

ADVERSE EVENT (AE) Any untoward medical occurrence in a patient or clinical investigation subject who was administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product [IHC-GCP 1.2]. (See EXPECTED ADVERSE EVENT, SERIOUS ADVERSE EVENT, and UNEXPECTED ADVERSE EVENT.)

ANONYMIZED INFORMATION Irrevocably stripped of identifiers, and a code is not kept to allow future re-linkage [TCPS Ch 5].

ANONYMOUS INFORMATION Information that never had identifiers associated with it (e.g. anonymous surveys) [TCPS Ch 5].

APPEAL Process by which an investigator can contest, in writing to FHREB, FHREB's disapproval of a research project, withdrawal of approval, or repeated deferrals.

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

ASSENT Affirmative agreement by an individual, such as a child or cognitively-impaired person, who is not competent to give legally valid informed consent to participate in research [TCPS Ch 3 – A 3.9-3.10].

AUDIT Process by which the FHREB examines a previously reviewed research protocol and research activities to date in order to ensure the continued protection of research participants and compliance with international, federal and provincial regulations and FHREB policies and procedures [IHC-GCP 1.6].

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

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

BIOBANKS Collection and retention of human biological materials in banks. Biobanks vary widely in their characteristics. Some are very small and others hold biological materials from thousands of individuals. They may be disease-specific or contain materials from a wide population base. Different types of human biological materials may be stored in biobanks, such as blood, tumour or tissue samples. Biobanks may include or be linked with databases of identifiable or non-identifiable information. Materials held in a biobank may be intended only for use in a specific study or a biobank may be established to provide access to biological materials for numerous studies over many years [TCPS Ch 12].

CAPACITY The ability of prospective or actual participants to understand relevant information presented and to appreciate the potential consequences of any given decision. This ability may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the time in question. The determination of capacity to participate in research, then, is not a static determination but a process that may change over time, depending on the nature of the decision the potential participant needs to make and changes in the participant's condition. Assessing capacity is a question of determining, at a particular point in time, whether a research participant (or potential participant) understands the nature and consequences, risks and potential benefits, of a particular research project [TCPS Ch 3].

CHILDREN Individuals who have not attained the legal age to be able to consent to treatment or procedures involved in research according to applicable law of the jurisdiction in which the research will be conducted. In British Columbia, individuals 19 years of age and older are of legal age and considered adults.

CLINICAL EQUIPOISE A genuine uncertainty on the part of the relevant expert community about the comparative therapeutic merits of each arm of a clinical trial. The tenet of clinical equipoise provides a clear moral foundation to the requirement that the health care of individuals not be disadvantaged by their participation in research [TCPS Ch 11].

CLINICAL TRIAL Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, radiopharmaceuticals, cells and other biological products, surgical procedures, radiologic procedures, devices, genetic therapies, natural health products, process-of-care changes, preventive care, and manual, behavioural and psychological therapies, etc. Clinical trials may also include questions that are not directly related to therapeutic goals – for example, drug metabolism – in addition to those that directly evaluate the treatment of study participants [TCPS Ch 11].

CODED See De-indentified information.

COERCION Involves a threat of harm or punishment for failure to participate. Coercion would negate the voluntariness of a decision to participate or to remain in a research study [TCPS Ch 3 – A 3.1].

COGNITIVELY-IMPAIRED PARTICIPANT A participant who has either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), an organic impairment (e.g., dementia), or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functioning to the extent that capacity for judgment and reasoning is significantly diminished. Individuals under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps also may have impaired ability to make decisions in their best interests [TCPS Ch 3].

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

COMPETENCE A legal term used to denote capacity to act on one's own behalf. A competent individual can understand information, consider the consequences of action and inaction, make decisions, and act on his or her own behalf. Competence may fluctuate as a function of the natural course of a physical or mental illness, response to treatment, effects of medication, and general physical condition [TCPS Ch 3]. (See INCOMPETENCE.)

