

## Metro South Health Research Biorepositories Glossary

### A

Access	The right to obtain or make use of or take advantage of something (as services or membership); the right to enter.
Acellular tissue product	A tissue product produced by treating tissue in such a way as to remove all cells, eg collagen.
Adverse outcome	An undesirable effect or untoward complication consequent to or reasonably related to biospecimen integrity.
Aerosol	A fine mist or spray that contains minute particles.
Age of majority	The age, usually 18 or 21 years, at which a person achieves full legal rights to make one's own decisions, enter into contracts, and be held personally accountable for the consequences of one's actions.
Aliquot	A process wherein a biospecimen is divided into separate parts which are typically stored in separate containers as individual samples. It pertains to a portion of the whole; any one of two or more samples of something, of the same volume or weight. The term aliquot may also be used as a noun to denote a single sample.
Altruism	The principle or practice of seeking the welfare of others (opposed to egoism).
Analyte	A substance or chemical constituent that is determined in an analytical procedure. Component represented in the name of a measurable quantity. This includes any element, ion, compound, substance, factor, infectious agent, cell, organelle, activity, property, or other characteristics which are to be determined.
Annotation	Additional information associated with a particular point in a document or other piece of information and/or explanatory information associated with a biospecimen.
Anonymisation	The process of removing particulars from samples, test results, or records to prevent traceability to the original patient/participant.
Anonymised samples	<p>Anonymised samples or data have had all identifying information removed, such that it is not possible for the researcher using them to identify the individual to whom they relate. The term is used to refer to both linked and unlinked anonymised data and samples.</p> <p>Linked anonymised samples or data are fully anonymous to the people who receive or use them (eg the research team) but contain information or codes that would allow others (eg the clinical team who collected them or an independent body entrusted with safekeeping of the code) to link them back to identifiable individuals.</p>

	Unlinked anonymised samples or data contain no information that could reasonably be used by anyone to identify the individuals who donated them or to whom they relate.
Anonymous	Identifiable personal information was not collected for the biospecimens and associated data or, if collected, was not maintained and cannot be retrieved, such that there is no way to trace the identity of the subject from whom the biospecimens were obtained.
Assay	A qualitative or quantitative analysis performed to determine the amount of a particular constituent in a biospecimen.
Assent	To agree, as to a proposal; concur. This term is used in the context of a child participant in research. It implies an act involving understanding. Even though a child may not be considered legally competent to consent to participate in research, the child may be considered competent to give his/her assent, that is — their opinion on whether they wish to participate in the research.
Associated data (information)	Personal, clinical, biochemical, genetic and phenotypic information about the patient/participant. Any factual information affiliated with a biospecimen, including but not limited to research, phenotypic, clinical, epidemiologic, and biospecimen-resource procedural data.
Attenuation	<p>A qualifying concept used both subjectively and objectively. Subjectively it describes the extent to which the patients/participant's concern about the use to which his or her donated tissue is put has diminished; a product may be considered attenuated if a donor does not see the human tissue product as "significant".</p> <p>Tissue may also be considered to have become attenuated in an objective sense if it has either lost the significant properties (such as genomic or cellular properties) to which importance may ordinarily have been attached, or if the use to which it is put does not involve these significant properties. For the purposes of researchers and ethics committees, it is likely to be the objective sense that is applied in the absence of knowledge about the particular significance that a donor may subjectively attach.</p>
Audit	A documented review of procedures, records, personnel functions, equipment materials, facilities, and/or vendors to evaluate adherence to written standard operating procedures or government laws and regulations.
Autopsy	Post-mortem examination of the organs and tissues of a body to determine cause of death or pathological conditions.
Axenic state	A state of non-contamination by or non-association with any other living organisms.

