CPHS/OPHS GLOSSARY OF TERMS

A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z |

A

Adverse Event	Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events may also be psychological in nature. (See also: Serious Adverse Event and Unexpected Adverse Event).
Amendment	Modification or change to a currently approved study (protocol or consent materials). All amendments require IRB review and approval prior to implementation (unless correcting only grammatical or typographical errors). (See also: Approval, Continuing Review, Minor Amendment and Expiration Date)
Anonymous	Anonymous data collection means that no identifiable information (e.g. name, address, student ID number, email address, phone number) is connected to the data either directly or through a coding system at any point in the study. In addition to videotapes and photographs, audio recordings are not considered to be anonymous. It is also possible that multiple pieces of information, none of which are identifiable on their own, may uniquely identify a person when brought together; in this case, the data would not be considered anonymous.
Approval	The determination of the IRB that the research satisfies the applicable University, State and Federal requirements for research involving human subjects and has permission to proceed. The approval period can vary and is described under Continuing Review. (See also: Amendment, Continuing Review and Expiration Date)
Assent	The agreement to participate in a research study given by a child or an adult who lacks full decision-making capacity or authority to give legally valid informed consent. In the absence of affirmative agreement, failure to object should not be construed as assent.
Assurance	A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and use of animals and stipulates the procedures through which compliance will be achieved.

Authorization	Under HIPAA, the granting of rights to access protected health information (PHI). Required by HIPAA for disclosures or uses other than for treatment, payment or operations (which are covered in the Notice of Privacy Practices). Treatment cannot be conditioned on granting of an authorization. An authorization is a specific, detailed document as to the PHI covered and its uses.
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 capacities to consider alternatives, make choices, and act without undue influence or interference of others.

| back to top |

B

Belmont Report	A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.
Beneficence	An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (l) 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. *Note:* Compensation or payment for participation in research is not considered to be a benefit of the research.
Berkeley Stem Cell Center	A multi-disciplinary group of scientists, physicians, and humanities and legal scholars at UC Berkeley committed to the study of new technologies of human stem cell research.
Biosafety Officer	The Biosafety Officer provides compliance assistance, technical information, and training to assist UC Berkeley faculty and staff in meeting the requirements of local, State and Federal regulations and established policies for the possession, use or transport of biohazards and potentially biohazardous materials. For more information, visit the Biosafety Website.

BUA	*Biological Use Authorization* - An authorization/approval number issued for research involving biological use(s) from the Biosafety Office at UC Berkeley. See also: Biosafety Officer.

| back to top |

C

California Public Records Act	Modeled after the Freedom of Information Act, the public may request to inspect the public records of California state and local agencies during business hours. There are nine exceptions and four exclusions to this statue. Also known as CPRA or California Freedom of Information Act.
CDC	*Centers for Disease Control and Prevention* - An agency within the Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC) is recognized as the lead federal agency for protecting the health and safety of people - at home and abroad, providing credible information to enhance health decisions, and promoting health through strong partnerships.
Certificate of Confidentiality	An advance grant of confidentiality issued to a research study by the Department of Health and Human Services, National Institutes of Health in certain circumstances or the Federal Drug Administration (FDA) for FDA-regulated research; It is intended to provide protection against forced disclosure, even against a subpoena, of individually identifiable research data. (This procedure has received little legal testing and it is not known if a Certificate of Confidentiality (CoC) would hold up if challenged.) Visit Certificate of Confidentiality Kiosk for more information.
Certification	The official notification by the institution to the supporting Department or Agency that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance. If required, it includes documentation to funding agencies that a PI has completed specific training in the ethical conduct of human subjects research.
CFR	*Code of Federal Regulations* - The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. It details the laws that govern research with human participants.

Children	Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In California, the legal age for such consent is usually 18 years old, but some exceptions apply under state law. California law or applicable laws of other states or countries where the research is being conducted will be considered by CPHS.
CITI	*Collaborative Institutional Training Initiative* - An online modular training program on research compliance topics. The human research protection training that is required for UCB faculty (with some exceptions), post docs, research staff, students (graduate/undergraduate) and volunteer research staff engaging in research.
Class I, II, III Devices	Classification by the Food and Drug Administration of medical devices according to potential risks or hazards. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control.
Classified Research	Research, either whole projects or portions thereof, that has a security classification established by a federal agency, *OR* industrially sponsored proprietary research for which the sponsor requires a delay in publication in excess of six months.
Clinical Investigation	Considered by the FDA to be any experiment that involves a *test article* and one or more *human subjects*, and that either: a) must meet the requirements for prior submission to the Food and Drug Administration; or b) the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The terms **research**, **clinical research**, **clinical study**, **study**, and **clinical investigation** are deemed to be synonymous. Note: The DHHS regulatory definition of research is different.
Clinical Laboratory Improvements Amendments	The Clinical Laboratory Improvement Amendments (CLIA) was passed by Congress in 1988. CLIA established quality standards for all laboratory tests to ensure the accuracy, reliability, and timeliness of patient test results, regardless of where the test was performed. CLIA defines a clinical laboratory as any facility which performs testing on specimens derived from humans for the purpose of providing data for the diagnosis, prevention, or treatment of disease in an individual, or for the purpose of health assessment. CLIA states that laboratories that perform tests on human specimens and report patient-specific results must be certified under the CLIA provisions. Researchers should use CLIA-certified laboratories when the results will be shared with subjects, or their physicians. Conversely, if researchers do not plan to share results with subjects, or their physicians, testing could be performed via any appropriate laboratory. For more information, refer to the CLIA Guidance.
Clinical Trial	An "applicable" clinical trial defined by the Food and Drug Administration is a trial that must be posted on clinicaltrials.gov. There are two main types of clinical trials: (1) Controlled, clinical investigations of a drug or biologic subject to FDA regulation; or

