Glossary of Division of AIDS Clinical Research Terms

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For Researchers

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Networks

Research in NIAID Labs

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Research Rules & Policies

This glossary applies to the terms found in the documents on the Division of AIDS Clinical Research Policies and Standard Procedures Documents website.

Please note that the Glossary is currently under revision.

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A

Adverse Drug Reaction (ADR)
In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic

dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase “responses to a medicinal product” means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out. (ICH E6)

Adverse Event (AE)
Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. (OHRP)
See Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events pdf

Advocate
An individual who has the background and experience to act in, and agrees to act in, the best interests of the child throughout the duration of the child’s participation in the research and who is not associated in any way (except in the role as an advocate or member of the IRB/EC) with the research, the investigator(s), or the guardian organization. The advocate is in addition to any other individual acting on behalf of the child as guardian or in loco parentis. (45 CFR §46.409(b) & 21 CFR §50.56(b))

Allegation
A disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communications. (ORI)

Assent
A child’s affirmative agreement to participate in research. Mere failure to object should not, absent of affirmative agreement, be construed as assent. (45 CFR §46.402(b) and 21 CFR §50.3(n))

Audit
Independent on-site quality assurance of monitoring performed at clinical research sites (including pharmacies and laboratories). Auditors must be fully distinct and independent from entities providing site monitoring services. (DAIDS)

Awardee
The institution receiving a grant, cooperative agreement, or contract that assumes legal, financial, and scientific responsibility for the funds and research. (DAIDS)

B

Basic Sciences Program (BSP)
The BSP is a program within DAIDS that focuses on the fields of pathogenesis, basic virology, immunobiology, and the discovery of novel therapeutic approaches, efficacy evaluation in lentivirus animal models, and epidemiology. (DAIDS)

Biological product
Any virus, therapeutic serum, toxin, antitoxin, or analogous product available to prevent, treat or cure diseases or injuries in man. The terms "biological product" or "biologic" are deemed to be synonymous within DAIDS policies. (DAIDS)

C

Case history
A detailed account of relevant information gathered about a subject. This information includes the case report forms and supporting data including, for example, signed and dated consent forms and medical records, including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes, as required for both IND and IDE clinical trials. (21 CFR 312.62(b) & 21 CFR §812.140(a)(3))

Central Data Management Facility
The group responsible for managing the database and handling and processing the data gathered during a clinical trial. The location can be the same as the data collection site. (DAIDS)

Children
Persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted. (45 CFR §46.402(a) and 21 CFR §50.3(o))

Clinical Investigation
Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA...or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. FDA has defined "clinical investigation" to be synonymous with "research". (FDA)

Clinical investigator
A qualified professional that conducts clinical research activities including: collaboration and information exchange with community representatives; recruitment; enrollment; protocol visit conduct; management of study products; assessment and reporting of critical events; collection and management of clinical research data; communication of data; and creation, maintenance and storage of research records including participant files, source documents, regulatory files, subject identification information, clinical reports, and case report forms. (DAIDS)

Clinical Quality Management Plan (cQMP)
A formal written document that defines the processes and procedures that guide quality management activities (including Quality Assurance and Quality Control) in the clinical setting and details the responsibility, scope, and frequency of these activities. (DAIDS)

Clinical research
Research conducted on participants, material, or data of human origin with an identifiable person as the source. Clinical research includes exploratory, behavioral, and observational studies. All clinical trials are a subset of clinical research (DAIDS).

