

## 10 Glossary

### General terms

Abuse-Liable	Pharmacological substances that have the potential for creating abusive dependency. Abuse-labile substances can include both illicit drugs (e.g., heroine) and licit drugs (e.g., methamphetamines).
Adjuvant Therapy	Therapy provided to enhance the effect of a primary therapy; auxiliary therapy
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).
Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)	Alcohol, Drug Abuse, and Mental Health Administration; reorganized in October 1992 as the Substance Abuse and Mental Health Services Administration (SAMHSA). ADAMHA included the National Institute of Mental Health (NIMH), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), the Office for Substance Abuse Prevention (OSAP), and the Office for Treatment Intervention (OTI). NIMH, NIAAA, and NIDA are now part of the National Institutes of Health (NIH).
Archived	On the shelf prior to submitting an application to the SHIRB
Assay	Lab test
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 seventeen 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.
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.
Autopsy	Examination by dissection of the body of an individual to determine cause of death and other medically relevant facts.
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. ( <a href="http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm">http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm</a> )

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.
<a href="#">Biologic</a>	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	<i>See: Masked Study Designs; Double-Masked Design; and Single-Masked Design.</i>
Cadaver	The body of a deceased person.
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). ( <i>See also, Cognitively Impaired, Competence.</i> )
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. ( <i>See also: Retrospective Studies.</i> )
Centers for Disease Control and Prevention (CDC)	An agency within the Public Health Service, Department of Health and Human Services.
Chair	Chair, Co-Chair, or Vice-Chair, as designated on IRB roster submitted to OHRP, unless otherwise indicated.
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)J].
Childre <b>CHILDREN'S RISK LEVEL (CRL) CRL 1 (45 CFR 46.404)</b> —	Research not involving greater than minimal risk.
<a href="#">Class I, II, III Devices</a>	Classification by the Food and Drug Administration of medical devices according to potential risks or hazards.
Clinical investigation	Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under

these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding non-clinical laboratory studies.

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.
Code of Federal Regulations (CFR)	"The codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation" <a href="http://www.gpoaccess.gov/cfr/about.html">http://www.gpoaccess.gov/cfr/about.html</a> 1)
Cognitively Impaired	Regulations related to human research are 45 CFR 46 (Title 45 , Part 46) and for the FDA only 21 CFR 50 and 56 (Title 21, Parts 50 and 56). Having either a psychiatric disorder ( <i>e.g.</i> , psychosis, neurosis, personality or behavior disorder, or dementia) or a developmental disorder ( <i>e.g.</i> , 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. ( <i>See also: Capacity.</i> )
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.
Common Rule	Regulations that govern human subjects of research and have been adopted by seventeen federal agencies, as delineated in Title 45 of the Code of Federal Regulations Part 46 Subpart A
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. ( <i>See also: Capacity.</i> )
Computerized Axial Tomography(CAT Scan)	An X-ray technique for producing images of internal bodily structures through the assistance of a computer.
Confidentiality	Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will

	<p>not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.</p>
Conflict of Interest	<p>An IRB member may not vote on a project, and is not counted towards a quorum when he/she or an immediate family member has a conflict of interest with a project being reviewed, defined as:</p> <ul style="list-style-type: none"><li>• Serving as a co-investigator or other member of the research team; or</li><li>• Receiving payments in excess of \$10,000 including salary, consulting fees, royalty or licensing payments from intellectual property, honoraria and/or gifts from the study sponsor over the past 12 months or anticipated for the next 12 months (excluding salary and other payments for services from Sunrise Health; or</li><li>• Having equity interest worth more than \$10,000 or more than 5% of the business entity as determined by reference to publicly listed prices (excluding mutual funds); or</li><li>• Having any equity interest if the value cannot be determined by reference to publicly listed prices (e.g., start-up companies); or</li><li>• Holding a position as director, officer, partner, trustee, employee, or any other position of management; or</li><li>• Holding patent rights or royalties from such rights whose value may be affected by the outcome of the research.</li></ul>
Continuing non-compliance	<p>A pattern of non-compliance that, in the judgment of the IRB Chair or convened IRB, indicates a lack of understanding of the regulations or institutional requirements that may affect the rights and welfare of participants, would have been foreseen as compromising the scientific integrity of a study such that important conclusions could no longer be reached, suggests a likelihood that non-compliance will continue without intervention, or frequent instances of minor non-compliance. Continuing non-compliance also includes failure to response to a request to resolve an episode of non-compliance.</p>
Contract	<p>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.</p>
Contraindicated	<p>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).</p>
Control (normal) Subjects	<p>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 IRB prefers the term</p>

