

Clinical Research Terminology

Adverse Event: An unfavorable and unintended medical occurrence in a subject who is administered a medicinal product that is not necessarily the cause of that occurrence. A subject may withdraw or be withdrawn from a research study if an adverse event becomes too severe.

Adverse Drug Reaction: An unfavorable and unintended medical occurrence in a subject who is administered a medicinal product that is the most probable cause of those occurrences. A subject may withdraw or be withdrawn from a research study if an adverse drug reaction becomes too severe.

Double-Blind Study: A study in which neither the subject nor the investigator knows which treatment a subject is receiving. However if medically necessary, the study pharmacist can reveal a subject's "blind".

Control Group: A group of subjects that receives no treatment, a standard treatment or a placebo.

Healthy Volunteer: A volunteer subject with no known significant health problems who participates in research to test a new drug, device, or intervention. Research with healthy volunteers is designed to develop new knowledge, not to provide direct benefit to study participants. Healthy volunteers in phase 1 trials serve as controls for patient groups in later phase trials.

Informed Consent: A process that involves: 1) giving a subject adequate information in straight-forward language regarding study-related procedures, risks and benefits in both oral and written form; providing the subject with the opportunity to consider all other options besides participation; 2) responding to the subject's questions; 3) ensuring that the subject comprehends all aspects of participation; and lastly 4) obtaining the subject's voluntary, signed consent form. If the subject is considered to be a minor or incompetent, a legal representative should sign on his/her behalf.

Institutional Review Board: An independent group of medical and non-medical members, whose responsibility is review research protocols to ensure the protection of the rights of human subjects. The IRB enforces strict rules for clinical trials, which are monitored nationwide by the Federal Drug Agency (FDA) and the National Institutes of Health (NIH).

Open-Label Study: A study in which both subject and investigator knows which treatment a subject is receiving (opposite of double-blind).

Patient Volunteer: A volunteer subject with a health problem, who participates in research to better understand, diagnose, treat or cure his/her disease/condition. Research procedures may or may not benefit the volunteer patient.

Protocol: A written document that describes the objectives, design and methods of a study.

Placebo: A harmless, inactive substance, designed to look like the active treatment. If a placebo is part of a study, you will always be informed of this fact in the consent form.

Randomization: The process of assigning trial subjects to treatment or control groups by random allocation (by chance, not choice), in order to reduce potential bias in the study results.

Single-Blind Study: A study in which only the subject is unaware of the treatment received.