



HUMAN SUBJECTS GLOSSARY 2008

21 CFR 50 Protection of Human Subjects: Food and Drug Administration (FDA) Regulations concerning all clinical investigations regulated by the FDA.

21 CFR 56 Institutional Review Boards: Food and Drug Administration (FDA) Regulations concerning the composition, operation and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the FDA.

45 CFR 46 Protection of Human Subjects: Department of Health and Human Services (DHHS) regulations for the protection of human participants of research supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable for such research.

A:

AAHRPP: Association for the Accreditation of Human Research Protection Programs, Inc.

ADVERSE EVENT: 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)

AMENDMENT: Any change to a study protocol other than typographical errors. Amendments must be reviewed by an Institutional Review Board (IRB) before the modification is implemented.

ANONYMOUS: Lacking identification; identifiers or other information that could identify the individual are removed.

APPROVED DRUGS: In the U.S., the Food and Drug Administration (FDA) must approve a substance as a drug before it can be marketed. The approval process involves several steps including pre-clinical laboratory and animal studies, clinical trials for safety and efficacy, filing of a New Drug Application by the manufacturer of the drug, FDA review of the application, and FDA approval/rejection of application

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 OF COMPLIANCE: A formal written, binding commitment submitted to a federal agency where an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures to be used to achieve compliance.

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 the University of South Alabama the Authorized Institutional Official is the Dean, College of Medicine.

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

AWARDEE: The recipient of Federal funding (also called “grantee”).

B:

BASELINE: 1. Information gathered at the beginning of a study from which variations found in the study are measured. 2. A known value or quantity with which an unknown is compared when measured or assessed. 3. The initial time point in a clinical trial, just before a participant starts to receive the experimental treatment which is being tested. At this reference point, measurable values such as CD4 count are recorded. Safety and efficacy of a drug are often determined by monitoring changes from the baseline values.

BELMONT REPORT: 1979 document that sets forth the tenants of the ethical treatment of research participants: autonomy (respect for persons), beneficence, and justice.

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 no harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

BENEFIT: A valued or desired outcome; an advantage. The UT COM IRB application requests information about the benefits to the research participants.

BIOLOGIC: Any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries.

BLIND: A randomized trial is "Blind" if the participant is not told which arm of the trial he is on. A clinical trial is "Blind" if participants are unaware on whether they are in the experimental or control arm of the study.

BREACH OF PROTOCOL: A form of adverse event includes, but is not limited to, breakdowns in approved procedures of the study, such as the consent process, violations of data confidentiality, or complaints by participants.

C:

CERTIFICATES OF CONFIDENTIALITY: Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Information regarding certificates is available at <http://grants1.nih.gov/grants/policy/coc/>.

CHILD: A person who has not attained the legal age for consent to treatment of procedures involved in research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.401(a)]. In Tennessee, individuals younger than 18 years of age are considered children for most health care situations, and informed consent for research then consists of the child's assent and the parent's permission).

CHILDREN'S RISK LEVEL (CRL)

CRL 1 (45 CFR 46.404)—Research not involving greater than minimal risk.

CRL 2 (45 CFR 46.405)—Research involving greater than minimal risk but of possible direct benefit to the child, in which the risk is at least as favorable to the subject as that presented by available alternative approaches.

CRL 3 (45 CFR 46.406)—Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the disorder or condition, in which the risk is minor relative to the potential improvement in knowledge to be applied to general understanding.

CRL 4 (45 CFR 46.407)—Research not meeting the specifications above, but which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health and welfare of children

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

CODE OF FEDERAL REGULATIONS (45 CFR 46): Department of Health and Human Services (DHHS) regulations for the protection of all human participants of research supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable for such research.

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 upon drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severe 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.

COLLABORATIVE IRB TRAINING INITIATIVE (CITI): An online training program for researchers and staff, hosted at University of Miami. Register at: <http://www.miami.edu/citireg/>

COLLABORATOR: Investigators participating on a research protocol.

