

DEFINITIONS OF COMMON RESEARCH-RELATED TERMS

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).

Adverse Effect: An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention.

Anonymity: Anonymity exists when there are no identifiers on project materials that could link the data with individual subjects. Even the research investigator cannot know the identity of participants.

Assent: Agreement to participate in proposed research, given by an individual not competent to give legally valid informed consent (e.g., a child or mentally limited person). Mere failure to object may not be construed as assent.

Assurance: A formal, written statement submitted to a federal agency attesting that an institution will comply with applicable rules governing research with human subjects.

Autonomy: Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

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

Benefit: A valued or desired outcome. An advantage.

Biologic: Any virus, therapeutic serum, toxin, antitoxin or analogous product used for the prevention, treatment or cure of diseases or injuries of humans.

Case Report Forms: The study-specific forms used for data collection during a research trial.

Children: Those who have not attained the legal age for consent to treatments or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted.

Class I, II, III Devices: Classification by the FDA of medical devices according to degree of potential risks or hazards.

Clinical Research Associate (CRA): An individual who represents the sponsor and who is responsible for the accuracy and management of data and overall supervision of day-to-day activities of the study. Also called a monitor.

Clinical Trial: A controlled study involving human subjects, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.

Code of Federal Regulations (CFR): A compendium of rules issued by federal agencies on a multiplicity of topics.

Cognitively Impaired: Having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., 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.

Cohort: A group of subjects initially identified as having one or more characteristics in common who are followed over time.

Common Rule: See Federal Policy.

Compensation: Payment or medical care provided to subjects injured in research. Does not refer to payments (remuneration) for participation in research.

Competence: 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. Competence may fluctuate as a function of the natural course of a mental illness, response to treatment, effects of medication, general physical health and other factors. Therefore, mental status should be reevaluated periodically. As a designation of legal status, competence or incompetence pertains to an adjudication in court proceedings that a person's abilities are so diminished that his or her decisions or actions (e.g., writing a will) should have no legal effect. Such adjudications are often determined by inability to manage business or monetary affairs and do not necessarily reflect a person's ability to function in other situations.

Confidentiality: Right of privacy and of non-release of disclosed personal information. The investigator should protect subjects against invasion of privacy and loss of confidentiality. Lack of secure handling of completed personality tests, questionnaires, interview protocols or data and recorded materials augments risk and must be avoided.

Contract: 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: Pertains to the use of a treatment that should not be used in certain individuals or conditions due to risks that are disadvantageous, or, perhaps, dangerous results.

Control: Subjects who are not given a treatment under study or do not have a given disorder, background or risk that is the object of study, and who are comparable to subjects in the study.

Crossover Design: A type of clinical trial in which each subject is given, at different times, both an experimental and a control therapy.

Data Points: Any text or numbers generated during a study.

Data and Safety Monitoring Board (DSMB): A committee of scientists, physicians, statisticians and others that collect and analyze data during the course of a clinical trial to monitor for adverse effects and other trends that would warrant modification or termination of the trial or notification of the subjects about new information that might affect their willingness to continue in the trial.

Declaration of Helsinki: A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associates in various countries. It has been revised several times, most recently in 2000.

Dependent Variables: The outcomes that are measured in an experiment. Dependent variables are expected to change as a result of an experimental manipulation of the independent variable(s).

Descriptive Study: A study that is not truly experimental (e.g., quasi-experimental, correlation, record review, case history, observational).

Diagnostic Procedure: A test used to identify a disorder or disease in a living person.

Double-blind Design: A study comparing two or more treatments in which neither the investigators nor the subjects know to which treatment group individual subjects have been assigned.

Drug: Any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.

Emancipated Minor: A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law, but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as self-support, marriage or procreation.

Emergency Use: Use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain prospective IRB approval.

Epidemiology: A scientific discipline that studies the factors determining the causes, frequency, and distribution of diseases in a community or given population.

Equitable: Fair or just. Used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.

Exclusion Criteria: A list of specific conditions which make an individual ineligible to enroll in a research study.