	(2) Controlled trials of devices with health outcomes and pediatric post-market surveillance.
Cloud Computing	Off-site, distant storage or data management servers typically owned and operated by a third party.
CoC	See: Certificate of Confidentiality.
Coercion	An overt or implicit threat of harm/negative consequences or reprisal is intentionally presented by one person to another in order to obtain compliance.
Cognitively Impaired Persons	Individuals who have either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders) an organic impairment (*e.g*., 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. This includes 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.
Coded Data Set	Data that has been stripped of identifiers (such as name or social security number) and assigned an identity code (typically a randomly generated number) which is associated with and unique to each specific individual; and a key to decipher the code exists, enabling linkage of the data to personal identifiers. This identity code should not offer any clue as to the identity of an individual.
COIC	See: Conflict of Interest Committee.
Competence	A legal term used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See also: Incompetence, Incapacity)
Confidentiality	Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Conflict of Interest Committee	A faculty committee that reports to the Vice Chancellor for Research and is responsible for the review, assessment, approval, and management of all financial disclosures related to research projects at UC Berkeley. For more information, visit the Conflict of Interest Committee (COIC) Website.
Consent	See: Informed Consent.
Continuing Noncompliance	A pattern of noncompliance that indicates an inability or unwillingness to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB.
Continuation Review	See: Continuing Review.
Continuing Review	The IRB review that must occur at least once every 12 months for all active, federally-regulated (FDA or DHHS) protocols, or every 10 years for all active, minimal risk, non-federally-regulated, non-FDA-regulated, non-Veterans Affairs protocols without financial conflicts of interest or NIH Certificates of Confidentiality, after the initial review and approval. Also referred to as renewal or continuation review. (See also: Amendment, Approval, and Expiration Date).
Covered Entity	A health plan, a health care clearinghouse, or a health care provider who electronically transmits health information in connection with a transaction for which the U.S. Department of Health and Human Services (HHS) has adopted a standard (e.g., transactions concerning billing and payment for services or insurance coverage). A covered entity can be an institution, organization or an individual. These organizations are subject to regulation by the Health Insurance Portability and Accountability Act (HIPAA).
CPHS	*Committee for Protection of Human Subjects* - the Institutional Review Board(s) (IRB) for the University of California at Berkeley.
CPRA	See: California Public Records Act.

| back to top |

D

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).
Deception	When an investigator gives false information to subjects or intentionally misleads them about some key aspect of the research. (This is sometimes referred to as "active deception.")
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.
De-identified Data (general)	Data that has been stripped of all elements (including but not limited to personal identifiers and codes with subsequent code key) that might enable a reasonably informed and determined person to deduce the identity of the subject.
De-identified Data (under HIPAA)	A record in which identifying information has been removed to render the health information not subject to the HIPAA rules. Information has been de-identified using either of the following methods: 1. by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members (*see list of Personal Identifiers under HIPAA*) or 2. by using statistical methods to establish de-identification. The covered entity may assign a code or other means of record identification to allow de-identified information to be re-identified if needed; however, the code must not be derived from, or related to, the removed identifiers and only the covered entity can have the re-linking information.
Device (Medical)	See: Medical Device.
DHHS	*Department of Health and Human Services* - (formerly known as DHEW - Department of Health, Education and Welfare (DHEW). One of the cabinet-level departments of the US federal government and the United States government's principal agency for protecting the health of all Americans and providing essential human services. The department includes more than 300 programs, covering a wide spectrum of activities; some of these include the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Office for Human Research Protections (OHRP).