COMMON RULE: Subpart A of the Federal Regulations for protecting human research participants (45 CFR 46), to which 17 U.S. Departments/Agencies subscribe. The Department/Agencies are:

- Dept. of Agriculture
- Dept. of Energy
- National Aeronautics and Space Administration
- Dept. of Commerce
- Consumer Product Safety Commission
- Agency for International Development
- Dept. of Housing and Urban Development
- Dept. of Justice
- Dept. of Defense
- Dept. of Veterans Affairs
- Environmental Protection Agency
- National Science Foundation
- Dept. of Transportation
- Central Intelligence Agency (by executive order)
- Dept. of Health and Human Services
- Social Security Administration (by statute)

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).

COMPASSIONATE USE: A method of providing experimental therapeutics prior to final FDA approval for use in humans. This procedure is used with very sick individuals who have no other treatment options. Often, case-by-case approval must be obtained from the FDA for "compassionate use" of a drug or therapy.

CONFIDENTIALITY: Pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of original disclosure.

CONFLICT OF INTEREST: A situation that may occur when an investigator's personal goal or role obligation conflicts with an obligation to uphold another party's interest, thereby compromising objectivity and impartiality.

CONTRACT: One of several mechanisms whereby the University of Tennessee funds research; used when work is performed for the Government or private sponsor.

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).

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.

COOPERATIVE AGREEMENT: One of several mechanisms whereby collaborative research is funded. In this type of agreement, the investigators negotiate project tasks and timelines.

COOPERATIVE RESEARCH: Those projects that involve more than one institution.

D:

DATA AND SAFETY MONITORING BOARD (DSMB): A committee of scientists, physicians, statisticians, and others 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) that would warrant modification or termination of the trial, or notification of the subjects about new information that might affect their willingness to continue in the trial.

DATA USE AGREEMENTS: Data for a Limited Data Set must be collected according to the terms of "an agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected." The data use agreement is the means by which a covered entity obtains satisfactory assurance that the recipient of the limited data set will use or disclose the PHI in the data set only for specific purposes.

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS, HHS): The United States government's principal agency for protecting the health of all Americans and

providing essential human services. DHHS is the largest grant-making agency in the federal government. DHHS agencies include:

- National Institutes of Health (NIH)
- Food and Drug Administration (FDA)
- Centers for Disease Control and Prevention (CDC)
- Indian Health Service
- Health Resources and Services Administration
- Substance Abuse and Mental Health Services Administration
- Agency for Healthcare Research and Quality
- Centers for Medicare and Medicaid Services
- Administration for Children and Families
- Administration on Aging

E:

EFFICACY: (Of a drug or treatment). The maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. In the procedure mandated by the FDA, Phase II clinical trials gauge efficacy, and Phase III trials confirm it.

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.

ENGAGED IN RESEARCH: An institution becomes engaged in human subjects research when its employees or agents (1) intervene or interact with living individuals for research purposes; or (2) obtain individually identifiable private information for research purposes. An institution is automatically considered to be engaged in human subjects research whenever it receives a direct DHHS award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award.

EQUITABLE: Fair or just, used in the context of selection of subjects 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.

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.

EXEMPTION/EXEMPT RESEARCH: Term used in the Federal Regulations to describe six categories of research which do not require full Institutional Review Board (IRB)

review. Only the IRB may determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt.

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.

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.

F:

FEDERALWIDE ASSURANCE (FWA): The Federal Policy (Common Rule) for the protection of human subjects at [Section 103\(a\)](#) requires that each institution "engaged" in Federally-supported human subject research file an "Assurance" of protection for human subjects. In December 2000, the Office of Human Research Protections (OHRP) developed an Institutional Review Board (IRB) Registration and a new Federalwide Assurance (FWA) intended to: 1) create a new registry of IRBs, and 2) streamline the assurance process to significantly reduce the administrative burden on individual institutions, other federal departments and agencies, and OHRP. The University of Tennessee College of Medicine at Chattanooga and Erlanger IRB has a Federalwide Assurance with OHRP.

FOOD AND DRUG ADMINISTRATION (FDA): Agency of the Department of Health and Human Services. The FDA has its own set of Federal Regulations for protecting human research participants.

FULL BOARD REVIEW: Review of proposed research at a convened meeting of the Institutional Review Board at which a majority of the membership 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.

