Glossary of Terms

This document exists to define terms used within the complete set of Ontario Institute for Cancer Research (OICR) Standard Operating Procedures (SOPs). Synonyms for common terms are also listed in this document.

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

A

Audit Trail: Documentation that allows reconstruction of the course of events.

B

Biological Sampling: Collecting, processing and analyzing of biospecimens.

Biorepository Personnel: Any staff/personnel at the collection centre who is/are involved with and conducts tasks for the biorepository. This may include the Principal Investigator or biorepository director, and other hospital staff who assist with various aspects of the program including technologists, pathologists, surgeons, OR staff, etc. Synonyms: Collection Centre Staff, Tumour Bank Staff.

Biospecimen: All biological material of human origin, including organs, tissues, bodily fluids, blood, teeth, hair and nails, and substances extracted from such material such as DNA and RNA. Synonyms: sample, biospecimen, biological sample, biological specimen, human biological material, biomaterial.

Buffy Coat: White blood cells found in peripheral blood. When whole blood is fractionated, the buffy coat layer is usually the middle, thin, white layer.

C

Category B Substance (IATA definition): An infectious substance which does not meet the criteria for inclusion in Category A.

Commercial Invoice: A legal document between the supplier and the customer to describe the details of a certain commodity. The commercial invoice is needed for all international non-document shipments, and is used for the customs in the country of destination to determine the customs value.

Compliance: The state of conformity of a regulated party or a product with a legislative or regulatory requirement or a recognized standard.

Confidentiality: Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity. (ICH)

Consented Participant: A participant who has consented to participating in the Biorespository or Clinical Trial and this consent has been documented on the Informed Consent Form.

Consignee: An individual agency, institution, or organization that receives specimens and assumes responsibility for storage, dispensing and tracking the disposition of specimens. Synonyms: Receiver.

Container (for diagnostic substances): Container designed, constructed, filled, closed, secured and maintained so that under normal conditions of transport, including handling, there will be no accidental release of dangerous goods that could endanger public safety.

Courier: An organization-approved shipping service with traceable delivery [i.e. Purolator (for Canadian shipments) or World Courier (for US and international shipments)].

Cryogenic Freezer: A cryogenic vessel used for storing samples at the collection centre. Samples should be stored in the vapour phase of liquid nitrogen to preserve the samples at a low temperature of -196°C..

Cryopreservation: A process for storing biological material at very low temperatures for lengthy periods of time.
Cryovial: A screw-capped 2mL specimen container used to store aliquots of tissue and fractionated blood.

Custodianship: Responsibility for safe keeping of tissue samples and associated data and control of their use and eventual disposal in accordance with the terms of the consent given by the participant and as regulated by the regulatory requirments. Custodianship implies some rights to decide how the samples are used and by whom, and also responsibility for safeguarding the interests of donors.

D

Data Management System (DMS):A software platform for collaborating on gathering, sharing, and using analytical data.

Diagnostic Specimens: Human material including blood and its components, tissue and tissue fluids that is offered for transport for the purpose of diagnosis, analysis or testing.

Digital Image: Electronic data file specifying the histological image of a representative tumour section.

DNase: Deoxyribonuclease is a type of enzyme that catalyzes the degradation of DNA into smaller components.

Donor: Refers to a participant whose information has been recorded into the biorepository data base and/or samples have been collected and stored.

Dry Ice: The solid phase of carbon dioxide, which is particularly useful for keeping samples frozen because of its very cold temperature of -78.5°C.

Dry Shipper: A cryogenic vessel used for transporting samples from the remote site to the central storage facility. Dry shippers should be recharged on a regular basis.

E

EDTA: ethylenediamine tetra-acetate. The EDTA binds calcium ions thus blocking the coagulation (clotting) cascade. Erythrocytes, leucocytes and thrombocytes are stable in EDTA anticoagulated blood for up to 24 hours.

F

Formalin-Fixed Paraffin Embedded (FFPE): Refers to a tissue block which contains tissue which was fixed in formalin and then embedded in paraffin for long term storage at room temperature.

