

Glossary of Terms for Reviewing Human Subjects Research

Active device: means a medical device that depends for its operation on a source of energy other than energy generated by the human body or gravity. A medical device that transmits or withdraws energy or a substance to or from a patient without substantially altering the energy or the substance is not an active device. *(Medical Devices Regulations)*

Active diagnostic device: means an active device that, whether used alone or in combination with another medical device, is intended to supply information for the purpose of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity. *(Medical Devices Regulations)*

Active therapeutic device: means an active device that, whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a biological function or structure for the purpose of treating or mitigating an illness or injury or a symptom of an illness or injury. *(Medical Devices Regulations)*

Adaptive design clinical trial: means a study that includes a prospectively planned opportunity for modification of one or more specified aspects of the study design and hypotheses based on analysis of data (usually interim data) from subjects in the study. Analyses of the accumulating study data are performed at prospectively planned timepoints within the study, can be performed in a fully blinded manner or in an unblinded manner, and can occur with or without formal statistical hypothesis testing. *(US HHS) See also "Progressive licensing" (Health Canada Progressive Licensing Framework)*

Adjuvant: Therapy provided to enhance the effect of a primary therapy; auxiliary therapy. *(IRB Guidebook)*

Aggregate data: The data have been averaged or grouped into ranges (e.g. 5 or 10-year age groupings). *(CIHR Best Practices)*

Assent: Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. *(IRB Guidebook)*

Assisted human reproduction: Any activity undertaken for the purpose of facilitating human reproduction. Examples include in vitro fertilization, donor insemination and intra-cytoplasmic sperm injection (ICSI). *(Health Canada Biotech)*

Audit: A systematic and independent examination of study related activities and documents to determine whether the evaluated study related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s). *(ICH GCP, 1.6)*

Author: A person who has made a substantial intellectual contribution to a submitted manuscript and accepts public responsibility for its content. *(ICMJE)*

Authorized third party: Any person with the necessary legal authority to make decisions on behalf of a prospective (study subject) participant who lacks the capacity to consent to participate, or to continue

to participate, in a particular research project. In other policies/guidance they are also known as “authorized third party decision makers.” (TCPS2)

Autonomy: The capacity to understand information and to be able to act on it voluntarily; the ability of individuals to use their own judgment to make decisions about their own actions, such as the decision to consent to participate in research. (TCPS2)

Benefit: A favourable consequence arising from a study, for example the demonstration that an investigational drug is effective in a randomized controlled trial or the identification of a workplace hazard in an observational study. (WHO Standards 2011)

Biobank: A collection of human biological materials. It may also include associated information about individuals from whom biological materials were collected. (TCPS2)

Bioengineering: Engineering applied to biological and medical systems, such as biomechanics, biomaterials and biosensors. Bioengineering also includes biomedical engineering, as in the development of aids or replacements for defective or missing body organs. (Health Canada Biotech)

Bioethics (and biomedical ethics): A discipline that studies the ethical implications of biological applications. (Health Canada Biotech)

Biohazard: A biological agent, such as an infectious microorganism, or a condition that constitutes a threat to humans, especially in biological research or experimentation. The potential danger, risk, or harm from exposure to such an agent or condition. (Health Canada Biotech)

Bioinformatics: The generation/creation, collection, storage (in databases), and efficient use of data/information from genomics in biological research to accomplish an objective (for example, to discover a new pharmaceutical or a new herbicide). (Health Canada Biotech)

Biologic: A drug that is prepared using a biological starting or source material (e.g. derived from a microorganism, virus, animal, human, or plant), and using for example, either conventional manufacturing methods, recombinant DNA technology, and/or other novel approaches. Some examples of biologics include vaccines, blood and its derivatives, certain hormones, and enzymes, recombinant DNA products, gene therapies, and transgenics. (Health Canada via FRSQ)

Biopharmaceuticals: This term is sometimes used for biologic drugs produced through rDNA technology, but essentially they also fall under the regulatory definition of a biologic. (Health Canada Biotech)

Biotechnology: A general term used to describe the use of biological processes to make products, in contrast to purely chemical processes. Biotechnology has been in practice for centuries and includes such traditional applications as the use of yeast in making beer, as well as modern applications like recombinant DNA techniques to improve crops). (Health Canada Biotech)

Blinding/Masking: A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s). (ICH GCP, 1.10)

Capacity: The ability of prospective or actual (subjects) participants to understand relevant information presented (e.g. purpose of the research, foreseeable risks, and potential benefits), and to appreciate the potential consequences of any decision they make based upon this information. *(TCPS2)*

Clinical equipoise: The existence of a genuine uncertainty on the part of the relevant expert community about what therapy or therapies are most effective for a given condition. *(TCPS2)*

Clinical research: (1) patient-oriented research: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies; (2) epidemiologic and behavioral studies; (3) outcomes research and health services research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. *(US HHS OER)*

