GLOSSARY

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

ABUSE-LIABLE
Pharmacological substances that have the potential for creating abusive dependency. Abuse-liable substances can include both illicit drugs (e.g., heroin) and licit drugs (e.g., methamphetamines).

ADVERSE EVENT
Any untoward or unfavorable occurrence in a human research participant associated with the research project.

Active consent requires parents to sign and return a form if they consent for their child to participate. See also Informed Consent.

Agents are defined as individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility.

ALLEGATION OF NON-COMPLIANCE
An unproven assertion of non-compliance. See also Non-Compliance.

HHS regulations at 45 CFR Part 46 do not address the designation of alternate IRB/IEC members. When reviewing rosters that include alternate members OHRP assumes that, in general, with respect to the capacity in which the primary IRB member was intended to serve, each alternate IRB member has experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member whom the alternate would replace. A designated alternate IRB member for a primary IRB member may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Substitution during a meeting commonly occurs when the primary member is (a) absent from the room for part of the meeting, or (b) recused from review of certain research protocols because the primary IRB member has a conflicting interest with respect to a specific research protocol.

AMENDMENT
See Modification.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ANONYMITY</td>
<td>The condition that exists when there are no identifiers on research materials that could link or identify the data to an individual subject even to the research investigators.</td>
</tr>
<tr>
<td>ASSENT</td>
<td>Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.</td>
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<tr>
<td>ASSURANCE</td>
<td>A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.</td>
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<tr>
<td>AUTHORIZED INSTITUTIONAL OFFICIAL</td>
<td>See Institutional Official.</td>
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<tr>
<td>AUTONOMY</td>
<td>Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.</td>
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<tr>
<td>BELMONT REPORT</td>
<td>A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.</td>
</tr>
<tr>
<td>BENEFICENCE</td>
<td>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.</td>
</tr>
<tr>
<td>BENEFIT</td>
<td>A valued or desired outcome; an advantage.</td>
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<tr>
<td>BIOLOGIC</td>
<td>Any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries.</td>
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<tr>
<td>BLIND STUDY DESIGNS</td>
<td>See Masked Study Designs, Double-Masked Design and Single-Masked Design.</td>
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<tr>
<td>BOARD</td>
<td>See Institutional Review Board.</td>
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<tr>
<td>CASE-CONTROL STUDY</td>
<td>A study comparing persons with a given condition or disease (the cases) and persons without the condition or disease (the controls) with respect to antecedent factors. (See also Retrospective Studies.)</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention; an agency within the Public Health Service, Department of Health and Human Services.</td>
</tr>
<tr>
<td>CHILD ASSENT</td>
<td>A child’s affirmative agreement to participate in research. Mere failure to object to research activities should not, absent affirmative agreement, be construed as assent. See also Informed Consent.</td>
</tr>
</tbody>
</table>
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.

CLINICAL RESEARCH  Having to do with the examination and treatment of patients. Pertaining to or founded on observation and treatment of participants, as distinguished from theoretical or basic science.

CLASS I, II, III DEVICES  Classification by the Food and Drug Administration of medical devices according to potential risks or hazards.

CLINICAL INVESTIGATION  Clinical investigation means any experiment in which a drug is administered or dispensed to, or used involving, one or more human research participants.

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

COLLABORATING INDEPENDENT INVESTIGATOR  A research team member who is not otherwise an employee or agent of any FWA assured institution who is conducting collaborative research activities with a University researcher and is requesting coverage under the University FWA.

CLINICAL RESEARCH  Having to do with the examination and treatment of patients. Pertaining to or founded on observation and treatment of participants, as distinguished from theoretical or basic science.

CLASS I, II, III DEVICES  Classification by the Food and Drug Administration of medical devices according to potential risks or hazards.

COLLABORATING INSTITUTIONAL INVESTIGATOR  A research team members who is not otherwise an employee or agent of the assured institution that will be the IRB of record who is conducting collaborative research activities outside the facilities of the assured institution and acting as an employee or agent of another assured institution with respect to his or her involvement in the research being conducted at the assured institution.

CODE OF FEDERAL REGULATIONS (CFR)  The federal compendium of regulations on numerous topics related to compliance with federal laws.

COGNITIVELY IMPAIRED  Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons’ with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.
COHORT
A group of subjects initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.

COLD CALLING
A term that refers to an Investigator who is conducting VA research and contacts veterans whom they do not know to invite them to participate in a research project.

