

The following vocabulary substitutions should be considered when writing a consent document.

1. **ABRASION** area where skin or other tissue is scraped away
2. **ABSORPTION** the way a drug or other substance enters the body
3. **ACUTE** lasting a short time but often causing a serious problem
4. **ADHESION** being stuck together
5. **ADRENAL GLAND** gland found over each kidney
6. **ADVERSE EFFECT** An effect upon your well being that may or may not be due to research participation
7. **AMNIOCENTESIS** removal of some of the water from around an unborn baby for laboratory testing
8. **ANALGESIC** drug used to control pain
9. **ANEMIA** decreased number of red blood cells
10. **ANESTHESIA** loss of sensation or feeling
11. **ANESTHETIC** drug is used to keep a person from feeling pain
12. **ANGIOPLASTY** operation to open up a narrowed blood vessel
13. **ANOXIA** no oxygen
14. **ANTACID** drug used to decrease acid in the stomach
15. **ANTIBIOTIC** drug used to stop or slow down the growth of bacteria and germs
16. **ANTIBODY** type of protein that helps protect the body against foreign matter, such as bacteria and viruses
17. **ANTIHIISTAMINE** drug used to treat allergic reactions
18. **ANTISEPTIC** substance used to stop or slow down the growth of germs
19. **APHASIA** not able to speak or write and not able to understand spoken or written words
20. **ARTERY** type of blood vessel that carries blood and oxygen from the heart to the rest of the body
21. **ARTHRITIS** swelling of one or more joints
22. **ASPHYXIA** suffocation, unable to get enough oxygen
23. **ASSAY** lab test
24. **ASSENT** agreement
25. **ATROPHY** wasting away or decrease in size
26. **AUDIOGRAM** report of a hearing test
27. **AUDIOLOGY** the study of hearing
28. **AUDIOMETER** tool used to measure hearing
29. **AUTONOMY** being able to make one's own decisions
30. **BACTERIA** microscopic creatures that live in and around us; they sometimes cause disease

31.	<b>BENEFIT</b>	a valued or desired outcome; an advantage
32.	<b>BENIGN</b>	something that has no bad effects or does not spread
33.	<b>BETA BLOCKER</b>	drug used to slow down the heart
34.	<b>BILATERAL</b>	having to do with both sides (of the body)
35.	<b>BIOLOGIC</b>	any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries
36.	<b>BIOPSY</b>	removal of tissue so it can be looked at under a microscope
37.	<b>BOLUS</b>	an amount given all at once
38.	<b>BONE MARROW</b>	soft tissue inside bones that makes blood cells
39.	<b>BRONCHITIS</b>	inflammation of the lungs
40.	<b>BRONCHUS</b>	tube that carries air from the windpipe to the lungs
41.	<b>BULIMIA</b>	eating disorder in which a person cannot stop eating and often vomits to make room for more food
42.	<b>CALCIPENIA</b>	low in calcium
43.	<b>CANCER RADIOTHERAPY</b>	treatment of cancer using X rays
44.	<b>CAPILLARY</b>	tiny blood vessel
45.	<b>CARCINOGENIC</b>	causing cancer
46.	<b>CARDIAC</b>	having to do with the heart
47.	<b>CARPAL BONES</b>	wrist bones
48.	<b>CATARACT</b>	clouding of the lens of the eye
49.	<b>CATHETER</b>	flexible tube
50.	<b>CEPHALALGIA</b>	headache
51.	<b>CEREBELLUM</b>	the part of the brain that controls the movement of the muscles and helps maintain balance
52.	<b>CHEMOTHERAPY</b>	treatment of disease using drugs
53.	<b>CHLOASMA</b>	tumor arising from the skin and other organs
54.	<b>CHRONIC</b>	lasting a long time
55.	<b>CLAVICLE</b>	collarbone
56.	<b>CLINICAL TRIAL</b>	an experiment with patients
57.	<b>COGNITIVELY IMPAIRED</b>	having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.
58.	<b>COHORT</b>	A group of subjects that have one or more characteristics in common and are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.
59.	<b>COMPENSATION</b>	Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research (Compare: Remuneration).
60.	<b>COMPETENCE</b>	Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice (See also: Incompetence, Incapacity).

