# GLOSSARY OF TERMS

**Accountability**: taking personal responsibility for one's conduct.

**Adverse event (AE)**: a medically undesirable event occurring in a research subject, such as an abnormal sign, symptom, worsening of a disease, injury, etc. A serious adverse event (SAE) results in death, hospitalization (or increased hospital stay), persistent disability, birth defect, or any other outcome that seriously jeopardizes the subject's health.

**Amendment**: a change to a research protocol approved by an institutional review board

**Audit**: a formal review of research records, policies, activities, personnel, or facilities to ensure compliance with ethical or legal standards or institutional policies. Audits may be conducted regularly, at random, or for-cause (i.e. in response to a problem).

**Autonomy**: A philosophical term meaning self-governance whereby one has the right, power or condition of self-governance. The individual has self-determinism and freedom from external control or coercion.

**Beneficence**: the ethical obligation to do good and avoid causing harm.

**Bioethics**: the study of ethical, social, or legal issues arising in biomedicine and biomedical research.

**Clinical trial**: an experiment designed to test the safety or efficacy of a type of therapy (such as a drug).

**Code of ethics**: Defines the core values of the field and provides guidance for what professionals should do when they encounter conflicting obligations or responsibilities in their work.

**Cognitive dissonance**: The cognitive process whereby individual's values and beliefs are challenged. The challenging process is necessary in moral reasoning to wrestle with moral dilemmas.

**Collaboration agreement**: an agreement between two or more collaborating research groups concerning the conduct of research. The agreement may address the roles and responsibilities of the scientists, access to data, authorship, and intellectual property.

**Commercialization:** the process of developing and marketing commercial products (e.g. drugs, medical devices, or other technologies) from research.

**Community review**: a process for involving a community in the review of research conducted on members of the community. Some research studies include community advisory boards as a way of involving the community.

**Confidentiality**: the obligation to keep some types of information confidential or secret. In science, confidential information typically includes: private data pertaining to human subjects, papers or research proposals submitted for peer review, personnel records, proceedings from misconduct inquiries or investigations, and proprietary data.

**Conflict of interest (COI)**: a situation in which a person has a financial, personal, political or other interest which is likely to bias his or her judgment or decision-making concerning the performance of his or her ethical or legal obligations or duties.

**Consequentialism**: an approach to ethics where right and wrong are based on the greater amount of good. The consequences of action play a major role in deciding the greater amount of good.

**Data management**: Practices and policies related to recording, storing, auditing, archiving, analyzing, interpreting, sharing, and publishing data.

**Deontic ethics (non-consequential)**: an ethical theory based on the ideal that we can perceive rightness apart from any consequences. This perspective believes that there is an inherent right, which must be followed regardless of any extraneous factors. Right and wrong are based on the ideal of what should be.

**Ethical dilemma**: A situation in which two or more potential actions appear to be equally justifiable from an ethical point of view, i.e. one must choose between the lesser of two evils or the greater of two goods.

**Ethical reasoning**: Making a decision in response to a moral dilemma based a careful and thorough assessment of the different options in light of the facts and circumstances and ethical considerations.

**Ethical relativism**: The view that ethical standards are relative to a particular culture, society, historical period, etc.

**Ethics (or morals)**: 1. Standards of conduct (or behaviour) that distinguish between right/wrong, good/bad, etc. 2. The study of standards of conduct.

**Helsinki Declaration**: ethical guidelines for conducting medical research involving human subjects research adopted by the World Medical Association.

**Honesty**: the ethical obligation to tell the truth and avoid deceiving others.

**Informed consent**: the process of making a free and informed decision (such as to participate in research). Individuals who provide informed consent must be legally competent and have enough decision-making capacity to consent to research. Research regulations specify the types of information that must be disclosed to the subject.

**Intellectual property**: legally recognized property pertaining to the products of intellectual activity, such as creative works or inventions. Forms of intellectual property include copyrights on creative works and patents on inventions.