COLLATERAL RESEARCH PARTICIPANTS
This is the collection of identifiable information about people who are not participants and have not consented to participate in the research project.

COLLABORATING INSTITUTIONAL INVESTIGATOR
A research team member who is not otherwise an employee or agent of the assured institution that will be the IRB of record who is conducting collaborative research activities outside the facilities of the assured institution and acting as an employee or agent of another assured institution with respect to his or her involvement in the research being conducted at the ensured institution.

COMPENSATION
(1) A financial or non-financial payment given to research participants for the involvement in a research project. The amount and the method and timing of disbursement must be consistent with the laws, regulations, and guidelines governing human subjects research and must not improperly influence a subject’s decision to participate. See also Renumeration.

(2) Payment or medical care provided to participants who are injured while participating in an IRB approved research project.

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

CONCEALMENT
The withholding of information about the specific purpose or procedures of the research without providing false or misleading information to the research participant. See also Direct Deception.

CONFIDENTIALITY
Pertains to privacy and non-disclosure of personal 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
A close personal or professional association with the submitting Investigator(s), direct participation in the research (e.g., protocol development, Principal or Sub-Investigator), or any significant financial interest in the sponsoring company defined as $10,000 or 5% ownership by the Investigators or their immediate family.
CONSENT
See Informed Consent.

CONSULTANT
An individual whom the IRB consults with because they are knowledgeable about the concerns related to certain vulnerable population and their qualifications that make them able to ascertain the acceptability of proposed research in terms of human research participant protections, institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

CONTINUING NON-COMPLIANCE
A pattern or repeated incidents of failure to comply with applicable laws and/or regulations, the ethical principles of the Belmont Report, IRB policies and procedures, or determinations of the IRB. See also Non-Compliance.

CONTRACT
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.

CONTRAINDICATED
Pertains to the use of a treatment that should not be used in certain individuals or conditions due to risks of disadvantageous, perhaps dangerous results (e.g., a drug may be contraindicated for pregnant women and persons with high blood pressure).

CONTROL (SUBJECTS) OR CONTROLS
Subject(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of subjects is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled.

COOPERATIVE RESEARCH ACTIVITIES
Research activities in which OU faculty, staff or students participate in human subject research projects through one or more cooperating institutions or when non-OU researchers conduct human subjects research as a member of a research team led by an OU researcher.

CORRESPONDENCE WITH EXTERNAL AGENCIES
Shall mean any letters, memos or emails sent to agencies of the federal government, funding agencies whether private or public or their agents.

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 AND SAFETY MONITORING
A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication
BOARD (DSMB) that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.

DATA MINING, SCRAPING AND MASHING A process of looking for patterns in large batches of data in order to generate new information. Data scraping often involves the use of a computer program that extracts data from large bases of data. Data mashing occurs when mined and scraped data are combined by internet-based applications.

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). 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.

DEBRIEFING Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)

DECISIONS MADE BY CHAIRPERSON Shall mean any letters, memos or email sent representing the decision or opinions of the Chairperson of the IRB or their respective designee as long as such correspondence does not imply review and approval of research subjects.

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 has been revised several times, most recently in October, 2013.

DEPENDENT VARIABLES The outcomes that are measured in an experiment. Dependent variables are expected to change as a result of an experimental manipulation of the independent variable(s).

DESCRIPTIVE STUDY Any study that is not truly experimental (e.g., quasi-experimental studies, correlation studies, record reviews, case histories, and observational studies).

DESIGNATED STAFF Shall mean staff designated by the Institutional Official in writing.

DESIGNEE A person selected or designated to carry out a duty or role if the formal responsible party is not available to perform this function. For the HRPP, designees are available for the Institutional Official, Director of Compliance, HRPP Director, and/or IRB Chair.

DEVICE (MEDICAL) See Medical Device.

DHHS Abbreviation for U.S. Department of Health and Human Services.
**DIAGNOSTIC (PROCEDURE)**
Tests used to identify a disorder or disease in a living person.

**DIRECT DECEPTION**
Providing false or misleading information to the research participant.

**DOUBLE-MASKED DESIGN**
A study design in which neither the Investigators nor the subjects know the treatment group assignments of individual subjects. Sometimes referred to as "double-blind."

**DRUG**
Any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.

**EMANCIPATED MINOR**
A legal status conferred upon persons who have not yet attained the age of legal competency 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.) Under Oklahoma law, a minor may consent to have health services delivered by a health professional (such services not to include research) if the minor is emancipated. (See 63 Okl. Stat. 2602 for additional information on emancipation).