	"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 " <b>blind</b> " " <b>masked</b> " (in which the subjects do not know which treatment they are receiving) or " <b>double blind</b> " or " <b>double-masked</b> " in which neither the subjects nor the researchers know the treatment assignments of individual subjects. In a <b>cross-over design</b> , 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>i.e.</i> , a blind or double-blind study). The subjects thus become their own controls.
Correlation Coefficient	A statistical index of the degree of relationship between two variables. Values of correlation coefficients range from -1.00 through zero to +1.00. A correlation coefficient of 0.00 indicates no relationship between the variables. Correlations approaching -1.00 or +1.00 indicate strong relationships between the variables. However, causal inferences about the relationship between two variables can never be made on the basis of correlation coefficients, no matter how strong a relationship is indicated.
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.
Data Use Agreement	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.
Dead Fetus	An expelled or delivered fetus that exhibits no heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord (if still attached) [45 CFR 46.203(f)]. Generally, some organs, tissues, and cells (referred to collectively as fetal tissue) remain alive for varying periods of time after the total organism is dead.
<a href="#">Debriefing</a>	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.)
Deception	In research means that the subject/respondent, at the time of the data collection, is not fully informed of the nature and purpose of the research in which she/he is involved so as to prevent potentially biased reporting of data/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, 1989, 1996, 2000 and 2002.
Department of Health, Education and Welfare (DHEW)	A federal agency, reorganized in 1980 as the Department of Health and Human Services (DHHS) and the Department of Education.
Department of health and Human Services (DHHS)	A federal agency, formerly the Department of Health, Education and Welfare (DHEW).
De-Identified Health Information	De-identified health information neither identifies nor provides a reasonable basis to identify an individual. There are two ways to de-identify information: either (1) a formal determination by a qualified statistician; or (2) the removal of specified identifiers of the individual and of the individual's relatives, household members, and employers is required, and is adequate only if the covered entity has no actual knowledge that the remaining information could be used to identify the individual.
Dependent Variables	he 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 ( <i>e.g.</i> , quasi-experimental studies, correlational studies, record reviews, case histories, and observational studies)
DHHS	U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).
Diagnostic (Procedure)	<b>DIAGNOSTIC (PROCEDURE)</b> Tests used to identify a disorder or disease in a living person.
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".
<a href="#">Drug</a>	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.
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.
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>i.e.</i> , from conception to the eighth week of pregnancy). ( <i>See also: Fetus.</i> )
Epidemiology	A scientific discipline that studies the factors determining the causes, frequency, and distribution of diseases in a community or given population.
Equitable	Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.
Ethics Advisory Board	An interdisciplinary group that advises the Secretary, HHS, on general policy matters and on research proposals (or classes of proposals) that pose ethical problems.
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. ( <i>See also: Fieldwork.</i> )
Existing Data	Data that existed prior to the initiation of a research project.
Expanded Availability	Policy and procedure that permits individuals who have serious or life-threatening diseases for which there are no alternative therapies to have access to investigational drugs and devices that may be beneficial to them. Examples of expanded availability mechanisms include Treatment INDs, Parallel Track, and open study protocols.
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 §46.110]. <a href="#">Expedited Categories</a>
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.
Failed Therapy	A treatment that failed to help subjects or patients.
False Negative	When a test <i>wrongly</i> shows an effect or condition to be <i>absent</i> (e.g., that a woman is <i>not</i> pregnant when, in fact, she <i>is</i> ).
False Positive	When a test <i>wrongly</i> shows an effect or condition to be <i>present</i> (e.g., that a woman <i>is</i> pregnant when, in fact, she is <i>not</i> ).
Family member	Means any one of the following legally competent persons: Spouse; parents; children (including adopted children); brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.
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)	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.")
Federal-Wide Assurance (FWA) of Protections for Human Subjects	is submitted to OHRP 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.
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: <i>Embryo</i> .)
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: <i>Ethnographic Research</i> .)
<a href="#">510 (K) Device</a>	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 is 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 <a href="#">CFR</a> 46.108].

