

## **APPENDIX D: GLOSSARY**

The definitions provided within this Glossary apply as they are used in the ethics and health research principles, structures and processes. These are based on the definitions in the Canadian Code of Ethical Conduct for Research Involving Humans (1996) and the ICH Guidelines for Good Clinical Practice.

### **Adverse Drug Reaction (ADR)**

In pre-approval clinical experience with a new medicinal product or its new usages, particularly where the therapeutic dose has not been established, all noxious and unintended responses to a medicinal product should be considered as ‘adverse drug reactions’. The phrase ADR indicates at least the probability of a causal relationship between a medicinal product and an adverse event. With regard to marketed medicinal products, the term applies to a drug-response that is noxious and unintended and which occurs at doses normally used in humans. (See the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.)

### **Adverse Event (AE)**

An adverse event may be any untoward medical occurrence in a patient or research participant who has received a pharmaceutical product that does not necessarily have a causal relationship with the treatment being researched. An adverse event (AE) may therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease associated with the use of a medicinal product under investigation, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

### **Anonymous Samples or Data**

*See De-identified samples or data*

### **Approval (in relation to Research Ethics Committees)**

The research ethics committee’s affirmation that the clinical trial has been reviewed and may be conducted at the nominated institution according to the constraints set out by the ethics committee, the institution, Good Clinical Practice (GCP), and legal requirements.

### **Benefit**

That which positively affects the interest or welfare of an individual or group, or the public generally.

### **Child**

Subject to law in the relevant jurisdiction, a child is a minor who lacks the legal ability to make a decision whether or not to participate in research.

### **Clinical Trial**

This is a preplanned, usually controlled, clinical study to determine the safety, efficacy or optimum dosage schedule (if appropriate) of one or more diagnostic, therapeutic, or prophylactic drugs, devices or interventions in humans selected according to predetermined criteria of eligibility.

### **Collectivities**

Distinct human groups with common identity, their own social structures, common customs and designated leaders or other persons who represent collective interests in dealing with researchers. Collectivities may include cultural or ethnic groups, and indigenous communities.

### **Competence**

The ability of a person or a group to understand and make choices in accord with their own fundamental values. The term ‘legal competence’ indicates that a person’s age and mental state satisfy certain basic legal requirements.

**Confidentiality**

Prevention of disclosure, other than to authorized individuals, of a sponsor's proprietary information or of a participant's identity.

**Consent**

The voluntary agreement of a person or group, based on adequate knowledge and understanding of relevant material, to participate in research. Informed consent is one possible result of informed choice, the other possibility is refusal.

**Deception**

Deception includes the withholding of essential information from research participants, deliberately misleading them about procedures and purposes, including studies in which participants are deliberately given misleading information about the purpose of a research study.

**De-identified (not re-identifiable, anonymous) Samples or Data**

The process of de-identification may be irreversible where the identifiers have been removed permanently or the data has been identified. These data are referred to as 'identified'. It should be recognised that the term 'de-identified' is used frequently, in documents other than this statement of the Ethics and Health Research: Principles, Structures and Processes, to refer to sets of data from which only names have been removed. Such data may remain 'potentially identifiable'.

*See also Identified Samples or Data and Potentially Identifiable Samples or Data.*

**Ethics**

A branch of moral philosophy concerned with the rational evaluation of right and wrong, justice and injustice, virtue and vice, good and bad, and related concepts and principles.

**Ethical and unethical**

Right or morally acceptable on one hand, wrong or morally unacceptable on the other. Conforming to the rationally acknowledged norms and standards of behaviour, or failure to conform to such norms and standards.

**Ethics Committee**

An independent body whose responsibility is to ensure the protection of the rights, safety and wellbeing of human participants involved in medical research (a trial). An ethics committee provides public assurance of that protection, by, reviewing and approving the trial protocol, the suitability of the investigator's facilities, and the methods and material to be used in obtaining and documenting the informed consent of the participants. Ethics committees should be independent of political, institutional, professional and market influences. The legal status of ethics committees in South Africa is established under the National Health Act, 2003 (Act No. 61 of 2003).

**Families**

A family is a primary social group most often consisting of parents and their offspring. However, a family may also be a group of people occupying the same dwelling place and consisting of persons who are not biologically related.

**Foetus**

In humans, a conceptus of seven to eight weeks' development until birth (term).

**Genetic Material**

Any source of DNA or RNA that can be tested to obtain genetic information. It includes cells, whether as single cells or as part of tissues, and extracted DNA and RNA.

