TITLE	WRITING AND REVISING SOPs
POLICY STATEMENT	The REB shall designate a team responsible for the annual review of its SOPs. This team will assess the relevance, clarity, and effectiveness of existing SOPs in light of current practices, applicable regulations, and emerging ethical considerations. Based on this assessment, the team will identify areas requiring revision and may propose updates or the development of new SOPs as needed. All proposed changes shall undergo a standardized process, including drafting, internal review, and formal approval by the REB. Once approved, all updates must be properly documented, dated, and communicated to relevant stakeholders to ensure consistent implementation.
OBJECTIVE OF THE ACTIVITY	The REB aims to align its operations with current ethical standards, regulatory requirements, and best practices. This process supports the continuous improvement of REB procedures, promotes transparency and accountability, and safeguards the integrity of ethical review processes.
SCOPE	This SOP on Writing and Revising SOPs outlines the procedures established by the Research Ethics Board (REB) to ensure the systematic development of new SOPs and the regular revision of existing ones. It applies to all REB activities related to the creation, modification, approval, and dissemination of its SOPs as officially published and distributed by the institution. The scope of this SOP begins with the identification of the need for a new SOP or revision of an existing one, followed by the drafting, internal review, and approval process. It concludes with the integration of the finalized SOP into the official SOP Manual and its communication to all relevant stakeholders. This SOP ensures that all procedural documents remain current, relevant, and aligned with institutional, ethical, and regulatory standards.

Workflow

STEP	ACTIVITIES	RESPONSIBILITY	TIMELINE	INTERFACE
1	Proposal and approval for revision or writing of a new SOP	Any REB Member or Staff	Within 5-7 calendar days	
	↓			
2	Designation of the SOP Team	CHAIR	Within 3 calendar days	
	↓			
3	Drafting of the revision or new SOP	SOP TEAM	Within 15 calendar days	
	↓			
4	Review and finalization of SOP	REB MEMBERS	Within 10 calendar days	
	↓			
5	Submission of finalized SOP to the institutional authority	CHAIR	Within 3 calendar days	
	↓			
6	Inclusion of the new or revised SOP in the SOP Manual and its dissemination	MEMBER SECRETARY	Within 5 calendar days	

Description of Procedures

Step 1 - Proposal for a revision of an SOP or a new SOP and its approval: The proposal for the revision of an existing SOP or the development of a new SOP may be initiated by any member of the Research Ethics Board (REB), the REB Secretariat, or other relevant institutional stakeholders who identify the need for change based on evolving regulatory requirements, operational challenges, or the need for clarification and improvement. The initiation of a request must be formally submitted in writing to the designated SOP review team, outlining the rationale for the proposed revision or new SOP, the specific areas of concern or improvement, and any supporting documentation.

Upon receipt of the proposal, the SOP review team shall conduct a preliminary assessment to determine its necessity and relevance. If deemed appropriate, a draft of the new or revised SOP will be prepared and reviewed internally. The draft shall then be presented for discussion and approval during a regular REB meeting. In cases where urgent updates are required, a special meeting may be convened to expedite the review and approval process. Final approval of the SOP requires a majority vote from REB members present during the meeting. Once approved, the

new or revised SOP shall be officially included in the REB SOP Manual and disseminated to all relevant parties.

Step 2 - Designation of the SOP Team: The designation of the SOP Team shall be carried out by the Chairperson of the Research Ethics Board (REB) in consultation with the REB members. The Chairperson will appoint individuals based on their expertise, experience, and familiarity with REB operations and ethical review processes. The SOP Team should ideally include representatives from both the REB membership and the REB Secretariat to ensure a balanced perspective on procedural and administrative matters. Selection criteria will consider each member's ability to contribute meaningfully to the review, development, and revision of SOPs. Once designated, the SOP Team shall be responsible for coordinating the annual review of existing SOPs, evaluating proposals for new or revised procedures, and ensuring that all updates align with institutional policies, regulatory standards, and ethical guidelines. The composition of the SOP Team may be reviewed periodically to maintain effectiveness and inclusivity in the SOP development process.

