Glossary

Phrases or Terms you may want to know

TYPES OF STUDIES/TRIALS:

- **CLINICAL TRIAL:** Answers specific questions about new vaccines, new drugs, new medical devices, or new ways of using known treatments. Clinical trials, which are also called clinical investigations and clinical research studies, are used to determine whether these new drugs, and devices should be introduced to the market.
- **TREATMENT TRIALS:** Test new drugs or medical devices, new combinations of drugs, or new approaches to surgery or radiation therapy.
- **PREVENTION TRIALS:** Designed 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 vitamins, vaccines, minerals, lifestyle changes, or drugs.
- **DIAGNOSTIC TRIALS:** Designed to find better tests or procedures for detecting or diagnosing a particular disease or condition. Diagnostic trials are conducted with people who have signs or symptoms of the disease or condition being studied.
- **QUALITY OF LIFE TRIALS (or Supportive Care trials):** Explore ways to improve comfort and quality of life for individuals with a chronic illness.

TRIAL PHASES:

- **PHASE I TRIALS:** First studies to determine the metabolism and pharmacologic actions of drugs in humans, to discover side effects associated with increasing doses, and to gain early evidence of effectiveness. This phase often includes healthy subjects.
- **PHASE II TRIALS:** Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication in study participants with the disease or condition. Phase II trials are designed to determine the common short-term side effects and risks of a drug.
- **PHASE III TRIALS:** Expanded controlled and uncontrolled trials after preliminary evidence suggests that drug effectiveness has been obtained. This phase is intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide adequate basis for physician labeling.
- **PHASE IV TRIALS:** Post-marketing studies to delineate additional information about a drug's risks, benefits, and optimal uses.

DIFFERENT TERMS YOU MAY SEE THROUGHOUT THE DOCUMENTS:

- **PROTOCOL:** All clinical trials are based on this organized study plan. The plan is carefully designed to safeguard participant health, as well as answer specific research questions. A protocol describes what types of people may participate in the trial, and provides a schedule and description of procedures, a description of the study drug or device and dosing instructions, and the length of the study. While in a clinical trial, participants are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of the drug or medical device being studied.

- **RANDOMIZATION:** A method, based on chance, by which study participants are assigned to a dosing group/regimen. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms. The researchers do not know which dose, drug, or medical device is better. From what is known at the time, any one of the dosing groups/regimens chosen could provide benefit to the study participant.
- **PLACEBO:** A placebo is an inactive pill, liquid, powder, or device that has no treatment value but looks like the drug or medical device being studied. In clinical trials, experimental drugs and medical devices are often compared with placebos to assess a treatment's effectiveness.
- **CONTROL:** Having a control allows researchers to compare results from a group being administered the experimental study intervention to a group being administered either placebo or a different study intervention.
- **BLINDING: Single-Blind:** A study in which one party, the investigator or the participant, is unaware of which study intervention is being administered.
- **Double-Blind:** Neither the participating individuals nor the study staff knows which participants are receiving the experimental study intervention and which are receiving a placebo (or another study intervention). Double-blind trials are thought to produce objective results, since the expectations of the investigator and the participant about the experimental drug do not affect the outcome.
- **OPEN-LABEL TRIAL:** A clinical trial in which the investigator and participants know which study intervention is being administered.
- **HIPAA:** Under the federal Privacy Rule, also known as the Health Insurance Portability and Accountability Act (HIPAA), use or disclosure of an individual's protected health information (PHI) requires the individual's authorization, unless the use or disclosure is determined by an IRB or Privacy Board to qualify for a waiver.

ADDITIONAL RESOURCES:

FOOD AND DRUG ADMINISTRATION (FDA):
http://www.fda.gov/oc/gcp/regulations.html

HEALTH AND HUMAN SERVICES (HHS):
http://www.hhs.gov/ohrp/outreach/

GOVERNMENT LISTING OF CURRENTLY ENROLLING CLINICAL TRIALS:
http://www.clinicaltrials.gov/

CENTER FOR INFORMATION AND STUDY ON CLINICAL RESEARCH PARTICIPATION
http://www.ciscrp.org/