

APPENDIX A. GLOSSARY OF TERMS

ADVERSE EVENT: Any untoward or unfavorable medical occurrence in the human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporarily associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

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.

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 participants and stipulates the procedures through which compliance will be achieved.

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

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.

BENEFIT: A valued or desired outcome; an advantage.

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 also: Retrospective Studies.)

CHILDREN: Persons who have not attained the legal age for consent (18 years in West Virginia) to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted.

CLINICAL TRIAL: A controlled study involving human participants, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.

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, may also be compromised in their ability to make decisions in their best interests.

COHORT: A group of participants 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.

COMPENSATION: Payment or medical care provided to participants injured in research; does not refer to payment (remuneration) for participation in research. (Compare: Remuneration.)

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. (See also: Incompetence, Incapacity.)

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 without permission in ways that are inconsistent with the understanding of the original disclosure.

CONTROL (PARTICIPANTS) or CONTROL: Participant(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 participants is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled.

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).

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

DEBRIEFING: Giving participants 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.)

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.

DESCRIPTIVE STUDY: Any study that is not truly experimental (e.g., quasi experimental studies, correlational studies, record reviews, case histories, and observational studies).

DHHS: A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).

DISSEMINATION: the distribution of findings and includes, but is not limited to, masters theses/dissertations, presentation at a scientific meeting or conference, submission to or publication (paper or electronic) in a scientific journal, and posting on the Internet.

DOUBLE MASKED DESIGN: A study design in which neither the investigators nor the participants know the treatment group assignments of individual participants. Sometimes referred to as "double blind."

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.)

EQUITABLE: Fair or just; used in the context of selection of participants to indicate that the benefits and burdens of research are fairly distributed.

ETHNOGRAPHIC RESEARCH: Ethnography is 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.)

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

EXPERIMENTAL STUDY: A true experimental study is one in which participants 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).

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.)

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.

GUARDIAN: An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care [45 CFR 46.402(3)].

HUMAN PARTICIPANTS: Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human participants are defined as: living individuals(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

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.)

INCOMPETENCE: Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. (See also: Incapacity.)

INFORMED CONSENT: 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, participants 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.

INSTITUTIONAL REVIEW BOARD: A specially constituted review body established or designated by an entity to protect the welfare of human participants recruited to participate in biomedical or behavioral research.

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

INTERVENTION: Both the physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

INTERACTION: Communication or interpersonal contact between an investigator and subject(s).

INVESTIGATOR: In clinical trials, an individual who actually conducts an investigation. Any interventions (e.g., drugs) involved in the study are administered to participants under the immediate direction of the investigator. (See also: Principal Investigator.)

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.

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

LONGITUDINAL STUDY: A study designed to follow participants forward through time. ≡

MASKED STUDY DESIGNS: Study designs comparing two or more interventions in which either the investigators, the participants, or some combination thereof do not know the treatment group assignments of individual participants. Sometimes called "blind" study designs. (See also: Double Masked Design; Single Masked Design.)

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.)

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.

MINIMAL RISK: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. **NOTE:** The definition of minimal risk for research involving prisoners differs somewhat from that given for noninstitutionalized adults.

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

NORMAL VOLUNTEERS: Volunteer participants used to study normal physiology and behavior or who do not have the condition under study in a particular protocol, used as comparisons with participants 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.

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 participants.

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

PERMISSION: The agreement of parent(s) or guardian to the participation of their child or ward in research.

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 actual power of a drug.

PRECLINICAL INVESTIGATIONS: Laboratory and animal studies designed to test the mechanisms, safety, and efficacy of an intervention prior to its applications to humans.

PRINCIPAL INVESTIGATOR: The scientist or scholar with primary responsibility for the design and conduct of a research project. (See also: Investigator.)

PRIVACY: Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

PRIVATE INFORMATION: 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 be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

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

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 participants and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

QUASI EXPERIMENTAL STUDY: A study that is similar to a true experimental study except that it lacks random assignments of participants to treatment groups. (See also: Experimental Study.)

RANDOM, RANDOM ASSIGNMENT, RANDOMIZATION, RANDOMIZED: Assignment of participants to different treatments, interventions, or conditions according to chance rather than systematically (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of participants to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between participant groups are the result of the experimental intervention.

REMUNERATION: Payment for participation in research. (NOTE: It is wise to confine use of the term "compensation" to payment or provision of care for research related injuries.) (Compare: Compensation.)

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

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 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.

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.

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.”

SENSITIVE TOPICS: Includes information that can be difficult for an individual to discuss or that could prove detrimental to the employment, reputation and/or well being of the individual. Sensitive topics include but are not limited to:

- sexual orientation, incest, rape, sexual molestation, deviant sexual behaviors or attitudes regarding sexual conduct (pedophilia, bestiality, etc.), practices of contraception, abortion and/or pregnancy
- substance use and/or abuse including, but not limited to, alcohol, marijuana, steroids, amphetamines, narcotics and any prescription medication legally or illegally obtained
- illegal behaviors
- information that, if released, could damage an individual’s financial standing, employability, or reputation within the community
- information that would normally be recorded in a patient’s medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination
- questions regarding mental health (e.g., suicide, depression, obsessive compulsive behaviors including, but not limited to, gambling, smoking, eating, etc.)
- traumatic experiences of an individual, including war or combat experiences of veterans

SERIOUS ADVERSE EVENT: Any event that:

- (1) results in death;
- (2) is life-threatening;
- (3) results in inpatient hospitalization or prolongation of existing hospitalization;
- (4) results in a persistent or significant disability/incapacity
- (5) results in a congenital anomaly/birth defect; or
- (6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed above.

SINGLE MASKED DESIGN: Typically, a study design in which the investigator, but not the participant, knows the identity of the treatment assignment. Occasionally the participant, but not the investigator, knows the assignment. Sometimes called "single blind design."

SOCIAL EXPERIMENTATION: Systematic manipulation of, or experimentation in, social or economic systems; used in planning public policy.

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

UNANTICIPATED PROBLEM: Any incident, experience, or outcome that meets all of the following criteria:

- (1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- (2) related or possibly related to a subject's participation in the research; and
- (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

UNEXPECTED ADVERSE EVENT: Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:

- (1) the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol's related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
- (2) the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

VOLUNTARY: Free of coercion, duress, or undue inducement. Used in the research context to refer to a participant's decision to participate (or to continue to participate) in a research activity.

VULNERABLE POPULATION: Any member of a group that has limited or diminished capacity to give informed consent. This would include but not be limited to minors (those individuals under 18 years of age), fetuses or the products of labor and delivery, pregnant women if the study may affect maternal health, prisoners, or any other individuals with diminished capacity to give informed consent.