61.	<b>CONFIDENTIALITY</b>	Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.
62.	<b>CONTRAINDICATED</b>	disadvantageous, perhaps dangerous; a treatment that should not be used in certain individuals or conditions due to risks (e.g., a drug may be contraindicated for pregnant women and persons with high blood pressure).
63.	<b>CONTRAINDICATIONS</b>	medical reasons that prevent a person from using a certain drug or treatment
64.	<b>CONTROL (SUBJECTS) OR CONTROLS</b>	Subject(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of subjects is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled.
65.	<b>CONTROLLED TRIAL</b>	study in which the experimental procedures are compared to a standard (accepted) treatment or procedure
66.	<b>CONTUSION</b>	bruise
67.	<b>CORNEA</b>	clear tissue covering the front part of the eye
68.	<b>CROSS-OVER DESIGN</b>	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.
69.	<b>CULTURE</b>	test for infection, or organisms that could cause infection
70.	<b>CUMULATION</b>	increased action of a drug when given over a period of time
71.	<b>CYTOID</b>	like a cell
72.	<b>DATA AND SAFETY MONITORING BOARD</b>	A committee of scientists, physicians, statisticians, and others that collect and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.
73.	<b>DEOXYRIBONUCLEIC ACID (DNA)</b>	material that makes up the genes
74.	<b>DEPRESSANT</b>	drug that slows down the action of the central nervous system
75.	<b>DHHS</b>	A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).
76.	<b>DIAGNOSTIC (PROCEDURE)</b>	tests used to identify a disorder or disease in a living person
77.	<b>DOUBLE BLIND TRIAL</b>	See Double-Masked Design
78.	<b>DOUBLE-MASKED DESIGN</b>	A study design in which neither the investigators nor the subjects know the treatment group assignments of individual subjects. Sometimes referred to as "double-blind."
79.	<b>DUCT</b>	tube that carries a body fluid
80.	<b>DYSPLASIA</b>	abnormal cells
81.	<b>EDEMA</b>	increased fluid
82.	<b>EFFICACY</b>	effectiveness
83.	<b>ELECTROCARDIOGRAM (ECG)</b>	picture of the electrical action of the heart
84.	<b>ELECTROENCEPHALOGRAPH (EEG)</b>	picture of brain wave activity
85.	<b>EMBOLUS</b>	blood clot

86.	<b>EMESIS</b>	vomiting
87.	<b>ENDORPHIN</b>	substance made by the body to stop pain
88.	<b>EPIDERMAL</b>	having to do with the outer layer of skin
89.	<b>EPIDERMIS</b>	outer layer of skin
90.	<b>ESOPHAGUS</b>	tube that goes from the throat to the stomach
91.	<b>EXPANDED AVAILABILITY</b>	Policy and procedure that permits individuals who have serious or life-threatening diseases for which there are no alternative therapies to have access to investigational drugs and devices that may be beneficial to them. Examples of expanded availability mechanisms include Treatment INDs, Parallel Track, and open study protocols.
92.	<b>EXPERIMENTAL</b>	Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness. (See also: Research.)
93.	<b>EXPERIMENTAL STUDY</b>	A true experimental study is one in which subjects are randomly assigned to groups that experience carefully controlled interventions manipulated by the experimenter according to a strict logic allowing causal inference about the effects of the interventions under investigation. (See also: Quasi-Experimental Study).
94.	<b>EXTRAVASATE</b>	to leak outside of a blood vessel
95.	<b>FDA</b>	Food and Drug Administration; an agency of the federal government that regulates food, drugs, medical devices, cosmetics, and other products to make sure they are safe and effective to use
96.	<b>FETAL MATERIAL</b>	The placenta, amniotic fluid, fetal tissue membranes, and umbilical cord
97.	<b>FETUS</b>	The product of conception from the time of implantation until delivery. If the delivered or expelled fetus is viable, it is designated an infant [45 CFR 46.203(c)]. The term "fetus" generally refers to later phases of development; the term "embryo" is usually used for earlier phases of development.
98.	<b>GENE THERAPY</b>	treatment of genetic disease accomplished by altering the genetic structure of either somatic (nonreproductive) or germline (reproductive) cells
99.	<b>GENETIC SCREENING</b>	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
100.	<b>GENOTYPE</b>	the genetic makeup of an individual.
101.	<b>GLUCOSE</b>	type of sugar found in the blood
102.	<b>GUARDIAN</b>	an individual who is authorized under state or local law to give permission on behalf of a child or an adult who is not able to make decisions.
103.	<b>GYNECOLOGIST</b>	doctor who specializes in treating a woman's organs that are related to pregnancy and childbirth
104.	<b>GYNECOLOGY</b>	the study of the reproductive system of women
105.	<b>HEMATOLOGIST</b>	doctor who treats blood disorders
106.	<b>HEMATOMA</b>	a bruise, a black and blue area
107.	<b>HEPARIN LOCK</b>	needle placed in the arm with blood thinner to keep the blood from clotting
108.	<b>HUMAN SUBJECTS</b>	people who take part in a research study by letting an investigator gather information about how they answer questions, respond to certain situations or react to an experimental product.
109.	<b>HYPEROPIA</b>	farsightedness
110.	<b>HYPERTENSION</b>	high blood pressure
111.	<b>HYPODERMIC</b>	under the skin
112.	<b>HYPOGLYCEMIA</b>	not enough sugar in the blood
113.	<b>HYPOTENSION</b>	low blood pressure