## B

Banking	The process of storing material or biospecimens for future use. See also 'Biobanking' and/or 'Research Biorepository'.
Barcode	A machine-readable representation of information in a visual format on a surface.
Batch	A specific quantity of biospecimens that is intended to have a uniform character and quality, within specific limits, and is produced or processed according to a single processing protocol during the same processing cycle. (See 'Lot').
Biobank (tissue bank, tumour bank, genebank)	An organised collection of biospecimens and any related information stored for one or more purposes. A biobank or a unit of a hospital or another body where activities of receiving, processing, preservation, storage or distribution of biospecimens and cells are undertaken. It may also be responsible for procurement or testing of human biological samples and cells. See 'Research Biorepository'.
Biohazard	<p>A biological or chemical substance that exerts toxic or pathologic effects on living entities and/or an organism, or substance derived from an organism that poses a threat to (primarily) human health.</p> <p>This can include medical waste, samples of a microorganism, virus or toxin (from a biological source) that can impact human health. It can also include substances harmful to animals.</p>
Biological safety hood	Cabinet designed to provide microbe-free work free work environment which enables workers to perform work on samples in an isolated area.
Biomarker	A biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition. Also called molecular marker and signature molecule.
Biomolecule	An organic molecule and especially a macromolecule (as a protein or nucleic acid) in living organisms.
Biorepository	See "Research Biorepository"
Biosafety	Safety with respect to the effects of biological research on humans and the environment.
Biosafety level	<p>Specific combinations of work practices, safety equipment, and facilities, which are designed to minimise the exposure of workers and the environment to infectious agents.</p> <ul style="list-style-type: none"> <li>• Biosafety level 1 applies to agents that do not ordinarily cause human disease.</li> <li>• Biosafety level 2 is appropriate for agents that can cause human disease, but whose potential for transmission is limited.</li> </ul>

	<ul style="list-style-type: none"> <li>Biosafety level 3 applies to agents that may be transmitted by the respiratory route which can cause serious infection.</li> <li>Biosafety level 4 is used for the diagnosis of exotic agents that pose a high risk of life-threatening disease, which may be transmitted by the aerosol route and for which there is no vaccine or therapy.</li> </ul>
Biospecimen	A quantity of tissue, blood, urine, or other human-derived material. A single biopsy may generate several biospecimens, including multiple paraffin blocks or frozen biospecimens. A biospecimen can comprise subcellular structures, cells, tissue (eg bone, muscle, connective tissue, and skin), organs (eg, liver, bladder, heart, and kidney), blood, gametes (sperm and ova), embryos, foetal tissue, and waste (urine, feces, sweat, hair and nail clippings, shed epithelial cells, and placenta). Portions or aliquots of a biospecimen are referred to as samples. For some biological collections “biospecimen” may have the same meaning as “specimen.” See ‘Specimen’.
Bloodborne pathogen	Pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus and human immunodeficiency virus.

## C

Calibration	The process of adjusting the output or indication on a measurement instrument to agree with value of the applied standard, within a specified accuracy.
Cell cultures	Cells that have been modified by being developed in culture but which generally retain the properties of the cells from which they were derived. Cell cultures are to be distinguished from significantly modified cell cultures.
Cells	The fundamental structural and functional units of living organisms. Cells may include dead or deactivated cells.
Certificate of confidentiality	<p>Issued to protect identifiable research information from forced disclosure. It allows the Principal Investigator and others who have access to research records to refuse to disclose identifying information on research patients/participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the Federal, State, or local level.</p> <p>Certificates of Confidentiality may be granted for research projects collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.</p>
Coded biospecimen/sample	Identifying information (such as name or social security number) that would enable the researchers to ascertain the identity of the individual to whom the private information or biospecimens pertain has been replaced