Exculpatory: Pertaining to that which relieves of a responsibility, obligation or hardship; clearing from accusation or blame.

Expanded Availability: Policy and procedures that permit individuals who have serious or life-threatening disease for which there are no alternative therapies to have access to investigational drugs and devices that may be beneficial to them. Examples are Treatment INDs and Parallel Track INDs.

Experimental: A term often used to denote a therapy (drug, device or procedure) that is unproven or scientifically unvalidated with respect to safety and efficacy. A procedure may be considered “experimental” without necessarily being part of a formal study to evaluate its usefulness.

Experimental Study: A true experimental study is one in which subjects are randomly assigned to groups that experience carefully controlled interventions manipulated by the investigator according to a strict logic that allows causal inference about the effects of the interventions under investigation.

Federal Policy: Federal regulations governing the involvement of human subjects in research. The Policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by and federal department or agency that takes appropriate administrative action to make the Policy applicable to such research. Currently, sixteen federal agencies have adopted the Federal Policy. For this reason, it is also known as the Common Rule.

Fetal Material: The placenta, amniotic fluid, fetal membranes and the umbilical cord.

Fetus: The product of conception from the time of implantation until a determination is made, following expulsion or extraction, that it is viable. The term “fetus” generally refers to later phases of development. The term “embryo” is usually used for earlier phases of development.

Food and Drug Administration (FDA): The federal agency responsible for enforcing the Food and Drug laws enacted by Congress regarding the research, manufacture, and safety of food and drugs.

Form FDA 1572: A form testifying to the investigator’s agreement to follow the protocol and the FDA requirements for investigators. Also called the “Statement of Investigator.”

Genotype: The genetic constitution of an individual.

Good Clinical Practices (GCPs): Practices and actions which encompass the Helsinki Statement and are defined by the Federal Regulations that must be followed in any clinical trial to ensure the quality of data and the safety of study participants.

Grant: Financial support provided for a 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.

Guardian: A person who is authorized by law to consent on behalf of a child or handicapped individuals to general medical care.

Historical Controls: Control subjects (followed at some time in the past or for whom data are available through records) who are used for comparison with subjects being treated concurrently. (Note: the condition of subjects may be compared with their own condition on a prior regimen, the effectiveness of which has already been established.)

Hypothesis: The proposition, to be tested statistically, about the expected outcome of the study.

Human Subject: Under DHHS regulations human subjects are living individuals about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual or 2) identifiable private information. Intervention includes both the physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact (e.g., questionnaires, interviews) between the investigator and the subject (45 CFR 46.102). Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject 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 subjects.

Under FDA regulations a human subject is defined as “an individual who is or becomes a participant in research, either as a recipient of a test article or as a control (21 CFR 50.03, 21 CFR §56.103(e), 21 CFR §312.3(b)). A subject may be either a healthy individual or a patient.” If the research involves a medical device, human subjects are individuals when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control (21 CFR §812.3(p)).

Human in vitro Fertilization: Any fertilization involving human sperm and ova that occurs outside the human body.

Incapacity: Refers to a person’s mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information and to make a choice. Often used as a synonym for incompetence.

Inclusion Criteria: A list of specific conditions that an individual must meet to enroll in a research study.

Incompetence: Legally, the inability to manage one’s affairs. Often used as a synonym for incapacity.

Infant: An ex utero fetus judged viable (i.e., likely to survive to the point of sustaining life independently).

Informed Consent: Informed consent means “knowing consent,” the exercise of a free power of choice without undue inducement, force, fraud, deceit, duress or other form of constraint or coercion. If the subjects are minors or are not capable of giving consent, parental, guardian or other legal representative consent is required. Use of a written consent form that includes all of the basic elements of informed consent must be documented by a signature of the subject or legally authorized representative.

Institution: A residential facility that provides food, shelter and professional services (including treatment, skilled nursing, intermediate or long-term care and custodial or residential care). Examples include general, mental or chronic disease hospitals, inpatient community mental health centers, halfway houses and nursing homes, alcohol and drug addiction treatment centers, homes for the aged or dependent, residential schools for the mentally or physically handicapped, and homes for dependent and neglected children.