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

**EMERGENCY USE**
Use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval. FDA regulations consider emergency use of regulated products to be Human Subjects Research. Use of any FDA regulated product is considered Human Subjects Research and requires IRB review.

**ENGAGEMENT IN RESEARCH ACTIVITIES**
Any individual who is involved in conducting human participant research. Such involvement would include: 1) obtaining information about living individuals by intervening or interacting with them for research purposes; 2) obtaining identifiable private information about living individuals for research purposes; 3) obtaining the voluntary informed consent of individuals to be subjects in research; and 4) studying, interpreting, or analyzing identifiable private information or data for research purposes.

See also Investigator and Key Study Personnel.

**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 and interaction with the persons or group being studied in the group's own environment, often for long periods of time. See also Fieldwork.

EXCULPATORY
Pertaining to that which relieves of a responsibility, obligation, or hardship; clearing from accusation or blame.

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 IRB Chairperson 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.

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

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 PARTICIPANT or SUBJECT
See Research Involving a Human Being as an Experimental Subject

EXPIRATION DATE
The expiration date of IRB approval is defined as the last date that the protocol is approved. The expiration date is the last day of the eleventh month from the date of IRB approval of a research project, modification, or continuing review. No research activities are allowed after the IRB expiration date.

EXPORT CONTROLS
Are those federal laws and regulations that govern the transfer or disclosure of goods, technology, software, services, and funds originating from the United States to persons or entities in foreign countries OR to foreign nationals anywhere.
FAMILY MEMBER  One who is part of the basic unit in society traditionally consisting of two parents rearing their own or adopted children; also: any of various social units differing from but regarded as equivalent to the traditional family.

FDA REGULATED RESEARCH  Research involving FDA-regulated products (e.g., investigational drugs, biological products, medical devices, and dietary supplements).

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.”

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.

FIELDWORK  Behavioral, social, or anthropological research involving the study of persons or groups in their own environment and without manipulation for research purposes (distinguished from laboratory or controlled settings). See also Ethnographic Research.

FOOD AND DRUG ADMINISTRATION (FDA)  An agency of the federal government established by Congress in 1912 and presently part of the Department of Health and Human Services.

FULL IRB REVIEW  Review of proposed research at a convened meeting where the 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.

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

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.
**GENERALIZABLE KNOWLEDGE**  
An activity may be thought to develop or contribute to generalizable knowledge if the information collected can be applied beyond a particular program.

**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.

**GRANT**  
Financial support provided for research study designed and proposed by the Principal Investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.

**HELSINKI DECLARATION**  
See *Declaration of Helsinki*.

**HHS**  
See *DHHS*.

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

**HUMAN PARTICIPANTS**  
Under the DHHS 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.

Under the FDA regulations, human subjects are defined as: individuals who are or become participants in research, either as recipients of the test article or as controls. A subject may be either a healthy individual or a patient. For research involving medical devices, a human subject is also an individual on whose specimen an investigational device is used.

Under the VA regulations, human subjects are living individuals about whom an investigator conducting research obtains data through intervention or interaction with the individuals or through identifiable private information. As required by 38 CFR 16.102(f) an intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes.

**HUMAN SUBJECTS RESEARCH**  
See *Research Study*.

**IDE**  
See *Investigational Device Exemptions*.

**IMPLIED CONSENT**  
See *Informed Consent*.
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<th>Term</th>
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<tr>
<td>IN VITRO</td>
<td>Literally, &quot;in glass&quot; or &quot;test tube;&quot; used to refer to processes that are carried out outside the living body, usually in the laboratory, as distinguished from in vivo.</td>
</tr>
<tr>
<td>IN VIVO</td>
<td>Literally, &quot;in the living body;&quot; processes, such as the absorption of a drug by the human body, carried out in the living body rather than in a laboratory (in vitro).</td>
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<tr>
<td>INCAPACITY</td>
<td>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.</td>
</tr>
<tr>
<td>INCOMPETENCE</td>
<td>Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. See also Incapacity.</td>
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<tr>
<td>IND</td>
<td>See Investigational New Drug.</td>
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<tr>
<td>INFORMATION, PRIVATE</td>
<td>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.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.</td>
</tr>
<tr>
<td>INFORMED CONSENT</td>
<td>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. See also Child Assent, Implied Consent, Parental Permission, Passive Consent, Surrogate Consent.</td>
</tr>
<tr>
<td>INSTITUTION</td>
<td>(1): Any public or private entity or agency (including federal, state, and local agencies).</td>
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<td></td>
<td>(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.</td>
</tr>
<tr>
<td>INSTITUTIONAL OFFICIAL (IO)</td>
<td>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.</td>
</tr>
</tbody>
</table>
**INSTITUTIONAL REVIEW BOARD**
A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

**INSTITUTIONALIZED COGNITIVELY IMPAIRED**
Persons who are confined, either voluntarily or involuntarily, in a facility for the care of the mentally or otherwise disabled (e.g., a psychiatric hospital, home, or school for the retarded).