Clinical trial: any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. *(ICMJE)*

Coercion: An extreme form of undue influence, involving a threat of harm or punishment for failure to participate in research. *(TCPS2)* See also “Undue influence” *(TCPS2)*

Compassionate access: Access to non-marketed or experimental drugs for someone who is gravely ill, with a poor quality of life and at a significant risk of death. *(Health Canada Glossary)*

Compensation: That which is given in recompense, as an equivalent rendered, or remuneration. *(WHO Standards 2011)*

Compliance: The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with a legislative or regulatory requirement or a recognized standard. *(HPFBI-QM-0001-2012)*

Confidentiality: An ethical and/or legal responsibility of individuals or organizations to safeguard information entrusted to them, from unauthorized access, use, disclosure, modification, loss or theft. *(TCPS2)*

Conflict of interest: The incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another. *(TCPS2)*

Institutional conflicts of interest: An incompatibility between two or more substantial institutional obligations that cannot be adequately fulfilled without compromising one or another of the obligations. *(TCPS2)*

(Author) conflict of interest: Exists when an author (or the author’s institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties. *(ICMJE)*

Potential for conflict of interest: Can exist regardless of whether a person believes that the relationship affects his or her scientific judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, of the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion. *(ICMJE)*

Disclosing conflict of interest: For the purposes of disclosure, the term “competing interest” should be considered synonymous with conflict of interest. *(ICMJE)*

Consent: See “Informed consent” *(WHO Standards 2011)*

Consultancy: Practice of giving expert knowledge and/or advice (as a consultant) within one’s particular field of expertise. The consultant works in an advisory capacity only and is usually not accountable for the outcome of the consulting exercise. *(ICMJE)*

Contract: A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract. *(ICH GCP, 1.17)*

Contraindicated: Disadvantageous, perhaps dangerous; a treatment that should not be used in certain individuals or conditions due to risks. *(IRB Guidebook)*

Control subjects: Subjects(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of study. *(IRB Guidebook)*

Controlled drug: A controlled drug means a substance included in Schedule I, II, III, IV or V of the *Controlled Drugs and Substances Act. (HPFBI-GUI-002)*

Cytogenetics: The study of the structure, function and abnormalities of human chromosomes. *(Health Canada Biotech)*

Data and Safety Monitoring Board: A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial. *(IRB Guidebook)*

Data holder: The Data holder may have custodianship and/or stewardship functions. These functions may be executed within the same institution/body or may be delegated to distinct but coordinated institutions/bodies. Data custodianship relates primarily to responsibility for data storage and integrity. Data stewardship relates primarily to responsibility for data definition and access authorization, particularly data access and disclosure to third parties. *(CIHR Best Practices)*

Data linkage: The merging or analysis of two or more separate data sets (e.g. health information and education information about the same individuals) for research purposes. *(TCPS2)*

Data set: A collection of information to be used for research purposes, including human biological materials. *(TCPS2)*

Debriefing: The full disclosure of the research purpose and other pertinent information to participants who have been involved in research employing partial disclosure or deception. Debriefing is typically done after participation has ended, but may be done at any time during the study. *(TCPS2)*

Delegated review: See "Expedited review" *(WHO Standards 2011)*

Dependent variables: The outcomes that are measured in an experiment. Dependent variables are expected to change as a result of an experimental manipulation of the independent variable(s). *(IRB Guidebook)*

Descriptive study: Any study that is not truly experimental (e.g., quasi-experimental studies, correlational studies, record reviews, case histories, and observational studies). *(IRB Guidebook)*

Diagnostics/Diagnostic products: A test, drug, medical device or kit used to diagnose a disease or medical condition. *(Health Canada Biotech)*

Direct access: Permission to examine, analyse, verify, and reproduce any records and reports that are important to evaluation of a clinical trial (study). Any party (e.g., domestic and foreign regulatory authorities, Sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and Sponsor's proprietary information. *(ICH GCP, 1.21)*

Direct Identifiers. These are variables such as name and address, health insurance number, etc., that provide an explicit link to a respondent. *(Statistics Canada) (CIHR Best Practices)*

Direct resources: Resources that were obtained in one's own name. This may refer to money, infrastructure, personnel, or contributions in kind. *(ICMJE)*

Documentation: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a study, the factors affecting a study, and the actions taken. *(ICH GCP, 1.22)*

Drug: A chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions. *(IRB Guidebook)*

Effectiveness: How well a drug does what it is intended to do under in "real world" circumstances. This is a measure of how well a drug treats the symptoms of a condition when average, everyday patients are taking it. *(Health Canada Glossary)*

Efficacy: How well a drug does what it is intended to do under ideal circumstances. This is a measure of how well a drug behave according to controlled scientific expectations when used in clinical trials and drug development. *(Health Canada Glossary)*