G:

GENE THERAPY: The treatment of genetic disease accomplished by altering the genetic structure of either somatic (non-reproductive) or germline (reproductive) cells.

GENOTYPE: The genetic constitution of an individual.

GENERALIZABLE KNOWLEDGE: Information gained from research that can be applied outside of the group involved in the research.

GUARDIAN: An individual who is authorized under applicable State or local law who has the legal, effective right to make decisions on behalf of a child.

H:

HARM: Injury, damage, or hurt to a participant in a research study.

HIPAA: Health Insurance Portability and Accountability Act. Insurance and privacy rules which became effective 4/14/03 and apply to health plans and human subjects research records.

HISTORICAL CONTROLS: Control participants (followed at some time in the past or for whom data are available through records) who are used for comparison with participants being treated concurrently. The study is considered historically controlled when the present condition of participants is compared with their own condition on a prior regimen or treatment.

HUMAN SUBJECT/HUMAN PARTICIPANT: A living person about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (e.g., medical records, employment records, or school records).

I:

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.

INJURY: Harm; for human subjects research purposes, a physical harm to a participant in a research study.

INSTITUTIONAL REVIEW BOARD (IRB): The formally appointed review committee at an institution established to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

INTERACTION: Communication or interpersonal contact between investigator and subject.

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

INVESTIGATIONAL DEVICE: Any instrument, apparatus, or other similar or related article, including component, part, or accessory, which is: (1) recognized in the official National Formulary, or the US Pharmacopeia, or any supplement to them; (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or (3) intended to affect the structure or any function of the human body or in animals; and does not achieve any of its principal intended purposes through chemical action within or on the human body or in animals and is not dependent upon being metabolized for the achievement of its principal intended purposes. *In vitro* diagnostic products are considered medical devices if they aid in the diagnosis of disease or medical/physiological conditions (e.g., pregnancy) by using human or animal components to cause chemical reactions, fermentation, and the like.

INVESTIGATIONAL DEVICE EXEMPTION (IDE): An investigational device exemption allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to FDA. Clinical studies are most often conducted to support a PMA.

INVESTIGATIONAL NEW DRUG (IND): A drug or biological product that is not approved by the FDA.

INVESTIGATIONAL NEW DRUG EXEMPTION: An exemption that allows one to use a drug or biologic before Food and Drug Administration (FDA) licensure. Diagnostic products intended for use in controlling other regulated products (such as those used to screen the blood supply for transfusion transmitted diseases) are regulated as biological products.

INVESTIGATOR: A researcher conducting a project. Investigators can be principal investigators or co-investigators.

IRB: Institutional Review Board

IRB APPROVAL: The determination of the Institutional Review Board (IRB) that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional, State, and Federal requirements.

J:

JCAHO: Joint Commission of the Accreditation of Healthcare Organizations

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.

K:

KEY PERSONNEL: All individuals responsible for the design and conduct of the study. This includes staff who interact with subjects and/or handle identifiable data.

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.

LIMITED DATA SETS (LDS): Concerning the type of data collected, Limited Data Sets contain "PHI that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement." A limited data set may include city; state; ZIP code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers. Direct identifiers listed in the Privacy Rule's limited data set provisions apply both to information about the individual and to information about the individual's relatives, employers, or household members.

LINK/LINKAGE: A code or other encryption that allows information obtained about an individual to be recorded in such a manner as to allow human subjects to be identified, either directly or indirectly.

LOCAL IRB: Institutional review board (IRB) responsible for oversight of the research in the geographic proximity of where the research is to be conducted.

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.

MINIMAL RISK: (1) 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 examination or tests. (2) *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. For prisoners, 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.

Note: The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.

N:

NCI: National Cancer Institute

NCQA: National Committee for Quality Assurance

NEONATE: A newborn.

NIH: National Institutes of Health

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

NONSCIENTIST: An individual who does not hold a terminal degree in a scientific discipline and does not practice science.

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 OF HUMAN RESEARCH PROTECTION (OHRP): Department of Health and Human Services office responsible for implementation of the DHHS Regulations for the Protection of Human Subjects (45 CFR 46) and the provision of guidance on ethical issues in biomedical or behavioral research. (Formerly known as the Office for Protection from Research risks (OPRR)).

