ACRONYMS

ADR	Adverse Drug Reaction
AE	Adverse Effects
ACI	Accreditation Canada International
CIOMS	Council for International Organizations of Medical Sciences
COI	Conflict of Interest
CRF	Case Report Form
CT	Clinical Trial
CTRD	Clinical Trial and Research Division
CRO	Contract Research Organization
CV	Curriculum Vitae
DOH	Department of Health
DSMB	Data Safety Monitoring Board
ETRS	Education Training and Research Services
EC	Ethics Committee
FDA	Food and Drug Administration
GCP	Good Clinical Practice
IC	Independent Consultant
IB	Investigator Brochure
ISO	International Standard Organization
ICF	Informed Consent Form
ICH GCP	International Conference on the Harmonisation of Good Clinical Practice
IERB	Institutional Ethics Review Board
IDE	Investigational Device Exemption
LAR	Legally Authorized Representative
MSO	Management Service Office
NSR	Non-Significant Risk
OR	Official Receipt
OJT	On-Job-Training
QM	Quality Manual
PFDA	Philippine Food and Drug Administration
PHREB	Philippine Health Research Ethics Board
PI	Principal Investigator
PHC	Philippine Heart Center
PHC-IERB	Philippine Heart Center-Institutional Ethics Review Board
PNHRS	Philippine National Health Research System
REC	Research Ethics Committee
SAE	Serious Adverse Event
SMS	Short Message Service
SR	Significant Risk
SJREB	Single Joint Review Ethics Board
SOP	Standard Operating Procedure
SoA	Statement of Account
SUSAR	Suspected Unexpected Serious Adverse Reaction
TRC	Technical Review Board
TOR	Terms of Reference
WHO	World Health Organization

TERMINOLOGIES

Active Study File	Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study.
Administrative Documents	Include official minutes of board meetings and policies and procedures both historical files and master files
Adult	For the purpose of consent, an adult is anyone 18 years or older
Adverse Event	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 AE can therefore be any unfavorable 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 Standard for Expedited Reporting).
Adverse Reaction	All untoward and unintended responses to a medicinal product related to any dose. The phrase "response to medicinal products" means that a causal relationship between a study medication and an AE is at least a reasonable possibility, i.e. the relationship cannot be ruled out.
Affiliated	A member who is employed in the institution where is research ethics is connected.
Agenda	A list of items to be taken up at a meeting.
Amendment	Any change in protocol and documents from that of previously IEC approved protocol/document
Archives	A designated place/section used for storage for completed protocols, inactive files or terminated studies.
Assent Form	Agreement by an individual not competent to give legally valid informed consent (*e.g.*, a child or cognitively impaired person) to participate in research.
Assessment Form	A form used by reviewers to evaluate the scientific and ethical merits of the protocol and the consent forms.
Assessment /Survey	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
Audit	A systematic and independent examination of approval activities and documents related to a research study or clinical trial 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.
Case Report Form	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.
Clinical Trial/Study	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of

	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.
Closed Study Files	Approved supporting documents (protocols, protocol amendments, informed consent, advertisements, investigator and site information), records containing communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to subjects, Scientific evaluations) that correspond to each study approved by the PHC for which a final report has been reviewed and accepted.
Compliance	Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements.
Confidentiality	Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.
Conflict of Interest	A conflict between a person's private interests and public obligations.
Consent Monitor	An impartial observer who ensures that the approved consent process is being followed properly.
Continuing Review	Review of progress report of a study, for "renewal" of IERB approval which must occur at least once per year.
Continuing Review Report	The form that PI completes and submits to the IERB to initiate the continuing review process.
Data Safety Monitoring Board	A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.
Decision	A position, judgement or opinion reached by the ERC to an application following review
Deviation/ Non – compliance/ Violation	Non-performance of the study in compliance with the approved protocol, ICH GCP, BFAD regulations and/or fail to respond to the IERB's request for information/action.
Document	May mean the following: o Study Protocol and related documents (such as case report forms, informed consent, diary form, scientific document, report, record, expert opinion or review) o IERB documents (Policies, Procedures, meeting minutes, advice and decisions)
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 results of a trial, the factors affecting a trial, and the actions taken and includes all actions or decisions given by the REC.
Emergency Meeting	An IERB meeting that is scheduled outside of a normally scheduled meeting to review study activities that require full IERB 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.
Ethics Review Board	A panel of individuals who review research proposals to ensure that the

