SOP NO.01

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.

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

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

Coding- a unique number assigned to a protocol indicating the year and series it was received.

Consensus- a collective agreement.

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.

Confidentiality- is the duty to not freely disclose private/research information entrusted to an individual or organization.

Database- a structured/organized collection of information so that the data can easily be accessed, managed and updated.

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

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.

Expertise- a proficiency, skill or know-how possessed, by experts in a certain academic or Professional field.

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.

Independent consultants- Resource persons who are not members of the Research Ethics Committee, 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 deliberations.

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

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.

Primary Reviewers- are members of the Research Ethics Committee (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 committee. 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.

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

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

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

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

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.

SOP NO. 02

Amendment- a change in /revision of the protocol made after its approval.

Initial Review- ethical and technical review conducted on the initially-submitted study documents. It may be expedited or full.

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.

Minimal Risk- term used when the **Researcher-** is the individual primarily responsible for the conceptualization, planning and implementation of a study.

Resubmissions- revised study proposals that are submitted after the initial review.

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.

SOP NO.3

Clarificatory Interview/meeting- is a meeting or consultation of the REC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC.

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

Full Review- 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.

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.

Protocol Deviation- non-compliance with the approved protocol that does not increase risk or decrease benefit to participants or 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 Violation- non-compliance with the approved protocol that increases risk or decreases benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

Reviewer- a regular member of the Research Ethics Committee 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.

Site Visit- is an activity of the REC where an assigned team goes to the research site or office for specific monitoring purposes.

SOP NO.4

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".

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

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

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.

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

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

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 REC Chair for his/her approval.

Early Termination- refers to the decision of the researcher, principal investigator, the institution, or sponsor to end the implementation of a study before its completion.

Final Report- 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 REC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

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

Format- general style or layout of the document

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

Outgoing Communications- are documents generated within the REC office intended for individuals or offices related to the operations of the REC

Protocol- 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.

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

Protocol-related submissions- other documents that are included (required) in the submission of the protocol, e.g., Informed Consent Forms, study tools (Interview guide, survey questionnaire, FGD guide) and CVs of the proponents and certificates of training.

Quorum- presence of the majority of the REC members including the non-affiliated and the non-scientist members.

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.

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

SOP NO.6

Appeal- a request of a researcher/ investigator for a reconsideration of the REC recommendation

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.

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

SOP NO.7

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.