Metro South Health Research Management Glossary

A

Australian Research Ethics Database (AU *RED*)	AU *RED* is a secure web-based Research Ethics Database that allows HREC Administrators and RGOs to store documents and report outcomes of HREC and research governance reviews. All details on the researcher's application forms are electronically uploaded into the Database.
Authorisation	Authorisation issued by the Chief Executive Officer, Metro South Health or delegate to conduct research at a site. Authorisation is contingent upon the research having received HREC approval and a satisfactory research governance assessment.

B

Benefit-sharing	When an organisation or individual delivers a benefit to the community other than any kind of payment or direct advantage to the donor of the human tissue. The concept of benefit sharing is relevant to equity and access in relation to the use of human tissue or human tissue products.
Best Practice	A technique, process, or protocol that has been shown or is otherwise believed to be state-of-the-science in that it provides superior results to those achieved by any other technique, process or protocol. Best practices may evolve as new evidence emerges. While best practices are consistent with all applicable ethical, legal, and policy statutes, regulations, and guidelines, they differ from guidance, policy, or law in that they are recommendations and are neither enforced nor required.
Breach	A deviation from the Code" where the extent, seriousness, wilfulness and/or consequences of the deviation are not significant and the deviation does not amount to research misconduct. The repetition or continuation of a breach may, however, lead to more serious consequences and may constitute research misconduct, particularly if the researcher has been counselled about the standards of research conduct required by Metro South Health. A failure by a Metro South Health researcher to take responsibility for achieving the standards required in the Code may amount to a breach.
Broad and Enduring Consent (also known as generic consent)	Consent which is broad in both scope and time, usually applicable to a wide range of future medical research use. Future uses of the sample may be unknown, but will be subject to legal and ethical requirements.

C

Certified Human Research Ethics Committee	An NHMRC certified committee permitted to review multi-centre research under the National Mutual Acceptance agreement as published on the Health Innovation, Investment and Research Office website.
Clinical Data	Factual information (as measurements or statistics) or observations relating to the patient/participant used as a basis for reasoning, discussion or calculation pertaining to clinical trials, diagnosis, or treatment. Data obtained through patient examination or treatment.
Clinical Research	Research conducted with human subjects or on material of human origin in which an investigator directly interacts with human subjects; includes development of new technologies, study of mechanisms of human diseases, therapy, clinical trials, epidemiology, behaviour and health services research.
Clock Day	Calendar day where a valid application, without outstanding queries, is being processed by the research ethics or governance officer. This excludes the time it takes for researchers to respond to queries.
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 (i.e. the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information of biospecimens.
Commercial/Industry-Sponsored Research Agreement	An agreement to fund research from a for-profit entity. These are distinguishable from grants in how sponsorship, publication, liability, data ownership and intellectual property are addressed.
Commercial Use or Commercialisation	Trade where a fee is charged for the purpose of making a profit. This is distinct from a gift – where custody is transferred without a fee being charged; and/or 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 no more than for the purposes of cost recovery.
Community	A collection of individuals, which may extend from the whole population to a smaller grouping associated by cultural, geographical, social or political factors or some other commonality.
Community Benefit	In the context of commercialisation of human tissue products, denotes benefit to the individual donor, family or ethnic grouping, benefit to others in the community, and issues of justice and equity of access to human tissue products. The notion of community benefit applied to availability of human tissue products for health purposes should ensure that those who would benefit have access to them.
Complainant	The person/s making an allegation against a Metro South Health researcher under this policy and procedures.