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

**INTERACTION**
In the context of research, interaction includes communication (including conversations, monitoring, gathering, or recording of data, which occurs via telephone, e-mail, or other electronic device) or interpersonal contact between the investigator, and or member of the research staff, or other individual who is gathering and recording data for a research study.

**INTERNATIONAL RESEARCH**
Research carried out in one of more country settings.

**INTERNET / SOCIAL MEDIA SERVICES**
Internet and mobile device-based services that provide a collection of ways for users to interact, such as social networking sites, blogs, discussion groups or other information sharing or communication services that support messaging, email, video, posting comments.

**INTERVENTION**
In research, intervention 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.

**INVESTIGATOR**
An individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB.

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. More than one investigator may conduct some research studies, and usually one investigator is designated the “principal investigator” with overall responsibilities for the study. In every human subjects research study, investigators have certain responsibilities regarding the ethical treatment of human subjects.

See also *Engagement in Research Activities and Key Study Personnel*.

**INVESTIGATIONAL DEVICE EXEMPTIONS (IDE)**
Exemptions from certain regulations found in the Medical Device Amendments that allow shipment of unapproved devices for use in clinical investigations.

**INVESTIGATIONAL NEW DRUG (IND) OR**
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...
DEVICE (IDE) population and not yet licensed for marketing.

INVESTIGATOR In clinical trials, an individual who actually conducts an investigation. Any interventions (e.g., drugs) involved in the study are administered to subjects under the immediate direction of the Investigator. See also Principal Investigator.

IRB See Institutional Review Board.

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.

KEY STUDY PERSONNEL Individuals who provide research project-related services or assistance and who have knowledge of the research protocol and the identity of research participants or their protected health information. Key personnel include principal investigators, co-principal investigators, sub-investigators, and research coordinators, and individuals from an affiliated institution. See also Engagement in Research Activities and Investigator.

LEGALLY AUTHORIZED REPRESENTATIVE A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research.

LEGALLY EFFECTIVE CONSENT See Informed Consent.

LONGITUDINAL STUDY A study designed to follow subjects forward through time.

MASKED STUDY DESIGNS Study designs comparing two or more interventions in which either the Investigators, the subjects, or some combination thereof do not know the treatment group assignments of individual subjects. Sometimes called "blind" study designs. See also Double-Masked Design; Single-Masked Design.

MATURE MINOR Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care). Note that a mature minor is not necessarily an emancipated minor. See also Emancipated Minor.

MEDICAL RESEARCH Relating to medicine or the practice of medicine. This includes studies in which the focused population has a specific medical diagnosis.

MEDICAL DEVICE A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes,
pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

MENTALLY DISABLED

See Cognitively Impaired.

MINIMAL RISK

A risk is minimal where 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.

MINOR PROTOCOL DEVIATION

A minor protocol deviation is any change, divergence, or departure from the research protocol that has not been approved by the IRB and that DOES NOT have a major impact on the participant's rights, safety, or well-being or on the completeness, accuracy, and reliability of the research project data.

MODIFICATION

A change or revision, to any item that was previously approved by the IRB (e.g. protocol, informed consent document, advertisement). Also referred to as Revision, Amendment.

MONITORING

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

MULTI-SITE MANAGEMENT PLAN

A document submitted to the IRB when a research project involves multiple data collection sites and researchers containing information regarding the communication process between sites and the management of information obtained during the course of the research project.

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.

NDA

See New Drug Application.

NEONATE

Newborn.

NEW DRUG APPLICATION

Request for FDA approval to market a new drug.

NIAAA

National Institute on Alcohol Abuse and Alcoholism; an institute in
NIH.

**NIDA**
National Institute on Drug Abuse; an institute in NIH.

**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.

**NIJ**
National Institute of Justice: NIJ is the research, development and evaluation agency of the U.S. Department of Justice and is dedicated to researching crime control and justice issues.