OFFICE OF RESEARCH INTEGRITY (ORI): Department of Health and Human Services office which monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through educational, preventive, and regulatory activities.

P:

PARTICIPANTS: For human subjects purposes, the individuals with whom investigators conduct research.

PEER REVIEW: An activity in which scientists submit their work to recognized experts in the field for fair and objective review; intended to screen unsound work and improve communication. Also called expert review and referee review.

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

PERSONAL IDENTIFIERS: Information obtained and recorded in such a manner that human subjects can be recognized, directly or through links to the subjects. Examples include names, social security numbers, codes.

PHASE 1, 2, 3,4 DRUG TRIALS: Different stages of testing drugs in humans, from first application in humans (Phase I) 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 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.

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 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 312.851].

PLACEBO CONTROLLED STUDY: A method of investigation of drugs in which an inactive substance (the placebo) is given to one group of participants, while the drug being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition.

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

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.

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

PROBABILITY: For human subjects purposes, used to describe the likelihood or risk (harm) to occur to a participant in a research study; must be balanced with the magnitude of the risk.

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.

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.

Q:

QUALITY ASSURANCE: Management tool involving procedures/methods for determining how well a program is running.

QUORUM: In order for an Institutional Review Board to vote on a protocol, 50% + 1 of the members must be in attendance. One of the attendees must be a nonscientist.

R:

RECOMBINANT DNA TECHNOLOGY: "The ability to chop up DNA, the stuff of which genes are made, and move the pieces, [which] permits the direct examination of the human genome," and the identification of the genetic components of a wide variety of disorders [Holtzman (1989), p. I]. Recombinant DNA technology is also used to develop diagnostic screens and tests, as well as drugs and biologics for treating diseases with genetic components. See Guidebook Chapter 5, Section H, "Human Genetic Research."

REMUNERATION: Payment for participation in research. Remuneration should be appropriate for the amount of effort involved, and not excessive and thereby coercive. Remunerations are not considered a benefit.

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: Exposure to injury, loss, or harm; in evaluation risks and benefits, the Institutional Review Board should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only “minimal risk.”

S:

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.

SUBPART A OF 45 CFR 46: The “core” of the Federal Regulations for the protection of research participants; includes requirements for Assurances of Compliance, IRB composition, informed consent, etc.

SUBPARTS B-D OF 45 CFR 46: Federal Regulations where added protections can be found for selected vulnerable populations

Subpart B: Pregnant women, human fetuses and neonates

Subpart C: Prisoners

Subpart D: Children

SURVEILLANCE: Ongoing, systematic collection, analysis, and interpretation of outcome-specific data, closely integrated with the timely dissemination of these data to those responsible for preventing and controlling disease or injury.

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

SUSPENSION: Interruption of research; Institutional Review Boards have authority to interrupt research when it is found that a previously approved research protocol is not being conducted in accordance with the IRB’s requirements or that the protocol has been associated with unexpected serious harm to participants.

SYSTEMATIC INVESTIGATION: Organized plan or protocol of an investigation.

T:

TERMINATE/TERMINATION: Acknowledgment by the Institutional Review Board that a research study has been completed; also an IRB may stop a study. See *suspension*.

U:

UNANTICIPATED PROBLEM: Unanticipated problems include, but are not limited to, breakdowns in the consent process, violations of confidentiality of the data, and complaints by research participants.

UNFORESEEABLE: Unanticipated harm to human research participants.

V:

VACCINE: A biologic product generally made from an infectious agent or its components - a virus, bacterium, or other microorganism -that is killed (inactive) or live-attenuated (active, although weakened). Vaccines may also be biochemically synthesized or made through recombinant DNA techniques.

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.

VULNERABLE POPULATION: Groups of persons who may lack the capacity to freely decide whether to participate in research due to any number of circumstances such as age, health status, etc. 45 CFR 46 identifies prisoners; children; pregnant women and human fetuses and neonates as vulnerable populations; however, mentally handicapped, educationally and economically deprived individuals are also vulnerable populations.

W:

WAIVE/WAIVER: Forgo the requirement of a particular rule, regulation or condition in a protocol and/or consent document.

X:**Y:****Z:**