of changes to, or the formal clarification of, a protocol.
Protocol Violation	A divergence from the protocol that materially (a) reduces the quality or completeness of the data, (b) makes the Informed Consent Form inaccurate, or (c) impacts a subject's safety, rights, or welfare. Example of protocol violations may include the following: - Inadequate or delinquent informed consent - Inclusion/exclusion criteria not met - Unreported serious adverse events - Improper breaking of the blind - Use of prohibited medication - Incorrect or missing test - Mishandled samples - Multiple visits missed or outside permissible windows -
R	
Regulatory Authorities	Bodies having the power to regulate. In the Malaysian Guideline for Good Clinical Practice the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities.
Research project	This is the term used to describe the overall research project. It incorporates the original application for funding and is distinct from the ethics protocol because it may involve more than the research outlined in the ethics protocol. A research project may have more than one ethics protocol associated with it, including animal ethics and biosafety protocols.
Review Panels	A committee, or other group that reviews and approves clinical studies at an investigative site. The primary responsibility of the committee is to ensure the protection of the rights and welfare of study participants. Also called Independent Review Committee, Ethics Committee, Human Protection Committee.

Risk	Risk refers to the magnitude and likelihood of harm arising as a result of research. It includes risk to the research participant(s), the researcher(s) and others who may be harmed as a result of the research. Risk may occur in a number of forms, including physical, emotional and reputational.
S	
Sponsor	An individual, company, institution, or organization that initiates a clinical investigation. The sponsor must comply with the responsibilities outlined in the regulations.
Standard Operating Procedure (SOP)	Detailed written instructions that provide a structure to ensure that activities are performed in a consistent manner.
Subject	An individual who participates in clinical research, either as a recipient of the test article or of the control. A subject may be either a healthy human or a patient.
Suspected Unexpected Serious Adverse Reactions Reports (SUSARs)	An adverse reaction, the nature of severity of which is not consistent with the applicable product information in the investigator's brochure for an unapproved investigational product, or on the package insert/summary of product characteristic for an approved product
Stigmatizing information	
U	
Unexpected Adverse Event	An adverse event that is unexpected for the investigational product and has not been reported in the investigator's brochure or package insert or is an event that is being reported in greater severity or frequency than the same event previously reported.
Unexpected Adverse Drug Reaction	An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g. Investigator's brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product).
V	
Vulnerable group/population	Individuals whose willingness to volunteer in a study may be unduly influenced by expectation of benefits, fear of retaliatory response, or lack of ability to understand trial-related issues. Some groups identified as vulnerable subjects are prisoners, children, unborn fetuses, homeless persons, and those incapable of giving consent.