Step 3 - Drafting of the revision or new SOP: The drafting of a revised or new Standard Operating Procedure (SOP) within the Research Ethics Board (REB) shall follow a standardized process to ensure clarity, consistency, and alignment with institutional and ethical standards. The REB utilizes a uniform SOP template designed to harmonize the structure and format of all SOPs. This template includes the following essential components: a descriptive title; a policy statement that outlines the guiding principles; the objective, which states the purpose and intended outcome of the SOP; and the scope, which defines its coverage and limitations. It also incorporates a workflow diagram that graphically presents the sequence of essential steps along with the responsible personnel for each step, followed by detailed instructions that elaborate on each part of the process.

Additional elements in the template include a glossary for defining key terms and acronyms; required forms and documents to be completed by different parties; and a document history table that records all versions from draft to final, including author names, version numbers, dates, and descriptions of main changes. References to related SOPs, policies, or guidelines used in the drafting process are also included.

Once the need for a new SOP or revision is approved, the designated SOP Team is responsible for drafting the content using the approved template. The draft must be reviewed internally and refined through feedback from relevant stakeholders. For coding, the REB uses a standard format: SOP XX/YY, where "XX" refers to the unique SOP number and "YY" refers to the version number, beginning with 01 for the initial version. This coding system facilitates tracking, retrieval, and version control of all SOP documents. Once finalized and approved through the REC's formal approval process, the SOP is incorporated into the SOP Manual and officially disseminated.

Step 4 - Review and approval of SOP: Once a draft version of a new or revised Standard Operating Procedure (SOP) is finalized by the designated SOP Team, it is formally submitted to the Research Ethics Board (REB) Secretariat. The Secretariat forwards the draft to the REB Chairperson, who ensures that the SOP is included as an agenda item in an upcoming regular REB meeting. In urgent cases, a special meeting may be convened specifically to address the SOP. Prior to the meeting, the draft is circulated to all REB members, typically at least one week in advance, to allow sufficient time for review and preparation of comments.

During the meeting, the draft SOP is presented and thoroughly discussed by REB members. Deliberations include evaluating the document's clarity, consistency with ethical standards, and alignment with institutional policies. REB members are encouraged to offer feedback and suggest revisions as necessary. Following the discussion, the Committee will decide on one of three possible actions: favorable approval, deferment for further revision, or an unfavorable decision if the draft is deemed unsuitable or unnecessary. All decisions, along with comments and justifications, are documented in the meeting minutes.

If the SOP receives favorable action, the final version, incorporating any agreed-upon edits, is prepared and submitted for formal approval. The REB Chairperson, and where required, the Head of the Institution, will sign the approved SOP, with the date of signing marking its formal endorsement. The SOP becomes effective on the date indicated in the document, usually upon signing, unless otherwise specified. The REB Secretariat is then responsible for updating the SOP Manual and disseminating the new or revised SOP to all relevant stakeholders.

In the event of an unfavorable outcome, the reasons for rejection are clearly documented and shared with the SOP Team, which may revise the document based on the feedback and resubmit it for future review. This process ensures that SOPs are developed, reviewed, and approved through a transparent, consistent, and accountable procedure that upholds the operational and ethical standards of the REC.

Step 5 – Submission of the SOP to the institutional authority

Step 6 - Inclusion of the new or revised SOP in the SOP Manual and its dissemination: Following the formal approval and signing of a new or revised Standard Operating Procedure (SOP), the REB Member Secretary is responsible for ensuring its inclusion in the official SOP Manual and its timely dissemination. The officially approved SOP shall be stored in both electronic and hard copy formats. An electronic copy will be uploaded to the designated institutional repository or REB-managed database, making it readily accessible to all relevant stakeholders. This electronic version will be made available immediately upon approval. For hard copies, reproduction and distribution shall be completed within thirty (30) days from the date of approval by the Head of the Institution.

The REB Member Secretary serves as the official custodian of all approved SOPs. The Member Secretariat is responsible for maintaining the master file of signed hard copies and ensuring version control. In the case of amended or revised SOPs, the newly approved version will be clearly labeled with an updated version number and date of effectivity. The old version will be marked as "Superseded" and archived separately from active documents to prevent unintentional use. These superseded versions shall be securely stored and cataloged for reference or audit purposes but will no longer be in circulation.

