Abdomen
Abdominal distention
Belly, Stomach
Bloating
Abnormal kidney function tests, which means the kidneys aren’t working properly. When the kidneys do not work properly, wastes can build up in your blood, leading to swelling in the arms and legs, tiredness and weakness. This could become severe, requiring hospitalization and dialysis to clean the wastes out of your blood. If the wastes are not removed from your blood, this could cause seizures and be life threatening.
Abnormal Liver Function Tests
Means that your liver is not functioning properly and can cause malaise, fatigue, and jaundice (yellowing of the skin). Although this is usually mild and reversible, this can be serious or life threatening.
ABSORB
take up fluids, take in
ABUSE-LIABLE
Pharmacological substances that have the potential for creating abusive dependency. Abuse-liable substances can include both illicit drugs (e.g., heroine) and licit drugs (e.g., methamphetamines).
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.
Alcohol, Drug Abuse, and Mental Health Administration; reorganized in October 1992 as the Substance Abuse and Mental Health Services Administration (SAMHSA). ADAMHA included the National Institute of Mental Health (NIMH), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), the Office for Substance Abuse Prevention (OSAP), and the Office for Treatment Intervention (OTI). NIMH, NIAAA, and NIDA are now part of the National Institutes of Health (NIH).
ADAMHA
ADENOPATHY
swollen lymph nodes (glands)
ADJUVANT
helpful, assisting, aiding, supportive
Decreased production of steroids by the body, which may cause weakness, confusion, fatigue, listlessness, low blood pressure, dizziness, weight loss, and loss of appetite. May also cause abdominal cramps, nausea, vomiting and diarrhea and changes in electrolytes (body salts). Symptoms may be worse at times of stress, such as high fevers, infection, surgery or a serious accident. If your adrenal glands do not produce enough hormones, you will need to take oral medications to replace the hormones.

Adrenal Suppression

Adverse Effect

An undesirably and unintended, although not necessarily unexpected, result of therapy or other intervention.

Agent

Drug, medication

Albumin

Protein found in blood

ALLERGIC REACTION

rash, hives, swelling, trouble breathing

Alopecia

Loss of hair

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.

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.

A research condition in which no one, including the researcher, knows the identities of research participants.

Anonymity

ANOREXIA

disorder in which person will not eat; lack of appetite

ANTECUBITAL

related to the inner side of the forearm

ANTIBIOTIC

drug that kills bacteria and other germs

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

In the U.S., the Food and Drug Administration (FDA) must approve a substance as a drug before it can be marketed. The approval process involves several steps including pre-clinical laboratory and animal studies, clinical trials for safety and efficacy, filing of a New Drug Application by the manufacturer of the drug, FDA review of the application, and FDA approval/rejection of application.

APPROVED DRUGS

ARM  Any of the treatment groups in a randomized trial. Most randomized trials have two "arms," but some have three "arms," or even more.

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

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

Assent  Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

ASSURANCE

Asthenia  Feeling weak and having no energy

ASTHMA  lung disease associated with tightening of air passages, making breathing difficult

AUTHORIZED INSTITUTIONAL OFFICIAL  An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.
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.

Autonomy
The personal capacity participants should possess in research conditions to consider alternatives, make choices, and act without undue influence or interference of others.

AUTOPSY
Examination by dissection of the body of an individual to determine cause of death and other medically relevant facts.

AXILLA
armpit

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.

BASELINE
A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

BELMONT REPORT
An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

BENEFICENCE
Benefit
A valued or desired outcome; an advantage.