Clinical research records
The records that describe or record the methods, conduct, and/or results of a clinical trial, and the actions taken. Examples of these documents may include, but are not limited to, all essential and source documents listed in the DAIDS Policy on Essential Documents Appendix. The records may be in any form, including written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms. Clinical research records include case histories and source documents. (DAIDS)

Clinical research site
Discrete locations (e.g., hospitals, outpatient clinics, health maintenance organizations, community health centers, private practices, clinics) supported and/or sponsored by NIAID (DAIDS) where qualified professionals conduct clinical research in accordance with Good Clinical Practice and applicable regulations. (DAIDS)

Clinical Research Site (CRS) Leader
The onsite senior research scientist responsible for the administrative and scientific components of the CRS. The CRS leader is responsible for overall site activities, including day-to-day operations, performance, and compliance at the site level. (DAIDS)

Clinical Sciences Review Committee (CSRC)
The Division of AIDS internal scientific review committee responsible for the programmatic review of therapeutic protocols sponsored by DAIDS. The review will include careful assessment of the scientific objectives, design, safety, ethics, and feasibility of proposed research protocols. Scientific representatives from collaborating NIH Institutes and Centers participate as appropriate. (DAIDS)

Clinical Site Monitoring Group (CSMG)
The group delegated by DAIDS to conduct periodic on-site monitoring visits to DAIDS Clinical Trial Units to evaluate the quality and validity of study data, compliance with Good Clinical Practices, and protection of research subjects. Reports findings to DAIDS. (DAIDS)

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.
See Common Rule definition of research at 45 CFR 46.102(d)
See Common Rule definition of human subject at 45 CFR 46.102(f)

The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo or other control) of the clinical trial.

An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related processes and/or endpoints. Examples include, but are not limited, to: drugs/small molecules/compounds, biologics, devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); and, treatment, prevention, and diagnostic strategies.

A health-related biomedical or behavioral outcome is defined as the pre-specified effect of an intervention on the study subjects. Examples include positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); disease processes; health-related behavior; and, well-being or quality of life

Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases:

Phase I. Tests a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects).

Phase II. Study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety.

Phase III. Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.

Phase IV. Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use. (NIH)

Clinical Trials Agreements (CTAS)
An agreement negotiated between DAIDS and a pharmaceutical collaborator providing an investigational agent for a Network study and DAIDS (as the study sponsor). Describes CTA's respective responsibilities and rights includes IND sponsorship, safety and data monitoring, and access to data. (DAIDS)

Clinical Trial Unit (CTU)
Clinical Trials Unit (CTU) is an entity composed of an administrative component and one or more Clinical Research Sites that contribute to the Network clinical research plan by conducting the clinical research (that is, executing clinical protocols). A CTU may also contribute scientific and clinical research expertise to the development of the Network clinical research plan. A CTU is responsible for developing and maintaining effective community relationships; enabling community participation in Clinical Research Sites, CTU, and Network activities; and ensuring that all clinical research is conducted in compliance with Network bylaws, policies and procedures, DAIDS policy and procedures, Federal regulations, and any applicable local requirements. (DAIDS)

Code of Federal Regulations (CFR)
The codification of the general and permanent rules published in the US Federal Register by the executive departments and agencies of the US federal government. It is divided into 50 titles that represent broad areas subject to US federal regulation. Each volume of the CFR is updated once each calendar year and is issued on a quarterly basis. (NIH)

Community Advisory Board (CAB)
Community Advisory Board (CAB) is an active group representing the local population(s) impacted by HIV/AIDS. CAB members work in close communication with CTU investigators and staff to include the local perspective in the implementation of the HIV/AIDS clinical research plan. (DAIDS)

Completion of a clinical research study
Occurs when the following activities are finished:

1. all research-related interventions or interactions with human subjects (e.g. when all subjects are off study);
2. all protocol-required data collection of identifiable private information described in the IRB/EC-approved research plan;
3. all analysis of identifiable private information described in the IRB/EC-approved research plan; and
4. primary analysis of either identifiable private or deidentified information. (DAIDS)

Conflict of Interest (COI)
A situation when someone has or is perceived to have competing professional obligations or personal or financial interests that would make it difficult to fulfill his duties fairly. (DAIDS)

Continuing noncompliance
A pattern of actions or omissions to act that suggests a future likelihood of reoccurrence and indicates an inability or unwillingness to comply with applicable regulations, laws or the requirements or determinations of the IRB/EC. (DAIDS)

