**GUIDE 628 – Lay Language for Informed Consent and Other Documents for Participant Use**

Since informed consent documents need to be accessible to their audience, and since the lay population is not generally well versed in technical and scientific terminology, such jargon should be explained or common terms should be substituted. Complex scientific concepts should be translated into simple concepts that the typical study participant can read and understand. Some examples of suggested lay language translations for informed consent forms are as follows:

|  |  |
| --- | --- |
| abdomen | belly, stomach |
| abdominal distention | bloating |
| absorb | take up fluids, take in |
| acid taste | sour taste |
| acidosis | condition when blood contains more acid than normal |
| acuity | clearness, keenness, esp. of vision and airways |
| acute | new, recent, sudden, urgent |
| acute cholecystitis | gall stones, which may cause upper abdominal pain and require hospitalization and surgery |
| adenopathy | swollen lymph nodes (glands) |
| adjuvant | helpful, assisting, aiding, supportive |
| adverse effect | side effect |
| aerosolized | converted to a vapor or mist to be inhaled |
| afebrile | without fever |
| agent | drug, medication |
| albumin | protein found in blood |
| allergic reaction | rash, hives, swelling, trouble breathing |
| alopecia | loss of hair |
| Alzheimer’s disease | a brain disorder characterized chiefly by an impairment in the ability to think and to remember |
| ambulate/ambulation/ ambulatory | walk, able to walk |
| analgesic | pain-relieving drug |
| anaphylaxis | serious, potentially life-threatening allergic reaction |
| anasarca | build up of fluid throughout the whole body, which occurs in severely ill people |
| anemia | low number of red blood cells, can causes tiredness and shortness of breath. May require a blood transfusion |
| anesthetic | a drug or agent used to decrease the feeling of pain, or eliminate the feeling of pain by putting you to sleep |
| angina | chest pain due to decreased oxygen getting to the heart |
| anorexia | disorder in which person will not eat; lack of appetite |
| antecubital | related to the inner side of the forearm |
| antibody | protein made in the body in response to foreign substance |
| anticonvulsant | drug used to prevent seizures |
| antiemetic | medication to prevent nausea/vomiting |
| antilipemic | a drug that lowers fat levels in the blood |
| antimicrobial | drug that kills bacteria and other germs |
| antiretroviral | drug that works against the growth of certain viruses |
| antitussive | a drug used to relieve coughing |
| aplastic anemia | a disorder caused by decreased production of red blood cells |
| arm | one part of a multiple-part study |
| arrhythmia | irregular heart beat |
| arterial thrombosis | blood clot in an artery that blocks the artery. This could be serious and life threatening. |
| arterial catheter | small tube placed in an artery |
| artery | one of the muscular blood vessels carrying blood from the heart to all parts of the body |
| arthralgia | joint pain |
| ascites | build up of fluid in the abdomen, which causes bloating and discomfort. This could require that the fluid be removed by a procedure called paracentesis. |
| aspiration | fluid entering the lungs, such as after vomiting |
| assay | lab test |
| asthenia | feeling weak and having no energy |
| asthma | lung disease associated with tightening of air passages, making breathing difficult |
| autoimmune enteritis | this is when your immune system attacks normal cells in your body, including the cells that line your digestive tract. This may result in bleeding and inflammation of the esophagus, bowel (intestines), and lower gi tract (colon), which can cause bleeding, diarrhea and perforations (holes). This could be serious or life threatening. Hospitalization and treatment with medications (steroids) may be necessary. This can become severe and may require surgical removal of parts of the intestines or colon. These surgical procedures might result in your having a stoma (hole) though which digested food passes. |
| axilla | armpit |
| basal acid output | acid produced by the resting stomach before food or medication |
| baseline | 1. Information gathered at the beginning of a study from which variations found in the study are measured. 2. A known value or quantity with which an unknown is compared when measured or assessed. 3. The initial time point in a clinical trial, just before a participant starts to receive the experimental treatment which is being tested. At this reference point, measurable values such as cd4 count are recorded. Safety and efficacy of a drug are often determined by monitoring changes from the baseline values. |
| benefit | a valued or desired outcome; an advantage |
| benign | not malignant or threatening, without serious consequences |
| bilirubinemia | high levels of bilirubin in the blood |
| bioavailability | the extent to which a drug or other substance becomes available to the body |
| biologic | treatment, or cure of diseases or injuries biopsy removal and examination of tissue |
| biopsy | surgical removal of a small bit of tissue for microscopic examination |