BENIGN
not malignant, without serious consequences

BID
twice a day
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubinemia</td>
<td>High levels of bilirubin in the blood. This may mean that too many red cells are being destroyed, or that the liver is not removing bilirubin from the blood properly.</td>
</tr>
<tr>
<td>BIOAVAILABILITY</td>
<td>the extent to which a drug or other substance becomes available to the body</td>
</tr>
<tr>
<td>BIOLOGIC</td>
<td>Any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries.</td>
</tr>
<tr>
<td>Biopsy</td>
<td>Removal and examination of tissue</td>
</tr>
<tr>
<td>BLIND</td>
<td>A randomized trial is &quot;Blind&quot; if the participant is not told which arm of the trial he is on. A clinical trial is &quot;Blind&quot; if participants are unaware on whether they are in the experimental or control arm of the study; also called masked.</td>
</tr>
<tr>
<td>Blood clots</td>
<td>One risk of chemotherapy is to have blood clots form that can lead to swelling in the arms and legs. These clots can travel to the lungs causing shortness of breath or to the brain causing a stroke. This may be serious or life threatening.</td>
</tr>
<tr>
<td>BOLUS</td>
<td>a large amount given all at once</td>
</tr>
<tr>
<td>BONE MASS</td>
<td>the amount of calcium and other minerals in a given amount of bone</td>
</tr>
<tr>
<td>Bowel perforation</td>
<td>Perforation of the digestive system (holes in the intestine) is another rare risk that has been reported with Thalidomide use. These &quot;holes&quot; will result in pain and may require surgery, treatment with antibiotics and could be life threatening.</td>
</tr>
<tr>
<td>BRADYCARDIA</td>
<td>slow heartbeat</td>
</tr>
<tr>
<td>Brain stem edema</td>
<td>Accumulation of fluid around the brain stem, This can be life threatening</td>
</tr>
<tr>
<td>BRONCHOSPASM</td>
<td>breathing distress caused by narrowing of the airways</td>
</tr>
<tr>
<td>CARCINOGENIC</td>
<td>cancer-causing</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
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<td>------</td>
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</tr>
<tr>
<td>CARCINOMA</td>
<td>type of cancer</td>
</tr>
<tr>
<td>CARDIAC</td>
<td>related to the heart</td>
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<tr>
<td>Cardiac arrest</td>
<td>Sudden, unexpected stopping of the heart.</td>
</tr>
<tr>
<td>Cardiac effusion</td>
<td>Collection of fluid around the heart</td>
</tr>
<tr>
<td>Cardiac toxicity</td>
<td>Damage to the heart</td>
</tr>
<tr>
<td>Cardiomyopathy</td>
<td>Heart muscle becomes damaged and the heart doesn't pump properly</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Heart and blood vessels</td>
</tr>
<tr>
<td>CARDIOVERSION</td>
<td>return to normal heartbeat by electric shock</td>
</tr>
<tr>
<td>Case Study</td>
<td>A research strategy that focuses on one case (an individual, a group, an organization, etc.) within its social context during one time period.</td>
</tr>
<tr>
<td>CAT SCAN</td>
<td>Abbreviation for Computerized Axial Tomography, an X-ray technique for producing images of internal bodily structures through the assistance of a computer.</td>
</tr>
<tr>
<td>CATHETER</td>
<td>a tube for withdrawing or giving fluids</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention; an agency within the Public Health Service, Department of Health and Human Services.</td>
</tr>
<tr>
<td>CENTRAL NERVOUS SYSTEM (CNS)</td>
<td>brain and spinal cord</td>
</tr>
<tr>
<td>CEREBRAL TRAUMA</td>
<td>damage to the brain</td>
</tr>
<tr>
<td>CESSATION</td>
<td>stopping</td>
</tr>
<tr>
<td>Changes in ECG</td>
<td>Changes to the electrical activity of the heart. These can be mild and not require treatment or may be serious.</td>
</tr>
<tr>
<td>CHD</td>
<td>coronary heart disease</td>
</tr>
<tr>
<td>CHEMOTHERAPY</td>
<td>treatment of disease, usually cancer, by chemical agents</td>
</tr>
<tr>
<td>CHRONIC</td>
<td>continuing for a long time, ongoing</td>
</tr>
<tr>
<td>Claim</td>
<td>A statement, similar to a hypothesis, which is made in response to the research question at hand, and that is backed up with evidence based on research.</td>
</tr>
<tr>
<td>CLINICAL</td>
<td>pertaining to medical care</td>
</tr>
<tr>
<td>CLINICAL INVESTIGATOR</td>
<td>A medical researcher in charge of carrying out a clinical trial's protocol.</td>
</tr>
<tr>
<td>CLINICAL TRIAL</td>
<td>an experiment involving human subjects</td>
</tr>
<tr>
<td>Cluster Sample</td>
<td>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.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Coagulation</td>
<td>Form blood clot</td>
</tr>
<tr>
<td></td>
<td>Having either a psychiatric disorder (e.g., psychosis, neurosis,</td>
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<tr>
<td></td>
<td>personality or behavior disorders, or dementia) or a developmental</td>
</tr>
<tr>
<td></td>
<td>disorder (e.g., mental retardation) that affects cognitive or emotional</td>
</tr>
<tr>
<td></td>
<td>functions to the extent that capacity for judgment and reasoning is</td>
</tr>
<tr>
<td></td>
<td>significantly diminished. Capacity for autonomy and voluntary</td>
</tr>
<tr>
<td></td>
<td>participation is thus impaired. Others, including people under the</td>
</tr>
<tr>
<td></td>
<td>influence of or dependent on drugs or alcohol, those suffering from</td>
</tr>
<tr>
<td></td>
<td>degenerative diseases affecting the brain, terminally ill patients, and</td>
</tr>
<tr>
<td></td>
<td>persons with severely disabling physical handicaps, may also be</td>
</tr>
<tr>
<td></td>
<td>compromised in their ability to make decisions in their best interests.</td>
</tr>
<tr>
<td>Cognitively Impaired</td>
<td>A group of subjects initially identified as having one or more</td>
</tr>
<tr>
<td></td>
<td>characteristics in common who are followed over time. In social</td>
</tr>
<tr>
<td></td>
<td>science research, this term may refer to any group of persons who are</td>
</tr>
<tr>
<td></td>
<td>born at about the same time and share common historical or cultural</td>
</tr>
<tr>
<td></td>
<td>experiences.</td>
</tr>
<tr>
<td>COHORT</td>
<td>unconscious state</td>
</tr>
<tr>
<td>COMMUNITY-BASED CLINICAL TRIAL (CBCT)</td>
<td>A clinical trial conducted primarily through primary-care physicians</td>
</tr>
<tr>
<td></td>
<td>rather than academic research facilities.</td>
</tr>
<tr>
<td></td>
<td>A method of providing experimental therapeutics prior to final FDA</td>
</tr>
<tr>
<td></td>
<td>approval for use in humans. This procedure is used with very sick</td>
</tr>
<tr>
<td></td>
<td>individuals who have no other treatment options. Often, case-by-case</td>
</tr>
<tr>
<td></td>
<td>approval must be obtained from the FDA for &quot;compassionate use&quot; of a</td>
</tr>
<tr>
<td></td>
<td>drug or therapy.</td>
</tr>
<tr>
<td>COMPASSIONATE USE</td>
<td>Payment or medical care provided to subjects injured in research;</td>
</tr>
<tr>
<td></td>
<td>does not refer to payment (remuneration) for participation in</td>
</tr>
<tr>
<td></td>
<td>research.</td>
</tr>
<tr>
<td>COMPENSATION</td>
<td>Used as a legal term to indicate a person’s capacity to act on one’s</td>
</tr>
<tr>
<td></td>
<td>own behalf; a person’s ability to understand information presented, to</td>
</tr>
<tr>
<td></td>
<td>realize the consequences of acting (or not acting) on that information,</td>
</tr>
<tr>
<td></td>
<td>and to make a choice</td>
</tr>
<tr>
<td>Competence</td>
<td>total disappearance of disease</td>
</tr>
<tr>
<td>COMPLETE RESPONSE</td>
<td></td>
</tr>
</tbody>
</table>
Confidentiality

