

## Definitions of Terms Used in Human Subjects Research

1. **Adverse effect:** An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy). IRBs should establish policies and procedures for monitoring such effects in approved studies.
2. **Age of Majority:** Pertains to the acquisition of control over one's person, decisions, and actions, and the correlative termination of the legal authority and responsibility of the parents or guardian(s) over the child's persons and affairs generally. In the State of Alabama and Nebraska, the age of majority is 19, in Mississippi, 21. In other states the age of majority is 18. At the age of majority a subject can sign consent to participate in research. If the subject is under the age of majority, a parent or guardian must sign a parental consent form.
3. **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.
4. **Assurance:** 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 [Federal Policy 46.103].
5. **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.
6. **Autonomy:** Personal capacity to consider alternatives makes choices, and act without undue influence or interference of others.
7. **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.
8. **Beneficence:** 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.
9. **Benefit:** A valued or desired outcome; an advantage.
10. **Biologic:** Any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries.
11. **Blind Study Designs:** See: Masked Study Designs; Double-Masked Design; and Single-Masked Design.
12. **Case-Control Study:** A study comparing persons with a given condition or disease (the cases) and persons without the condition or disease (the controls) with respect to antecedent factors. (See: Retrospective Studies.)

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14. **Certification:** The official notification by the University that a research project or activity involving human subjects has been approved by the IRB.
15. **Children (minors):** Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
16. **Clinical investigation/trial:** A controlled study involving human subjects, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.
17. **Coercion:** persuading an otherwise unwilling person to do something by using force or threats
18. **Cohort:** A group of subjects, initially identified as having one or more characteristics in common, who 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.
19. **Cognitively impaired:** Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. 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.
20. **Compensation:** Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research.
21. **Competency:** 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*.)
22. **Confidentiality:** 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, in ways that are inconsistent with the understanding of the original disclosure, without permission.
23. **Cooperative research projects:** Those projects normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to the grantee or prime contractor (such as a contractor with the grantee, or a subcontractor with the prime contractor).
24. **Control(s):** Subject(s) used for comparison who are not given a treatment under study or 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.

25. **Contraindicated:** 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).
26. **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.
27. **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.
28. **Data and Safety Monitoring Board:** A committee of scientists, physicians, statisticians, and others that collects and analyzes accumulating 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.
29. **Debriefing:** Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from Standard English, in which debriefing is obtaining rather than imparting information.)
30. **Deception:** giving the appearance or perception different from the true one.
31. **Declaration of Helsinki:** A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It was revised in 1975 and 1989.
32. **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).
33. **Descriptive Study:** Any study that is not truly experimental (e.g., quasi-experimental studies, correlational studies, record reviews, case histories, and observational studies).
34. **Device (medical):** Therapeutic, diagnostic, or prosthetic articles which do not interact chemically with the body (e.g., pacemakers, intrauterine contraceptive devices, diagnostic test kits, crutches, artificial joints).
35. **DHEW** A federal agency: U.S. Department of Health, Education and Welfare; reorganized in 1980 as the Department of Health and Human Services (DHHS) and the Department of Education.

36. **DHHS** A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).
37. **Double-Masked Design:** 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." marriage, parenthood, financial independence, or other means, depending on state law.
38. **Emancipated Minor:** A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation. (See also: *Mature Minor*.)
39. **Emergency use:** The 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 IRB approval.
40. **Ethnographic Research:** The study of people and their culture. Ethnographic research, also called fieldwork, involves observation of and interaction with the persons or group being studied in the group's own environment, often for long periods of time. (See also: *Fieldwork*.)
41. **Experimental:** 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*.)
42. **Experimental Study:** A study 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*).
43. **FDA** Food and Drug Administration; an agency of the federal government established by Congress in 1912 and presently part of the Department of Health and Human Services.
44. **Federal Policy (The)** the federal policy that provides regulations for the involvement of human subjects in research. The Policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any 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. (Also known as the "Common Rule.")
45. **FWA:** Federal Wide Assurance. Contract entered between AUM and the OHRP (Office of Human Research Protection/HHS Health and Human Services) to guarantee protections to human subjects in research. FWA approval qualifies an entity to apply for NIH, NSF, etc. funding opportunities.
46. **Fieldwork:** Behavioral, social, or anthropological research involving the study of persons or groups in their own environment and without manipulation for research purposes (distinguished from laboratory or controlled settings). (See also: *Ethnographic Research*.)

