

Homewood Institutional Review Board

Glossary

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A

ADVERSE EVENT (AE) A harmful event affecting one or more participants that may be associated with research interventions or other research procedures, including the handling of private information. Examples include emotional distress, exacerbation of an existing mental disorder, a breach of confidentiality, and a complication from use of a medical device. (See **EXPECTED ADVERSE EVENT**, **SERIOUS ADVERSE EVENT**, and **UNEXPECTED ADVERSE EVENT**.)

ADVERTISING See **DIRECT ADVERTISING**.

APPEAL Process by which an investigator can contest, in writing to HIRB, HIRB's disapproval of a research project, withdrawal of approval, or repeated deferrals. HIRB has sole discretion to alter its decision; no other official or body at or associated with JHU may intervene.

APPROVAL Authorization by an IRB, after review of a research project, that permits the project to be conducted at an institution within the conditions set forth by the IRB and in accordance with Federal regulations and other institutional requirements [45 CFR 46.102].

ASSENT Affirmative agreement by an individual, such as a child or cognitively-impaired person, who is not competent to give legally valid informed consent to participate in research. Failure to object to participation absent affirmative agreement does not qualify as assent.

ASSURANCE See **FEDERALWIDE ASSURANCE**.

AUDIT Process by which HIRB examines a previously reviewed research protocol and research activities to date in order to ensure the continued protection of research participants and compliance with Federal, state, and local laws and regulations and HIRB policies and procedures.

AUTHORIZATION AGREEMENT A joint agreement, approved by OHRP, in which multiple institutions agree to participate in a research project while relying on the review of one primary IRB's review and approval in order to avoid duplication of effort.

AUTONOMY Freedom and capacity to self-govern; capacity to weigh alternatives, make decisions, and act independently without others' undue influence or interference. An autonomous individual can provide legally effective informed consent to participate in research.

B

THE BELMONT REPORT Issued by the National Commission for the Protection of Human Subjects in 1979, this document identifies basic ethical principles that should be followed in human participant research.

BENEFICENCE One of three essential ethical principles featured in *The Belmont Report*; entails an obligation to protect people from harm through avoidance of known harms, minimization of possible risks, and maximization of possible benefits.

BENEFIT Something that is useful to or improves the well-being of a participant or other individuals, such as treatment for a problem. Benefits can be direct or indirect. For instance, a direct benefit could improve participants' condition while an indirect benefit might improve scientific understanding of the condition but not directly alter it.

C

CERTIFICATE OF CONFIDENTIALITY A document issued by the National Institutes of Health (NIH) and other HHS agencies that provides protection against compelled disclosure (e.g., subpoena) of names and other identifying information about participants enrolled in sensitive biomedical, behavioral, clinical, or other research, including research on mental health and the use and effect of alcohol and other psychoactive drugs. Certificates are not limited to Federally supported research.

CERTIFICATE OF TRANSLATION Document signed by someone other than the investigator(s) attesting that a non-English translation of the English informed consent document is accurate.

CHILDREN Individuals who have not attained the legal age for consent to treatment or procedures involved in research according to applicable law of the jurisdiction in which the research will be conducted. In Maryland, individuals 18 years of age and older are of legal age (released from parental authority) and considered adults [http://mlis.state.md.us/cgi-win/web_statutes.exe - section 24]. (Also called **MINORS**.) There are several exceptions, such as marriage and childbearing, that can qualify individuals under the age of 18 as emancipated minors.

CLASS PROTOCOL Description of research to be undertaken by students in a class or classes to learn more about the process of research and to satisfy course objectives. An instructor must serve as the PI.

CLINICAL TRIAL A controlled research study that includes human participants and usually is designed to test the effectiveness of drugs and treatments.

CODE OF FEDERAL REGULATIONS (CFR) A compilation of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government of the United States of America [<http://www.gpoaccess.gov/cfr/about.html>].

COGNITIVELY-IMPAIRED PARTICIPANT A participant who has either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), an organic impairment (e.g., dementia), or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functioning to the extent that capacity for judgment and reasoning is significantly diminished. Individuals 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 also may have impaired ability to make decisions in their best interests.