A research condition in which no one except the researcher(s) knows the identities of the research participants. The treatment of information that a participant has disclosed to the researcher in a relationship of trust and with the expectation that it will not be revealed to others in ways that violate the original agreement, unless permission is granted by the participant.

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

An agreement; as used here, an agreement that a specific research activity will be performed at the request, and under the direction, of the agency providing the funds. Research performed under contract is more closely controlled by the agency than research performed under a grant.

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. Such individuals should not be involved in the study.

CONTROL GROUP

The standard by which experimental observations are evaluated. 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 EXPERIMENT

An experimental design with two or more randomly selected groups (an experimental group and control group) in which the researcher controls or introduces the independent variable and measures the dependent variable at least two times (pre- and post-test measurements).
CONTROLLED TRIAL
research study in which the experimental treatment or procedure is compared to a standard (control) treatment or procedure

Convenience Sample
A non-probability sample that is determined by selecting participants that are readily accessible (convenient) to the researcher, (examples in studies of Colorado College 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

CORRELATION COEFFICIENT
A statistical index of the degree of relationship between two variables. Values of correlation coefficients range from -1.00 through zero to +1.00. A correlation coefficient of 0.00 indicates no relationship between the variables. Correlations approaching -1.00 or +1.00 indicate strong relationships between the variables. However, causal inferences about the relationship between two variables can never be made on the basis of correlation coefficients, no matter how strong a relationship is indicated.

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. They vary together in some way, but the variation of one does not itself cause the variation of the other

CROSS-OVER DESIGN
A type of clinical trial in which each subject experiences, at different times, both the experimental and control therapy. For example, half of the subjects might be randomly assigned first to the control group and then to the experimental intervention, while the other half would have the sequence reversed.

CT SCAN (CAT)
computerized series of x-rays (computerized tomography)

CULTURE
test for infection, or for organisms that could cause infection

CUMULATIVE
added together from the beginning

CUTANEOUS
relating to the skin

CVA
stroke (cerebrovascular accident)
DATA SAFETY AND MONITORING BOARD (DSMB)

An independent committee, composed of community representatives and clinical research experts, that reviews data while a clinical trial is in progress to ensure that participants are not exposed to undue risk. A DSMB may recommend that a trial be stopped if there are safety concerns or if the trial objectives have been achieved.

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. Deception should only be used when the researcher feels that participant knowledge about the study would alter participants’ behavior or responses in the study. Deception should not cause any adverse consequences to the participants, and participants should be debriefed after running the study. IRB guidelines on the use of deception should be reviewed. A study that cannot justify the use of deception may not receive IRB approval.

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 conducted to find better tests or procedures for diagnosing a particular disease or condition. Diagnostic trials usually include people who have signs or symptoms of the disease or condition being studied.

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
DIC – A condition that is associated with uncontrolled clotting and bleeding in the body that can cause serious bleeding and organ damage. This can be serious and life threatening.

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

device using sound waves to diagnose or test

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.

DOSE-RANGING STUDY
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).

Double-Blind Design
A modification of the effect of a drug when administered with another drug. The effect may be an increase or a decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either drug.

DRUG-DRUG INTERACTION

Duration
Length of time involved

DVT (deep venous thrombosis)
Blood clot formed in the veins of the leg

DYSPLASIA
abnormal cells

Echocardiogram
Using soundwaves for examination of the heart

Edema
Build up of fluid in the body causing swelling.

