

**Adverse Event:** An unfavorable change in the health of a participant, including abnormal laboratory findings, that happens during a clinical study or within a certain time period after the study has ended. This change may or may not be caused by the intervention being studied.

**Adverse Event Reporting Plan:** A description of how adverse events will be defined, identified, documented, reported, reviewed, and resolved during the conduct of a study.

**Assent:** A child's affirmative agreement to participate in research, which must not merely be a child's failure to object to participation. An Institutional Review Board must determine that adequate provisions are made for soliciting the assent of children to participate in research, including the need to obtain parental permissions.

**Bias:** Any tendency which prevents unprejudiced consideration of a question or topic.

**Breach:** An impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of the protected health information.

**Certificate of Confidentiality:** A document that protects investigators and institutions from being forced to release information that would identify research participants. Such certificates protect against some legal demands for information such as some court orders and subpoenas.

**Clinical Research:** Medical research that involves people to test treatments and therapies.

**Clinical Trial:** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

**Coercion:** An overt or implicit threat of harm intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that they will lose access to needed health services if they do not participate in the research.

**Co-Investigator:** An investigator who partners with a principal investigator on studies requiring their scientific or methodological expertise.

**Confidentiality:** Confidentiality refers to the duty of anyone entrusted with health information to keep that information private. Informed consent documents often contain a statement about confidentiality which describes what, if any, confidentiality of records identifying the subject will be maintained and secured by the study team.

**Consolidated Standard of Reporting Trials or CONSORT:** Guidelines that are intended to improve the reporting of randomized controlled trials (RCT), enabling readers of reports to understand a trial's design, conduct, analysis, and interpretation, and to assess the validity of its results.

**Community:** Social groups sharing key characteristics and values. Communities can be simultaneously characterized by their geographic proximity, economic interests, identities, health conditions and resources.

**Community Advisory Board:** A group of non-scientist volunteers that serves as a link between a community and clinical and translational researchers on a study team. A Community Advisory Board (CAB) may review and monitor studies and help teach the community about the research.

**Community-Based Participatory Research or CBPR:** A collaborative research approach that equitably involves community members, researchers, and other stakeholders in the research process and recognizes the unique strengths that each brings. The aim of CBPR is to combine knowledge and action to create positive and lasting social change.

**Community Engagement:** The process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to improve the health of the individuals in that community. Community engagement can take many forms, and partners can include organized groups, agencies, institutions, or individuals. Collaborators may be engaged in health promotion, research, or policy making.

**Community Partners:** Social groups, institutions, agencies, organizations, and individuals that actively contribute to a research study or are formally or informally included as part of a study team.

**Coordinator:** Clinical Research Coordinators provide managerial leadership for health research studies and ensure day-to-day study tasks are completed and that the study team is trained. Coordinators often report to and communicate regularly with principal investigators about their studies.

**Data Management Plan:** A description of how study data will be collected, stored, protected, and validated in ways that ensure that the clinical databases contain accurate data for purposes of analyzing study results.

**Data Manager:** A member of the study team that oversees all data collection, ensures data are recorded and managed as specified in the protocol document, and who prepares data for analysis.

**Data Safety Monitoring Board or DSMB:** An independent committee that reviews a clinical trial's progress and safety and that advises investigators as to whether to continue, modify, or terminate their studies.

**Data Safety Monitoring Plan:** A plan to assure safety of participants and validity of the data with oversight to human subjects' protections by the investigator, study team and appropriate external reviewers.

**Double Data Entry:** A strategy to ensure data quality in which the same data is entered by two separate individuals and then compared to ensure they match; helps control for errors due to mistakes in data entry.

**Unexpectedness:** Previously unobserved or undocumented phenomena associated with a health intervention or study are referred to as "unexpected," in that their nature and severity are not consistent with information provided in the relevant product information (e.g., approved professional package insert or product label).

**Fabrication:** Making up any research data or results, including recording or reporting any made up study data or results.

**Falsification:** Manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in any research records.

**Focus Group:** A small to medium-sized group of people who are assembled to facilitate communication based on a guided discussion to generate data from several people at the same time.

**Food and Drug Administration (FDA):** A U.S. Department of Health and Human Services (HHS) agency that reviews clinical research and regulates the marketing of foods, drugs, devices, and cosmetics.

**Good Clinical Practice (GCP):** An international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials.

**Grant Proposal:** A formal proposal submitted to a government or civilian agency that outlines a proposed project and shows budgetary requirements and requests monetary assistance in the form of a grant.

**The Health Insurance Portability and Accountability Act (HIPAA):** A federal law passed in 1996 that sets privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals, and other health care providers. HIPAA was developed by the Health and Human Services agency to give patients access to medical records and improve their control over the use and disclosure of personal health information.

**Informed Assent:** When children or minors (<18 years of age) are involved in research, the regulations require the assent of the child or minor and the permission of the parent(s), in place of the consent of the subjects.

**Informed Consent:** A voluntary agreement to participate in human subjects' research or undergo a medical procedure that is based on a person's adequate knowledge and understanding of that research or procedure.

**Institutional Review Board (IRB):** An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction

**International Conference on Harmonisation:** The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) was established in 1990 to bring together the regulatory authorities and pharmaceutical industry to discuss and harmonize scientific and technical aspects of drug registration. The ICH works to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner.

**Interventionist:** Members of a study team that administer study interventions that require special expertise and training, such as clinical psychologists, therapists, and educators, for example.

**Interventions:** Physical procedures and other manipulations of human subjects or their environment that are carried out for the purposes of gathering research data.

**IRB Protocol:** A concise version of the research protocol with required elements for review by a human subjects' review board or IRB. The IRB Protocol generally includes a description of the study, research design, sample recruitment, study procedures, questionnaires, or measures to be used in the study, and data analysis plan.

**Legally Acceptable Representative (LAR):** An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective participant, to the participant's participation in the research study.

**Measurement Error:** Observational error (or measurement error) is the difference between a measured value of quantity and its true value. In statistics, this type of error is expected; some random variability is an inherent part of things being measured and analyzed.

**Monitor/Auditor:** A member of a study team that ensures proper study procedures are being followed and that the study protocol is being carried out consistently between study sites. Monitors and Auditors are usually involved in more complex and multi-site studies.

**National Institutes of Health (NIH):** A U.S. Department of Health and Human Services (HHS) agency that conducts and supports biomedical and behavioral research to create fundamental knowledge of living systems and reduce the burden of illness and disability.

**Office of Human Research Protection:** A U.S. Department of Health and Human Services (HHS) office that provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by HHS.

**Office of Research Integrity (ORI):** A U.S. Department of Health and Human Services (HHS) office that promotes integrity in biomedical and behavioral research supported by the Public Health Service by monitoring institutional investigations of research misconduct and facilitating the responsible conduct of research.

**Patient-Centered Outcomes Research:** Patient-Centered Outcomes Research (PCOR) is comparative clinical effectiveness research of the impact on health outcomes of two or more preventive, diagnostic, treatment, or healthcare delivery approaches. This framework focuses on outcomes that matter to patients and ensures that patients and other stakeholders help to prioritize research topics, design, and conduct the studies, and share the results.

**Patient Partners:** Patients and those with lived experience of a health issue being studied, as well as their family members, caregivers, and the organizations that are representative of the population of interest in a particular study.

**Plagiarism:** The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

**Portable Storage Device (PSD):** A small hard drive designed to hold any kind of digital data. This is slightly different from a portable media player, which stores and plays music and movies. Some are fixed size hard drives of varied memory capacity.

**Principal Investigator (PI):** The study lead who is responsible for overseeing all aspects of the study. The investigator typically generates research questions, writes grant proposals to obtain funding, and manages all scientific aspects of the study.

**Privacy:** Refers to the right of an individual to keep their health information private, including such things as medical records and individually identifiable health information.

**Procedures Manual:** Provides instructions for consistent study procedure implementation and data collection across participants and clinical sites. The procedures manual details the study's organization, operations, study procedures, data management, and quality control.

**Protocol Amendments:** A written description of a change(s) to or formal clarification of a protocol, typically submitted by an investigator to an Institutional Review Board for review.

**Protocol Deviation:** A protocol deviation occurs when, without significant consequences, the activities on a study diverge from the Institutional Review Board-approved protocol.

**Quality Assurance:** All planned and systematic actions established to ensure that the study is performed, and the data are generated, documented, and reported in compliance with Good Clinical Practice and the applicable regulatory requirements.

**Quality Control:** The operational techniques and activities undertaken within an established quality assurance system, to verify that the requirement for quality of the study-related activities have been fulfilled.

**Random Error:** Fluctuations in the measured data, such as those due to the precision limitations of the measurement device; random errors often result from the study teams' inability to take exact measurements with perfect reliability over time.

**Relatedness:** A term intended to indicate that a determination has been made that the event had a reasonable possibility of being related to exposure to the product or intervention.

**Reproducibility:** The capacity of replicating the results of a given study.

**Research Assistant (RA):** A study team member responsible for basic administrative and scientific activity required for a study, such as recruiting participants and collecting data from participants.

**Research Bias (also Experimenter Bias):** The tendency of study team members performing the research to unduly influence the results, often manifested by attempts to confirm a certain result without scientific evidence.

**Research Misconduct:** Any fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

**Research Nurse:** A member of the study team that carries out medical procedures that require a licensed medical practitioner.

**Research Protocol (also Clinical Protocol, Protocol):** A complete written description of, and scientific rationale for, clinical study activities; protocol documents provide the framework by which the clinical studies will be conducted. They include, among other information, the study objectives, study design, population to be studied, study intervention, study procedures, safety assessment, clinical management, statistical considerations, data handling, and informed consent document(s).

**Rigor:** Scientific rigor is the strict application of scientific methods to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.

**Risk:** The probability of harm or physical, psychological, social, or economic injury to research participants that results from their participation in a study.

**Serious Adverse Events:** Serious adverse events (SAEs) include events that result in death, are life threatening (an event in which the patient was at risk of death at the time of the event), require or prolong inpatient hospitalization, result in persistent or significant disability or incapacity, or result in a

congenital anomaly; important medical events may also be considered serious when, based on medical judgment, they may jeopardize the person exposed and may require medical or surgical intervention to prevent one of the outcomes listed above (e.g., death or prolonged hospitalization).

**Social and Behavioral Research:** Social and behavioral research applies the behavioral and social sciences to the study of people's or animals' responses to certain stimuli (both external and internal). Such research is conducted by scientists of myriad academic disciplines including sociology, psychology, anthropology, economics, political science, and history.

**Social Determinants of Health:** Conditions affecting human health, functioning and quality of life that are found in the environments in which people are born, live, learn work, play, worship, and age.

**Source Documents:** Original documents, data, and records used for research purposes. Different types of source documents include but are not limited to hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial.

**Sponsor:** A federal agency, industry, foundation, or organization that reviews grant applications submitted by principal investigators and selects studies for funding; Sponsors monitor progress of the studies they fund to ensure study objectives are met and the findings are disseminated.

**Stakeholders:** Members of constituencies based on professional, rather than personal, experience. For example, these constituencies can include clinicians, purchasers, payers, industry, hospitals and health systems, policy makers, and training institutions.

**Standard Operating Procedures (SOPs):** Detailed, written instructions to achieve uniformity of the performance of a specific function; individual SOPs are often organized into a Procedures Manual/Manual of Operations (MOP).

**Statistician:** A study team member that works with the principal investigator and co-investigator to help design the data analysis plan, analyze the data, and interpret study findings, possibly as a co-investigator or consultant.

**Systematic Error:** Reproducible inaccuracies that are consistently occur. Such systematic errors are often due to a problem which persists throughout the entire experiment.

**Translational Science:** Translational science aims to accelerate the process of turning biomedical research discoveries into real-world applications that improve people's health, such as diagnostics, treatments, and cures.

**Transparency:** The clear and accurate reporting of study scientific and operational details so that others may reproduce and extend the findings; transparency is an essential element of scientific rigor.

**Treatment Fidelity:** The methodological strategies used to monitor and enhance the reliability and validity of behavioral and clinical interventions.

**Vulnerable Populations:** Participants belonging to or identifying with a group that may need special protections when participating in research; federal agency definitions of vulnerable populations vary, but tend to include children, prisoners, pregnant women, handicapped or mentally disabled persons, and the economically or educationally disadvantaged.

**Waiver of Consent:** An approval granted by an Institutional Review Board of research for which a signed informed consent form is not required. According to the governing federal regulations for documentation of informed consent (45 CFR 46.117), a waiver of consent may be used when the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context OR the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.