COMMON RULE Another name for 45 CFR 46, Subpart A, the Federal regulations governing the protection of human research participants. Eighteen Federal departments and agencies have adopted the Common Rule and require institutions, such as JHU, that receive their support to comply with these regulations.

COMPENSATION (1) Money or gifts given to participants for participation in research. (Also referred to as **PAYMENT**.) Consent forms should not describe payment as a benefit of participation. (2) Money or medical treatment provided to participants injured by the research.

COMPETENCE A legal term used to denote capacity to act on one's own behalf. A competent individual can understand information, consider the consequences of action and inaction, make decisions, and act on his or her own behalf. Competence may fluctuate as a function of the natural course of a physical or mental illness, response to treatment, effects of medication, and general physical condition. (See **INCOMPETENCE**.)

CONFIDENTIALITY Refers to the privacy of human research participants and efforts to control access to information related to their participation in order to protect their privacy.

CONSENT See **INFORMED CONSENT**.

CONTINUING NONCOMPLIANCE A pattern of noncompliance that, in the judgment of the HIRB Chair or convened board, suggests that, without intervention, instances of noncompliance likely will continue. Continuing noncompliance includes failure to respond to a request to resolve an episode of noncompliance.

CONTINUING REVIEW The periodic oversight of human participant research projects by an IRB. At a minimum according to Federal regulations, HIRB must review every nonexempt study at least annually [45 CFR 46.108(e)]. HIRB reviews projects on at more frequent basis when necessary to ensure the protection of human participants.

CONTROL PARTICIPANTS Participants used for comparison who are not given a treatment or who do not have a given condition, background characteristic, or risk factor that is the focus of study. Sometimes referred to as **CONTROLS** or **CONTROL GROUP**.

CONTRAINDICATED Potentially problematic, perhaps harmful. A contraindicated treatment should not be used by certain individuals or under certain conditions due the risks associated with its use (e.g., a drug that raises blood pressure is contraindicated for people with high blood pressure).

COORDINATING CENTER An entity that organizes multi-site observational studies, clinical trials, or other research. Coordinating centers that receive or possess individually identifiable (either directly or through coding systems) private information for research purposes are considered to be engaged in research.

D

DATA SAFETY MONITORING BOARD (DSMB)/SAFETY MONITORING COMMITTEE (SMC) A group of scientists, physicians, bioethicists, statisticians, and other experts that collects and analyzes data during the course of a research project involving greater than minimal risk. The group monitors data for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of a trial involves a placebo control) that would warrant modification or termination of the study or notification of participants about new information that might affect their willingness to continue in the study. The group also monitors the confidentiality of participants' data to ensure their privacy.

DATA SAFETY MONITOR (DSM) A scientist, physician, bioethicist, statistician, or other expert who collects and analyzes data during the course of a research project involving greater than minimal risk. The individual monitors data for adverse effects and other trends that would warrant modification or termination of the study or notification of participants about new information that might affect their willingness to continue in the study. The DSM also monitors the confidentiality of participants' data to ensure their privacy.

DEBRIEFING Providing participants previously undisclosed information about the research following completion of their participation.

DECEPTION The intentional withholding from participants of information related to the research or the intentional provision of false information about some aspect of the research. Deception is not allowed unless it is essential to the goals of the research and approved by HIRB. A waiver of the informed consent requirements is required.

DECISION-MAKING CAPACITY Generally understood as the ability to understand the choice(s) presented, to appreciate the implications of choosing one alternative over another, and to make and communicate a choice. Term is often defined in state statutes.

DECISIONALLY-IMPAIRED PARTICIPANT A participant whose capacity for judgment and reasoning is impaired and who therefore may be incapable of giving informed consent without a legally authorized representative (LAR). (See **COGNITIVELY-IMPAIRED PARTICIPANT**.)

DECLARATION OF HELSINKI A code of ethics for clinical research, approved by the World Medical Association in 1964 and revised in 1975 and 1989. Numerous medical associations in many countries have adopted this code, which expounds the need for review of research protocols by an independent committee.

DESCRIPTIVE STUDY A study that is not experimental, such as a record review, case history, observational study, correlational research, and quasi-experimental study.

DHHS (DEPARTMENT OF HEALTH AND HUMAN SERVICES) The Federal agency responsible for protecting Americans' health and providing human services. Also referred to as HHS.