EEG
electric brain wave tracing (electroencephalogram)

Efficacy
Effectiveness

ELECTROCARDIOGRAM
electrical tracing of the heartbeat (ECG or EKG)

Changes in electrolytes (body salts) which usually do not cause any symptoms but that can sometimes cause fatigue, muscle weakness, cramping, rigidity, irregular heart beat, or seizures. This can be severe and possibly life threatening. This could require hospitalization and intravenous treatment

Electrolyte changes
May indicate inflammation of the pancreas, which could result in abdominal pain and discomfort and could require hospitalization and intravenous treatment.

Elevated lipase, amylase
Elevated PTT, INR
Tests that measure how long it takes the blood to clot. If these tests are elevated, it means that your blood isn’t clotting normally and you have an increased risk of bleeding or bruising. This could be serious and life threatening and may require hospitalization and a blood transfusion.

Elevated uric acid levels
Which may worsen kidney function; cause joint pain (gout) and kidney stones. May cause kidney failure, which may be reversible

ELIGIBILITY CRITERIA

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

Emancipated Minor

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. Common endpoints are severe toxicity, disease progression, or death.

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

Ethnographic Research
Ethnography is the study of people and their cultures. Ethnographic research involves observation of and interactions with the people or group being studied in the group’s own environment, often for long periods of time

EVALUATED, ASSESSED
examined for a medical condition

Excrete
Discharge, pass
EXEMPT

Research that is determined to meet the criteria set out by Federal Policy for exempt status and thus does not need review.

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.

Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

Expedited Review

A drug that is not FDA licensed for use in humans, or as a treatment for a particular condition

EXPERIMENTAL DRUG

The group in an experimental design study that receives treatment in the form, or in various forms, of the independent variable. This group can thus be compared to the control group.

Experimental Group

EXTERNAL

to leak outside of a planned area, such as out of a blood vessel

EXTRAVASATE

Feeling tired

Fatigue

U.S. Food and Drug Administration, the branch of federal government that approves new drugs

FDA

The federal policy that provides regulations for the involvement of human participants in research. The Policy applies to all research involving human participants that is conducted, supported, or otherwise participant to regulation by any federal department or agency.

Federal Policy

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. Research conducted in natural, real-life settings, outside the laboratory. This involves observation and, in many cases, interactions with the people being studied.

Fluid in lungs
Can cause shortness of breath. If severe, it may require hospitalization and treatment. It can be serious or life threatening.

Fluoroscope
X-ray machine
Review of proposed research at a convened meeting at which the majority of the IRB members are present, including one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

Full Board Review
Review of proposed research at a convened meeting at which the majority of the IRB members are present, including one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

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.

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

GRANT
Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.

Graph
Chart, records

Guardian
An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care.
GvHD Graft –Versus Host Disease

This is a condition in which immune cells from the donor’s tissue attack your organs. The risk of severe GVHD depends on the type of BMT (bone marrow transplant) or SCT (stem cell transplant) and the quality (how closely) the patient and donor cells match. There are acute and chronic forms of GVHD. Acute GVHD usually affects the skin, intestines, and liver and may start one week to three months after transplant. Chronic GVHD begins later and can affect these organs as well as the lung, mucous membranes and/or other organs.

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

Hematuria

Blood in urine

HEMODYNAMIC MEASURING

measuring of blood flow

HEMOLYSIS

breakdown in red blood cells

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. This may cause high blood pressure or swelling of the face, hands, feet, or the entire body. This can progress to acute kidney failure.

Hemolytic Uremic Syndrome

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

HERITABLE DISEASE

disease that can be transmitted to one’s offspring, resulting in damage to future children

May cause fatigue, weight loss, rapid heartbeat, sweating, trouble with heat, nervousness.

High thyroid function

pertaining to the disease status of body tissues or cells

HISTOPATHOLOGIC

a portable machine for recording heart beats

Hormone

A chemical in the body
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. May cause sleepiness, weakness and if severe, may cause coma. It may also decrease kidney function.

**Hyperkalemia**
High levels of potassium in the blood, which can cause the heart to stop beating. This can be very serious and life threatening.

**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.

**Hypokalemia**
Decreased levels of potassium in the blood, which can cause irregular heart beat.

**Hypomagnesemia**
Decreased levels of sodium in the blood, which can cause confusion, seizures, fatigue and low levels of consciousness.

**Hyponatremia**
Low phosphate, which may result in muscle weakness, bone pain, confusion and muscle breakdown

**Hypophosphatemia**
Patches of the skin turn lighter than the surrounding skin

**Hypotensive**
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.

**Hypothesis**
a decrease of oxygen in the blood

**HYPOXEMIA**
a decrease of oxygen reaching body tissues
HYSTERECTOMY
surgical removal of the uterus, ovaries (female sex glands), or both uterus and ovaries

I.V. Push
Rapid injection into a vein

IATROGENIC
caused by a physician or by treatment

IDE
investigational device exemption, the license to test an unapproved new medical device

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
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

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. Often used as a synonym for incompetence.
The medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe.

INCOMPETENCE
Used as a legal term to indicate the inability to manage one's own affairs.