	ethical principals are incorporated into the study design, that the proposed research activities include no unnecessary risks, that potential risks to study participants are minimized, and that overall potential benefit to the individual, or to society, is reasonable in relation to the risks.
Expected Serious Adverse Event / Reaction	A serious adverse event /reaction that could be reasonably expected when taking into account the likely course of the disease or condition during the course of the study or expected from the study medication(s).
Expedited Review	review process by only two or more designated IERB members who then report the decision to the full Board meeting.
Expiration Date	IERB approval which expires at 11:59 PM on the last day of the IERB approval period.
Final Report	Refers to the final draft report before publication.
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.
Guideline	A written suggestion, rule, etc., intended as a guide for specific practice or action.
Impartial Witness	A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally authorized representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.
Implantables	Intracardiac device occludes (PDA, ADA, VSD), embolization devices for PDA, offer C-V shunts.
IERB	The Institutional Ethics Review Board is an independent body 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.
IERB Record Keeping	Maintains records relating to research, including materials submitted by investigators for IERB review (or exemption), documentation of IERB activities, and other required records, such as IERB correspondence, rosters, and policies. All records are retained in a secure manner that allows for a review of the history of IERB actions and for inspection by authorized personnel.
IERB Reviewer's Evaluation Form	Form used to assess a study protocol if it has fulfilled requirements for ethical review.
Independent Consultant	An expert who gives advice, comments and suggestion upon review of the study protocols with no affiliation to the institutes or investigators proposing the research protocols.
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.
Initial Review	The review of a protocol for the first time to assess its scientific soundness and compliance with ethical principles Institution Any public or private entity or agency where research is conducted.
Inspection	The act by regulatory authorities of conducting an official review of documents, facilities, records, and any other resources that are deemed by

	the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO) facilities, Office of Ethics, or at other establishments deemed appropriate by the regulatory authorities.
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. See also Sub investigator.
Investigator Brochure	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.
Legally Authorized Representative	A legally authorized representative is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participation in the procedure(s) involved in the research.
Major Violation	Any factor determined by IERB Chair or IERB member as warranting review of the violation by the convened IERB shall be considered as a major violation. Examples of major violations may include, but are not limited to: • Failure to obtain informed consent, i.e., there is no documentation of informed consent, or informed consent is obtained after initiation of study procedures; • Enrolment of a subject who did not meet all inclusion/exclusion criteria; • Performance of study procedure not approved by the IERB; • Failure to report serious unanticipated problems/adverse events involving risks to subjects to the IERB and (if applicable) to the sponsor; • Failure to perform a required lab test that, in the opinion of the Principal Investigator, may affect subject safety or data integrity; • Drug/study medication dispensing or dosing error; • Study visit conducted outside of required time frame that, in the opinion of the PI or IERB, may affect subject safety; • Failure to follow safety monitoring plan.
Master File	A file for storage of all the originally signed and dated documents
Medical and scientific Member	Are responsible for the review of the technical and science components of research protocol i.e., appropriateness of the research design and methods, sample size calculation, soundness of the inclusion and exclusion criteria, internal and external validity of the study tools and procedures.
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).
Meeting	Deliberation between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
Members	Individuals serving as regular or alternate members in the REC.
Member Secretary	REC member who heads the secretariat.
Minimal Risk	The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.

