GLOSSARY

No	Terms	Definition
1.	**Abuse-liable**	Pharmacological substances that have the potential for creating abusive dependency. Abuse-liable substances can include both illicit drugs (*e.g*., heroine) and licit drugs (*e.g*., methamphetamines).
2.	**Academic Research Organization (ARO)**	An academic organization that sponsors trial or is contracted by the sponsor to perform one or more of a sponsor's trial-related activities, including but no limited to: protocol development and design, recruitment of investigators, study management and coordination, monitoring, data management, and statistical analysis. An ARO uses academic leaders and/or clinicians to provide leadership and may be affiliated with academic institutions.
3.	**Adverse Drug Reaction (ADR)**	A response to an investigational drug that occurs at any dose and is noxious and unintended. A response to a marketed drug that is noxious. Unintended and that occurs at dose normally used for prophylaxis, diagnosis, therapy, or for modification or physiological function. Adverse drug reactions can be expected or unexpected.
4.	**Adverse Event (AE)**	Any unfavorable change that may effect 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 vitals 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)
5.	**Amendment**	See protocol Amendment
6.	**Assent**	An agreement to participate (*e.g.*, a child or cognitively impaired person) in clinical research. Assent may be required from children who are of adequate age and emotional maturity to understand the concept of the study but are incapable of grasping all the details of the study.
7.	**Assurance**	A legally binding written document that requires a public or private institution to comply with applicable federal minimum standards for the protection of human subjects in research
8.	**Audit**	An independent and systematic review of study data, associated records, protocol procedures, study conduct, and interim or final study reports to determine whether the information is accurate and whether the study has been carried out in compliance with the

		protocol, standard operating procedures, good clinical practice, and applicable regulations. Sponsors may conduct internal audits, audits of AROs/CROs designated to perform sponsors responsibilities, an audits of investigative sites participating in a clinical trials. Audits may also be performed to review manufacturing practices, laboratory processes, and storage facilities.
9.	**Beneficence**	An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.
10.	**Blinding**	A procedure in which one or more parties in a clinical trial are kept unaware of the treatment assignments, while in a double blind study, the subjects, investigators, and study personnel are unaware of the treatment assignment, mechanism exist to unblind the code, commonly called breaking the blind. An open or open label study has no blinding of the subject or the study stuff.
11.	**Belmont report**	A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978
12.	**Case report form (CRF)**	A printed, optical, or electronic document used to record protocol-required information for each subject in the study
13.	**Children (in clinical research)**	Individuals who are under the legal age to give consent for participant in a clinical research study. The assent of children who are considered of adequate age and emotional maturity may be required for study participation. Specific legal age is determined under the applicable laws in the jurisdiction where the research is being conducted.
14.	**Compliance**	Adherence to protocol requirements, standards of good clinical practice, and applicable regulations
15.	**Confidentiality**	Prevention of unauthorized disclosure of a sponsor's proprietary information or of a subject's identity and personal medication information
16.	**Compensation**	Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research
17.	**Contract Research Organization (CRO)**	An organization contracted by the sponsor to perform one or more of a sponsor's trial-related activities, including but not limited to:

		protocol development and design, recruitment of investigators, study management and coordination, monitoring, data management, and statistical analysis. Compare to Academic Research Organization (ARO)
18.	**Consent Form**	See Informed Consent
19.	**Control Group**	The group of patients who receive the standard treatment (no treatment or placebo) and who are compared to the group of patients receiving the investigational treatment
20.	**Curriculum Vitae (CV)**	A summary of an investigator's education, training, and experience, similar to a resume
21.	**Declaration of Helsinki**	A statement of ethical principles developed by the 18th World Medical Assembly, Helsinki, Finland, June 1964, to provide guidance to physicians who practice biomedical research involving human subjects. The declaration sets forth the requirements for the ethical treatment of patients and research volunteers. It mandates obtaining informed consent and stresses the overriding importance of the subject's needs as individuals over the needs of science and society. The basic thrust of the Declaration of Helsinki is incorporated in the Code of Federal Regulations (21 CFR 312)
22.	**Debriefing**	Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)
23.	**Drug Accountability**	Records of the receipt and disposition of investigational drug supplies.
24.	**Eligibility Criteria**	Rules for selecting subjects to participate in a clinical trial. Participant must meet all of the inclusion criteria for trial entry and not have any of the exclusion criteria
25.	**Endpoint**	An indicator measured to assess the effect of a treatment or theraphy-an assessment of safety, efficacy, or another study objective. Also called outcome, variable, parameter, marker, and measure
26.	**Ethnographic Research**	Ethnography is the study of people and their culture. Ethnographic research, also called fieldwork, involves observation of and interaction with the persons or group being studied in the group's own environment, often for long periods of time. (*See also: Fieldwork*.)