| blind | a randomized trial is "blind" if the participant is not told which arm of the trial he is on |
| bolus | a large amount given all at once |
| bone mass | the amount of calcium and other minerals in a given amount of bone |
| bowel perforation | hole in the digestive system |
| bradycardia | slow heartbeat |
| brain stem edema | accumulation of fluid around the brain stem, this can be life threatening |
| broad spectrum | has a broad range of effectiveness, e.g., drug suppresses infections due to many classes of bacteria rather than just one class |
| bronchospasm | breathing distress caused by narrowing of the airways |
| calorie | the energy value of food |
| carcinogenic | cancer-causing |
| cardiac | related to the heart cardiac arrest sudden, unexpected stopping of the heart. |
| cardiac effusion | collection of fluid around the heart |
| cardiac toxicity | damage to the heart |
| cardiomyopathy | heart muscle becomes damaged and the heart doesn’t pump properly |
| cardiovascular | heart and blood vessels |
| cardioversion | return to normal heartbeat by electric shock |
| case study | a research strategy that focuses on one case (an individual, a group, an organization, etc.) within its social context during one time period |
| CAT (CT) scan | a computerized x-ray examination |
| catheter | a tube for withdrawing or giving fluids |
| central line | a thin plastic tube placed through a vein in the upper chest wall or nect and advanced into a large vein near the heart |
| central nervous system (CNS) | brain and spinal cord |
| cerebral trauma | damage to the brain |
| cerebrospinal fluid (CSF) | fluid surrounding the brain and spinal cord |
| cessation | stopping |
| chemotherapy | treatment of disease, usually cancer, by chemical agents |
| chronic | continuing for a long time, ongoing |
| care cluster sample | a probability sample that is determined by randomly selecting clusters of people from a population and subsequently selecting every person in each cluster for inclusion in the sample |
| claustrophobic | fear of being enclosed in a small space |
| clinical | pertaining to medical |
| clinical trial | an experiment in patients |
| cognitive | thinking |
| cognitively impaired | having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished |
| cohort | a group of subjects initially identified as having one or more characteristics in common who are followed over time |
| coma | unconscious state |
| compassionate use | a method of providing experimental therapeutics prior to final FDA approval for use in humans |
| compensation | payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research |
| competence | a legal term to indicate a person’s capacity to act on one’s own behalf ; a person’s ability to understand information presented, to realize the consequences of acting (or not acting) on that information, and to make a choice. |
| complete response | total disappearance of disease |
| confounding factor | any factor that might serve as an alternative explanation for a study’s result; confounding factors include non-randomized samples, selection bias, and any arbitrary differences between people that are being compared. |
| congenital | present before birth |
| conjunctivitis | redness and irritation of the thin membrane that covers the eye |
| consolidation phase | treatment phase intended to make a remission permanent (follows induction phase) |
| constipation | difficulty passing stools |
| contract | an agreement |
| contraindicated | disadvantageous, perhaps dangerous; a treatment that should not be used in certain individuals or conditions due to risks. For instance, a drug may be contraindicated for pregnant women and people with high blood pressure |
| control group | in many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo |
| controlled trial | research study in which the experimental treatment or procedure is compared to a standard (control) treatment or procedure |
| contraindicated | should not be used |
| convenience sample | a non-probability sample that is determined by selecting participants that are readily accessible (convenient) to the researcher, (examples in studies of UH students might include going to an organizational meeting or hanging out outside of the Student Center and asking students exiting the lunchroom to take a survey) |
| cooperative | group association of multiple institutions to perform clinical trials |
| coronary | related to the blood vessels that supply the heart, or to the heart itself |
| correlational relationship | a relationship where two variables are associated (this can be measured in terms of strength and direction using statistical tests) but not causally related |
| cross-over design | a type of clinical trial in which each subject experiences, at different times, both the experimental and control therapy |
| culture | test for infection, or for organisms that could cause infection |
| cumulative | added together from the beginning |
| cutaneous | relating to the skin |
| debilitation | weakened condition |