Emergency preparedness plans: Plans that detail an institution's policies and procedures for addressing research ethics review during public health outbreaks, natural disasters, and other publicly declared emergencies. *(TCPS2)* See also "Publicly declared emergency" *(TCPS2)*

Enforcement: Actions that may be taken to induce, encourage or compel compliance with the Food and Drugs Act and its associated Regulations. *(HPFBI-QM-0001-2012)*

Epidemiology: A scientific discipline that studies the factors determining the causes, frequency, and distribution of diseases in a community or given population. *(IRB Guidebook)*

Equipoise: See "Clinical equipoise" *(TCPS2)*

Equitable: Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed. *(IRB Guidebook)*

Essential documents: Documents, which individually and collectively permit evaluation of the conduct of a study and the quality of, the data produced. *(ICH GCP, 1.23)*

Ethical drug: a drug that in accordance with Federal Legislation does not require a prescription, but that is generally prescribed by a medical practitioner, e.g. nitroglycerine. **Note:** As ethical drugs are not listed in any Schedule to the *FDA* or *FDR* they do not require a Drug Establishment License for the activity of wholesale. *(HPFBI-GUI-002)*

Ethical guidelines: Guidance documents which assist with decisions relating to the responsibility to adhere to established and relevant standards of ethical principles and practice. *(WHO Standards 2011)*

Evidence-based approach to decision making: The use of high-quality evidence to make informed choices. High-quality evidence is scientific, experiential, and includes other types of evidence deemed appropriate. *(Health Canada Glossary)*

Exculpatory language: as applies to informed consent to research, any written or verbal communication that has "the general effect of freeing or appearing to free an individual or an entity from responsibility for malpractice or negligence, or from blame, fault, or guilt." *(OHRP and FDA guidance)*

Expedited review: Review of proposed research by the REB Chair or a designated voting member or group of voting members rather than by the entire REB. *(WHO Standards 2011)*

Experimental study: A true experimental study is one in which subjects are randomly assigned to groups that experience carefully controlled interventions manipulated by the investigator according to a strict logic allowing causal inference about the effects of the interventions under investigation. *(IRB Guidebook)*

Fairness: Being impartial and using sound judgment free of prejudice or favouritism. *(Tri-Agency RCR)*

Full Board review: A review conducted at a convened meeting of the Research Ethics Board where a majority of the REB members are present, and the expertise required by applicable regulations is represented to form quorum. *(adapted IRB Guidebook)*

Funding agreement: A written agreement that sets out the terms and conditions that an Agency and a researcher agree to for a particular grant or award. It defines the researcher's responsibilities, what constitutes a breach of the agreement, and the consequences of a breach. *(Tri-Agency RCR)*

Gene therapy: The treatment of genetic disease accomplished by altering the genetic structure of either somatic (nonreproductive) or germline (reproductive) cells. *(IRB Guidebook)*

Genetic counseling: The explanation of the meaning and implication of information revealed in genetic research to a participant by someone with the experience or training to provide the appropriate context and support. *(TCPS2)*

Genetic disease: A disease or condition caused by a change or mutation in a gene, or a change in the chromosomes. *(Health Canada Biotech)*

Genetic engineering: The technique of removing, modifying or adding genes to a DNA molecule to change the information it contains. By changing this information, genetic engineering changes the type or amount of proteins an organism is capable of producing. *(Health Canada Biotech)*

Genetic screening: Tests to identify individuals who have an inherited predisposition to a certain phenotype or who are at risk of producing offspring with inherited diseases or disorders. *(IRB Guidebook)*

Genetic testing: means the analysis of DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis *(Medical Devices Regulations)*

Genetics: The study of how traits are passed on in families and how genes are involved in health and disease. *(Health Canada Biotech)*

Genome: All of an organism's genetic information, including all of the DNA that makes up the genes that are carried on the chromosomes. *(Health Canada Biotech)*

Genomics: The comprehensive study, using high throughput technologies, of the genetic information of a cell or organism, including the function of specific genes, their interactions with each other and the activation and suppression of genes. For purposes of describing Genome Canada's mandate it also includes related disciplines such as bioinformatics, epigenomics, metabolomics, metagenomics, nutrigenomics, pharmacogenomics, proteomics and transcriptomics.. *(Genome Canada)*

Grant: Financial assistance mechanism providing monetary aid, property, or both to an eligible person, group of people (e.g., research group), or other entity (e.g., research institute) to carry out an approved research project or study. *(ICMJE)*

Good Clinical Practices: Generally accepted clinical practices that are designed to ensure the protection of the rights, safety and well-being of clinical trial subjects and other persons, and the good clinical practices referred to in C.05.010 of Division 5 of the *Food and Drug Regulations*. *(Division 5 C.05.001)*

Half-life: The time required for the decay of half of a sample of particles of a radionucleotide or elementary particle. *(Health Canada Biotech)*