DIRECT ADVERTISING Written scripts, mailings, printed flyers, posters, newspaper advertisements, press releases, television and radio spots, videotapes, web pages and electronic mailings that are intended to be seen or heard by prospective participants to solicit their participation in a study.

E

EMANCIPATED MINORS Individuals who have not yet reached the age of majority (adulthood) according to state law but who have achieved legally recognized independence from parents, for instance by marrying or becoming a parent, and can consent to participate in research. (See **MINORS**.)

ENGAGED IN RESEARCH An institution becomes engaged in human participant research when its employees or agents (i.e., individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility) intervene or interact with living individuals for research purposes or obtain individually identifiable private information for research purposes [45 CFR 46.102(d & f)].

EQUITABLE Fair and equal. Used to refer to the just selection of research participants, which requires that the risks and benefits of research are distributed fairly among potential participant populations.

ETHNOGRAPHIC RESEARCH A descriptive study of people and their culture. Ethnographic research typically consists of observation and/or interaction with people or groups in their natural environment, sometimes over long periods of time. Also referred to as **FIELD WORK**.

EXEMPT REVIEW Review to determine if a study is minimal risk and falls into one of six categories delineated in Federal regulations as potentially exempt [45 CFR 46.101]. Studies deemed exempt by HIRB are released from compliance with Federal regulations [45 CFR 46] at HIRB's discretion. Investigators are nevertheless required to treat participants ethically.

EXCULPATORY LANGUAGE Words through which the prospective participant and/or the participant's legally authorized representative (LAR) is made to waive, or appear to waive, any of the participant's legal rights or is made to release, or appear to release, the investigator, the sponsor, the institution, or its agents from liability for negligence. Such language is not permitted in the informed consent process.

EXPECTED ADVERSE EVENT An adverse event that is anticipated, usually based on previous studies, and described in the consent form, the study protocol, and the investigator's brochure in clinical studies of an investigational product. Expected adverse events include adverse events that are recognized during the course of a study; determined, after review by an IRB, not to require the study to be stopped or the intervention to be modified; and classified for the remainder of the study as expected adverse events. (See **ADVERSE EVENT** and **UNEXPECTED ADVERSE EVENT**).

EXPEDITED REVIEW Review of proposed human participant research by the HIRB chair or one or more designated voting members instead of the full board. Federal rules permit expedited review for certain categories of research involving no more than minimal risk and for minor changes in ongoing research the IRB has previously approved [45 CFR 46.110].

F

FDA (FOOD AND DRUG ADMINISTRATION) Federal agency responsible for assuring the safety, efficacy, and security of human drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation [21 CFR 50, 56, 312, and 812]. The FDA also is

responsible for advancing public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable and facilitating public access to accurate, science-based information about the use of medicines and foods to improve health.

FEDERALWIDE ASSURANCE (FWA) A written, binding commitment submitted to OHRP by an institution engaged in human participant research in which the institution promises to comply with applicable Federal regulations governing such research and specifies the procedures it will follow to ensure compliance [45 CFR 46.103]. The Johns Hopkins University Homewood Schools' Federalwide Assurance is No. 00005834.

FERPA (FAMILY EDUCATIONAL RIGHTS AND PRIVACY ACT) A Federal law protecting the privacy of students' school records [34 CFR Part 99] [<http://www.ed.gov/policy/gen/guid/fpco/ferpa/index.html>].

FETUS The product of conception from implantation until delivery.

FIELD WORK Behavioral, social, or anthropological research in which people or groups are studied in their natural environment. (Also see **ETHNOGRAPHIC RESEARCH**.)

FULL BOARD REVIEW Review of a proposed human participant research project at a convened IRB meeting at which a majority of members is present, including at least one member whose primary concerns are not scientific. A majority of those present must approve the research for it to receive IRB approval [45 CFR 46.108].

G

GRANT Financial support provided by an agency to principal investigator(s) in response to their submission of a research proposal and request for funding. In contrast to a contracting agency, a granting agency does not exercise direct control over research it funds.

GUARDIAN An individual who has the legal authority according to state or local laws to consent on a child's behalf to general medical care and, by extension, to consent to the child's participation in research [45 CFR 46.402].