Minor Violation	A violation that does not impact on subject safety or does not substantially alter risks to subjects shall be considered as a minor violation. Examples of minor violations may include, but are not limited to: Implementation of unapproved recruitment procedures; • Missing original signed and dated consent form (only a photocopy available); • Missing pages of executed consent form; • Inappropriate documentation of informed consent, including: missing subject signature; ✓ missing investigator signature; ✓ copy not given to the person signing the form; ✓ someone other than the subject dated the consent form; ✓ individual obtaining informed consent not listed on IERB approved study personnel list. • Use of invalid consent form, i.e., consent form without IERB approval stamp or outdated/expired consent form; • Failure to follow the approved study procedure that, in the opinion of the PI, does not affect subject safety or data integrity; ✓ Study procedure conducted out of sequence; ✓ Omitting an approved portion of the protocol; ✓ Failure to perform a required lab test; ✓ Missing lab results; ✓ Enrollment of ineligible subject (e.g., subject's age was 6 months above age limit); ✓ Study visit conducted outside of required time frame; • Over-enrollment; • Enrollment of subjects after IERB-approval of study expired or lapsed; • Failure to submit continuing review application to the IERB before study expiration.
Minutes of the Meeting	An official record of the business discussed and transacted at a meeting, conference, etc.
Monitoring	The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Multicenter Study	A study conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.
Non-affiliated Member	A member who is not connected to the institution.
Non-member of the IERB	Any relevant person/persons who presently is/are not a member/member of the IERB such as regulatory authorities, monitors, auditors, assessors, surveyors, participants, etc.
Non-scientific Member	A member that primarily entrusted to review the information sheets used in obtaining consent, parental consent and assent.
Non-Significant Risk (NSR) Device	An investigational device that does not pose a significant risk.
On – site SAE	Serious adverse events that happen within the institution.
Off – site SAE	Serious adverse events that happen outside the institution.
Pharmacogenetics	studies how the genetic characteristics affect the individual's drug response.
Pharmacogenomics	studies how the inherited genetic variations are utilized to predict patient's drug response.
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 process.
Phase III study	A study expanded to controlled and uncontrolled trials performed after preliminary evidence suggesting efficacy of the drug has been obtained. They are intended to gather the additional information about efficacy and safety that is needed to evaluate the overall benefit – risk relationship of the drug to provide an adequate basis for physician labeling.
Phase IV	study A study of a medical product conducted after marketing authorization approval to provide continuing safety evidence of the product when it is available for use of the general population.
Policy/Procedure	Detailed, written instructions, in a certain format, describing all activities and action undertaken by an organization to achieve uniformity of the performance of a specific function. The aim of the policy/procedure and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice.
Primary Reviewer	Point person given the primary task of evaluating the protocol and/or ICF with the use of assessment form.
Principal Investigator	The scientist or scholar with primary responsibility for the design and conduct of a research project.
Protocol	A document that describes the objective(s), design, methodology, statistical considerations, and organization 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.
Protocol Amendment	A written description of a change(s) to, or formal clarification of a protocol.
Protocol Deviation/Violation	Any change during protocol implementation that does not comply with REC approved version.
Quorum	The number of present members required to act on any motion presented for action during a full board meeting, in addition to types of members required to be present based on international and national guidelines and regulations.
Randomization	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.
Regulatory Authorities	Bodies having the power to regulate. In the ICH GCP Guideline, 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	Any social science, biomedical, behavioral, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new generalizable knowledge.
Research Ethics Committee	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 amendments and of the methods and material to be used in

