Terms to Know

A glossary of terms used to talk about clinical trials.

**Adverse event**: a negative health change that occurs during treatment. It can be directly related to treatment or caused by something else.

**Control group**: the group of participants who do not receive the new test or treatment being studied in a clinical trial. The control group receives the standard care for their cancer. It is also called the control arm of a study.

**Double-blind method**: a way of conducting a clinical trial in which researchers and participants do not know which treatment the subjects are receiving during the trial. The study pharmacist knows the treatment but is not involved in evaluating participant results. The double-blind method is used to help prevent bias in clinical trial results.

**Eligibility criteria**: The requirements defined for a person to participate in a clinical trial. Inclusion criteria are the characteristics that potential clinical trial participants must have to be included in the study. Exclusion criteria are characteristics that make a patient not eligible to participate in the trial.

**Institutional Review Board (IRB)**: a group made up of doctors, scientists, advocates, and community members that is tasked with evaluation and approval of clinical trial protocols. The IRB ensures that patient safety standards as well as legal and ethical research standards are met.

**Investigational group**: the group of participants who receive the new test or treatment being studied in a clinical trial. It is also called the investigational arm, the intervention group, or the experimental group of a study.

**Placebo**: a drug or treatment without therapeutic effects, sometimes called a “sugar pill”. Placebos are typically given to the control group in a clinical trial to be compared to the investigational treatment. Placebos are very rarely used in cancer clinical trials, and only in cases when there is not an established standard of care for that cancer.

**Protocol**: a written document that describes the characteristics of a clinical trial, including participant eligibility criteria, treatment schedules and dosage, testing plans, and the outcomes that are being measured.

**Randomization**: a way of assigning clinical trial participants to study groups by chance. In a cancer clinical trial, the study groups are the investigational group, that receives the investigational treatment, and the control group, which receives the standard of care. Randomization is used to help prevent bias in clinical trial results. Random assignment of participants to investigational and control groups helps researchers know that results are due to the investigational treatment and not affected by other factors.

**Sponsor**: the organization, institution, or individual responsible for the clinical trial. They oversee and pay for the trial, and collect and analyze data.

**Standard of care (Standard treatment)**: the treatment that is accepted by medical experts as the correct treatment for a disease. It is also known as standard therapy, standard medical care, or best practice.

**Subject**: an individual participating in a clinical trial. It can refer to patient volunteers or healthy volunteer participants.