Compliance Risk	Compliance risk is the risk of exposure to legal or financial penalties or other material losses (including reputational damage) due to a failure to prevent, detect or reduce the undesired or unacceptable effects of non-compliance with external laws, regulations and other externally imposed requirements.
Compliance Risk Management	Compliance risk management is the program of activities to address or mitigate compliance risk, including the establishment of culture, policy, procedures and processes.
Confidential Information	Information, acquired by a person in the person's capacity as a designated person, from which a person who is receiving or has received a public sector health service could be identified, as defined in section 139 of the *Hospital and Health Boards Act 2011 (Qld).*
Confidentiality	Treatment of information so that it is not divulged in ways that are inconsistent with the understanding of the original disclosure. Particularly, the ethical principle or legal right that a physician or other health professional will hold secret all information relating to a patient/participant, unless the patient/participant gives consent permitting disclosure.
Complainant	An individual who raises a concern about potential misconduct in research or who makes an allegation of research misconduct.
Conflict of Interest	Exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the Public Health Service–funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to: • Public disclosure of significant financial interests; • Monitoring of research by independent reviewers; • Modification of the research plan; • Disqualification from participation in all or a portion of the research funded by the Public Health Service; • Divestiture of significant financial interests; or • Severance of relationships that create actual or potential conflicts. Prejudice or bias that may occur when one's impartiality is compromised by opportunities for personal gain or occupational advancement, or by the chance that one's work may support a favoured point of view or social agenda.
Corrupt Conduct	Section 15 of the Crime and Corruption Act 2001 (Qld) defines corrupt conduct which could involve any of the following: (a) abuse of public office; (b) bribery, including bribery relating to an election; (c) extortion;

	(d) obtaining or offering a secret commission; (e) fraud; (f) stealing; (g) forgery; (h) perverting the course of justice; (i) an offence relating to an electoral donation; (j) loss of revenue of the State; (k) sedition; (l) homicide, serious assault or assault occasioning bodily harm or grievous bodily harm; (m) obtaining a financial benefit from procuring prostitution or from unlawful prostitution engaged in by another person; (n) illegal drug trafficking; (o) illegal gambling
Coronial Investigation Documents	A coronial investigation document has the same meaning as 'investigation document' as defined in the *Coroners Act 2003 (Qld).*
Corporate Governance	Encompasses the rules, relationships, policies, systems and processes whereby authority within organisations is exercised and maintained.

D

Data	A collection or single item of factual information, derived from measurement or research, from which conclusions may be drawn.
Database	A structured collection of records or data that is stored in a computer system so that a computer program or person using a query language can consult it to answer queries.
Deficit	The balance in a project fund when the expenses recorded exceed the revenues recorded.
Demographic Data	Information pertaining to the statistical characterisation of human populations or segments of human populations; e.g. characterisation by age, sex, race, or income.
Designated Person	The person nominated by Metro South Health to be responsible for monitoring compliance with the Code. The Designated Person has authority to secure documents and other evidence that may be related to the investigation of allegations. Where necessary, the Designated Person should endeavour to make arrangements in the local workplace so there is fairness for all parties until allegations are resolved.
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 biospecimens.

E

End User	A health care practitioner, scientist, or laboratory staff member who performs an appropriate procedure, test, or archival function and/or the ultimate consumer of a finished product.
Ethical Approval (positive ethical opinion)	Independent ethical scrutiny of the research has been carried out by a Human Research Ethics Committee to ensure the safety, rights, dignity and well-being of participants (and researchers) are protected, and a positive opinion of the research has been given by the committee.
Evaluation	Systematic, objective appraisal of the significance, effectiveness and impact of activities or condition according to specified objectives and criteria.
Expected Future Funding	The amount of revenue not yet received, supported by a third-party document stating the amount and period, and for which there is reasonable assurance of collection.

F

Fabrication	Making up data, source material, methodologies, finding or results, including graphs and images, and recording or reporting them.
Falsification	Manipulating, changing or omitting research materials, equipment, processes, data or results, including graphs and images, without proper acknowledgement such that the research is not accurately represented in the research findings, conclusions or records.
For-profit Organisation	One that intends to pay a dividend or like benefit to the organisation or another party.
Formal Investigation	An authorised, focused and detailed examination or inquiry, for which an investigator(s) is formally appointed to uncover facts and determine the truth of an allegation. This may include collecting, processing, analysing, storing, and evaluating the information and proving findings and recommendations.

G

Genomics	The study of the complete genetic complement of an organism or organ.
Gift or Donation	Where custody is transferred without a fee or other benefit being charged. See ‘Commercialisation’.
Giving InFormation To Research (GIFTR) Initiative	The Giving InFormation To Research (GIFTR) initiative gives patients admitted to certain Queensland public hospitals the option to consent for their medical information to be used in GIFTR health research. The information will only be used for GIFTR approved research projects considered to be low risk and non-interventional. No information that could identify an individual is made public, and no physical participation is required.

