

General terms

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).

Archived

On the shelf prior to submitting an application to the IRB

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 form may be required for subjects between seven and thirteen years of age.

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 the institution will institute to maintain compliance.

Benefit

A valued or desired outcome; an advantage.

Biologic

Any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries. Biologics include vaccines and blood products, as well as similar substances synthesized bio-chemically or created through DNA techniques.

Blind Study Designs

See: Masked Study Designs; Double-Masked Design; and Single-Masked Design.

Capacity (to make decisions)

The ability of an individual to understand the choices presented, to appreciate the implications of choosing one alternative or another, and to make and communicate a decision (e.g., to participate in a particular study). *(See also, Cognitively Impaired, Competence.)*

Case Controlled 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.)*

Class I, II, III Devices

Classification by the Food and Drug Administration of medical devices according to potential risks or hazards.

Clinical Trial

A controlled study involving human subjects, designed to determine the safety and effectiveness of a drug, biologic, device or other treatment or behavioral intervention.

Cognitively Impaired

Having either a psychiatric disorder (*e.g.*, psychosis, neurosis, personality or behavior disorder, 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. (*See also: Capacity.*)

Compensation

Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research.

Competence

Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (*See also: Capacity.*)

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 (normal) Subjects

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 the 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. The term "normal" implies that a subject with a given condition is not "normal". Therefore, the HSPC prefers the term "control" to the term "normal".

Controlled Study

Research that involves at least two groups: one that receives the intervention being evaluated, and the other that receives either a placebo or another intervention (usually one that has been proven safe and effective). Sometimes the study also is described as "**blind**" "**masked**" (in which the subjects do not know which treatment they are receiving) or "**double blind**" or "**double-masked**" in which neither the subjects nor the researchers know the treatment assignments of individual subjects. In a **cross-over design**, each subject receives, at different times during the trial, both the experimental intervention and the control intervention, usually without knowing which is being given at any time (*i.e.*, a blind or double-blind study). The subjects thus become their own controls.

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.

Data & Safety Monitoring Board

A committee of scientists, physicians, statisticians, and others not otherwise involved that collects and analyzes 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). The Data and Safety Monitoring Board has authority to "break the code" and determine which subjects have received the experimental treatment and which received the control intervention. The DSMB can recommend that a clinical trial be modified or, suspended or terminated if necessary, to protect subjects. In addition, it may recommend that the consent form be modified and that subjects already enrolled be provided with additional information about the risks and benefits of continuing their participation.

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.)

DHHS

U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).

Double-Masked Design

A study in which neither the investigators nor the subjects know the treatment group assignments of individual subjects. Sometimes referred to as "double-blind."

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.

Embryo

Early stages of a developing organism, broadly used to refer to stages immediately following fertilization of an egg through implantation and very early pregnancy (*i.e.*, from conception to the eighth week of pregnancy). (*See also: Fetus.*)

Ethnographic Research

Ethnography is the study of people and their culture. Ethnographic research, also called fieldwork, involves observation of an 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 [45 CFR 46.110].

False Negative

When a test *wrongly* shows an effect or condition to be *absent* (*e.g.*, that a woman is *not* pregnant when, in fact, she *is*).

False Positive

When a test *wrongly* shows an effect or condition to be *present* (*e.g.*, that a woman *is* pregnant when, in fact, she is *not*).

FDA

Food and Drug Administration.

Fetal Material

The placenta, amniotic fluid, fetal membranes, and umbilical cord.

Fetus

The product of conception from the time of implantation until delivery. If the delivered or expelled fetus is viable, it is designated an infant [45 CFR

46.203(c)]. The term "fetus" generally refers to later phases of development; the term "embryo" is usually used for earlier phases of development. (See also: *Embryo*.)

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*.)

510 (K) Device

A medical device that is considered substantially equivalent to a device that was or is being legally marketed. A sponsor planning to market such a device must submit notification to the FDA 90 days in advance of placing the device on the market. If the FDA concurs with the sponsor, the device may then be marketed. 510(k) is the section of the Food, Drug and Cosmetic Act that describes pre-market notification; hence the designation "510(k) device."

Full Board/Committee 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].

Gene Therapy

The treatment of genetic disease accomplished by altering the genetic structure of either somatic (non-reproductive) or germ line (reproductive) cells.

Genetic Screening

Tests to identify persons who have an inherited predisposition to a certain phenotype or who are at risk of producing offspring with inherited diseases or disorders.

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)]. A guardian may also be appointed by a court to make decisions for an incompetent adult.

Human *In Vitro* Fertilization

Any fertilization involving human sperm and ova that occurs outside the human body.

Human Subject

Individuals whose physiologic or behavior 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 [45 [CFR](#) 46.102(f)].

IDE

See: Investigational Device Exemptions.

IND

See: Investigational New Drug.

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 [Federal Policy § 116.21 [CFR](#) 50.20 and 50.25].