Gatekeeper	An individual or organization that controls access to research records, documents, or specimens.
Gene Therapy	The treatment of genetic disease accomplished by altering the genetic structure of either somatic (non-reproductive) or germ line (reproductive) cells.
General Assurance	Obsolete term, previously used to denote an institutional assurance covering multiple research projects.
General Controls	Certain FDA statutory provisions designed to control the safety of marketed drugs and devices. The general controls include provisions on adulteration, misbranding, banned devices, good manufacturing practices, notification and record keeping, and other sections of the Medical Device Amendments to the Food, Drug and Cosmetic Act [21 U.S. Code §360(c) (Food, Drug and Cosmetic Act §513)].
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.
Genotype	The genetic constitution of an individual.
Good Clinical Practice (GCP)	Good Clinical Practice (GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial participants are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. (International Code of Harmonisation for Good Clinical Practice (ICH GCP)).
Grant	<b>GRANT</b> 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.
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.
Health Insurance Portability & Accountability Act (HIPAA)	Passed in 1996, Public Law 104-191 is a federal law that allows a person to keep his/her health insurance when changing jobs, hence the "portability." It also imposes new requirements on the disclosure of protected health information (PHI) for research.
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 <i>In Vitro</i> Fertilization	Any fertilization involving human sperm and ova that occurs outside the human body.
Human Research Protection Plan (HRPP)	A system that includes all structural units, policies, and activities critical to protecting individuals studied in research and that is

	managed in accordance with these standards and with applicable federal, state and local laws. Some components of the HRPP may external to the organization seeking accreditation, but the essential components of an HRPP should be identifiable in all cases.
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 <a href="#">CFR</a> 46.102(f)].
Humanitarian Use Device (HUD)	An HUD is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. <i>See: Investigational Device Exemptions.</i>
<a href="#">IDE</a>	
Identifiable Personal Information	Information relating to a reasonably identifiable person who has a reasonable expectation of privacy, including information about personal characteristics such as culture, age, religion and social status, as well as their life experience and educational, medical or employment histories. <i>See: Investigational New Drug.</i>
<a href="#">IND</a>	
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 [Federal Policy § 116.21 <a href="#">CFR</a> 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	Persons who are confined, either voluntarily or involuntarily, in a

Cognitively Impaired	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.
Interaction	Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
Intervention	Includes communication or inter-personal contact between investigator and subject.
<a href="#">Investigational Device Exemptions (IDE)</a>	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].
<a href="#">Investigational New Drug or Device</a>	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: <i>Principal Investigator</i> .)
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 <i>in vivo</i> .
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 ( <i>in vitro</i> ).
IRB	<i>See: Institutional Review Board</i>
IRB Approval	The determination of the IRB that the research study has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.
Justice	An ethical principal discussed in Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.
Key Personnel	All individuals responsible for the design and conduct of the study. This includes staff that interacts with subjects and/or handles identifiable data.
Lactation	The period of time during which a woman is providing her breast milk to an infant or child.
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)].
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.
LOD Score	An expression of the probability that a gene and a marker are linked.
Longitudinal Study	A study designed to follow subjects forward through time.
Major Modifications	Modifications to a research project and/or consent documents that present additional risk to subjects such as dosage escalation, additional procedures or tests, significant increases in time commitment by subject, etc. Substantive protocol revisions also are considered major modifications.
Major Violation	A violation that may impact subject safety, affect the integrity of study data and/or affect subject's willingness to participate in the study.
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. ( <i>See also: Double-Masked Design; Single-Masked Design.</i> )
Mature Minor	Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes ( <i>e.g.</i> , consenting to medical care).
<a href="#">Medical Device</a>	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. <i>See also "Significant Risk Device" and "Non-significant Risk Device."</i>
Medical Device Amendments (MDA)	Amendments to the Federal Food, Drug and Cosmetic Act passed in 1976 to regulate the distribution of medical devices and diagnostic products.
Mentally Disabled	<i>See Cognitively Impaired</i>
Metabolism (of a drug)	The manner in which a drug is acted upon (taken up, converted to other substances, and excreted) by various organs of the body.
<a href="#">Minimal Risk</a>	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.

