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Active Files – an electronic or hard copy file of study documents submitted to the Institutional Review Board and contains active records.

Active File Database - Systematically organized or structured repository of indexed information (usually as a group of linked data files) that allows easy retrieval, updating, analysis and output of data stored usually in a computer. This data could be in the form of graphics, report, scripts, tables and text, etc., representing almost every kind of information.

Active Study – is an ongoing study, implementation of which is within the period covered by ethics clearance.

Agenda- the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a "Call to Order".

Administrative Communication – refers to the in-coming and out-going communications acted upon by the Institutional Review board thru its Chair or the Secretariat.

Adverse Events – any untoward or undesirable medical occurrence in a patient or participant in clinical investigation after use or administration of an investigational product. This is not necessarily caused by the treatment. See also drug reaction, serious adverse event and suspected unexpected serious adverse reaction.

Amendment- a change in or revision of the protocol made after it has been approved.

Anonymized Biological Specimen - biological specimens that have been stripped of all identifiers (including codes) that would link directly to the individual. However, health and demographic data are retained, such as height, weight, age, diagnosis, socio-ethnic group, etc.)

Approval - favorable or affirmative decision of the Institutional Review Board 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 Minutes – a written records of the proceedings of the meetings (either special or regular meeting) conducted by the IRB which is adopted and approved by the majority of the members during the subsequent meeting of the IRB.

Archiving – storing of a collection of information or documents such as letters, official papers or any recorded material considered permanently valuable, and recorded on a media suitable for long term storage.

Assent - authorization for one's own participation in research given by a minor or another subject 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. It is the review of feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children:

0-under 7: No assent
7-under 12: Verbal Assent
12-under15: Simplified Assent Form
15-under18:Co-sign informed consent form with parents
(*See also child's assent and surrogate assent.)*

Assessment Form- evaluation tool accomplished by the reviewers when appraising the protocol or the informed consent form.

Business arising from the minutes- are matters generated from the discussions in the previous meeting that need continuing attention and require reporting.

Child Assent - An agreement or expressed willingness of a minor to take part in the research when a child cannot give full consent. Children often can understand some, but not all parts of a research study. Assent is the child's way of saying that he/she agrees to take part in the research to the degree that he/she understands it. It differs from consent since consent is the permission given by a parent or guardian to a child to take part in the research. Older children or youth may give their own consent if they are mature enough to completely or totally understand the research, and the consent or decision to participate is freely given with the premise that they are given enough information to make a choice and they understood the information provided to them (Retrieved from www.caringforkids.cps.ca/healthybodies/ HealthResearch.htm and http://www.ncbi.nlm.nih.gov/pmc/articles/ PMC2606084/). The factors to be considered by the IRB are "age, psychologic state, and the maturity of the children involved" and to understand and determine whether and how assent must be documented. The assent can be an interactive process between the child and the researcher, involving disclosure, discussion, obtaining an understanding of the proposed research activity, and determining the child's preference regarding participation. The process involves "(a) providing information about the proposed research to the minor, (b) establishing shared decision-making by the child and the proxy concerning participation together with the proxy, (c) making an assessment of the child's understanding of the proposed research, and (d) soliciting an expression of the child's willingness to participate in the proposed research" (Kon, A. A. (2006). Assent in Pediatric Research. Pediatrics, 117, 1806—1810. Retrieved from http://www. pediatrics.org/cgi/content/full/117/5/1806). (*See also assent and surrogate assent.)*

Clinical Research- is a study undertaken involving a particular person or group of people with the purpose of increasing knowledge and determining how well treatment or diagnostic test works in a particular patient population. This research can include: Studies of mechanisms of human disease; Studies of therapies or interventions for disease; Clinical trials and Studies to develop new technology related to disease.