CONFIDENTIALITY The obligation of an individual or organization to safeguard information entrusted to it by another. The ethical duty of confidentiality includes obligations to protect information from unauthorized access, use, disclosure, modification, loss or theft. Fulfilling the ethical duty of confidentiality is essential to the trust relationship between researcher and research participant, and to the integrity of the research enterprise [TCPS Ch 5].

CONSENT See INFORMED CONSENT.

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

CONTINUING REVIEW The periodic oversight of human participant research projects by an FHREB. At a minimum according to TCPS and Federal regulations, the FHREB must review every study at least annually. FHREB reviews projects on at more frequent basis when necessary to ensure the protection of human participants [TCPS Ch 6 – A 6.14].

CONTROL PARTICIPANTS Sometimes referred to as CONTROLS or CONTROL GROUP **and include** participants used for comparison who are not given a treatment or who do not have a given condition, background characteristic, or risk factor that is the focus of study [TCPS Ch 11].

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

DATA SAFETY MONITORING BOARD (DSMB) A multi-disciplinary, independent expert advisory group that is responsible for safeguarding the interests of participants in randomized controlled trials, assessing the safety and efficacy of study procedures and monitoring the overall conduct of a study. It is composed of scientists with expertise in the clinical area, statisticians, pharmacists and individuals with expertise in ethics. Where the size and complexity of the trial support the establishment of a DSMB, it plays an important role in ensuring the safety of study participants. The Board ensures the overall safety of participants based on a review of the totality of evidence and the principle of the emergence of evidence that is likely to influence clinical practice; advises the principal investigator and research steering committees about the conduct of the trial and the integrity of the data, so as to protect the validity and scientific credibility of the trial; and develops and operates under a DSMB Charter governing the activities of the DSMB [TCPS Ch 11 - A 11.3].

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

DECEPTION The intentional withholding from participants of information related to the research or the intentional provision of false information about some aspect of the research. Deception is not allowed unless it is essential to the goals of the research and approved by FHREB [Ch 3 – A 3.7].

DECISION-MAKING CAPACITY Generally understood as the ability to understand the choice(s) presented, to appreciate the implications of choosing one alternative over another, and to make and communicate a choice. Term is often defined in legislation [TCPS Ch 3].

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

DE-IDENTIFIED/CODED INFORMATION Direct identifiers are removed and replaced with a code. Depending on access to the code, it may be possible to re-identify specific research participants (e.g. participants are assigned a code name and the principal investigator retains a list that links the code name with the participant's actual name so data can be re-linked if necessary) [TCPS Ch 5].

DELEGATED REVIEW

Delegated Review is reserved for those studies that are defined as minimal risk. A study is considered to be of minimal risk "... if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk" [TCPS C1]. See Expedited Review.

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

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

DIRECTLY IDENTIFYING INFORMATION Identifies a specific individual through direct identifiers (e.g. name, social insurance number, personal health number). See Identifiable Information.

EMBRYO A human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being [TCPS Ch 12].

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

EQUITY The distribution of benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it.

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

EXPECTED ADVERSE EVENT An adverse event that is anticipated, usually based on previous studies, and is described in the consent form, the study protocol, and the investigator's brochure in clinical studies of an investigational product. Expected adverse events include adverse events that are recognized during the course of a study; determined, after review by a REB, not to require the study to be stopped or the intervention to be modified; and classified for the remainder of the study as expected adverse events [ICH-GCP 1.2]. (See ADVERSE EVENT and UNEXPECTED ADVERSE EVENT).

EXPEDITED REVIEW A term which has been replaced by the term "Delegated Review". Review of proposed human participant research by one of the FHREB co-chairs or instead of the full board. Expedited/Delegated Review is permitted for certain categories of research involving no more than minimal risk and for minor changes in ongoing research the FHREB has previously approved. See Delegated Review.

FAIRNESS Treating all people with equal respect and concern.