47. **Full Board Review:** Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least 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 [Federal Policy 46.108].
48. **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. (*Compare: Contract.*)
49. **Guardian:** An individual who is authorized under applicable state or local law to consent on behalf of another person (i.e., children) to general medical care.
50. **Helsinki Declaration:** *See: Declaration of Helsinki*
51. **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. The study is considered historically controlled when the present condition of subjects is compared with their own condition on a prior regimen or treatment.
52. **Human subject:** A living individual about whom an investigator (professional or student) conducting research obtains: a) data through intervention or interaction with the individual, or b) identifiable, private information.
53. **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. (*See also: Incompetence.*)
54. **Incapacity:** Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. (*See also: Incapacity.*)
55. **Independent Variables:** The conditions of an experiment that are systematically manipulated by the investigator.
56. **Informed consent:** The knowing, legally effective consent of any individual or the individual's legally authorized representative. Such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
57. **Interaction:** The communication or interpersonal contact between investigator and subject.
58. **Intervention:** Includes both physical procedures by which data are gathered (i.e., venipuncture) and manipulation of the subject or the subject's environment that are performed for research purposes.

59. **Investigational (new drug or device):** A drug or device permitted by the FDA to be tested on humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.
60. **Institution (1):** Any public or private entity or agency (including federal, state, and local agencies) [Federal Policy 46.102(b)].
61. **Institution (2):** 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.
62. **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 biomedical or behavioral research [Federal Policy 46.102(g), 46.108, 46.109].
63. **Institutionalized:** Confined, either voluntarily or involuntarily (e.g., a hospital, prison, or nursing home).
64. **Internally Funded:** Funding for the research project is provided by the institution. Examples: department funding, Research Council, etc.
65. **investigator:** 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*.)
66. **IRB** See: *Institutional Review Board*.
67. **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.
68. **Legally Authorized Representative:** 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 research procedure(s).
69. **Longitudinal Study:** A study designed to follow subjects forward through time.
70. **Masked Study Designs:** 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 the individual subjects. Sometimes called "blind" study designs. (See also: *Double-Masked Design*; *Single-Masked Design*.)
71. **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. (See also: *Emancipated Minor*.)

72. **Medical Device:** A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.
73. **Mentally Disabled:** See: *Cognitively Impaired*.
74. **Minimal risk:** Probability and magnitude of physical or psychological harm that does not exceed those encountered in ordinary, everyday life or in the performance of routine medical or psychological examinations.
75. **Monitoring:** The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections.
76. **Non-therapeutic Research:** Research that has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the current subjects, although it may benefit subjects with a similar condition in the future.
77. **Normal Volunteers:** 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.
78. **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.
79. **Nuremberg Code:** 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.
80. **Office for Protections from Research Risks (OPRR):** The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.
81. **Open Design:** An experimental design in which both the investigator(s) and the subjects know the treatment group(s) to which the subjects are assigned.
82. **Parent:** A child's biological or adoptive parent.

83. **Paternalism:** Making decisions for others against or apart from their wishes with the intent of doing them good.
84. **Permission:** The agreement of the parents or guardians to the participation of their child or ward in research.
85. **Pharmacology:** The scientific discipline that studies the action of drugs on living systems (animals or human beings).
86. **Phase 1, 2, 3, 4 Drug Trails:** Different stages of testing drugs in humans, from first application in humans (Phase 1) through limited and broad clinical tests (Phase 3), to post marketing studies (Phase 4).
- a. **PHASE 1 DRUG TRIAL** Phase 1 trials include the initial introduction of an investigational new drug into humans. These studies are typically conducted with healthy volunteers; sometimes, where the drug is intended for use in patients with a particular disease, however, such patients may participate as subjects. Phase 1 trials are designed to determine the metabolic and pharmacological actions of the drug in humans, the side effects associated with increasing doses (to establish a safe dose range), and, if possible, to gain early evidence of effectiveness; they are typically closely monitored. The ultimate goal of Phase 1 trials is to obtain sufficient information about the drug's pharmacokinetics and pharmacological effects to permit the design of well-controlled, sufficiently valid Phase 2 studies. Other examples of Phase 1 studies include studies of drug metabolism, structure-activity relationships, and mechanisms of actions in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects involved in Phase 1 investigations is generally in the range of 20-80.
  - b. **PHASE 2 DRUG TRIAL** Phase 2 trials include controlled clinical studies conducted to evaluate the drug's effectiveness for a particular indication in patients with the disease or condition under study, and to determine the common short-term side effects and risks associated with the drug. These studies are typically well-controlled, closely monitored, and conducted with a relatively small number of patients, usually involving no more than several hundred subjects.
  - c. **PHASE 3 DRUG TRIAL** Phase 3 trials involve the administration of a new drug to a larger number of patients in different clinical settings to determine its safety, efficacy, and appropriate dosage. They are performed after preliminary evidence of effectiveness has been obtained, and are intended to gather necessary additional information about effectiveness and safety for evaluating the overall benefit-risk relationship of the drug, and to provide adequate basis for physician labeling. 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 under specific conditions, the sponsor applies to the FDA for approval to market the drug. Phase 3 trials usually involve several hundred to several thousand patient-subjects.
  - d. **PHASE 4 DRUG TRIAL** Concurrent with marketing approval, FDA may seek agreement from the sponsor to conduct certain postmarketing (Phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use. These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient



populations or other stages of the disease, or use of the drug over a longer period of time [21 CFR 312.85].