Clinical trial- is a planned scientific research or study among human volunteers to determine the effects of treatment or diagnostic test on their safety, efficacy, and its effect on quality of life. It is also a systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reactions to investigational products, and/or to study the absorption, distribution, metabolism, and excretion of the products with the object of ascertaining their efficacy and safety (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products) It is also defined as investigative work to

evaluate new drugs, medical devices, biologics, or other interventions to patients in strictly scientifically controlled settings.

Collegial Decision - marked by power or authority vested equally in each of the member of the IRB to arrive at a certain decision in a meeting.

Complaint- the act of expressing discontent or unease about certain events or arrangements in connection with a study.

Confidentiality - 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.

Confidentiality Agreement - A letter sent to the investigator/institution to document their agreement to treat all information regarding the investigational product and the clinical trial in a confidential manner.

Conflict of Interest- a situation in which aims or concerns of two (primary and secondary) different interest are not compatible such that decisions may adversely affect the official/primary duties.

Consensus - a general agreement about something: an idea or opinion that is shared by all the members of the IRB.

Continuing Review- is the decision of the IRB to extend the ethical clearance of the study based on an assessment that the research is proceeding according to the approved protocol and there is reasonable expectation of its completion.

Corporate Values - The operating philosophies or principles that guide
an organization's internal conduct as well as its relationship with its customers, partners,
and stakeholders. It is usually summarized in the mission statement or in the company's statement of core values.

Database- a collection of information (e.g. regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analysed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

Decision- the result of the deliberations of the IRB in the review of a protocol or other submissions.

Draft Meeting Minutes- Proceedings of the meeting prepared by the Secretariat.

Drug or Device- health product used for diagnosis or treatment.

Early Termination- is ending the implementation of a study before its completion. This is a decision made by the sponsor or a regulatory authority and/or recommended by the Data Safety Monitoring Board, researcher/investigator in consideration of participant safety, funding issues, protocol violations, and data integrity issues.

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Exempt from Review- a decision made by the IRB Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGHHR 2017 The Research Ethics Review Process Guideline 3.1. This means that the protocol will not undergo an expedited nor a full review.

Expedited review – review of studies that do not entail more than low risk to study participants and those involving participants not belonging to a vulnerable groups aim to demonstrate due to diligence and high standards in the system of protection of human participants. The scope of the Expedited review applies to initial and post-approval submissions on protocols which have been classified as not involving more than low risk to study participants and whose participants do not belong to vulnerable groups.

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.

Good Clinical Practice (GCP) - International ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing and reporting studies. Insures that the data reported is credible and accurate, and that subject's rights and confidentiality are protected.

Honorarium – a voluntary payment for professional services for which no fees are nominally due. (Webster's Universal Dictionary; 2006, p.253)

Inactive Study – a study whose proponent has not communicated with the IRB with regard to issues pertaining to the approval or implementation of the study – within the period of time required by the IRB.

Incoming Communications- are documents which are directed to and received at the IRB office.

Independent Consultant – an expert who gives advice, comments and suggestions upon review of the study protocols with no affiliation to the institution or investigator proposing the research proposal.

Informed Consent - The voluntary verification of a patient's willingness to participate in a clinical trial, along with the documentation thereof. This verification is requested only after complete, objective information has been given about the trial, including an explanation of the study's objectives, potential benefits, risks and inconveniences, alternative therapies available, and of the subject's rights and responsibilities in accordance with the current revision of the Declaration of Helsinki.

Initial Review- the ethical assessment of the first complete set of the study documents submitted to the IRB for assessment that can be expedited or full review.

Initial submission- refers to all new study protocols or researches submitted to the Institutional Review Board for review.

Institution - Location of research. Retains ultimate responsibility for human subject regulation compliance.