**NIMH**
National Institute of Mental Health; an institute in NIH.

**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).

**NON-COMPLIANCE**
A proven failure to follow the regulations or the requirements and determinations of the IRB.

**NON-SCIENTIFIC MEMBER**
Nonscientific members are expected to provide input on areas germane to his/her knowledge, expertise and experience, professional and otherwise. Nonscientific members advise the IRB if additional expertise in a nonscientific area is required to assess if research project adequately protects the rights and welfare of subjects.

**NONSIGNIFICANT RISK DEVICE**
An investigational medical device that does not present significant risk to the patient. See also *Significant Risk Device*.

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

**NONVIALBE NEONATE**
An expelled or delivered neonate which, although it is living, cannot possibly survive to the point of sustaining life independently, even with the support of available medical therapy. Although it may be presumed that an expelled or delivered neonate is nonviable at a gestational age less than 20 weeks and weight less than 500 grams, 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 Department of Health and Human Services, responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.

ONLINE IDENTITIES

In some online contexts, users represent themselves visually by creating a persona, or an avatar, to represent the participant's identity.

OPEN DESIGN

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

PARENTAL PERMISSION

The agreement of parent(s) or guardian(s) to the participation of their child or ward in research. The term "parent" means a "child's biological or adoptive parent." The term "guardian" means "an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. See also Guardian, Legally Authorized Representative.

PASSIVE CONSENT

Where a potential research subject must actively indicate that they wish to opt out of being included in the research is not acceptable. Passive consent, which is ethically questionable, requires parents to sign and return a form if they refuse to allow their child to participate in research. Active consent requires parents to sign and return a form if they consent for their child to participate. The OU IRB does not allow passive consent. See also Informed Consent.

PASSIVE DATA COLLECTION

Passive Data Collection: This type of research involves no interaction or intervention with the individual about whom data is being collected (examples: public twitter feeds; public Facebook profiles or wall postings; information from public/open chat rooms, whether the data is collected through silent observation or from archives; etc.).

PATERNALISM

Making decisions for others against or apart from their wishes with the intent of doing them good.

PERMISSION

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

PERSONAL (OR PROTECTED) HEALTH INFORMATION (PHI)

Individually identifiable health information is that which can be linked to a particular person. Specifically, this information can relate to:
1) The individual's past, present or future physical or mental health or condition,
2) The provision of health care to the individual, or,
3) The past, present, or future payment for the provision of health care to the individual.

Common identifiers of health information include names, social security numbers, addresses, and birth dates.

PERSONAL IDENTIFYING INFORMATION

Defined by the Office of Management & Budget as “Information which can be used to distinguish or trace an individual's identity, such as their name, social security number, biometric records, etc. alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name, etc.”

PHARMACOLOGY

The scientific discipline that studies the action of drugs on living systems (animals or human beings).

PHASE 1 TRIALS

Includes the initial introduction of an investigational new drug into humans. These studies are typically conducted with healthy volunteers; sometimes, where the drug is intended for use in patients with a particular disease, however, such patients may participate as subjects. Phase 1 trials are designed to determine the metabolic and pharmacological actions of the drug in humans, the side effects associated with increasing doses (to establish a safe dose range), and, if possible, to gain early evidence of effectiveness; they are typically closely monitored. The ultimate goal of Phase 1 trials is to obtain sufficient information about the drug’s pharmacokinetics and pharmacological effects to permit the design of well-controlled, sufficiently valid Phase 2 studies. Other examples of Phase 1 studies include studies of drug metabolism, structure-activity relationships, and mechanisms of actions in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects involved in Phase 1 investigations is generally in the range of 20-80.

PHASE 1, 2, 3, 4 DRUG TRIALS

Different stages of testing drugs in humans, from first application in humans (Phase 1) through limited and broad clinical tests (Phases 2 and 3), to post-marketing studies (Phase 4).

PHASE 2 TRIALS

Includes controlled clinical studies conducted to evaluate the drug’s effectiveness for a particular indication in patients with the disease or condition under study, and to determine the common short-term side effects and risks associated with the drug. These studies are typically well controlled, closely monitored, and conducted with a relatively small number of patients, usually involving no more than several
hundred subjects.

PHASE 3 TRIALS
Involves 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 and 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 TRIALS
Studies conducted after a drug has been approved by the FDA 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.

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.

PHYSICAL
Concerning the corporeal body.