| debrief | giving participants previously undisclosed information about the research project following completion of their participation in research. In studies involving deception, if the participants are not informed of the deception in the informed consent, the IRB-SBS requires a signed debrief form for each participant following completion of his/her participation in the study |
| deception | the intentional withholding of information from participants, or deception about the study’s purpose and exact nature, that is deemed necessary by the researcher in order to meet the study’s goals |
| dehydrate | lose water or body fluids |
| dermatitis | skin irritation, rash |
| dermatologic | pertaining to the skin |
| deteriorate | condition to grow worse |
| diagnostic trials | refers to trials that are are conducted to find better tests or procedures for diagnosing a particular disease or condition |
| diarrhea | frequent, loose watery stools, which can cause dehydration and may require hospitalization and treatment with intravenous fluids |
| diastolic | lower number in a blood pressure reading |
| distal | toward the end, away from the center of the body |
| distal parathesias | numbness and tingling in the hands and feet. |
| diuretic | water pill or drug that causes increase in urination |
| doppler | device using sound waves to diagnose or test |
| dose-ranging study | a clinical trial in which two or more doses of an agent (such as a drug) are tested against each other to determine which dose works best and is least harmful |
| double-blind design | an experiment in which neither the participants nor the research staff who interact with them knows the memberships of the experimental or control groups. Also known as double-masked design (see single-blind design and open design) |
| duration | length of time involved |
| dysplasia | abnormal cells |
| edema | build up of fluid in the body causing swelling. |
| efficacy | effectiveness |
| electrocardiogram (ECG or EKG) | electrical tracing of the heartbeat |
| electrodes | pieces of metal attached to wires |
| electroencephalogram (EEG) | a recording of the brain’s electrical activity |
| electrolyte changes | changes in electrolytes (body salts), which usually do not cause any symptoms but that can sometimes cause fatigue, muscle weakness, cramping, rigidity, irregular heartbeat, or seizures |
| elevated lipase, amylase | may indicate inflammation of the pancreas, which could result in abdominal pain and discomfort and could require hospitalization and intravenous treatment elevated uric acid levels may worsen kidney function; cause joint pain (gout) and kidney stones |
| eligibility criteria | summary criteria for participant selection; includes inclusion and exclusion criteria emancipated minor a legal status given to those individuals who have not yet attained the age of legal competency as defined by state law, but who are entitled to adult treatment because of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation |
| emesis | vomiting, throwing up |
| empirical | based on experimental data, not on a theory. |
| encephalopathy | disease of the brain that severely alters thinking. |
| endoscopic examination | examination of an internal part of the body with a lighted tube |
| endpoint | overall outcome that the protocol is designed to evaluate |
| enteral | by way of the intestines |
| enzyme | a chemical in the blood that causes chemical changes |
| epidemiology | The branch of medical science that deals with the study of incidence and distribution and control of a disease in a population. |
| epidural | outside the spinal cord |
| epistaxis | bloody nose |
| equitable | fair or just; used in the context of selection of participants to indicate that the benefits and burdens of research are fairly distributed |
| erythema | redness of the skin |
| esophagus | Swallowing tube between throat and stomach |
| ethnographic research | ethnography is the study of people and their cultures |
| evaluated | assessed, examined for a medical condition |
| excrete | discharge, pass |
| expanded access | refers to any of the FDA procedures, such as compassionate use, parallel track, and treatment IND that distribute experimental drugs to participants who are failing on currently available treatments for their condition and also are unable to participate in ongoing clinical trials |
| experimental drug | a drug that is not FDA licensed for use in humans, or as a treatment for a particular condition |
| experimental group | the group in an experimental design study that receives treatment in the form, or in various forms, of the independent variable |
| external | outside the body |
| extravasate | to leak outside of a planned area, such as out of a blood vessel |
| failed therapy | subjects do not “fail therapies” but rather therapies fail to help subjects |
| fatigue | feeling tired |
| febrile | feverish |
| fetus | unborn baby |
| fever | abnormally high body temperature |
| fibrillation | irregular beat of the heart or other muscle fibrosis scars fibrous having many fibers, such as scar tissue |
| field research | behavioral, social, or anthropological research involving the study of people or groups in their own environment and without manipulation for research purposes |
