Active Study File	Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study.
Administrative Documents	Documents include official minutes of Board meetings as described in Standard Operating Procedures, both historical and Master Files as described in SOP# FE 027
Adverse Drug Reaction	In the pre-clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between the product and the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.
Adverse Event	Any untoward medical occurrence in a patient or clinical investigation participant which happens after the administration of an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.
Agenda	A list of things to be done; a program of business at a meeting.
Amendment to the Protocol	A written description of a change/s to, or formal clarification of a protocol and changes in any other supporting documentation made from the originally approved protocol by the research ethics review body after the study has begun.
Amendment protocol package	A package of the amended parts and related documents of the protocol, previously approved by the IRB whereby in the course of the study, the PI may decide to make changes in the protocol.
Annual Report	An annual synoptic document that outlines and analyses activities, especially summarizing the research proposals reviewed over the last year
Approval	Favorable or affirmative decision of the Research Ethics Committee following a review of the protocol and other required documents and thus research may already be started and undertaken as set forth by the ethics committee, CPG, the institution , and relevant regulatory terms

Approved Protocols	Protocols that have been *approved without stipulations* or *approved with recommendations* by the CHH IRB may proceed. Protocols that have been *approved with stipulations* by the CHH IRB may not proceed until the conditions set by the CHH IRB in the decision have been met. Protocols should be amended and submitted to the CHH IRB within *one* month for re-review.
Assent	Authorization for one's owns participation in research given by minor or another participant who lacks the capability to give informed consent. The assent is a requirement for research, in addition to consent, given by a parent, or legal guardian. It is an agreement by an individual not competent to give legally valid informed consent like a child or cognitively impaired person to participate in research
Audit	A systematic and independent examination of research trial approval activities and documents to determine whether the review and approval activities were conducted and data were recorded and accurately reported according to the SOPs, GCP, Declaration of Helsinki and applicable regulatory requirements for storage of the originally signed and dated documents
Belmont Report	A statement of basic ethical principles governing research involving human participants issued by the National Commission for the Protection of Human Subjects in 1978 on the conduct of biomedical and behavioral research involving human subjects including guidelines to ensure that research is conducted in accordance with the principles.
Benefits	Any direct or indirect good effect or something of positive value to health or welfare from the research study to the participants; something that promotes or enhances well-being. See also direct benefits and indirect benefits.
Bias	The systematic tendency of any factors associated with the design, conduct, analysis and evaluation of the results of a clinical trial to make the estimate of a treatment effect deviate from its true value.

Bioequivalence	The absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate (e.g., in certain extended release dosage forms) , certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action. This applies only if the difference in the rate at which the active ingredient or moiety becomes available at the site of drug action is intentional and is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug (Food and Drug Administration, US Department of Health and Human Services. (2009). Code of Federal Regulations, Food and Drugs, 21(5), Subchapter D, Part 320.USA; FDA)
Biologic or Biological Product	Any attenuated or inactivated virus or bacteria, or subcomponents attached to adjuvants, toxoids, hyperimmune serum and analogous products applicable to diagnosis, prevention, treatment, or cure of diseases or injuries to man, obtained or derived from living matter-animals, plants or microorganisms or parts thereof. It includes preparations primarily designed to develop a type of immunity or preparations that are concerned with immunity (Department of Health (DOH) Administrative Order No. 47-A series of 2001, Rules and regulations on the registration including approval and conduct of clinical trials, and lot or batch release certification of vaccines and biologic products).
Blinding	Also known as **masking,** is a procedure in which one or more parties of the trial are kept unaware of the treatment assignment(s). Single blinding usually refers to the subjects being unaware which treatment he/she is receiving, while double-blinding usually refers to the subjects, investigator(s), monitor(s), and in some cases, data analyst(s) being unaware of the treatment assignment(s) (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice.
Case Record Form or 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 participant.

Clarification	Minor changes needed in consent document, protocol or other study materials Minor clarification(s) re: specific aspect of study or additional information requested from PI
Clinical Trial	Any research study that prospectively assigns human participants or groups of humans to one or more health related interventions to evaluate the effect on pre-defined health outcomes
Clinical Trial Office	An institute or an office where the study takes place and where the principal investigator and/or his/her staff may be reached.
Compensation	Payment and/or medical care received or provided to subjects injured in research. Payment received by the research participants may include reimbursement for lost earnings, travel costs and other expenses incurred as a study participant, as recompense for inconvenience and time spent. It does not include remuneration for participating in the study.
Competence	Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice (IRB Guidebook, US Department of Health and Human Services, retrieved from *http://www.hhs.gov/ohrp/irb/irb.glossary.htm*
Completed Assessment Form	An official record of the review decision along with comments and dated signature of the reviewer.
Conference	A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.
Confidentiality	The expectation from respondents and research participants that data or information relayed or communicated is kept secret. It also pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure (*http://www.hhs.gov/ohrp/irb/irb.glossary.htm)*