	<p>The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults. [See 45 CFR 46.303(d)]</p>
Minor Modifications	<p>Modifications to a research project and/or consent document that poses no additional risk to subjects such as changes in title, co-investigator(s), funding sources; addition or modification of procedures that fall into one of the categories eligible for expedited review; or modifications that maintain similar or increased safeguards to protect the subject.</p>
Minor Violation	<p>A violation that does not affect subject safety, compromise the integrity of study data and/or affect subject's willingness to participate in the study.</p>
Monitoring	<p>The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections. 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.</p>
Morbidity	<p>Undesired result or complication</p>
Mortality	<p>Death; death rate</p>
National Commission	<p>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.</p>
National Institutes of Health (NIH)	<p>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. (<a href="http://www.nih.gov">www.nih.gov</a>)</p>
Necrosis	<p>Death of tissue</p>
<a href="#">New Drug Application (NDA)</a>	<p>Request for FDA approval to market a new drug.</p>
NIH	<p>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.</p>
Non-affiliated Member	<p>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).</p>
Non-compliance	<p>Any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with federal regulations or institutional policies governing such research. Non-compliance actions may range from minor to serious, be unintentional or willful, and may occur once or several times. The</p>

degree of non-compliance is evaluated on a case-by-case basis and will take into account such considerations as to what degree subjects were harmed or placed at an increased risk and willfulness of the non-compliance. Examples include, but are not limited to:

1. Failure to obtain IRB approval;
2. Inadequate or non-existent procedures for the informed consent process;
3. Inadequate supervision;
4. Failure to follow recommendations made by the IRB;
5. Failure to report adverse events or protocol changes; and
6. Failure to provide ongoing progress reports.

[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*.)

Non-therapeutic Research

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

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*.)

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.

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.osophs.dhhs.gov)
Office of Research Compliance	Sunrise Health Office of Research Compliance (SHORC). The Sunrise Health support staff for the SHIRB
Open Design	An experimental design in which both the investigator(s) and the subjects know the treatment group(s) to which subjects are assigned.
Oncology	The study of tumors or cancer
ORC	<i>See: Office of Research Compliance</i>
Paternalism	Making decisions for others against or apart from their wishes with the intent of doing them good.
Percutaneous	Through the skin
Permission	The agreement of parent(s) or guardian to the participation of their child or ward in research [45 CFR 46.402(c)].
Pharmacology	The scientific discipline that studies the action of drugs on living systems (animals or human beings).
<a href="#">Phase 1,2,3,4 Drug Trials</a>	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).
<a href="#">Phase 1 Drug Trial:</a>	<p>Phase 1 trials include the initial introduction of an investigational new drug into humans.</p> <p>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.</p> <p>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.</p>
<a href="#">Phase 2 Drug Trial:</a>	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].

Phenotype

The physical manifestation of a gene function.

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.

Post-Amendments  
Devices

Medical devices marketed after enactment of the 1976 Medical Device Amendments.

Pre-Amendments  
Devices

Medical devices marketed before enactment of the 1976 Medical Device Amendments.

Pre-clinical  
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.
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 person with primary responsibility for the design and conduct of a research project. (See <i>also: Investigator</i> )
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 ( <i>e.g.</i> , 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.
Private Information	Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable ( <i>i.e.</i> , the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining information to constitute research involving human subjects.
PROBAND	The person whose case serves as the stimulus for the study of other members of the family to identify the possible genetic factors involved in a given disease, condition, or characteristic.
Prophylactic	Preventive or protective; a drug, vaccine, regimen, or device designed to prevent, or provide protection against, a given disease or disorder.
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.
Protected Health Information (PHI)	Individually identified health information including demographic data, that relates to: <ul style="list-style-type: none"><li>• the individual's past, present or future physical or mental health or condition,</li><li>• the provision of health care to the individual, or</li><li>• the past, present, or future payment for the provision of health care to the individual</li><li>• and that identifies the individual or for which there is a reasonable</li></ul>

basis to believe can be used to identify the individual. Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).