| flourescein | a florescent dye that can be injected into an arm vein to help examination of the blood vessels inside the eye |
| fluoroscope | x-ray machine |
| flushing | warmth and reddening of the skin |
| fungus | form of infection |
| gait | walk |
| gastrointestinal | stomach and intestines |
| general anesthesia | pain prevention by giving drugs to cause loss of consciousness, as during surgery |
| generalizability | the ability to apply the results of a specific study to groups or situations beyond those actually studied |
| genetics\* | the study of heredity genomics, the study of genes and their functions, and related techniques |
| genomics\* | The study of genes and their functions, and related techniques |
| genetics v. genomics  \*(Based on W.H.O. definitions) | The main difference between genomics and genetics is that genetics scrutinizes the functioning and composition of the single gene, whereas genomics addresses all genes and their interrelationships in order to identify their combined influence on the growth and development of the organism (Based on W.H.O. definitions) |
| genetic screening | tests to identify persons who have an inherited predisposition to a certain phenotype or who are at risk of producing offspring with inherited diseases or disorders |
| genotype | the genetic constitution of an individual |
| gestational | pertaining to pregnancy |
| guardian | an individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care |
| headache | pain in the head |
| heart palpitations | heart beats that are fast and hard |
| hematocrit | amount of red blood cells in the blood |
| hematoma | blood clot; a bruise, a black-and-blue mark or lump caused by the escape of blood into the tissues |
| hematuria | blood in urine |
| hemodynamic measuring | measuring of blood flow |
| hemolysis | breakdown in red blood cells |
| hemolytic uremic syndrome | red blood cells begin to dissolve, which leave wastes in the blood and the kidneys are unable to get rid of excess fluid and wastes |
| hemoptysis | vomiting blood hemorrhage loss of blood (heavy bleeding) |
| hemorrhagic cystitis | inflammation of the bladder with severe bleeding |
| heparin lock | needle placed in the arm with blood thinner to keep the blood from clotting |
| hepatitis | liver inflammation |
| hepatoma | cancer or tumor of the liver |
| heritable disease | disease that can be transmitted to one’s offspring, resulting in damage to future children |
| high thyroid function | may cause fatigue, weight loss, rapid heartbeat, sweating, trouble with heat, nervousness |
| histopathologic | pertaining to the disease status of body tissues or cells |
| hives | an itchy, bumpy skin rash |
| holter monitor | a portable machine for recording heart beats |
| hormone | a chemical in the body |
| human subjects | Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information. |
| hypercalcemia | high levels of calcium in the blood |
| hyperglycemia | high blood sugar |
| hyperkalemia | high levels of potassium in the blood, which can cause the heart to stop beating |
| hyperkeratosis | thickening of the skin, nails |
| hypernatremia | high blood sodium level |
| hyperpigmentation | darkening of the skin |
| hyperpyrexia | high body temperature, a fever |
| hypertension | high blood pressure |
| hyperuricemia | excess amount of uric acid in the blood, gout, which can cause pain in the joints |
| hypoglycemia | low blood sugar |
| hypokalemia | decreased levels of potassium in the blood, which can cause irregular heart beat |
| hypomagnesemia | low magnesium, which may result in muscle cramps, weakness, tremors or irregular heartbeat |
| hyponatremia | decreased levels of sodium in the blood, which can cause confusion, seizures, fatigue and low levels of consciousness |
| hypophosphatemia | low phosphate, which may result in muscle weakness, bone pain, confusion and muscle breakdown |
| hypopigmentation / vitiligo | patches of the skin turn lighter than the surrounding skin |
| hypotensive | low blood pressure |
| hypothesis | a supposition or assumption advanced as a basis for reasoning or argument, or as a guide to experimental investigation |
| hypothesis | a testable statement of how two or more variables are expected to be related to one another |
| hypoxemia | a decrease of oxygen in the blood |
| hypoxia | a decrease of oxygen reaching body tissues |
| hysterectomy | surgical removal of the uterus, ovaries (female sex glands), or both uterus and ovaries |
| iatrogenic | caused by a physician or by treatment |
| idiopathic | of unknown cause |
| immunity | defense against, protection from |
| immunization | administration of a substance to prevent disease |
| immunoglobin | a protein that makes antibodies |
| immunological effects | effect on the immune system |
| immunosuppressive | drug which works against the body's immune (protective) response, often used in transplantation and diseases caused by immune system malfunction |
| immunotherapy | giving of drugs to help the body's immune (protective) system; usually used to destroy cancer cells |
| incapacity | refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice |
| inclusion/exclusion criteria | the medical or social standards determining whether a person may or may not be allowed to enter a clinical trial |