Disadvantaged Persons	Individuals lacking the normal or usual necessities and comforts of life, such as proper housing, educational opportunities, adequate medical care etc.
DOD	*Department of Defense (includes Air Force, Army, Advanced Research Projects Agency, and Navy)* - The mission of the Department of Defense is to provide the military forces needed to deter war and to protect the security of our country. The department's headquarters are at the Pentagon.
DOE	*Department of Energy* - The Department of Energy's mission is to advance energy technology and promote related innovation in the United States.
DoED	*Department of Education* - The U.S. Department of Education's mission is to: Strengthen the Federal commitment to assuring access to equal educational opportunity for every individual; Supplement and complement the efforts of states, the local school systems and other instrumentalities of the states, the private sector, public and private nonprofit educational research institutions, community-based organizations, parents, and students to improve the quality of education; Encourage the increased involvement of the public, parents, and students in Federal education programs; Promote improvements in the quality and usefulness of education through Federally supported research, evaluation, and sharing of information; Increase the accountability of Federal education programs to the President, the Congress, and the public.
DOT	*Department of Transportation* - The mission of DOT is to serve the United States by ensuring a fast, safe, efficient, accessible and convenient transportation system that meets our vital national interests and enhances the quality of life of the American people, today and into the future.
Drug	• A substance recognized by an official pharmacopoeia or formulary; • A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; • A substance (other than food) intended to affect the structure or any function of the body; or • A substance intended for use as a component of a medicine but not a device or a component, part, or accessory of a device. • Note: *Biological products* (e.g., vaccine, virus, or blood) are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)
DSMB	*Data and Safety Monitoring Board/Committee (DSMB or DSMC)* - An appointed independent group consisting of at least three (3) members assigned to conduct interim monitoring of accumulating data from research activities to assure the continuing safety of research participants, relevance of the study question, appropriateness of the study, and integrity of the accumulating data.

	Membership should include expertise in the relevant field of study, statistics, and research study design.
DSMP	*Data and Safety Monitoring Plan* - A plan to oversee the implementation of a study protocol for subjects' safety and compliance monitoring.

| back to top |

E

Economically Disadvantaged Persons	See: Disadvantaged Persons.
Educationally Disadvantaged Persons	See: Disadvantaged Persons.
EH&S	See: Environment, Health and Safety.
Emancipated Minor	A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation. (See also: Mature Minor)
Encryption	Refers to the algorithmic transformation of a data set to an unrecognizable form from which the original data set or any part thereof can be recovered only with knowledge of a secret decryption key of suitable length, and using a suitable algorithm.
Engaged (in human subjects research)	In general, an institution is considered *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. For more information, see the Office for Human Research Protections (OHRP) Guidance on Engagement of Institutions in Human Subjects Research

Environment, Health and Safety	UCB Office responsible for providing a safe and healthy environment for faculty, staff, students, and visitors. The mission of the Office of Environment, Health and Safety (EH&S) is to prevent or to minimize injuries and illnesses through the recognition, evaluation, and control of potential hazards arising from University activities. For more information, see the EH&S Website.
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.
Exempt Review	Review of human subjects research that involves almost no risk to human subjects. There are six (6) federally-defined exempt categories. UCB requires review by a member of OPHS staff, an IRB Chair or a designated voting member to determine whether the research qualifies as exempt under one or more of the exempt categories.
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 specific categories of research listed in the regulations at Federal Register Volume 63, No 216 involving no more than minimal risk and for minor changes in approved research.
Experimental	Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness. (See also: Research)
Experimental Study	A true experimental study is one in which subjects are randomly assigned to groups that experience carefully controlled interventions manipulated by the experimenter according to a strict logic allowing causal inference about the effects of the interventions under investigation.
Experimental Subject’s Bill of Rights	A list of the rights described in California Health & Safety Code, Sections 24172 and 24173, that must be offered to all subjects of medical experimentation. This list of rights must be written in a language in which the subject is fluent. (See also: Medical Experimentation).

Expiration Date	The date signifying the end of the period for which CPHS has approved the research. (See also: Amendment, Approval, and Continuing Review)
External Adverse Event	From the perspective of a UCB Investigator engaged in a multicenter clinical trial, external adverse events are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial (not under UCB IRB authority).

| back to top |

F

Faculty Advisor	See: Faculty Sponsor.
Faculty Sponsor	A faculty member who has Principal Investigator or Exceptional PI status per University policy and agrees to sponsor the research of a student or postdoctoral investigator. The Faculty Sponsor/ Faculty Advisor is responsible for overseeing the protection of the rights and welfare of the human subjects and adherence to CPHS requirements as well as applicable federal regulations and state statutes.
FDA	*Food and Drug Administration* - Established by Congress in 1912 and presently part of the Department of Health and Human Services, the FDA oversees safety of foods, drugs, devices, biologics and cosmetics for human use.
FDA Advisory Councils	Groups of experts which provide advice and recommendations to the FDA.
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, seventeen federal agencies have adopted the Federal Policy. Also referred to as the “Common Rule.”

Federalwide Assurance	The Federal Policy for the Protection of Human Subjects requires that each institution "engaged" in Federally-supported non-exempt human subject research file in "Assurance" of protection for human subjects. The Assurance formalizes the institution's commitment to protect human subjects. The requirement to file an Assurance includes both "awardee" and collaborating "performance site" institutions. Per Federal Policy, awardees and their collaborating institutions become "engaged" in human subject research whenever their employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain, release, or access individually identifiable private information for research purposes.
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. The term "fetus" generally refers to later phases of development; the term "embryo" is usually used for earlier phases of development. (See also: Embryo)
FIC	*Fogarty International Center (NIH)* - The Fogarty International Center promotes and supports scientific research and training internationally to reduce disparities in global health.
FOIA	*Freedom of Information Act* - Federal law which requires federal agencies to disclose records when requests are made in writing. There are nine exemptions and three exclusions to this statute.
Full Board Review	See: Full Committee Review.
Full Committee Review	Review of proposed research at a convened meeting at which a majority of the IRB members are present, including at least one member whose primary concerns are in nonscientific areas. For the review of FDA-regulated research, there shall be at least one member who is a physician. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.
FWA	See: Federalwide Assurance.