IND
investigational new drug, the license to test an unapproved new drug

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
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammation</td>
<td>Swollen, red, and painful</td>
</tr>
<tr>
<td>INFORMED CONSENT</td>
<td>The process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study.</td>
</tr>
<tr>
<td>INFUSION</td>
<td>slow injection of a substance into the body, usually into the blood by means of a catheter</td>
</tr>
<tr>
<td>INGESTION</td>
<td>eating; taking by mouth</td>
</tr>
<tr>
<td>Insomnia</td>
<td>Inability to sleep</td>
</tr>
<tr>
<td>Institutional Review Board (IRB)</td>
<td>A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.</td>
</tr>
<tr>
<td>Institutionalized</td>
<td>Confined, either voluntarily or involuntarily (e.g., a hospital, prison, or nursing home).</td>
</tr>
<tr>
<td>Instruments in Testing</td>
<td>Specify what instruments are to be used and how they are used</td>
</tr>
<tr>
<td>INTERFERON</td>
<td>drug which acts against viruses; antiviral agent</td>
</tr>
<tr>
<td>INTERMITTENT</td>
<td>occurring (regularly or irregularly) between two time points; repeatedly stopping, then starting again</td>
</tr>
<tr>
<td>Interstitial pneumonitis, pneumonitis</td>
<td>Inflammation of the lungs, which can cause shortness of breath and difficulty breathing. If severe, this can be life threatening. 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. Intervention includes communication or interpersonal contact between investigator and participant.</td>
</tr>
<tr>
<td>Intervention</td>
<td></td>
</tr>
<tr>
<td>Intracatheter</td>
<td>Small tube in a vein</td>
</tr>
<tr>
<td>INTRAMUSCULAR</td>
<td>into the muscle; within the muscle</td>
</tr>
<tr>
<td>INTRAPERITONEAL</td>
<td>into the abdominal cavity</td>
</tr>
<tr>
<td>INTRATHECAL</td>
<td>into the spinal fluid</td>
</tr>
<tr>
<td>INTRAVENOUS (IV)</td>
<td>through the vein</td>
</tr>
<tr>
<td>INTRAVESICAL</td>
<td>in the bladder</td>
</tr>
<tr>
<td>INTUBATE</td>
<td>the placement of a tube into the airway</td>
</tr>
<tr>
<td>INVASIVE PROCEDURE</td>
<td>puncturing, opening, or cutting the skin</td>
</tr>
</tbody>
</table>
INVESTIGATIONAL METHOD

A treatment method which has not been proven to be beneficial or has not been accepted as standard care.

INVESTIGATIONAL NEW DRUG

A new drug, antibiotic drug, or biological drug that is used in a clinical investigation. It also includes a biological product used in vitro for diagnostic purposes.

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 decreased oxygen in a tissue (usually because of decreased blood flow)

ISCHEMIA

Yellowing of the skin

Jaundice

An ethical principle that requires fairness in the distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly

Justice

Individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested on the corresponding grant application/contract proposal.

Key Personnel

surgical procedure in which an incision is made in the abdominal wall to enable a doctor to look at the organs inside

LAPAROTOMY

A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Legally Authorized Representative

wound or injury; a diseased patch of skin

LESION

sleepiness, tiredness

LETHARGY

low white blood cell count

LEUKOPENIA

fat

LIPID

creation of insensitivity to pain in a small, local area of the body, usually by injection of numbing drugs

LOCAL ANESTHESIA

restricted to one area, limited to one area

LOCALIZED

An expression of the probability that a gene and a marker are linked.

LOD SCORE
Longitudinal Study
A study in which data are collected from the same sample at least two different times. A study designed to follow participants through time. Abnormal decrease in sugar in the blood, which can cause weakness, fatigue, and if severe, can cause loss of consciousness.

Low blood sugar / hypoglycemia
May cause fatigue, weight gain, fluid retention, feeling cold, decreased cognitive function.

Low thyroid function
You have an increased risk of infection. You should call your doctor immediately if you have a fever or other signs of infection.

Low white cell count
the cavity of an organ or tube (e.g., blood vessel)

LUMEN
an x-ray of the lymph nodes or tissues after injecting dye into lymph vessels (e.g., in feet)

LYMPHANGIOGRAPHY
a type of white blood cell important in immunity (protection) against infection

LYMPHOCYTE
a cancer of the lymph nodes (or tissues)

LYMPHOMA
a vague feeling of bodily discomfort, feeling badly

MALAISE
condition in which something is not functioning properly

cancer or other progressively enlarging and spreading tumor, usually fatal if not successfully treated

MALIGNANCY
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). A mature minor is not necessarily an emancipated minor

Mature Minor

MEDICAL DEVICE AMENDMENTS (MDA)

MEDULLABLASTOMA
a type of brain tumor

MEGALOBLASTOSIS
change in red blood cells

Metabolic Acidosis
The body becomes more acid. This can lead to a decreased function in a number of organs. This can be serious and life threatening.

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

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. The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.

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. This level of risk includes no deception of participants, no sensitive, culturally taboo, or socially controversial material that is likely to evoke responses which could distress participants.