Harm: Anything that has a negative effect on participants' welfare, broadly construed. The nature of the harm may be social, behavioral, psychological, physical or economic. *(TCPS2)*

Health care professional: means a person who is entitled under the laws of a province to provide health services in the province. *(Medical Devices Regulations)*

Health product: Encompasses products subject to the Food and Drugs Act, managed along the following broad categories: 1. Biologics (both regular and biotechnology-based products) 2. Pharmaceuticals (both regular and biotechnology-based products) 3. Medical devices 4. Natural Health Products. *(Health Canada Biotech)*

Honesty: Being straightforward, and free of fraud and deception. *(Tri-Agency RCR)*

Human biological materials: Tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials. *(TCPS2)*

Human health: World Health Organization defines health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. *(Health Canada Biotech)*

Human subjects: Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. *(IRB Guidebook)*

Identifiable information: Information that may reasonably be expected to identify an individual, alone or in combination with other available information. Also referred to as "personal information." *(TCPS2)*

Directly identifying information – The information identifies a specific individual through direct identifiers (e.g. name, social insurance number, personal health number). *(TCPS2)*

Indirectly identifying information – The 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). *(TCPS2)*

Coded information – Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g. the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary). *(TCPS2)*

Anonymized information – The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low. *(TCPS2)*

Anonymous information – The information never had identifiers associated with it (e.g. anonymous surveys) and risk of identification of individuals is low or very low. *(TCPS2)*

Immunodeficiency: An innate, acquired, or induced inability to develop a normal immune response. *(Health Canada Biotech)*

Impartial witness: A person, who is independent of the trial (study), who cannot be unfairly influenced by people involved with the trial (study), who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form (document) and any other written information supplied to the subject. (*ICH GCP 1.26*)

Impracticable: means a degree of difficulty in doing something under given conditions, where the degree of difficulty is greater than would arise if something is merely inconvenient to do but may be less than if something is impossible. (*CIHR Best Practices*)

Incapacity: Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (*IRB Guidebook*)

Incentive: Anything offered to participants, monetary or otherwise, to encourage participation in research. (*TCPS2*)

Incidental findings: Unanticipated discoveries made in the course of research that are outside the scope of the research. (*TCPS2*)

Incompetence: Technically, a legal term meaning inability to manage one's own affairs. (*IRB Guidebook*)

Independent variables: The conditions of an experiment that are systematically manipulated by the investigator. (*IRB Guidebook*)

Indirect resources: Resources that were obtained through or from one's institution (as opposed to in one's own name). This may refer to money, infrastructure, personnel, or contributions in kind. (*ICMJE*)

Informed consent: Is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation. (*WHO Standards 2011*)

Inspection: On-site monitoring and assessment (by a Regulatory Authority) against the applicable requirements of the Food and Drugs Act and its associated Regulations. Inspections are routinely conducted on a predetermined cycle or as required to assess compliance. (*HPFBI-QM-0001-2012*)

Institution: Organization such as, but not limited to, a university, hospital, clinic, or biomedical research centre providing services to the public. (*ICMJE*)

Intellectual property: A form of creative endeavor that can be protected through a trademark, patent, copyright, industrial design or integrated topography. The patent system offers the only protection available for the intellectual products of research. (*Health Canada Biotech*)

Interaction: includes communication or interpersonal contact between investigator and subject (*45 CFR 46.102(f)(1)*)

Intervention: includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (45 CFR 46.102(f)(1))

Investigational product: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain more information about an approved use. (ICH GCP, 1.33)

Investigator: See “Principal Investigator” (TCPS2) and “Sponsor-Investigator” (ICH GCP 1.54)

Investigator’s Brochure: A compilation of the (preclinical) clinical and nonclinical data on the investigational product(s) that is relevant to the study of the investigational product(s) in human subjects. (ICH GCP, 1.36)

In vitro fertilization: A procedure to help infertile couples conceive. Eggs are removed from the woman and fertilized with the man's sperm in the laboratory. Fertilized eggs can then be transferred to the woman's uterus to try to establish a pregnancy or they can be frozen for future use. (Health Canada Biotech)

Legally acceptable representative: An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial (study). (ICH GCP, 1.37)

Longitudinal study: A study designed to follow subjects forward through time. (IRB Guidebook)

Marketing authorization: A legal document issued by Health Canada, authorizing the sale of a drug or a device based on the health and safety requirements of the *Food and Drug Act* and its associated *Regulations*. The marketing authorization may be in the form of a Notice of Compliance (NOC), Drug Identification Number (DIN). (HPFBI-GUI-002)

Medical device: See active device (*Medical Devices Regulations*)

Medical emergency: A situation in which one or more individuals requires urgent medical care. (TCPS2)

MedRA: Medical Dictionary for Regulatory Activities terminology developed under the auspices of ICH and maintained by MSSO (owned by Northrop Grumman), and provides an international medical dictionary applicable to all phases of drug development. (ICH Glossary)

Memorandum of Understanding: The agreement between the Agencies and institutions eligible to receive and manage research funding from the Agencies. A commitment to adhere to the TCPS is a part of the MOU. (TCPS2)

Metabolism (of a drug): The manner in which a drug is acted upon (taken up, converted to other substances, and excreted) by various organs of the body. (IRB Guidebook)

Minimal risk research: Research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research. *(TCPS2)*

Monitoring: The act of overseeing the progress of a clinical trial (study), and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s). *(ICH GCP, 1.38)*

Multicentre 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. *(ICH GCP, 1.40)*

Nanotechnology: The application of scientific knowledge to manipulate and control matter in the nanoscale to make use of size- and structure-dependent properties and phenomena distinct from those associated with individual atoms or molecules or with bulk materials. The term "nanoscale" is defined as 1 to 100 nanometers (nm) inclusive. *(Health Canada nanotechnology-based health products and food)*

Natural Health Product: Vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines, such as traditional Chinese medicines, probiotics, and other products, such as amino acids and essential fatty acids. *(Health Canada Glossary)*

No Objection Letter: This document is issued by Health Canada within the review period if no clinical or quality deficiencies are identified and the Clinical Trial Application (CTA) or Clinical Trial Application Amendment (CTA-A) is deemed acceptable. *(Health Canada Glossary)*

Non-identifiable data: Any element or combination of elements that allows direct or indirect identification of an individual was never collected or has been removed, although some elements may indirectly identify a group or region. *(CIHR Best Practices)*

Non-therapeutic research: Research that has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the current subjects, although it may benefit subjects with a similar condition in the future. *(IRB Guidebook)*

Notice of Compliance: Certifies that a drug complies with the *Food and Drugs Act* and *Regulations*. It is issued once Health Canada concludes that the benefits of the drug outweigh the risks, and it confers the ability to market a drug. *(Health Canada Glossary)*

Notice of Non-compliance: This document may be issued if the submission does not meet the requirements of the *Food and Drugs Act* and *Regulations*. It outlines outstanding issues and may request further information. *(Health Canada Glossary)*

Null hypothesis: Proposition, to be tested statistically, that the experimental intervention has "no effect," meaning that the treatment and control groups will not differ as a result of the intervention. It is anticipated that the data will demonstrate some effect from the intervention, thereby allowing the investigator to reject the null hypothesis. *(IRB Guidebook)*

Nutraceutical: A product isolated or purified from food that is generally sold in medicinal forms not usually associated with food. A nutraceutical has been demonstrated to have a physiological benefit or provide protection against chronic disease. *(Health Canada Biotech)*

Ongoing research: Research that has received REB approval and has not yet been completed. *(TCPS2)*

Over-the-Counter: a non-prescription drug, which still requires a market authorization. **Note:** OTC drugs are not considered pharmaceuticals; as per the *FDA* or *FDR* therefore they do not require a DEL for the activity of wholesale. *(HPFBI-GUI-002)*

Patent: Exclusive right, granted by the government to an inventor (or his or her assignee), to make use of his or her invention (product, process, or design) for a specified time, generally 20 years, in exchange for a public disclosure of the invention. *(ICMJE)*

Pathogen: An agent that causes disease, especially a living microorganism such as a bacterium or fungus. *(Health Canada Biotech)*

Personal information: Identifiable information about an individual. *(TCPS2)* See also "Identifiable information" *(TCPS2)*

Pharmaceutical product: is any chemical substance intended for use in the medical diagnosis, cure, treatment, or prevention of disease, disorders, or other illness. *(TCPS2)*

Pharmacodynamics: The study of how drugs achieve their therapeutic effect. *(Health Canada Biotech)*

Pharmacogenetics: The study of genetic differences among individuals that relate to drug response. *(Health Canada Biotech)*

Pharmacogenomics: The study of variability in the expression of individual genes that relate to disease susceptibility and drug response at the cellular, tissue, individual and population level. *(Health Canada Biotech)*

Pharmacokinetics: The study of how drugs are absorbed, distributed and cleared from the body. *(Health Canada Biotech)*

Pharmacovigilance: The science and activities relating to the detection, assessment, understanding, and prevention of adverse reactions or any other drug-related problem. *(Health Canada Glossary)*

Policy: Policies provide direction for decision-making and are concerned with what is to be achieved rather than how to achieve it. *(HPFBI-QM-0001-2012)*

Placebo: A chemically inert substance given in the guise of medicine for its psychologically suggestive effect; used in controlled clinical trials to determine whether improvement and side effects may reflect imagination or anticipation rather than actual power of a drug. *(IRB Guidebook)*

Preclinical investigations: Laboratory and animal studies designed to test the mechanisms, safety, and efficacy of an intervention prior to its applications to humans. *(IRB Guidebook)*

