## Guidance – Consent Form Lay Language

| 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  |
| a auto ab ala austitia | gall stones, which may cause upper abdominal pain and require                  |
| acute cholecystitis    | hospitalization and surgery  |
| adenopathy             | swollen lymph nodes (glands)   |
| adjuvant               | helpful, assisting, aiding, supportive   |
| agent                  | drug, medication   |
| albumin                | protein found in blood   |
| allergic reaction      | rash, hives, swelling, trouble breathing                                       |
| alopecia               | loss of hair   |
| ambulate/ambulation/   | 11 11 . 11   |
| ambulatory             | walk, able to walk   |
| analgesic              | pain-relieving drug  |
| anaphylaxis            | serious, potentially life-threatening allergic reaction                        |
|                        | build up of fluid throughout the whole body, which occurs in severely ill      |
| anasarca               | people   |
|                        | low number of red blood cells, can causes tiredness and shortness of           |
| anemia                 | breath. May require a blood transfusion  |
|                        | a drug or agent used to decrease the feeling of pain, or eliminate the         |
| anesthetic             | 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                   |
| arrhythmia             | irregular heart beat   |
|                        | blood clot in an artery that blocks the artery. This could be serious and life |
| arterial thrombosis    | threatening  |
| arterial catheter      | small tube placed in an artery   |
| 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 dis ease associated with tightening of air passages, making breathing difficult  |
|---------------------------------|---|
| autoimmune enteritis            | this is when your immune system attacks normal cells in your body,<br>including the cells that line your digestive tract. This may result in bleeding<br>and inflammation of the esophagus, bowel (intestines), and lower gi tract<br>(colon), which can cause bleeding, diarrhea and perforations (holes). This<br>could be serious or life threatening. Hospitalization and treatment with<br>medications (steroids) may be necessary. This can become severe and may<br>require surgical removal of parts of the intestines or colon. These surgical<br>procedures might result in your having a stoma (hole) though which digested<br>food passes |
| axilla                          | armpit  |
| baseline                        | 1. Information gathered at the beginning of a study from which variations<br>found in the study are measured. 2. A known value or quantity with which an<br>unknown is compared when measured or assessed. 3. The initial time point in<br>a clinical trial, just before a participant starts to receive the experimental<br>treatment which is being tested. At this reference point, measurable values<br>such as cd4 count are recorded. Safety and efficacy of a drug are often<br>determined by monitoring changes from the baseline values.   |
| benefit                         | a valued or desired outcome; an advantage   |
| benign                          | not malignant, 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<br>body  |
| 1 · 1 ·                         | any therapeutic serum, toxin, anti-toxin, or analogous microbial product  |
| biologic                        | applicable to the prevention, treatment, or cure of diseases or injuries  |
| biopsy                          | removal and examination of tissue<br>a randomized trial is "blind" if the participant is not told which arm of the trial  |
| blind                           | he is on  |
| bolus                           |   |
|                                 | a large amount given all at once<br>the amount of calcium and other minerals in a given amount of bone  |
| bone mass<br>bowel perforation  |   |
| bradycardia                     | perforation of the digestive system<br>slow heartbeat   |
| brain stem edema                | accumulation of fluid around the brain stem, this can be life threatening   |
| bronchospasm                    | breathing distress caused by narrowing of the airways   |
| 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  |
|                                 | a research strategy that focuses on one case (an individual, a group, an  |
| case study                      | organization, etc.) within its social context during one time period  |
| case study<br>catheter          | a tube for withdrawing or giving fluids   |
|                                 |   |
| central nervous system<br>(CNS) | brain and spinal cord   |
| cerebral trauma                 | brain and spinal cord<br>damage to the brain  |
| cerebrai trauma                 | luamage to the Dram   |

