ANNEX 1. LIST OF ACRONYMS AND GLOSSARY OF TERMS

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ACRONYMS

ADR	Adverse Drug Reaction
AE	Adverse Effects
CHED	Commission on Higher Education
CIOMS	Council for International Organizations of Medical Sciences
COI	Conflict of Interest
CRF	Case Report Form
CRO	Contract Research Organization
CV	Curriculum Vitae
DOH	Department of Health
DOST	Department of Science and Technology
DSMB	Data Safety Monitoring Board
FDA	Food and Drug Administration
GCP	Good Clinical Practice
IB	Investigator Brochure
ICF	Informed Consent Form
ICH GCP	International Conference on the Harmonisation of Good Clinical Practice
MREB	Multi – Site Research Ethics Board
PCHRD	Philippine Council for Health Research and Development
PHIC	Philippine Health Insurance Corporation
PHREB	Philippine Health Research Ethics Board
PI	Principal Investigator
PNHRS	Philippine National Health Research System
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
TOR	Terms of Reference
WHO	World Health Organization

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GLOSSARY OF TERMS

Active Study Files	Supporting and approved documents, records containing communications, and reports that correspond to each active (current) study approved by the research ethics committee
Administrative documents	Documents include official minutes of Board meetings, voting records and the standard operating procedures (SOPs), both historical files and Master Files, SOP distribution, implementation and file maintenance.
Adverse event (AE)	Any untoward medical occurrence in a patient or clinical investigation participant administered 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 items to be taken up at a meeting
Archives	A designated place/section used for storage for completed protocols, inactive files or terminated studies
Assent Form	A form used to explain the study related procedures to minors or research volunteers who lack the capacity to give consent in order to get their agreement to join the study. It is a supplementary form to the informed consent given by the guardian or the legally acceptable representative
Assessment Form	A form used by reviewers to evaluate the scientific and ethical merits of the protocol and the consent forms
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

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	and clinical study are synonymous.
Comparator (Product)	An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.
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	Conditions in which professional judgment concerning a primary interest (such as patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)
Coordinator (Site)	The person at the study site who is responsible for managing the study Sometimes, the Principal Investigator is also the site coordinator and manager.
Deviation/ Non – compliance/ Violation	Any event that is not in accordance with regulations or approval given by the REC
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.
Exempt from Review	A protocol with negligible risk that does not require REC review
Expedited Review	A review process done by two or more designated REC members for study protocols determined to be minimal risk and subsumed within the criteria . At PCMC, recommendations of reviewers shall be brought to a Full board meeting for final approval.
Final Report	An obligatory review of study activities presented as a written report to the REC after the last subject has completed all visits and all adverse experiences have been brought to appropriate resolution. Complete, comprjehensive written description of a completed trial that describes the experimental materials and statistical design, presentation and evaluation of the trial results and statistical analyses.
Full Board Review	Review and deliberation on a study on a study protocols determined to be more than minimal risk, and discussed during a panel meeting, thus subject to quorum requirements
Guideline	A written suggestion, rule, etc., intended as a guide for specific practice or action
Historical File	A document file which was effectively used in the past and presently became obsolete or expired, but still had to be kept in a file for reference purposes.

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Inactive Study File	Supporting and approved documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communication and correspondence with the investigator, and reports (including but not limited to progress reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the REC for which a final report has been reviewed and accepted Inactive study files are archived for a minimum of three years following the completion of the study. These files can be retrieved as needed.
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	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
Investigational Medical Device	A medical device which is the object of clinical research to determine its safety or effectiveness
Investigational Device Exemption (IDE)	Investigational Device Exemption allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Pre-market Approval (PMA) application or a Pre-market Notification submission to the regulatory agency. Clinical studies are most often conducted to support a PMA. Only a small percentage of studies require clinical data to support the application. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

	An IDE is approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by the regulatory agency. An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements that would apply to devices in commercial distribution. Sponsors need not submit a PMA (Pre-Market Approval) or Pre-Market Notification, register their establishment, or list the device while the device is under investigation. Sponsors of IDE'S are also exempt from the Quality System (QS) Regulation except for the requirements for design control.
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 Subinvestigator.
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 Acceptable Representative	An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

Majority Vote	A vote by one – half plus One of REC members attending a formal meeting that meets the quorum requirements
Master File	Original copies of documents such as SOPs, guidelines, instruction, manual with real signatures of preparers, reviewers and authorized persons are systematically stored in secured cabinets with limited access.
Medical Device	A medical device is 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-occular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kids for *in vitro* diagnosis of disease and other conditions, (for example, pregnancy).
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

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	or during the performance of routine physical or psychological examinations
Minutes	The official record of events, activities, and actions taken on agenda items presented to a duly constituted (quorum present) independent board review meeting. The minutes identify fully each protocol and/ or activity and record the outcomes of each voting action. The board votes separately on each collective set or each item submitted for review: protocol, consent form, investigator, and advertisement(s). The record notes the decision of the REC for or against approval, the number of abstaining votes, and the reason for the abstention(s), without identifying the individual member's names.
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-Medical, Non-Scientific Member	REC member with a lay person's perspective about protocols being reviewed by the ethics committee
Non-significant Risk Device (NSR)	A non-significant risk device is an investigational device that does not pose a significant risk. (See SOP on Review of Medical Device Study).
On – site SAE	Serious adverse events that happen within the institution
Off – site SAE	Serious adverse events that happen outside the institution
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

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	available for use of the general population
Primary Reviewer	Point person given the primary task of evaluating the protocol and/or ICF with the use of assessment form
Progress Report	An ongoing review of each investigator's study activities presented as a written report to obtain extended approval for the study from the REC. Generally, these reports are due annually with the REC sending a written notification reminding the investigator of this obligation. More frequent reports may be requested at the discretion of the REC.
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. This requires formal approval by the sponsor.
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 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.

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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 Serious Adverse Drug Reaction (Serious ADR)	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, or - is a congenital anomaly/birth defect (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).
Significant Risk Device	A significant risk device is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of tjhe subject, (2) is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the subject, (3) is for a 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 subject, or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of the participants.
Site Visit	An action taken by REC members or representatives which involves going to a study site to assess how the investigators are conducting a trial or research and maintaining proper documentation for an ERC approved protocol
SOP Team	A selected group of ad hoc REC members and administrative staff who oversee the preparation, review and revision of the REC SOPs

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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 where participants for a study are recruited and where the actual study is conducted
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 a research or a clinical trial as a recipient of an investigational product or an intervention.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	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) (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).
Trial 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).
Terminated Study	A study approved by the Ethics Committee that is being recommended for termination before its scheduled completion
Unexpected Event / Unanticipated Risk (UE / UR)	sometimes discovered during the course of the studies, it include any event that in the Investigators' opinion, may adversely affect the rights, welfare and safety of the study participants.

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.

References:

1. International Conference on the Harmonisation of Good Clinical Practice, 1997
2. Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6(R2), 2016
3. Standard Operating Procedures UP Manila Research Ethics Board (UPMREB), 2012