	with a number, letter, symbol, or combination thereof (ie the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information of biospecimens.
Coded data	A code is used in place of identifiers to protect the confidentiality of the individual during routine use, but it is possible for the user to break the code and thus identify the individual from whom they were obtained.
Cold chain	A temperature-controlled supply chain.
Collection	May refer to the practice or technique of collecting a biospecimen or to a specific sample or group of samples that has been isolated for future research purposes. See 'Retrieval'.
Commodification	The process by which something that is considered to have great intrinsic worth and meaning (in this case the human body) is turned into something that can be bought and sold and hence treated as an object (in this case implying disrespect for the person).
Common data elements	Annotations collected in a uniform manner across multiple institutions to allow sharing of data in a standardised format.
Consumables	Items that are liable to be used up or exhausted (a.k.a. disposables).
Container	Enclosure for one unit or more units of biospecimen(s).
Cost recovery	Receiving payment or advantage to cover only the reasonable costs (not including profit) of retrieval, handling, storing, distribution and use of human tissue or human tissue products. Charging a sufficient amount for products and services such as biospecimen collection, processing, storage, and shipping to recover or partially recover operational fees incurred by a biospecimen resource.
Cryoprotectant	<p>An additive or mixture of additives that allow living cells, tissues, organs and organisms to survive exposure to cryogenic temperatures, of which the main type is a colligative cryoprotectant. This is a protective additive that must be able to penetrate the cell, applied to prevent damage caused by excessive cell volume changes and the toxic concentration of solutes (ie, colligative injury).</p> <p>An osmotic cryoprotectant is an additive that does not penetrate the cell. It confers additional protection by osmotically withdrawing water from the cell (osmotic dehydration), consequently reducing the amount of water that is available to form ice. Mixtures of colligative and osmotic cryoprotectants are often used in plant, algal and microbial cryoprotective solutions, as well as in cryoprotective solutions for some mammalian cells.</p>
Culling	Reviewing and eliminating biospecimens in a collection or an entire collection either by destruction or transfer to a new Custodian.

<p>Custodian</p>	<p>The individual responsible for the management of a research biorepository. The Custodian works with other key stakeholders in the management of the resource including the tracking of all relevant documentation for the resource and for ensuring that Standard Operating Procedures (SOPs) regarding access to the resource are in place and implemented according to appropriate guidelines.</p> <p>The Custodian also has responsibility for safe keeping of samples and control of their use and eventual disposal in accordance with the terms of the consent given by the donor and any legal and good practice requirements.</p> <p>This incorporates the authority to access, use and destroy the samples and data held. The research biorepository Custodian is considered to be either, an individual researcher, Principal Investigator, Chief Executive, Executive Director of relevant institute, head of department, director or the department or institute responsible for creating the research biorepository.</p>
<p>Custodianship</p>	<p>Use and control, but not ownership, of human tissue or human tissue products. Implies an obligation to preserve and maintain but does not confer a right to sell, and includes obligations deriving from the terms at the time of donation and the understanding of the donor about the uses of the tissue.</p> <p>Custodianship implies some rights to decide how the samples are used and by whom, and also responsibility for safeguarding the interests of the donors. The steward of the resource, maintaining and building it for the public good in accordance with its purpose.</p> <p>The caretaking responsibility for biospecimens that extends from collection through research use. Responsible custodianship requires careful planning and transparent policies to ensure the long-term physical quality of the biospecimens, the privacy of human research participants, the confidentiality of associated data, and the appropriate use of biospecimens and data.</p> <p>Custodianship is to be distinguished from 'Guardianship' (see below) in relation to tissue and tissue products. (See also 'Ownership', 'Stewardship').</p>

## D

Databank	It covers 'a wide range of data types and methodologies' and common types of research using databanks, including 'epidemiology, pathology, genetics and social sciences'. In this sense, research biorepositories are a subset of the wider, more generic term 'databanks' as used in the National Statement but extended by the inclusion of biospecimens.
De-identify	The removal from a biospecimen of all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members.
Dehydration	Removal of water from a tissue.
Desiccation	Excessive loss of moisture; the process of drying up.
Designated Officer - <i>Transplantation and Anatomy Act 1979 (Qld)</i>	<p>The medical superintendent of a hospital and his or her nominees (being medical practitioners) appointed by the medical superintendent in writing are, for the purposes of the <i>Transplantation and Anatomy Act 1979 (Qld)</i>, designated officers for that hospital.</p> <p>The person or body having control and management of a hospital may, in writing, appoint persons to be, for the purposes of the <i>Transplantation and Anatomy Act 1979</i>, designated officers for that hospital.</p>
Derivative	A substance that can be made from another substance.
Deviation	An intentional or unintentional event that is a departure from a procedure or a normal practice.
Dewar	A specialised container to hold liquefied gases. A Dewar may also be referred to as a Dewar flask or Dewar vessel.
Discontinuation of participation	<p>Discontinuation of a subject's participation in research means discontinuation of one or more of the following activities described in the research biorepository's approved protocol:</p> <ul style="list-style-type: none"> <li>• interacting or intervening with the subject</li> <li>• collecting individually identifiable private information about the subject without the investigator interacting or intervening with the subject</li> <li>• collecting individually identifiable biospecimens originating from the subject without the investigator interacting or intervening with the subject</li> <li>• using or testing individually identifiable biological specimens already collected by the Investigator.</li> </ul>
Disinfectant	An agent that reduces the number of viable microorganisms.
Disposition	Final destination of biospecimens.
Distribution	A process that includes receipt of request for biospecimens, selection of appropriate biospecimens, and final inspection, in conjunction with subsequent shipment and delivery of biospecimens to another research biorepository, biospecimen collection centre or laboratory.