H

HHS Department of Health and Human Services, the Federal agency responsible for protecting Americans' health and providing human services Also called DHHS.

HIPAA (HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT) Passed by Congress in 1996, this law requires uniform Federal privacy protections for individually identifiable health information [Public Law 104-191]. DHHS issued final regulations, known as the "Privacy Rule," implementing the privacy provisions of HIPAA [<http://www.hhs.gov/ocr/hipaa/>].

HIRB The Homewood Institutional Review Board, which is the IRB that reviews research associated with the JHU Homewood Divisions.

HOMEWOOD DIVISIONS The Johns Hopkins University Applied Physics Laboratory, Krieger School of Arts and Sciences, Peabody Institute, School of Advanced International Studies, School of

Professional Studies in Business and Education, and Whiting School of Engineering. (Also referred to as **HOMEWOOD SCHOOLS**.)

HRPP (HUMAN RESEARCH PROTECTIONS PROGRAM) The array of protections that are in place throughout the Homewood Divisions to ensure the rights and safety of human participants in research associated with the divisions.

HRPP ADVISORY COMMITTEE The coordinating and policy-making body for the various components of HRPP, including the Homewood IRB (HIRB), the Research Projects Administration Office, the Institutional Official (IO), and the Office of General Counsel.

HUMAN PARTICIPANT RESEARCH When an investigator obtains, for research purposes, (1) data through intervention or interaction with a living individual or (2) identifiable private information about a living individual. Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the participant or the participant's environment for research purposes. Interaction includes communication or interpersonal contact between investigator and participant. 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 that has been provided for specific purposes by an individual that the individual reasonably expects will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the investigator can ascertain the identity of the participant and the participant's data) in order for the activities to constitute human participant research.

HUMAN PARTICIPANTS Individuals whose behavioral or physiological characteristics and responses are the focus of study by an investigator (professional or student) in a research project. Federal regulations define human participants as living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual(s) or (2) identifiable private information [45 CFR 46.102].

HUMAN SUBJECTS See **HUMAN PARTICIPANTS**. Subjects is an outdated term for participants.

I

IDENTIFYING INFORMATION Any item or combination of items in the data that could lead directly or indirectly to the identification of a research participant [45 CFR 46.102(f)].

INCAPACITY Refers to an individual's inability to understand information, consider the consequences of action and inaction, make decisions, and act on his or her own behalf. Sometimes used synonymously with **INCOMPETENCE**. (See **COMPETENCE**.)

INCOMPETENCE Refers to an individual's inability to understand information, consider the consequences of action and inaction, make decisions, and act on his or her own behalf. Sometimes used synonymously with **INCAPACITY**. (See **COMPETENCE**.)

INDIVIDUAL STUDENT RESEARCH A study undertaken by an individual student, such as a thesis or dissertation, in collaboration with a faculty member. The faculty member must serve as the PI for HIRB to approve the study.

INFORMED CONSENT A process through which a person's voluntary agreement to participate in research is obtained after the person has been informed of the physical, psychological, and social

risks and potential benefits posed by the study as well as the procedures involved [45 CFR 46.116]. Informed consent is usually demonstrated by signing a consent form, but it may be provided orally (under specific criteria approved by HIRB).

INSTITUTION Any public or private entity or agency (including Federal, state, and other agencies) [45 CFR 46.102].

INSTITUTIONAL OFFICIAL (IO) For the JHU Homewood Schools, the IO is the Dean of Research and Graduate Education in the Krieger School of Arts and Sciences. The IO has ultimate responsibility for the institutional commitment made in HIRB's Federalwide Assurance (FWA). The IO is authorized to assure HIRB complies with the terms of the FWA and is ultimately responsible for the review and oversight of human participant research conducted in association with or supported by the Homewood Divisions. The IO cannot be an IRB member or chairperson.

INSTITUTIONAL REVIEW BOARD (IRB) A specially constituted review body recognized by the Office for Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS) to protect the welfare of human participants in behavioral or biomedical research at a specific institution [45 CFR 46.102, 108, & 109].

INSTITUTIONALIZED Voluntarily or involuntarily confined to an institution such as a psychiatric hospital, prison, or nursing facility.

INTENTIONAL NONCOMPLIANCE Fraud or deception by a member or members of the research team. The intent is usually to mislead study participants, investigators, study sponsors, or others regarding study procedures or results.