27.	**Exclusion criteria**	Rules of eligibility that exclude an individual from participation in a study
28.	**Expended Availability**	Policy and procedure that permits individuals who have serious or life-threatening diseases for which there are no alternative therapies to have access to investigational drugs and devices that may be beneficial to them. Examples of expanded availability mechanisms include Treatment INDs, Parallel Track, and open study protocols
29.	**Expedited Review**	Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research
30.	**Expedited Adverse Event Reporting**	Reporting of adverse events designated by the protocol/sponsor to the FDA within specified time frames
31.	**Experimental Study**	true experimental study is one in which subjects are randomly assigned to groups that experience carefully controlled interventions manipulated by the experimenter according to a strict logic allowing causal inference about the effects of the interventions under investigation. (*See also: Quasi-Experimental Study*).
32.	**Food and Drug Administration**	A division of the Department of Health and Human Services responsible for assuring the safety and efficacy of pharmaceuticals, biological product, and medical devices, and the safety of foods and cosmetics. Primary FDA offices are located in Rockville, Maryland, the internet address is www.fda.gov
33.	**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
34.	**Good Clinical Practice (GCP)**	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.
35.	**Good Laboratory Practice (GLP)**	Regulation found in the Title 21, Part 58, that apply to clinical laboratories performing analyses for clinical trials. Key provision of Good laboratory practice regulations are requirements for creating

		a quality assurance unit, developing standard operating procedures, analyzing of the investigational product for concentration, uniformity, and stability, and the maintaining, calibrating, and standardizing instruments.
36.	**Guardian**	An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care
37.	**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.
38.	**Grant**	Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant. (*Compare: Contract*.)
39.	**Inclusion Criteria**	Rules of eligibility that an individual must meet in order to participate in a clinical study. See elegibility criteria.
40.	**Industry sponsored trial**	trials sponsored by Pharmaceutical company
41.	**Informed Consent**	A process by which a subject voluntarily confirms his or her willingness to participate in a 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.
42.	**Inspection**	An official review by regulatory authorities of documents, facilities, records, and other study-related resources. Inspections may be carried out at investigative sites, at the facilities of the sponsor, at organizations performing sponsor-delegated activities, or at other establishments deemed appropriate by the authorities performing the inspection.
43.	**Institutional Review Board (IRB)**	A board, 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.

44.	**International Conference on Harmonization (ICH)**	A committee established to develop a unified standard for the European Union, Japan and the United States, and to facilitate the mutual acceptance of clinical data by regulatory authorities in these jurisdictions
45.	**Investigational New Drug (IND) Application**	An application that sponsors must submit to the FDA before beginning studies of an investigational drug in humans. An IND is an application for exemption from the laws that prevent the distribution an use of pharmaceutical agents that have not been approved for use by the FDA. The IND should describe the plan for treatment, previous human experience with the investigational drug, the structural formula, animal test result, and manufacturing information. Also called the Notice of Claimed Investigational Exemption for a New Drug.
46.	**Investigational New Drug (IND) Safety Report**	A report issued by the sponsor of an investigational product when a safety issue arises. The report is submitted to the FDA an to investigators participating in the clinical trial
47.	**Investigative Site**	The location where a study is being conducted. Site locations include physicians offices, hospitals and outpatient clinics. Also known as study site
48.	**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.
49.	**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.
50.	**Investigator Initiated trials**	Trials initiated by Investigator and are funded by MOH grant, other govt grant, university grant, local NGO , international bodies ,other grant bodies or self funding
51.	**Letter of agreement**	A letter outlining the terms of the contract between the sponsor