DNA	Deoxyribonucleic acid, a self-replicating material which is present in nearly all living organisms as the main constituent of chromosomes. It is the carrier of genetic information.
Donor	Living or deceased individual who is the source of the biospecimen in accordance with established medical criteria, procedures and privacy regulations. The term “subject”, “individual”, “participant” may be used in the same context as donor, especially as the context relates to human specimens.
Dry ice	Solid phase carbon dioxide (CO <sub>2</sub> ). CO <sub>2</sub> solidifies at -78.5°C.

## E

Environment monitoring system	An automated, centralised monitoring system that monitors environmental conditions and alarms in conjunction with remote access, security features and electronic data storage.
Epidemiologic	Of or relating to epidemiology, the study of the causes, incidence, and distribution of disease in the population and its application for prevention or control.
Equipment	Single apparatus or set of devices or apparatuses needed to perform a specific task.
Ergonomics	The science that explores human abilities and limitations, and applies that knowledge to improve a person’s interactions with their environment, tools, products and practice.
Exchange or trade	Where something is transferred in return for some payment or advantage. Not-for-profit exchange or trade includes payment for transfer of custody or for access (to tissue or a product derived from human tissue) but only for the purposes of cost recovery. See ‘Commercialisation.

## F

Foetal organs/foetal tissue	Foetal organs and tissues and derived products are considered to be human organs and tissues and derived products for the purposes of these guidelines. The <i>National Statement</i> contains guidelines for the use of foetal tissue.
Freeze-dried	Dehydrated for storage by conversion of the water content of a frozen biospecimen to a gaseous state under vacuum. Also called ‘Lyophilised’.
Function check	The set of routines that show an instrument to be ready for operation.

## G

Genomics	The study of the complete genetic complement of an organism or organ.
Glass transition	See ‘Vitrification’.



## H

Human biological material	<p>Biological material collected from an individual at the time of inclusion in the research biorepository (eg blood, urine or tissue sample) or derived from material collected (eg DNA extracted).</p> <p>The terms human biological material, human biological samples, human material, material and samples are used interchangeably and refer to all biological material of human origin, including organs, tissues, bodily fluids, teeth, hair and nails; but not established cell lines. Many of the principles and approaches in this guidance could equally apply to extracted material such as DNA and RNA. See 'Biospecimen' and 'Specimen'.</p>
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## I

Ice nucleation	Also termed "seeding" is the point at which ice crystals are first initiated in a cryopreserved sample; usually applied in the context of controlled rate cooling.
Identifier/identifying information	<p>Information (eg name, social security number, medical record or pathology accession number etc) that would enable the identification of the human subject. For some biospecimens this information might include the taxon name and collection number.</p> <p>Information where the identity of an individual is apparent or can reasonably be ascertained by the holder of the information. Information that may directly, or indirectly, lead to identifying individuals from whom the samples and associated information are collected as a link (or multiple links) exists between the patients/participant's personal identifiers and the data.</p>
Incident	Any unplanned occurrence that deviates from Standard Operating Procedures (SOPs) or applicable government laws and regulations during biospecimen retrieval, processing, labelling, storage or distribution that may affect subsequent use of those biospecimens.
Independent (related to review and monitoring personnel or committees)	Identified as having no conflict of interest. Having no association with the governance or running of the research biorepository, no association with the funding for the research biorepository, not being a researcher using the research biorepository and not being associated with any government institutions associated with the research biorepository or the Metro South Health Biorepository Governance Framework.
Informatics	An occupational discipline which unites information science with computer science. It is concerned with the development of techniques for the collection and manipulation of data, and the use of such data.
Information management system	The software, hardware, documentation, support, operating procedures and training necessary to annotate, track, and distribute biospecimens within a biospecimen resource or resources.