Critical event
Any unanticipated study-related incident that causes or increases the risk of harm to participants or others or has a significant adverse impact on study outcomes or integrity. A single incident that is determined to be a critical event may represent more than one class of critical event. (DAIDS)

CTU Administrative Unit
This CTU component provides oversight of the grantee award. Each CTU must have an administrative structure that resides within the Awardee institution. It is not a requirement that this component function as a clinical trial site. (DAIDS)

CTU Principal Investigator
The Principal Investigator is listed as the Grantee on the Notice of Award and is responsible for all CTU activities and CTU performance. This includes responsibility for affiliated clinical research sites (CRS), including communications, site performance and financial management. The principal investigator also provides CTU scientific and administrative representation to the Network(s).

D

Data and Safety Monitoring Board (DSMB)
The DSMB is an independent panel of experts established by NIAID and charged with the responsibility of monitoring the progress of trials, the safety of participants, and the efficacy of treatments being tested. The DSMB also makes recommendations to NIAID concerning continuation, termination or modification of the studies based on observed beneficial or adverse effects of any of the interventions under study. This panel is funded separately by NIAID. (DAIDS)

Data Collection Site
The location where clinical trial data is collected and case report forms are completed (usually the trial site). (DAIDS)

Division of AIDS (DAIDS)
The Division within the NIAID that has the primary responsibility for basic and clinical research on HIV/AIDS. (DAIDS)

DAIDS funded
NIAID (DAIDS) is providing financial support for the clinical trial or study. (DAIDS)

DAIDS Protocol Registration Office (PRO)
An office within the DAIDS Regulatory Support Contract (RSC) that receives and processes all protocol registration materials for DAIDS. (DAIDS)

DAIDS RSC Safety Office
The Office contracted to receive Expedited Adverse Event reports that are submitted to DAIDS. (DAIDS)

Division of AIDS (DAIDS) Safety Office
The Office to which adverse events requiring expedited reporting are submitted. Currently located in the Regulatory Affairs Branch (RAB) support contract and managed through RAB. (DAIDS)

DAIDS Regulatory Support Center (RSC)
A contract that provides clinical, regulatory, and technical support services for NIAID (DAIDS)-supported and -sponsored clinical trials. (DAIDS)

DAIDS sponsored
NIAID (DAIDS) is responsible for the management (including submission of the Investigational New Drug Application

(IND) to the Food and Drug Administration (FDA) and the initiation of the study) and oversight for the clinical trial or study. (DAIDS)

DAIDS supported
Clinical research activities would be considered to be supported by NIAID (DAIDS) under one or more of the following circumstances:

1. NIAID (DAIDS) provides direct funding to an institution via a grant, contract or cooperative agreement for the clinical research activities; or (b) indirect funding via a subcontract executed under a NIAID (DAIDS) supported award to another institution; and/or
2. NIAID (DAIDS) provides other tangible support for the clinical research activities which includes, but is not limited to, regulatory support, site monitoring services, study product supply, management and distribution services; and/or
3. NIAID (DAIDS)-supported central laboratory or data management center receives from other organization specimens or data for processing or analysis and the results or analyses will be used to direct involvement of some or all subjects in the conduct of the clinical research activities. (DAIDS)

DAIDS Tables for Grading Adult and Pedicatric Adverse Experiences (Toxicity Tables)
Lists of common terms and severity (intensity) parameters used to describe adverse events occurring in DAIDS-sponsored clinical studies/trials. (DAIDS)

Drug
Article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.(FDA)

E

EAE Form
The Expedited Adverse Event (EAE) paper form to be completed if DAERS system is not available. (DAIDS)

Essential Documents
Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. (ICH E6)

EAE Reporting Days
The days that count toward the 3-day timeline provided for reporting of EAEs to DAIDS. See DAIDS EAE Reporting manual for criteria used to determine reporting days. (DAIDS)

Expedited adverse event (EAE)
An adverse event that meets the criteria for expedited reporting, as specified in the applicable DAIDS manual. (DAIDS)

F

Fabrication
Making up data or results and recording or reporting them. (ORI)

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

Federalwide Assurance (FWA)
Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by the Office for Human Research Protections (OHRP) for institutions engaged in non-exempt human subjects research conducted or supported by the U.S. Department of Health and Human Services (HHS). Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR 46, as well as the Terms of Assurance. (See Federalwide Assurance (FWA) for the Protection of Human Subjects .)