To support dissemination, the Member Secretary will prepare and distribute copies (in either hard or soft format, depending on the recipient's role and need) to all concerned parties, including REB members, Secretariat staff, and other relevant institutional units. This process concludes with the formal filing of the approved SOP in the REB's master SOP Manual—both digital and physical versions—ensuring that the most current and authoritative procedures are easily accessible and clearly identified for use in REB operations.

Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

Standard Operating Procedures - are the step-by-step description of the different procedures done to accomplish the objective of an activity. They consist of clear, unambiguous instructions for ethical review to ensure quality and consistency.

Coding - unique number assigned to a particular SOP that reflects its serial position among the SOPs and version number to indicate the number of times it has been revised.

Format- general style or layout of the document

Date of Effectivity – date when the guidelines shall be enforced.

Forms

Request for Creation/Revision of an SOP

SOP Template

History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	*2025 May 15*	*JCMorillo*	*First draft*

References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Glossary

Active Files – are documents pertaining to protocols which are currently being assessed, managed or monitored by the REB.

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

Adjournment – Formal closure of the meeting. Motion for adjournment and record of the time are minuted.

Administrative Documents/File – documents that pertain to the operations of the REB and are not directly related to a study or protocol. Examples include the SOPs, Membership files, Agenda and minutes files, administrative issuances.

Administrative Issuance – official communications or announcements from institutional authorities

After-approval reports – are reports, e.g. progress report, protocol deviation/violation report, amendment, early termination report, final report, application for continuing review, required by the REB for submission by the researcher/investigator after the study has been approved for implementation.

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".

Alternate Members – individuals who possess the qualifications of specified regular members. They are called to attend a meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting.

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

Anonymization – process of removing the link between the research participant and the personally identifiable data, in such a way that the research participant cannot be determined nor traced.
Appeal – a request of a researcher/ investigator for a reconsideration of REB recommendation.

Appointing authority - the institutional official that has the power to designate or appoint
individuals to specific offices or roles.

Archiving- is the systematic keeping of protocol files in storage after the studies have been completed with final reports accepted, or terminated or declared inactive.

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

Ballot – voting (indicating a choice) by writing the choice on a form for the purpose. Ballots are subsequently counted to determine how the majority of members voted for decision-making.

Benefits – summary of probable positive or favorable outcomes ranging from benefit to the community (or society), indirect gains such as education, or direct therapeutic value

Business Arising from the Minutes – are matters generated from the discussions in the previous meeting that need continuing attention and require reporting.

Clarificatory Interview/meeting – is a face-to-face consultation between the REC and the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REB.

Clinical Auditor – an individual who systematically and independently examines trial related activities and documents at a particular period as a significant step in quality control.

Clinical Monitor- an individual who oversees the progress of a clinical trial.

Clinical Trial – a systematic study on pharmaceutical products in human subjects (including research participants and other volunteers in order to discover or verify the effects of and/or identify and adverse reactions to investigational products with the object of ascertaining their efficacy and safety.

Coding- a unique number assigned to a document. A protocol code indicates the year and order of receipt. The SOP code indicates its serial position among the other SOPs and its version number.

Collegial Decision – a course of action arrived at after a group deliberation where members were considered of equal authority such that the course of action is considered as a group action and is not ascribed to any one member.

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

Confidentiality – is the duty to refrain from freely disclosing private/ research information entrusted to an individual or organization.

Confidentiality of Documents – pertains to the recognition and awareness that certain documents that have been entrusted or submitted to the REB must not be freely shared or disclosed.

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

Conforme- an indication of acceptance of or agreement to an assignment or designation

Consensus – a collective agreement.

- *the process of arriving at a decision without voting but by generating the overall sentiment of a group such that deliberations continue until no more strong objections are registered.*

Continuing Review - is the decision of the REB to extend ethical clearance of a study beyond the initial period of effectivity based on an appreciation that the research is

proceeding according to the approved protocol and there is reasonable expectation of its completion.

Controlled document – pertains to the document that has been entrusted or submitted to the REB that must not be freely shared or disclosed such that it is appropriately tagged and its distribution carefully tracked, monitored and appropriately recorded. .

Database – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

Date of Effectivity – date when the guidelines shall be enforced.

Decision – the result of the deliberations of the REB in the review of a protocol or other submissions.

Draft Meeting Agenda – the order of business that includes the list of topics or items recommended for discussion in a meeting. This is endorsed to the REB Chair for his/her approval.