Institutional Review Board: A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in research.

Institutionalized: Confined, either voluntarily or involuntarily (e.g., a hospital, prison, or nursing home).

Interaction: Interaction includes communication or interpersonal contact between investigator and subject.

Intervention: Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Investigational Device: A medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device.

Investigational Device Exemptions (IDE): Exemptions from certain regulations found in the Medical Device Amendments that allow shipment of unapproved devices for use in clinical investigations.

Investigational New Drug (IND): A drug permitted by the FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population, and thus, not yet licensed for marketing.

Investigational New Drug (IND) Application: A document compiled by a sponsor and submitted to the FDA to register a drug for human testing. It is required before clinical testing can begin.

Investigational New Drug (IND) Safety Report: A sponsor's written notification to the FDA and all participating investigators of any adverse event that is both serious and unexpected associated with the study medication used in clinical trials conducted under an IND.

Investigator: Clinician responsible for conducting the study.

Investigator's Brochure: A manual that guides the investigator in conducting a clinical trial. It summarizes the research information to date and gives data on the drug chemistry, formulation, dosage, and route of administration.

In vitro: Used to refer to processes that are carried out outside the living body, usually in the laboratory, as distinguished from in vivo.

In vivo: Processes, such as the absorption of a drug by the human body, carried out in a living body rather than in vitro.

IRB: See Institutional Review Board.

Justice: An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

Lactation: The period of time during which a woman is providing her breast milk to an infant or child.

Lead Compound: The promising therapeutic agent that is identified by the sponsor and becomes the focus of drug development research.

Legally Authorized Representative: A person authorized either by statute or by court appointment to make decisions on behalf of another person.

Longitudinal Study: A study designed to follow subjects forward through time.

Mature Minor: Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care). Note that a mature minor is not necessarily an emancipated minor.

Medical Devices: Diagnostic or therapeutic articles that do not interact chemically with the body. Such devices may include diagnostic test kits, crutches, electrodes, prescribed beds, pacemakers, arterial grafts, intraocular lenses and orthopedic pins.

Minimal Risk: 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.

Monitor: Designated individual selected by a sponsor or contract research organization to oversee the progress of a clinical investigation.

New Drug Application (NDA): Request for FDA approval to market a new drug.

Nonaffiliated Member: Member of an institutional review board who has no ties to the institution, its staff or faculty. This individual is usually from the local community.

Nonsignificant Risk Device: An investigational medical device that does not present significant risk as described above. The determination that a device presents a nonsignificant risk is first made by the sponsor. If the IRB agrees with the sponsor's finding that a device presents nonsignificant risk, the device is considered a nonsignificant risk device.

Normal Subject: Subjects used in study of normal physiology and behavior, or subjects who do not have the condition under study in a particular protocol used as comparisons with subjects who do have the condition. "Normal" does not necessarily connote normal in all respects. For example, patients with broken legs may serve as normal volunteers in studies of metabolism, cognitive development and the like. Similarly, patients with heart disease but without diabetes may be "normals" in a study of diabetes complicated by heart disease.

Null Hypothesis: The proposition, to be tested statistically, that the experimental intervention has no effect, meaning that the treatment and control groups will not differ as a result of the intervention. Investigators usually hope that the data will demonstrate some effect from the intervention, thereby allowing the investigator to reject the null hypothesis.

Nuremberg Code: A code of research ethics developed during the trials of the Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.

Office for Human Research Protections (OHRP): The office within the Department of Health and Human Services (DHHS) responsible for implementing DHHS regulations governing research involving human subjects.

Open Design: An experimental design in which both the investigator(s) and the subjects know the treatment group to which subjects are assigned.

Parent: A child's biological or adoptive parent.

Permission: The agreement of the parent(s) or guardian to the participation of the child, handicapped individual, or ward in the research.

Pharmacokinetic: Related to the absorption, distribution, metabolism and elimination of drugs by the body.

Pharmacology: The scientific discipline that studies the action of drugs on living systems (animals or humans).