Form FDA 1572
FDA required document in which clinical investigators agree to conduct the clinical trials according to Federal Regulations. The Form FDA 1572 is signed and submitted to the IND sponsor. (DAIDS)

Full Regulatory Review
The final review of the protocol, including the sample informed consent(s), by the Regulatory Affairs Branch (RAB) prior to medical officer sign off and distribution to the sites. (DAIDS)

G

Guardian
An individual who is authorized to consent on behalf of a child to general medical care under applicable local law where the research is being conducted. (45 CFR §46.402(e))

For clinical trials conducted under FDA regulations, a guardian is an individual who is authorized to consent on behalf of a child to general medical care when general medical care includes participation in research under the applicable local law where the research is being conducted. A guardian is also an individual who is authorized to consent on behalf of a child to participate in research. (21 CFR §50.3(s))

Good Clinical Practice (GCP)
An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. (ICH E6)

H

I

Independent Safety Monitor
The physician or other appropriate expert who is independent of the study and available to review SAEs and other safety data in a timely fashion and recommends appropriate actions to the study team and the National Institutes of Allergy and Infectious Diseases (NIAID). (DAIDS)

Informed Consent Form (ICF)
A document that provides the elements of informed consent as found in 21 CFR 50.25 and 45 CFR 46.116 (DAIDS)

Informed Consent Process

A process by which a participant voluntarily confirms his or her willingness to participate in a particular study after having been informed of all aspects of the trial that are relevant to the participant's decision to participate. (ICH E6)

Institutional Review Board/Ethics Committee (IRB/EC)
The board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of participants in research. IRB/EC reviewing DHHS sponsored research must be registered with OHRP and identified on the institute FWA. (DAIDS)

Institutional Review Board/ Ethics Committee (IRB/EC) records
The documentation maintained by the institution, or when appropriate, an IRB/EC, of IRB/EC activities, as required by HHS 45 CFR §§46.103(b)(3-5) and §46.115

International Conference on Harmonisation (ICH) Guidelines
Developed, through a collaboration between the FDA and regulatory agencies in Japan and the European Union, to "harmonize" regulatory requirements to produce marketing applications acceptable to the United States, Japan, and the countries of the European Union. (DAIDS)

Investigational Device Exemption (IDE)
Similar to an IND, allows an unapproved medical device to be used for investigational purposes. For more information, go to 21 CFR Part 812 and NIAID Human Subjects Resources portal. (NIAID)

Investigational New Drug (IND)
A drug or biological product that is used in a clinical investigation. The terms "investigational new drug" and "investigational drug" are deemed to be synonymous within DAIDS policies. (DAIDS)

Investigational New Drug Application (IND)
A request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application or Biologics/Product License Application. (FDA) Application required by the US FDA before clinical trials of an investigational drug or biological agent may be initiated. An IND is also required if the US FDA has not approved the route of administration, dosage level, or patient population for the drug or biological agent. (DAIDS)

Investigator IND
An IND submitted by an physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. (DAIDS)

Investigator of Record (IoR)
The individual at the CRS responsible for ensuring that a clinical trial is conducted in accordance with the protocol, applicable U.S. federal regulations, in-country regulations and any provisions imposed by the reviewing IRB/EC/other regulatory entity. This person is the signatory for the Form FDA 1572 for studies conducted under an IND or the DAIDS Investigator of Record Agreement for non-IND studies. (DAIDS)