G

Good Clinical Practice (GCP) - FDA accepted definition: A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Good Laboratory Practice (GLP): A set of regulations to establish standards for the conduct and reporting of nonclinical laboratory studies that are intended to assure the quality and integrity of safety data submitted to the FDA. (FDA)

Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments [Organisation for Economic Co-operation

and Development (OECD)]

H

Handling: Loading, unloading, packing or unpacking dangerous goods in a means of containment for the purposes of, in the course of or following transportation and includes storing them in the course of transportation.

H + E Stain: Hematoxylin and Eosin is used for routine staining of tissue sections on microscopic slides.

Human Biological Material (HBM): Materials originating from human bodies for research.

I

IATA: International Air Transportation Association is an international industry trade group of airlines with the mission to represent, lead, and serve the airline industry.

IHC: Immunohistochemistry refers to the process of detecting antigens (e.g., proteins) in cells of a tissue section by staining with antibodies which specifically bind to antigens in biological tissues. Immunohistochemical staining is widely used in the detection of abnormal cells such as those found in cancerous tumors.

Impartial Witness: A person, independent of the biorepository program or clinical trial, who cannot be unfairly influenced by people involved with the research, who attends the informed consent process if the subject cannot read, and who reads the informed consent form and any other written information supplied to the subject. (ICH definition)

Inclusion Criteria: The criteria that study subjects must meet to be eligible for participation in the biorepository program or clinical trial.

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in the biorepository program, after having been informed of all aspects of the research that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form. (ICH definition)

Informed Consent Form (ICF): **T**he ICF is a written form that provides the subject with information essential to making an informed decision about participating in the bioerepository program or clinical trial. The signature of the study subject indicates the intent of the subject to give informed consent. synonyms: consent form.

ISH: In Situ Hybridization is a type of hybridization that uses a labeled complementary DNA or RNA strand (i.e., probe) to localize a specific DNA or RNA sequence in a portion or section of tissue.

J

K

L

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 research (ICH definition).

Logical Security: Consists of software safeguards for systems, including user identification and password access, authentication, access rights and authority levels.

M

Material Transfer Agreement (MTA): A contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.

MedDRA: Medical Dictionary for Regulatory Activities is a clinically validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry throughout the entire regulatory process, from pre-marketing to post-marketing activities, and for data entry, retrieval, evaluation, and presentation.

N

Non-therapeutic Study: A trial/study in which there is no anticipated direct clinical benefit to the subject. (ICH definition)

O

Optical Cutting Temperature (OCT): A compound used to embed tissue samples prior to frozen sectioning in order to mount sections of a sample onto slides for analysis.

P

Paraffin Block: formalin-fixed paraffin-embedded tissue within a cassette.

Pathologists' Assistant (PA): A health professional, qualified lab technologist or other qualified research team member\. Synonyms: pathology technologist, pathology assistant, research assistant, pathology research assistant, research technologist.

Patient Specimen: Specimens collected directly from humans or animlas, including but not limited to, excreta, sectra, blood and its components, tissue and tissue fliud swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention (IATA definition).

PBS: Phosphate buffered saline is a water-based salt solution commonly used in biological research to help maintain a constant pH.

PCR: Polymerase Chain Reaction is a biochemical technology in molecular biology to amplify a single or a few copies of a piece of DNA across several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence.

Pharmacodynamic (PD) sample: A sample used to study the biochemical and physiological effects of drugs on the body and the mechanisms of drug action and the relationship between drug concentration and effect.

Pharmacogenomic (PG) sample: A sample used to study the effects of genetic variation on drug response in patients by correlating gene expression or single-nucleotide polymorphisms with a drug's efficacy or toxicity.

Pharmacokinetic (PK) sample: A sample used to study the mechanisms of absorption and distribution of an administered drug, the rate at which a drug action begins and the duration of the effect, the chemical changes of the substance in the body, and the effects and routes of excretion of the metabolites of the drug.

Physical Security: Primarily concerned with restricting physical access by unauthorized personnel to controlled facilities using controlled access methods.

PIPEDA: Personal Information Protection and Electronic Documents Act is a set of rules to govern the collection, use, and disclosure of personal information in a manner that recognizes the right of privacy of individuals with respect to their personal information.