114.	<b>HYPOTHERMIA</b>	low body temperature
115.	<b>IDIOSYNCRASY</b>	rare side effect of a drug; unusual reaction of a person to a drug
116.	<b>IN VITRO</b>	literally, "in glass" or "test tube" used to refer to processes that are done outside the living body, usually in the laboratory, as distinguished from in vivo.
117.	<b>IN VIVO</b>	literally, "in the living body" processes, such as the absorption of a drug by the human body, carried out in the living body rather than in a laboratory (in vitro).
118.	<b>INCAPACITY</b>	Refers to a person's mental status and an 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 (See also: Incompetence).
119.	<b>INCOMPETENCE</b>	Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. (See also: Incapacity.)
120.	<b>INFLAMMATION</b>	swelling, redness, and pain in tissues caused by injury or damage
121.	<b>INFLUENZA</b>	the flu
122.	<b>INFORMED CONSENT</b>	A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25].
123.	<b>INSTITUTIONAL REVIEW BOARD</b>	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
124.	<b>INTRAMUSCULAR (IM) INJECTION</b>	injection of a substance into a muscle (e.g., upper arm or backside)
125.	<b>INTRAVENOUS (IV) INJECTION</b>	injection of a substance into a vein
126.	<b>INVESTIGATOR</b>	In clinical trials, an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions (e.g., drugs) involved in the study are administered to subjects under the immediate direction of the investigator (See also: Principal Investigator).
127.	<b>LACTATING</b>	making milk
128.	<b>LACTATION</b>	period of time during which a woman is providing her breast milk to an infant or child
129.	<b>LATERAL</b>	toward or having to do with one side (of the body)
130.	<b>LEGALLY AUTHORIZED REPRESENTATIVE</b>	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
131.	<b>LESION</b>	abnormal area of tissue, such as a wound, sore, rash, or boil
132.	<b>LIBIDO</b>	sexual desire
133.	<b>LIPID</b>	fat
134.	<b>LYMPHOMA</b>	cancerous growth made up of lymph tissue
135.	<b>MACRO</b>	large or long
136.	<b>MAGNETIC RESONANCE IMAGING</b>	produces multiple images of organs and structures within the body by using a large magnet to attract electrons within the body used; as a diagnostic tool (See also MRI).
137.	<b>MASKED STUDY DESIGNS</b>	Study designs comparing two or more interventions in which either the investigators, the subjects, or some combination thereof do not know the treatment group assignments of individual subjects. Sometimes called "blind" study designs(See also: Double-Masked Design; Single-Masked Design).
138.	<b>MASTECTOMY</b>	surgery to remove a breast
139.	<b>MEDICAL DEVICE</b>	a product, such as crutches, an x-ray machine, pacemaker, toothbrush, bandage, contact lenses, etc., that is used in treatment, prevention, or diagnosis of a medical