Investigator of Record (IoR) Agreement
A document required by DAIDS for Non-IND studies. The IoR is required to sign and date this document accepting full responsibility for the conduct of the trial at their CRS.(DAIDS)

J

K

Key Personnel
Individuals who are involved in the design and conduct of NIH-funded human subjects' clinical research. This includes all individuals named on the Form FDA 1572 or DAIDS Investigator of Record Agreement and any clinical research site personnel who have more than minimal involvement with the conduct of the research (performing study evaluations or procedures or providing intervention) or more than minimal study conduct-related contact with study subjects or confidential study data, records, or specimens. (NIH)

L

Label
The FDA approved label is the official description of a drug product which includes indication (what the drug is used for); who should take it; adverse events (side effects); instructions for uses in pregnancy, children, and other populations; and safety information for the patient. Labels are often found inside drug product packaging. (ICH E6)

Legally marketed product
A product that received licensure or approval for marketing in the United States (U.S.) (FDA)

M

Medical Officers
A DAIDS staff member or member from another sponsoring Institute or Centers that monitors the safety and efficacy of the intervention(s) for ongoing studies and those in development. (DAIDS)

Minimal Risk
The probability and magnitude of harm or discomfort anticipated in the 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. (45 CFR §46.102(i) and 21 CFR §50.3(k))

Monitors
Individuals qualified by education or experience, whose primary role is to ensure compliance with the applicable regulations, policies, and standard procedures, as well as compliance with the study protocol as approved by the institutional review board or research ethics board. (DAIDS)

DAIDS Monitor
A monitor who is contracted by DAIDS. (DAIDS)

External Non-DAIDS Monitor
A qualified monitor not contracted by DAIDS and not employed or supervised by the study investigators, network, or site, has no affiliation with any of the participating clinical research sites, and has no role in trial conduct except as a site monitor. The monitor must be contracted or supplied by an organization (i.e. pharmaceutical sponsor, CRO, or academic institution) that conducts independent clinical site monitoring utilizing its own monitoring and reporting SOPs and having a distinct and independent supervisory structure for monitoring services. (DAIDS)

Internal Non-DAIDS Monitor
A qualified employee of a network involved with conduct of the clinical trial having no affiliation with any of the participating clinical research sites and not involved with the conduct of the trial at any participating clinical research site except for his/her role as a monitor. (DAIDS)

N

Notice of Grant Award (NGA)
The legally binding document that notifies the grantee and others that an award has been made. It contains or references all terms and conditions of the award, and documents the obligation of US federal funds. (NIH)

O

Observational Study
A type of study in which individuals are observed or certain outcomes are measured, but no treatments or interventions are assigned by the study. (DAIDS)

Office for Policy in Clinical Research Operations (OPCRO)
An office in the Division of AIDS (DAIDS) that provides a variety of clinical research management resources and oversight to DAIDS clinical research portfolio. This includes overseeing the development, standardization, implementation and execution of policies, procedures and standards of conduct for all of DAIDS domestic and international clinical research. (DAIDS)

P

Parent
The child's biological or adoptive parent.(45 CFR §46.402(d) and 21 CFR §50.3(p))

Participant
A living individual about whom an investigator conducting research obtains:

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information. (45 CFR 46).

The terms "participant " and "subject" are deemed to be synonymous within DAIDS policies. (DAIDS)

Permission
The agreement of parent(s) or guardian to the participation of their child or ward in research. (45 CFR §46.402(c) and 21 CFR §50.3(r))

Pharmacist of Record
A licensed/registered pharmacist who performs the day to day pharmacy activities and study product management including but not limited to the procurement, storage, preparation, dispensing and final disposition of study products for DAIDS sponsored or funded clinical research trial(s) must be identified as the Pharmacist of Record. (DAIDS)

Pharmacy

Any facility, building, or room used to perform one or more of the following functions: storage, preparation, dispensing, management of study products, (example: dispensary, drug storage unit, drug store). (DAIDS)