| incompetence | used as a legal term to indicate the inability to manage one’s own affairs |
| induction | start |
| induration | hardening |
| indwelling | remaining in a given location, such as a catheter; an indwelling catheter is a thin, flexible plastic tube that remains in a vein or artery for hours or days |
| infarct | death of tissue due to lack of blood supply |
| infectious disease | disease that is transmitted from one person to the next |
| inflammation | swollen, red, and painful |
| informed consent | the process of learning the key facts about a clinical trial before deciding whether or not to participate |
| infusion | slow injection of a substance into the body, usually into the blood by means of a catheter |
| ingestion | eating; taking by mouth |
| insomnia | inability to sleep |
| institutionalized | confined, either voluntarily or involuntarily (e.g., a hospital, prison, or nursing home) |
| interferon | drug which acts against viruses; antiviral agent |
| intermittent | occurring (regularly or irregularly) between two time points; repeatedly stopping, then starting again |
| interstitial pneumonitis, pneumonitis | inflammation of the lungs, which can cause shortness of breath and difficulty breathing |
| intervention | includes both physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes |
| intracatheter | small tube in a vein |
| intramuscular | into the muscle; within the muscle |
| intraperitoneal | into the abdominal cavity |
| intrathecal | into the spinal fluid |
| intravenous (IV) | through the vein |
| intravesical | in the bladder |
| intubate | the placement of a tube into the airway |
| invasive procedure | puncturing, opening, or cutting the skin |
| investigational method | a treatment method which has not been proven to be beneficial or has not been accepted as standard care |
| investigator | the individual(s) designated to have the appropriate level of authority and responsibility to direct the research project and/or activity |
| irradiation | x-ray |
| ischemia | decreased oxygen in a tissue (usually because of decreased blood flow) |
| jaundice | yellowing of the skin |
| laparotomy | Surgical procedure in which an incision is made in the abdominal wall to enable a doctor to look at the organs inside. |
| Legally Authorized Representative (LAR) | a person authorized either by statute or by court appointment to make decisions on behalf of another person |
| lesion | wound or injury; a diseased patch of skin |
| lethargy | sleepiness, tiredness |
| leukopenia | low white blood cell count |
| lipid | fat |
| local anesthesia | creation of insensitivity to pain in a small, local area of the body, usually by injection of numbing drugs |
| localized | restricted to one area, limited to one area |
| longitudinal study | a study in which data are collected from the same sample at least two different times |
| low blood sugar / hypoglycemia | abnormal decrease in sugar in the blood, which can cause weakness, fatigue, and if severe, can cause loss of consciousness |
| low thyroid function | may cause fatigue, weight gain, fluid retention, feeling cold, decreased cognitive function |
| low white cell count | increased risk of infection |
| lumbar puncture | spinal tap |
| lumen | the cavity of an organ or tube (e.g., blood vessel) |
| lymphangiography | an x-ray of the lymph nodes or tissues after injecting dye into lymph vessels (e.g., in feet) |
| lymphocyte | a type of white blood cell important in immunity (protection) against infection |
| lymphoma | a cancer of the lymph nodes (or tissues) |
| malaise | a vague feeling of bodily discomfort, feeling badly |
| malfunction | condition in which something is not functioning properly |
| malignancy | cancer or other progressively enlarging and spreading tumor, usually fatal if not successfully treated |
| manometer | instrument for measuring pressure |
| magnetic resonance imaging (MRI) | study of body structure by a magnetic field and radio waves |
| mature minor | someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (e.g. consenting to medical care) |
| medullablastoma | a type of brain tumor |
| megaloblastosis | change in red blood cells |
| metabolic acidosis | the body becomes more acid |
| metabolism | chemical changes which provide energy |
| metabolize | process of breaking down substances in the cells to obtain energy |
| metastasis | spread of cancer cells from one part of the body to another |
| metronidazole | drug used to treat infections caused by parasites (invading organisms that take up living in the body) or other causes of anaerobic infection (not requiring oxygen to survive) mi myocardial infarction, heart attack |
| minimal | slight |
| minimal risk | a risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests |
| moderate risk | a risk is moderate when it includes non-public behavior or data and/or allows for connection of the response to the individual’s identity |
| monitor | check on; keep track of; watch carefully |
| monitoring | the collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and participant protections |
| morbidity | undesired result or complication |
