Glossary of Research Terms

Adverse Event
An unwanted experience or abnormal finding that takes place during the clinical trial and is harmful to the patient.

Blinded Study
Single blinded: when the participant does not know whether he or she is getting the study medication or getting the placebo or the standard, already-approved drug. Double-blinded: when neither the researcher nor the participant knows who is getting the placebo or the standard, already-approved drug and who is getting the study drug.

Clinical Research Coordinator/Study Coordinator
Typically, members of a research team who are responsible for recruiting, screening, and enrolling study participants, as well as ensuring adherence to Good Clinical Practice guidelines.

Clinical Trial or Study
A research project designed to test the safety and/or effectiveness of drugs, medical devices, procedures, or prevention.

Efficacy
Proof that a drug or a device improves the disease or condition. A drug passes efficacy trials if it is effective at the dose tested and effective against the illness for which it is prescribed.

Food and Drug Administration (FDA)
The U.S. government agency that enforces laws on the manufacturing, tests and use of drugs and medical devices; it approves a new drug or device to make it available to the public after the trial is completed.

Human Subject
A person who volunteers to participate in a clinical study as a recipient of the experimental treatment, a control who receives the standard treatment, or a healthy volunteer who receives no treatment.

Informed Consent Process
The process of explaining a clinical study to a potential participant so they can decide whether to be a volunteer in a study. If the person decides to participate, they sign and date a written Informed Consent Form that fully describes the study and their rights as a participant.

Institutional Review Board
An independent committee that reviews all studies involving human subjects to decide if the study should occur and ensures the rights, privacy and welfare of participants in research.

Investigator/Principal Investigator
The person who leads the research team and is in charge of the study.

Glossary of Research Terms (Continued)

Placebo
A placebo is an inactive pill, liquid or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or treatment. No sick participant receives a placebo if there is a known beneficial treatment.

Prevention Trials
Refers to trials that aim to find better ways to prevent disease in people who have never had the disease, or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals or lifestyle changes.

Protocol
A study plan on which all clinical trials are based. The plan is carefully designed to protect the health of the participants, as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study.

Randomization
A method based on chance, like flipping a coin, to determine if a participant will be in an experimental group or a control group. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial areas.

Randomized Trial
A study in which participants are randomly (that is, by chance) assigned to one of two or more treatment areas of a clinical trial.

Standard Treatment
A treatment currently in wide use and considered to be effective in the treatment of a specific disease or condition and, if a drug or device, approved by the FDA.

Treatment Trials
Trials that test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.