Institution (1)

Any public or private entity or agency (including federal, state, and local agencies) [Federal Policy § .102(b)].

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 (IRB)

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.

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, home, or school for the retarded). Individuals in nursing homes who are suffering from dementia are also institutionalized cognitively impaired.

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 812.20].

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.*)

In Vitro

Literally, "in glass" or "test tube;" used to refer to processes that are carried out outside the living body, usually in the laboratory, as distinguished from *in vivo*.

In Vivo

Literally, "in the living body;" processes, such as the absorption of a drug by the human body, carried out in the living body rather than in a laboratory (*in vitro*).

IRB

See: Institutional Review Board

Legally Authorized Representative

A person authorized either by statute, by court appointment, or by a health care proxy to make decisions on health 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 [Federal Policy § .102(c)].

Longitudinal Study

A study designed to follow subjects forward through time.

Masked/Blinded Study Design

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 individual subjects. 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).

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. See also "*Significant Risk Device*" and "*Non-significant Risk Device*."

Minimal Risk

A risk is minimal when 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 test [45 CFR 46.102(i)]. 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 non-institutionalized adults. [See 45 CFR 46.303(d)]

New Drug Application (NDA)

Request for FDA approval to market a new drug.

NIH

National Institutes of Health: a federal agency within the Public Health Service, DHHS, comprising 21 institutes and centers. It is responsible for carrying out and supporting biomedical and behavioral research.

Non-significant Risk Device

An investigational medical device that does not present significant risk to the patient or research subject, taking into account all of the risks inherent in the study (for example, if the device must be inserted surgically). (See also: *Significant Risk Device*.)

Nonviable Fetus

An expelled or delivered fetus which, although it is living, cannot possibly survive to the point of sustaining life independently, even with the support of available medical therapy [45 CFR 46.203(d) and (e)]. Although it may be presumed that an expelled or delivered fetus is nonviable at a gestational age less than 20 weeks and weight less than 500 grams [*Federal Register* 40 (August 8, 1975):33552], a specific determination as to viability must be made by a physician in each instance. (See *also: Viable Infant.*)

Office for Protection 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.

Office of Research Compliance (ORC)

The Sunrise Health support staff for the IRB

Open Design

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

OPRR

See: Office for Protection from Research Risks.

ORC

See: Office of Research Compliance

Phase 1,2,3,4 Drug Trials

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).

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.

Phase 2 Drug Trial:

Phase 2 trials include controlled 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.

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 an 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.

Phase 4 Drug Trial:

Concurrent with marketing approval, FDA may seek agreement from the sponsor to conduct certain post-marketing (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].

PHS

Public Health Service. Part of the U.S. Department of Health and Human Services, it includes FDA, NIH, CDC, SAMHSA, and HRSA.

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 application to humans.

Pregnancy

The period of time from confirmation of implantation of a fertilized egg within the uterus until the fetus has entirely left the uterus (i.e., has been delivered). Implantation is confirmed through a presumptive sign of pregnancy such as missed menses or a positive pregnancy test [45 CFR 46.203(b)]. This "confirmation" may be in error, but, for research purposes, investigators would presume that a living fetus was present until evidence to the contrary was clear. Although fertilization occurs a week or more before implantation, the current inability to detect the fertilization event or presence of a newly fertilized egg makes a definition of pregnancy based on implantation necessary.

Pre-market Approval

Process of scientific and regulatory review by the FDA to ensure the safety and effectiveness of Class III devices.

Principal Investigator

The scientist or scholar with primary responsibility for the design and conduct of a research project. Defined by Sunrise Health as a Sunrise Health employee, or researcher with a Sunrise Health medical staff appointment or employee of Sunrise Health (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 [45 CFR 46.303(c)].

Privacy

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

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.

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)

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 [45 CFR 46.102(d)].

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 I Risk.*)

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 (ADAMHA).

Significant Risk Device

An investigational medical device that presents a potential for serious risk to the health, safety, or welfare of the subject and are:

- intended for use as an implant; or

- purported or represented to be of use in supporting or sustaining human life; or
- intended for a use that is of substantial important in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health; or
- a potential source of serious risk to the health, safety, or welfare of human subjects.

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."

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.

Sponsor-Investigator

An individual who both initiates and actually conducts, along or with others, a clinical investigation. Corporations, agencies, or other institutions do not qualify as sponsor-investigators.

Viable Infant

When referring to a delivered or expelled fetus, the term "viable infant" means likely to survive to the point of sustaining life independently, given the benefit of available medical therapy [45 CFR 46.203(d)]. This judgment is made by a physician. In accordance with DHHS regulations, the Secretary, HHS, may publish guidelines to assist in the determination of viability. Such guidelines were published in 1975, and specify an estimated gestational age of 20 weeks or more and a body weight of 500 grams or more as indices of fetal viability [Federal Register 40 (August 8, 1975):33552]. These indices depend on the state of present technology and may be revised periodically. (See also: Nonviable Fetus.)

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.