<p>Informed consent</p>	<p>In the context of the Metro South Health Research Biorepository Governance Framework, a person's decision to donate that is voluntary and based on sufficient information and adequate understanding of the activity and the implications of participation. There are two duties involved: a duty to inform and a duty to obtain consent.</p> <p>The aim of communicating suitably presented information to potential participants and seeking consent should not be merely a matter of satisfying a formal requirement. It requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the activity.</p> <p>The aim should be mutual understanding between the donors and those involved in obtaining, storing and using the tissue. A person who donates tissue for research purposes is considered a participant in research for the purposes of the National Statement and the donor is the subject of obligations in relation to the use and storage of the tissue.</p> <p>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.</p>
<p>Infrastructure</p>	<p>The basic facilities, equipment, or underlying framework that is necessary for a system or organisation to function.</p>
<p>Initiators</p>	<p>The researchers, government entities and/or organisations involved in setting up the research biorepository.</p>
<p>Institutional Biosafety Committee (IBC)</p>	<p>A Committee constituted in accordance with the <i>Gene Technology Act 2000</i> and the <i>Gene Technology Regulations 2001</i>. The aim of an IBC is to protect the health and safety of people, and the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs). An IBC also aims to ensure that researchers are aware of and comply with institutional Work Health and Safety policies and all relevant research safety requirements.</p>
<p>Internal governance Structure</p>	<p>A governance structure established by a custodian as part of the specific research biorepository's Research Protocol. Internal governance structures include but are not limited to, Research Management Committee, Scientific-Review Committee, Research Protocol and Standard Operating Procedures.</p>

Interoperability	The ability of systems or tools to both access and use data from a remote data resource.
Inventory	The act or process of taking an inventory. A detailed, itemised list, report, or record of samples in a biospecimen resource, especially a periodic survey of all stored biospecimens.

## J

## K

## L

Label	Any written, printed or graphic material on or affixed to a specimen container or package.
Legacy biospecimen	Biospecimens available for research once all protocol-specified endpoints, including clinical and research biorepository studies, have been completed. These remaining biospecimens could be made available by the research biorepository for correlative studies (subject to application, scientific review, and approval).
Liquid Nitrogen (LN <sup>2</sup> )	Coolant used to cool and store samples. Nitrogen becomes liquid at -196 °C. Samples stored in the vapour phase of liquid nitrogen are -190 °C and warmer, depending on the distance from the liquid phase.
Liquid nitrogen dry shipper	A container used for sending samples in the vapour phase of liquid nitrogen.
Longitudinal data	Data in which the same units are observed over multiple time periods.
Lot	A quantity of reagents, supplies or containers that is processed or manufactured at one time and identified by a unique identification number. See 'Batch'.
Lyophilised	Dehydrated for storage by conversion of the water content of a frozen biospecimen to a gaseous state under vacuum. Also called 'Freeze-dried'.

## M

Maintenance	Those activities that prolong the life of an instrument or minimise breakdowns or mechanical malfunctions. Examples include cleaning, changing parts, fluids, tubing, lubrication, electronic checks etc.
Material Transfer Agreement (MTA)	An agreement that governs the transfer of tangible research materials and data between two organisations, when the recipient intends to use it for his or her own research purposes. It defines the rights and obligations of the provider and the recipient with respect to the use of the materials. Generally signed between a provider and a recipient, is used to document the transfer of materials, with or without information, either to an entity (ie the recipient) and/or away from an entity (ie the provider) subject to a number of terms and conditions.