PLACEBO
An inert substance or sham activity used in the guise of treatment; used in controlled clinical trials as a comparator to determine if an investigational therapy is more effective than no treatment.

PLANNED EMERGENCY RESEARCH
Planned research in a life-threatening emergency where the requirement to obtain prospective informed consent has been waived and is covered by 21 CFR 50.24. The research plan must be approved in advance by the FDA, or DHHS, and the IRB, and the project, as well as its results, are publicly disclosed to the community in which the research is conducted.

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 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. 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 the presence of a newly fertilized egg makes a definition of pregnancy based on implantation necessary.

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

**PRISONER**
An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution.

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

**PRISONER OF WAR**
Department of the Navy regulations at SECNAVINST 3900.39D, define a Prisoner of War (POW) as a detained person as defined in Articles 4 and 5 of the Geneva Convention Relative to the Treatment of Prisoners of War of August 12, 1949. In particular, one who, while engaged in combat under orders of his government is captured by the armed forces of the enemy.

Department of the Army regulations at 70-25, define a Prisoner of War, under *Prisoner*, as any person (adult or minor) involuntarily confined or detained in a penal or correctional institution (for example, jail, workhouse, house of detention, prison, military stockade, or brig). The term is intended to encompass individuals detained pending arraignment, trial, or sentencing; and prisoners of war including detained personnel).

For other DoD Components, the definition of Prisoner of War will be specific to the DoD component regulation.

Under VA regulations, a *former prisoner of war* (POW) is defined in Title 38 U.S.C. 101(32) as a person who, while serving in the active military, naval, or air service, was forcibly detained or interned in the line of duty by:

an enemy government or its agents, or a hostile force, during a period of war, or

a foreign government or its agents, or a hostile force, under
circumstances which the Secretary finds to have been comparable to the circumstances under which persons have generally been forcibly detained or interned by enemy governments during periods of war.

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

PROTECTED HEALTH INFORMATION
Individually identifiable health information is that which can be linked to a particular person. Specifically, this information can relate to: 1) The individual's past, present or future physical or mental health or condition, 2) The provision of health care to the individual, or, 3) The past, present, or future payment for the provision of health care to the individual.

PROTECTION OF PUPIL RIGHTS AMENDMENT (PPRA)
PPRA is a law intended to protect the rights of pupils and the parents of pupils in programs funded by the US Department of Education (ED). The PPRA was written to protect the rights of parents and students in two specific ways: 1) any material used by students in ED funded surveys, analyses, or evaluations will be made available to parents to inspect prior to use with their child, and 2) it ensures that schools and contractors acquire written parental consent before a minor student is required to participate in ED funded surveys, analyses, or evaluations which may reveal personal information.

PRIVATE INFORMATION
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).

This information may be clearly private (a medical record or personal diary), but may also include a person’s Facebook profile that is set so only friends can see messages or photographs.

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the 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.

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**

Events that are departures from the specific protocol procedures approved by the IRB.

**PROTOCOL DEVELOPMENT**

Some external research projects provide funding for the design of the protocol and the development of the data collection instruments. During the period of time between when study funding is available to the investigator and the human subjects research project is approved by the IRB, investigators may get permission for protocol development activities in order to release funding for study personnel. No human research activities, including recruitment or advertising, can occur during protocol development. When the investigator is ready to commence research activities, a new study application and related supporting materials must be submitted to the IRB using the standard review procedures.

**QUASI-EXPERIMENTAL STUDY**

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

**QUORUM**

A quorum consists of members or their alternates and includes at least one member whose expertise is in a scientific area, one member whose expertise is in a nonscientific area, and one member who is not otherwise affiliated with the University. A quorum is achieved if at least five IRB members and one half of the members for the IRB are present.

**RADIOACTIVE DRUG**

Any substance defined as a drug in the Federal Food, Drug and Cosmetic Act that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. Included are any non-radioactive reagent kit or nuclide generator to be used in the preparation of a radioactive drug and "radioactive biological products." Drugs such as carbon-containing compounds or potassium-containing salts containing trace quantities of naturally occurring radio-nuclides are not considered radioactive drugs.

**RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC)**

An institutional committee responsible for the use of radioactive drugs in human subjects for research purposes. Research involving human subjects that proposes to use radioactive drugs must meet various FDA requirements, including limitations on the pharmacological dose and the radiation dose. Furthermore, the 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.

**RADIO-PHARMACEUTICAL**

Drug (compound or material) 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.

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.