INVESTIGATOR Scientist(s) or scholar(s) with responsibility for the design and/or conduct of a research project. (Also see **PRINCIPAL INVESTIGATOR**.)

INVESTIGATOR'S BROCHURE A compilation of clinical and non-clinical information relevant to the clinical use of an investigational agent, such as an Investigational New Drug (IND). Describes the rationale and features of the investigational agent in sufficient detail to allow investigators, regulatory authorities, institutional review boards, and ethics committees to assess the risks and benefits to participants. The investigator's brochure is a required component of an FDA IND application [21 CFR 312.23 (5)].

IRB (INSTITUTIONAL REVIEW BOARD) See **INSTITUTIONAL REVIEW BOARD**.

IRB OF RECORD An IRB is considered the IRB of Record when it assumes IRB responsibilities for another organization.

J

JUSTICE One of three ethical principles specified in *The Belmont Report*. Requires fair distribution of research burdens and benefits among all populations of individuals.

K

KEY STUDY PERSONNEL Members of the research team who contribute in a substantive way to the scientific development, design, or conduct of the study. This list includes the PI, other investigators,

and project coordinators. Depending upon their role, it may include consultants, research assistants, and others. Anyone who interacts directly with research participants or their individually identifiable data qualifies.

L

LEGALLY AUTHORIZED REPRESENTATIVE (LAR) An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in a research study [45 CFR 46.102].

M

MATURE MINORS Individuals who have not reached legal adult status, as defined by state law, but who may be treated as adults in certain situations such as when consenting to medical care. Mature minors are not necessarily emancipated minors. (See **EMANCIPATED MINOR**.)

MENTALLY DISABLED See **COGNITIVELY IMPAIRED**.

MINIMAL RISK When the probability and magnitude of anticipated physical or psychological harm or discomfort in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102] 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 a routine physical examination.

MINORS Individuals who have not attained the legal age for consent to treatment or procedures involved in research according to applicable law of the jurisdiction in which the research will be conducted. In Maryland, individuals 18 years of age and older are of legal age (released from parental authority) and considered adults [http://mlis.state.md.us/cgi-win/web_statutes.exe - section 24]. (Also called **CHILDREN**.) There are several exceptions, such as marriage and childbearing, that can qualify individuals under the age of 18 as emancipated minors.

MONITORING Process of collecting and analyzing information from ongoing research to ensure the protection of research participants.

MINUTES Official record of the proceedings of a meeting.

N

NATIONAL COMMISSION The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created in 1974 with the passage of the National Research Act (PL 93-348). One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In response to this charge, the Commission published, in 1979, *The Belmont Report*, subtitled *Ethical Principles for the Protection of Human Subjects of Research*. The National Commission also produced reports and recommendations regarding IRBs and research involving children, fetuses, prisoners, children, and individuals institutionalized as mentally infirm. These reports and recommendations have been largely codified as 45 CFR 46 (including Subparts A through D), 21 CFR 50, and 21 CFR 56.

NEONATE A living newborn infant.

NONAFFILIATED IRB MEMBER A required member of the IRB who has no other ties to the parent institution, its staff, or its faculty. This member usually belongs to the local community and can be a minister, lawyer, business person, teacher, homemaker, etc.

NONCOMPLIANCE Failure to comply during the conduct of human participant research with relevant Federal, state, or local laws or regulations or HIRB policies and procedures. Noncompliance can range from minor and sporadic to serious and continuing and may be intentional. (See **CONTINUING NONCOMPLIANCE**, **INTENTIONAL NONCOMPLIANCE**, and **SERIOUS NONCOMPLIANCE**.)

NUREMBERG CODE A code of research ethics developed from the Nuremberg War Crimes Trial of Nazi war criminals, in which physicians were charged with performing brutal medical experiments on detainees in concentration camps during World War II. The Nuremberg Code stresses that consent to participation in clinical research studies be voluntary and that research risks be minimized and not outweigh potential benefits.

O

OHRP (OFFICE FOR HUMAN RESEARCH PROTECTIONS) An administrative office within the Department of Health and Human Services (DHHS). OHRP implements Federal regulations for the protection of human research participants [45 CFR 46] and provides guidance on ethical issues in biomedical and behavioral research. OHRP previously operated as the **OFFICE FOR PROTECTION FROM RESEARCH RISKS (OPRR)**.