Principal Investigator: The leader of a research team who is responsible for the conduct of the research, and for the actions of any member of the research team. *(TCPS2)*

Privacy: The state or condition of being alone, undisturbed, or free from attention, as a matter of choice or right; seclusion; freedom from interference or intrusion; absence or avoidance of publicity or display; secrecy, concealment, discretion; protection from public knowledge or availability. (*WHO Standards 2011*)

Privacy risks: The potential harms that (subjects) participants, or the groups to which they belong, may experience from the collection, use, and disclosure of personal information for research purposes. (*TCPS2*)

Procedure: See “Standard operating procedure” (*HPFBI-QM-0001-2012*)

Product monograph: A product monograph is a factual scientific document describing the drug. It is devoid of promotional material and describes the properties, claims, indications, and conditions of use for the drug. It also contains any other information that may be required for optimal, safe, and effective use of the drug. (*Health Canada Glossary*)

Progressive Licensing: The concept of a progression in knowledge about a drug over its full life-cycle, rather than placing the focus primarily upon pre-market assessment. This represents a fundamental shift from the idea that the pre-market testing of a drug assures its safety and efficacy. (*Health Canada Progressive Licensing Framework*) See also “Adaptive design clinical trial” (*US HHS*)

Prospective studies: Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data. (*IRB Guidebook*)

Proteomics: The study of the protein products of genes, protein-protein interactions and protein sub-cellular localization. Examples. (*Health Canada Biotech*)

Protocol: See “Research protocol” (*WHO Operational Guidelines – 2000*)

Publicly declared emergency: An emergency situation which, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public office (in accordance with legislation and/or public policy). Publicly declared emergencies are extraordinary events that arise suddenly or unexpectedly, and require urgent or quick responses to minimize devastation. Examples include hurricanes and other natural disasters, large communicable disease outbreaks, catastrophic civil disorders, bio-hazardous releases, environmental disasters, and humanitarian emergencies. (*TCPS2*)

Publicly available information: Any existing stored documentary material, records or publications, which may or may not include identifiable information, and that has no restrictions on its use or distribution, or that may be released under certain legal conditions. (*TCPS2*)

Qualification: The ability of an employee to demonstrate that he/she has completed training or has knowledge of an area of qualification, within the position qualification, in a relevant position category of a particular training curriculum. (*HPFBI-QM-0001-2012*)

Qualitative research: An approach that aims to understand how people think about the world and how they act and behave in it. This approach requires researchers to understand phenomena based on discourse, actions, and documents, and how and why individuals interpret and ascribe meaning to what they say and do, and to other aspects of the world (including other people) they encounter. (*TCPS2*)

Quality assurance: refers to a systematic process to determine whether the quality control system is working and effective. Most often, quality assurance in clinical trials (studies) is implemented by the sponsor through independent auditing of quality control activities and, where applicable, by regulatory authorities through inspection of quality control systems and activities. *(WHO Handbook for GCP)*

Quality control: For a clinical trial (study), “quality control” encompasses steps taken during the clinical trial (study) (e.g. investigator supervision, sponsor monitoring, and any ongoing review by regulatory authorities) to ensure that the trial (study) meets protocol and procedural requirements and is reproducible. *(WHO Handbook for GCP)*

Quality improvement: refers to a systematic process for taking the knowledge gained through quality assurance audits and activities and using this knowledge to make changes in systems and activities to increase the ability to fulfill quality requirements then and for the future. *(WHO Handbook for GCP)*

Quality management: Coordinated activities to direct and control an organization with regard to quality. *(HPFBI-QM-0001-2012)*

Quality systems: for clinical trials (studies) are formalized practices (e.g. monitoring programs, auditing programs, complaint handling systems) for periodically reviewing the adequacy of clinical trial activities and practices, and for revising such practices as needed so that data and process quality are maintained. *(WHO Handbook for GCP)*

Quorum: A quorum is the minimum number of members that must be present to constitute a valid meeting where decisions can be taken concerning submissions put forward for ethical review. A meeting is quorate when a quorum is present. *(WHO Standards 2011)*

Radiopharmaceuticals: include drugs either of chemical or biological origin which are intentionally made radioactive for the purpose of diagnosing illness, as well as kits that are used for the preparation of radiopharmaceutical and radionuclide generators. Radiopharmaceuticals are used as diagnostic or therapeutic agents and are always prepared and administered by health care professionals; they are never self-administered. *(Health Canada BRGT)*

Randomization: Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically. Random assignment of subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention. *(IRB Guidebook)*

Regulation: A law made by a person or body that has been granted (delegated) law-making authority. A regulation is used both to indicate a specific type of delegated legislation as well as to refer generically to all forms of delegated legislation. *(Health Canada Biotech)*

Regulatory authority: means a government agency or entity in another country that has signed a Mutual Recognition Agreement with Canada, having a legal right to control the use or sale of drugs within that country and that may take enforcement action to ensure that drugs marketed within its jurisdiction comply with legal requirements. *(HPFBI-GUI-002)*

Remission: A period in which the signs and symptoms of a disease are diminished or in abeyance. The term "remission" is used when one cannot say with confidence that the disease has been cured. (*IRB Guidebook*)

Reproductive technology: See "Assisted human reproduction" (*Health Canada Biotech*)

Requirements: In the context of decisions, requirements are binding elements that express ethical considerations whose implementation the ethics committee requires or views as obligatory in pursuing the research. (*WHO Operational Guidelines – 2000*)

Research: An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. (*TCPS2*)

Research directive: Written instructions used to express an individual's preferences for participation in future research, in the event that the individual loses capacity. It is intended to guide the individual's authorized third party in deciding whether or not to give substitute consent for the individual to participate in research. (*TCPS2*)

Research ethics education and training: The provision of materials and corresponding instruction by an institution to research ethics board (REB) members or researchers with regard to the core principles and understanding of this Policy (TCPS2), basic ethics standards, applicable institutional policies, and legal or regulatory requirements. (*TCPS2*)

Research protocol: A document that provides the background, rationale, and objective(s) of a research project and describes its design, methodology, and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol. (*WHO Operational Guidelines – 2000*)

Retrospective studies: Research conducted by reviewing records from the past (*e.g.*, birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events through interviews or surveys. (*IRB Guidebook*)

Risk: The possibility of the occurrence of harm. The level of foreseeable risk posed to participants by their involvement in research is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties. (*TCPS2*)

Secondary use of data for research: The data may have been collected originally for (i) a non-research purpose (*e.g.* for health care administrative purposes or for health care insurance billing purposes), or (ii) a different research purpose (*e.g.* for a study on a different but related disease). (*CIHR Best Practices*)

Security: Measures taken to protect information. It includes physical, administrative, and technical safeguards. (*TCPS2*)

Site visit: An inspection visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of protection of human subjects or the capability of study personnel to conduct the research. (*IRB Guidebook*)

Source data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial (study) necessary for the reconstruction and evaluation of the trial (study). Source data are contained in source documents (original records or certified copies). *(ICH GCP, 1.51)*

Source documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, 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 or study). *(ICH GCP, 1.52)*

Sponsor of research: A person or entity (organization, government agency, public institution, company, etc.) that contributes to the creation and/or dissemination of new knowledge by ensuring that the appropriate arrangements are in place for the financing, initiation, management/governance, monitoring, and reporting of a research project or study by pledging money in advance and/or providing products, services, and/or other resources. The sponsor does not conduct the research project or study but is always a stakeholder. *(ICMJE)*

Sponsor-Investigator: An individual who both initiates and conducts, alone or with others, a clinical trial (study), and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator. *(ICH GCP 1.54)*

Standard: established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. *(ISO/IEC Guide)*

Standard operating procedure: An established and generic series of logical steps followed in a definite regular order that ensures the consistent and uniform approach to activities or processes. Procedures are concerned with how to achieve a task rather than what is to be achieved. *(HPFBI-QM-0001-2012)*

Statistical significance: A determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. Or, more simply put, the probability of coming to a false positive conclusion. If the probability is less than or equal to a predetermined value, then the null hypothesis is rejected at that significance level. *(IRB Guidebook)*

Stewardship: The preservation of public good by ensuring that the social and the ethical issues related to biotechnology are addressed, and that the federal government has an effective regulatory regime and the science capacity to protect human and animal health and the environment. *(Health Canada Biotech)*

Stopping rules: Statistically significant end points and safety considerations for a clinical trial (study) that are determined in advance, and, once reached, dictate that the trial (study) must be terminated. *(TCPS2)*

Subject identification code: A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial related data. *(ICH GCP 1.58)*

Surveillance: Systematic collection, analysis, interpretation and dissemination of data generated by the laboratory and private and public domain literature to assist in the planning and implementation of research, evaluation and management of risks and public health interventions and programs. (*Health Canada Biotech*)

Surveys: Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures. (*IRB Guidebook*)

Therapeutic intent: The research physician's intent to provide some benefit to improving a subject's condition (e.g., prolongation of life, shrinkage of tumor, or improved quality of life, even though cure or dramatic improvement cannot necessarily be effected.) This term is sometimes associated with Phase 1 drug studies in which potentially toxic drugs are given to an individual with the hope of inducing some improvement in the patient's condition as well as assessing the safety and pharmacology of a drug. (*IRB Guidebook*)

Therapeutic misconception: A misunderstanding, on the part of research subjects, of the purpose, benefits, and/or risks of clinical trials. Often subjects do not understand that research is aimed primarily at producing knowledge and may not provide any therapeutic benefit to them. (*adapted TCPS2*)