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Investigator - a person responsible for the conduct of the critical trial at a trial site. If trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and be called the principal investigator (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice (E6, R1); It is a person responsible for the trial and for the rights, health and welfare of the subjects in the trial. The investigator should have qualifications and competence in accordance with local laws and regulations as evidenced by an up-to-date curriculum vitae and other credentials. Decisions relating to, and to provisions of, medical or dental care must always be the responsibility of a clinically competent person legally allowed to practice medicine or dentistry (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products); The investigator must be a qualified scientist who undertakes scientific and ethical responsibility, either on his/her behalf or on behalf of an organization, for the ethical and scientific integrity of a research project at a specific site or group of sites. (*See principal investigator)*

Institutional Review Board - is an independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it 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, by, among other things, reviewing and approving / providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. International Conference on Harmonization (ICH) – Guideline for Good Clinical Practice (GCP) E6 (R1), art. 1.27) (*See also SPHI Institutional Review Board)* 174

Investigator's Brochure- compilation of all relevant clinical and non-clinical information and data on the investigational product.

IRB Protocol Number – a series of coded number assigned to submitted protocols for review.

IRB Staff – refers to the Staff and Clerk Secretaries hired by the administration to work full time in the IRB office.

Logbook- a real-time chronological record of incoming protocols that includes the Date/Time ofReceipt, Title of the Document, Name of the Proponent, Name and Signature of the submitting Entity, Name and Signature of the Receiving Person and Action done. 186

Minimal risk - A risk is minimal 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.

Minutes of the Meeting – an official record of the proceedings in a meeting.

Monitoring- is the process of checking or scrutinizing research participants' health status during a clinical trial, and/or to oversee the progress of a trial or research and/or to check researcher's compliance with the protocol and regulatory requirements in which the protocol is given ethical approval.

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Non-Affiliated Member - Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty and who will represent the interest and concerns of the community. This individual is usually from the local community (*e.g.*, minister, business person, attorney, teacher, and homemaker).

Outgoing Communications – are documents generated within the IRB office intended for individuals or officers related to the operations of the IRB.

Post-approval reports- are accounts of the ongoing implementation of an approved study (e.g., progress report, amendment, safety report, protocol deviation/violation, early termination, final report, or application for continuing review) that are required to be submitted by the researcher to the IRB for monitoring purposes.

Phase I Clinical Trial- refers to the first introduction of a drug into humans. Normal volunteer participants are usually studied to determine the levels of drugs at which toxicity is observed. Such studies are followed by doseranging studies in research participants for safety and, in some cases, early evidence of effectiveness.
Phase I studies can involve one or a combination of the following (Guidelines on General Considerations for Clinical Trials (ICH-E8). Published in the Federal Register on December 17, 1997 (62 FR 66113)). US Department of Health and Human Services, Food and Drug Administration):
a) Estimation of Initial and Safety Tolerability
b) Pharmacokinetics assessing the drug's absorption, distribution, metabolism, and excretion either a separate study or part of an efficacy, safety and tolerability
c) Pharmacodynamics to provide an estimate of the activity and potential efficacy and may guide the drug's dosage and dose regimen
d) Early measurement of drug's activity

Phase II Clinical Trial- consists of controlled clinical trials designed to demonstrate efficacy and relative safety of the investigative new drug. Normally, these are performed on a limited number of closely monitored patients suffering from a disease or condition for which the active ingredient is intended.
This phase also aims at the determination of appropriate dose ranges or regimens and (if possible) clarification of dose-response relationships to provide an optimal background for the design of extensive therapeutic trials (WHO).
Some innovative pharmaceutical companies have added an additional layer called Phase Ib/IIa before proceeding to Phase II. The former employs a placebo arm and employs surrogate biomarkers assumed to predict the drug's therapeutic or adverse effects in the disease target population. This allows the right endpoint to be selected for Phases II and III. Participants employed are patients with the target disease but some bridging studies employ additional normal healthy participants. The main objective of this transition phase is to evaluate the safety and establish the pharmacokinetics of multiple doses of the drug and monitor any effects on biological markers of disease activity.