| mortality | death |
| motility | the ability to move |
| mucosa, mucous membrane | moist lining of digestive, respiratory, reproductive, and urinary tracts |
| mucositis/stomatitis | sores in the mouth and esophagus, which may be painful and cause difficulty swallowing |
| myalgia | muscle aches |
| myocardial | pertaining to the heart muscle |
| myocardial infarction (MI) | heart attack |
| nasogastric tube | tube placed in the nose, reaching to the stomach |
| nausea | feeling sick to the stomach |
| necrosis | death of tissue |
| neoplasia/neoplasm | tumor, may be benign or malignant |
| neuroblastoma | a cancer of nerve tissue |
| neurologic deficits | a neurologic deficit is a decrease in the function of the brain, spinal cord, muscles, and/or nerves |
| neurological | pertaining to the nervous system |
| neuropathy | damage to the nerves which can cause numbness, pain, and weakness |
| neurotransmitter | chemical messenger in the nervous system |
| neutropenia | condition in which the number of white bloods cells called neutrophils is abnormally low |
| noninvasive | not breaking, cutting, or entering the skin |
| nosocomial | acquired in the hospital |
| null hypothesis | the proposition, to be tested statistically, that the experimental intervention has “no effect,” meaning that the treatment and control groups will not differ as a result of the intervention |
| occlusion | closing; blockage; obstruction |
| off-label use | a drug prescribed for conditions other than those approved by the fda |
| oncology | the study of tumors or cancer |
| open design | an experimental design in which both the investigator(s) and the participants know the treatment group(s) to which participants are assigned |
| open-ended questions | survey questions that allow respondents to answer in their own words |
| open-label trial | a clinical trial in which doctors and participants know which drug or vaccine is being administered |
| ophthalmic | pertaining to the eye |
| opportunistic infections | an infection caused by an organism that usually does not cause illness, but causes disease when a person’s immune response (resistance) to infection is impaired |
| oral administration | by mouth |
| orphan drugs | an FDA category that refers to medications used to treat diseases and conditions that occur rarely |
| orthopedic | pertaining to the bones |
| ostealgia | bone pain |
| osteopetrosis | rare bone disorder characterized by dense bone |
| osteoporosis | softening of the bones |
| ovaries | female sex glands |
| palpitation | rapid heart beat parameter measure |
| pancreatitis / inflammation of the pancreas | inflammation of the pancreas causing pain in the upper abdomen |
| pancytopenia | abnormal decrease in the levels of all type of blood cells |
| parenteral | given by injection |
| participant | individuals whose physiological or behavioral characteristics and responses are the object of study in a research project |
| patency | condition of being open |
| paternalism | making decisions for others against or apart from their wishes with the intent of doing them good |
| pathogenesis | development of a disease or unhealthy condition |
| peer review | review of a clinical trial by experts chosen by the study sponsor |
| percutaneous | through the skin |
| perfusate | washing solution |
| peripheral | not central |
| peripheral blood | vein blood |
| peritoneal cavity | abdominal cavity |
| PET scan (positron emission tomography) | a technique that “labels” active areas of the brain; it requires the injection of small amounts of radioactive tracers |
| pharmacokinetics | the study of the way the body absorbs, distributes, and gets rid of a drug |
| pharmacology of a drug | how the body handles this drug |
| phenotype | the physical manifestation of a gene function |
| phlebitis | irritation or inflammation of the vein |
| placebo | an inactive substance; a pill/liquid that contains no medicine a physical or emotional change |
| placebo effect | occurring after a substance is taken or administered, that is not the result of any special property of the substance |
| placenta | afterbirth |
| plasma | fluid found in the blood |
| platelet | part of blood that causes clots |
| pleural effusion | collection of fluid around the lungs in the chest cavity, which can cause shortness of breath and may require treatment |
| pneumothorax | air inside the chest wall compressing the lung |
| population | the entire group (or set or type) of people from which a researcher samples, and to which she or he would ideally like to generalize |
| potential | possible |
| potentiate | increase or multiply the effect of a drug or toxin (poison) by giving another drug or toxin at the same time (sometimes an unintentional result) |
| potentiator | an agent that helps another agent work better |
| preclinical | refers to the testing of experimental drugs in the test tube or in animals - the testing that occurs before trials in humans may be carried out |
| prenatal | before birth |
| prevention trials | refers to trials to find better ways to prevent disease in people who have never had the disease or to prevent a disease from returning |
| privacy | a person’s capacity to control the extent, timing, and circumstances of shared oneself (physically, behaviorally, or intellectually) with others |
| private information | includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public |
| PRN | as needed |
| probability sample | a subset of the population chosen in such a way that every member of the population has a known (nonzero) chance of being selected into the sample |
| prognosis | outlook, probable outcomes |
| prone | lying on the stomach |
| prophylaxis | use of drugs to prevent disease |
| prospective studies | studies designed to observe outcomes or events that occur after the group of participants has been identified. prospective studies do not have to involve manipulation or intervention but may be purely observational or involve only the collection of data instead. |
| prosthesis | artificial part, most often limbs, such as arms or legs |
| protected health information | name, address, elements of dates related to an individual (e.g., birthdate), email address, numbers; telephone, fax, social security, medical record, health beneficiary/health insurance, certificate or license numbers, vehicle, account numbers, characteristics, or codes (e.g., global positioning system (gps) readings), web urls, internet protocol (io) addresses, biometric identifiers (e.g. voice, fingerprints), full face photographs or comparable images |
| proteinuria | excess protein in the urine |
| protocol | a study plan on which all clinical trials are based |
| proximal | closer to the center of the body, away from the end |
| pruritis | itchy skin |
| psychosis | nervous breakdown |
| pulmonary | pertaining to the lungs |
| pulmonary embolism | a blood clot that causes a sudden blockage in a lung artery, usually due to a blood clot that traveled to the lung from the leg |
| pulmonary fibrosis | tissue in the lungs becomes stiff making breathing difficult, resulting in shortness of breath, and if severe, can cause heart failure |
| pulmonary hypertension | abnormally high blood pressure in the blood vessels in the lungs, which makes it harder to pump blood into the lungs |
| quasi-experiment | an experimental design that is missing one or more aspects of the (classic) controlled experiment. |
| radiation therapy | x-ray or cobalt treatment |
| random | by chance (like the flip of a coin) |
| randomization | a method based on chance by which study participants are assigned to a treatment group |
| Raynaud’s Syndrome | an autoimmune disorder causing blood vessels to spasm when exposed to cold |
| receptors | molecules on or in cells that interact with hormones, neurotransmitters, drugs, etc. |
| recombinant | formation of new combinations of genes |
| reconstitution | putting back together the original parts or elements |
| recruiting | the period during which a trial is attempting to identify and enroll participants |
| recruitment status | indicates the current stage of a trial |
| recur | happen again |
| refractory | not responding to treatment |
| regeneration | re-growth of a structure or of lost tissue |
| regimen | pattern of giving treatment |
| relapse | the return of a disease |
| reliability | the degree to which a measure yields consistent results |
| remission | disappearance of evidence of cancer or other disease |
| remuneration | payment for participation in research; this is different from compensation, which typically refers to payment for research-related injuries |
| renal | pertaining to the kidneys |
| replicable | possible to duplicate |
| representative sample | a sample in which the participants closely match the characteristics of the population, and thus, all segments of the population are represented in the sample |
| research | a systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge |
| resect | remove or cut out surgically |
| respiratory failure | difficulty breathing with low levels of oxygen in the blood, which could be serious and life threatening and require you to have a tube inserted into your windpipe that is hooked up to a machine to help you breathe |
| respondents | research participants, who fill out a survey, are interviewed, participate in an experiment, are observed in a naturalistic setting, or who are otherwise studied |
| retrospective study | a study looking back over past experience |
| rhabdomyolysis | rhabdomyolysis is a breakdown of muscle fibers |
| rigors | chills and shivering |
| saline | salt water solution |
| sample | a subset of a given population used for research purposes |
| sarcoma | a type of cancer |
| screening | examination, test |
| secretion | release |
| sedative | a drug to calm or make less anxious |
| seizures | convulsions |
| seminoma | a type of testicular cancer (found in the male sex glands) |
| sepsis | infection in the bloodstream |
| sequentially | in a row, in order |
| serotonin | one of the chemicals that act as messengers in the nervous system |
| side effects | any undesired actions or effects of a drug or treatment |
| simultaneous | at the same time |
| single-blind design | typically, a study design in which the investigator, but not the participant, knows the identity of the treatment assignment. occasionally the participant, but not the investigator, knows the assignment. also known as single-masked design |