DNA resulting from the insertion into the chain, by chemical or biological means, of a sequence (a whole or partial chain of DNA) not originally (biologically) present in that chain. Recombinant DNA technology is also used to develop diagnostic screens and tests, as well as drugs and biologics for treating diseases with genetic components.

To disqualify (oneself) as a reviewer for a research project based on a real or perceived conflict of interest.

A financial or non-financial payment given to research participants for the involvement in a research projects. The amount and the method and timing of disbursement must be consistent with the laws, regulations, and guidelines governing human subjects research and must not improperly influence a subject’s decision to participate. See also Compensation.

Research as defined by DHHS regulations is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A research project generally is described in a protocol that sets forth explicit objectives and formal procedures designed to reach those objectives.

Research as defined by FDA regulations is any experiment that involves a test article and one or more human subjects, and is subject to requirements for prior submission to the FDA that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Food, Drugs, and Cosmetics Act, or need not meet the requirements for prior submission to the FDA under these sections of the Food, Drug, and Cosmetics Act, but the results of which are intended to be later submitted to, or held for inspections by, the FDA as part of an application for a research or marketing permit. For research involving drugs, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice. The terms research, clinical research, clinical study, study and clinical investigation are synonymous.

Research as defined by VA regulations is the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. See Human Participants.
<table>
<thead>
<tr>
<th>Term</th>
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</thead>
<tbody>
<tr>
<td>RESEARCH PROJECT</td>
<td>A term used as a standardized term in reference to Human Subjects Research, human research, etc. of only those projects that are under the purview of the IRB.</td>
</tr>
<tr>
<td>RESEARCH INVOLVING A HUMAN BEING AS AN EXPERIMENTAL SUBJECT</td>
<td>An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction [32 CFR 219.102(f), reference (c)]. Examples include, but are not limited to, a physical procedure, a drug, a manipulation of the subject or subject’s environment, or the withholding of an intervention that would have been undertaken if not for the research purpose. See Human Participants.</td>
</tr>
<tr>
<td>RESEARCH PARTICIPANT</td>
<td>Any research procedure that, when utilized as a component of an intervention or measurement procedure, elevates physical risks by increasing the probability of development of a negative physical outcome (i.e., elevated blood pressure, arrhythmia).</td>
</tr>
<tr>
<td>RESEARCH PROCEDURE THAT MAY RESULT IN GREATER THAN A MINIMAL LEVEL OF PHYSICAL RISK</td>
<td>Any research procedure that, when utilized as a component of an intervention or measurement procedure, elevates physical risks by increasing the probability of development of a negative physical outcome (i.e., elevated blood pressure, arrhythmia).</td>
</tr>
<tr>
<td>RESPECT FOR PERSONS</td>
<td>An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and those persons with diminished autonomy is protected.</td>
</tr>
<tr>
<td>RETROSPECTIVE STUDIES</td>
<td>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.</td>
</tr>
<tr>
<td>REVIEW AND APPROVAL OF RESEARCH PROJECTS</td>
<td>Any action or decision taken by the IRB through full or expedited review mechanisms, which grants or may appear to grant Investigators with initial or continuing approval or research, training or educational projects involving human subjects.</td>
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<td>RESEARCH PROCEDURE THAT MAY RESULT IN GREATER THAN A MINIMAL LEVEL OF PHYSICAL RISK</td>
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</tr>
<tr>
<td>REVIEW (OF RESEARCH)</td>
<td>The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis. See Modification.</td>
</tr>
<tr>
<td>REVISION</td>
<td>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 &quot;minimal risk.&quot; (See also: Minimal Risk.)</td>
</tr>
</tbody>
</table>
**ROUTINE INTERNAL CORRESPONDENCE**

Means any action, letters, memos or emails between the IRB and staff and members of the faculty or staff of the institution/organization that provides information concerning the review of research protocols by the IRB or staff which do not imply or appear to imply approval of this activity.

**SCHOLARLY MISCONDUCT**

See also *Scientific Misconduct*.

**SCIENTIFIC MEMBER**

Scientific members are expected to review assigned studies, as well as contribute to the evaluation of a research project on its scientific merits and standards of practice. These members are able to advise the IRB if additional expertise in a scientific area is required to assess if a research project adequately protects the rights and welfare of subjects.

**SCIENTIFIC MISCONDUCT**

Scientific misconduct is the violation of the standard codes of scholarly conduct and ethical behavior in professional scientific research.

**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 subjects. 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).