**Harm**

That which adversely affects the interest or welfare of an individual or a group;

Harm extends to physical harm, discomfort, anxiety, pain, psychological disturbance and includes placing a person at social disadvantage.

### **Health**

WHO defines health as ‘a state of physical, mental and social well-being and not merely the absence of disease or infirmity’.

### **Human Tissue**

Includes the substance, structure and texture of which the human body or any part or organ of it is composed, that is removed or separated from living human being; and includes blood, blood components and waste products.

### **Identified Samples or Data**

Data that enables the identification of a specific individual is referred to as ‘identified data’. Examples of identifiers may include the individual’s name, date of birth or address. In particularly small sets of data even information such as a post code may be an identifier.

*See also:* De-identified Samples or Data and Potentially Identifiable Samples or Data.

### **Informed Consent**

A process by which participants voluntarily confirm their willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to their decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form. Informed consent is a process seeking to encapsulate a researcher’s moral duty to provide sufficient information to allow potential participants to make an informed, free and rational choice whether or not to participate in a research project.

### **Justice**

This concept concerning fairness or equity is often divided into three parts. Procedural justice is concerned with the fair methods of making decisions and settling disputes; distributive justice seeks to ensure fair distribution of benefits and burdens, while corrective justice is concerned with correcting the wrongs and harms through compensation or retribution.

### **Minimal Risk**

This anticipates that the probability and magnitude of harm or discomfort to be experienced in the research will not be greater than those ordinarily encountered in daily life.

### **Monitoring**

The review by a research ethics committee of ongoing research. Monitoring may take several forms, including review of annual reports, formal review of the informed consent process, establishment of a safety monitoring committee, a periodic review by a third party of the documents generated by the study, a review of reports of adverse events, and a random audit of the particular processes.

### **Multi-centre Research**

The conduct of a research project by researchers in several autonomous institutions or organisations. This includes multi-centre clinical trials.

### **Multi-centre Trial**

A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

### **Non-therapeutic**

Interventions not directed to the benefit of the individual but rather towards improving scientific knowledge or technical application.

**Personal Information**

Personal Information is defined as information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a materials form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion (Privacy Act No.119 of 1988 as amended).

**Placebo**

A product or substance known to be without effect; usually used as a control to be compared against a potentially effective substance or method that is being subjected to clinical trial.

**Principal Investigator**

A principal investigator is a South African-based researcher who has sole or joint responsibility for the design, conduct, analysis and reporting of the trial. The principal investigator is also responsible for the delegation of responsibilities during research.

**Privacy**

Privacy implies a zone of exclusivity where individuals and collectivities are free from scrutiny of others. It may also include control over the extent, timing and circumstances of sharing oneself with others, whether physically, intellectually or in terms of behaviour.

**Protocol**

A document that provides the background, rationale and objectives of the research and describes its design, methodology, organisation and the conditions under which it is to be performed and managed.

**Qualitative Research**

Qualitative research attempts to understand phenomena in entirety. It comprises research to understand social and cultural problems, and focuses on interactive processes to collect subjective information that is not structured numerically, but intuitively. Qualitative research attempts to understand human experience. It analyses thematic and narrative information. The investigator interacts with people in a sustainable manner.

**Randomisation**

The process of assigning trial participants to treatment or control groups, using chance to determine the assignment

**Research**

This involves systematic investigations to establish facts, principles and knowledge.

**Research Participant**

Living individual (or group of living individuals) about whom a researcher conducting research obtains data through intervention or interaction with the person or identifiable private information.

**Respect for Persons**

This has two fundamental aspects:

- Respect for the autonomy of those individuals who are capable of making informed choices, and respect for their capacity for self determination;
- Protection of persons with impaired or diminished autonomy, that is, those individuals who are incompetent or whose voluntariness is compromised.

**Risk**

The magnitude of a harm and the probability of its occurrence.

*See also* Minimal risk

**Serious Adverse Effect (event or reaction)**

Any untoward medical occurrence that at any dose:

- results in death;
- is life-threatening;
- requires in-patient hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability or incapacity;
- results in a congenital anomaly or birth defect.

**Sponsor**

An individual, company, institution or organisation that assumes financial responsibility for all or part of a particular research study or clinical trial.

**Therapeutic**

Descriptive of interventions directed to the wellbeing of the individual or community involved.

**Vulnerable Participants**

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

**Well-being (of the trial participants)**

The physical and mental integrity of the participants participating in a clinical trial.