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.

Exempt from Review – a decision made by the REB 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.

Exemption Report – a list of protocols submitted for review that were deemed not to require the conduct of either expedited or full review. This report is presented during a regular committee meeting or as required by the institutional authority.

Expedited Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

Expedited Review Reports – is an enumeration of protocols (including titles, code number,
proponent, submission date, names of reviewers and decisions) that underwent expedited review presented during a regular REB meeting for information of the REB members and for record purposes.

Final Meeting Agenda - is the order of business that includes the list of topics or items approved for discussion in a meeting by the REB Members in a regular or special meeting.

Final Meeting Minutes – Proceedings of the meeting that have been approved by the REB members.

Final Reports/ Close Out Reports – is a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of all participants. The REB requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

Format- general style or layout of the document

Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

Honorarium- monetary payment for a specific professional service.

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

Incoming Communications – are documents which are directed to and received at the REB office.

Independent consultants - individuals who are not members of the Research Ethics Board, but whose expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but are non-voting during the deliberation.

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

Initial Submission – a set of documents consisting of the full proposal and other study-related documents that is received by the REB so that ethical review can be done.

Intellectual property –refers to intangible creations of the human mind (such as inventions, literary and artistic works, designs, and symbols, names and images used in commerce, that are considered as owned by the one who thought of it. Intellectual property includes information and intellectual goods.

Intellectual property right – the exclusive right given to persons over the use of the creations of his/her mind for a certain period of time.

Logbook – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, 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.

Major Modification – is a recommended revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data,statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.

Majority rule- is a policy based on the principle that the decision made by the greater number should be carried/accepted.

Meeting Minutes – the official narration and record of the proceedings of the assembly of REB Members, based on the agenda.

Medical Members – are individuals with academic degrees in the medical profession and a master's in the nursing profession.

Minimal Risk – term used when the probability and magnitude of harm or discomfort anticipated in a research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Minor Modification - – is a recommended revision of particular aspect/s of the study or related documents that do not impact on potential risks/harms to participants and on the integrity of the research, e.g. incomplete documentation, incomplete IC elements, unsatisfactory IC format)

More than Minimal Risk - term used when the probability and magnitude of harm or discomfort anticipated in a research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Non-affiliated Member/s – are regular members who are not in the roster of personnel or staff of the Institution. They are not employees of the institution since they do not receive regular salary or stipend from the institution.

Non-medical members- are individuals without academic degrees in the medical profession nor a master's degree in the nursing profession.

Non-Scientists – are individuals whose primary interest is not in any of the natural, physical and Social sciences and whose highest formal education is a bachelor's degree.

Operations-related Matters – are items included in the agenda that are not directly related to any protocol under review.

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

Physical Plant Division – unit within the institution that is in charge of the maintenance and use of physical facilities.

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 be submitted by the researcher to the REB for monitoring purposes.

Primary Reviewers – are members of the Research Ethics Board (usually a scientist and a non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the board. The non-scientist member shall focus on the review of the Informed Consent process and form and reflect on community values, culture and tradition in order to recommend acceptance, non-acceptance or improvement of the informed consent process and form. The primary reviewers shall present their findings and recommendations during the meeting for discussion.

Principal Investigator - the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial

Progress Report – A systematized description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form . The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the REB based on the level of risk.

Protocol – the documentation of the study proposal that includes a presentation of the rationale and significance of the study, background and review of literature, study objectives, study design and methodology, data collection, dummy tables, plan for analysis of data, ethical consideration, and dissemination plan.

Protocol database - a collection of information about protocols that is structured and organized for easy access, management, interpretation, analysis and updating. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

Protocol Deviation – non-compliance with the approved protocol that does not increase risk nor decrease benefit to participants and does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.

Protocol File/Folder – is an organized compilation of all documents (physical or electronic form) related to a study.

Protocols for Full Review – Study proposals that require an en banc ethical because they entail more than minimal risks to the participants and/or that participation generates vulnerability issues.

Protocol Index – is a chronological record of the documents in the protocol file. The protocol index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document. The index is pasted inside the cover page of the protocol file/folder for easy reference and checking.

Protocol-related Documents- consist of all other documents aside from the proposal/protocol itself that are required to be submitted for review, e.g., Informed Consent Form ,Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions.

