

DEFINITIONS AND TERMS

ADVERSE EVENT: Any untoward occurrence in a research participant. The occurrence need not have a clear causal relationship with the individual's participation in the research; an AE can be any unfavorable and unintended sign, symptom, event or occurrence affecting a participant's physical, mental, social, financial, legal, or psychological well-being. An unanticipated AE should be reported to the Committee as soon as possible after it is identified.

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. An assent is typically paired with a permission from a parent or guardian, and together they comprise the informed consent to participate.

ASSURANCE: A formal written, binding commitment that is submitted to a federal agency in which an institution agrees to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved. UNLV's Assurance is number is FWA00002305 and will expire January 12, 2008.

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. At UNLV the Authorized Institutional Official is Dr. Mark Rudin, Assistant Vice President for Research Services.

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 1979. A summary of the Belmont Report is available at <http://www.fda.gov/oc/ohrt/IRBS/belmont.html>. These principles permeate human subjects research to this day.

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. UNLV's human research application requests information about the direct benefits accruing to the research participants.

CHILDREN: Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.401(a)]. In Nevada, individuals younger than 18 years of age are considered children for most research situations, and informed consent then consists of the child's assent and the parent's permission. (See also: Assent)

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.

COMPENSATION: Payment for participation in research. Compensation should be appropriate for the amount of effort involved, and not excessive and thereby coercive. Compensation is not considered a benefit.

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.

CONSENT: *See Informed Consent*

CONTROL (SUBJECTS) or CONTROLS: 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.

CO-PRINCIPAL INVESTIGATOR (CO-PI): The other primary scholar or researcher involved in conducting the research; if the project is for a thesis or dissertation, the student is the co-PI.

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.)

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).

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 subjects to indicate that the benefits and burdens of research are fairly distributed.

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.

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.")

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.

HELSINKI DECLARATION: See: Declaration of Helsinki

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

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.

INCOMPETENCE: A legal term meaning inability to manage one's own affairs, and often used as a synonym for 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, 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.

INSTITUTIONAL REVIEW BOARD (IRB): A specially constituted, federally mandated review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research. UNLV has two IRB's – Social Behavioral and Biomedical.

INVESTIGATOR: A researcher conducting the project. Investigators can be Principal Investigators or CO-Principal Investigators. Students are always CO-Principal Investigators.

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.

LEGALLY AUTHORIZED REPRESENTATIVE: 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.

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).

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 non-institutionalized adults.

NONAFFILIATED MEMBER: A federally mandated member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (e.g., business person, attorney, teacher,).

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.

OFFICE OF HUMAN RESEARCH PROTECTION: The office within the Department of Health and Human Services, responsible for implementing DHHS regulations (45CFR46 Part 46) governing research involving human subjects

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

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

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

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

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.

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.

OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS (OPRS): The UNLV office that serves as an administrative hub for UNLV IRB's overseeing responsible conduct of research.

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.

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."

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.

SUBJECTS (HUMAN): participant is the preferred term since it more correctly portrays the participatory aspects of social science research. Sometimes "subject" more accurately describes the role.

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

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