Pharmacy Ancillary Supplies
Any materials or tools that may be used in a pharmacy to perform and support the day to day activities and functions of the pharmacist, such as needles and syringes, oral syringes, prescription vials and lids, gowns, masks, IV solutions, diluents. (DAIDS)

Pharmacy Equipment
Apparatus (device or machinery) that is utilized to ensure the physical and scientific integrity of the study product during shipment, storage, handling, and preparation. Examples of pharmacy equipment are; biological safety cabinets, refrigerators, -20 C freezers, -70 C freezers, air conditioners, dehumidifiers, thermometers, vortex machines, temperature alarm systems, limited access/security systems (alarms, key lock) in study product and pharmacy regulatory file storage areas, locking file and storage cabinets, shelving, counting trays for tablets and capsules, graduated cylinders, spatulas, study product containers, fax machines, computers, and printers. (ICH E6)

Plagiarism
Using another person's ideas, processes, results, or words as one’s own without giving credit. (ORI)

Possibly related to the research
There is a reasonable possibility that the adverse event, incident, experience or outcome may have been caused by the procedures involved in the research. (OHRP)

Principal Investigator (PI)
The qualified person designated by the applicant institution to direct the funded research program. PIs oversee the scientific and technical aspects of an award and the day-to-day management of the research. (DAIDS)

Protocol
A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. (ICH E6)

Protocol Amendment
A written description of a change(s) to or formal clarification of a protocol. (ICH E6)

Protocol Deviation/Violation
An unplanned excursion from the protocol that is not implemented or intended as a systematic change. Protocol deviation is also used to refer to any other, unplanned instance(s) of protocol noncompliance. For example, situations in which the investigator failed to perform tests or examinations as required by the protocol or failures on the part of study subjects to complete scheduled visits as required by the protocol, would be considered protocol deviations. (DAIDS)

Protocol Registration
The process established by DAIDS to ensure that all sites participating in NIAID (DAIDS)-supported and/or -sponsored clinical research that is reviewed by a DAIDS Scientific Review Committee conduct the research in accordance with requirements for human subjects protection and the use of investigational new drugs (where applicable). The process includes initial protocol registration, amendment registration, continuing review documentation, deregistration and submission of other required documents. (DAIDS)

Protocol Registration Submissions

The most common types of submissions that a CRS may send to the DAIDS Protocol Registration Office (PRO) include the following:

1. Initial – The first time a CRS submits a consent type, language and/or version of a protocol to the PRO.
2. Amendment – A revision to a protocol made by the Protocol Team/Chair/Awardee that requires DAIDS review and final approval/sign-off before implementation; amendments are also referred to as “full version amendments.” The changes to the protocol are incorporated into the protocol document itself and will result in the change to the DAIDS protocol version number (e.g. 2.0, 3.0, etc.).
3. Letter of Amendment (LoA) - A revision to a protocol made by the Protocol Team/Chair/Awardee through a short letter that requires DAIDS final approval/sign-off before implementation. Changes described in an LoA are listed in a document which is separate from the protocol document itself and will NOT result in the change to the DAIDS protocol version number.
4. Continuing/Annual Reviews – An IRB/EC re-review of a protocol conducted on at least an annual basis as required by 45 CFR 46 for all federally funded research studies as well as by 21 CFR 56 for IND studies.
5. Change of IoR – When there is a change in the Investigator of Record at a CRS for a protocol.
6. Deregistration- When a CRS no longer has participants on study (all follow-up has been completed) and does not plan to enroll additional subjects and /or if no participants were ever enrolled at the CRS and the study has closed to accrual. (DAIDS)

Protocol Registration Team (PRT)
A Team within OPCRO responsible for managing the PR System, which includes oversight of the DAIDS PRO. (DAIDS)

Prevention Sciences Review Committee (PSRC)
The Division of AIDS internal scientific review committee responsible for the programmatic review of vaccine and prevention protocols sponsored by DAIDS. The review will include careful assessment of the scientific objectives, design, safety, ethics, and feasibility of proposed research protocols. Scientific representatives from collaborating NIH Institutes and Centers participate as appropriate. (DAIDS)