| cessation            | stopping  |
|----------------------|---|
| chemotherapy         | treatment of disease, usually cancer, by chemical agents                        |
| chronic              |   |
|                      | continuing for a long time, ongoing   |
| clinical             | pertaining to medical care  |
| cluster sample       | a probability sample that is determined by randomly selecting clusters of       |
| 1                    | people from a population and subsequently selecting every person in each        |
|                      | cluster for inclusion in the sample   |
| a anitivaly impaired | having either a psychiatric disorder (e.g., psychosis, neurosis, personality    |
| cognitively impaired | 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                 |
|                      | a group of subjects initially identified as having one or more characteristics  |
| cohort               | in common who are followed over time  |
| coma                 | unconscious state   |
|                      | a method of providing experimental therapeutics prior to final FDA approval     |
| compassionate use    | for use in humans   |
|                      | payment or medical care provided to subjects injured in research; does not      |
| compensation         | refer to payment (remuneration) for participation in research                   |
|                      | a legal term to indicate a person's capacity to act on one's own behalf; a      |
| competence           | 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; |
| 0                    | 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                 |
|                      | treatment phase intended to make a remission permanent (follows                 |
| consolidation phase  | induction phase)  |
| consolidation phase  |   |
| constipation         | difficulty passing stools   |
| contract             | an agreement  |
| contraindicated      |   |
| contraintercated     | 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    |
| 01                   | drug or treatment, while the control group is given either a standard           |
|                      | treatment for the illness or a placebo  |
|                      | research study in which the experimental treatment or procedure is              |
| controlled trial     | compared to a standard (control) treatment or procedure                         |
| · · · · ·            | a non-probability sample that is determined by selecting participants that      |
| convenience sample   | are readily accessible (convenient) to the researcher, (examples in studies of  |
|                      | Stanford students might include going to an organizational meeting or hanging   |
|                      | out outside of rastall 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      |
|                      | a relationship where two variables are associated (this can be measured in      |
| correlational        | terms of strength and direction using statistical tests) but not causally       |
| relationship         | related   |
| L                    |   |

| 1 .                       | a type of clinical trial in which each subject experiences, at different times,  |
|---------------------------|--|
| cross-over design         | 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  |
| debilei                   | 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  |
| 1 1                       | refers to trials that are are conducted to find better tests or procedures for   |
| diagnostic trials         | diagnosing a particular disease or condition   |
| 111                       | frequent, loose watery stools, which can cause dehydration and may   |
| diarrhea                  | require hospitalization and treatment with intravenous fluids  |
| diastolic<br>distal       | lower number in a blood pressure reading   |
|                           | 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<br>a clinical trial in which two or more doses of an agent (such as a drug) are |
| dose-ranging study        | tested against each other to determine which dose works best and is least  |
|                           | 0  |
|                           | harmful<br>an experiment in which neither the participants nor the research staff who  |
| double-blind design       | interact with them knows the memberships of the experimental or control  |
| 8                         | groups. Also known as double-masked design (see single-blind design and  |
|                           |  |
| duration                  | open design)<br>length of time involved  |
| dysplasia                 | abnormal cells   |
| echocardiogram            | using soundwaves for examination of the heart  |
| edema                     | build up of fluid in the body causing swelling.  |
| efficacy                  | effectiveness  |
| electrocardiogram         | electrical tracing of the heartbeat (ECG or EKG)   |
|                           | changes in electrolytes (body salts), which usually do not cause any   |
| electrolyte changes       | symptoms but that can sometimes cause fatigue, muscle weakness,  |
|                           | cramping, rigidity, irregular heart beat, or seizures  |
|                           | may indicate inflammation of the pancreas, which could result in abdominal   |
| elevated lipase, amylase  | 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  |
|                           | summary criteria for participant selection; includes inclusion and exclusion   |
| eligibility criteria      | criteria   |
| Sublinity efficina        | Interna  |