Plasma: Blood fraction remaining after red blood and white blood cells are removed from whole blood. When whole blood is fractionated, the plasma layer is usually the upper, pale yellow layer.

Power Outage: Interruption of the regular supply of electricity to the biorepository freezer and/or liquid nitrogen storage tank.

Prospective Consent: Prospective consent is obtained prior to the participent undergoing surgery or biopsy to remove the tumour for usual patient care. It is envisaged that consent could be obtained prior to surgery in the surgeon's office or in the pre-operative clinic / area.

Q

Qualifications: A quality, ability, or accomplishment that makes a person suitable for a particular position or task.

Quality Assurance (QA): All those planned and systematic actions that are established to ensure that the biorepository program is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

Quality Control (QC): The operational techniques and activities undertaken within the quality assurance system that measures the attributes and performance of a process, or item, against defined standards, to verify that the stated requirements are fully met.

R

Recruitment: The processes and activities used to identify donors for the biorepository, from a base population through to enrolment into the program.

Recruitment Log: The form/spreadsheet used to record patient pre-screening and screening activities.

Research Ethics Board (REB): An independent body (a review board or a committee, institutional, regional, national or supranational) constituted of medical and scientific 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 research and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the research project, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the research or biorepository program participants.

Retrospective Consent: Retrospective consent is obtained after the patient has undergone surgery or biopsy to remove the tumour for usual patient care.

RNase: Ribonuclease is a type of enzyme that catalyzes the degradation of RNA into smaller components.

RPMI: Roswell Park Memorial Institute is a form of medium used in cell culture and tissue culture.

S

Safety: Processes, procedures and technologies to ensure freedom from danger or harm.

Specimen: Includes fresh-frozen tissue samples (tumour or normal-adjacent), paraffin blocks (formalin-fixed) and peripheral blood samples

Standard Operating Procedures (SOPs): Detailed, written instructions to achieve uniformity of the performance of a specific function.

Storage: Maintenance of specimens for future use.

Storage Device: Physical location and long-term storage of samples (freezer, paraffin block storage).

Subject: An individual (patient or healthy volunteer, if applicable) who participates in the biorepository or clinical trial. Synonyms: study patient, study subject, donor, research participant.

T

Tissue Micro Array (TMA): Consists of paraffin blocks in which up to 1000 separate tissue cores are assembled in array fashion to allow multiplex histological analysis, such as immunohistochemistry and fluorescent in situ hybridization.

Tissue Processor: Mechanical device that facilitates processing of formalin-fixed tissue by embedding in paraffin. It automatically removes the water from formalin-fixed tissues and replaces it with a series of solutions resulting in the impregnation of the tissue with paraffin wax. The firmness of the paraffin wax enables the tissue to be sectioned into microscope slides.

Tourniquet: In regards to venipuncture, a constrictive band, placed over an extremity to distend veins for the purpose of blood aspiration or intravenous injections. Materials used may be rubber, latex or other synthetic elastic material. A blood pressure cuff may also be used.

U

UN #: A specially assigned code set forth by the United Nations Committee of Experts (UNCOE) in “Recommendations on the Transport of Dangerous Goods", Eleventh Revised Edition, 1999, published by the United Nations (UN).

Universal Precautions: A set of precautions developed and designed by the Center of Disease Control and Prevention to prevent transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other blood borne pathogens when providing first aid or health care or doing research.

User Acceptance Testing (UAT): Final testing of an application by the end user to ensure the application meets their requirements prior to implementing the application.

V

Vapour Phase of Liquid Nitrogen: The space above liquid nitrogen within a closed container, such as a liquid nitrogen freezer. Gaseous phase of liquid nitrogen.

W

Waybill: Courier documentation completed by the specimen shipper detailing in general the contents of the package and its destination.

WHO Drug Dictionary: An international classification of medicines created by the WHO Programme for International Drug Monitoring that is used by pharmaceutical companies, clinical trial organizations, and drug regulatory authorities for identifying drug names in spontaneous Adverse Drug Reaction reporting and pharmacovigilance in clinical trials.

X

Y

Z