OPPR (OFFICE FOR PROTECTION FROM RESEARCH RISKS) Former office within the National Institutes of Health that was responsible for implementing DHHS regulations governing research involving human participants. Replaced by OHRP (**OFFICE FOR HUMAN RESEARCH PROTECTIONS**).

P

PARENT The biological or adoptive mother or father of a child.

PARTICIPANT An individual enrolled in a research project who, unless the IRB has waived the informed consent requirement, has provided legally effective informed consent.

PAYMENT Money or gifts given to participants for participation in research. Consent forms should not describe payment as a benefit of participation. (Also referred to as **COMPENSATION**.)

PERMISSION Consent of parent(s) or guardian to the participation of a child or ward in research [45 CFR 46.402(c)].

PILOT ACTIVITIES Small-scale studies to refine a research design, determine the feasibility of a larger study, or test a research instrument. (Also referred to as **PILOT STUDIES** and **PILOT RESEARCH**.)

PPRA (PROTECTION OF PUPIL RIGHTS AMENDMENT) The Protection of Pupil Rights Amendment (PPRA) [20 USC § 1232h; 34 CFR Part 98] applies to programs and schools that receive funding from the U.S. Department of Education (ED) [<http://www.ed.gov/policy/gen/guid/fpco/ppra/>]

index.html]. It requires that schools and contractors obtain written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation that involves protected information.

PRINCIPAL INVESTIGATOR (PI) Scientist or scholar who has primary responsibility for the design and/or conduct of a research project. Sometimes multiple investigators share primary responsibility and function as Co-PIs. (Also see **INVESTIGATOR**.)

PRISONERS Individuals involuntarily confined in a penal institution, including individuals sentenced under a criminal or civil statute or detained pending arraignment, trial, or sentencing [45 CFR 46.303(c)]. The term also applies to individuals detained in other facilities, such as drug detoxification or alcoholism treatment centers, under statutes or commitment procedures that provide these as alternatives to incarceration in a penal institution or criminal prosecution.

PRIVACY Freedom from intrusion by others into physical, behavioral, or intellectual aspects of oneself. Control over the circumstances, including the extent and timing, of sharing aspects of oneself with others.

PRIVATE INFORMATION Includes facts about attitudes and behaviors that an individual can reasonably expect not to be shared with people the individual has not authorized to have access to the information [45 CFR 46.102(f)]. Examples include medical records, school records, and answers to survey questions about illegal and embarrassing behaviors.

PROSPECTIVE STUDY A research design in which participants are identified and studied over time. Many prospective studies are observational and do not include manipulation or intervention.

PROTOCOL The formal design or plan of an experiment or research activity — akin to a blueprint — which is submitted to an IRB for review and often also used in applications to funding agencies. The protocol includes a description of the proposed research design and methodology, eligibility requirements for prospective participants, informed consent process, treatment regimen(s), and methods of analysis that will be performed on the data collected. The body of HIRB applications for new research consists of the research protocol.

Q

QUASI-EXPERIMENTAL STUDY An experimental study that lacks random assignment of participants to groups.

QUORUM A majority of the IRB voting members, including at least one member whose primary concerns are in nonscientific areas. At IRB meetings, a quorum must be established and maintained for the deliberation and vote on all matters needing full board approval.

R

RANDOM ASSIGNMENT Assignment of participants to groups, such as the control and treatment groups, by chance. No characteristics of the participants, such as gender or medical history, or other factors are used to make systematic assignments to research groups. Random assignment is unpredictable. It is a key element of experimental research because it increases the likelihood that differences found between or among groups are the result of the experimental manipulation.

REMUNERATION See PAYMENT.

REPOSITORY A storage site and/or mechanism for collecting, storing, and distributing human biological materials for research purposes.

RESEARCH A systematic investigation designed to develop or contribute to generalizable knowledge. May include research development, testing, and evaluation activities [45 CFR 46.102].

RESPECT FOR PERSONS One of three essential principles of ethical research identified in *The Belmont Report*. Requires that potential and enrolled participants' autonomy be respected and participants with diminished autonomy be protected.