	obtaining and documenting informed consent of the trial subjects.
Research Proposal	A document written for the purpose of obtaining funding for a research project. In addition to including the research protocol, it also includes information on the investigators (e.g., their CVs and institutional affiliation), approvals from various relevant organizations and persons, budgets, dissemination plans, etc.
Research Protocol	A document describing in detail how a research study is to be conducted in practice, including the study design and methodology, data analysis plan, and a budget. A research protocol is part of a research proposal.
Re-submission Report Form	An official record of the review decision along with comments and dated signature of the reviewer.
Revision History Files	A collection of previous official versions of a document, table of contents, relevant information regarding changes and all preplanned deviations.
Risk	The probability of harm or discomfort to study participants. Acceptable risk differs depending on the conditions for which the product is being tested. A product for sore throat, for example, will be expected to have a low incidence of side effects. However, unpleasant side effects may be an acceptable risk when testing a promising treatment for a life-threatening illness.
Scientists	Professionals with advanced training and expertise in the medical or non – medical areas of science.
Secretariat	Group of persons providing administrative support to the operations of the REC.
Serious Adverse Event (SAE) or Severe Adverse Events	To ensure no confusion or misunderstanding of the difference between the terms "serious" and "severe", which are not synonymous, the following note of clarification is provided: The term "severe" is often used to describe the intensity (severity) of a specific event (as in mild, moderate, or severe myocardial infarction); the event itself, however, may be of relatively minor medical significance (such as severe headache). This is not the same as "serious," which is based on patient/event outcome or action criteria usually associated with events that pose a threat to a patient's life or functioning. Seriousness (not severity) serves as a guide for defining regulatory reporting obligations. Any untoward medical occurrence that at any dose: • Results in death • Is life-threatening* • Requires inpatient hospitalization or prolongation of existing hospitalization** • Results in persistent or significant disability/incapacity • Is a congenital anomaly/birth defect Other important medical event(s)*** *The term 'life-threatening' in the definition of 'serious' refers to an event in which the patient was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe. **Hospitalization for a pre-existing condition, including elective procedures, which has not worsened, does not constitute a serious adverse event. *** Other events that may not result in death, are not life threatening, or do not require hospitalization, may be considered a serious adverse event

	when, based upon appropriate medical judgment, the event may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above. (See the ICH Guideline for Clinical Safety Data Management: Definitions and Standard for Expedited Reporting).
Serious Adverse Reaction (SAR) / Suspected Serious Adverse Reaction (SSAR)	An adverse event (expected or unexpected) that is both serious and, in the opinion of the reporting investigator, believed with reasonable probability to be due to one of the study treatments, based on the information provided.
Significant Risk (SR) Device	An investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the participant, (2) is purported or represented to be for use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the participant, is for use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the participant, or otherwise presents a potential for serious risk to the health, safety, or welfare of the participant.
Site Visit	An action that IERB or its members visit study sites to assess how well the selected investigators are conducting researches, taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the studies. Normally site visit shall be arranged in advance with the principal investigators.
Site Visit Report	Report that includes a summary of what the team reviewed concerning the significant findings/facts, deviations and deficiencies, conclusions, action taken or to be taken and/or actions recommended to secure compliance.
Site Visit Team	IERB designated members who perform site visit.
Sponsor	An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.
Standard Operating Procedure (SOP)	Detailed, written instructions, in a certain format, describing all activities and actions undertaken by an organization to achieve uniformity of the performance of a specific function.
Study Site	An institution, hospital, clinic or any community were participants for a study are recruited and where the actual study is conducted
Study Termination	A permanent end to IRB approval prior to study expiration that includes a permanent halt in the enrolment of new subjects, approved activities involving previously enrolled subjects, and other research activities
Sub-investigator	Any individual member of the study team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also Investigator.
Subject	An individual who participates in research or a clinical trial as a recipient of an investigational product or an intervention.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	A serious adverse drug 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 Medicinal Product Characteristics for an approved

	product). (See the ICH Guideline for Clinical Safety Data Management: Definitions and Standard for Expedited Reporting). When determining the expectedness of an AE consideration should be given to: • the underlying condition of the subject -co-morbidity -concomitant medications • patient population severity and frequency of the occurrence An unexpected adverse event meets one or more of the following criteria: • not attributed to the underlying condition of the subject being studied • not attributed to the patient population being studied • not anticipated on the basis of prior experience with the drug under investigation or with related drugs • not identified in the product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product) • not defined in the study protocol
Site	The location(s) where trial-related activities are actually conducted.
Technical Review	The process of examining, assessing or evaluating a research protocol by technical experts, seasoned researchers, statisticians, and other relevant specialist or authority to ensure the scientific soundness and appropriateness of the objectives and design of the study and the qualifications of the investigator(s).
Termination	Discontinuance, by sponsor or by withdrawal of IRB or FDA approval, of an investigation before completion.
Training/Course	A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.
Unexpected Adverse Reaction	An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's brochure or summary of product characteristics).
Vulnerable 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, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.
Workshop	A group of people engaged in study or work on a creative project or subject.