FEDERALWIDE ASSURANCE (FWA) A written, binding commitment submitted to the United States Office of Health Research Protections (OHRP) by an institution engaged in human participant research in which the institution promises to comply with applicable US Federal regulations governing such research and specifies the procedures it will follow to ensure compliance.

FETAL TISSUE includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains genetic information about the fetus [TCPS Ch 12].

FETUS A human organism during the period of its development beginning on the 57th day following fertilization or creation, excluding any time during which its development has been suspended, and ending at birth [TCPS Ch 12].

FINANCIAL CONFLICTS OF INTEREST Real, potential or perceived financial conflicts of interest are a feature of some clinical trials [TCPS Ch 11].

FREEDOM OF INFORMATION AND PROTECTION OF PRIVACY ACT (FOIPPA) Provides individuals with specific information and privacy rights with regard to information that is collected or controlled by public bodies in British Columbia.

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

GRANT Financial support provided by an agency to principal investigator(s) in response to their submission of a research proposal and request for funding.

HUMAN BIOLOGICAL MATERIALS Materials originating from human bodies for research contributes greatly to the advancement of biomedical science. The sources of these materials could be from patients following diagnostic or therapeutic procedures, autopsy specimens, donations of organs or tissue from living or dead humans, body wastes or abandoned tissue. Biological materials may also be sought from individuals for use in a specific research project [TCPS Ch 12].

HUMAN PARTICIPANTS/SUBJECTS Individuals whose behavioral or physiological characteristics and responses are the focus of study by an investigator in a research project.

HUMAN REPRODUCTIVE MATERIALS A sperm, ovum or other human cell or a human gene, and includes a part of any of them [TCPS Ch 12].

IDENTIFYING INFORMATION Any item or combination of items in the data that could lead directly or indirectly to the identification of a research participant [TCPS Ch 5].

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

INCENTIVES Anything offered to participants, monetary or otherwise, for participation in research (incentives differ from reimbursements and compensation for injury) [TCPS Ch 3 – A 3.1].

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

INDIRECTLY IDENTIFYING INFORMATION Can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g. date of birth, place of residence or unique personal characteristic).

INFORMATION Researchers may seek to collect, use, share and access different types of information about research participants. Such information may include personal characteristics, such as age, culture, educational background, employment history, health care, life experience, religion, social status or other matters where an individual has a reasonable expectation of privacy. Information may be categorized along a spectrum of identifiability. (See DIRECTLY-IDENTIFIABLE, INDIRECTLY IDENTIFIABLE, DE-IDENTIFIED, CODED, ANONYMIZED, ANONYMOUS INFORMATION)

INFORMED CONSENT A process through which a person's voluntary agreement to participate in research is obtained after the person has been informed of the physical, psychological, and social risks and potential benefits posed by the study as well as the procedures involved [TCPS Ch3, ICH-GCP 1.28]

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

INVESTIGATOR Individuals with the responsibility for the design and/or conduct of a research project [ICH-GCP 1.3.4]. (Also see PRINCIPAL INVESTIGATOR)

INVESTIGATOR'S BROCHURE A compilation of clinical and non-clinical information relevant to the clinical use of an investigational agent (e.g. drug). Describes the rationale and features of the investigational agent in sufficient detail to allow investigators, regulatory authorities, research ethics boards, and ethics committees to assess the risks and benefits to participants.

JUSTICE The obligation to treat people fairly and equitably [TCPS Ch 1].

KEY STUDY PERSONNEL Members of the research team who contribute in a substantive way to the scientific development, design, or conduct of the study. This list includes the principal investigator (PI), other investigators, and project coordinators. Depending upon their role, it may include consultants, research assistants, and others. Anyone who interacts directly with research participants or their individually identifiable data qualifies.

MINIMAL RISK The probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research [TCPS Ch 6 – A 6.12].