Phase I (Clinical) Trial: The first stage in testing an unapproved (by the FDA) drug in man. The drug is administered to a small number of normal subjects to generate preliminary information on its safe dosage,

toxicity, tolerance, absorption and metabolism. However, in some instances, if the drug is intended to treat a specific disease, it may be appropriate to test the drug in patients with that disease.

Phase II (Clinical) Trial: The second stage in testing a new drug in man generally carried out on patients with the disease or condition of interest to obtain information on the treatment efficacy and to supplement information on safety obtained from Phase I trial.

Phase III (Clinical) Trial: The third and usually final stage in testing a drug in man. The study is designed to include a control treatment and random allocation to treatment on a large subject population in different clinical settings. The drug is used as would be when marketed and the study is primarily concerned with assessments of dosage effects and efficacy and safety. Once this phase is completed, the drug manufacturers may request permission to market the drug by submission of a New Drug Application to the FDA.

Phase IV (Clinical) Trial: Generally carried out after FDA approval and licensure of the drug for that indication. The study is a randomized controlled trial designed to evaluate the long-term safety and efficacy of a drug for the given information.

Phlebotomist: An individual trained to draw blood.

Physical Risk: Any strenuous or unusual physical activity or procedure required of a subject, use of compounds that might alter the subject's biochemical milieu, exposure to strong stimulation or placement in a situation that could lead to violence. The investigator is responsible for anticipating circumstances which might endanger the subject's physical well being and for bringing these circumstances to the attention of the IRB.

Physiological Risk: Any experimental condition that induces personality change or intense changes in a subject's feelings or motivations, or that may induce such changes that extend beyond the experimental or debriefing period. Subjection to deceit, to demeaning or dehumanizing procedures, to humiliation and embarrassment. The investigator has the responsibility to eliminate or minimize the effects of psychological risk to subjects and to bring these matters to the attention of the IRB.

Placebo: An inactive or inert substance, identical in appearance to the active form of the drug. It is administered to patients to determine whether effects observed during clinical trials are actually caused by the study drug or by the psychophysiological (psychosomatic) effects of the treatment.

Preclinical Investigations: Laboratory and animal studies designed to test the mechanisms, safety and efficacy of an intervention prior to its application in humans.

Pregnancy: The period from confirmation of implantation of a fertilized egg within the uterus until the fetus has entirely left the uterus (i.e., has been delivered). Although fertilization occurs a week or more before implantation, the current inability to detect the fertilization event or the presence of a newly fertilized egg makes a definition of pregnancy based on implantation necessary.

Pre-market Approval: Process of scientific and regulatory review by the Food and Drug Administration to ensure the safety and effectiveness of Class III devices.

Principal Investigator: The scientist or scholar with primary responsibility for the design and conduct of a research project.

Prisoner: An individual involuntarily confined in a penal institution, including persons (a) sentenced under a criminal or civil statute, (b) detained pending arraignment, trial or sentencing, and (c) 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 penal institution [45 CFR 46.303(c)].

Private Information: Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject 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 subjects.

Proband: The person whose case serves as the stimulus for the study of other members of the family to identify the possible genetic factors involved in a given disease, condition or characteristic.

Prospective Studies: Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. These studies need not involve manipulation or intervention, but may be purely observational or involve only the collection of data.

Protocol: A protocol is the researcher's plan of a scientific experiment or treatment. A protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regime(s) and the proposed methods of data analysis.

Public Health Service (PHS): Part of the US Department of Health and Human Services. The PHS includes agencies such as the Food and Drug Administration, the National Institutes of Health and the Centers for Disease Control

Quality Assurance: A system of activities whose purpose is to provide assurance that the overall control of quality is being done effectively.

Quasi-experimental: A study that is similar to a true experimental study except that it lacks random assignments of subjects to treatment groups.

Radiopharmaceuticals: Drugs, compounds, or materials labeled or tagged with a radioisotope. These materials are largely physiological in action and, in many cases, function much like materials found in the body. The principal risk associated with these materials is the radiation exposure to the body or to specific organ systems when they are injected in the body.