Phase III Clinical Trial trial(s)- in larger (and possibly varied) research participant groups with the purpose of determining the short- and long-term safety/ efficacy balance of formulation(s) of the active ingredient, and of assessing its overall and relative therapeutic value. This is performed after a reasonable probability of a drug's effectiveness has been established. These trials should preferably be

of a randomized double-blind design, but other designs may be acceptable (e.g., long-term safety studies).
The pattern and profile of any frequent adverse reactions must be investigated and special features of the product must be explored (e.g., clinically relevant drug interactions, factors leading to differences in effect such as age). Generally, the conditions under which these trials are carried out should be as close as possible to normal conditions of use (WHO).

Phase IV Clinical Study- research conducted after the national drug registration authority (i.e., FDA) has approved a drug for distribution or marketing. This phase is carried out on the basis of the product characteristics on which the marketing authorization was granted and is normally in the form of post-marketing surveillance or assessment of therapeutic value or treatment strategies. Although methods may differ, these studies should use the same scientific and ethical standards as applied in pre-marketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, among others, are normality considered as trials for new pharmaceutical products (WHO).

Philippine Health Research Ethics Board- the national policymaking body on health research ethics, created under DOST Special Order No. 091, which is mandated to ensure that all phases of health research shall adhere to the universal ethical principles that value the protection and promotion of the dignity of health research participants.

Placebo- a substance that is not biologically active, does not interact with other substances nor is it expected to affect the health status of an individual; it may be an inactive pill, liquid, or powder that has no treatment value.

Placebo-Controlled Trials- clinical trials that assign the administration of a placebo to the control group while the test drug is given to the experimental group.

Primary reviewers- refer to the members of the IRB assigned by the Chair or Member-Secretary to review and present the findings and recommendations on the study protocol for review during the IRB full-board meeting.

Principal Investigator - the chief or person primarily responsible for the implementation of a research project. (*See also investigator)*

Privacy- is the right or claim or state or ability or condition of an individual or group or institution to conceal or seclude or hide themselves or information about themselves and thus reveal or expose themselves selectively; it is a conceptual space defining the individual's boundary as a person, intrusion of which is limited by human rights and by law. It is right to determine when, how, and to what extent information about someone is communicated to others. (*See also Confidentiality)*

Progress Report – report required by SPHI IRB to be submitted by the Principal Investigator to monitor the safety of participants enrolled in a study.

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. Some of these considerations may be provided in other documents referred to in the protocol. (WHO, Operational Guidelines for Ethics Committees That Review Biomedical Research, Geneva 2000, TDR/PRD/ETHICS/ 2000, p. 22); 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. (International Conference on Harmonisation (ICH) – Guideline for Good Clinical Practice (GCP) E6 (R1), art. 1.44). (*See also research protocol)*

Protocol Amendment - A written description of a change/s to, or formal clarification of a protocol and changes on any other supporting documentation made from the originally approved protocol by the research ethics review body after the study has begun.

Protocol Deviation/Violation – failure to comply with the procedures in the approved protocol or to comply with national/international guidelines in the conduct of human research.

Protocol Package Acknowledgment Receipt - a letter or information sent to signify that the package containing protocol-related documents has been received by the IRB Staff.

Query- the act of asking for information or clarification about a study.

Quorum- Presence of at least five members, including at least one lay or non-scientific member, one non-affiliated member and with gender representation, to make decisions about the proposed research.

Randomization, Random Assignment -process of assigning research participants to treatment or control groups using an element of chance to determine the assignments to reduce bias (ICH-GCP).

Real Time Recording – Recording of data or information that take place instantaneously or in the same timeframe as it is happening.

Regulatory and Accrediting Authorities- person/s appointed by and responsible to the sponsor or contract research organization for monitoring and reporting progress of the trial and for verification of data (WHO, Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products)

Research participants or subjects - An individual who participates in a biomedical research project, either as the direct recipient of an intervention (e.g., study product or invasive procedure), as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research, or a person with a condition unrelated to the research carried out who volunteers to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated. (WHO, Operational Guidelines for Ethics Committees That Review Biomedical Research, Geneva 2000, TDR/PRD/ETHICS/ 2000, p. 22).