Good Faith	As applied to a Complainant, Good Faith means having a belief in the truth of one's allegation or concern that a reasonable person in the Complainant's position could have based on the information known to the Complainant at the time. A Complainant's allegation or concern is not in Good Faith if made with knowing or reckless disregard for information that would negate the allegation or concern. Good Faith as applied to a committee member means carrying out the duties assigned impartially for the purpose of helping Metro South Health meet its responsibilities under the applicable laws, rules, regulations and agency requirements regarding the responsible conduct of research. A committee member does not act in Good Faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the matter under inquiry or investigation.
Governance	Governance refers to the optimal operation of research biorepositories according to prescribed and published standards, including open review and recording to ensure best practice. The processes and structures that an organisation 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.

H

Health Related Finding	A finding that has potential health or reproductive importance for a research patient/participant, which is discovered in the course of conducting research, including both pertinent findings and incidental or unsolicited findings.
Health Services	A health service is a service for maintaining, improving, restoring or managing people's health and wellbeing.
Honest Broker	An individual, organisation, or system acting for, or on behalf of, a covered entity to collect and provide health information to research investigators in such a manner whereby it would not be reasonably possible for the investigators or others to identify the corresponding patients-subjects directly or indirectly. The honest broker cannot be one of the investigators. The information provided to the investigators by the honest broker may incorporate linkage codes to permit information collation and/or subsequent inquiries (i.e. a "re-identification code"); however, the information linking this re-identification code to the participants/patient's identity must be retained by the honest broker and subsequent inquiries are conducted through the honest broker.

Human Research Ethics Committee (HREC)	A local authority that evaluates research projects involving human beings, including genetic research. The primary function is to protect the welfare and rights of human participants in research in accordance with requirements stated in the National Statement.
Human Research Participant	See 'Human Subject'.
Human Subject	A living individual about whom an investigator (whether professional or student) conducting research obtains: • data through intervention or interaction with the individual; or • identifiable private information. See 'Participant, Patient and/or Patient/Participant'.

I

Identifiable	The identity of the subject is or may readily be ascertained by the investigator or associated with the information.
Identifier/Identifying Information	Information (e.g. name, social security number, medical record or pathology accession number, etc.) that would enable the identification of the subject. For some specimens this information might include the taxon name and collection number. 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 participant's personal identifiers and the data.
Informed Consent	A process by which information concerning the proposal and any collection, use or disclosure of an individual's samples or associated data is presented to the patient/participant or patients/participant's substitute decision maker with an opportunity for them to ask questions, after which specific approval is documented. Three main elements to consent include: • full disclosure to the individual of appropriate information (e.g. the purpose, methods, risks and benefits of participation); • the individual must have the capacity to understand the proposal and the implications of participation in it; and • consent must be given voluntarily, without coercion, inducement or influence. 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. 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. 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. 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.
Infrastructure	The basic facilities, equipment, or underlying framework that is necessary for a system or organisation to function.
Initiators	The researchers, government entities and/or organisations involved in setting up the research biorepository.
Inquiry	The informal process to determine whether a formal investigation of research misconduct allegations should be conducted.
Institution	Any public or private entity or agency or medical or dental facility where research/clinical trials are conducted.
Institutional Biosafety Committee (IBC)	A Committee constituted in accordance with the *Gene Technology Act 2000* and the Gene Technology Regulations 2001. 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.
Institutional Human Research Ethics Committee	An institution's local authority that evaluates research projects involving human beings, including genetic research. The primary function is to protect the welfare and rights of human participants in research.