Metro South Health Research Biorepository Governance Framework	<p>The set of authorities, processes, and procedures guiding key operational decisions made within a research biorepository. Governance affects access to biospecimens as well as custodial relationships and responsibilities and should be part of the resource's general custodianship plan.</p> <p>The processes and structures that Metro South Health uses to set its objectives/goals, appoint the management whose responsibility it is to achieve these goals and to oversee management in its pursuit of these goals. Governance mechanisms are needed to put in place internal controls and risk management systems.</p>
Metro South Health Research Biorepository/ies	<p>A Metro South Health organised collection of biospecimens (collected from patients/participants being treated within any Metro South Health facility) and any related information stored for one or more purposes. Research biorepository is also the collective term for research tissue banks, biobanks, tumour banks and tissue sample collections.</p> <p>Metro South Health research biorepositories are structured resources that can be used for the purpose of genetic research which can include human biological materials, information generated from the analysis of human biological materials and extensive associated information.</p>
Micro-organisms	Comprises all prokaryotes (archaea and bacteria), some eukaryotic organisms (fungi, yeasts, algae, protozoa) non-cellular entities (eg viruses), their replicable parts and other derived materials eg genomes, plasmids, cDNA.
Mono-research biorepository	A collection aimed at supporting a specific, single research project (project specific collection).
Morphogenetic competence (or potential)	Terms used to describe the state of cells that are able to respond to stimuli and in vitro manipulations and undergo morphogenesis, usually to produce differentiated structures comprising, shoots, roots and embryos.

## N

Necropsy	See 'Autopsy'.
Nomenclature	The devising or choosing of names for things, especially in a science or other discipline.
Non-validated results	Research results where there is insufficient evidence to clinically validate the findings.
Not-for-profit agency	One that pays no dividend (or equivalent) to its members or anyone else.

## O

Oligo-research biorepository	Collection aimed at supporting several research projects, a research group or research consortium (a group of project specific collections).
Organ	Differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy.

## P

Package	A product container with any accompanying materials or components.
Paraffin embedded	A method of preserving biospecimens where they are chemically or otherwise fixed and then infiltrated with molten wax, which later solidifies.
Performance verification	The set of processes that demonstrate an instrument to run according to expectations.
Personal information	All identifiable information about individuals, living or dead. This includes written and electronic records and information obtained from samples.
Poly-research biorepository	Collection aimed at supporting undetermined, multiple users with Human Research Ethics Committee approved research projects, through a defined access/application process.
Preservation	Use of chemical agents, alterations in environmental conditions or other means during processing and storage to prevent or retard biological or physical deterioration of a biospecimen.
Prevalence	The total number of cases of a given disease in a specified population at a designated time. It is differentiated from "incidence," which refers to the number of new cases in the population at a given time.
Process validation studies	The process of demonstrating that a specific procedure will consistently produce expected results within predetermined specifications.
Processing	Any procedure employed after biospecimen collection but prior to its distribution, including preparation, testing, and releasing the specimen to inventory and labelling.
Project management	The application of knowledge, skills, tools and techniques to a broad range of activities to meet the requirements of the particular project.
Proteomics	The global analysis of cellular proteins. Proteomics uses a combination of sophisticated techniques including two-dimensional (2D) gel electrophoresis, image analysis, mass spectrometry, amino acid sequencing, and bio-informatics to resolve comprehensively, to quantify, and to characterise proteins. The application of proteomics provides major opportunities to elucidate disease mechanisms and to identify new diagnostic markers and therapeutic targets.

Prospective	A study or collection maintained for expected or likely use in the future.
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## Q

Quality	Conformance of a biospecimen or process with pre-established specifications or standards.
Quality Assurance (QA)	An integrated system of management activities involving planning, implementation, documentation, assessment, and improvement to ensure that a process or item is of the type and quality needed for the project. See 'Quality Management System'.
Quality Control (QC)	<p>An integral component of quality management composed of the aggregate of processes and techniques used to detect, reduce, and correct deficiencies in an analytical process.</p> <p>Specific tests defined by the Quality Assurance (QA) or Quality Management System (QMS) program to be performed to monitor procurement, processing, preservation and storage; specimen quality; and test accuracy. A surveillance process in which the actions of people and performance of equipment and materials are observed in some systematic, periodic way that provides a record of consistency of performance and action taken when performance does not conform to standards set by the biorepository.</p> <p>QC is a set of procedures designed to monitor the test method and the results to assure test system performance; QC includes testing control materials, charting the results and analysing them to identify sources of error, and determining, performing and documenting any remedial action taken as a result of this analysis. These may include but are not limited to: performance evaluations, testing, and controls used to determine accuracy and reliability of the research biorepository's equipment and operational procedures as well as monitoring of the supplies, reagents, equipment and facilities.</p>
Quality Management System (QMS)	The systematic monitoring and evaluation of the various aspects of a project, process, service or facility to maximise the probability that minimum standards of quality are being attained.