| back to top |

G

Guardian	An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care.

| back to top |

H

Health information and Individually identifiable health information	Health information means any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of any individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual. Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and is created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
Helsinki Declaration	See: Declaration of Helsinki.
HIPAA	The Health Insurance Portability and Accountability Act (HIPAA) regulates the protection of private health information for individuals. HIPAA's "Privacy Rule" sets standards for the use and disclosure of Protected Health Information (PHI) obtained from a covered entity (refer to: Covered Entity). For more information, see *CPHS' HIPAA Guidelines*.
HRPP	See: Human Research Protection Program.

Human Research Data Set	A body of informational elements, facts, and statistics about a living individual obtained for research purposes. This includes information collected by an investigator through intervention/interaction with the individual or identifiable private information obtained without intervention/interaction with the individual.
Human Research Protection Program	The systematic and comprehensive approach by an organization to the protection of human subjects in research.
Human Subject	A living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information. Sometimes also referred to as Participant. (See also: Research)

| back to top |

I

IDE	*Investigational Device Exemption* - IDE refers to the regulations under 21 CFR 812. An approved IDE means that the IRB (and FDA for significant risk devices) has approved the sponsor's study application and all the requirements under 21 CFR 812 are met.
Identifiable Information	Information that can be linked to specific individuals either directly or indirectly through coding systems, or when characteristics of the information are such that by their nature a reasonably knowledgeable and determined person could ascertain the identities of individuals.
Identity-Only Data Set	Set of data that contains any and all personal identifiers absolutely necessary for future conduct of the research and the key to the identity code that can be used to link or merge personal identifiers with the coded set.
Incapacity	Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence. (See also: Incompetence)

Incompetence	Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. (See also: Incapacity)
IND	*Investigational New Drug Application* - An Investigational New Drug Application (IND) is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application or Biologics/Product License Application.
Individual Investigator Agreement	An agreement that permits an individual collaborator who is not affiliated with an institution with its own IRB or ethics review board to rely on UC Berkeley's IRB review. Also referred to as an IIA.
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, and the institution or agents thereof from liability for negligence.
Institution (1)	Any public or private entity or agency (including federal, state, and local agencies).
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; nursing homes; alcohol and drug addiction treatment centers; residential schools for the mentally or physically handicapped; and homes for dependent and neglected children.
Institutional Official	The individual who signs and has the authority to sign the institution's Assurances, making a commitment on behalf of the institution that federal regulations and policies will be followed. The Institutional Official at UCB is the Vice Chancellor for Research.
Institutional Review Board	A committee charged with reviewing and approving the use of human subjects in all research projects to ensure that the safety and welfare of subjects are protected. The IRB serves as an institutional compliance committee and is responsible for reviewing reported instances of regulatory noncompliance related to the use of human subjects in research. At UC Berkeley, the IRB is called Committee for Protection of Human Subjects (CPHS).

Institutionalized	Confined, either voluntarily or involuntarily (e.g., a hospital, prison or nursing home).
Interaction	Any form of communication or interpersonal contact between an investigator and a human subject.
Inter Institutional Agreement	An agreement that permits an institution with a Federalwide Assurance (FWA) to rely on the IRB review of another institution with an FWA. Also referred to as an IIA. (See also: Memorandum of Understanding)
Internal Adverse Event	From the perspective of a UCB Investigator engaged in a multi-center clinical trial, *internal adverse events* are those adverse events experienced by subjects enrolled by the UCB Investigator(s) (under UCB IRB authority). In the context of a single-site study, all adverse events would be considered *internal adverse events*.
Intervention	Physical procedures by which data are gathered and manipulations of the individual or the individual's environment that are performed for research purposes, including using individuals to evaluate or test devised products or materials developed through research.
Investigator	Any individual who contributes in a substantive way to the design, conduct, and/or analysis of the data of a study at or on behalf of UCB.
IO	See: Institutional Official.
IRB	See: Institutional Review Board.

| back to top |

J

Justice	An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

| back to top |

K

Key Personnel	The individuals with a significant role in the conduct of the research (e.g., principal investigator, study coordinator, research associate).

| back to top |

L

Laser Safety Program	This program is intended to provide UC Berkeley staff, researchers, students and visitors with a safe laser use environment. All Class 3 and 4 lasers on the campus must be registered with the UC Berkeley Non-Ionizing Radiation Safety Program. The Office of Environment, Health & Safety administers this program for the UC Berkeley Non-Ionizing Radiation Safety Committee (NIRSC). For more information, visit the Laser Safety Program Website
Legally Authorized Representative	A person authorized either by statute or by court appointment to make legal 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 Set	Protected Health Information that excludes the *16 categories of direct identifiers* outlined by HIPAA 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. *The 16*

identifiers are:

1. Names;
2. Postal address information , other than town or city, state, and zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate / license numbers;
11. Vehicle identifiers and serial numbers (including license plate numbers);
12. Device identifiers and serial numbers;
13. Web universal Resource Locators (URLs);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints; and
16. Full-face photographic images and any comparable images.

