Adverse event – any untoward medical occurrence in a clinical investigation participant given an investigational product and which does not necessarily have a causal relationship with treatment received.

Alternate member - a member who have similar expertise as the regular member for who he/she is serving as a replacement. He/she will assume all the responsibilities of the member for whom he/she is serving as a replacement

Approved – affirmative decision of the RERB that the clinical trial and all pertinent documents have been reviewed and may be conducted in the institution within the constraints set forth by the RERB, the institution, Good Clinical Practice, and applicable regulatory requirement.

Audit – a systematic and independent examination of trial related activities and documents to determine whether all activities were conducted according to ethical standards 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.

Conflict of interest – A conflict of interest arises when member/s of the RERB hold/s interests with respect to specific applications for review that may jeopardize his/her ability to provide a free and independent evaluation of the proposal focused on the protection of human participant. Some forms of conflicts may include, but not limited to, financial, material, institutional, or social ties to the research.

Expedited review – a form of protocol review on studies that enroll participants in a low-risk study with minimal risk to study participants and minor revisions in the protocol or informed consent

Full board review – form of protocol review on high risk studies that enroll participants, including but not limited to heart failure, COPD in exacerbation, pediatric patients, special/vulnerable population, and major revisions in the protocol or informed consent

Good Clinical Practice – a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and results are accurate and credible, and that the rights, integrity, and confidentiality of trial subjects are protected.

Independent consultant – a professional/expert who is invited by the RERB to assist in reviewing protocols where RERB lacks expertise.

Investigator's Brochure– a compilation of the clinical and nonclinical data on the investigational product which is relevant to the study of the product in human participant

Lay member– member of the RERB who can either be a non-practicing medical doctor, non-medical, but may be an allied health professional, or non-scientific, or non-institutionally related

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 RERB. Generally, these reports are due annually with the RERB sending a written notification reminding the investigator of this obligation. More frequent reports may be requested at the discretion of the RERB.

Protocol– a document that describes the objectives, design, methodology, statistical considerations, and organization of a trial. This usually gives the background and rationale for the trial.

Protocol Amendment- A change to the study protocol during the planning or course of the trial. The amendment is a foreseen change to the study plan that requires formal approval by the sponsor.

Serious adverse events (SAE) or serious adverse drug reactions (SADR)
Any untoward medical occurrence that at any dose:

- Results in death
- Is organ or life threatening
- Requires in patient hospitalization
- Results in persistent or significant disability
- Results in pregnancy

Vulnerable subjects- A category of research participants that includes children, prisoners, pregnant women, handicapped or mentally disabled persons and economically or educationally disadvantaged persons who are likely inclined to coercion or undue influence