Glossary of Terms – Human Subjects Research

A

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).

ASSENT

A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

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 [45 CFR 46.103].

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.

AUTONOMY

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

B

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.

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.

C

CHILDREN

Persons 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 [45 CFR 46.402].

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.

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.

COMPENSATION

Payment or medical care provided to subjects 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.

CONSENT

See: Informed Consent.

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. *(Compare: Grant.)*

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.

D

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.

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

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).

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.

E

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 [45 CFR 46.111].

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, for minor changes in approved research, and research for which limited IRB review is a condition of exemption [45 CFR 46.110].

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.)*

EXPERIMENTAL STUDY

A true experimental study is one in which subjects are randomly assigned to groups that experience carefully controlled interventions manipulated by the experimenter according to a strict logic allowing causal inference about the effects of the interventions under investigation. *(See also: Quasi-Experimental Study)*

F

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.

FEDERAL POLICY (THE) FOR THE PROTECTION OF HUMAN SUBJECTS ("COMMON RULE")

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, 15 federal agencies are official signatories of the Federal Policy (also known as the "Common Rule") with the rule codified in their own Code of Federal Regulations.

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 [45 CFR 46.108].

G

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.)*

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(e)].

H

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 (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [45 CFR 46.102(e)(1)].

I

IMPAIRED DECISION-MAKING CAPACITY

Also considered "impaired consent capacity." In the context of human subjects research, this was discussed by the Subcommittee on Inclusion of Individuals with Impaired Decision-making in Research (part of the Secretary's Advisory Committee on Human Research Protections (SACHRP)) at their March 27, 2008, and March 4, 2009 meetings. Recommendations for considering this in human subjects research include: an individual's consent capacity is not simply present or absent and is best understood as occurring along a continuum; impaired consent capacity occurs in a wide variety of conditions and diseases, is task-specific, and depends on the nature and complexity of the relevant decision-making process. Throughout the course of a study, impairment in capacity may change (improve or worsen) depending on what condition the participant has.

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.)*

INDEPENDENT VARIABLES

The conditions of an experiment that are systematically manipulated by the investigator.

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 [45 CFR 46.116].

INSTITUTION (1)

Any public or private entity or agency (including federal, state, and local agencies) [45 CFR 46.102(f)].

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.

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 [45 CFR 46.102, 46.108, and 46.109].

INSTITUTIONALIZED

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

INSTITUTIONALIZED COGNITIVELY IMPAIRED

Persons who are confined, either voluntarily or involuntarily, in a facility for the care of the mentally or otherwise disabled (e.g., a psychiatric hospital).

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 [21 CFR 812].

INVESTIGATIONAL NEW DRUG OR DEVICE

A drug or device permitted by FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.

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.)*

IRB

See: Institutional Review Board.

J

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.

L

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 [45 CFR 46.102(i)].

LONGITUDINAL STUDY

A study designed to follow subjects forward through time.

M

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.)*

MENTALLY DISABLED

See: Cognitively Impaired.

MINIMAL RISK

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the 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. [45 CFR 46.102(j)]. 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.

• The definition of minimal risk for research involving prisoners differs somewhat from that given for noninstitutionalized adults, and is as follows: A risk is minimal where the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.. [See 45 CFR 46.303(d)]

MONITORING

The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections.

N

NATIONAL COMMISSION

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. An interdisciplinary advisory body, established by Congressional legislation in 1974, which was in existence until 1978, and which issued a series of reports and recommendations on ethical issues in research and medicine, many of which are now embodied in federal regulations.

NIH

National Institutes of Health: A federal agency within the Public Health Service, DHHS, comprising 27 institutes and centers. It is responsible for carrying out and supporting biomedical and behavioral research.

NONAFFILIATED MEMBER

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., minister, business person, attorney, teacher, homemaker).

NONTHERAPEUTIC 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.

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.

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 Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.

O

OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP)

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.

OHRP

See: Office for Human Research Protections.

P

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 [45 CFR 46.402(c)].

PHS

Public Health Service. Part of the U.S. Department of Health and Human Services (DHHS), it includes eight of the eleven operating divisions of the DHHS, including: Food and Drug Administration (FDA), National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Indian Health Service, Agency for Toxic Substances and Disease Registry, Agency for Healthcare Research and Quality, Substance Abuse and Mental Health Services Administration, and Health Resources and Services Administration (HRSA).

PRESIDENT'S COMMISSION

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. An interdisciplinary advisory group, established by Congressional legislation in 1978, which was in existence until 1983, and which issued reports on ethical problems in health care and in research involving human subjects.

PRINCIPAL INVESTIGATOR

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

PRISONER

An individual involuntarily confined or detained in a penal institution, including persons: (1) sentenced under a criminal or civil statue; (2) detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and (3) detained pending arraignment, trial, or sentencing. [45 CFR 46.303(c)].

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.

Q

QUASI-EXPERIMENTAL STUDY

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

R

RANDOM, RANDOM ASSIGNMENT, RANDOMIZATION, RANDOMIZED

Assignment of subjects 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 subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject 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, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge [45 CFR 46.102(l)].

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 for protocols approved by the convened IRB, reviews may, if deemed appropriate and the reasons for which are documented, also be conducted on a continuous or periodic basis [45 CFR 46.109].

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.)*

S

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).

SUBJECTS (HUMAN)

See: Human Subjects.

SURVEYS

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

T

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.

THERAPY

Treatment intended and expected to alleviate a disease or disorder.

V

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.

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.