		condition and does not act on the body through chemical action.
140.	<b>MONITOR</b>	check on, keep track of, watch carefully
141.	<b>MORBIDITY</b>	undesired result or complication
142.	<b>MORTALITY</b>	death or death rate
143.	<b>MRI (MAGNETIC RESONANCE IMAGING)</b>	the use of magnetic waves to look at soft tissues of the body
144.	<b>MUCOID</b>	slimy
145.	<b>MYOPIA</b>	nearsightedness
146.	<b>NASO-GASTRIC TUBE</b>	Tube that goes through the nose and into the stomach
147.	<b>NECROSIS</b>	death of tissue or skin
148.	<b>NEUROLOGIST</b>	doctor who treats disorders of the central nervous system and nerves
149.	<b>NEUROSIS</b>	mental and emotional disorder
150.	<b>NUREMBERG CODE</b>	A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.
151.	<b>ONCOLOGY</b>	the study of cancer
152.	<b>OPEN DESIGN</b>	An experimental design in which both the investigator(s) and the subjects know the treatment group(s) to which subjects are assigned
153.	<b>OPHTHALMOLOGIST</b>	doctor who treats eye disorders
154.	<b>ORAL ADMINISTRATION</b>	giving a drug by mouth
155.	<b>ORTHODONTIST</b>	dentist who treats teeth and jaw disorders
156.	<b>ORTHOPEDIST</b>	doctor who treats bone and joint disorders
157.	<b>OTOLOGIST</b>	doctor who treats disorders of the ear
158.	<b>OTORHINOLARYNGOLOGIST</b>	doctor who treats disorders of the ear, nose, and throat
159.	<b>OTOSCOPE</b>	tool used to look into the ear
160.	<b>PAP TEST</b>	microscope test used to detect virus infection of the cervix or cancer of the vagina, cervix, or lining of the uterus (Also called Pap Smear).
161.	<b>PATHOGENIC</b>	causing disease
162.	<b>PERCUTANEOUS</b>	through the skin
163.	<b>PHALANX</b>	finger or toe bone
164.	<b>PHARYNX</b>	throat
165.	<b>PHASE 1 DRUG TRIAL</b>	The first use of a new drug in humans happens in a Phase 1 study. These studies are usually conducted with healthy volunteers; but if a drug is very poisonous, or is used to treat a deadly disease, sick patients who have that disease might be subjects. Usually, there are about 20 – 80 human subjects in Phase 1 studies. Phase 1 trials are conducted to see how the drug acts in the body, if it is safe to use, and to find out the safe dose range. If the results of the Phase 1 studies are good, testing continues in Phase 2 studies.
166.	<b>PHASE 2 DRUG TRIAL</b>	Phase 2 trials include controlled clinical studies to see if a new drug is effective to treat for a particular disease or condition, therefore, the subjects who are given the drug have the condition that the drug is supposed to treat. The side effects are also studied, and more information is gathered about the best dose. Phase 2 studies are also conducted with a relatively small number of patients, usually involving no more than several hundred subjects. If the evidence from the Phase 2 studies show that a drug is probably effective and relatively safe, Phase 3 studies are conducted.
167.	<b>PHASE 3 DRUG TRIAL</b>	During Phase 3 trials, the new drug is given to a larger number of patients in different clinical settings to gather as much information as possible about the drug's safety and effectiveness, the best dosage, and to gather labeling information.

Investigators also want to make sure that the drug has more benefits than risk. For example, a drug meant to treat a deadly disease, like some cancers, may have very bad side effects. But, if it can stop the cancer, the side effects may be considered acceptable. On the other hand, even if a drug is very effective in the treatment of a common headache, for example, but has bad side effects, that drug would be considered too toxic (poisonous) to be used to treat that condition.

In Phase 3 studies, the drug is used the way it would be administered when marketed. When these studies are completed and the sponsor believes that the drug is safe and effective, the sponsor applies to the FDA for approval to market the drug. Phase 3 trials usually involve several hundred to several thousand patient-subjects.