## R

Reach-through rights	<p>Rights claimed by the provider of materials to the recipient's downstream discoveries to which the provider would not otherwise be entitled through its ownership or patent coverage of the material alone.</p> <p>Examples of reach-through rights required by providers in exchange for use of their material by the recipient might include ownership of recipient's discoveries,</p>
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	license exclusivity, or payments upon the sale of the discovery. Reach-through rights may give the provider an unfairly high level of compensation for the research use of the material by the recipient.
Remnant biospecimens	Remaining portion of a biospecimen obtained for clinical purposes that is no longer needed for its original purpose and that would otherwise be discarded.
Removal	See 'Retrieval'.
Repository	An entity that receives, stores, processes and/or distributes specimens, as needed. It encompasses the physical location as well as the full range of activities associated with its operation. It may also be referred to as a 'Research Biorepository' or 'Biobank'.
Research biorepository	<p>An organised collection of biospecimens (collected from patients being treated within any Metro South Health facility and/or research project participants) and any related information stored for one or more purposes.</p> <p>Research biorepositories are structured resources that can be used for the purposes of research which can include biospecimen, information generated from the analysis of biospecimens and extensive associated information. The term research biorepository specifically excludes transplantation tissue banks and diagnostic genetic services. It is an organisation, place, room, or container (a physical entity) where biospecimens are stored. A collection of biological specimens that is acquired for a defined purpose. Biospecimen resources vary considerably, ranging from formal institutions to informal collections in a researcher's freezer.</p> <p>In the context of Metro South Health, only research biorepositories containing human biospecimens intended for research purposes are addressed. The physical structure, policies, biospecimens and data contained within it are defined collectively as the Metro South Health Research Biorepository Governance Framework. Management responsibility of the biospecimen resource is led by the Custodian for the collection. Biospecimen resources may be stored in a repository or laboratory, depending on the numbers of specimens contained therein.</p> <p>Research biorepository is also the collective term for research tissue banks, biobanks, tumour banks and human biological material collections. For the sake of consistency, research biorepository will be used throughout the Metro South Health Research Biorepository Governance Framework and may be considered synonymous with biobank and repository etc.</p>

Research involving human subjects	An undertaking intended to extend the knowledge through a disciplined inquiry or systematic investigation that involves: a) living human subjects, b) human remains, cadavers, tissues, biological fluids, embryos, or fetuses, or c) medical records or other personal information.
Retrieval	The removal, acquisition, recovery, harvesting or collection of biospecimens.
RNA	Ribonucleic acid, a nucleic acid present in all living cells. Its principal role is to act as a messenger carrying instructions from DNA for controlling the synthesis of proteins, although in some viruses RNA rather than DNA carries the genetic information.

## S

Safety	Processes, procedures and technologies to ensure freedom from danger or harm.
Sample	A single unit or portion obtained from one biospecimen or a single unit of human biological material collected or derived from material collected. See 'Biospecimen' and 'Human Biological Material'.
Shipping manifest	A written description of the contents of the shipped package.
Significantly modified cell cultures	Cells that have undergone major alterations (eg adding or deleting genes) such that they do not closely resemble the original cell type although they still retain the genomic information of the original cells. See 'Cell Culture'.
Source facility	Those sites that contribute biospecimens to the research biorepository. The source facility may be a clinic, hospital or individual investigator, and, in some instances, the research biorepository may be the source facility, (eg when the research biorepository does blood or biospecimen collections for normal controls).
Space planning	The process of designing the layout of a building, suite, or laboratory for optimal efficiency in the intended purpose.
Specimen	A specific tissue, blood sample etc taken from a single subject or donor at a specific time. For some biological collections "specimen" may have the same meaning as "biospecimen." See 'Biospecimen' and 'Human Biological Material'.
Stakeholder	One that has a stake or an interest in an enterprise. In the context of the Metro South Health Research Biorepository Governance Framework, the term stakeholder embraces research participants, patient advocates, researchers, clinicians, and biospecimen resource operational/managerial personnel.
Standard Operating Procedure (SOP)	An established procedure to be followed in carrying out a given operation or in a given situation. See Work Instruction.