Randomization or Randomized Clinical Trials: Assignment of subjects to different treatments, interventions or conditions according to chance rather than with reference to some aspect of their condition, history or prognosis.

Remuneration: Payment for participation in research; however, the term "compensation" is generally used in research.

Research: Under HHS Regulations (46.102) research is defined as a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to "generalizable knowledge." The general rule is that if there is any element of research in an activity, that activity should

undergo review for the protection of human subjects. For example, some “demonstration” and “service” programs may include research activities.

Under FDA Regulations (21 CFR 56.102) the term “clinical investigation” is synonymous with “research” and is defined as “any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Food, Drug and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. Clinical investigations regulated by the FDA under Sections 505(i) and 520(g) of the Act, include investigations of food, dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. The term “clinical investigation” does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part.

Research is subject to 21 CFR Parts 50 and 56 when it involves the use of any drug other than the use of an approved drug in the course of medical practice. Research is subject to 21 CFR Parts 50 and 56 when it involves the use of any medical device other than the use of an approved medical device in the course of medical practice.

Respect for Persons: An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

Retrospective Studies: Research conducted by reviewing records (i.e., birth and death certificates, medical records, school or employment records) or information about past events elicited through interviews with persons who have, and controls who do not have, a disease under investigation.

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. Federal regulations define only “minimal risk.”

Scientific Review Group: A group of highly-regarded experts in a given field, convened by the National Institutes of Health to advise on the scientific merit of applications for research grants. Also known as “study sections.”

Significant Risk Device: An investigational medical device that (1) is intended as an implant and presents a potential for serious risk to the health, safety or welfare of a subject; (2) is purported or represented to be of use in supporting or sustaining human life and presents a potential for serious risk to the health, safety or welfare of a subject; (3) is for a use of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise preventing impairment of human health, and which presents a potential for serious risk to the health, safety or welfare of a subject; (4) otherwise presents a potential for serious risk to the health, safety or welfare of a subject; or (5) other than minimal risk.

Single-blind Design: Typically, a study designed in which the investigator, but not the subject, knows the treatment assignment. Occasionally the subject, rather than the investigator, knows the assignment.

Site Visit: A visit by agency officials, representatives or consultants to the location of a research activity to assess an investigation or the adequacy of IRB protection of human subjects.

Source Documents: The original recording of data about a research participant. Examples of sources documents are: history and physical report; laboratory results; diagnostic test results; physician progress notes; nurses notes; etc.

Sponsor (of a drug trial): The developer of a new drug who distributes it to investigators and physicians for clinical trials, and who is responsible for securing FDA clearance for trials and form reporting the results of those trials to the FDA. A sponsor may be either a private pharmaceutical manufacturer, a research institute, a clinical investigator or a federal agency.

Sponsor: The company/person who initiates the study.

Subject: See Human Subject.

Surveys: Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

Teratogenic: An agent that causes abnormal fetal development.

Terminally Ill: Terminally ill patients are those who are deteriorating from a life-threatening disease or condition for which no effective standard treatment exists.

Test Article: Any drug (including a biological product for human use), medical device for human use, or any other article subject to regulation under the Food, Drug, and Cosmetic Act of 1938 or under sections 351 and 354-360F of the Public Health Service Act.

Therapeutic Intent: The research physician's intent to provide some benefit to improving a subject's condition (e.g., prolongation of life, shrinking of tumor, or improved quality of life, even though cure or dramatic improvement cannot necessarily be effected). This term is sometimes associated with Phase I drug studies in which potentially toxic drugs are given to an individual with the hope of inducing some improvement in the patient's condition, as well as assessing the safety and pharmacology of a drug.

Therapeutic Research: Research involving an intervention that has the likelihood of providing a therapeutic, diagnostic or preventive benefit to the subjects.

Vaccine: A biologic product generally made from an infectious agent or its components (such as a virus, bacterium, or other microorganism) that is killed or weakened. Vaccines may also be biochemically synthesized or made through recombinant DNA techniques.

Vulnerable Subjects: Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, ethnic minority groups, refugees, minors, and those incapable of giving consent.

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.