87. **PHS** Public Health Service. Part of the U.S. Department of Health and Human Services, it includes FDA, NIH, CDC, SAMHSA, and HRSA.
88. **Placebo**: A chemically inert substance given in the guise of medicine for its psychologically suggestive effect: used in controlled clinical trials to determine whether improvement and side effects may reflect imagination or anticipation rather than the actual power of a drug.
89. **Principal Investigator**: The scientist or scholar with primary responsibility for the design and conduct of a research project.
90. **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 [45 CFR 46.303(c)].
91. **Privacy**: Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
92. **Private Information**: Behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information, provided for specific purposes by an individual, which that individual can reasonably expect will not be made public, (i.e., a medical record.)
93. **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.
94. **Prophylactic**: Preventive or protective; a drug, vaccine, regimen, or device designed to prevent, or provide protection against, a given disease or disorder.
95. **Prospective Studies**: Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data. IRBs should note that prospective studies do *not* qualify for exemption under Federal Policy §45 CFR 46.101(b)(4) because the data or specimens in prospective studies are not extant at the time the study begins.
96. **Protocol**: The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

97. **Purity:** The relative absence of extraneous matter in a drug or vaccine that may or may not be harmful to the recipient or deleterious to the product.
98. **Quasi-Experimental Study:** A study that is similar to a true experimental study except that it lacks random assignment of subjects to treatment groups. (See also: *Experimental Study*.)
99. **Random, Random Assignment, Randomization, Randomized Conditions, and Randomized Trials:** Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematic (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research because it increases the probability that differences observed between subject groups are the result of the experimental intervention.
100. **Remuneration:** Payment for participation in research. (NOTE: The use of the term "compensation" is confined to payment or provision of care for research-related injuries.)
101. **Research:** Systematic investigation designed to develop or contribute to general knowledge. Under this definition some demonstration, service, and training projects may be considered to include research activities.
102. **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.
103. **Retrospective Studies:** Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.
104. **Review (of research):** The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis [Federal Policy 46.108(e)].
105. **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." (See also: *Minimal Risk*.)
106. **SAMHSA** Substance Abuse and Mental Health Services Administration; includes the Center for Substance Abuse Prevention, the Center for Substance Abuse Treatment and the Center on Mental Health Services. Previously the Alcohol, Drug Abuse, and Mental Health Administration.
107. **Scientific Review Group:** A group of highly regarded experts in a given field, convened by NIH to advise NIH on the scientific merit of applications for research grants and contracts. Scientific review groups are also required to review the ethical aspects of proposed involvement of human subjects. Various kinds of scientific review groups exist, and are known by different names in

different institutes of the NIH (e.g., Study Sections, Initial Review Groups, Contract Review Committees, or Technical Evaluation Committees).

108. **Secretary:** A U.S. Cabinet Officer. In the context of DHHS-conducted or -supported research, usually refers to the Secretary of Health and Human Services.
109. **Significant Risk Device:** An investigational medical device that presents a potential for serious risk to the health, safety, or welfare of the subject.
110. **Single-Masked Design:** 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. Sometimes called "single-blind design."
111. **Site Visit:** A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of IRB protection of human subjects or the capability of personnel to conduct the research.
112. **Social Experimentation:** manipulation of, or experimentation in, social or economic systems; used in planning public policy.
113. **Sponsor** (of a drug trial): A person or entity that initiates a clinical investigation of a drug usually the drug manufacturer or research institution that developed the drug. The sponsor does not actually conduct the investigation, but rather distributes the new drug to investigators and physicians for clinical trials. The drug is administered to subjects under the immediate direction of an investigator who is not also a sponsor. A clinical investigator may, however, serve as a sponsor-investigator. The sponsor assumes responsibility for investigating the new drug, including responsibility for compliance with applicable laws and regulations. The sponsor, for example, is responsible for obtaining FDA approval to conduct a trial and for reporting the results of the trial to the FDA.
114. **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.
115. **Statistical Significance:** A determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. Or, more simply put, the probability of coming to a false positive conclusion. [See McLarty (1987), p. 2.] If the probability is less than or equal to a predetermined value (e.g., 0.05 or 0.01), then the null hypothesis is rejected at that significance level (0.05 or 0.01).
116. **Surveys:** Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.
117. **Test article:** Any drug/biological product/medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations.

118. **Therapeutic Intent:** The research physician's intent to provide some benefit to improving a subject's condition (e.g., prolongation of life, shrinkage of tumor, or improved quality of life, even though cure or dramatic improvement cannot necessarily be effected.) This term is sometimes associated with Phase 1 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.
119. **Therapy:** Treatment intended and expected to alleviate a disease or disorder.
120. **Variable** (noun) 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.
121. **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.
122. **Vulnerable Population:** study populations that require special protections as required from OHRP. These include: pregnant women, prisoners, elderly, participants under the age of 19, physically or mentally challenged.