Protocol Team
A team of individuals comprised of grantees, investigators, statisticians, and other protocol support personnel who work to develop concepts into NIAID (DAIDS)-funded and/or -sponsored research studies. DAIDS medical officers may be involved as members of this team. (DAIDS)

Q

Quality Assurance (QA)
A periodic, systematic, objective and comprehensive examination of the total work effort to determine the level of compliance with accepted Good Clinical Practice (GCP) standards. For example, a monthly peer review of source documents compared to CRF pages to determine adherence to protocol requirements. (DAIDS)

Quality Control (QC)
The real time, on-going (“day-to-day”) observation and documentation of a site’s work processes to ensure that accepted procedures are being followed. For example, reviewing demographic information for accuracy on each Case Report Form (CRFs) page prior to entry into the database. (DAIDS)

Quality Management
The overall psystem that includes all activities involved in Quality Assurance and Quality Control including the

assignment of roles and responsibilities, the reporting of results and the resolution of issues identified during the review. (DAIDS)

R

Regulatory Affairs Branch (RAB)
A branch of DAIDS within the Office of Clinical Research Policy and Resources (OPCRO). RAB performs regulatory surveillance over clinical trials sponsored/funded by DAIDS. (DAIDS)

Research misconduct
Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion. (42 CFR §93.103)

Research misconduct records include records related to investigations of research misconduct and records of research misconduct proceedings

Records related to investigations of research misconduct: The records containing data or results that embody the facts resulting from scientific inquiry. These include research proposals, laboratory records, physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding. (42 CRF §93.224)

Records of research misconduct proceedings: Records showing the actions that an institution has taken related to alleged research misconduct. (42 CFR §93.223) Examples of these records include the records that the institution secures for the research misconduct proceedings, except for duplicate records; the documentation of the determination of irrelevant or duplicate records; the inquiry report and final documents produced in the course of preparing that report, including documentation of any decision not to investigate; the investigation report and all records in support of that report, including the recordings or transcriptions on each interview conducted. (42 CRF §93.317(a))

S

Safety Monitoring Committee (SMC)
An independent group of experts that advises NIAID and the study investigators for some Phase I and most Phase II trials. The primary responsibility of the SMC is to monitor participant safety. (DAIDS)

Sample Informed Consent (SIC)
An informed consent developed by the protocol team for a specific protocol that will help guide participating sites in the development of their site specific informed consent. (DAIDS)

Serious Adverse Drug Experience
Any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or 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 on of the outcomes listed in this definition. (21 CFR 312)

Serious noncompliance
An event that occurs within the context of the research that meets the following criteria:

1. results in an increased physical, psychological, safety, or privacy risk that compromises the rights and welfare of research participants; and
2. indicates a serious breach in compliance with applicable regulations, laws or the requirements or determinations of the IRB/EC. (DAIDS)

Scientific Review Committee (SRC)
A reviewing body within DAIDS to review the concepts and protocols developed by various programs within DAIDS (e.g., CSRC and PSRC).(DAIDS)

Serious Adverse Event (SAE)
Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. This includes important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent one of the outcomes listed in the definition above. (ICH E6 and E2A)

Site Pharmacist

A licensed/registered pharmacist who performs the day to day pharmacy activities and study product management including but not limited to the procurement, storage, preparation, dispensing and final disposition of study products for DAIDS-supported and/or -sponsored clinical trial(s) must be identified as the Site Pharmacist. (DAIDS)

Site Specific Informed Consent
An informed consent developed by a participating site based upon the sample informed consent which is reviewed and approved by the site's designated IRB/IEC and is used to consent subjects at the site for a specific clinical trial. (DAIDS)

Source Data
All information in original records and certified copies of original records of clinical findings, observations, or other activities in a study necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies). (ICH E6)