		and an investigator. Contents of a letter of agreement usually include the terms of the study, including the start and anticipated end of the study, payment methods, data confidentiality, publishing requirements, and product liability issues
52.	**Letter of Indemnification**	A legal document indicating protection or exemption from liability. The letter of indemnification usually protects the investigator and investigative site from claims by the study participant that harm was caused as a result of participation in the clinical trial. It does not, however, protect the investigator from claims resulting from negligence on the part of the investigator.
53.	**Longitudinal study**	A study designed to follow subjects forward through time.
54.	**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
55.	**Monitoring**	The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections
56.	**Permission**	Agreement of parent of guardians of a child or ward to participate in clinical research
57.	**Phase 1,2,3, 4 Drug Trials**	Different stages of testing drugs in humans, from first application in humans (Phase 1) through limited and broad clinical tests (Phase 3), to post marketing studies (Phase 4). • **Phase 1 Drug Trial** Phase 1 trials include the initial introduction of an investigational new drug into humans. These studies are typically conducted with healthy volunteers; sometimes, where the drug is intended for use in patients with a particular disease, however, such patients may participate as subjects. Phase 1 trials are designed to determine the metabolic and pharmacological actions of the drug in humans, the side effects associated with increasing doses (to establish a safe dose range), and, if possible, to gain early evidence of effectiveness; they are typically closely monitored. The ultimate goal of Phase 1 trials is to obtain sufficient information about the drug's pharmacokinetics and pharmacological effects to permit the design of well-controlled, sufficiently valid Phase 2 studies. Other examples of Phase 1 studies include studies of drug metabolism, structure-activity relationships, and mechanisms

		of actions in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects involved in Phase 1 investigations is generally in the range of 20-80. • **Phase 2 Drug Trial** Phase 2 trials include controlled clinical studies conducted to evaluate the drug's effectiveness for a particular indication in patients with the disease or condition under study, and to determine the common short-term side effects and risks associated with the drug. These studies are typically well-controlled, closely monitored, and conducted with a relatively small number of patients, usually involving no more than several hundred subjects. • **Phase 3 Drug Trial** Phase 3 trials involve the administration of a new drug to a larger number of patients in different clinical settings to determine its safety, efficacy, and appropriate dosage. They are performed after preliminary evidence of effectiveness has been obtained, and are intended to gather necessary additional information about effectiveness and safety for evaluating the overall benefit-risk relationship of the drug, and to provide and adequate basis for physician labeling. In Phase 3 studies, the drug is used the way it would be administered when marketed. When these studies are completed and the sponsor believes that the drug is safe and effective under specific conditions, the sponsor applies to the FDA for approval to market the drug. Phase 3 trials usually involve several hundred to several thousand patient-subjects. • **Phase 4 Drug Trial** Concurrent with marketing approval, FDA may seek agreement from the sponsor to conduct certain postmarketing (Phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use. These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time
58.	**Placebo**	An inactive agent given to a study subject instead of an active drug. To keep subjects and investigators unaware of the treatment assignment, the placebo often matches the study drug in

		appearance. This helps to blind the study and reduces bias based on knowledge of the treatment. Often called a sugar pill
59.	**Preclinical Investigations**	Laboratory and animal studies designed to test the mechanisms, safety, and efficacy of an intervention prior to its applications to humans.
60.	**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
61.	**Protocol Amendment**	A written description of changes to, or the formal clarification of, a protocol.
62.	**Prospective Studies**	Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.
63.	**Quality Assurance**	The planned and systematic actions that are established to ensure that a trial is conducted and data are collected and recorded according to the protocol, standards of the Good Clinical Practice and applicable regulations.
64.	**Randomization**	The process of assigning trial subjects to treatment and control groups using the element of chance, random treatment assignment are performed to reduce bias/ Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically (*e.g.*, as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention
65.	**Remuneration**	Payment for participation in research. (NOTE: It is wise to confine use of the term "compensation" to payment or provision of care for research-related injuries.)
66.	**Retrospective Studies**	Research conducted by reviewing records from the past (*e.g.*, birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research

67.	**Risk**	The possibility of harm or discomfort for subjects participating in a clinical trial
68.	**Single Blind Study**	See Blinding
69.	**Sponsor**	An individual, company, institution, or organization that initiates a clinical investigation. The sponsor must comply with the responsibilities outlined in the regulations.
70.	**Sponsor- Investigator**	An individual who both initiates and conduct a clinical trials, and who directs the use, administration, and distribution of the investigational product. The obligations of a sponsor-investigator include both those of the sponsor and the investigator.
71.	**Standard Operating Procedure (SOP)**	Detailed written instructions that provide a structure to ensure that activities are performed in a consistent manner.
72.	**Sub-Investigator**	An individual member of a clinical trial team to whom trial-related activities or procedures have been delegated by the investigator. While some sponsors ask sites to list non-physicians participating in the study in section 6 of the form FDA 1572, the FDA regards sub-investigators as those individuals authorized bt the PI to make medical judgment and decision regarding study patients.
73.	**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.
74.	**Unblinding**	Determination of the study treatment administered. Unblinding should only occur when subsequent clinical treatment depends upon knowledge of the study treatment given.
75.	**Unexpected Adverse Drug Reaction**	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
76.	**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.
77.	**Voluntary**	Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity

78.	**Vulnerable Subjects**	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.