MONITOR

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

MRI

magnetic resonance imaging, diagnostic pictures of the inside of the body, created using magnetic rather than x-ray energy

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.
Multiple Relationships (Financial Conflicts of Interest)

- **a. income**: including receiving past, current, or expecting future income in the form of salary, stock or stock option/warranties, equity, dividends, royalties, profit sharing capital gain, forbearance of forgiveness of a loan, interest in real or personal property, or involvement in a legal partnership with the sponsor.

- **b. consultant**: receiving past, current, or expecting future income in the form of consulting fees, honoraria, gifts, gifts to the University, or payments resulting from seminars, lectures, or teaching engagements, or service on a non-federal advisory committee or review panel.

- **c. service**: serving in a corporate or for-profit leadership position, such as executive officer, board member, fundraiser officer, agent, member of a scientific advisory board, member of a scientific review committee, or member of a data safety monitoring committee, regardless of compensation.

- **d. intellectual property**: inventor on a patent or copyright involving technology/processes and/or products licensed or expected to be licensed to the sponsor.

**Myalgia**
Muscle aches

**MYOCARDIAL**
pertaining to the heart muscle

**MYOCARDIAL INFARCTION**
heart attack

**NASOGASTRIC TUBE**
tube placed in the nose, reaching to the stomach

**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

**Neurologic deficits**
A neurologic deficit is a decrease in the function of the brain, spinal cord, muscles, and/or nerves. Neurologic deficits include inability to speak, decreased sensation, loss of balance, weakness, cognitive dysfunction, visual changes, abnormal reflexes, and problems walking.

**NEUROLOGICAL**
pertaining to the nervous system

**Neuropathy**
Damage to the nerves which can cause numbness, pain, and weakness
Neutropenia
Condition in which the number of white blood cells called neutrophils is abnormally low. This increases the risk of infection, which may be serious or life threatening.

NEW DRUG APPLICATION
Request for FDA approval to market a new drug.

NIAAA
National Institute on Alcohol Abuse and Alcoholism; an institute in NIH.

NIDA
National Institute on Drug Abuse; an institute in NIH.

NIH
the National Institutes of Health

NIMH
National Institute of Mental Health; an institute in NIH.

Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher).

Non-affiliated Member

Non-therapeutic Research
Research that has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the current participants, although it may benefit participants with a similar condition in the future.

NONINVASIVE
not breaking, cutting, or entering the skin

Volunteer subjects used to study normal physiology and behavior or who do not have the condition under study in a particular protocol, used as comparisons with subjects who do have the condition. "Normal" may not mean normal in all respects. For example, patients with broken legs (if not on medication that will affect the results) may serve as normal volunteers in studies of metabolism, cognitive development, and the like. Similarly, patients with heart disease but without diabetes may be the "normals" in a study of diabetes complicated by heart disease.

NORMAL VOLUNTEERS

NOSOCOMIAL
acquired in the hospital

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. Investigators usually hope that the data will demonstrate some effect from the intervention, thus allowing the investigator to reject the null hypothesis.

Null Hypothesis

OCCLUSION
closing; blockage; obstruction

NONINVASIVE
OFF-LABEL USE
A drug prescribed for conditions other than those approved by the FDA.

Office for Human Research Protections (OHRP)
The Health and Human Services (HHS) office that oversees the regulation of research involving human research participants.

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. These are often serious and life threatening.

ORAL ADMINISTRATION
by mouth

ORPHAN DRUGS
An FDA category that refers to medications used to treat diseases and conditions that occur rarely. There is little financial incentive for the pharmaceutical industry to develop medications for these diseases or conditions. Orphan drug status, however, gives a manufacturer specific financial incentives to develop and provide such medications.

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. This could become severe and cause nausea and vomiting, fever and rapid heart rate. This could require hospitalization and may be life threatening.

Pancytopenia
Abnormal decrease in the levels of all type of blood cells
PARENTERAL given by injection

Individuals whose physiological or behavioral characteristics and responses are the object of study in a research project. Under federal regulations, human participants 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.

Participant

PATENCY condition of being open

Making decisions for others against or apart from their wishes with the intent of doing them good.

Paternalism

PATHOGENESIS development of a disease or unhealthy condition

Review of a clinical trial by experts chosen by the study sponsor. These experts review the trials for scientific merit, participant safety, and ethical considerations.

PEER REVIEW

PER OS (PO) by mouth

PERCUTANEOUS through the skin

PERIPHERAL not central

Peripheral Blood

Vein blood

the study of the way the body absorbs, distributes, and gets rid of a drug

PHARMACOKINETICS

Initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients.

PHASE I TRIALS

Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks.

PHASE II TRIALS

Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide and adequate basis for physician labeling.

PHASE III TRIALS

Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use.

PHASE IV TRIALS
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

PLACEBO EFFECT  A physical or emotional change, occurring after a substance is taken or administered, that is not the result of any special property of the substance. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving 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.

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 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)
POTENTIATE  an agent that helps another agent work better
POTENTIATOR  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.