MINORS Individuals who have not attained the legal age for consent to treatment or procedures involved in research according to applicable law of the jurisdiction in which the research will be conducted. In British Columbia, individuals 19 years of age and older are of legal age and are considered adults.

MONITORING Process of collecting and analyzing information from ongoing research to ensure the protection of research participants [ICH-GCP 1.3.8].

MINUTES Official record of the proceedings of a meeting.

NEONATE A living newborn infant.

NONAFFILIATED REB MEMBER A required member of the REB who has no other ties to the parent institution, its staff, or its faculty. This member usually belongs to the local community.

NONCOMPLIANCE Failure to comply during the conduct of human participant research with relevant federal and provincial regulations or FHREB policies and procedures. Noncompliance can range from minor and sporadic to serious and continuing and may be intentional [ICH-GCP 1.15]. (See CONTINUING NONCOMPLIANCE, INTENTIONAL NONCOMPLIANCE, and SERIOUS NONCOMPLIANCE.)

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

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

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

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

PERSONAL INFORMATION Any recorded information about an identifiable individual other than contact information. Information can be in paper, electronic or photographic form, or as tissue about which can reasonably be said to identify an individual. Includes facts about attitudes and behaviors that an individual can reasonably expect not to be shared with people the individual has not authorized to have access to the information. Examples include medical records, school records, and answers to survey questions about illegal and embarrassing behaviors.

PHASE I CLINICAL TRIALS Researchers test a new drug or treatment in a small group of people, often for the first time, to evaluate its toxicity and other side effects, and to determine a safe dosing range. Participants in Phase I clinical trials are usually healthy volunteers or patients who have failed conventional therapy. Pharmacokinetic studies (the study of the absorption, distribution, metabolism, and elimination of a drug or ingested compound) are one example of Phase I clinical trials [TCPS Ch 11 – A 11.6].

PHASE II CLINICAL TRIALS Primarily examine the safety (e.g. short-term side effects) and efficacy of new drugs. They are conducted in populations with the disease or condition sought to be treated by the drug [TCPS Ch 11 – A 11.6].

PHASE III CLINICAL TRIALS Determine the drug or treatments' efficacy by comparing it with commonly used treatments, monitoring for side effects and collecting additional information to evaluate the overall risk-benefit relationship of the drug. This information will help support the safe use of the drug or treatment. These studies may lead to a new drug being marketed in Canada or to the use of an approved drug for a new indication. The drug or treatment is given to a large group of patients, often at several sites [TCPS Ch 11 – A 11.6].

PHASE IV CLINICAL TRIALS Post-regulatory approval studies primarily examine the long-term effectiveness and toxicity of already-marketed drugs. They may also be designed to determine the effectiveness of the treatment or intervention in different populations, or to look at quality-of-life issues [TCPS Ch 11 – A 11.6].

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

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

PRIVACY An individual's right to be free from intrusion or interference by others. It is a fundamental right in a free and democratic society. Individuals have privacy interests in relation to their bodies, personal information, thoughts and opinions, personal communications with others and spaces they occupy. Research affects these various domains of privacy in different ways, depending on its objectives and methods. An important aspect of privacy is the right to control information about oneself. The concept of consent is related to the right to privacy. Privacy is respected if an individual has an opportunity to exercise control over personal information by consenting to, or withholding consent for, collection, use and/or disclosure of information [TCPS Ch 5].

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

PROTOCOL The formal design or plan of an experiment or research activity — akin to a blueprint — which is submitted to the FHREB for review and often also used in applications to funding agencies. The protocol includes a description of the proposed research design and methodology, eligibility requirements for prospective participants, informed consent process, treatment regimen(s), and methods of analysis that will be performed on the data collected [ICH-GCP 1.44].

QUORUM A majority of the FHREB voting members, including at least two members have expertise in relevant research disciplines, fields, and methodologies covered by the REB; at least one member is knowledgeable in ethics; at least one member is knowledgeable in the law (but that member cannot be the institution's legal counsel or risk manager); and at least one community member who has no affiliation with the institution. At REB meetings, a quorum must be established and maintained for the deliberation and vote on all matters needing full board approval [TCPS Ch 6 – A 6.4].