Confidentiality Agreement	Sometimes called Secrecy or Nondisclosure agreements An agreement designed to protect trade secrets, information and expertise from being misused by those who have learned about them. The type of information that can be included under the umbrella of confidential information is virtually unlimited. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.
Conflict of interest	A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties. There are three key elements in this definition: financial interest; official duties; professional interest. A conflict of interest occurs when: • An individual's private interest differs from his or her professional obligations to the institute. • Professional actions or decisions occur that an independent observer might reasonably question. • A conflict depends upon situation and not on the character or actions of the individual. • Potential conflicts of interest must be disclosed and managed as per policy.
Controlled Trials	A trial in which one group of participants is given an experimental drug, while another group (the control group) is given either a standard treatment for the disease or a placebo.
Council of International Organizational of Medical Sciences (CIOMS)	An international, nongovernmental not-for-profit organization established jointly by WHO and UNESCO in 1949. CIOMS serves the scientific interests of the international biomedical community in general and has been active in promulgating guidelines for ethical conduct of research, among other activities.

Declaration of Helsinki	A set of ethical principles for medical research involving human subjects, including research on identifiable human material and data.
De-identified	Removal of elements connected with data which might aid in associating those data with an individual (e.g. name, birth date, social security number, home address, telephone number, email address, medical record number, health plan beneficiary numbers, full-face photographic images (Applied Clinical Trials, 2009)
Device	An instrument , apparatus, implement, machine, invention, implant, in vitro reagent, or other article intended for use in the diagnosis, treatment, or prevention of disease
Disapproval	A negative action of the Ethics Committee on the protocol. The study cannot be implemented if it has been disapproved by the Committee.
Discontinuation	The deed of terminating participation in a clinical trial by a research (dropout) earlier than the completion of all protocol-required terms. In some cases, the discontinuation may be initiated by the investigator for a cause or inability to locate or follow up subject or by the sponsor.
Double blinding	One in which neither the subject nor any of the investigator or sponsor staff who are involved in the treatment or clinical evaluation of the subjects are aware of the treatment received
Drug	A substance used as medication or used in the diagnosis, cure, mitigation, treatment or prevention of disease.
Effective	The degree to which a diagnostic test or treatment produces a desired result in patients in the daily practice of medicine (https://www.ecri.org/patient/references).
Efficacy	An indication that the therapeutic effect of a clinical trial intervention is acceptable, that is, at least as good as the control intervention or standard of care to which it is compared. It is the ability of a treatment modality to produce an effect to alleviate a disease.
Eligibility criteria	The list of conditions that guide the enrollment of participants into a study. The criteria describe both the inclusionary and exclusionary factors.
Emergency meeting	A CHH IRB meeting that is scheduled outside of a normally scheduled meeting to review study activities that require full CHH IRB review and approval. In order to hold an emergency meeting, a quorum must be maintained throughout the entire discussion and voting portions of the meeting. Emergency meetings may be held via teleconference, if applicable.

Ethic review	The evaluation of a research protocol by an ethics review committee to promote the safety and protection of the dignity of human participants. A systematic process by which this independent committee evaluates a study protocol to determine if it follows ethical and scientific standards for carrying out biomedical research on human participants
Exclusion criteria	Factors utilized to determine whether an individual is ineligible for a clinical trial or research study.
Expedited review	A review process by only two or more designated CHH IRB members who then report the decision to the full Board meeting. An expedited review is a *speedy* one for minor *changes to the approved protocol* and for *research proposal* with *minimal risk in nature*.
Expedited approval	An CHH IRB approval granted only by the Chairman of the CHH Board or a designated CHH board member (not the Full Board) for minor changes to current CHH IRB approved research activities and for research which involves no more than minimal risk.
Full board review	Review of proposed research at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary concerns are in non-scientific areas.
Good Clinical Practice (GCP) Guidelines	International ethical and scientific quality standards for designing, conducting, recording and reporting trials that involve the participation of human subjects. These are standards and procedures for clinical trials that encompass the design, protocol approval, monitoring, termination, audit, analyses, reporting and documentation of human studies.
Guardian	One who is legally responsible for the care and management of the person or property of an incompetent person or a minor or someone who can make important personal decisions in behalf of another person.
Guidelines	A set of rules or recommendations intended to effect a course of action.
Inclusion criteria	Factors used to determine a participant's eligibility to be part of a trial or research. These factors are justified by the purpose of the researching in conducting the research.