| snowball sample | a non-probability sample that is created by using members of the group of interest to identify other members of the group (for example, asking a participant at the end of an interview for suggestions about who else to interview) |
| social experimentation | systematic manipulation of, or experimentation in, social or economic systems; used in planning public policy |
| somnolence | sleepiness |
| specimen | a sample, as of human tissue, blood or urine, used for diagnostic or pathological analyses |
| spirometer | an instrument to measure the amount of air taken into and exhaled from the lungs |
| staging | an evaluation of the extent of the disease |
| standard of care | a treatment plan that the majority of the medical community would accept as appropriate |
| standard treatment | a treatment currently in wide use and approved by the FDA, considered to be effective in the treatment of a specific disease or condition |
| statistical significance | the probability that an event or difference occurred by chance alone. In clinical trials, the level of statistical significance depends on the number of participants studied and the observations made, as well as the magnitude of differences observed |
| stenosis | narrowing of a duct, tube, or one of the blood vessels in the heart |
| Stevens-Johnson syndrome | skin condition that causes painful blisters and sores of the skin and mucous membranes, especially in the mouth |
| stimuli | something which causes a change |
| stomatitis | mouth sores, inflammation of the mouth |
| stratify | arrange in groups for analysis of results (e.g., stratify by age, sex, etc.) |
| structured interview | a data collection method in which an interviewer reads a standardized interview schedule to the respondent and records the answers |
| study endpoint | a primary or secondary outcome used to judge the effectiveness of a treatment |
| stupor | stunned state in which it is difficult to get a response or the attention of the subject |
| subclavian | under the collarbone |
| subcutaneous | under the skin |
| supine | lying on the back |
| supine position | lying on the back |
| supplement | add |
| supportive care | general medical care aimed at symptoms, not intended to improve or cure underlying disease |
| survey | a study in which the same data are collected from all members of the sample using a highly structured questionnaire and analyzed using statistical tests |
| syndrome | a condition characterized by a set of symptoms |
| systolic | top number in blood pressure; pressure during active contraction of the heart |
| T-lymphocytes | type of white blood cells |
| tachycardia | fast heart rate |
| teratogenic | capable of causing malformations in a fetus (developing baby still inside the mother’s body) |
| testes/testicles | male sex glands |
| theory | a general explanation about a specific behavior or set of events that is based on known principles and serves to organize related events in a meaningful way |
| therapy | treatment intended and expected to alleviate a disease or disorder |
| thrombocytopenia | Low number of platelets, which may cause bleeding and bruising. May require a blood transfusion. Bleeding may be serious or life threatening. |
| thrombosis | clotting |
| thrombus | blood clot |
| tinnitus | ringing in the ears |
| titration | a method for deciding on the strength of a drug or solution; gradually increasing the dose |
| topical | on the surface |
| topical anesthetic | applied to a certain area of the skin and reducing pain only in the area to which applied |
| toxicity | side effects or undesirable effects of a drug or treatment |
| transdermal | through the skin |
| transiently | temporarily |
| trauma | injury; wound |
| treatment trials | refers to trials which test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy |
| triglyceride level | level of one of the types of fat in the blood |
| ultrasound | examination using sound waves |
| Unanticipated Problem | an unanticipated problem involving risk to human participants or others, is one that (1) was unforeseen at the time of its occurrence, and (2) indicates that participants or others are at an increased risk of harm uptake absorbing and taking in of a substance by living tissue |
| urticaria | hives |
| validity | the degree to which a measure assesses what we think it is assessing |
| valvuloplasty | plastic repair of a valve, especially a heart valve |
| variable | any characteristic or trait that can vary from one person to another (race, sex, academic major) or for one person over time (age, political beliefs) |
| varices | enlarged veins |
| vasospasm | narrowing of the blood vessels |
| vector | a carrier that can transmit disease-causing microorganisms (germs and viruses) |
| venipuncture | needle stick, blood draw, entering the skin with a needle |
| vertical transmission | spread of disease |
| visual disturbances | inability to see properly |
| void | urinate |
| voluntary | free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity |
| ward | persons who are wards of the state or any other agency, institution, or entity |