|                       | a legal status given to those individuals who have not yet attained the age     |
|-----------------------|---|
| emancipated minor     | 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 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                            |
|                       | The branch of medical science that deals with the study of incidence and        |
| epidemiology          | distribution and control of a disease in a population.                          |
| epidural              | outside the spinal cord   |
| epistaxis             | bloody nose   |
|                       | fair or just; used in the context of selection of participants to indicate that |
| equitable             | the benefits and burdens of research are fairly distributed                     |
| erythema              | redness of the skin   |
| ethnographic research | ethnography is the study of people and their cultures                           |
| evaluated, assessed   | examined for a medical condition  |
| excrete               | discharge, pass   |
|                       | refers to any of the FDA procedures, such as compassionate use, parallel        |
| expanded access       | 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                            |
|                       | a drug that is not FDA licensed for use in humans, or as a treatment for a      |
| experimental drug     | particular condition  |
|                       | the group in an experimental design study that receives treatment in the        |
| experimental group    | 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                |
| fatigue               | feeling tired   |
| 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   |
|                       | behavioral, social, or anthropological research involving the study of people   |
| field research        | or groups in their own environment and without manipulation for research        |
|                       |   |
| fluoroscope           | purposes<br>x-ray machine   |
|                       | form of infection   |
| fungus                |   |
| gait                  | walk  |
| gastrointestinal      | stomach and intestines  |
|                       | pain prevention by giving drugs to cause loss of consciousness, as during       |
| general anesthesia    | surgery   |
| 1. 1                  | the ability to apply the results of a specific study to groups or situations    |
| generalizability      | beyond those actually studied   |

|                       | tests to identify persons who have an inherited predisposition to a certain    |
|-----------------------|--|
| genetic screening     | phenotype or who are at risk of producing offspring with inherited diseases or |
|                       | disorders  |
| anotuno               | the genetic constitution of an individual                                      |
| genotype              |  |
| gestational           | pertaining to pregnancy  |
| anandian              | an individual who is authorized under applicable state or local law to give    |
| guardian<br>headache  | permission on behalf of a child to general medical care                        |
|                       | 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   |
| hematuria             | blood in urine   |
| hemodynamic           |  |
| measuring             | measuring of blood flow  |
| hemolysis             | breakdown in red blood cells   |
| hemolytic uremic      | red blood cells begin to dissolve, which leave wastes in the blood and the     |
| syndrome              | 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    |
| hepatoma              | cancer or tumor of the liver   |
|                       | disease that can be transmitted to one's offspring, resulting in damage to     |
| heritable disease     | future children  |
|                       | may cause fatigue, weight loss, rapid heartbeat, sweating, trouble with        |
| high thyroid function | heat, nervousness  |
| histopathologic       | pertaining to the disease status of body tissues or cells                      |
| holter monitor        | a portable machine for recording heart beats                                   |
| hormone               | a chemical in the body   |
|                       | Individuals whose physiologic or behavioral characteristics and responses      |
| human subjects        | 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  |
|                       | high levels of potassium in the blood, which can cause the heart to stop       |
| hyperkalemia          | 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  |
|                       | excess amount of uric acid in the blood, gout, which can cause pain in the     |
| hyperuricemia         | joints   |
|                       | decreased levels of potassium in the blood, which can cause irregular heart    |
| hypokalemia           | beat   |
|                       | low magnesium, which may result in muscle cramps, weakness, tremors or         |
| hypomagnesemia        | irregular heartbeat  |
|                       | decreased levels of sodium in the blood, which can cause confusion,            |
| hyponatremia          | seizures, fatigue and low levels of consciousness                              |

|  | low phosphate, which may result in muscle weakness, bone pain, confusion     |
|--|--|
| hypophosphatomia                       | and muscle breakdown   |
| hypophosphatemia<br>hypopigmentation / |  |
| vitiligo                               | patches of the skin turn lighter than the surrounding skin                   |
| hypotensive                            | low blood pressure   |
|  | a supposition or assumption advanced as a basis for reasoning or             |
| hypothesis                             | argument, or as a guide to experimental investigation                        |
|  | a testable statement of how two or more variables are expected to be         |
| hypothesis                             | related to one another   |
| hypoxemia                              | a decrease of oxygen in the blood  |
| hypoxia                                | a decrease of oxygen reaching body tissues                                   |
| Пурбліа                                | surgical removal of the uterus, ovaries (female sex glands), or both uterus  |
| hustonostomu                           | and ovaries  |
| hysterectomy                           | caused by a physician or by treatment  |
| iatrogenic<br>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  |
| 1                                      | giving of drugs to help the body's immune (protective) system; usually used  |
| immunotherapy                          | 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                    | the medical or social standards determining whether a person may or may      |
| criteria                               | 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                            |
| 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  |
|  | the process of learning the key facts about a clinical trial before deciding |
| informed consent                       | whether or not to participate  |
|  | slow injection of a substance into the body, usually into the blood by means |
| infusion                               | of a catheter  |
| ingestion                              | eating; taking by mouth  |
| insomnia                               | inability to sleep   |
| • .•• •• •                             | confined, either voluntarily or involuntarily (e.g., a hospital, prison, or  |
| institutionalized                      | nursing home)  |
| interferon                             | drug which acts against viruses; antiviral agent                             |
|  | occurring (regularly or irregularly) between two time points; repeatedly     |
| intermittent                           | stopping, then starting again  |
|  | , inflammation of the lungs, which can cause shortness of breath and         |
| pneumonitis                            | difficulty breathing   |