Standard Operating Procedures (SOPs) Manual	A group of SOPs detailing specific policies of a research biorepository and the procedures required to be used by the staff/personnel. See 'Work Instruction' and 'Research Protocol'.
Standard precautions	<p>Standard precautions are based on the principle that all blood, body fluids, secretions, excretions except sweat, non-intact skin, and mucous membranes may contain transmissible infectious agents, and include a group of infection-prevention practices.</p> <p>These include: hand hygiene; use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure; and safe injection practices. Also, equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a manner to prevent transmission of infectious agents.</p>
Stem cell	A cell that remains relatively undifferentiated and is capable of self-renewal and generating more differentiated cells.
Sterility	Absence of detectable, viable, contaminating microorganisms.
Storage	Maintenance of biospecimens under specified conditions for future use.
Subject	See 'Human Subject' and 'Donor'.
Sustainable	Of, relating to, or being a method of using a resource so that the resource is not depleted.

## T

Taxon	Any recognised category in the taxonomic hierarchy. For many purposes, the category "species" is the most important.
Telemetry system	A system that allows for measurements to be taken from a distance, usually via radio wave transmission and reception of the information.
Tg	The glass transition temperature marks the temperature at which a fluid becomes so viscous it appears solid. The extreme viscosity reduces diffusion and molecular restructuring, slowing reactions that might otherwise cause samples to deteriorate. The Tg for pure water is -132 °C.
Third party	Any person excluding the research biorepository patient/participant and people involved in managing and operating the research biorepository.
Tissue	An aggregate of cells with different specialised characteristics that are organised anatomically, usually in the fixed framework of an organic matrix. The architectural organisation that is maintained contributes to the performance of a specific collective function. Tissues are parts of organs. The term tissue is most often referred to in the context of solid tissue, as originating from a solid organ; however, tissue also can be defined broadly to include collections of cells and

	the extracellular matrix and/or intercellular substances from bodily fluids such as blood. See 'Human Biological Materials'.
Tissue product	Any product derived from human tissue, including those used for medical research, diagnostics, medical devices, therapeutic activities or consumer products such as cosmetics. A "product" involves some level of manipulation to transform human tissue into something functionally different from the source tissue. Cell cultures including stem cell cultures are considered to be human tissue products.
Totipotency	In the context of plants, means that a single somatic (non-germ line) cell has the ability to differentiate along a developmental pathway and regenerate a plant. More generally, the potential for an undifferentiated cell to regenerate into a complete new plant.
Trade	An exchange that may or may not involve profit.

## U

Unique identifier	A set of characters used as a code that is unique in the context or the system for which it is created. It serves as a means of identification and reference (often instead of a name) for an entity, person, thing, function, procedure, activity, variable, or body of data.
Use Case	A document that describes the interaction between a user or other initiator of the interaction and a system, represented as a sequence of simple steps leading to a particular goal.

## V

Validation	The act of confirming a product or service which meets the requirements for which it was intended. A statistical method of partitioning a sample of data into subsets such that the analysis is initially performed on a single subset, while the other subsets are retained for subsequent use in confirming and validating the initial analysis.
Vitrification	Refers to the transformation of a glass-forming liquid into a glass, which usually occurs upon rapid cooling. It is a dynamic phenomenon occurring between two distinct states of matter (liquid and glass), each with different physical properties.

## W

Work Instructions (Standard Operating Procedures)	Work Instructions or Standard Operating Procedures are controlled documents designed to give instructions for performing routine and essential processes, to ensure that they are performed consistently and in a manner upholding prescribed Metro South Health quality and integrity.
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Y  
Z

For more definitions please see:  
[Metro South Health Research Management Glossary](#)