PRECLINICAL  before birth
PRENATAL  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. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.
PREVENTION TRIALS  The scientist or scholar with primary responsibility for the design and conduct of a research project
Principal Investigator
Prisoner

An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g. for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution.

Privacy

A person’s capacity to control the extent, timing, and circumstances of shared oneself (physically, behaviorally, or intellectually) with others. 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. Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

Private Information

PRN

as needed

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.

Probability Sample

PROGNOSIS

outlook, probable outcomes

PRONE

lying on the stomach

Prophylaxis

Use of drugs to prevent disease

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.

Prospective Studies

PROSTHESIS

artificial part, most often limbs, such as arms or legs
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. May cause fluid retention.
A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

PROTOCOL

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 a blood clot that traveled to the lung from the leg. Pulmonary embolism is a serious condition that can cause:
- Permanent damage to part of your lung from lack of blood flow to lung tissue
- Low oxygen levels in your blood
- Damage to other organs in your body from not getting enough oxygen.
If a clot is large, or if there are many clots, pulmonary embolism can cause death.

Pulmonary embolism
Tissue in the lungs becomes stiff making breathing difficult, resulting in shortness of breath, and if severe, can cause heart failure.

Pulmonary fibrosis
Abnormally high blood pressure in the blood vessels in the lungs, which makes it harder to pump blood into the lungs. May cause fatigue, shortness of breath, chest pain, and ankle swelling. Can lead to loss of consciousness and could be serious and life threatening.

**Pulmonary Hypertension**

**QD**

every day; daily

**QID**

four times a day

The collection of non-numerical data. Often multi-method in focus, qualitative research involves an interpretive, meaning-driven approach to its participant matter.

**Qualitative Research**

The collection of numerical data in order to describe, explain, predict and/or control phenomena of interest.

**Quantitative Research**

An experimental design that is missing one or more aspects of the (classic) controlled experiment.

**Quasi-experiment**

A quorum will be a majority (greater than 50 per cent) of the voting members of the IBC. For reasons other than conflict of interest, abstentions do not alter the quorum, or change the number of votes required.

**Quorum**

**RADIATION THERAPY**

x-ray or cobalt treatment

**RANDOM**

by chance (like the flip of a coin)

A method based on chance by which study participants are assigned to a treatment group. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms. The researchers do not know which treatment is better. From what is known at the time, any one of the treatments chosen could be of benefit to the participant.

**RANDOMIZATION**

A study in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms of a clinical trial. Occasionally placebos are utilized.

**RANDOMIZED TRIAL**

An autoimmune disorder causing blood vessels to spasm when exposed to cold. This occurs especially in the fingers and toes causing them to turn red, pale, and then blue in succession and is usually painful. If this becomes severe, it can progress to local gangrene.

**Raynaud’s Syndrome**

**RBC**

red blood cell

**RECOMBINANT**

formation of new combinations of genes
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>RECONSTITUTION</td>
<td>putting back together the original parts or elements</td>
</tr>
<tr>
<td>RECRUITING</td>
<td>The period during which a trial is attempting to identify and enroll</td>
</tr>
<tr>
<td></td>
<td>participants. Recruitment activities can include advertising and other</td>
</tr>
<tr>
<td></td>
<td>ways of soliciting interest from possible participants.</td>
</tr>
<tr>
<td>RECRUITMENT STATUS</td>
<td>Indicates the current stage of a trial</td>
</tr>
<tr>
<td>RECUR</td>
<td>happen again</td>
</tr>
<tr>
<td>REFRACTORY</td>
<td>not responding to treatment</td>
</tr>
<tr>
<td>REGENERATION</td>
<td>re-growth of a structure or of lost tissue</td>
</tr>
<tr>
<td>REGIMEN</td>
<td>pattern of giving treatment</td>
</tr>
<tr>
<td>RELAPSE</td>
<td>the return of a disease</td>
</tr>
<tr>
<td>Reliability</td>
<td>The degree to which a measure yields consistent results.</td>
</tr>
<tr>
<td>REMISSION</td>
<td>disappearance of evidence of cancer or other disease</td>
</tr>
<tr>
<td></td>
<td>Payment for participation in research; this is different from</td>
</tr>
<tr>
<td></td>
<td>compensation, which typically refers to payment for research-related</td>
</tr>
<tr>
<td></td>
<td>injuries</td>
</tr>
<tr>
<td>Remuneration</td>
<td>pertaining to the kidneys</td>
</tr>
<tr>
<td>RENAL</td>
<td></td>
</tr>
<tr>
<td>REPLICABLE</td>
<td>possible to duplicate</td>
</tr>
</tbody>
</table>
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. A representative sample allows results to be generalized from the sample to the population.

Research
A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

RESEARCH DIRECTOR
The scientist or scholar with primary responsibility for the supervision of the principal investigator of a research project.

RESECT
remove or cut out surgically

Respect for Persons
An ethical principle requiring that individual autonomy be respected and that persons with diminished autonomy be protected

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.

Restricted Use or Limited Data Set
Files that have restrictions imposed regarding their use in research and contain data fields such as social security numbers, names, protected health information or other life history markers that might enable an unauthorized user to identify a participant.