LUR

Laser Use Registration **-** All Class 3and 4 lasers on the Berkeley campus are required to be operated under a campus Laser Use Registration (LUR). Use of a Class 3 or 4 laser or laser system without an approved LUR is a violation of campus safety policy. (See also: Laser Safety Program.)

| back to top |

M

Mature Minor	Someone who has not reached adulthood (as deemed by state law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care) as permitted by California State Law. Note that a mature minor is not necessarily an emancipated minor. (See also: Emancipated Minor)
Medical Device	An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: • Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; • Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in human or other animals; or • Intended to affect the structure or any function of the body of human or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of human or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
Medical Experimentation	Medical Experimentation is defined by the State of California as: • the severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject; • the use of an investigational drug or device; or • The withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.
Memorandum of Understanding	An agreement between UC campuses and UC managed laboratories that will, under certain conditions, allow research to be reviewed by the IRB at only one location rather than having to go through the entire IRB review process at every campus engaged in the research. (See also: IRB Authorization Agreement)
Mentally Disabled	See: Cognitively Impaired.

Minimal Risk (1)	For non-prisoner studies: the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.
Minimal Risk (2)	For studies involving prisoner(s): 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.
Minor Amendment	Minor changes are defined as changes that, if considered independently from the overall research, involve no significant alteration in research design or fall into one or more categories allowing exempt or expedited review, and involve no more than minimal risk to participants.

| back to top |

N

NASA	*National Aeronautics and Space Administration* - NASA is a leading force in scientific research and in stimulating public interest in aerospace exploration, as well as science and technology in general.
National Commission	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. An interdisciplinary advisory body, established by Congressional legislation in 1974, which was in existence until 1978, and which issued a series of reports and recommendations on ethical issues in research and medicine, many of which are now embodied in federal regulations.
NCI	*National Cancer Institute (NIH)* - An institute within NIH. The National Cancer Institute's goal is to stimulate and support scientific discovery and its application to achieve a future when all cancers are uncommon and easily treated.
NCURA	*National Council of University Research Administrators* - An organization of individuals involved in the administration of sponsored programs at colleges, universities, and teaching hospitals.

NEI	*National Eye Institute (NIH)* - An institute within NIH. The National Eye Institute (NEI) conducts and supports research that helps prevent and treat eye diseases and other disorders of vision. This research leads to sight-saving treatments, reduces visual impairment and blindness, and improves the quality of life for people of all ages.
Neonate	A new born.
NHGRI	*National Human Genome Research Center (NIH)* – An institute within NIH. The National Human Genome Research Institute supports genetic and genomic research, investigation into the ethical, legal and social implications surrounding genetics research, and educational outreach activities.
NHLBI	*National Heart, Lung, and Blood Institute (NIH)* - An institute within NIH. The National Heart, Lung, and Blood Institute (NHLBI) provides leadership for a national program in diseases of the heart, blood vessels, lung, and blood; blood resources; and sleep disorders. Since October 1997, the NHLBI has also had administrative responsibility for the NIH Woman's Health Initiative.
NIA	*National Institute on Aging (NIH)* - An institute in NIH. The National Institute on Aging (NIA) leads a broad scientific effort to understand the nature of aging and to extend the healthy, active years of life.
NIEHS	*National Institute of Environmental Health Sciences (NIH)* - An institute within NIH. The mission of the National Institute of Environmental Health Sciences (NIEHS) is to reduce the burden of human illness and dysfunction from environmental causes by understanding each of these elements and how they interrelate.
NIH	*National Institutes of Health* - A groups of federal agencies within the Public Health Service, DHHS, comprising 21 institutes and centers. These entities are responsible for carrying out and supporting biomedical and behavioral research.
NIMH	*National Institute of Mental Health (NIH)* - An institute within NIH. The mission of the National Institute of Mental Health (NIMH) is to diminish the burden of mental illness through research.
NIRSC	*Non-Ionizing Radiation Safety Committee* – A body that sets UCB laser safety policy and is responsible for laser safety policy development and enforcement. They are directly accountable to the Provost for Research and their main function is to resolve safety concerns associated with laser use or with this manual. The NIRSC is responsible for oversight of the program and coordinating with the Laser Safety Officer to assure compliance with CCR, Title 8. (See also: Laser Safety Program)

Nonaffiliated Member	Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, homemaker).
Noncompliance	Failure to adhere to regulations, policies, procedures or special conditions related to the conduct of research. Examples of such noncompliance include, but are not limited to, failure to obtain/maintain approval for research; coercion of human subjects; performing unapproved procedures; and conducting research at unapproved sites. (See also: Simple (Minor) Noncompliance and Serious and Continuing Noncompliance)
Nonsignificant Risk Device	An investigational medical device that does not present significant risk to the patient. (See also: Significant Risk Device)
Nonviable Neonate	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)
NSF	*National Science Foundation* - The National Science Foundation (NSF) is an independent agency of the U.S. Government. Their mission is to promote the progress of science; to advance the national health, prosperity, and welfare; and to secure the national defense.
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.