Therapy: Treatment intended and expected to alleviate a disease or disorder. (*IRB Guidebook*)

Third-party: Person or entity (organization, government agency, public institution, company, etc.) that is not directly involved in a transaction/agreement between two principal parties but that may nevertheless have various interests (financial, legal, etc.) at stake in this transaction/ agreement. (*ICMJE*)

Translational research: Human translational research can range from advancing discoveries to early proof of concept in humans, to developing evidence through RCTs, to moving evidence-based medicine into community practice through delivery, dissemination and diffusion of research, to evaluating the community outcomes of a scientific discovery in practice. (*CIHR International Review Panel Report*)

Undue influence: The impact of an unequal power relationship on the voluntariness of consent. This may occur when prospective participants are recruited by individuals in a position of authority over them (e.g. doctor/patient, teacher/student, employer/employee). (*TCPS2*) See also "Coercion." (*TCPS2*)

Vaccine: A biologic product generally made from an infectious agent or its components, a virus, bacterium, or other microorganism that is killed (inactive) or live attenuated (active, although weakened). Vaccines may also be biochemically synthesized or made through recombinant DNA techniques. (*IRB Guidebook*)

Variable: An element or factor that the research is designed to study, either as an experimental intervention or a possible outcome (or factor affecting the outcome) of that intervention. (*IRB Guidebook*)

Validation: means confirmation by examination and the provision of objective evidence that the requirements for a specific intended use have been fulfilled (*ISO 8402:1994*)

Vector: A vehicle that carries foreign genes into an organism and inserts them into the organism's genome. Modified viruses are used as vectors for gene therapy. (*Health Canada Biotech*)

Virus: A submicroscopic particle that can infect other organisms. It cannot reproduce on its own but infects an organism's cell in order to use that cell's reproductive machinery to create more viruses. It usually consists of a DNA or RNA genome enclosed in a protective protein coat. (*Health Canada Biotech*)

Voluntary: Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity. (*IRB Guidebook*)

Vulnerable research subjects: Vulnerable persons who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study 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 may also be considered vulnerable. (*WHO Standards 2011*) See also "Autonomy" (*TCPS2*)

Witness: See "Impartial Witness" (*ICH GCP 1.26*)

Xenografts: A type of tissue graft in which the donor and recipient are of different species. Also called heterografts. (*Health Canada Biotech*)

Xenotransplantation: The transplantation of living cells, tissues and organs from one species to another. The term is usually used to describe animal-to-human transplants. An example is the transplant of a kidney from a pig to a human. The principal reason for medical and scientific inquiry in this area is to find alternatives to human organs and tissue transplants. (*Health Canada Biotech*)

Key to Reference Glossaries:

- . **CIHR Best Practices** - [CIHR Best Practices for Protecting Privacy in Health Research](#)
- . **Division 5** - [Food and Drug Regulations Division 5](#)
- . **Health Canada Biotech** - [Health Canada Biotechnology Glossary](#)
- . **Health Canada BRGT** - [Health Canada Biologics, Radiopharmaceuticals and Genetic Therapies](#)
- . **Health Canada Glossary - Progressive Licensing** [Health Canada Drugs and Health Products Glossary](#)
- . **HPFBI-QM-0001-2012** - [Health Products and Food Branch Inspectorate – Quality System Framework for the Inspectorate Quality Management System](#)
- . **HPFBI-GUI-002** - [Health Products and Food Branch Inspectorate Guidance on Drug Establishment Licenses \(GUI 0002\)](#)
- . **ICH GCP** - [International Conference on Harmonization \(ICH\) of Technical Requirements for the Registration of Pharmaceuticals for Human Use Good Clinical Practice \(GCP\): Consolidated Guidelines](#)

- . **IRB Guidebook** - [Office for Human Research Protection IRB Guidebook](#)
- . **ICMJE** - [International Committee of Medical Journal Editors Conflict-of-Interest: Glossary of Terms](#)
- . **ISO/IEC Guide** - [ISO/IEC Guide 2:2004, Standardization and related activities - General vocabulary](#)
- . **Medical Devices Regulations** - [Medical Devices Regulations Interpretation](#)
- . **TCPS2** - [2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#)
- . **Tri-Agency RCR** - [Tri-Agency Framework: Responsible Conduct of Research](#)
- . **US HHS** - US Department of Health and Human Service [Guidance for Industry Adaptive Design Clinical Trials for Drugs and Biologics – February 2010](#) -
- . **US HHS OER** - US Department of Health and Human Service [Office of Extramural Research Glossary](#)
- . **WHO Handbook for GCP** - http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf
- . **WHO Standards 2011** - [Standards and operational guidance for ethics review of health-related research with human participants](#)
- . **45 CFR 46.102(f)(1)** - [US Code of Federal Regulations Title 45 § 46.102 Definitions](#)