Independent consultant	An expert who gives advice(s), comment(s), and suggestion(s) upon review of the study protocols with no affiliation to the institute(s) or investigator(s) proposing the research proposal.
Informed Consent Document	a written, signed and dated paper confirming participant's willingness to voluntarily participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate.
Initial Review	The first time review of that protocol made by two or three individual reviewers (CHH IRB members or non-members) in advance of the full Committee meeting, and comments of the reviewers will be reported to the full Committee meeting.
Institutional Review Board (IRB)	Ethics review committee organized in a particular institution to ensure that health research is conducted according to international ethical principles, national and institutional guidelines. This is an independent body constituted of medical, scientific and non-scientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Intervention	A drug product or medicinal product, device, test articles, therapy, or process being investigated in a research or clinical study that is hypothesized to have an effect on the outcome(s) of the research being
Interventional study	A research that includes measures or technology to purposely affect the course of an illness. These measures aim to improve health or condition of an individual or a group of individuals or change the course of disease.
Investigational New Drug (IND)	A drug that has never been seen in the market because it is under investigation of its efficacy and safety and not yet been approved for marketing by the local authorities. The drug is therefore approved for used only at some certain study sites.
Investigator	A person responsible for the conduct of the clinical trial at a trial site. A person responsible for the trial and for the rights, health and welfare of the subjects in the trial.
Investigator initiated studies	Studies which are initiated by the principal investigators. This would include staff initiated studies. Where staff could mean consultant/resident/intern medical staff or nursing staff of CHH.

Majority vote	A motion is carried out if one half plus one member of the required quorum votes in its favor.
Medical Device	Any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized. Medical devices include items such as diagnostic test kits, crutches, electrodes, prescribed beds, pacemakers, arterial grafts, intra-ocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis of disease and other conditions (for example, pregnancy).
Minimal risk	A risk where the probability and magnitude of harm or discomfort anticipated in the proposed 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.
Minor protocol deviation	The result of an unintentional deviation or omission from a protocol that CHH IRB has approved or determined to be exempt, or the conduct of research without IRB review that would have qualified for an exemption. These deviations do not negatively affect the rights, safety, or welfare of the subjects.
Major protocol deviation	A deviation that adversely affects the rights or welfare of participants. Some examples are: the deviation has increased the risk and/or decreased the benefit to individual subjects; the non-exempt research has occurred without appropriate CHH IRB review and approval; when egregious or intentional deviation has occurred; and/or another situation exists which the IRB has determined to be a major deviation.
Minutes	An official record of the business discussed and transacted at a meeting, conference, etc.
Non-disclosure of data	The withholding of or refusal to reveal information derived from research.
Participants' rights	Recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world. … It is essential … that Human Rights should be protected by the rule of law.
Pharmacodynamics	The study of what a drug does to the body.

Pharmacogenetics	The field of biochemical genetics concerned with drug responses due to genetically controlled variations.
Pharmacokinetics	The study of what the body does to a drug.
Phase I study	Initial introduction of an investigational new drug (IND) into humans, studies designed to determine the metabolism and pharmacological actions of drugs in humans, and studies designed to assess the side effects associated with increasing doses.
Phase II study	A Study of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.
Phase III study	A Study expands controlled and uncontrolled trials performed after preliminary evidence suggesting effectiveness of the drug has been obtained. They are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.
Phase IV study	A study that seeks to expand an approved medication's use into a new population, new indication, or new dose.
Placebo	A substance that is not biologically active does not interact with other substances nor it is expected to affect the health status of the individual. It is an inactive pill, liquid, or powder that has no treatment value. In clinical trial, experimental treatments are often compared with placebo to assess the experimental treatment's effectiveness.
Principal investigation (PI)	The lead scientist for a particularly well-defined social science, biomedical, behavioral or epidemiological research project, responsible and accountable for the appropriate conduct of the research.
Protocol	A document that provides the background, rationale, and objective(s) of a biomedical research project and describes its design, methodology, and organization, including ethical and statistical considerations.
Protocol amendment	A written description of a change(s) to or formal clarification of a protocol.
Protocol deviation	A protocol deviation occurs when, without significant consequences, the activities on a study diverge from the Institutional Review Board-approved protocol, e.g., missing a visit window because the subject is traveling. Not as serious as a protocol violation.

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.
Quorum	A fixed minimum percentage or number of members of the committee who must be present before the members can conduct valid business.
Risk	The probability of discomfort or harm or injury (physical, psychological, social or economic) occurring as a result of participation in a research study.
Serious Adverse Event (SAE)	Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of ongoing hospitalization, results in persistent or significant disability/incapacity, or in a congenital anomaly/birth defect.
Sponsor	An individual, a company, an institution or an organization which take responsibility for the initiation, management and/or financing of a clinical trial.
Sponsor initiated studied	Studies which are initiated by a funding agency/sponsor company.
Standard of care or treatment	Healthcare intervention or regimen that is generally accepted by health practitioners and experts as beneficial to an individual needing such care. Standard treatment is the treatment that is currently thought to be effective in medical practice.
Suspected Unexpected Adverse Drug Reaction (SUSAR)	An adverse reaction, the nature or severity of which is not consistent with the informed consent / information sheets or the applicable product information (e.g., investigator's brochure for the unapproved investigational product or package insert / summary of product characteristics for an approved product.
Termination of the research	Ending or discontinuing a research study before its scheduled completion when the safety or benefit of the study participants is doubtful or at risk.
Undue influence	An inappropriate power, pressure or control or domination which may be mental, moral or physical that deprives a person of freedom of judgment, choice and thus, substitutes another's choice or desire in place of its own.
Voluntary	Free of coercion, duress, or undue inducement; used in research context to refer to a subject's decision to participate.
Vulnerability	A substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities.