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 *(guided by the Office of Human Research Protections (HHS) recommendations on adverse event reporting)*

Assent: Child's agreement to participate in research, which is not just a failure to object

Bias: Any tendency which prevents unprejudiced consideration of a question

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

Certificates of Confidentiality: Document that protects investigators and institutions from being forced to release information that would identify research participants; Certificates protect against legal demands for information such as court orders and subpoenas

Clinical Protocol (also Research Protocol, Protocol): A complete written description of, and scientific rationale for, clinical study activities; protocol documents provide the framework by which the clinical trials will be conducted and 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) *(Excerpts and SBR adaptations from NIAID, Division of AIDS policy on protocol documents)*

Clinical Research: Medical research that involves people to test new 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 he or she will lose access to needed health services if he or she does not participate in the research *(From OHRP, HHS guidance on informed consent)*

Co-Investigator: Partners with a principal investigator on studies requiring scientific or methodological expertise

Confidentiality: Refers to the duty of anyone entrusted with health information to keep that information private

Consolidated Standard of Reporting Trials or CONSORT: Guideline that is intended to improve the reporting of parallel-group randomized controlled trial (RCT), enabling readers to understand a trial's design, conduct, analysis and interpretation, and to assess the validity of its results

Coordinator: Ensures day-to-day study tasks are completed and study team is trained; communicates regularly with the PI about the study

Data Management Plan: A description of how study data will be collected, stored, protected, and validated so that the clinical database accurately reflects the data collected and is able to be used for purposes of analyzing study data *(Adapted from NIDCR's Data Management Considerations guidance)*

Data Manager: Oversees all data collection; ensures data are recorded and managed as specified in the protocol document; prepares data for analysis

Data Safety Monitoring Boards or DSMB: Independent committee that reviews a clinical trial's progress and safety and advises whether to continue, modify, or terminate it

Data Safety Monitoring Plan: Plan to assure safety of participants and validity of the data

Double Data Entry: 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

Expectedness: Previously unobserved or undocumented 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 data or results and recording or reporting them

Falsification: Manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record

Focus Groups: A demographically diverse group of people assembled to participate in a guided discussion about a particular product before it is launched, or to provide ongoing feedback on a political campaign, television series, etc.

Food and Drug Administration (FDA): HHS agency that reviews clinical research to regulate 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 entity that outlines a proposed project and shows budgetary requirements and requests monetary assistance in the form of a grant

HIPAA: Law from 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; developed by HHS, HIPAA gives patients access to medical records and improves 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 based on adequate knowledge and understanding to participate in human subjects research or undergo a medical 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 Institutional Review Board 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) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. On 23 October 2015, ICH announced organisational changes as it marks 25 years of successful harmonisation."

Interventionist: Administers study intervention, requiring special expertise and training (clinical psychologist, therapist, educator, etc.)

Interventions: Physical procedures and other manipulations of human subjects or their environment for gathering research data

IRB Protocol: A term used to describe a concise version of the clinical protocol with required elements for review by a human subjects review board or IRB; it 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 clinical trial

Measurement Error: Observational error (or measurement error) is the difference between a measured value of quantity and its true value. In statistics, an error is not a "mistake"; variability is an inherent part of things being measured and of the measurement process

Monitor/Auditor: Ensures proper study procedures are being followed and that the study protocol is being carried out consistently between study sites; usually involved in more complex studies

National Institutes of Health (NIH): Federal government 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: Provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS)

Office of Research Integrity (ORI): 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

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 256GB, 320GB, etc.

Principal Investigator (PI): The study lead; responsible for overseeing all aspects of the study; generate ideas, writes grant proposals to obtain funding, and manages all scientific aspects of the study

Privacy: Refers to the right of an individual to keep his or her health information private

Procedures Manual: Provides instructions for consistent study procedure implementation and data collection across participants and clinical sites. Details the study's organization, operations, study procedures, data management, and quality control *(From NIDCR's Clinical research toolkit)*

Protocol Amendments: A written description of a change(s) to or formal clarification of a protocol

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 those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented ad reported in compliance with Good Clinical Practice and the applicable regulatory requirements

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

Random Error: Fluctuations in the measured data due to the precision limitations of the measurement device; random errors usually result from the experimenter's inability to take the same measurement in exactly the same way to get exact the same number

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

Reproducibility: The ability to replicate the results of a study

Research Assistant (RA): Responsible for recruiting participants and collecting data from participants

Research Bias (also Experimenter Bias): Process where the scientists performing the research influence the results, in order to portray a certain outcome

Research Misconduct: The fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results

Research Nurse: Carries out medical procedures requiring a licensed practitioner during a study

Rigor: Scientific rigor is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results *(From NIH website on Rigor and Reproducibility)*

Risk: Probability of harm or physical, psychological, social, or economic injury resulting from participation in a research study

Serious: 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 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 the following academic disciplines: sociology, psychology, anthropology, economics, political science, and history

Source Documents: Original documents, data, and records (e.g., 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: Federal funding agency, industry or foundation that reviews grant applications submitted by principal investigators and selects studies for funding; typically monitors progress of a study to ensure study objectives are met and study findings are disseminated

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: Works with the principal investigator and co-investigator to help design the data analysis plan, analyze the data, and interpret study findings; possibly a co-investigator or consultant

Systematic Error: Reproducible inaccuracies that are consistently in the same direction; systematic errors are often due to a problem which persists throughout the entire experiment

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 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 *(From 45 CFR 46; NIH; CDC; WHO)*

Waiver of Consent: A circumstance in research where 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; each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern

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