Institutional Review Board	A specially constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioural research. Any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of the research and conduct periodic review of such research.
Intellectual Property	A commercially valuable product of the human intellect, in a concrete or abstract form, such as a copyrightable work, a protectable trademark, a patentable invention or a trade secret.
Interaction	Communication or interpersonal contact between investigator and subject.
Interested Party	People and/or bodies with a material interest or involvement in allegations of breaches of the Code or research misconduct and may include: • a complainant • a respondent • a Metro South Health researcher • staff, students, supervisors and trainees working with a complainant or respondent • research collaborators including those at other institutions • collaborating institutions and industry collaborators • journals and other media through which the research in question was or may be reported • professional registration bodies • funding bodies providing financial support for the research in question • the public.
Internal Governance Structure	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.
Intervention	Physical procedures by which data are gathered (for example vein puncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
Invention	Any art or process (way of doing or making things), machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under relevant patent legislation.
Investigation	The formal process to make a determination of research misconduct in response to allegations.

J

K

L

M

Management	Comprises directing and controlling a group of one or more people or entities for the purpose of coordinating and harmonising that group towards accomplishing a goal. Management often encompasses the deployment and manipulation of human resources, financial resources, technological resources, and natural resources. Management is responsible for achieving the objectives/goals set for the organisation. Governance mechanisms ensure this management is fair and equitable.
Material Transfer Agreement	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 (i.e. the recipient) and/or away from an entity (i.e. the provider) subject to a number of terms and conditions.
Metro South Health Human Research Ethics Committee (HREC)	Metro South Health's local authority that evaluates research projects involving human beings, including genetic research. The primary function is to protect the welfare and rights of human participants in research.
Misconduct	Misconduct means: (a) inappropriate or improper conduct in an official capacity, or (b) inappropriate or improper conduct in a private capacity that reflects seriously and adversely on the public service: • Unauthorised release or disclosure of confidential and/or patient information • Misuse of Metro South Hospital and Health Service assets and/or equipment eg vehicles, fuel cards, mobile telephones, computers etc. • Conducting a private business during working hours and/or utilising Metro South Health resources to conduct a private business • Conflicts of interest including contracting and/or approving a contract on behalf of Metro South Hospital and Health Service with a firm or business in which an interest is held

	• Theft and/or fraudulent dealings of the property/ possessions of Metro South health clients or patients • Assault in the workplace of fellow employees, patients or other persons. • Utilising the Metro South Health computer network for accessing or transmitting pornographic images • Causing, or attempting to cause or conspiring to cause, detriment to another person because (or in the belief that) another person has made or may make a public interest disclosure pursuant to the *Public Interest Disclosure Act 2010 (Qld)* • Other serious misconduct which would tend to bring Metro South Health into disrepute and which is likely to result in disciplinary action, including dismissal • Wilful neglect which may be defined as malicious or reckless conduct.
Multi-centre Research	A research project undertaken by a group of institutions (or individuals) at more than one site.

N

National Health and Medical Research Council (NHMRC)	Australia's leading expert body promoting the development and maintenance of public and individual health standards. NHMRC brings together within a single national organisation the functions of research funding and development of advice. The NHMRC is established under the *National Health and Medical Research Council Act 1992 (Cth).*
National Mutual Acceptance Scheme	National approach to single ethical review of multi-centre research in which participating states of Australia have agreed to accept the scientific and ethical review of an HREC from a public health facility located outside of the institution's state.
National Statement	The 'National Statement on Ethical Conduct in Human Research (2007) – Updated May 2015' ("National Statement) issued by the National Health and Medical Research Council (NHMRC) as in force from time to time.
NHMRC	National Health and Medical Research Council of Australia.
Non-identifiable	Information from which the holder of the information cannot reasonably ascertain the identity of a specific individual. This includes information that has never been labelled with individual identifiers or from which they have been permanently removed.
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

Obligation(s)	The requirement to do what is imposed by law, promise, or contract; a duty.

Online Forms	A secure web-based platform, which integrates with AU RED, and has the ability to electronically uploaded research study documentation.
Oversight	An independent individual or committee responsible for reviewing and evaluating policies and practices prior to their introduction and during the operation of a research management activity.
Ownership	Implies a right to unrestricted use and the right to sell or otherwise dispose of property.