| back to top |

O

Office for Protection of Human Subjects	Office for Protection of Humans Subjects (OPHS) is a division of the Office of Research Administration and Compliance. The OPHS staff provide administrative support to UC Berkeley's Committee for Protection of Human Subjects (CPHS) and serve as a liaison between the committee, and the research community as well as other administrative units. For more information, visit the CPHS-OPHS Website.
Off-Label use	When physicians use a drugs, biologics and devices for a condition not approved by FDA labeling. Physicians using good medical practice and the best interests of the patient may use legally available products for treatment (i.e., non-research purposes) using their best knowledge and judgment.
OHRP	*Office for Human Research Protection (formerly known as OPRR - Office for Protection from Research Risks)* - An office within the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.
ONR	*Office of Naval Research* - The Office of Naval Research (ONR) sponsors science and technology in support of the U.S. Navy and Marine Corps. Founded in 1946, ONR today funds work at more than 450 universities, laboratories, and other organizations.
OPHS	See: Office for Protection of Human Subjects.
OPRR	*Office for Protection from Research Risks (DHHS)* - See: Office for Human Research Protections (OHRP).

| back to top |

P

Parent	A child's biological or adoptive parent.
Parent Permission	The agreement of parent(s) or guardian to the participation of their child or ward in research.
Personal Identifiers under HIPAA	List of 18 Identifiers 1. Names. 2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census: a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people. b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000. 3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older. 4. Telephone numbers. 5. Facsimile numbers. 6. Electronic mail addresses. 7. Social security numbers. 8. Medical record numbers. 9. Health plan beneficiary numbers. 10. Account numbers. 11. Certificate/license numbers. 12. Vehicle identifiers and serial numbers, including license plate numbers. 13. Device identifiers and serial numbers. 14. Web universal resource locators (URLs).

15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

There are also additional standards and criteria to protect individual's privacy from re-identification. Any code used to replace the identifiers in datasets cannot be derived from any information related to the individual and the master codes, nor can the method to derive the codes be disclosed. For example, a subject's initials cannot be used to code their data because the initials are derived from their name. Additionally, the researcher must not have actual knowledge that the research subject could be re-identified from the remaining identifiers in the PHI used in the research study. In other words, the information would still be considered identifiable is there was a way to identify the individual even though all of the 18 identifiers were removed.

Phase 1, 2, 3, 4 Drug Trials	Different stages of testing drugs in humans, from first application in humans (Phase 1) through limited (Phase 2) and broad clinical tests (Phase 3), to post marketing studies (Phase 4).
PHI	See: Protected Health Information.
PI	See: Principal Investigator.
Postdoctoral Investigator	A postdoctoral scholar with a UCB appointment who conducts research. Student/Postdoctoral investigators are <u>not</u> considered by CPHS to be principal investigator (PI) on any research project unless granted exceptional PI status. *Postdoctoral scholars who wish to perform human research at UCB and do not have exceptional PI status must obtain the sponsorship of a faculty member with PI status.* A postdoctoral investigator has primary responsibility for the design, execution, and management of his or her research project and is involved in the project in a significant manner. S/he is also responsible for the protection of the rights and welfare of the human subjects and adherence by all study personnel to CPHS requirements as well as applicable federal regulations, and state statutes. *Note: If a postdoctoral scholar is doing work that is funded by grant on which a faculty member is PI, the faculty member must be listed on the CPHS application as Principal Investigator and the student should be listed as co-investigator or study personnel.*
Practicable	Capable of being done of being done, effected, or put into practice with the available means; feasible.

Preclinical Investigations	Laboratory and animal studies designed to test the mechanisms, safety, and efficacy of an intervention prior to its applications to humans.
Pregnancy	The period of time from implantation of a fertilized egg within the uterus until the fetus has entirely left the uterus (i.e., has been delivered). A woman shall be assumed to be pregnant if she exhibits any presumptive sign of pregnancy such as missed menses or a positive pregnancy test. This "assumption" may be in error, but, for research purposes, investigators would presume that a living fetus was present until there is clear evidence to the contrary.
Pregnant Woman	A woman who is in a state of pregnancy (See also: Pregnancy).
Premarket 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	An employee of UCB (usually with an academic appointment) who is eligible under University policy to submit proposals for extramural support of a research, training, or public service project, and to perform research involving human subjects. A PI has primary responsibility for the design, execution, and management of a research project and is involved in the project in a significant manner. The PI is also responsible for the protection of the rights and welfare of the human subjects and adherence by all study personnel to CPHS requirements as well as applicable federal regulations, and state statutes. As a general rule, the PI on the grant funding the research must be listed as the PI on the CPHS application. All academic senate faculty members, and a few other categories listed in the policy, have PI status by title (i.e. as part of their appointment). Those who do not have PI status by title can request status *by exception* through the office of the Vice Chancellor for Research.