Retrospective study
Research conducted by reviewing records from the past or by obtaining information about past events elicited through interviews or surveys.

Rhabdomyolysis
Rhabdomyolysis is a breakdown of muscle fibers. It occurs when muscle cells die and release cell contents into the blood stream. It can cause muscle pain and a number of health problems, including damage to the kidneys. If severe, this could be life threatening.

Rigors
Chills and shivering

Risk
The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.
RISK-BENEFIT RATIO
The risk to individual participants versus the potential benefits. The risk/benefit ratio may differ depending on the condition being treated.

Saline
Salt water solution

Sample
A subset of a given population used for research purposes.

SARCOMA
a type of cancer

Screening
Examination, test

Secondary Data Set
Data that can be used in research and comes from public or private documents, including medical records, police reports, vital statistic records, student record.

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. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental drugs must be evaluated for both immediate and long-term side effects

Simultaneous
At the same time

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

A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of IRB protection of human participants or the capability of personnel to conduct the research.

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).

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

SPONSOR-INVESTIGATOR  
An individual who both initiates and actually conducts, alone or with others, a clinical investigation. Corporations, agencies, or other institutions do not qualify as sponsor-investigators.

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. May cause difficulty eating and swallowing. This is similar to the skin damage from a severe burn and is serious and life threatening.

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. (Not to be confused with an in-depth interview.)

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
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUPINE</td>
<td>lying on the back</td>
</tr>
<tr>
<td>Supine Position</td>
<td>Lying on the back</td>
</tr>
<tr>
<td>Supplement</td>
<td>Add general medical care aimed at symptoms, not intended to improve or cure underlying disease</td>
</tr>
<tr>
<td>SUPPORTIVE CARE</td>
<td>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.</td>
</tr>
<tr>
<td>Survey</td>
<td>a condition characterized by a set of symptoms</td>
</tr>
<tr>
<td>SYNDROME</td>
<td>top number in blood pressure; pressure during active contraction of the heart</td>
</tr>
<tr>
<td>SYSTOLIC</td>
<td>type of white blood cells</td>
</tr>
<tr>
<td>T-lymphocytes</td>
<td>Fast heart rate</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>capable of causing malformations in a fetus (developing baby still inside the mother’s body)</td>
</tr>
<tr>
<td>TERATOGENIC</td>
<td>male sex glands</td>
</tr>
<tr>
<td>TESTES/TESTICLES</td>
<td>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. A theory is not as specific as a hypothesis.</td>
</tr>
<tr>
<td>Theory</td>
<td>Treatment intended and expected to alleviate a disease or disorder. Low number of platelets, which may cause bleeding and bruising. May require a blood transfusion. Bleeding may be serious or life threatening.</td>
</tr>
<tr>
<td>THERAPY</td>
<td>cloting</td>
</tr>
<tr>
<td>THROMBOSIS</td>
<td>blood clot</td>
</tr>
<tr>
<td>THROMBUS</td>
<td>three times a day</td>
</tr>
<tr>
<td>TID</td>
<td>Ringing in the ears</td>
</tr>
<tr>
<td>Tinnitus</td>
<td>a method for deciding on the strength of a drug or solution; gradually increasing the dose</td>
</tr>
<tr>
<td>TITRATION</td>
<td>on the surface</td>
</tr>
<tr>
<td>TOPICAL</td>
<td>applied to a certain area of the skin and reducing pain only in the area to which applied</td>
</tr>
<tr>
<td>TOPICAL ANESTHETIC</td>
<td>side effects or undesirable effects of a drug or treatment through the skin</td>
</tr>
</tbody>
</table>
Transient Ischemic Attack (TIA)
A brief episode of decreased oxygen to the brain causing blurred vision, dizziness, faintness, and numbness. A TIA is like a mini-stroke.

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.

Disturbances in the minerals and chemicals in your system, which could result in life threatening complications if not managed appropriately. TLS is caused by the sudden, rapid death of cancer cells in response to treatment. When cancer cells are killed by a cancer drug, they may spill their inner (intracellular) contents, which accumulate faster then they can be eliminated. This debris from the cancer cells can change the balance of the chemistry of the body, and it could result in dangerous disturbances. Symptoms of tumor lysis syndrome may include severe nausea and vomiting, shortness of breath, an irregular heartbeat, urine abnormalities, severe fatigue and/or joint pain.

Tumor lysis syndrome

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

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).

Variable
An element or factor that the research is designed to study, either as an experimental intervention or a possible outcome (or factor affecting the outcome) of that intervention.

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. |
| **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. |
| **Voluntary Participation** | The principle that study participants choose to participate of their own free will, rather than being coerced or forced to participate. For IRB purposes, this is a key part of your study proposal; you must demonstrate that participants will be participating voluntarily for a study to be approved by the IRB. |
| **WARD** | Persons who are wards of the State or any other agency, institution, or entity. |
| **WBC** | white blood cell |
| **Within-participants Design** | A research design in which each participant experiences, at different times, all levels of the independent variable (or both the experimental and control treatment). Thus, each participant is tested once in each condition |