Protocol Violation- non-compliance with the approved protocol that may result in an increased risk or decreased benefit to participants or significantly affect their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

Provisional Meeting Agenda – is the order of business that includes the list of topics or items approved for discussion in a meeting by the REB Chair.

Provisional Meeting Minutes – Proceedings of the meeting that have been noted or approved by the Presiding officer.

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

Quorum – the minimum number (i.e., majority of the members) and type of members of the REB that are required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least 5 regular members including the non-affiliated and the non-scientist members.

Real-time Recording – the process of documenting the minutes of the meeting as the meeting proceeds simultaneously.

REB Operations- the overall activities of the REB that reflect performance of its functions and responsibilities.

Regular Meeting – a periodically scheduled assembly of the REB.

Regular Members – are members constituting the research to ethics committee, who receive official appointments from the institutional authority with specific terms and responsibilities including review of research proposals and attendance of meetings.

Regulatory Authorities – refer to government agencies or institutions that have oversight or control over the conduct of research, e.g., Department of Health, Food and Drug Administration, Research
Institutions

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. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.,

Researcher- is the individual primarily responsible for the conceptualization, planning and implementation of a study.

Researcher-Initiated Studies – are research activities whose conceptualization, protocol development and implementation are done by a researcher or group of individuals who may request for external funding support.

Resubmissions- the revised study proposals that are forwarded to the REB in response to the recommendations given during the initial review.

Reviewer- a regular member of the Research Ethics Board who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee.

Risks – summary of probable negative or unfavorable outcomes ranging from inconvenience, discomfort, or physical harm based on the protocol.

Room-use Restriction – the rule that limits the use of a document within the designated premises.

Secret Ballot – is a system of casting votes (opinions or choices) such that the voters are not identified or are anonymous.

Scientists – are individuals whose formal education is at least a master's degree in a scientific discipline, e.g. biology, physics, social science, etc.

Serious Adverse Event (SAE) – is an event observed during the implementation of a study where the outcome is any of the following:

- *Death*
- *Life threatening*
- *Hospitalization (initial or prolonged)*
- *Disability or permanent damage*
- *Congenital anomaly/ birth defect*
- *Required intervention to prevent permanent impairment or damage (devices)*
- *Other serious (important medical) events*

whether or not it is related to the study intervention .

Site Visit – is an action of the REB (based on established criteria) in which an assigned team goes to the research site or office for specific monitoring purposes.

Site Visiting Team – members/staff of the REB (2-4 members) assigned by the REB Chair to formally go to the research site, meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures to ensure promotion of the rights, dignity and well-being of participants and protection of integrity of data.

Special meeting – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action.

Sponsor- an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial.

Sponsored Clinical Trials – are systematic studies on pharmaceutical products in human subjects (including research participants and other volunteers), whose conceptualization, protocol development and support for their conduct are the responsibilities of sponsors who manufactured the products, in compliance with the requirements of regulatory authorities.

Standard Operating Procedures - are the step-by-step description of the different procedures done to accomplish the objective of an activity.

Status of participants – summary of what happened to (condition of) participants recruited to the study, including those that completed the study, those that dropped out, or those withdrawn for specific reasons in accordance with the protocol.

Study Documents – include all materials (protocol, forms, certificates, research tools) pertinent to a research proposal that have to be submitted to the REB for review.

Study-related Communications – documents that refer to an exchange of information or opinions regarding a study, usually between the REB and the researcher.

Study Site - physical location of where the study is being conducted, e.g., community, institutional facility.

SUSAR – Suspected Unexpected Serious Adverse Reaction – is a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug insert.

SAE Subcommittee – a group of experts designated to analyze SAE/SUSAR reports and make the necessary recommendations to the REC. The experts may or may not be members of the REC.

Termination package refers to the entitlements of study participants in the event of discontinuance of the study, which can come in the form of access to the study intervention, treatment, or information, for purposes of adherence to the principle of fairness for all concerned.

Term of office – the specified length of time that a person serves in a particular designation /role.

Voting – the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is majority wins.

Vulnerable Groups – participants or potential participants of a research study who may not have the full capacity to protect their interests and may be relatively or absolutely incapable of deciding for themselves whether or not to participate in the research. They may also be at a higher risk of being harmed or to be taken advantage of.