RESEARCH PROTOCOL See PROTOCOL.

RETROSPECTIVE STUDIES Investigation of past events through review of records, such as medical records, death certificates, school files, or information about past events collected through interviews or surveys.

REVIEW The evaluation of research protocols by an IRB to ensure human participants' safety in compliance with Federal regulations. (Also see CONTINUING REVIEW.)

RISK The possibility of physical, psychological, or social harm or injury resulting from participation in a research study. The likelihood and magnitude of possible harm varies from minimal to significant. Federal regulations define only one level of risk — minimal. (Also see MINIMAL RISK.)

S

SAFETY MONITORING COMMITTEE (SMC) See DATA SAFETY MONITORING BOARD (DSMB).

SECONDARY PARTICIPANT When a participant is asked to provide private information about another person who can be identified, that person may be considered a secondary participant and his or her consent may be required before the primary participant is allowed to provide information about him or her.

SERIOUS ADVERSE EVENT (SAE) An adverse event that involves death, is life threatening, requires inpatient hospitalization or prolongs existing hospitalization, causes a persistent or significant disability or incapacity, causes a congenital anomaly or birth defect, or, in the judgment of the investigators or safety monitors, significantly increases risk to study participants. (See ADVERSE EVENT.)

SERIOUS NONCOMPLIANCE Failure to follow Federal, state, or local laws or regulations or HIRB policies and procedure in the conduct of research, thereby increasing risks to participants, decreasing potential benefits to participants, and/or compromising the integrity of HRPP, in the judgment of either the HIRB Chair or the convened board.

STATISTICAL CENTER An organization that processes data. Statistical centers that receive or possess individually identifiable (either directly or through coding systems) private information for research purposes are engaged in human participant research.

STUDENT RESEARCH See CLASS PROTOCOLS and INDEPENDENT STUDENT RESEARCH.

STUDY (NOUN) All components of a research project.

SURVEYS A research method in which information is collected through written questionnaires, telephone interviews, or similar procedures.

T

TEST OF UNDERSTANDING An oral or written test given to prospective participants to determine if they comprehend adequate information about the study to provide informed consent.

U

UMBRELLA REVIEW HIRB review of a grant application in which there are multiple sub-studies to be funded. Umbrella approval does not authorize research with human participants; instead it simply acknowledges the grant submission. Separate applications for the individual sub-studies must be submitted to and approved by HIRB before research with human participants can occur.

UNANTICIPATED PROBLEM Any undesirable and unintended event, such as a breach of confidentiality, that is or may be related to the research *and* is harmful or potentially harmful to one or more research participants or other individuals associated with the research. To qualify as an unanticipated problem, actual harm does not have to occur; risk of harm is sufficient. Adverse events (AEs) and serious adverse events (SAEs) that are unanticipated qualify as unanticipated problems when they are or may be due to the research; this includes anticipated AEs and SAEs that are worse than expected in magnitude and/or frequency.

UNEXPECTED ADVERSE EVENT (UAE) An adverse event whose nature, severity, and/or frequency is unanticipated and thus not described in the information provided in the consent form, the research protocol, or the investigator's brochure in clinical studies of an investigational product. When definitely or possibly due to the research, a UAE qualifies as an unanticipated problem.

V

VULNERABLE PARTICIPANT An individual, such as a child, who lacks the capacity to provide informed consent or whose willingness to participate in research may be unduly influenced by others.

VOLUNTARY Without coercion or duress and not as a result of undue influence.

W

WAIVER OF CONSENT Federal regulations permit IRBs to release investigators from or alter informed consent requirements in a limited number of circumstances, such as a medical emergency. The IRB also is permitted to waive documentation of informed consent under certain conditions.

WARD OF THE STATE Individual in state custody, whose rights and safety are guarded by the state (e.g., minor, mentally incompetent person).

WHISTLE-BLOWERS Individuals who report sensitive information to HIRB regarding potential noncompliance with Federal regulations and/or HIRB policies and procedures regarding the conduct of human participant research.

REFERENCES

This glossary includes definitions found in the Federal Code of Regulations governing human participant research [45 CFR 46] and OHRP's Institutional Review Board Guidebook [http://www.hhs.gov/ohrp/irb/irb_glossary.htm].