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.
Protocol Deviation	Any alteration/modification to the IRB-approved protocol. The protocol includes the detailed protocol, protocol summary, consent form recruitment materials, questionnaires, and any other information relating to the research study.
Protocol Exception	Any temporary protocol deviation that is approved by the IRB prior to its initiation, e.g., enrollment of a subject who does not meet the eligibility criteria. NOTE: Any permanent change to the protocol constitutes an amendment that must be submitted to the IRB for approval prior to initiation.
Protocol Violation	Any protocol deviation that is not approved by the IRB prior to its initiation or implementation.
Purity	The relative absence of extraneous matter in a drug or vaccine that may or may not be harmful to the recipient or deleterious to the product.
Quality Improvement (QI)	Periodic examination of organizational activities, policies, procedures and performance to identify best practices and target areas in need of improvement; includes implementation of corrective actions or policy changes where needed.
Quasi-Experimental Study	A study that is similar to a true experimental study except that it lacks random assignments of participants to treatment groups.
Quorum	A majority of voting members of an IRB, including at least one member whose primary expertise is in a nonscientific area.
Radioactive Drug	Any subjects defined as a drug in §201(b)(1) of the Federal Food, Drug and Cosmetic Act that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons [21 CFR 310.3(n)]. Included are any non-radioactive reagent kit or nuclide generator that is intended to be used in the preparation of a radioactive drug and "radioactive biological products as defined in 21 CFR 600.3(ee). Drugs such as carbon-containing compounds or potassium-containing salts containing trace quantities of naturally occurring radionuclides are not considered radioactive drugs.
Radioactive Drug Research Committee (RDRC)	An institutional committee responsible for the use of radioactive drugs in human participants for research purposes. Research involving human participants that proposes to use radioactive drugs must meet various FDA requirements, including limitations on the pharmacological dose and the radiation dose. Furthermore, the

	<p>exposure to radiation must be justified by the quality of the study and the importance of the information it seeks to obtain. The committee is also responsible for continuing review of the drug use to ensure that the research continues to comply with FDA requirements, including reporting obligations. The committee must include experts in nuclear medicine and the use of radioactive drugs, as well as other medical and scientific members [21 CFR 36.1].</p>
Radiopaque Contrast Agents	<p><b>RADIOPAQUE CONTRAST AGENTS</b> Materials that stop or attenuate radiation that is passed through the body, creating an outline on film of the organ(s) being examined. Contrast agents, sometimes called "dyes," do not contain radioisotopes. When such agents are used, exposure to radiation results only from the X-ray equipment used in the examination. The chemical structure of radiopaque contrast agents can produce a variety of adverse reactions, some of which may be severe — and possibly life-threatening — in certain individuals.</p>
Radiopharmaceuticals	<p>Drugs (compounds or materials) that may be labeled or tagged with a radioisotope. These materials are largely physiological or sub-pharmacological in action, and, in many cases, function much like materials found in the body. The principal risk associated with these materials is the consequent radiation exposure to the body or to specific organ systems when they are injected into the body.</p>
Random, Random Assignment, Randomization, Randomized	<p>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.</p>
Recombinant DNA Technology	<p>"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. 1]. Recombinant DNA technology is also used to develop diagnostic screens and tests, as well as drugs and biologics for treating diseases with genetic components.</p>
Remission	<p>A period in which the signs and symptoms of a disease are diminished or in abeyance. The term "remission" is used when one cannot say with confidence that the disease has been cured.</p>
Remuneration (payment)	<p>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.) (<i>Compare: Compensation.</i>)</p>
<a href="#">Research</a>	<p>A systematic investigation (<i>i.e.</i>, the gathering and analysis of information) designed to develop or contribute to generalizable knowledge [45 CFR 46.102(d)].</p>
Respect for Persons	<p>An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished</p>