|                        | includes both physical are address by which data are esthered and                 |
|------------------------|---|
| 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  |
|                        | a treatment method which has not been proven to be beneficial or has not          |
| investigational method | been accepted as standard care  |
|                        | the individual(s) designated to have the appropriate level of authority and       |
| investigator           | 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   |
|                        | Surgical procedure in which an incision is made in the abdominal wall to          |
| laparotomy             | enable a doctor to look at the organs inside.                                     |
| legally authorized     | a person authorized either by statute or by court appointment to make             |
| representative (LAR)   | 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   |
|                        | creation of insensitivity to pain in a small, local area of the body, usually by  |
| local anesthesia       | injection of numbing drugs  |
| localized              | restricted to one area, limited to one area                                       |
|                        | a study in which data are collected from the same sample at least two             |
| longitudinal study     | different times   |
| low blood sugar /      | abnormal decrease in sugar in the blood, which can cause weakness,                |
| hypoglycemia           | fatigue, and if severe, can cause loss of consciousness                           |
| nypogiyeenna           | may cause fatigue, weight gain, fluid retention, feeling cold, decreased          |
| low thyroid function   | cognitive function  |
| low white cell count   | increased risk of infection   |
| lumen                  | the cavity of an organ or tube (e.g., blood vessel)                               |
|                        | an x-ray of the lymph nodes or tissues after injecting dye into lymph vessels     |
| lymphanaiaananhy       |   |
| lymphangiography       | (e.g., in feet)   |
| 1                      | a type of white blood cell important in immunity (protection) against             |
| lymphocyte             | 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                          |
|                        | cancer or other progressively enlarging and spreading tumor, usually fatal if     |
| malignancy             | not successfully treated  |
| 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) |
| 1 11 1 1               |   |
| 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       |
| metiomuazoie       | 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                                  |
|                    | a risk is moderate when it includes non-public behavior or data and/or           |
| moderate risk      | allows for connection of the response to the individual's identity               |

| monitor                  | check on; keep track of; watch carefully  |
|--------------------------|---|
|                          | the collection and analysis of data as the project progresses to assure the   |
| monitoring               | 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  |
| mu aggitia latamatitia   | sores in the mouth and esophagus, which may be painful and cause difficulty swallowing  |
| mucositis/stomatitis     | muscle aches  |
| myalgia                  |   |
| myocardial               | pertaining to the heart muscle  |
| myocardial infarction    | heart attack  |
|                          | tube placed in the nose, reaching to the stomach  |
| nasogastric tube         | nci the national cancer institute   |
| nausea                   | feeling sick to the stomach   |
| necrosis                 | death of tissue   |
| neoplasia/neoplasm       | tumor, may be benign or malignant   |
| neuroblastoma            | a cancer of nerve tissue  |
|                          | a neurologic deficit is a decrease in the function of the brain, spinal cord,   |
| neurologic deficits      | muscles, and/or nerves  |
| neurological             | pertaining to the nervous system  |
| neuropathy               | damage to the nerves which can cause numbness, pain, and weakness   |
| • 4                      | condition in which the number of white bloods cells called neutrophils is   |
| neutropenia              | abnormally low  |
| pancreatitis /           | not breaking, cutting, or entering the skin   |
| nosocomial               | acquired in the hospital  |
|                          | the proposition, to be tested statistically, that the experimental intervention   |
| null hypothesis          | 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   |
| uncology                 | an experimental design in which both the investigator(s) and the  |
| open design              | 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<br>a clinical trial in which doctors and participants know which drug or vaccine |
| anon label sola          | 1 1 0   |
| open-label trial         | 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  |
|                          | an FDA category that refers to medications used to treat diseases and   |
| orphan drugs             |   |
|                          | conditions that occur rarely  |
| orthopedic               |   |
| orthopedic<br>ostealgia  | conditions that occur rarely  |
| orthopedic               | conditions that occur rarely<br>pertaining to the bones   |