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. Some of these considerations may be provided in other documents referred to in the protocol. (*See also protocol)*

Risk - the probability of discomfort or harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Risks to research participants must be justified by the anticipated benefits to the subjects or to society. The investigator(s) and IRB must assess the risks and benefits of proposed research. (*See also minimal risk)*

Resubmission – study protocols/documents returned after having minor or major revisions.

Reportable Negative Events (RNE)- are occurrences in the study site that indicate risks or actual harms to participants and to members of the research team and to integrity of data.

Serious adverse Event - or serious adverse drug reaction is an adverse event that results to death, life-threatening incident or causes immediate risk of death from the event; results to in-patient or prolongation of hospitalization, causes significant disability, incapacity, and congenital anomaly or another episode which is considered a significant hazard to the participant. See also adverse event or unexpected adverse event. Also, any untoward medical occurrence that at any dose: - results in death, - is life-threatening, - requires in-patient hospitalization or prolongation of existing hospitalization, -results in persistent or significant disability/incapacity, or - is a congenital anomaly/birth defect (International Conference on Harmonisation (ICH) - Guideline for Good Clinical Practice (GCP) E6 (R1), art. 1.50) (*See adverse event)*

Side Effect- undesired effect of a treatment which is either immediate or long-term.

Sponsor- an individual, company, institution, or organization that takes responsibility for initiating, managing, and financing a clinical trial.

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.

Site Visit – any visit made in the study site to check compliance with GCP and IRB approved protocol and related documents.

SPHI Institutional Review Board - ethics review committee organized by the St. Paul's Hospital of Iloilo, Inc. 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 lay members, whose responsibility it 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. [ICH E6 1.31]

Standard Operating Procedure (SOP) – detailed written instruction in a certain format describing the activities and actions undertaken by an organization to achieve uniformity of the performance of a specific function.

SOP Team – an ad hoc committee composed of IRB members designated to rewrite/revise the IRB SOP.

Study Documents - 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.

Study Protocol Related Document – refers to all records, accounts, notes, report, data and ethics communications (submission, approval and progress reports) collected, generated or used in connection with the Study, whether in written, electronic, optical or other form, including all recorded original observations and notations of clinical activities such as CRFs and all other reports and records necessary for the evaluation and construction of the Study. (*See also study document*)

Surrogate Assent – surrogate assent – Necessary when an adult is not able to provide consent for themselves to participate in research due to: cognitive impairment, lacking capacity, or suffering from a serious or life-threatening disease. This is a protocol-specific request of the investigator, and must be reviewed and approved accordingly by the IRB (Retrieved from http://www.virginia.edu/vpr/irb/hsr/surrogate_assent.html). (*See also assent and child's assent)*

Suspected Unexpected Serious Adverse Reaction - is an adverse reaction that has not been anticipated, nor previously experienced, or observed, and is not consistent with the informed consent, information sheets or applicable product information in the investigator's protocol or brochure, product or package insert or summary of product characteristic. (*See also adverse event and serious adverse event)*

Submission – all protocols submitted to the SPHI IRB for ethical review.

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. (IRB Guidebook, US DHHS)

Vulnerability - refers to 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, or being a junior or subordinate member of a hierarchical group. (CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva 2002, General Ethical Principles)

Vulnerable persons/groups - are 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. (International Conference on Harmonisation (ICH) – Guideline for Good Clinical Practice (GCP) E6 (R1), art. 1.61) Vulnerable persons are those who are relatively incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. (CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva 2002, Commentary on Guideline 9) These are also classes of individuals who have characteristics that lessen their capacity to

protect their own interests or promote their own welfare; these are “persons whose situation or characteristics may make them unable to provide free and informed consent to participate in research. This group includes children, institutionalized persons, those who have cognitive impairments, and those in a position of inferiority”(http://www.pre.ethics.gc.ca.engish/tutorial/glossary.cfm#cdownloaded on July 9, 2010)

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