168.	<b>PHASE 4 DRUG TRIAL</b>	As a condition of approval, FDA may want more studies to get additional information about the drug's risks, benefits, and optimal use. These studies, which are Phase 4 trials, could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, studying the drug in other patient populations or other stages of the disease, or studying the drug when given over a longer period of time than recommended on the label.
169.	<b>PLACEBO</b>	Something that appears to be real, but is fake. In a clinical trial, one group of subjects (the control group) may be given a placebo and another group (the treatment group) is given active treatment to find out if the experimental drug is any better than no treatment and to see if the effects are the result of imagination or anticipation rather than actual power of a drug.  (A placebo is often referred to as a "sugar pill". A placebo probably doesn't have any sugar in it, and it doesn't even have to be a pill.)
170.	<b>PODIATRIST</b>	foot doctor
171.	<b>POLYDIPSIA</b>	too much thirst
172.	<b>POSTPARTUM</b>	after childbirth
173.	<b>POTENTIATION</b>	increase in drug action from using two drugs together instead of using each drug alone
174.	<b>PRINCIPAL INVESTIGATOR</b>	The scientist or scholar with primary responsibility for the conduct of a research project (See also: Investigator).
175.	<b>PRN</b>	as needed
176.	<b>PROCTOLOGIST</b>	doctor who treats disorders of the rectum and anus
177.	<b>PROGNOSIS</b>	forecast of the probable outcome of a disease
178.	<b>PROSPECTIVE STUDIES</b>	Studies that gather information about events that occur after the identification of the group of subjects to be studied. Prospective studies may involve intervention (like administration of a drug) or may be purely observational or may involve only the collection of data.
179.	<b>PROSTHESIS</b>	artificial body part
180.	<b>PROTOCOL</b>	The plan of study. The protocol includes a description of what the research hopes to prove, how the study will be carried out, etc.
181.	<b>PROXIMAL</b>	nearest
182.	<b>PRURITUS</b>	itchiness
183.	<b>PSYCHOLOGIST</b>	doctor who helps people understand the workings of the mind, thought, and behavior
184.	<b>PSYCHOSIS</b>	severe mental disorder; craziness
185.	<b>PSYCHOSOMATIC</b>	having a connection between the mind and physical symptoms
186.	<b>PULMONARY NEOPLASM</b>	lung tumor
187.	<b>RANDOM</b>	by chance, like the flip of a coin
188.	<b>RELAPSE</b>	the return of a disease
189.	<b>RENAL</b>	having to do with the kidney

190.	<b>RESEARCH</b>	a systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to general knowledge
191.	<b>RETROSPECTIVE</b>	looking back over past experience
192.	<b>RISK</b>	the probability of harm or injury (physical, psychological, social, economic) occurring as a result of participation in a research study
193.	<b>SCAPULA</b>	shoulder blade
194.	<b>SERUM</b>	clear liquid part of blood
195.	<b>SHUNT</b>	artificial or natural channel running between two other channels
196.	<b>SINGLE-BLIND</b>	Typically, a study design in which the investigator, but not the subject, knows the identity of the treatment assignment. Occasionally the subject, but not the investigator, knows the assignment.
197.	<b>SLEEP APNEA</b>	breathing problems while sleeping
198.	<b>SOMATIC</b>	having to do with the body
199.	<b>SPONSOR (OF A DRUG TRIAL)</b>	A person or entity that initiates and pays for a clinical investigation of a drug — usually the drug manufacturer or research institution that developed the drug. The sponsor provides the protocol (study plan), makes sure the study is conducted according to the plan, and enforces compliance with applicable laws and regulations. The sponsor usually obtains FDA approval to conduct a trial and for reporting the results of the trial to the FDA.
200.	<b>STERNUM</b>	breastbone
201.	<b>SUBCUTANEOUS (SC)</b>	under the skin
202.	<b>SUBLINGUAL</b>	under the tongue
203.	<b>SYNDROME</b>	set of signs that happen at the same time in the body
204.	<b>THORAX</b>	the chest
205.	<b>TITRATION</b>	slow increase or decrease in drug dosage, guided by patient's responses
206.	<b>TOLERANCE</b>	decrease in response to a fixed dosage of drug; over time, higher and higher doses of a drug are needed to get the desired effect
207.	<b>TOPICAL APPLICATION</b>	giving a medication by putting it directly on the skin
208.	<b>TOXICITY</b>	any harmful effect of a drug or poison
209.	<b>TRACHEA</b>	windpipe
210.	<b>TRANQUILIZER</b>	drug used to control anxiety
211.	<b>TRANSDERMAL</b>	through the skin
212.	<b>UROLOGIST</b>	doctor who treats disorders of the urinary tracts of men and women
213.	<b>VOLUNTARY</b>	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.