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

REMUNERATION See PAYMENT.

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

RESEARCH Undertaking designed to extend and generalize knowledge through a disciplined inquiry or systematic investigation.

RESEARCH ETHICS BOARD An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a study and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the study protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the study subjects [TCPS Ch 6].

RESEARCH PROTOCOL See PROTOCOL.

RETROSPECTIVE STUDIES Investigation of past events through review of records, such as medical records, death certificates, etc.

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

RISK The possibility of physical, psychological, or social harm or injury resulting from participation in a research study. The likelihood and magnitude of possible harm varies from minimal to significant.

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

SECONDARY USE The use in research of information originally collected for a purpose other than the current research purpose. Common examples are social science or health survey datasets that are collected for specific research or statistical purposes, but then re-used to answer other research questions [TCPS Ch 5].

SECURITY Measures used to protect information and includes physical, administrative and technical safeguards. An individual or organization fulfils its confidentiality duties, in part, by adopting and enforcing appropriate security measures. Physical safeguards include the use of locked filing cabinets and the location of computers containing research data away from public areas. Administrative safeguards include the development and enforcement of organizational rules about who has access to personal information about research participants. Technical safeguards include use of computer passwords, firewalls, anti-virus, encryption and other measures that protect data from unauthorized access, loss or modification [TCPS Ch 5].

SERIOUS ADVERSE EVENT (SAE)/ SERIOUS ADVERSE DRUG REACTION 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 [IHC-GCP 1.50]. (See ADVERSE EVENT)

SERIOUS NONCOMPLIANCE Failure to follow federal or provincial regulations or FHREB policies and procedure in the conduct of research, thereby increasing risks to participants, decreasing potential benefits to participants, and/or compromising the integrity of the research in the judgment of either the FHREB Chair or the FHREB. .

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

STUDY (NOUN) All components of a research project.

SUBJECT An individual enrolled in a research project who, unless the REB has waived the informed consent requirement, has provided legally effective informed consent. Also known as Participant.

SUBSTITUTE DECISION MAKER An individual (or entity) authorized under applicable law to consent on behalf of a subject.

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

UNDUE INFLUENCE May arise when potential participants are recruited by individuals in a position of authority. The influence of power relationships on the voluntariness of consent should be judged from the perspective of prospective participants, since the individuals being recruited may feel constrained to follow the wishes of those who have some form of control over them (e.g. physician/care provider and patient, employer and employees, teachers and students, commanding officers and members of the military or correctional officers and prisoners) [TCPS Ch 3 – A 3.1].

UNEXPECTED ADVERSE EVENT (UAE) An adverse event whose nature, severity, and/or frequency is unanticipated and thus not described in the information provided in the consent form, the research protocol, or the investigator's brochure in clinical studies of an investigational product. When definitely or possibly due to the research, a UAE qualifies as an unanticipated problem [IHC-GCP 1.60].

VULNERABLE PARTICIPANT An individual, such as a child, who lacks the capacity to provide informed consent or whose willingness to participate in research may be unduly influenced by others [IHC-GCP 1.6.1].

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

WAIVER OF CONSENT The REB may approve a consent procedure that does not include or that alters some or all of the elements of consent or may waive the requirement to seek informed consent, provided that the REB finds and documents that all of the following apply: (a) the research involves no more than minimal risk to the participants; (b) the alteration or waiver is unlikely to adversely affect the welfare of the participants; (c) it is impossible to carry out the research and to answer the

research question properly, given the research design, without the alteration or waiver; (d) whenever possible and appropriate, the participants will be debriefed and provided with additional pertinent information after participation or at a later time during the study; and (e) the altered or waived consent does not involve a therapeutic intervention, or other clinical or diagnostic interventions [TCPS Ch 3 – A 3.7].