P

Public Health Act Approval	An approval of the Director-General under section 284 of the *Public Health Act 2005* for the person to be given health information held by Queensland Health for research purposes.
Participant, Patient and/or Patient/Participant	An individual who agrees to be involved in a research study/research project and/or research biorepository and provides data and/or sample/s in accordance with established medical criteria, procedures and practice and in compliance with the law including any privacy requirements. See 'Human Subject'.
Personal Information	All identifiable information about individuals, living or dead. This includes written and electronic records and information obtained from samples.
Plagiarism	The appropriation of another person's ideas, processes, results, or words without giving appropriate credit; or the reuse of one's own work, ideas, processes, results, or words without proper acknowledgement of the previous use or without the permission of any person who may have acquired copyright or intellectual property rights by virtue of such previous use.
Principal Investigator	An individual who is autonomous regarding their research activities; and has an academic or research appointment which: must commence by the effective date of funding; and allows the individual to pursue the proposed research project, to engage in independent research activities for the entire duration of the funding; to supervise trainees, and to publish the research results; and obliges the individual to conform to institutional regulations concerning the conduct of research, the supervision of trainees, and the employment conditions of staff. A Principal Investigator must be a research scientist of recognised stature in his/her scientific discipline and has the demonstrated ability to ensure quality control and to administer and integrate all components of the program. Individual research project leaders must be individuals whose scientific publications demonstrate their potential to contribute to the overall theme of the program project. Core leaders must have appropriate expertise and be qualified for their role(s) in their core unit.

	A Principal Investigator (PI) is the holder of an independent grant administered by a university and the lead researcher for the grant project, usually in the sciences, such as a laboratory study or a clinical trial. The phrase is also often used as a synonym for "head of the laboratory" or "research group leader."
Privacy	The condition or state of being free from public attention to intrusion into or interference with one's acts or decisions. The ability of a person to control the availability of information about and exposure of him- or herself.
Private Information	Includes information about behaviour that occurs in a context in which an individual can reasonably expect that no observation recording is taking place, and information that has been provided for specific purposes by an individual and which can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e. the identity of the participant is or may readily be ascertained by the investigator associated with the information) in order for obtaining the information to constitute research involving human participants.
Private-Public Partnership (PPP)	A cooperative venture between the public and private sectors built on the expertise of each partner and involves the allocation of resources, risks and rewards.
Procedure	A series of steps designed to result in a specific outcome when followed in order.
Prospective	A study or collection maintained for expected or likely use in the future.

Q

QCAT	Queensland Civil and Administrative Tribunal.
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)	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. 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. 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.
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.
Queensland Health	Means the Department of Health and all Hospital and Health Services.

R

Research	Systematic investigation, research development, testing, and evaluation, designed to develop or contribute to generalisable knowledge. Methodical investigation into a subject in order to discover facts, establish or revise a theory, or develop a plan of action based on the facts discovered. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.
Research Contracts (or Research Agreements)	An agreement between Metro South Health and one (1) or more external parties, natural or legal (i.e. a corporation), that is to perform research or research related activities, and/or is to be administered by Metro South Health. Such research contracts may include, but are not limited to, written agreements, letters, grants, and memoranda of understanding.
Research Integrity Adviser (Advisor in Research Integrity)	Employees appointed by Metro South Health who can be approached in confidence to discuss matters relating to the Australian Code for the Responsible Conduct of Research 2007 ("the Code") including what may constitute a breach of the Code and/or research misconduct, the rights and responsibilities of individuals in relation to allegations, and Metro South Health Polices and Procedures for managing allegations. A Research Integrity Adviser should not be involved in a case if they have a perceived or actual conflict of interest. A Research Integrity Adviser's role should not involve assessment or investigation of allegations.

	A Research Integrity Adviser can explain options for taking action. These options may include: • Not proceeding or withdrawing the allegation if discussion resolves the concerns. • Referring the allegation to the relevant delegate for resolution. • Where a (perceived or actual) conflict of interest exists with the relevant delegate the matter is to be referred to the Designated Person.
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.

Research Misconduct	Deviations from the Code which:
	• are intentional and deliberate, reckless, or amount to gross and persistent negligence; and
	• result in serious consequences, such as false information on the public record, or adverse effects on research participants, animals or the environment.
	