Prisoner	An individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
Privacy	Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
Private Information	Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, as well as information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., private conversation).
Protected Health Information	**I**ndividually identifiable health information (refer to: Personal Identifiers under HIPAA); transmitted or maintained in any form or medium (electronic, oral or paper) by a covered entity or its business associates (See also: Health information and Individually identifiable health information*)*.
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.

| back to top |

Q

| back to top |

R

Recruitment Registry	An organization that collects and maintains contact information from individuals who have agreed to join an established subject pool in order to receive information about available research.
Recruitment Database	An organization that collects and maintains contact information, as well as health, demographic, and/or screening data, from individuals who have agreed to join an established subject pool in order to receive information about available research. The subject pool data may also be used to determine eligibility for future invitation to participate in research and included in the evaluation of study outcomes.
Radiation Safety Committee	A body of faculty and other radiation experts appointed by the Vice Chancellor for Research (VCR) to establish policies and procedures for the use of ionizing radiation at UC Berkeley. In addition, the Radiation Safety Committee (RSC) maintains surveillance over the program and provides periodic program status reports to the VCR. Surveillance activities include the review and approval of radiation-use applications and the review of Environment, Health & Safety radiation safety and radioactive waste related operations. (See also: RUA - Radiation Use Authorization) For more information, visit the RSC Website.
Regs	Short for "regulations."
Regulations	The contractual rules and procedures governing sponsored research projects.
Related	An event is considered related if it is at least *possibly related to the research* (i.e., there is a reasonable possibility that the incident, experience or problem may have been caused by the procedures involved in the research). *Probably related* – An event that in the judgment of the researcher is likely caused by the research activities or likely affected the rights and welfare of the participants. The event has a *timely relationship* to the research and *follows a known pattern of response*, but a potential alternative cause may be present. *Possibly related* – An event that in the judgment of the researcher is possibly caused by the research activities or that possibly affected the rights and welfare of the participants. The event has a *timely relationship* to the research; however no *known pattern of response exists*, and an alternative cause may be more likely, but a possible relationship to research activities cannot reasonably be ruled out. *Unrelated* – An event that in the judgment of the researcher is known and is in no way related to any aspect of the research activities

	or in no way affected the rights and welfare of the participants.
Renewal	See: Continuing Review.
Research	A systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge. (See also: Human Subject)
Research Health Information	The University of California employs the term “Research Related Health Information” (RHI) to identify types of data used in research that would be personally identifiable but not considered Protected Health Information (PHI) under the HIPAA “Privacy Rule.” RHI shares some characteristics with HIPAA PHI, but the key distinction between RHI and PHI is that PHI is associated with or derived from a healthcare service event, i.e., the provision of care or payment for care. RHI is not associated or derived from the provision of care or payment for care.
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.
RHI	See: Research Health Information.
Risk	The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both magnitude of possible harm may vary from minimal to significant. (See also: Minimal Risk)
Risk/Benefit ratio	The risk to a participant versus the potential benefits; the risk/benefit ratio differs depending on the nature of the research. The principle of beneficence requires a systematic assessment of all possible harms, including physical, psychological, social, and economic. The principle of beneficence requires both protecting participants against risk of harm and consideration of not only the benefits for the participant, but also the societal benefits that might be gained from the research.
RUA	Radiation Use Authorization – A written authorization for specific uses of radiation and radioactive material granted by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC) to the Radiation Use Authorization (RUA) holder. An approved RUA is required before purchasing or using any source of ionizing radiation at UC Berkeley.

| back to top |

S

Screening	The process of finding out, whether the subject is suitable for the study in question. It is based on exclusion criteria defined in the study protocol, such as age, current state of health and medication, medical history, etc. Before screening procedures, the subject is required to give his/her written informed consent to participate in the study.
SCRO	See: Stem Cell Research Oversight Committee.
Secretary	A U.S. Cabinet Officer. In the context of DHHS-conducted or -supported research, usually refers to the Secretary of Health and Human Services.
Serious Adverse Event	Any adverse event temporally associated with the subject's participation in research that meets any of the following criteria: 1. results in death; 2. is life-threatening (places the subject at immediate risk of death from the event as it occurs); 3. requires inpatient hospitalization or prolongation of existing hospitalization; 4. results in a persistent or significant disability/incapacity; 5. results in a congenital anomaly/birth defect; or 6. any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (Examples include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).
Serious Noncompliance	Noncompliance that adversely affects the rights or welfare of participants.