| ovaries                            | female sex glands  |
|------------------------------------|--|
| palpitation                        | rapid heart beat parameter measure   |
| prospective studies                | studies designed to observe outcomes or events that occur after the group<br>of participants has been identified. prospective studies do not have to<br>involve manipulation or intervention but may be purely observational or<br>involve only the collection of data instead.  |
| prosthesis                         | artificial part, most often limbs, such as arms or legs  |
| protected<br>health<br>information | name, address, elements of dates related to an individual (e.g., birthdate),<br>email address, numbers; telephone, fax, social security, medical record, health<br>beneficiary/health insurance, certificate or license numbers, vehicle, account<br>numbers, characteristics, or codes (e.g., global positioning system (gps)<br>readings), web urls, internet protocol (io) addresses, biometric identifiers (e.g.<br>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  |
|                                    | a blood clot that causes a sudden blockage in a lung artery, usually due to  |
| pulmonary embolism                 | a blood clot that traveled to the lung from the leg  |
|                                    | tissue in the lungs becomes stiff making breathing difficult, resulting in   |
| pulmonary fibrosis                 | shortness of breath, and if severe, can cause heart failure  |
|                                    | abnormally high blood pressure in the blood vessels in the lungs, which  |
| pulmonary                          | makes it harder to pump blood into the lungs   |
|                                    | an experimental design that is missing one or more aspects of the (classic)  |
| quasi-experiment                   | controlled experiment.   |
| radiation therapy                  | x-ray or cobalt treatment  |
| random                             | by chance (like the flip of a coin)<br>a method based on chance by which study participants are assigned to a  |
|                                    |  |
| randomization                      | treatment group<br>an autoimmune disorder causing blood vessels to spasm when exposed to   |
| Raynaud's Syndrome                 | cold   |
| recombinant                        | formation of new combinations of genes   |
| reconstitution                     | putting back together the original parts or elements   |
|                                    | the period during which a trial is attempting to identify and enroll   |
| recruiting                         | 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   |
|                                    | payment for participation in research; this is different from compensation,  |
| remuneration                       | which typically refers to payment for research-related injuries  |
| renal                              | pertaining to the kidneys  |