	Examples of research misconduct include:
	• fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, for example:
	  ○ fabrication of research results
	  ○ falsification or misrepresentation of research results
	  ○ falsification or misrepresentation to obtain research funding
	  ○ misleading ascription of authorship
	• failure to declare or manage serious conflicts of interest
	• conducting research without ethics approval as required by legislation or avoidable failure to follow research proposals as approved by a research ethics committee, particularly where this failure may result in unreasonable risk or harm to humans, animals or the environment
	• wilful concealment or facilitation of research misconduct by others
	• repeated or continuing breaches of the Code, especially where the respondent has been the subject of previous counselling or specific direction. This instance this matter may be dealt with to under other misconduct procedures. See Corrupt Conduct.
	
	For the purpose of Research Management Policies and Procedures, research misconduct does not include honest differences in judgement about the management of a research project, and may not

	include honest errors that are minor or unintentional (which may, however, constitute a breach of the Code requiring specific action by the relevant supervisor or institution).
Research Personnel	All personnel involved in the conduct of research in Metro South Health. This includes, but is not limited to, those personnel working in laboratory, administrative, clinical or support areas.
Research Related Activities	Include, but are not limited to: testing and evaluation, the collection and analysis of data, writing, editing or translating, and the organisation of meetings for the communication and discussion of research results. For purposes of the Research Management Compliance Framework, research related activities also include services provided by contracting organisations to support research projects in Metro South Health.
Resource Sharing	The sharing of materials and data in a timely manner.
Respondent	An individual who is the subject of a concern regarding research misconduct or an allegation of research misconduct.
Retrospective	Relating to or being a study or collection (as of a disease) that looks back on or deals with past events or situations.
Risk	Relates to future consequences, arising from present causes or foreseeable events, which if materialised, have the potential for impacting Metro South Health adversely i.e. financially, legally or otherwise.

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'.
Secondary Research	Any research use beyond the scope of the primary study.
Special Health Care	Special health care, of an adult, is health care of the following types: • removal of tissue from the adult while alive for donation to someone else; • sterilisation of the adult; • termination of a pregnancy of the adult; • participation by the adult in special medical research or experimental health care; • electroconvulsive therapy or a non-ablative neurosurgical procedure for the adult; and/or • prescribed special health care of the adult.
Special Health Matter	A special health matter, for an adult, is a matter relating to special health care of the adult.

Special Medical Research or Experimental Health Care	Special medical research or experimental health care, for an adult, means: • medical research or experimental health care relating to a condition the adult has or to which the adult has a significant risk of being exposed; or • medical research or experimental health care intended to gain knowledge that can be used in the diagnosis, maintenance or treatment of a condition the adult has or has had.
Sponsor	An individual, company, institution, or organisation that takes responsibility for the initiation, management, and/or financing of a research project involving human research subjects.
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	An established procedure to be followed in carrying out a given operation or in a given situation. See Work Instruction.
State-wide Ethics Review Processes	A Queensland approach to single ethical review of multi-centre research in which participating sites within Queensland public hospital have agreed to accept the scientific and ethical review of an HREC from a Queensland public health facility.
Statutory Health Attorney	For a health matter, an adult's statutory health attorney is the first, in listed order, of the following people who is readily available and culturally appropriate to exercise power for the matter: • a spouse of the adult if the relationship between the adult and the spouse is close and continuing; • a person who is 18 years or more and who has the care of the adult and is not a paid carer for the adult; • a person who is 18 years or more and who is a close friend or relation of the adult and is not a paid carer for the adult.
Subject	See 'Human Subject' and 'Donor'.

T

Therapeutic Goods Administration (TGA)	The TGA is a division of the Commonwealth Department of Health and Ageing. The objective of the *Therapeutic Goods Act 1989 (Cth)* which came into effect on 15 February 1999, is to provide a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines and ensure the quality, safety and performance of medical devices.

	The TGA is responsible for administering the provisions of the legislation. The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard. At the same time the TGA aims to ensure that the Australian community has access, within a reasonable time, to therapeutic advances.
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.

U

V

Valid Application	A valid application is an AU *RED* status applied by the HREC or Research Governance Office when an application is deemed to contain all required documentation.

W

Work Instructions (Standing Operating Procedures)	Work Instructions or Standing 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.

X
Y
Z