Source documents
The original documents, data, and records containing clinical findings, observations, or other activities in a clinical research study that allows the reconstruction and evaluation of the study. Examples of source documents include: 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. (ICH E6 §1.51 and 1.52)

Sponsor
A person (individual, corporation or agency) who initiates a clinical investigation, but who does not actually conduct the investigation. That is the test articles is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g. corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor, and the employees are considered to be investigators. (FDA)

Sponsor-Investigator
An individual who both initiates and actually conducts, alone or with others, a clinical investigation. For example, under whose immediate direction the test article is administered, dispensed to, or used involving a subject and who also submitted the IND. (FDA)

Standard Operating Procedures (SOPS)
Written procedures designed to ensure data and analysis quality by requiring uniform performance of specific functions by the group(s) that fall within their scope. An SOP is designed to provide a high level overview of tasks or functions performed. An SOP, by definition, must be followed unless a documented exception is approved. (DAIDS)

Study Products
Any drug, biologic, vaccine, radiopharmaceutical, item or device that are either provided for the study or identified in the protocol as being a study product. (DAIDS)

Subject
A living individual about whom an investigator conducting research obtains:

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information. (45 CFR 46)

For research conducted under U.S. FDA regulations, a subject is an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. (21 CFR 56)

The terms " participant " and “subject” are deemed to be synonymous within DAIDS policies. (DAIDS)

Suspected Unexpected Serious Adverse Reaction (SUSAR)
A SUSAR is an event that is:

1. Serious (See SAE definition)
2. Related (i.e., there is a reasonable possibility that the AE may be related to the study agent); and
3. Unexpected (See unexpected AE definition) (DAIDS)

Suspension of IRB approval
An IRB/EC action to temporarily withdraw approval for a study, which results in stopping some or all of the research-related activities for the study. (DAIDS)

Termination of IRB approval
An IRB/EC action to permanently withdraw approval for a study which results in stopping the research and all research-related activities for the study. (DAIDS)

T

Tentative Drug Approval
If a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference list drug product (an approved drug product to which new generic versions are compared), FDA issues a tentative approval letter to the applicant. The tentative approval letter details the circumstances associated with the tentative approval. FDA delays final approval of the generic drug product until all patent or exclusivity issues have been

resolved. A tentative approval does not allow the applicant to market the generic drug product in the United States. (DAIDS)

Therapeutics Research Program (TRP)
The TRP is a program within the DAIDS that is responsible for the scientific, administrative, and operational management of the clinical therapeutic research programs funded by the Division. (DAIDS)

U

Unanticipated Problems
Events that must be reported to Office of Human Research Protections (a) unanticipated problems involving risks to subjects or others or (b) any serious or continuing noncompliance with policy requirements or determinations of the IRB and (c) any suspension or termination of IRB approval. (OHRP)

Unanticipated problems involving risk to subjects or others
Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:

1. unexpected given the research procedures that are described in the protocol-related documents; and the characteristics of the subject population being studied;
2. related or possibly related to a subject's participation in the research; and
3. suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized. (OHRP)See the Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events pdf.

Unexpected adverse event
Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:

1. the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol–related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
2. the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event. (OHRP) See the Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events pdf.

Unexpected Adverse Drug Experience
Any adverse drug experience, the specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended. (21 CFR 312)

U. S. Food and Drug Administration (FDA)
A public health agency within the United States Department of Health and Human Services. FDA's mission is to promote and protect public health by helping safe and effective products reach the market in a timely way and monitoring of products for continued safety after they are in use as authorized by The Federal Food and Cosmetic Act. The Agency regulates all clinical investigations in support of marketing applications. (DAIDS)

V

Vaccine and Prevention Research Program (VPRP)
The VPRP is a program within the DAIDS that supports the discovery and development of vaccines and other biomedical and behavioral interventions to prevent AIDS. (DAIDS)

W

Ward
A child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law. (21 CFR 50.3(q))

X

Y

Z

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