**Justice**: 1. treating people fairly. 2. An ethical principle that obligates one to treat people fairly. Distributive justice refers to allocating benefits and harms fairly; procedural justice refers to using fair processes to make decisions that affect people; formal justice refers to treating similar cases in the same way. In research with people the principle of justice implies that subjects should be selected equitably.

**Negligence**: a failure to follow the standard of care, which results in harm to a person or organization. In science, research that is sloppy, careless, or poorly planned or executed may be considered negligent.

**Non-compliance**: the failure to comply with research regulations, institutional policies, or ethical standards.

**Patent**: a right, granted by a government, which allows the patent holder to exclude others from making, using, or commercializing an invention for a period of time, typically 20 years. To be patented, an invention must be novel, non-obvious, and useful. The patent holder must publicly disclose how to make and use the invention in the patent application.

**Peer review**: The process of using experts within a scientific or academic discipline (or peers) to evaluate articles submitted for publication, grant proposals, or other materials.

**Privacy**: a state of being free from unwanted intrusion into one's personal space, private information, or personal affairs.

**Protocol**: a set of steps, methods, or procedures for performing an activity, such as a scientific experiment.

**Quality control/quality assurance**: processes for planning, conducting, monitoring, overseeing, and auditing an activity (such as research) to ensure that it meets appropriate standards of quality.

**Randomized controlled trial (RCT)**: an experiment, such as a clinical trial, in which subjects are randomly assigned to receive an experimental intervention or a control.

**Relativism**: The position that states either that a) there is no standard of right and wrong b) no one has the right to make moral judgements c) right and wrong are unknowable because of different societies and cultures and d) no one should judge others concerning right or wrong.

**Reproducibility**: the ability for an independent researcher to achieve the same results of an experiment, test, or study, under the same conditions. A research paper should include information necessary for other scientists to reproduce the results. Reproducibility is different from repeatability, in which researchers repeat their own experiments to verify the results. Reproducibility is one of the hallmarks of good science.

**Research**: A systematic attempt to develop new knowledge.

**Research ethics**: 1. Ethical conduct in research. 2. The study of ethical conduct in research.

**Research integrity**: following ethical standards in the conduct of research.

**Respect for persons**: a moral principle, which holds that we should respect the choices of autonomous decision-makers and that we should protect the interests of those who have diminished autonomy

**Risk**: the product of the probability and magnitude (or severity) of a potential harm.

**Situational ethics**: The position that every ethical or moral decision is made on the spot and no consistency is shown between individual decisions.

**Teleological ethics (consequential)**: Matters of right and wrong are decided on the isse of the greater amount of good.

**Transparency**: in science, openly disclosing information that concerned parties would want to know, such as financial interests or methodological assumptions.

**Utilitarianism**: An ethical theory which holds that the right thing to do is to produce the greatest balance of good/bad consequences for the greatest number of people. Act utilitarians focus on good resulting from particular actions while rule utilitarians focus on happiness resulting from following rules. Utilitarians may equate the good with happiness, satisfaction of preferences, or some other desirable outcomes.

**Value:** something that is worth having or desiring, such as happiness, knowledge, justice or virtue

**Virtue**: a morally good or desirable character trait, such as honesty, courage, compassion, modesty, fairness, etc.

**Virtue ethics**: a theory that emphasizes developing virtue as opposed to following rules or maximizing good/bad consequences.

**Voluntariness**: the ability to make a free (un-coerced) choice.

**Vulnerable subject**: a research subject who has an increased susceptibility to harm or exploitation due to his or her compromised ability to make decisions or advocate for his/her interests or his/her dependency. Vulnerability may be based on age, mental disability, institutionalization, language barriers, socioeconomic deprivation, or other factors..

**Withdrawal**: Participants may voluntarily withdraw or be withdrawn by the researcher to protect them from harm or ensure the integrity of the study. Subjects who withdraw from a study may request to have their samples removed from the study (i.e. destroyed).