**SERIOUS NON-COMPLIANCE**

Disregarding or failing to comply with applicable laws and/or regulations, the ethical principles of the Belmont Report, IRB policies and procedures, or determinations of the IRB. See also *Non-Compliance*.

**SERIOUS ADVERSE EVENT**

For FDA safety reporting purposes, any adverse drug experience occurring at any dose that results in any of the following outcomes: (1) Death, (2) a life-threatening adverse drug experience, (3) inpatient hospitalization or prolongation of existing hospitalization, (4) a persistent or significant disability/incapacity, or (5) a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an 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.

**SIGNIFICANT RISK DEVICE**

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

**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.

SPECIAL POPULATION
Individuals whose willingness to volunteer in a research project may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

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. An 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, alone or with others, a clinical investigation. Corporations, agencies, or other institutions do not qualify as Sponsor-Investigators.

STATISTICAL SIGNIFICANCE
A determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. Or, more simply put, the probability of coming to a false positive conclusion. If the probability is less than or equal to a predetermined value (e.g., 0.05 or 0.01), then the null hypothesis is rejected at that significance level (0.05 or 0.01).

STUDY SECTION
See Scientific Review Group.

SUBFORM
A form within the IRB’s application that appears in the electronic information system based on the answer an investigator provides to an application question. Subforms gather additional details about what is being proposed by the investigator in order for the IRB reviewer to make a determination.

SUBJECTS (HUMAN)
See Human Participants.
**SURROGATE CONSENT**

An individual who gives consent for another person who has limited capacity to make voluntary and informed decisions about participation in a research project. Federal regulations and state laws provide additional guidance and restrictions governing surrogate consent and who is eligible to sign as a legally authorized representative. See also *Informed Consent*.

**SURVEYS**

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

**SYSTEMATIC INVESTIGATION**

The term systematic investigation is generally thought of as a predetermined method for answering certain questions or studying a specific program or topic.

**TECHNICAL NON-COMPLIANCE**

Non-compliance that is neither serious nor continuing non-compliance.

**TEST ARTICLE**

Any drug (including a biological product for human use), medical device for human use, or any other article subject to regulation by the Food and Drug Administration.

**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 affected.) 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.

**TECHNICAL NON-COMPLIANCE**

Non-compliance that is neither serious nor continuing non-compliance.

**THERAPY**

Treatment intended and expected to alleviate a disease or disorder.

**THIRD-PARTY WITNESS**

An individual not involved in the study or related to the study who observes the consent process attesting that the participant was provided the study information.

**TRANSNATIONAL RESEARCH**

Research that is done with the purpose of comparing across the countries.

**UNANTICIPATED / UNEXPECTED**

For purpose of VA research projects, the terms “unanticipated” and “unexpected” refer to an event or problem in VA research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

Any incident, experience, or outcome that meets all of the following criteria:

a. Is unanticipated or unexpected.

b. Is related to the research

c. Involves new or increased risks to participants or others.

**UNIFORM**

Legislation adopted by all 50 States and the District of Columbia that
<table>
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<tr>
<td><strong>ANATOMICAL GIFT ACT</strong></td>
<td>Indicates procedures for donation of all or part of a decedent's body for such activities as medical education, scientific research, and organ transplantation.</td>
</tr>
<tr>
<td><strong>VACCINE</strong></td>
<td>A biologic product generally made from an infectious agent or its components — a virus, bacterium, or other microorganism — that is killed (inactive) or live-attenuated (active, although weakened). Vaccines may also be biochemically synthesized or made through recombinant DNA techniques.</td>
</tr>
<tr>
<td><strong>VARIABLE (NOUN)</strong></td>
<td>An element or factor that the research is designed to study, either as an experimental intervention or a possible outcome (or factor affecting the outcome) of that intervention.</td>
</tr>
<tr>
<td><strong>Viable Infant</strong></td>
<td>When referring to a delivered or expelled fetus, the term &quot;viable infant&quot; means likely to survive to the point of sustaining life independently, given the benefit of available medical therapy. A physician makes this judgment. 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. These indices depend on the state of present technology and may be revised periodically. See also Nonviable Fetus.</td>
</tr>
<tr>
<td><strong>Voluntary</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Vulnerable Subjects</strong></td>
<td>Groups of potential research participants who are entitled to additional protections according to federal regulations including Prisoners, Children, Pregnant Women and Fetuses. See also Special Populations.</td>
</tr>
</tbody>
</table>