	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." <i>(See also: Minimal Risk.)</i>
Roentgen Equivalent in Man (REM)	The unit of measurement for a dose of an ionizing radiation that produces the same biological effect as a unit of absorbed does (1 rad) of ordinary X-rays. One millirem is equal to 1/1000 of a rem.
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).
Scientific Review Group	A group of highly regarded experts in a given field, convened by NIH to advise NIH on the scientific merit of applications for research grants and contracts. Scientific review groups are also required to review the ethical aspects of proposed involvement of human participants. Various kinds of scientific review groups exist, and are known by different names in different institutes of the NIH (e.g., Study Sections, Initial Review Groups, Contract Review Committees, or Technical Evaluation Committees).
Secretary	U.S. Cabinet Officer. In the context of DHHS-conducted or -supported research, usually refers to the Secretary of Health and Human Services.
<a href="#">Significant Risk Device</a>	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 or 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."
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.
Social Experimentation	Systematic manipulation of, or experimentation in, social or economic systems; used in planning public policy.
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.
Sterility (1)	The absence of viable contaminating microorganisms; aseptic state.
Sterility (2)	The inability to procreate; the inability to conceive or induce conception.
Substance Abuse and Mental Health Services Administration (SAMSHA)	Includes the Center for Substance Abuse Prevention, the Center for Substance Abuse Treatment and the Center on Mental Health Services. Formerly the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). ( <a href="http://www.samhsa.gov/">www.samhsa.gov/</a> )
Surveys	Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.
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.
Uniform Anatomical Gift Act	Legislation adopted by all 50 States and the District of Columbia that indicates procedures for donation of all or part of a decedent's body for such activities as medical education, scientific research, and organ transplantation.
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 bio-chemically synthesized or made through recombinant DNA techniques.

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 take part (or to continue to take part) in a research activity.

## **Acronyms**

### **ADAMHA**

Alcohol, Drug Abuse, and Mental Health Administration  
Reorganized in October 1992 as the Substance Abuse and Mental Health Services Administration (SAMHSA).

### **AE**

Adverse Effect or Adverse Event

### **AIL**

Authorized Institutional Official

### **CAT Scan**

Computerized Axial Tomography

### **CDC**

Centers for Disease Control and Prevention

### **CFR**

Code of Federal Regulations

### **CHMC**

Children's Hospital and Medical Center

### **CITI**

Collaborative IRB Training Initiative

### **CRF**

Case Report Form

### **CRL**

Children's Risk Level

### **CRC/GCRC**

Clinical Research Center/General Clinical Research Center

### **CRO**

Contract Research Organization or Clinical Research Organization

### **DSMB**

Data and Safety Monitoring Board

**DHEW**

U.S. Department of Health, Education and Welfare  
Reorganized in 1980 as the Department of Health and Human Services (DHHS) and the Department of Education.

**DHHS**

U.S. Department of Health and Human Services

**FDA**

U.S. Food and Drug Administration

**FHCRC**

Fred Hutchinson Cancer Research Center

**FWA**

Federalwide Assurance (USDHHS)

**GCS**

Grants & Contract Services (Renamed OSP, Office of Sponsored Programs.)

**HIPAA**

Health Insurance Portability and Accountability Act of 1996

**HMC**

Harborview Medical Center

**HRSA**

Health Resources and Services Administration ([www.hrsa.gov](http://www.hrsa.gov))

**IBC**

Institutional Biosafety Committees

**ICF or CF**

Informed Consent Form or Consent Form

**IDE**

Investigational Device Exemption

**IND**

Investigational New Drug or Device (FDA)

**IRB**

Institutional Review Board

**LAR**

Legally Authorized Representative

**LDS**

Limited Data Sets

**MDA (s)**

Medical Device Amendments

**MPA**

Multiple Project Assurance

**MTA**

Materials Transfer Agreement

**NIH**

National Institutes of Health

**NDA**

New Drug Application

**NSF**

National Science Foundation

**OHRP**

Office for Human Research Protection

**OPRR**

Office for Protection from Research Risks (Renamed OHRP.)

**OSP**

Office of Sponsored Programs (formerly GCS, Grants and Contract Services.)

**PHS**

U.S. Public Health Service

**RDRC**

Radioactive Drug Research Committee

**REM**

Roentgen Equivalent in Man

**RSC**

Radiation Safety Committee

**SAE**

Serious Adverse Event

**SPA**

Single Project Assurance

**VA**

Veterans Affairs

**VAPSHCS**

Veterans Affairs Puget Sound Health Care System