Significant Risk Device	An investigational device that: • Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; • Is purported or represented to be for use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; • Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or • Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. Note: An IDE application must be submitted to the FDA if the device involved in the research is determined to be significant risk.
Simple (Minor) Noncompliance	Failure to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB.
SPO	See: Sponsored Projects Office.
Sponsor	For FDA-regulated research: The entity who initiates, but who does not actually conduct, the research (e.g., a pharmaceutical company). The sponsor may or may not also be the entity that is funding the research. For non-FDA-regulated research: The entity who funds the research. Also referred to as the “funder.”
Sponsor-Investigator	An individual who both initiates and actually conducts the research. A sponsor-investigator must meet the requirements and obligations of both the investigator and the sponsor described in FDA regulations.
Sponsored Projects Office	The Sponsored Projects Office (SPO) is a division of the Office of Research Administration and Compliance. SPO staff is responsible for reviewing and submitting contract and grant proposals, accepting grants, and negotiating contracts for extramurally-funded research, training, and public service projects. SPO staff act as UCB's institutional official in matters involving the sponsor's awarding office. SPO is also responsible for post-award activities, such as approving certain actions delegated to the campus by sponsors, obtaining sponsor approvals as required, resolving problems that arise during the project period, reviewing consultant agreements, and assuring compliance with University and sponsor policies and regulations. For more information, visit the SPO Website.
Stem Cell Research Oversight Committee	The Stem Cell Research Oversight Committee (SCRO) is a campus committee appointed by the Vice Chancellor for Research and charged with ensuring that research involving the derivation or use of human stem cells at the University of California, Berkeley is conducted with the highest ethical and scientific research standards, and in compliance with all applicable federal and state regulations, University policies, and the requirements of extramural research sponsors. For more information, visit the Stem Cell

	Research Webpage.
Student Investigator	An undergraduate or graduate student enrolled at UCB who conducts research with human subjects. Student investigators are not considered by CPHS to be principal investigator (PI) on any research project. *Students who wish to perform human research at UCB must obtain the sponsorship of a faculty member with PI status.* A Student Investigator has primary responsibility for the design, execution, and management of his or her research project and is involved in the project in a significant manner. S/he is also responsible for the protection of the rights and welfare of the human subjects and adherence by all study personnel to CPHS requirements as well as applicable federal regulations, and state statutes. *Note: If a student is doing work that is funded by grant on which a faculty member is PI, the faculty member must be listed on the CPHS application as Principal Investigator and the student should be listed as study personnel.*
Student Subject Pool	A subject pool that is typically comprised of undergraduate students enrolled in particular courses requiring, as part of the curriculum, research experience either through participation in one or more research projects, or an alternative assignment in lieu of participation in research.
Subject Pool	An aggregation of people from which research participants may be recruited. Also see: Student Subject Pool.
Surrogate Consent	Consent obtained from a legally authorized representative on behalf of a participant determined to lack decision-making capacity. AB 2328, codified as California Health & Safety Code Section 24178 and effective January 1, 2003, clarifies who may serve as a research subject's "legally authorized representative", referenced in 45 CFR 46 and therefore authorized under those federal regulations to provide surrogate consent for the potential research subject to participate in research.

| back to top |

T

Therapeutic Misconception	Research participant's belief that enrolling in a research study will provide therapeutic benefit. Participants confuse the goal of clinical therapy which is to provide benefit to the individual patient and where any new knowledge gained is incidental and the goal of research which is to gain knowledge to help future patients (generalizable) and where therapeutic benefit to individual maybe secondary.

| back to top |

U

UCOP	University of California Office of the President.
Unanticipated	An event is when "unanticipated" when it was unforeseeable at the time of its occurrence. Unanticipated and unexpected are not synonymous. A research protocol can monitor for an unexpected event, but cannot monitor for an unforeseen event. All unanticipated events are unexpected but not vice versa.
Unanticipated Problems Involving Risk to Participants or Others	An incident, experience, or outcome that meets all of the following criteria: 1. unexpected (in terms of nature, severity or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; 2. related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and 3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Undue Influence	Improper influence that deprives a person of freedom of choice or substitutes another's choice or desire for the person's own.
Unexpected	An event is unexpected when its specificity and severity are not accurately reflected in the informed consent document.
Unexpected Adverse Event	Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is ***not*** consistent with either: 1. the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the IRB-approved documents (e.g., applicable investigator brochure, current protocol narrative, current informed consent document), and (b) other relevant sources of information, such as product labeling and package inserts; or 2. the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

| back to top |

V

VA	*Veterans Affairs* - The Department of Veterans Affairs (VA) was established on March 15, 1989. It succeeded the Veterans Administration and has responsibility for providing federal benefits to veterans and their dependents. Headed by the Secretary of Veterans Affairs, VA is the second largest of the 14 Cabinet departments and operates nationwide programs of health care, financial assistance and national cemeteries.
VCR	*Vice Chancellor for Research* - The Institutional Official (IO) for human research at UCB.
Viable Infant	When referring to a delivered or expelled fetus, the term "viable infant" means likely to survive to the point of sustaining life independently, given the benefit of available medical therapy [45 CFR 46.203(d)]. This judgment is made by a physician. In accordance with DHHS regulations, the Secretary, HHS, may publish guidelines to assist in the determination of viability. Such guidelines were published in 1975, and specify an estimated gestational age of 20 weeks or more and a body weight of 500 grams or more as indices of fetal viability [Federal Register 40 (August 8, 1975): 33552]. These indices depend on the state of present technology and may be revised periodically. (See also:

	Nonviable Fetus)
Voluntary	Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.
Vulnerable Subject	Human subjects/participants who are likely to be vulnerable to coercion or undue influence (e.g., students, subordinates, patients). Also, individuals who cannot give informed consent because of limited autonomy (e.g., children, mentally ill, prisoners).

| back to top |

W
X
Y
Z

| back to top |