| replicable             | possible to duplicate   |
|------------------------|---|
|                        | a sample in which the participants closely match the characteristics of the                         |
| representative sample  | population, and thus, all segments of the population are represented in the                         |
|                        | sample  |
|                        | a systematic investigation (i.e., the gathering and analysis of information)                        |
| research               | designed to develop or contribute to generalizable knowledge  |
| resect                 | remove or cut out surgically  |
|                        | difficulty breathing with low levels of oxygen in the blood, which could be                         |
| respiratory failure    | 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                                    |
|                        | research participants, who fill out a survey, are interviewed, participate in                       |
| respondents            | an experiment, are observed in a naturalistic setting, or who are otherwise                         |
|                        | studied   |
| 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)  |
| sequentially           | in a row, in order  |
| side effects           | any undesired actions or effects of a drug or treatment   |
| simultaneous           | at the same time  |
| sinutaneous            | typically, a study design in which the investigator, but not the participant,                       |
| single-blind design    | knows the identity of the treatment assignment. occasionally the participant, but                   |
| 8 8                    |   |
|                        | not the investigator, knows the assignment. also known as single- masked                            |
|                        | design<br>a non-probability sample that is created by using members of the group of                 |
| snowball sample        | interest to identify other members of the group (for example, asking a                              |
| 1<br>1                 |   |
|                        | participant at the end of an interview for suggestions about who else to                            |
|                        | interview)<br>systematic manipulation of, or experimentation in, social or economic                 |
| social experimentation |   |
| somnolence             | systems; used in planning public policy<br>sleepiness   |
| sommorence             |   |
| anagiman               | a sample, as of human tissue, blood or urine, used for diagnostic or                                |
| specimen               | pathological analyses<br>an instrument to measure the amount of air taken into and exhaled from the |
| aniromator             |   |
| spirometer             | lungs   |
| staging                | an evaluation of the extent of the disease  |
| standard of same       | a treatment plan that the majority of the medical community would accept                            |
| standard of care       | as appropriate  |
|                        | a treatment currently in wide use and approved by the FDA, considered to                            |
| standard treatment     | 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         |
|--------------------------|--|
| statiotical orginiteance | clinical trials, the level of statistical significance depends on the number of  |
|                          | participants studied and the observations made, as well as the magnitude of      |
| - 4 - 10 <b>!</b> -      | differences observed   |
| stenosis                 | narrowing of a duct, tube, or one of the blood vessels in the heart              |
| Stevens-Johnson          | skin condition that causes painful blisters and sores of the skin and mucous     |
| syndrome                 | 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.)     |
|                          | a data collection method in which an interviewer reads a standardized            |
| structured interview     | interview schedule to the respondent and records the answers                     |
|                          | a primary or secondary outcome used to judge the effectiveness of a              |
| study endpoint           | treatment  |
|                          | stunned state in which it is difficult to get a response or the attention of the |
| stupor                   | subject  |
| subclavian               | under the collarbone   |
| subcutaneous             | under the skin   |
| supine                   | lying on the back  |
| supine position          | lying on the back  |
| supplement               | add  |
|                          | general medical care aimed at symptoms, not intended to improve or cure          |
| supportive care          | underlying disease   |
| survey                   | a study in which the same data are collected from all members of the             |
| survey                   | sample using a highly structured questionnaire and analyzed using                |
|                          | statistical tests  |
| syndrome                 | a condition characterized by a set of symptoms                                   |
|                          | top number in blood pressure; pressure during active contraction of the          |
| systolic                 | heart  |
| T-lymphocytes            | type of white blood cells  |
| tachycardia              | fast heart rate  |
|                          | capable of causing malformations in a fetus (developing baby still inside the    |
| teratogenic              | mother's body)   |
| testes/testicles         | male sex glands  |
| theomy                   | a general explanation about a specific behavior or set of events that is         |
| theory                   | 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               |
|                          | Low number of platelets, which may cause bleeding and bruising. May              |
| thrombocytopenia         | require a blood transfusion. Bleeding may be serious or life threatening.        |
| thrombosis               | clotting   |
| thrombus                 | blood clot   |
| tinnitus                 | ringing in the ears  |
|                          | a method for deciding on the strength of a drug or solution; gradually           |
| titration                | increasing the dose  |
| topical                  | on the surface   |
|                          | applied to a certain area of the skin and reducing pain only in the area to      |
| topical anesthetic       | which applied  |
| toxicity                 | side effects or undesirable effects of a drug or treatment                       |
| to more y                | inde enceds of undeshable enceds of a drug of treatment                          |

| transdermal                   | through the skin   |
|-------------------------------|--|
| transiently                   | temporarily  |
| trauma                        | injury; wound  |
|                               | refers to trials which test new treatments, new combinations of drugs, or  |
| treatment trials              | new approaches to surgery or radiation therapy   |
| unanticipated problem<br>(UP) | an unanticipated problem involving risk to human participants or others, is<br>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   |
|                               | a carrier that can transmit disease-causing microorganisms (germs and  |
| vector                        | viruses)   |
| venipuncture                  | needle stick, blood draw, entering the skin with a needle  |
| vertical transmission         | spread of disease  |
| visual disturbances           | inability to see properly.   |
| 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<br>entity   |